TECHNICAL SPECIFICATION

ISO/TS 10974

First edition
2012-05-01

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

Reference number
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Contents

Page

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to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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

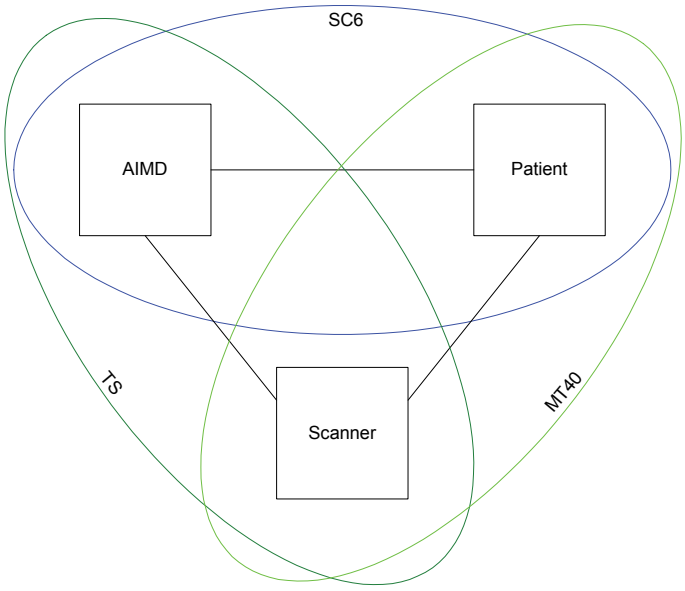
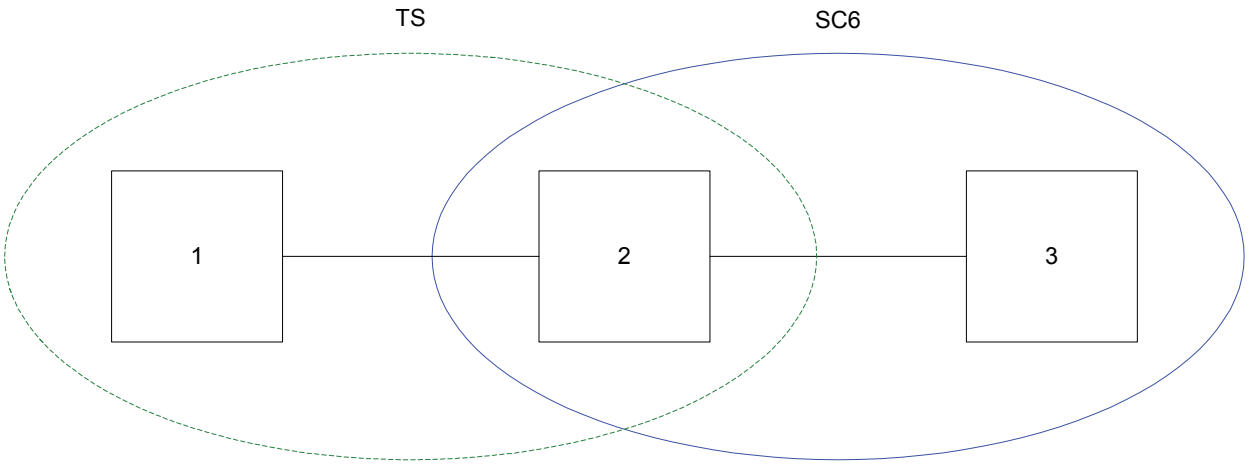


Figure 1 — Diagram showing the responsibilities of product committees and illustrating the extent of the scope of this Technical Specification in terms of the effects between AIMDs and MR scanners

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.



1. Hazardous situation/mechanism/phenomenon: Interactions between the AIMD and scanner and resulting phenomenon, e.g. induced voltage.
2. Hazard: Potential source of harm, e.g. heating or malfunction. A knowledge of known or foreseeable hazards resulting from physical interactions will guide comprehension, selection and development of TS test methods.
3. Risk: Probability of occurrence of harm x severity of harm.

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

Test methods described in this Technical Specification are primarily designed and intended as bench-top tests using equipment and techniques to simulate the fields (B_0 static, gradient, and RF) found in MR 1,5 T scanners. Although, in a few cases, clinical scanner tests are implied, in all others, the AIMD manufacturer assumes the burden for development and validation of clinical scanner-based test methods. Furthermore, the test signals and parameters specifically described within this Technical Specification for bench-top testing (e.g. Clause 8) are not being encouraged or recommended for use on clinical scanners and to do so might result in scanner damage.

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

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

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

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

The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) draw attention to the fact that it is claimed that compliance with this Technical Specification may involve the use of a patent concerning gradient vibration given in Clause 12.

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

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

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

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

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

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

1 Scope

This Technical Specification is applicable to implantable parts of active implantable medical devices (AIMDs) intended to be used in patients who undergo a magnetic resonance scan in 1,5 T, cylindrical bore, whole body MR scanners for imaging the hydrogen nucleus.

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

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

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

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

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

NOTE 4 All safety requirements for MRI scanners can be found in IEC 60601-2-33.

2 Normative references

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

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

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

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

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

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

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

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
$B_{1\mathrm{RMS}}$
root mean square (RMS) of B_1, the radio frequency magnetic induction

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

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
$t_{\mathrm{s,eff}}$
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 sustainment 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

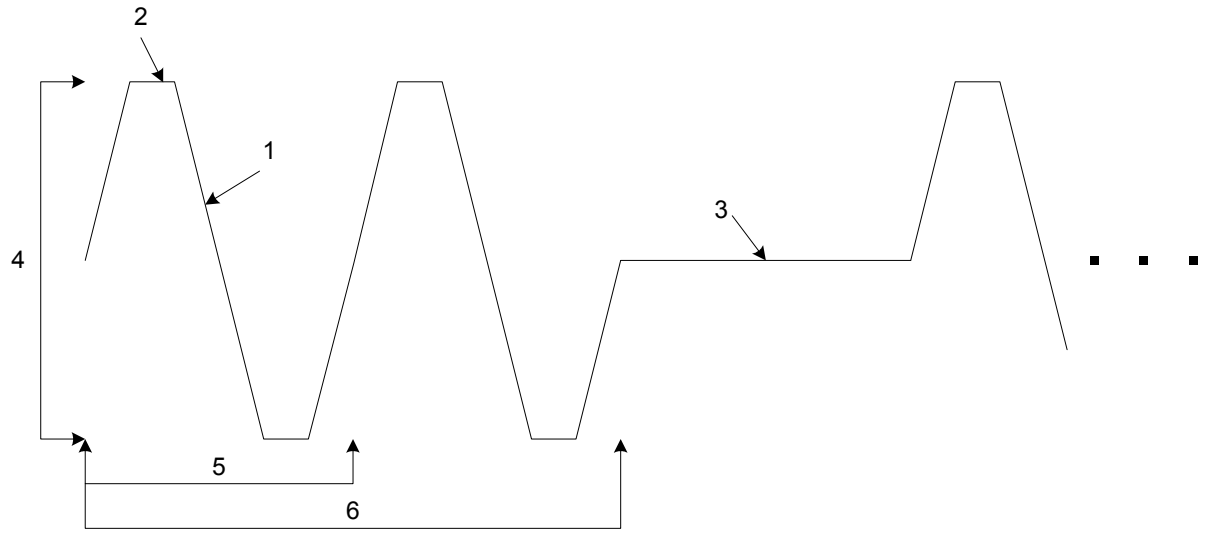
8.1 Gradient sequence of sequences

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)

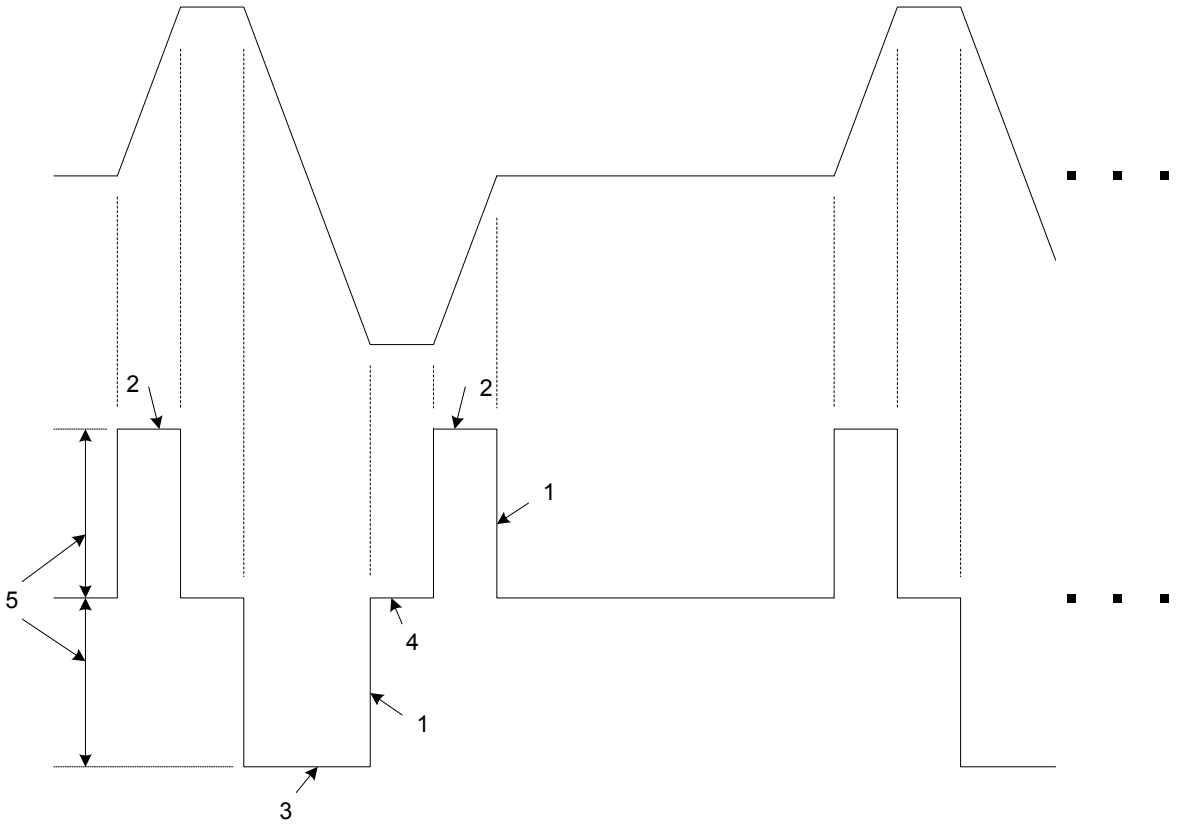
Figure 3 – Gradient test signal

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

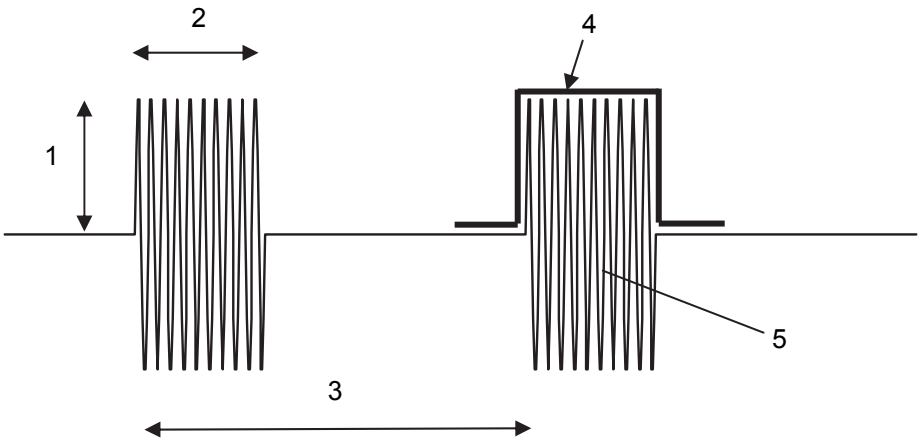
The test signal used to simulate the RF field is shown in Figure 5. It is defined by three variable parameters: B_1 peak amplitude at the isocentre, pulse width, and pulse period. One set of parameter values constitutes a

single sequence (e.g. B_1 = 1 μT, pulse width = 50 μs, 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 (μT) 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 ± 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							
	50μs	100μs	200μs	500μs	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)
		$E_{\mathrm{RMSmax,\ in\ vivo}}$	$E_{\mathrm{RMSmax,\ in\ vivo}}$
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 $B_{1\mathrm{RMS}}$ *in vivo* field values for testing in accordance with Tier 1

Body part	Normal mode	First level mode
Head	7,0 µT	7,0 µT
Trunk	7,0 µT	7,0 µT
Extremities	7,0 µT	7,0 µT
NOTE As the maximum $B_{1\mathrm{RMS}}$ is not limited by the SAR limits but by the limitations of the commercial scanners, the $B_{1\mathrm{RMS}}$ to be used for magnetic coupling is set to 7 µT. 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 ($l/l_{resonance}$)	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 (ε_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.

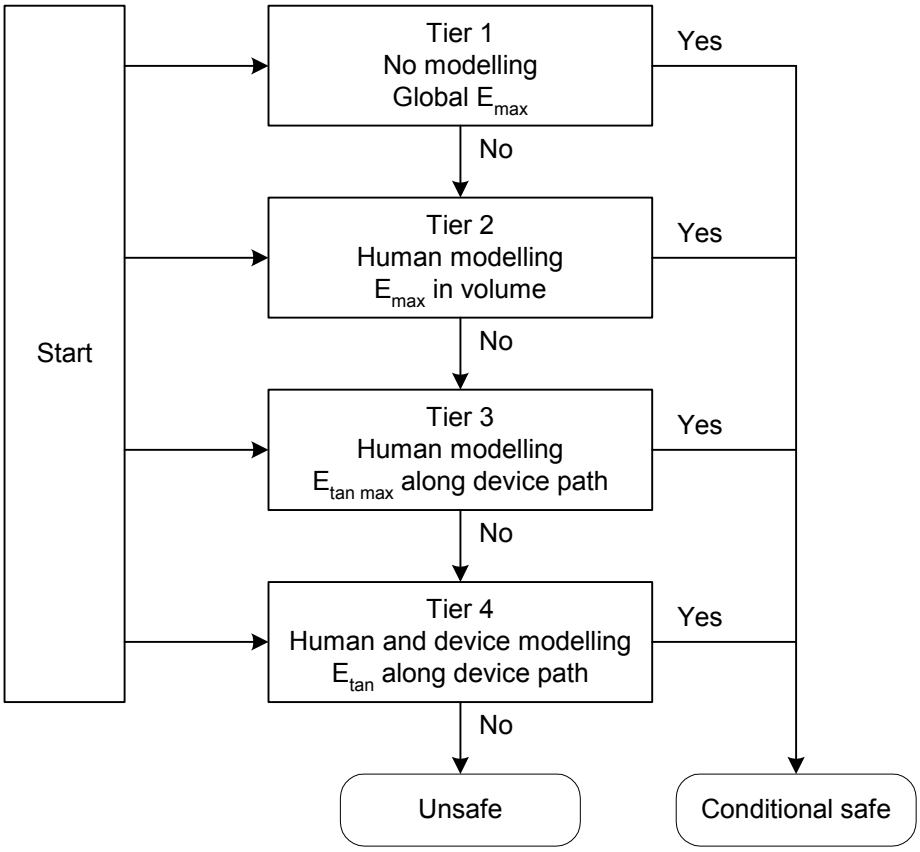
10.2.4 Tier 4

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. $B_{1\mathrm{RMS}}$, 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 ± 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 ± 5 %
B_{1RMS}	> 2 µT
Deviation from Uniform Etan-field over the entire AIMD path	< ± 1 dB (Phase < ± 20 degrees)
Drift of Etan-field during assessment	<0,25 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+/-5 MHz	64+/-5 MHz	—
Dynamic range	<0,1 to >20 µT	<0,01 to 100 W/kg	<10 to >40 °C
Deviation from linearity	<±0,2 dB	<±0,2 dB	<±0,2 K
Noise (avg. <10 s)	<0,1 µT	<0,01 W/kg	<0,1 K
Spherical isotropy directivity	<0,4 dB	<0,4 dB	—
Spatial resolution	<5 mm	<3 mm	<1 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_{measl}.

— Step 8: perform pattern matching and determination of the matching uncertainty ($u_{\text{pattern matching}}$).

— 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, $u_{\text{pattern matching}}$.

— 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 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.

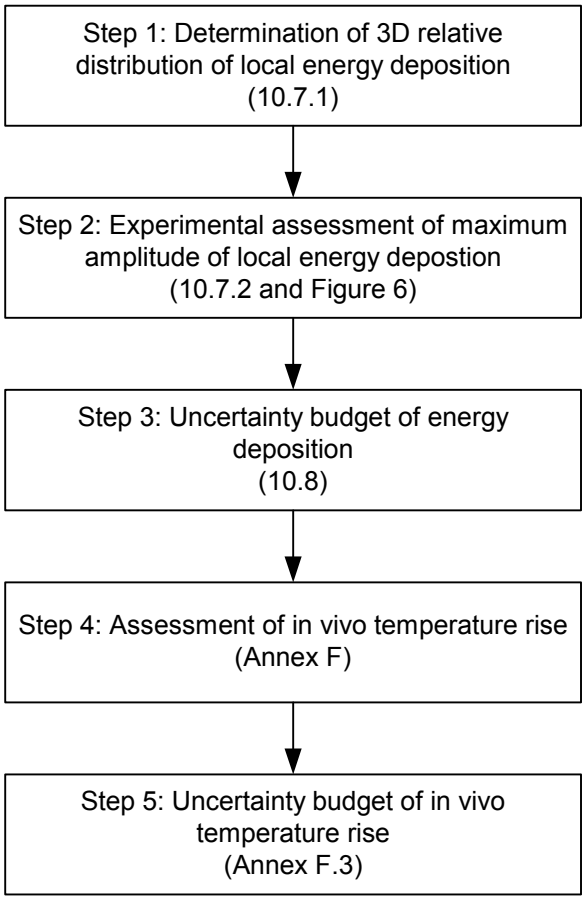


Figure 7 — Block diagram of the steps for the assessment of the maximum temperature rise *in vivo*

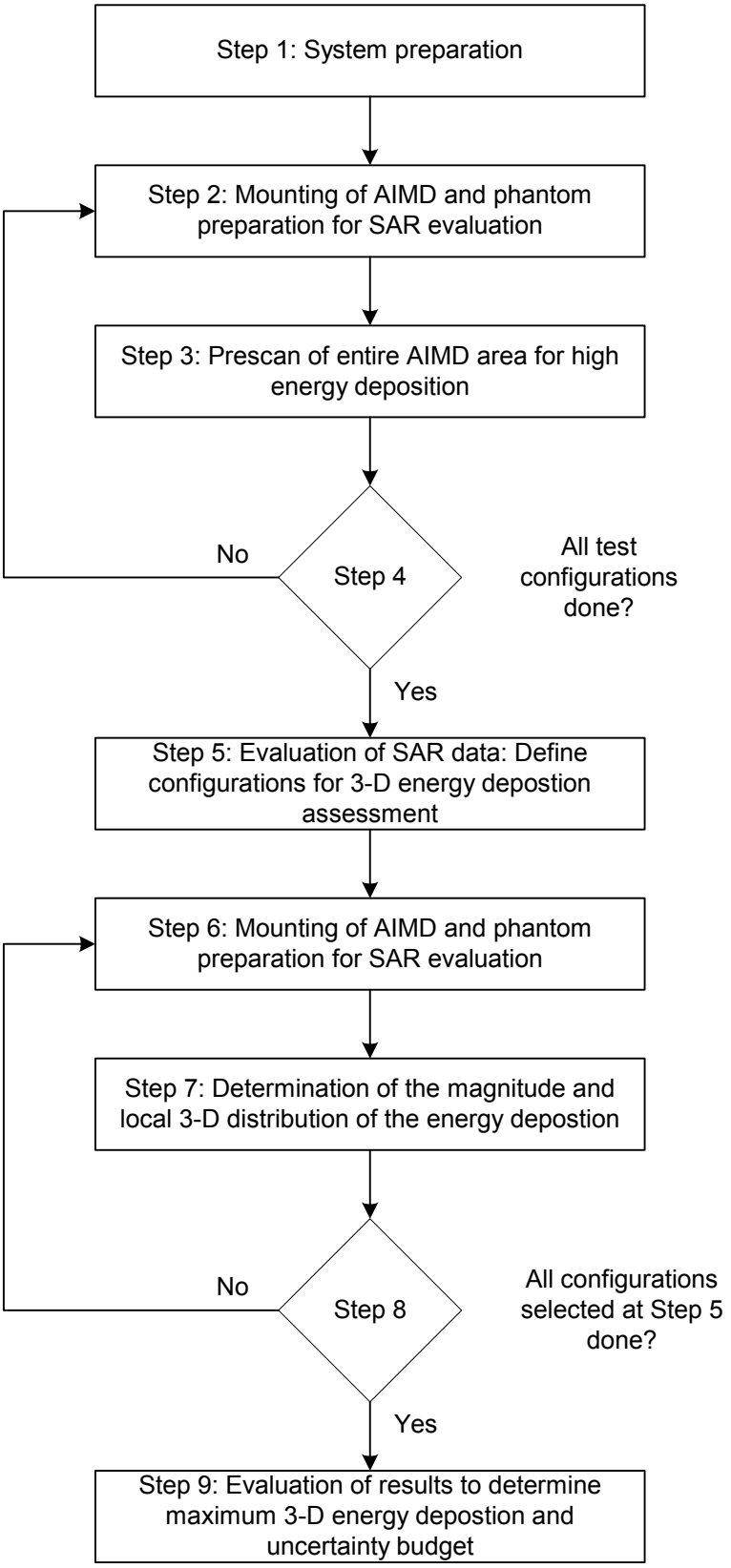


Figure 8 — Block diagram of the steps for experimentally determining the maximum amplitude

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 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 dB/dt (or more precisely, $\partial B/\partial t$).

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 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 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 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 m $\leq$ |z| $\leq$ 0,4 m). For scanners with atypically short bores, the region of maximum dB/dt may be located closer to isocentre (|z| < 0,3 m).

11.2.2 Determination of clinical *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 dB/dt which represents currently available MR scanner limits. Note that the mean square value of the resulting 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.

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

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.

a) Plots of data from the test, including recording of the maximum temperature rise after the steady state is reached.

b) Record of gradient waveforms from the search coils.

c) 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.

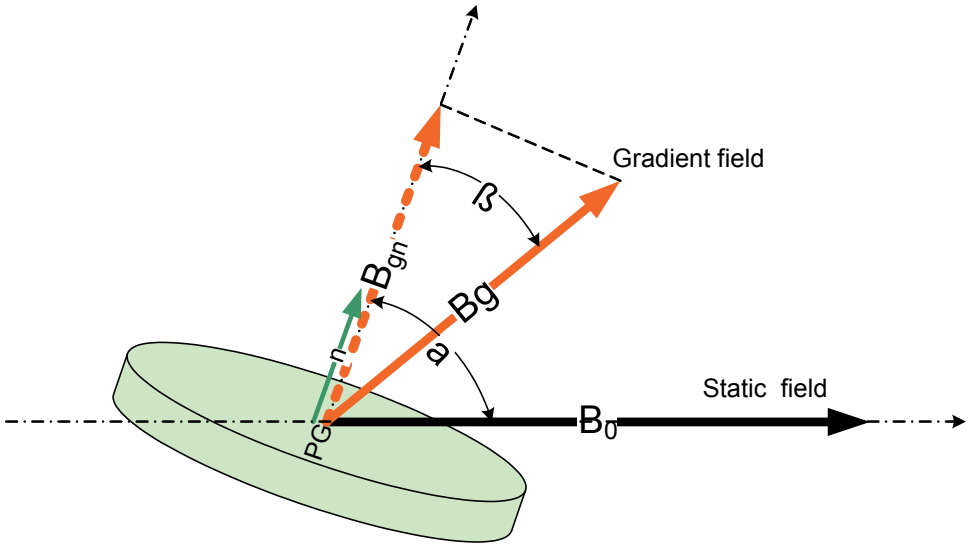


Figure 9 – Torque due to gradient-induced eddy current and static B_0 field

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

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 *in vivo* 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.

d) Demonstrate the equivalency of the shaker table or other vibration equipment to the MR vibration response.

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.

12.4 Test method for the evaluation of patient discomfort during exposure to gradient-induced vibration

12.4.1 General requirements

Patient discomfort testing is performed to assess a patient's qualitative sensation of the AIMD vibration. This information may be useful in developing device labelling and literature. If the quantitative patient tissue damage testing in 12.5 is performed, the patient discomfort test described in this subclause may be omitted by the AIMD manufacturer.

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. The gradient field pulse sequences shall be equivalent to the protocols specified in 12.2.3.

Human volunteers shall be used to conduct the test as follows.

a) The investigator shall guide or otherwise indicate to the volunteer the approximate target location of the required B_0 and gradient field dB/dt and the expected device orientation for maximum gradient-induced AIMD vibration.

b) The volunteers shall hold the AIMD in their hand and move the device into the magnetic fields, as described in step a).

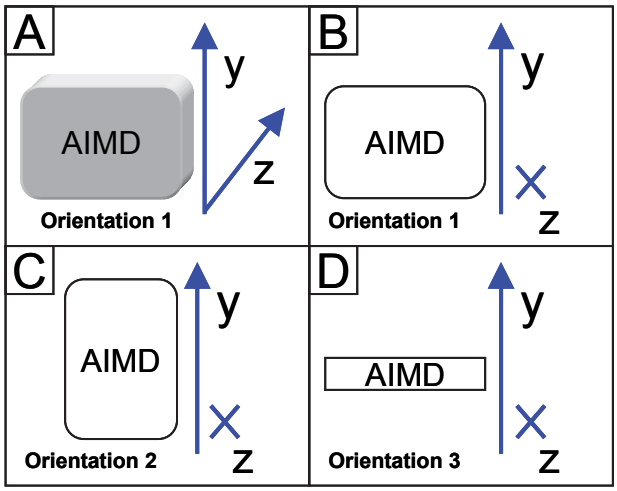
c) Using 12.3.1.2 and Figure 10 as a guide, the volunteers shall empirically determine the AIMD location and orientation that maximizes the perceived vibration.

d) The volunteers shall note the vibratory sensation and apply an intensity score according to Table 14.

Table 14 – Vibration intensity score

Score	Vibration assessment
0	No vibration felt
1	Onset of sensation – a slight humming may be felt
3	Modest vibration that would not cause any physical discomfort during a 15 min scan
5	Slightly uncomfortable vibration that could be tolerated if medically necessary
7	Modestly painful vibration that can be withstood for 1 or 2 min, but not for 15 min
10	Significantly painful vibration that can be withstood for only a few seconds

Perform the vibration assessment with the device oriented with each of the three AIMD surface normals oriented in the y direction (Figure 10). Since the vibration is a qualitative sensation, it shall be assessed by several volunteers.



NOTE 1 This figure is applicable for lab testing using G_y-induced vibration.

NOTE 2 The two arrows in each of the illustrations represent y-axis and z-axis unit vectors.

NOTE 3 Image A is a 3-D representation of the first orientation.

NOTE 4 Images B to D provide 2-D illustrations of the three orientations. In the 2-D illustrations, the z-axis unit vector is orthogonal to the plane of the printed page.

Figure 10 — Illustration of the three orthogonal AIMD orientations used for gradient vibration test and evaluation

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.

12.4.2 Conducting patient discomfort testing using a research scanner

The requirements specified in 12.4.1 apply.

12.4.3 Conducting patient discomfort testing using simulated fields

The requirements specified in 12.4.1 apply.

12.4.4 Conducting patient discomfort testing using a clinical scanner

Use of a clinical scanner for patient discomfort testing is preferred. The requirements specified in 12.4.1 apply. For the purpose of patient discomfort testing, testing at a vibration level substantially above worst-case clinical exposure is not beneficial.

The AIMD manufacturer shall determine the approximate target location for the volunteer vibration discomfort testing. The AIMD manufacturer shall provide rationale for the testing location consistent with the AIMD type and the associated MR Conditional labelling.

Both G_x and G_y produce a significant dB/dt orthogonal to B_0 (transverse field) in regions where $|B_0| \approx |B_0|_{MAX}$. Typically, G_x and G_y will produce maximum transverse dB/dt when the z-axis location is between 0,35 m and 0,45 m on either side of isocentre. dB_x/dt and dB_y/dt will increase as the test location is moved radially from the bore centreline toward the inner wall of the bore along the horizontal (x) or vertical (y) reference axis. The AIMD manufacturer shall determine the radial distance, d, from the bore centreline used for vibration testing.

It may be possible to achieve the required clinical exposure vector product of dB/dt and B_0 for patient discomfort testing in a clinical scanner that is not worst case by using one or more of the following techniques.

— Conducting the test using a B_0 greater than clinical worst case. For example, if the MR Conditional labelling restricts scanning to 1,5 T scanners, testing in a 3 T scanner using a dB/dt that is less than worst case may provide the required vector product of dB/dt and B_0.

— Testing in a location that is not clinically relevant for the AIMD but produces a larger vector product of dB/dt and B_0 may allow testing to worst case on a scanner that is not worst case. 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 the required test condition.

— 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 greatest conductive AIMD surfaces. This orientation may not be clinically relevant for some AIMDs. When this is the case, it may be possible to conduct worst-case testing on a scanner that is not worst case.

The following steps should be used for the assessment:

1) Hold the implant with your fingers about 30 cm from isocentre (assuming a cylindrical bore). Wear hearing protection for this test. The greatest conductive surface of the implant shall face in the vertical direction.

2) With gradients operating, move the AIMD incrementally along a line where x=0, y=d, and 0,35 m < z < 0,45 m to find the location of maximum vibration. Use this location as the approximate target location for volunteer vibration discomfort testing.

12.4.5 Conducting patient discomfort testing using a shaker table or other vibration test equipment

Vibration shaker tables or other vibration test equipment are not appropriate for patient discomfort testing.

12.5 Test method for the evaluation of risk of tissue injury during exposure to gradient-induced vibration

12.5.1 General requirements

12.5.1.1 The vector cross ($\times$) product of MR gradient field dB/dt and B_0 used to evaluate the risk of patient tissue injury shall be greater than or equal to the maximum cross product the AIMD will be exposed to during MR examinations when the MR Conditional labelling conditions of use are observed. The gradient field dB/dt vector used to establish the requirement for risk evaluation shall be determined using either Tier 1 dB/dt exposure requirements or dB/dt exposure requirements developed using Tier 2 methods. If Tier 2 methods are used to establish the dB/dt requirement, the AIMD manufacturer shall provide supporting rationale (see 12.2.2).

NOTE The magnitude of the vector cross ($\times$) product is maximized when the two vectors are perpendicular.

Vibration testing undertaken for the purpose of evaluating the risk of tissue injury due to gradient field-induced AIMD vibration may be conducted using a vector cross product of gradient field dB/dt and B_0 that is different from the maximum exposure during clinical MR examinations. If this is the case, vibration test results can be scaled accordingly for tissue injury risk assessment.

12.5.1.2 The gradient field pulse sequence or B(t) waveforms shall be equivalent to the protocols identified in 12.2.3.

12.5.1.3 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 plane of the AIMD's greatest conductive surface orthogonal to each of the two other mutually perpendicular axes (see Figure 10).

12.5.1.4 The gradient field dB/dt waveform(s) used to conduct the testing shall be monitored and recorded using a planar single axis search coil as described IEC 60601-2-33:2010, 201.12.4.105.2.2, or equivalent planar single axis search coil. The search coil cross-sectional area should be selected to be similar to that of the AIMD. The search coil or other sensor shall be oriented to measure 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 and the plane of the AIMD's greatest conductive surface shall be no greater than 1 cm.

12.5.1.5 The recorded waveform shall have a sampling rate sufficient to capture the details of the dB/dt waveform and prevent aliasing of the dB/dt signal. The waveform record length and associated notations shall be sufficient to allow subsequent reproduction of the dB/dt exposures used to conduct the testing. If the RMS value of dB/dt is not directly recorded, the recorded dB/dt waveforms and associated notations shall provide sufficient information to allow post-processing to calculate RMS dB/dt.

12.5.1.6 The vector cross product of gradient field dB/dt and B_0 the AIMD is exposed to during testing shall be known and controlled in order to achieve accurate and repeatable test results. As a consequence, a means of accurately locating the AIMD within the research scanner bore and orienting the AIMD relative to the gradient field vector, B, and the static field vector, B_0, will be needed.

12.5.1.7 The following procedure should be used for measuring acceleration:

1) Identify a test location within the scanner bore where the gradient field B is perpendicular to static field B_0 and the relative magnitude of gradient field B is large.

2) Place accelerometers on the periphery of the implant, as shown in Figure 11. The accelerometers are in a line along B_0. The accelerators shall measure the vertical component of acceleration. Alternatively, or in addition to accelerometer measurements, AIMD vibration-induced tissue force may be assessed using force transducers. The remainder of this subclause illustrates the use of accelerometers.

3) Apply an intense gradient sequence and record acceleration.

4) Rotate the implant by 90 degrees in the horizontal plane. Relocate the accelerometers as shown in Figure 12.

5) Apply an intense gradient sequence and record acceleration.

6) Measure and record AIMD accelerations for each of the six orientations shown in Figure 13.

NOTE 1 In general dB/dt, vibration amplitude and the location at which maximum vibration occurs will be scanner and sequence dependent. dB/dt vector and magnitude need to be characterized by use of a search coil for each particular test sequence. This information is not otherwise available.

NOTE 2 Low mass accelerometer(s) are appropriate.

NOTE 3 Device fixture and mounting is important. A lightly constrained device, e.g. mounted in a tissue stimulant, will reveal fundamental resonance modes.

12.5.1.8 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.

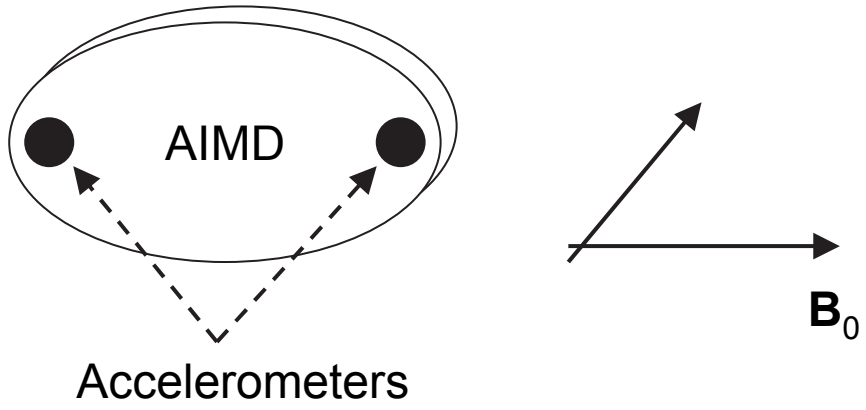


Figure 11 — Accelerometer placement for gradient vibration testing with long axis of device along B_0

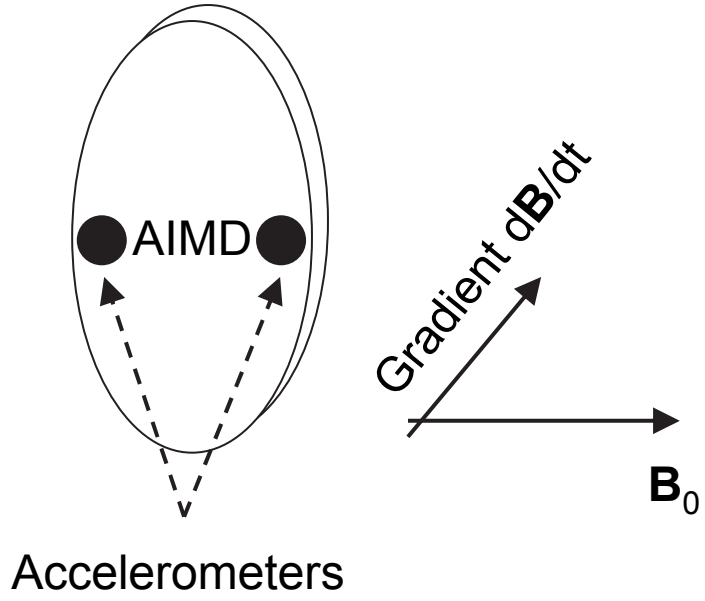


Figure 12 – Accelerometer placement for gradient vibration testing with long axis of device orthogonal to B_0

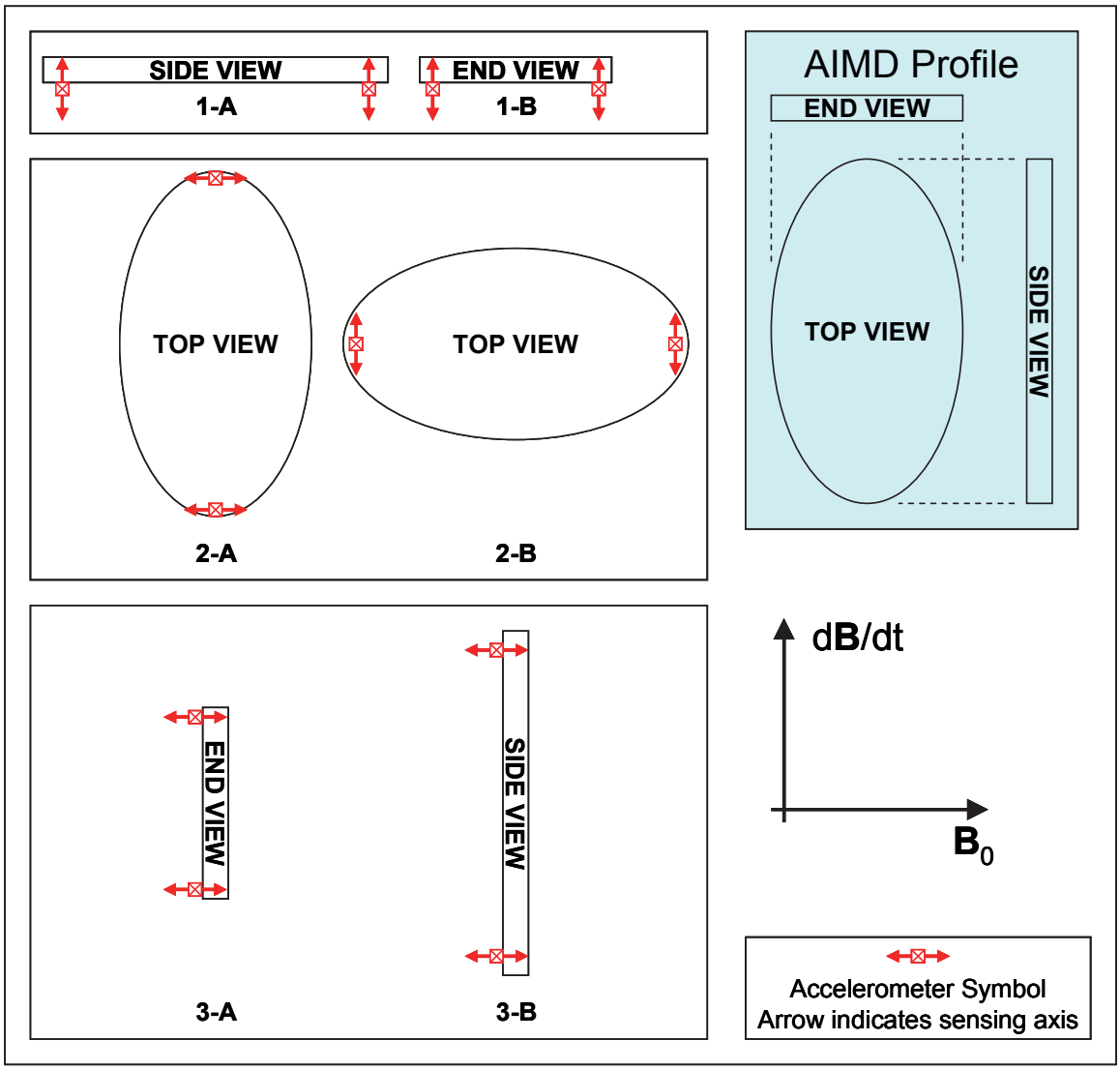


Figure 13 — The six AIMD test orientations relative to the gradient field *dB/dt* vector and static field (B_0) vector for vibration testing

12.5.2 Conducting testing for the evaluation of risk of tissue injury using a research scanner

The requirements specified in 12.5.1 apply.

12.5.3 Conducting testing for the evaluation of risk of tissue injury using simulated fields

The requirements specified in 12.5.1 apply.

12.5.4 Conducting testing for the evaluation of risk of tissue injury using a clinical scanner

The requirements specified in 12.5.1 apply.

12.5.5 Conducting testing for the evaluation of risk of tissue injury using a shaker table or other vibration test equipment

Vibration shaker tables or other vibration test equipment are not appropriate for the evaluation of risk of tissue injury.

12.6 Uncertainty assessment

The requirements specified in R.4 shall apply.

12.7 Test report

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

— Record of MR gradient waveforms from the sensing coils or other source.

— Theoretical or empirical rationale justifying the test conditions.

— If gradient-induced AIMD vibration testing for tissue injury assessment was conducted using a $B_0 \times dB/dt$ exposure different from the clinical *in vivo* exposure, the information needed to scale vibration measurement results to account for this difference shall be provided.

— Record of accelerometer output waveforms observed during gradient-induced AIMD vibration testing for tissue injury assessment. The recorded waveforms shall have a sampling rate sufficient to capture the details of the acceleration waveform and prevent aliasing of the signal. The recorded waveform shall have sufficient length to fully characterize the pulse sequence.

— Measured peak and RMS AIMD vibration accelerations. If peak and RMS accelerations are not measured or otherwise determined during testing, the recorded acceleration waveforms, along with other data and information included in the test report, shall be sufficient to allow post processing to determine peak and RMS accelerations.

13 Protection from harm to the patient caused by B_0-induced force

Displacement force produced by the static magnetic field (B_0) has the potential to cause unwanted movement of a device containing magnetic materials. For a paramagnetic, diamagnetic, or ferromagnetic device below saturation, the location of maximum displacement force is at the point where the product of the magnitudes of the magnetic field (B_0) and the spatial gradient of the magnetic field (∇B_0) is at a maximum. The same is true for paramagnetic material above saturation. It is possible that this location is off the central axis of the bore of the scanner. For a ferromagnetic device above the magnetic saturation point, the maximum displacement force will occur at the location where ∇B_0 is at a maximum. Almost always, devices that can be labelled MR Conditional are composed of paramagnetic materials.

Test the device as described in ASTM F2052. The manufacturer shall establish acceptance criteria for the magnetically induced deflection force. Observe all reporting requirements in ASTM F2052 in addition to the requirements of 9.5.

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

14 Protection from harm to the patient caused by B_0-induced torque

Magnetically induced torque produced by the static magnetic field (B_0) has the potential to cause unwanted movement of a device containing ferromagnetic materials. The magnetically induced torque is a function of B_0 and should be measured where the static magnetic field is homogeneous (e.g. isocentre). The torque is evaluated using a torsional pendulum method. If the maximal torque is less than the product of the longest dimension of the medical device and its mass, then the magnetically induced torque is less than the worst-case torque on the device due to gravity. For this condition, it is assumed that any risk imposed by the application of the magnetically induced torque is no greater than any risk imposed by normal daily activity in the Earth's gravitational field.

Test the device in accordance with the requirements in ASTM F2213. Observe all reporting requirements in ASTM F2213 in addition to the requirements in 9.5.

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

15 Protection from harm to the patient caused by image artefact

The AIMD may interfere with the acquisition of MR data resulting in artifacts that may compromise MR images. An evaluation should be performed (see 22.9).

It is recommended that AIMD manufacturers avoid signal-producing materials, such as elastomers, and conductive materials and materials whose susceptibility differs from water.

NOTE 1 MR equipment manufacturers have compatibility test procedures that might provide guidance.

NOTE 2 ASTM F2119 specifies a test method for evaluating MR image artifacts from passive implants. Similar methods could be used to evaluate the MR image artifact from an AIMD.

NOTE 3 It may be advisable to investigate artifacts caused by induced currents.

16 Protection from harm to the patient caused by gradient-induced extrinsic electric potential

16.1 General

Extrinsic electric potential is the result of gradient field-induced voltages that develop between the distal and proximal ends of the lead system of an AIMD. If the potential is high enough, it could be directly responsible for unintended stimulation or injury of adjacent tissue or could indirectly lead to the same through rectification of induced voltages or modification of output pulses due to superposition. In any case, the result is an unintended consequence of electromagnetic interactions between the MR scanner gradient pulsed fields and the AIMD and is not considered a device failure or malfunction, per se. The tests in this clause are for the purpose of determining the effects of the extrinsic electric potential, if any.

The test approach for gradient-induced extrinsic electric potential is similar to gradient-induced malfunction. From Figure 16, the test flow alternatives are the same, except for radiated testing. Using a radiated field is not practical due to the large uniform field area required for a device with leads attached, and is not recommended. The injected method uses the injected voltage levels and injection network as found in Clause 20.

NOTE 1 Although a radiated method may be used, a method is not provided in this edition of the Technical Specification. If a manufacturer intends to use a radiated method, development and validation of the method is left to the manufacturer.

NOTE 2 This test is not necessary for devices without conductive leads, such as implantable infusion pumps.

16.2 Test procedure

In general, the requirements of Clause 20 and 20.2 apply. Using the injected voltage test levels determined from Tier 1, Tier 2, or Tier 3, apply the gradient sequence of sequences from 8.1 to the voltage injection network (Annex D). Some sequences may be omitted with appropriate rationale and documentation by the manufacturer. Sequences may not be omitted for Tier 1 testing.

Test signals shall be applied from terminal to terminal (i.e. bipolar output configuration) and terminal to case (i.e. unipolar output configuration), as appropriate, depending on device capability. If AIMD therapy is to be

delivered during scanning, according to the manufacturer's MR Conditional labelling, then the following condition also applies:

— synchronize/apply test signals to coincide with AIMD therapy output.

NOTE If the injection network of Annex D is used, apply the test level to Input C and measure the device output signal using Port K.

Current flow from the distal electrode into the volume impedance of the relevant tissue shall be evaluated for unintended consequences of induced extrinsic electric potential including unintended stimulation and modification of output pulses due to superposition. Additional guidance on evaluating gradient-induced current flow due to lead port interface impedance is found in Annex T.

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

16.3 Uncertainty assessment

The requirements specified in 20.2.6 apply.

16.4 Test report

The requirements specified in 9.5 apply.

17 Protection from harm to the patient caused by RF rectification

17.1 General

RF rectification of induced voltages can occur if the induced voltage is high enough to cause non-linear circuit elements to conduct, e.g. an input protection diode. The resulting rectified voltage is an unintended consequence of electromagnetic interactions between the MR scanner RF pulsed fields and the medical device and is not considered a device failure or malfunction, per se. The tests in this clause are for the purpose of measuring the amount of rectified voltage, if any.

The test approach for RF rectification is the same as it is for RF-induced malfunction. From Figure 14 the test flow alternatives are the same, except for radiated testing. Using a radiated field for measuring rectified voltage levels is extremely difficult and unreliable and is not recommended.

NOTE 1 Although a radiated method may be used, a method is not provided in this edition of the Technical Specification. If a manufacturer intends to use a radiated method, development and validation of the method is left to the manufacturer.

The maximum injected voltage level used for RF-induced malfunction is used for RF rectification and applied with the same injection network. The only difference is measuring the rectified voltage level instead of monitoring device performance and behaviour.

NOTE 2 This test is not necessary for devices without conductive leads, such as implantable infusion pumps.

17.2 Test procedure

In general, the requirements of Clause 19 and 19.2 apply. Using an injection network (e.g. Annex E), apply signal to terminal C to achieve the maximum injected voltage test level (see 19.2.1) at each device port (terminals F and G). Device ports (at the proximal end of the lead) shall be measured for their rectified voltage level and checked for acceptable levels in accordance with the manufacturer’s MR Conditional labelling.

NOTE If the injection network of Annex E is used, apply the test level to input C and measure the rectified voltage level using port K and port K'.

It is not necessary to perform the entire RF sequence of sequences table (Table 5). One parameter combination (pulse width and pulse period) is sufficient. A suggestion is to use a pulse width long enough to observe rectification voltages and a pulse period that gives a moderate duty cycle for the amplifiers.

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

17.3 Uncertainty assessment

The requirements specified in 19.2.4 apply.

17.4 Test report

The requirements specified in 9.5 apply.

18 Protection from harm to the patient caused by B_0-induced malfunction

18.1 General

The B_0 field of the scanner could have certain effects on the AIMD, such as, but not limited to, device reset, re-programming, magnetic remanence, battery drain and permanent damage. For the test described in this clause, the device is subjected to an appropriate static magnetic field level while being monitored for proper functionality in accordance with the manufacturer's MR Conditional labelling.

18.2 Test procedure

The device shall be exposed to a uniform static magnetic field of flux density of 1,5 T over its entire area. All parts of the device that contain elements susceptible to magnetic fields shall be exposed. Exposure duration to the static magnetic field shall be sufficient to assess device functionality and the effects of residual magnetism. Exposure durations shall be justified by the AIMD manufacturer, but shall not be shorter than 1 min.

A lower magnetic flux density test level may be used if the manufacturer can demonstrate that all magnetically sensitive elements have obtained their maximum saturation at that lower test level and will not change their behaviour or characteristics above that lower test level. However, the test level shall not be lower than 0,5 T. The manufacturer shall document the rationale used to meet this requirement.

The device shall be exposed to the required B_0 vector field along three orthogonal axes. Orient the device three times, each time along a different axis. Additionally, if the device contains components that are magnetically sensitive, the manufacturer shall include exposures that align and anti-align these sensitive components with the B_0 vector field.

Field sensing elements, e.g. Hall effect or reed switches, that are normally expected to actuate with an applied magnetic field, shall be taken into consideration.

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. Evaluation of the device after the test shall include assessment of the effects of remanence.

18.3 Test equipment

18.3.1 Generating the B_0 field

To generate the B_0 test field, either a clinical MR scanner or other magnet sufficient to generate the required field strength may be used.

18.3.2 Phantom and tissue simulation medium

It is not necessary to use a phantom or to place the device in saline.

18.4 Uncertainty assessment

The requirements of R.5 shall apply.

18.5 Test report

The requirements of 9.5 apply.

19 Protection from harm to the patient caused by RF-induced malfunction

19.1 Introduction of tiered approach

The RF field of a scanner could have certain effects on the AIMD such as, but not limited to, a failure to deliver the intended therapy, re-programming, device re-set and permanent damage. These effects are caused by the unwanted induction of voltage on the leads or directly on internal circuits if the RF field penetrates the device enclosure. The tests in this clause are based on monitoring device behaviour and performance for proper functionality in accordance with the device MR Conditional labelling.

The approach taken in this clause for functional testing is based on the four RF tiers (Clause 10) and uses either radiated or injected immunity tests. An overview is shown in Figure 14. Beginning with Tier 1, each tier describes a progressively more rigorous analytic method for determining the E-field induced in the body by the B_1 field. The E-field is either used directly for radiated immunity testing or for determining injected voltage test levels.

Although no electromagnetic modelling or computational analysis is required for Tier 1 (it uses pre-determined E-field levels) it uses the most conservative (highest) E-field test values. Tier 2 and Tier 3 require electromagnetic computational analysis using numerical human body models. Tier 4 requires the most rigorous electromagnetic computational analysis and the development of AIMD models but has the potential to predict the lowest *in vivo* E-field and, hence, the lowest injected voltage test levels. The methodology of this approach is similar to the RF tiers in Clause 10 for calculating *in vivo* temperature increase except, in this case, the tiers are used to calculate E-field and induced voltage exposure levels for assessing device behaviour.

The choice of tier requires, at a minimum, consideration of the device type, implant location, lead configuration and orientation, immunity to radiated fields and signal levels, and availability of test equipment, among other factors. The more susceptible the device is, the higher the tier (4 is higher than 1) that is likely to be required.

The choice of tier can also influence the choice of test method, i.e. radiated versus injected. For example, lower tiers, in particular Tier 1, will have E-field values (e.g. hundreds or thousands of V/m) that make radiated testing impractical. Tier 4 is only applicable to the injected method since the intermediate analytic E-field values cannot be used for radiated testing.

Injected testing is recommended in most cases, not only because of repeatability, but because the E-field can be scaled downwards to a practical level. Then the induced voltage can be measured at the ports of the device (proximal end of lead) and the measured voltage scaled back up accordingly to use for the injected test level. The E-field cannot be scaled for radiated testing.

The radiated method is also not appropriate for testing devices with leads attached. The *in vivo* induced E-fields found in a scanner are non-uniform, and although the tiered approach described in this clause has steps in the method for multiplying the measured induced voltage with a resonant length weighting factor (also called phase factor) to account for non-uniform fields, this factor cannot be applied to a uniform radiated E-field test.

NOTE A device that does not normally use leads, but has conductive contacts on the surface, may use either the radiated or injected method. An external antenna is treated the same as a lead.

Devices without conductive leads or accessible patient connected terminals shall use a radiated method unless it can be shown that radiated fields cannot penetrate the device enclosure and do not influence device behaviour and functionality. The same requirement applies to devices with conductive leads if those devices have inadequate shielding from electromagnetic waves. All potential points of RF entry shall be evaluated, in particular antenna ports that are used for communication purposes.

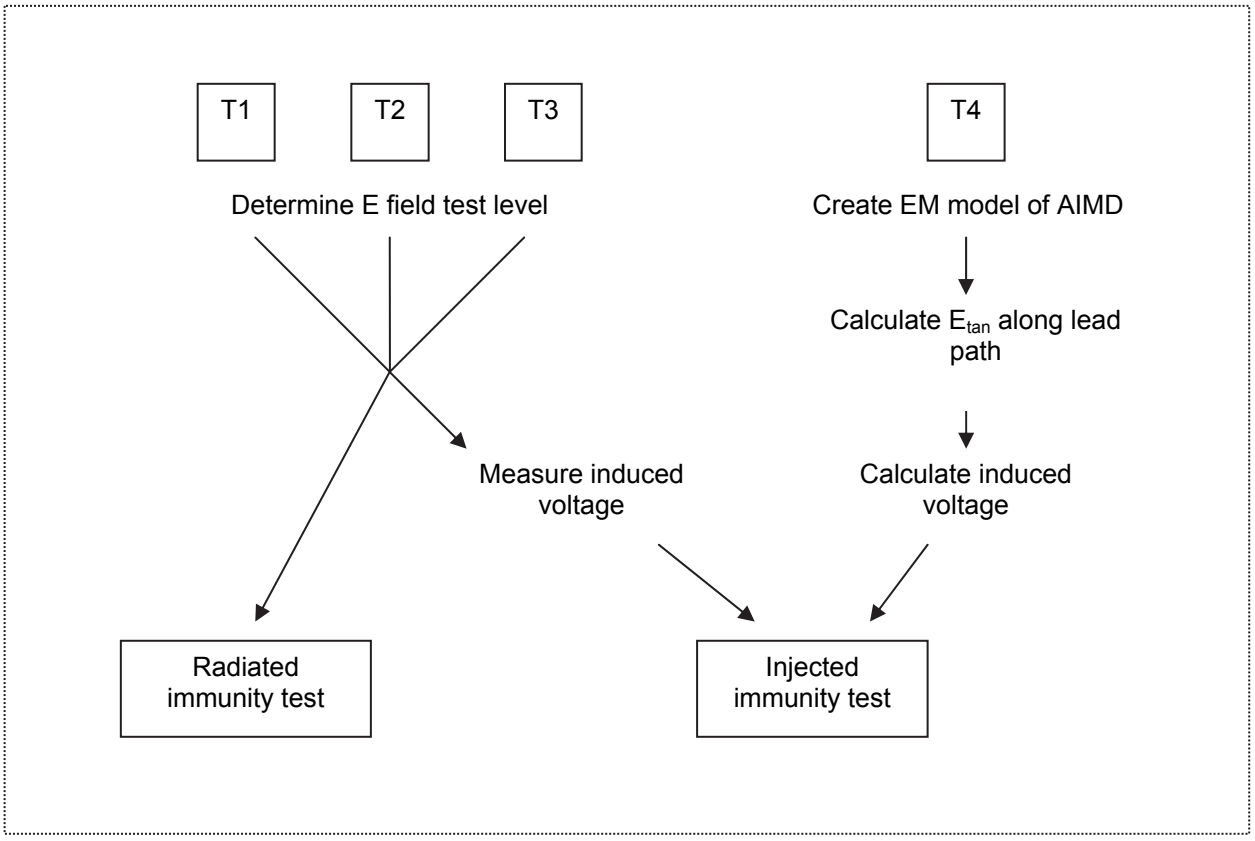


Figure 14 – Test flow alternatives for RF-induced malfunction

The method of each tier is shown in Figure 14. Tiers 1 to 3 use the same steps but differ in the computational methods for Step 1 and Step 5. All three tiers use an empirical approach for determining the induced voltage and an AIMD electromagnetic model is not required. Tier 4 requires an AIMD model and calculates the induced voltage rather than measuring it.

Note that radiated immunity testing uses the E-field level from Step 1 in Tiers 1 to 3. The same level is used for the exposure level for measuring the induced voltage in Step 3. Tier 4 is only applicable to injected testing.

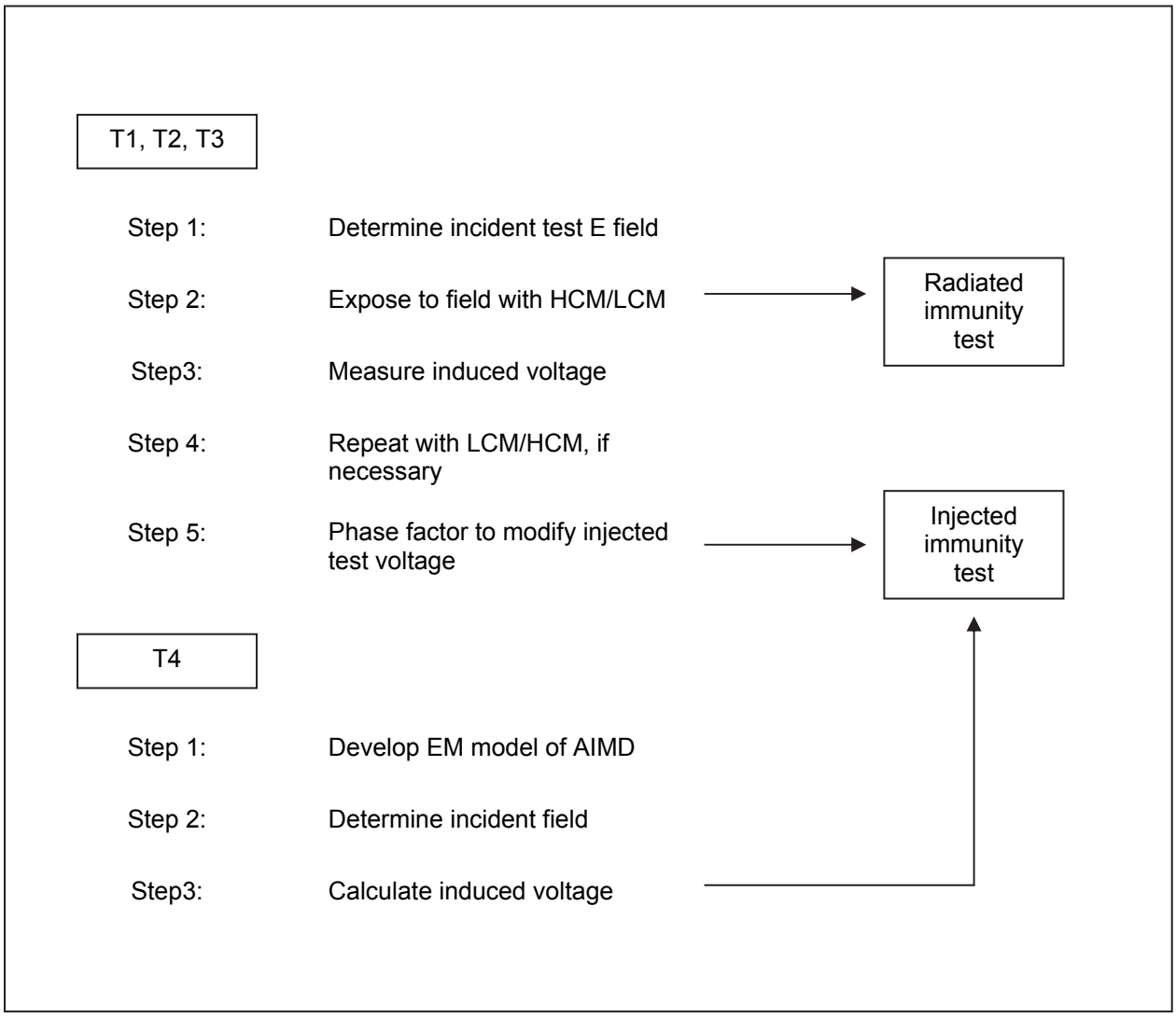


Figure 15 – Step-by-step tier methods

19.2 Injected immunity test

19.2.1 Using the tiers

For injected immunity testing, follow Steps 1 to 5 of Tiers 1 to 3, or Steps 1 to 3 of Tier 4, as described in 10.2 and shown in Figure 14. Some steps are modified as indicated below (only modified steps are shown; see 10.2 for other steps).

Tier 1, Step 1: The values of E-field in Table 6 are RMS values based on SAR and heating tests. For functional test purposes, peak instantaneous values should be used. Peak values should be based on commercially available scanner hardware capabilities. Therefore, the maximum E-field seen by the implanted device for functional test purposes is many times higher than the values in Table 6. Also, there is no distinguishing difference for normal and first level modes for functional testing.

Table 15 indicates the E-field value applicable to Tier 1 for functional testing (see Annex P). The value is expressed in peak V/m for testing purposes.

Table 15 – E-field level for Tier 1

Body part	Normal and first level mode E (peak) (V/m)
Head	2 700
Trunk	4 200
Extremities	5 100

NOTE These E-field strengths are based on using the RF sequence of sequences test waveform as described in 8.2. Using other waveforms might change the amplitude requirements.

Tiers 1 to 3, Step 2: This step refers to a uniform E-field that is tangential to the lead at every point. One way to accomplish this is by using a circular or semi-circular (where a straight section is placed between the ends to lengthen the phantom in order to accommodate devices with longer leads) phantom placed in a bench-top RF birdcage coil (see 10.5). In this set-up, the E-field induced by the B_1 field is uniform and tangential along the circumference of the phantom.

The E-field may be scaled downwards to a practical level, as long as the signal-to-noise ratio is better than 10. The scaling factor will be used in Step 3 to adjust the measured voltage upwards.

NOTE Although a clinical scanner may be used, a method is not provided in this edition of this Technical Specification. If a manufacturer intends to use a clinical scanner method, development and validation of the method is left to the manufacturer.

Tiers 1 to 3, Step 3: Instead of SAR at the distal end, measure the induced voltage at the ports of the device (i.e. at the proximal end of the lead where it connects to the device). This Technical Specification does not define a specific measurement technique. However, this is not a trivial matter and great care should be taken to ensure accurate data. The following points should be taken into consideration:

— measurement cables may pick up induced voltages that may be equal to or greater than the actual voltage at the port of the device;

— induced voltage measurements should be made at the ports of the device with and without the leads inserted into the device to evaluate the "noise" pickup of the measurement system;

— the induced voltages may be different on each port, therefore voltages should be measured on all ports of the device.

The measured voltage shall be scaled up according to the scaling factor used for the E-field test level in Step 2. This absolute voltage level will be used for the injected voltage test level after applying the resonant length weighting factor (phase factor) in Step 5.

NOTE 1 This method is applicable to AIMD leads with non-active elements. For this type of lead, the relationship between E-field and induced voltage is linear. Leads that contain active elements are not addressed in this Technical Specification.

NOTE 2 If the AIMD has non-linearly behaving ports, the voltage level cannot be scaled up without the usage of a very well defined tissue equivalent network. Non-linear components at the lead port will have a different impedance level at higher voltage levels and also with different operation modes of the AIMD.

Tiers 1 to 3, Step 5: The absolute voltage level from Step 3 shall be multiplied by the square root of the resonant length weighting factor (phase factor). This new voltage level will be used for the maximum injected voltage test level.

Tier 4, Step 3: Compute the induced voltage that would appear at the proximal end of the lead at the ports of the device. This voltage level will be used for the maximum injected voltage test level.

19.2.2 Test procedure

Using the RF voltage injection network (Annex E), inject the RF sequence of sequences test signals from 8.2 into the network. There is no use of a saline tank phantom in the performance of the actual injected test.

NOTE 1 The injection network in Annex D presents a 50 ohm impedance to the AIMD input ports; it should be shown that the calculated injected voltage is conservative when the real source impedance of the device leads in tissue is taken into account.

The injected voltage test level determined from Tiers 1 to 3, Step 5, or Tier 4, Step 3, is used as the maximum test voltage. This voltage level corresponds to (represents) the maximum B_1 amplitude of 30 μT peak from Table 4. All other test voltages are scaled accordingly. For example, test voltages representing 1, 2, 5, 10 and 20 μT will be equivalent to 1/30, 2/30, 5/30, 10/30, and 20/30, respectively, of the maximum test voltage.

NOTE 2 The B_1 peak amplitude level of 30 μT is for reference purposes. It is not actually used for testing.

The manufacturer shall demonstrate, through testing or design analysis, that device performance and behaviour, according to its MR Conditional labelling, is not affected by simultaneous application of a static magnetic field equivalent to B_0 field strength. One way to do this is to demonstrate that there are no elements (e.g. ferromagnetic components) which are used in the construction of the AIMD that can be affected by a B_0 field. The manufacturer shall document the rationale and method used to meet this requirement.

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.

19.2.3 Test equipment

19.2.3.1 Generating the *E*-field

For generating the required E-field, an RF birdcage coil is recommended with specifications as described in Annex J. Other methods may be used, if validated.

19.2.3.2 Phantom and tissue simulation medium

See Annex M for phantom description. See Annex L for tissue medium.

19.2.3.3 RF injection network

The RF injection network is based on Annex D and Figure D.5 from ANSI/AAMI PC69, reproduced in Annex E. The bias, T, consists of a series capacitor element, C, and an inductor element, L. The purpose of the capacitor element C is to perform as a low impedance element at 64 MHz. It also blocks any biologic signals (for example, the output pulses of a cardiac pacemaker). Inductor L is intended to perform as a very low impedance element at low frequencies to allow cardiac or therapeutic output pulses to freely pass. Resistor R2 forms the biologic load impedance that the AIMD would see as referenced to its housing. This impedance value, R2, should be adjusted based on the load impedance presented to the device. At the same time, the inductor L performs as a very high impedance at 64 MHz, thereby preventing 64 MHz signals from going to the monitoring equipment. An oscilloscope is generally located at points K and K', which allows for continuous monitoring of therapeutic output and also for observation of the possibility of RF rectification.

19.2.4 Uncertainty assessment

The requirements of R.6.1 shall apply.

19.2.5 Test report

The requirements of 9.5 apply.

19.3 Radiated immunity test

19.3.1 Using the tiers

For radiated immunity testing, follow Step 1 and Step 2 of Tiers 1 to 3 as described in 10.2 and shown in Figure 15. Some steps are modified as indicated below (only modified steps are shown; see 10.2 for other steps).

NOTE 1 Tier 4 is not applicable.

Tier 1, Step 1: The value of E-field is determined in the same way as it is for injected immunity tests. Refer to 19.2.1 for more information.

Tiers 1 to 3, Step 2: This step refers to a uniform E-field that is applied over the entire area of the device enclosure, without leads. One way to accomplish this is by using a GTEM or anechoic chamber as described in IEC 61000-4-3. The E-field cannot be scaled downwards for radiated immunity testing.

NOTE 2 Although a clinical scanner may be used for the radiated method, its use is not recommended. If a manufacturer intends to use a clinical scanner method, development and validation of the method is left to the manufacturer.

19.3.2 Test procedure

After immersing the device in the tissue simulation medium as described in Annex L, perform the radiated immunity test using the RF sequence of sequences test signals from 8.2.

The E-field level determined from Tier 1, Tier 2 or Tier 3, Step 1, is used as the maximum applied test level. This level corresponds to (represents) the maximum B_1 amplitude of 30 µT peak from Table 4. All other radiated test levels are scaled accordingly. For example, test levels representing 1, 2, 5, 10 and 20 µT will be equivalent to 1/30, 2/30, 5/30, 10/30, and 20/30, respectively, of the maximum E-field test level. The maximum E-field test level cannot be scaled.

NOTE 1 The B_1 peak amplitude level of 30 µT is for reference purposes. It is not actually used for testing.

The manufacturer shall demonstrate, through testing or design analysis, that device performance and behaviour, according to its MR Conditional labelling, is not affected by simultaneous application of a static magnetic field equivalent to B_0 field strength. One way to do this is to demonstrate that there are no elements (e.g. ferromagnetic components) which are used in the construction of the AIMD that can be affected by a B_0 field. The manufacturer shall document the rationale and method used to meet this requirement.

This method is not appropriate for devices with leads attached. Instead, use the injected immunity test.

NOTE 2 A device that does not normally use leads but has conductive contacts on the surface may use either the radiated or injected method.

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.

19.3.3 Test equipment

19.3.3.1 Generating the *E*-field

A uniform E-field is necessary for this test. In general, the area of uniform field can be small because modern AIMD device size (without leads attached) is small. A birdcage coil is not recommended in this case. An anechoic chamber (see IEC 61000-4-3), GTEM (see IEC 61000-4-20), parallel plate TEM plane or other suitable method for generating large fields may be used, if validated.

19.3.3.2 Phantom and tissue simulation medium

A non-specific phantom may be used for this test. See Annex L for tissue medium.

19.3.3.3 AIMD monitoring equipment

These requirements apply, in addition to the requirements of 9.2.

If additional monitoring apparatus is located outside the AIMD, then an analysis shall be performed to account for any changes in field distribution caused by the monitoring apparatus. It should be expected that external monitoring equipment or a shielded twisted pair cable or bud light is going to have an effect on field distribution. However, if the manufacturer can demonstrate and account for how induced voltage is affected, then this method would be acceptable. Such circuitry could be placed inside the device, if there is sufficient room. For example, the RF voltage monitoring signal could be communicated outside the device using a non-conducting transmission medium (e.g. fibre optic). Transmission of the monitoring signal via inductive or radiating means is not recommended unless it can be ensured that the transmission and transmitting device do not interfere with the B_1 fields. This will also need to be accounted for in the uncertainty budget.

19.3.4 Uncertainty assessment

The requirements of R.6.2 shall apply.

19.4 Test report

The requirements of 9.5 apply.

20 Protection from harm to the patient caused by gradient-induced malfunction

20.1 Introduction of tiered approach

The gradient field of a scanner could have certain effects on the performance of an AIMD such as, but not limited to, a failure to deliver the intended therapy, memory corruption or loss of device programmed settings. These effects can be caused by the unwanted induction of voltage on the patient leads or directly on internal circuits if the gradient field penetrates the device enclosure. The tests in this clause are based on monitoring device behaviour and performance for proper functionality in accordance with device MR Conditional labelling.

The approach taken in this clause for functional testing is based on tiered test levels and uses radiated and injected immunity tests. An overview is shown in Figure 16. The radiated test shall be applied to all devices (with or without conductive leads) unless it can be shown that the device enclosure is completely shielded from magnetic fields so that device behaviour and functionality is not influenced. The test is normally performed without patient leads. The injected test shall be applied to all devices with conductive patient electrodes, leads or other conductive elements such as external antennas or leadless electrode terminals.

NOTE 1 Although a clinical scanner may be used for the radiated method, its use is not recommended. If a manufacturer intends to use a clinical scanner method, development and validation of the method is left to the manufacturer.

NOTE 2 External antennas are treated the same as leads. Insulated antennas not able to pass low frequency gradient current are excluded from conducted injected testing.

Tier 1 is based on worst-case values for the rate of change of the incident magnetic field, dB/dt, on the surface of two different defined volumes of radius 20 cm and 25 cm, where the radius is defined as the distance from the z-axis as defined by the isocentre (see Table 16). 20 cm is the "compliance volume" defined in IEC 60601-2-33 and 25 cm is defined as the "implant volume". This method results in very conservative test values without computational or modelling requirements.

NOTE 3 Implant volume is large enough to contain the chest and hips of the 95th percentile human male.

Tier 2 requires either (Case 1) electromagnetic computational analysis of the maximum incident magnetic field over the specific AIMD lead loop area or device area, or (Case 2) computational analysis of the maximum specific AIMD lead loop area. Both cases have the potential to reduce test levels compared to Tier 1.

Tier 3 requires the most rigorous electromagnetic computational analysis, computing the induced tangential E-field over the lead path, and has the potential to predict the lowest injected voltage test levels.

The choice of method will depend on consideration of device type, implant location, lead configuration and orientation, and immunity to injected signal levels, among other factors.

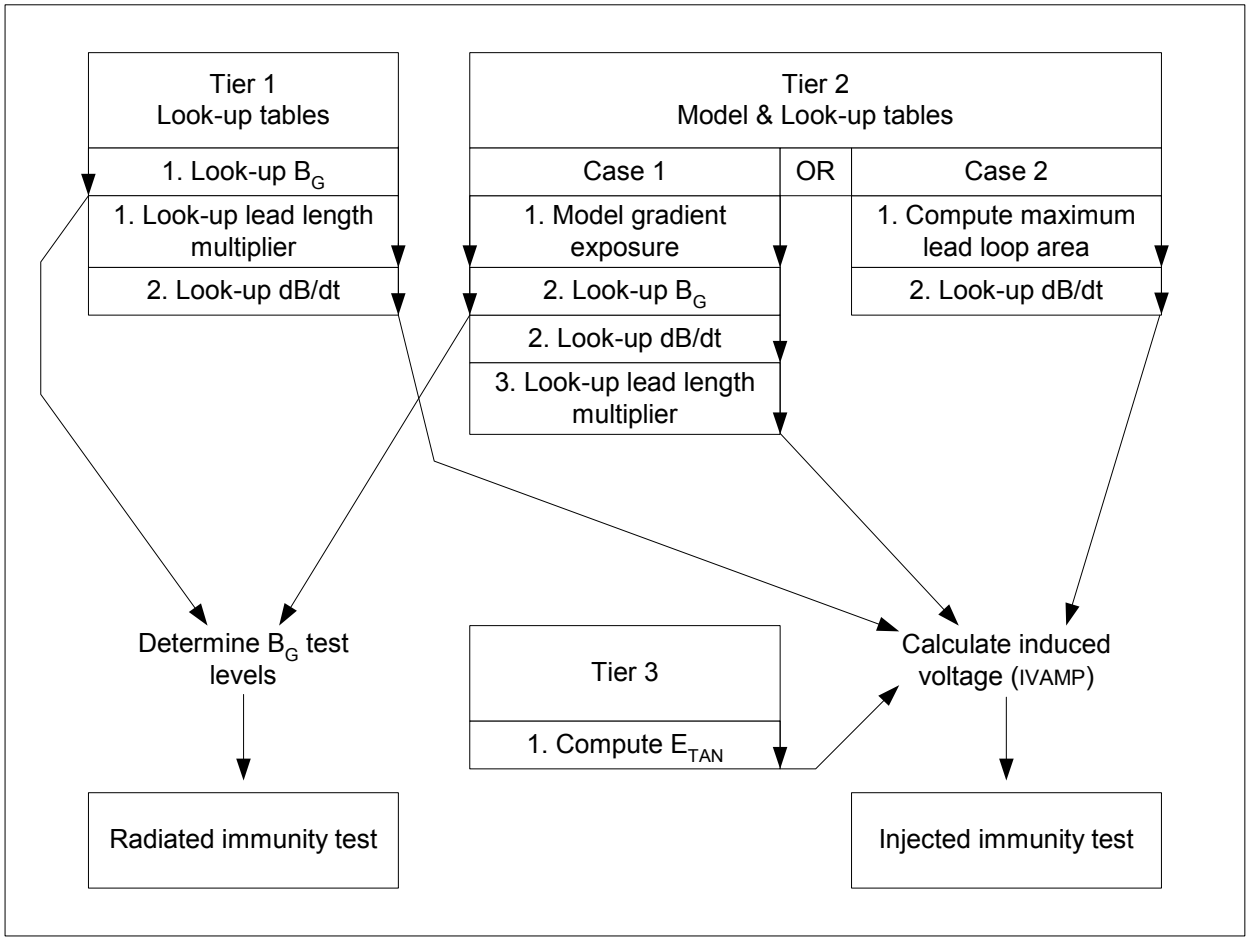


Figure 16 – Test flow alternatives for gradient-induced malfunction

20.2 Injected immunity test

20.2.1 Tier 1

This tier is intended for devices with leads as a first approximation of the maximum voltage induced in the lead system from the gradient field. It also applies to any other conductive terminals on the device, including leadless terminals and an external antenna. It presumes an induced E-field tangential to conductive elements at every point. This tier will produce the highest induced voltage, and hence, the highest injected test voltages of any method in this clause. It does not require any electromagnetic computational analysis.

Lead position and length within the patient and the bore will determine the amount of exposure to induced E-fields caused by the gradients. This tier provides two sets of test levels based on lead length and location within either the compliance volume or implant volume. Look-up tables provide corresponding lead length factors and dB/dt values used to calculate injected voltage test levels.

Lead length factors for AIMDs located completely within the compliance volume are determined from Table 18 and for AIMDs located within the larger implant volume, Table 19. If any portion of the system is outside the compliance volume and still within the implant volume, Table 19 shall be used. For systems where any portion is located outside the implant volume, Tier 3 shall be used.

Values in Table 18 and Table 19 are normalized to 1 T/s (see Annex B for the derivation of lead length factors). Multiplying the lead length factor by a particular dB/dt will yield a maximum theoretical induced voltage level. The values in Table 16 , which represent dB/dt values for the compliance and implant volumes, are based on calculations of the maximum 3-D vector slew rate on the surface of the defined volume, when the three gradients (x+y+z) are slewed simultaneously. The compliance volume table is based on a maximum rate of change of the incident gradient magnetic field of 150 T/s and the implant volume table is based on a maximum of 200 T/s.

Injected voltage test levels are calculated as follows. The largest volume containing portions of a system shall apply to the entire system:

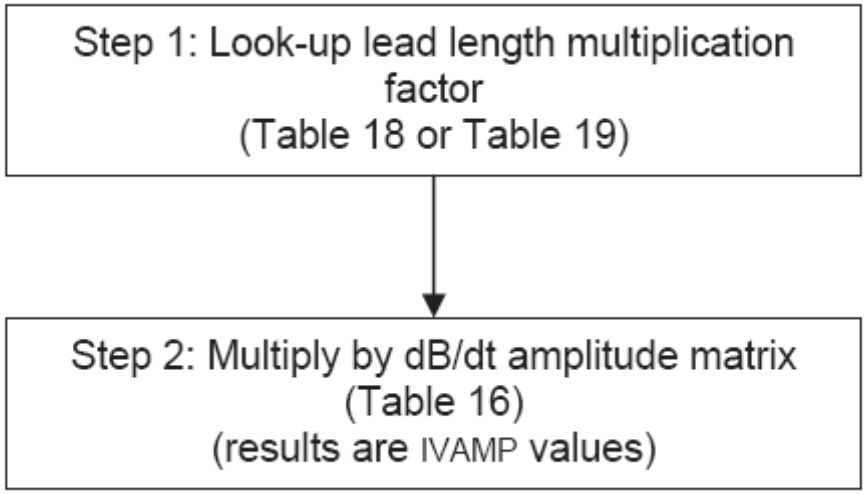


Figure 17 — Summary of steps to calculate injected voltage test levels for Tier 1

Step 1: Based on location in the bore and lead length, look up the lead length factor from the appropriate table (either Table 18 or Table 19). This factor represents the voltage that would be induced in a given lead length by a normalized time-varying magnetic field of 1 T/s.

Step 2: Based on location in the bore, multiply every applicable dB/dt value in Table 16 [dB/dt = f (B_G, TSLEW)] by the lead length factor determined in Step 1. All dB/dt values are used for the implant volume. The resulting matrix of IVAMP values, tabulated by the gradient-induced EMF pulse width, TBPW (Figure 4), are required for the injected voltage test levels for the gradient sequence of sequences.

Table 16 – *dB/dt* amplitude matrix

	B_G (mT) shown for reference only						
	1	2	5	10	20	30	40
TBPW (ms)	*dB/dt* values in T/s						
	Implant volume only						
	Compliance volume and implant volume						
0,2	5	10	25	50	100	150	200
0,4	2,5	5	12,5	25	50	75	100
1,0	1	2	5	10	20	30	40
2,0	0,5	1	2,5	5	10	15	20

NOTE Each column of *dB/dt* values corresponds to a particular value of B_G. TAPW (the single-sided slew pulse width of Figure 4) is 0,5x TBPW shown in this table. The right hand column applies only to implant volume.

EXAMPLE A 1 m lead located in the implant volume has a lead length factor of 0,150 from Table 19. Multiplying this factor by all *dB/dt* values in Table 16 yields the results for TAMP shown in Table 17.

Table 17 — Example for 1 m lead located in implant volume

TBPW (ms)	IVAMP (V)						
0,2	0,750	1,500	3,750	7,500	15,000	22,500	30,000
0,4	0,375	0,750	1,875	3,750	7,500	11,250	15,000
1,0	0,150	0,300	0,750	1,500	3,000	4,500	6,000
2,0	0,075	0,150	0,375	0,750	1,500	2,250	3,000

The values of IVAMP shown in Table 17 would all be applied as injected voltage test levels, with their corresponding single and double-sided slew pulse widths (TAPW and TBPW), using the test signal shown in Figure 4. If this example had been for the compliance volume, the last column on the right in Figure 16 would not have applied.

Length factors may be scaled linearly for intermediate lengths. Devices with leadless terminals shall use the distance between them as l.

Table 18– Lead length multiplication factor for calculating the injected voltage test level for the *compliance* volume

Lead length, l (cm)	Length factor	Lead length, l (cm)	Length factor
≤ 5	0,008	80	0,096
10	0,016	85	0,105
15	0,023	90	0,113
20	0,030	95	0,122
25	0,036	100	0,131
30	0,041	110	0,149
35	0,046	120	0,166
40	0,050	130	0,183
45	0,054	140	0,199
50	0,057	150	0,216
55	0,060	160	0,232
60	0,062	170	0,249
65	0,067	180	0,265
70	0,077	190	0,281
75	0,086	200	0,298
NOTE Length factors are normalized to 1 T/s.			

Table 19 – Lead length multiplication factor for calculating the injected voltage test level for the implant volume

Lead length, l (cm)	Length factor	Lead length, l (cm)	Length factor
≤ 5	0,008	80	0,102
10	0,016	85	0,114
15	0,023	90	0,126
20	0,030	95	0,138
25	0,036	100	0,150
30	0,041	110	0,172
35	0,046	120	0,194
40	0,050	130	0,216
45	0,054	140	0,237
50	0,057	150	0,258
55	0,060	160	0,280
60	0,062	170	0,301
65	0,067	180	0,321
70	0,078	190	0,342
75	0,090	200	0,363
NOTE Length factors are normalized to 1 T/s.			

NOTE These injected voltage test levels are based on using the injected voltage test signal in Figure 4. Using other waveforms might change the amplitude requirements.

20.2.2 Tier 2

This tier is intended for devices with leads as an alternative calculation of voltage induced in the lead system from the gradient field. It requires electromagnetic computational analysis or spatial models and has the potential to predict a lower induced voltage than Tier 1 and, hence, lower injected voltage test levels.

This tier uses a similar procedure and tables from Tier 1 except that the manufacturer can determine either (Case 1) the maximum exposure to gradient field strength (mT) or (Case 2) the maximum specific AIMD lead loop area (m^2).

For Case 1, the rate of change of the incident magnetic field is not specified as it is in Tier 1. If it can be demonstrated that the lead loop area will be exposed to a gradient field strength (mT) that is less than the basis for Tier 1, it is then possible to perform the injected immunity test using smaller values of injected voltages.

For Case 2, the maximum specific AIMD lead loop area (m^2) is not specified as it is in Tier 1. If it can be demonstrated that the maximum lead loop area is less than the basis for Tier 1, it is then possible to perform the injected immunity test using smaller values of injected voltages.

NOTE The basis for Tier 1 is 200 T/s for any point on the surface of the implant volume and 150 T/s for any point on the surface of the compliance volume.

For Case 1, the injected voltage test levels are calculated as indicated in Figure 18.

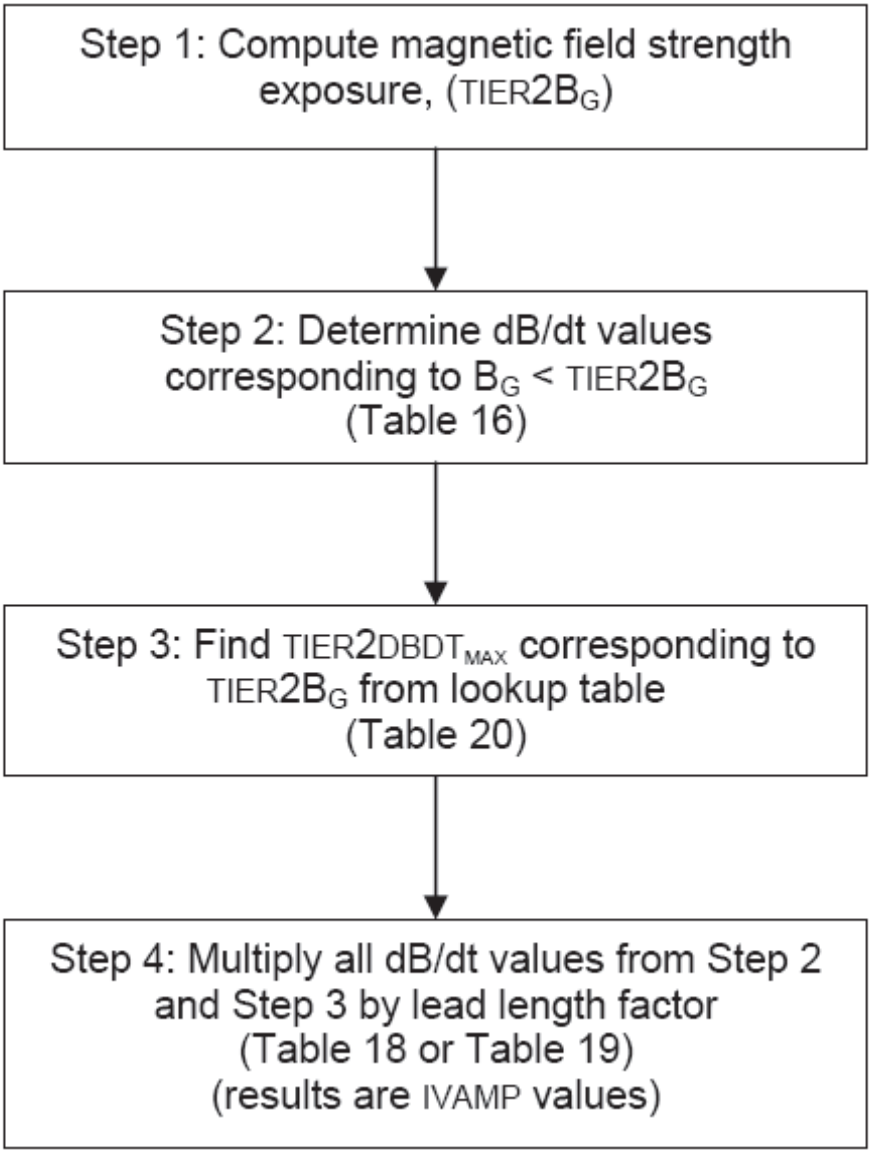


Figure 18 — Summary of steps to calculate injected voltage test levels for Tier 2, case 1

Step 1: Using models of the gradient coils, compute the maximum peak-to-peak exposure to 3-D vector gradient field strength (mT) normal to an area bounded by a specific lead path based on position and orientation within the bore. For the purposes of this subclause, call this computed value TIER2B_G. Field strength TIER2B_G shall be considered to be uniform throughout the bounded area and shall represent the maximum 3-D vector slew rate, anywhere within the defined volume, when the three gradients (x+y+z) are slewed simultaneously.

Step 2: Compare TIER2B_G to the values of B_G in Table 16. Select all *dB/dt* values corresponding to B_G less than TIER2B_G.

Step 3: New values of *dB/dt* corresponding to TIER2B_G are found in Table 20. For the purposes of this subclause, call these four *dB/dt* values TIER2DBDT$_{MAX}$.

Step 4: Multiply all *dB/dt* values from Step 2 and Step 3 by the appropriate lead length factor from Table 18 or Table 19 based on lead length and AIMD location in the bore. The largest volume-containing portions of a system shall apply to the entire system. The resulting matrix of IVAMP values, tabulated by the gradient-induced EMF pulse width, TBPW (Figure 4), are required for the injected voltage test levels for the gradient

sequence of sequences. Some combinations may be reduced with appropriate rationale and documentation by the manufacturer. For AIMDs with any portion located outside the implant volume, Tier 3 shall be used.

Table 20 — Look-up table for TIER2DBDT$_{MAX}$

tbpw (ms)	tier2B_G (mT) (shaded rows) / tier2dbdt$_{max}$ (T/s) (unshaded rows)									
	1	2	3	4	5	6	7	8	9	10
0,2	5	10	15	20	25	30	35	40	45	50
0,4	2,5	5	7,5	10	12,5	15	17,5	20	22,5	25
1,0	1	2	3	4	5	6	7	8	9	10
2,0	0,5	1	1,5	2	2,5	3	3,5	4	4,5	5
	11	12	13	14	15	16	17	18	19	20
0,2	55	60	65	70	75	80	85	90	95	100
0,4	27,5	30	32,5	35	37,5	40	42,5	45	47,5	50
1,0	11	12	13	14	15	16	17	18	19	20
2,0	5,5	6	6,5	7	7,5	8	8,5	9	9,5	10
	21	22	23	24	25	26	27	28	29	30
0,2	105	110	115	120	125	130	135	140	145	150
0,4	52,5	55	57,5	60	62,5	65	67,5	70	72,5	75
1,0	21	22	23	24	25	26	27	28	29	30
2,0	10,5	11	11,5	12	12,5	13	13,5	14	14,5	15
	31	32	33	34	35	36	37	38	39	40
0,2	155	160	165	170	175	180	185	190	195	200
0,4	77,5	80	82,5	85	87,5	90	92,5	95	97,5	100
1,0	31	32	33	34	35	36	37	38	39	40
2,0	15,5	16	16,5	17	17,5	18	18,5	19	19,5	20

EXAMPLE Suppose Step 1 yielded a value for TIER2B_G of 25 mT for a 1 m lead located in the implant volume. The resulting dB/dt values, TIER2DBDT$_{MAX}$, from Table 20 would be 125 T/s, 62,5 T/s, 25 T/s and 12,5 T/s. From Table 16, all other required values of dB/dt would correspond to B_G values less than 25 mT. All of these dB/dt values, when multiplied by the lead length factor for 1 m of 0,150, yield the complete list of IVAMP injected voltage test levels shown in Table 21, applicable for this example.

Table 21 — Example for 1 m lead located in implant volume based on TIER2B_G

TBPW (ms)	IVAMP (V)					
0,2	0,750	1,500	3,750	7,500	15,000	18,750
0,4	0,375	0,750	1,875	3,750	7,500	9,375
1,0	0,150	0,300	0,750	1,500	3,000	3,750
2,0	0,075	0,150	0,375	0,750	1,500	1,875

For Case 2, the injected voltage test levels are calculated as shown in Figure 19.

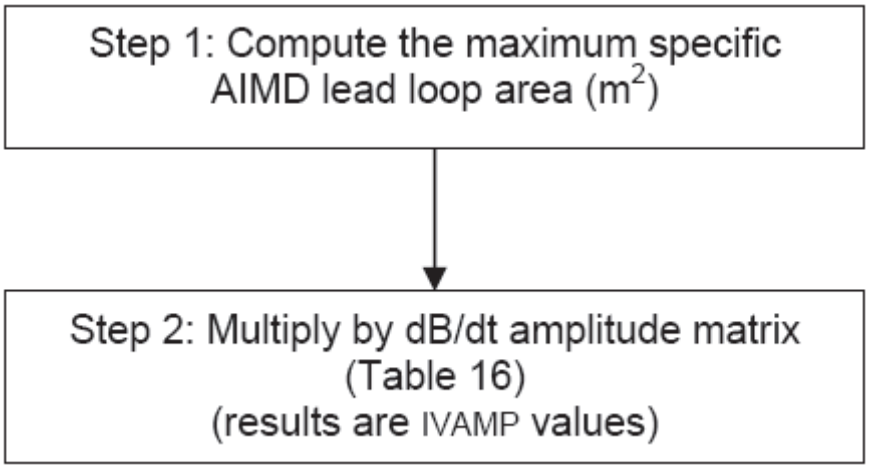


Figure 19 — Summary of steps to calculate injected voltage test levels for Tier 2, case 2

Step 1: Using spatial models or computation of the system's geometry as implanted, determine the maximum possible AIMD lead loop area (m^2).

Step 2: Based on the location of the AIMD in the bore, multiply every applicable dB/dt value in Table 16 (dB/dt = f (B_G, TSLEW) by the AIMD lead loop area determined in Step 1. The largest volume-containing portions of a system shall apply to the entire system. All dB/dt values are used for the implant volume. The resulting matrix of IVAMP values, tabulated by the gradient-induced EMF pulse width, TBPW (Figure 4), are required for the injected voltage test levels for the gradient sequence of sequences. Some combinations may be reduced with appropriate rationale and documentation by the manufacturer. For AIMDs with any portion located outside the implant volume, Tier 3 shall be used.

EXAMPLE Suppose Step 1 yielded a value from ANSI/AAMI PC69, Annex L, of 0,032 m^2 for the worst-case lead loop area of a unipolar lead. From Step 2 the determination of the largest volume-containing portion of the system was the implant volume. The resulting applicable dB/dt values would be all the values listed in Table 16. These dB/dt values, when multiplied by the loop area of 0,032, yield the complete list of IVAMP injected voltage test levels shown in Table 22, applicable for this example.

Table 22 – Example of unipolar lead with a maximum loop area of 0,0319m^2 in the implant volume

TBPW (ms)	IVAMP (V)						
0,2	0,160	0,319	0,798	1,595	3,190	4,785	6,380
0,4	0,080	0,160	0,399	0,798	1,595	2,393	3,190
1,0	0,032	0,064	0,160	0,319	0,638	0,957	1,276
2,0	0,016	0,032	0,080	0,160	0,319	0,479	0,638

20.2.3 Tier 3

This tier is intended for devices with leads as a more accurate calculation of voltage induced in the lead system from the gradient field. It requires electromagnetic computational analysis and has the potential to predict the lowest *in vivo* E-field and, hence, the lowest injected voltage test levels.

Injected voltage test levels are calculated as shown in Figure 20.

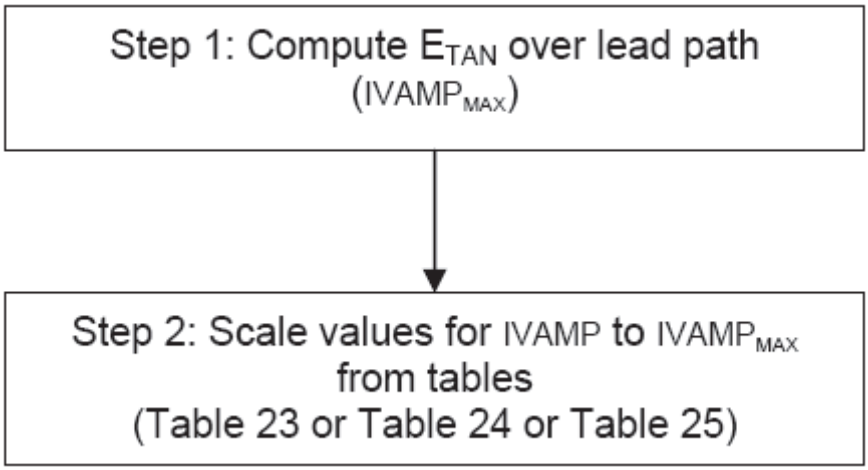


Figure 20 — Summary of steps to calculate injected voltage test levels for Tier 3

Step 1: Using models of the gradient coils, determine the tangential E-field over the anatomically relevant lead path. Compute the resulting induced voltage and apply this calculated value as the maximum injected voltage test level. For the purposes of this subclause, call this voltage level TAMPMAX.

Step 2: From the appropriate injected voltage scaling table, compute all values of IVAMP to use for the gradient sequences. Values of IVAMP are scaled to $IVAMP_{MAX}$. If the entire system is within the compliance volume use Table 23, otherwise use Table 24 for the implant volume. If any portion of the system is located outside the implant volume use Table 25.

Table 23 – Injected voltage scaling factors for compliance volume

TBPW (ms)	IVAMP (V)							
0,2	0,033 3	0,066 7	0,166 7	0,333 3	0,666 7	$IVAMP_{MAX}$		
0,4	0,016 7	0,033 3	0,083 3	0,166 7	0,333 3	0,500 0		
1,0	0,006 7	0,013 3	0,033 3	0,066 7	0,133 3	0,200 0		
2,0	0,003 3	0,006 7	0,016 7	0,033 3	0,066 7	0,100 0		

Table 24 – Injected voltage scaling factors for implant volume

TBPW (ms)	IVAMP (V)							
0,2	0,025 0	0,050 0	0,125 0	0,250 0	0,500 0	0,750 0	ivampmax	
0,4	0,012 5	0,025 0	0,062 5	0,125 0	0,250 0	0,375 0	0,500 0	
1,0	0,005 0	0,010 0	0,025 0	0,050 0	0,100 0	0,150 0	0,200 0	
2,0	0,002 5	0,005 0	0,012 5	0,025 0	0,050 0	0,075 0	0,100 0	

Table 25 – Injected voltage scaling factors for outside implant volume

TBPW (ms)	IVAMP (V)							
0,2	0,020	0,040	0,100	0,200	0,400	0,600	0,800	$IVAMP_{MAX}$
0,4	0,010	0,020	0,050	0,100	0,200	0,300	0,400	0,500
1,0	0,004	0,008	0,020	0,040	0,080	0,120	0,160	0,200
2,0	0,002	0,004	0,010	0,020	0,040	0,060	0,080	0,100

20.2.4 Test procedure

Perform the injected immunity test using the gradient sequence of sequences as described in 8.1 with the gradient test signal shown in Figure 4 with injected voltage test levels, IVAMP, determined from Tier 1, 2, or 3, as appropriate. The injection network of Annex D may be used. Some sequences may be omitted with appropriate rationale and documentation by the manufacturer. Sequences may not be omitted for Tier 1 testing.

NOTE Evidence should be provided that the gradient test signal level in combination with the tissue equivalent network of Annex D provides a conservative test when the real source impedance of the device leads in tissue is taken into account. Procedure for selection of capacitor Cx according to Annex D may not apply.

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.

20.2.5 Test equipment

20.2.5.1 Phantom and tissue simulation medium

Not used for gradient injection test.

20.2.5.2 Gradient injection network

The gradient injection network is based on Annex D and Figure D.2 from ANSI/AAMI PC69, reproduced in Annex D.

20.2.6 Uncertainty assessment

The requirements of R.7.1 shall apply.

20.2.7 Test report

The requirements of 9.5 apply.

20.3 Radiated immunity test

20.3.1 Applicability

The radiated test applies to all devices (with or without conductive leads) unless it can be shown that the device enclosure is completely shielded from magnetic fields so that device behaviour and functionality is not influenced. The test is normally performed without patient leads.

NOTE The injected test is used for all devices with conductive leads or other conductive elements such as external antennas or leadless electrode terminals.

20.3.2 Tier 1

This tier is intended for devices as a first approximation of the effects of induced voltages on internal circuits and components caused by exposure to a scanner's gradient field. It presumes orthogonality of circuits and components to the gradient field. Because a typical device enclosure occupies a small area, another presumption is made that the gradient field will be a maximum over the entire surface area.

This tier uses the highest gradient field strengths and hence will produce the highest induced voltages of any method in this clause. It does not require any electromagnetic computational analysis.

Radiated field test levels are calculated as shown in Figure 21.

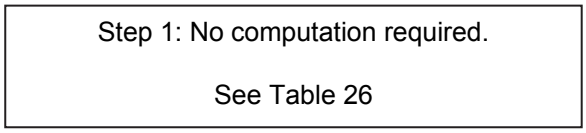


Figure 21 — Summary of steps to calculate radiated field test levels for Tier 1

Step 1: The device location within the patient and the bore will determine the amount of exposure to magnetic fields caused by the gradients. This tier provides two sets of test levels based on location within the bore. For devices located completely within the volume defined as the compliance volume, use B_G values of 30 mT and less. For devices located within the larger volume defined as the implant volume, use B_G values of 40 mT and less. For devices where any portion is located outside the implant volume, Tier 2 shall be used.

Table 26 – Tier 1 radiated gradient field strength requirements

Device location	B_G test values (mT)
Completely within compliance volume	1, 2, 5, 10, 20, 30
Inside implant volume	1, 2, 5, 10, 20, 30, 40
Any portion outside implant volume	Use Tier 2

20.3.3 Tier 2

This tier is intended for devices as a more accurate calculation of exposure to gradient magnetic field levels. It requires electromagnetic computational analysis and has the potential to predict lower exposure levels and, hence, lower test levels than those used for Tier 1 (maximum test levels are not specified as they are for Tier 1).

Radiated field test levels are calculated as follows:

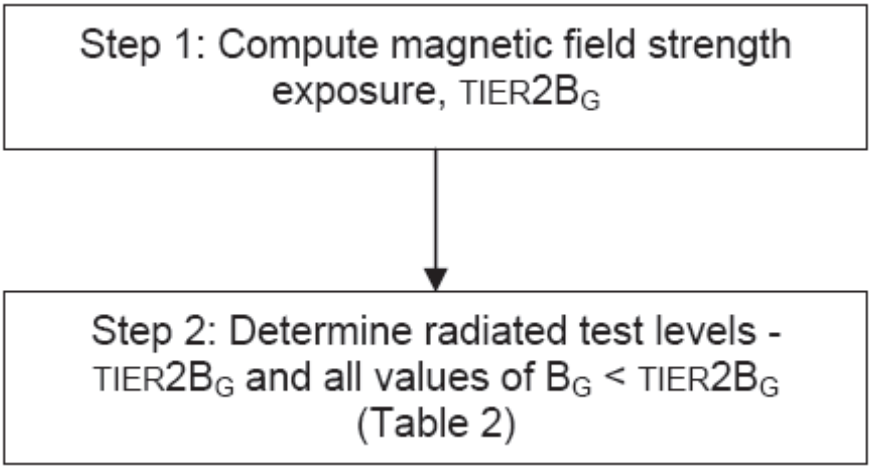


Figure 22 — Summary of steps to calculate radiated field test levels for Tier 2

Step 1: Using models of the gradient coils, compute the maximum peak-peak exposure to 3-D vector gradient field strength (mT) normal to the largest surface of the device, based on position and orientation within the bore. For the purposes of this subclause, call this computed value TIER2B_G. Field strength, TIER2B_G, shall be considered to be uniform and orthogonal over the largest surface of the device, including leads, if applicable.

Step 2: The calculated value, TIER2B_G, and all B_G values from Table 2 that are less than TIER2B_G, shall be applied as radiated field test levels (see Table 27).

Table 27 – Tier 2 radiated gradient field strength requirements

Device location	Test values (B_G mT)
Anywhere	TIER2B_G and all values of B_G less than TIER2B_G (see Table 2)

20.3.4 Test procedure

Perform the radiated immunity test using the gradient sequence of sequences as described in 8.1 with the gradient test signal shown in Figure 3 with the gradient field strength, B_G, determined from Tier 1 or Tier 2, as appropriate. Some sequences may be omitted with appropriate rationale and documentation by the manufacturer. Sequences may not be omitted for Tier 1 testing.

This test is normally performed without patient leads. For leads, see 20.2. The tissue simulation medium is not required if tested without leads.

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.

NOTE Although a clinical scanner may be used for the radiated method, its use is not recommended. If a manufacturer intends to use a clinical scanner method, development and validation of the method is left to the manufacturer.

20.3.5 Test equipment

20.3.5.1 Generating the magnetic field

An appropriate lab coil may be used.

NOTE Further development is planned in a future edition of this Technical Specification.

20.3.5.2 Phantom and tissue simulation medium

See 11.3.3 for more information.

20.3.6 Uncertainty assessment

The requirements of R.7.2 shall apply.

20.3.7 Test report

The requirements of 9.5 apply.

21 Combined fields test

The purpose of the combined fields test is to provide an additional assurance of AIMD operation according to its MR Conditional labelling (above and beyond the test results from Clause 10 to Clause 20) under simultaneous exposure to static, gradient and RF field conditions representative of the clinical MR scanner environment. A successful outcome of this test (combined fields) is a qualitative confirmation of some of the test results (from Clause 10 to Clause 20) realizing the limitations of exposure to a minimal set of scanner sequences.

NOTE 1 A combined fields test is not adequate, on its own, to fulfil the stated purposes in Clause 1 of this Technical Specification.

Combined fields testing is recommended when the results of the individual field tests in Clause 10 to Clause 20 are uncertain as to the effects imposed by the simultaneous application of all three scanner fields or when there is uncertainty over the use of bench-top tests. The following exceptions apply.

— B_0-induced force (Clause 13).

— B_0-induced torque (Clause 14).

— B_0-induced malfunction (Clause 18).

— Heating evaluations. Evaluation of the spatially-resolved additive heating of gradient fields (Clause 11) and RF fields (Clause 10) is preferred above combined fields test approaches.

— Gradient-induced vibration if testing in accordance with Clause 12 was performed in a scanner. An RF field is not needed for testing.

For all other hazards from Table 1, combined fields testing is recommended. Additional functional tests under combined high-field conditions are recommended for different typical and defined MR sequences in order to demonstrate that none of the parameters are affected more than predicted from the tests in Clause 10 to Clause 20. These tests are AIMD dependent and should be selected by the manufacturer case by case. Performance and behaviour should be monitored during and after the test for proper functionality in accordance with the manufacturer's MR Conditional labelling.

NOTE 2 MR Compatibility protocols provided by MR vendors (see IEC 60601-2-33:2010, 201.7.9.3.101) may be helpful in designing combined field tests.

22 Markings and accompanying documentation

22.1 Markings on item(s) as appropriate, including the AIMD, packaging, accompanying documentation and the patient implant card, shall include the term "MR Conditional" together with the corresponding icon (symbol). The icon (symbol) is specified in ASTM F2503-08, Table 1 and Table 2. The conditions under which the AIMD can be scanned safely shall be included in the accompanying documentation.

Compliance shall be checked by inspection.

22.2 If the patient implant card contains an MR Conditional symbol, the card shall contain a statement directing users to up-to-date information, e.g.: "Please refer to [insert appropriate manufacturer URL] for up-to-date information regarding MR Conditional labelling and instructions for this device." The card will specify sufficient model information to correctly locate the appropriate MR Conditional labelling for all AIMD system components (e.g. leads, pulse generator).

Compliance shall be checked by inspection.

22.3 The accompanying documentation shall contain warning notices regarding the hazards that could be caused by performing an MR procedure on a patient with an AIMD. This information shall also include the patient risks associated with not following the instructions for safe scanning provided by the AIMD manufacturer.

Compliance shall be checked by inspection.

22.4 The accompanying documentation shall consider the risks due to implant location, abandoned or fractured leads, and to other AIMDs or passive implants.

Compliance shall be checked by inspection.

22.5 If appropriate, the accompanying documentation shall give a method for determining that the AIMD is working correctly following the MRI examination.

Compliance shall be checked by inspection.

22.6 The accompanying documentation shall include instructions for safely performing the MR procedure on the patient. This might include patient preparation, procedural instructions, special AIMD operating modes, peripheral equipment needed, necessary patient monitoring during and after scanning, or other similar instructions to ensure safety.

Compliance shall be checked by inspection.

22.7 The accompanying documentation shall describe all the conditions for safe scanning that apply to an AIMD that is labelled “MR Conditional”. This might include, for example, AIMD settings and operating modes, device configuration (component parts), and MR scanner limitations related to spatial encoding gradients (dB/dt), static magnetic field, and RF fields and transmit RF coil type.

Compliance shall be checked by inspection.

22.8 The accompanying documentation shall describe all intended and expected behaviour and performance during an MRI scan that applies to an AIMD labelled "MR Conditional". This shall include the intended and expected behaviour and performance regarding the hazards listed in Table 1.

Compliance shall be checked by inspection.

22.9 The accompanying documentation shall include advice that the patient should be warned to notify medical personnel that they have an AIMD before entering the MR environment and to present their patient ID card, if they have been given one.

Compliance shall be checked by inspection.

22.10 The AIMD may interfere with the acquisition of MR data, resulting in artifacts that may compromise MR images. The accompanying documentation shall contain a statement concerning AIMD-induced MR image artifacts.

Compliance shall be checked by inspection.

Annex A
(informative)

Gradient vibration patent declaration form

Patent Statement and Licensing Declaration Form for ITU-T/ITU-R Recommendation | ISO/IEC Deliverable

Patent Statement and Licensing Declaration
for ITU-T/ITU-R Recommendation | ISO/IEC Deliverable

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Patent Holder:

Legal Name	Medtronic, Inc.
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(*)Number	ISO/TS 10974
(*)Title	Requirements for the safety and compatibility of magnetic resonance imaging for patients with an active implantable medical device

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Name of authorized person	**Charles L. Dennis, II**
Title of authorized person	**Vice President, Innovation Portfolio & Intellectual Property, Cardiac Rhythm Disease Management**
Signature	
Place, Date	11 November 2010

Annex B
(informative)

Derivation of lead length factor for injected voltage test levels for gradient-induced malfunction

B.1 General

Table 18 and Table 19 were created to provide, in conjunction with Table 16, a worst-case test signal amplitude to simulate an induced electromagnetic force, EMF, generated by a time-dependent magnetic field.

Planning discussions regarding radiated tests were based on placing a lead in a semi-circle or half-ellipse configuration. The normal vector of the surface area enclosed by the lead was considered to be parallel to the external magnetic field of a gradient "coil" system. These configurations were discussed due to their ease of experimental set-up and reasonable approximation of pacemaker and neurostimulator lead placement.

Maxwell's equation for free space that relates the E-field to a time-dependent magnetic field is given in Equation (B.1). The EMF is the line integral of the E-field, Equation (B.2).

$$\nabla \times E = -\frac{\partial B}{\partial t} \tag{B.1}$$

$$EMF = \oint E \cdot dl = \int \nabla \times E \cdot da = \int \frac{\partial B}{\partial t} \cdot da \tag{B.2}$$

To create Table 18 and Table 19, the following assumptions were made.

a) For leads shorter than 63 cm:

   1) the E-field is spatially uniform and is in the direction of the lead path.

b) For leads longer than 63 cm:

   1) the time-dependent magnetic field is uniform for all space;

   2) the surface area traced by the lead path is either a semi-circle or a half-ellipse (the normal vector of the surface area enclosed by the lead is parallel to the time-dependent magnetic field vector direction).

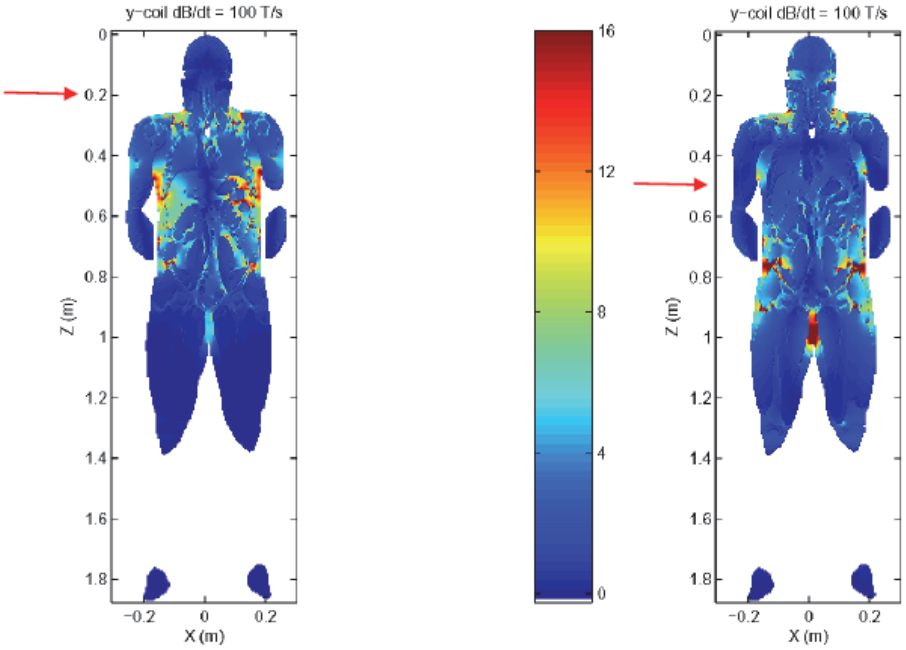
B.2 Leads shorter than 63 cm

Simulations were performed of a gradient field from a typical MRI with a maximum $\partial B/\partial t$ of 100 T/s at a cylinder radius of 20 cm (see Figure B.1). These simulations indicate that peak E-field values can reach 16 V/m and on average are approximately 10 V/m.

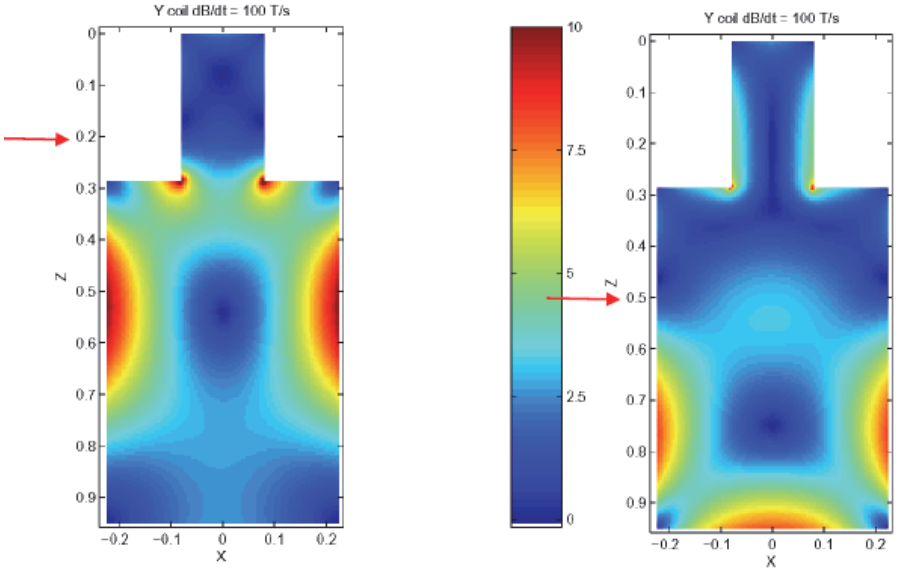
For short leads it is possible that the lead will be orientated in the same direction as the E-field from the $\partial B/\partial t$ of the gradient field. For leads measuring 10 cm or shorter, an E-field magnitude of 16 V/m was used to determine induced EMF and then scaled to 1 T/s.

For leads longer than 10 cm, an E-field magnitude of 10 V/m for the equation $E \cdot l$ will be equal to $\partial B/\partial t \cdot A$(semi-circle) when the lead length is 63 cm. Therefore, for lead lengths greater than 10 cm and up to 60 cm, an E-field magnitude of 10 V/m was used to determine induced EMF and then scaled to 1 T/s. To prevent a

discontinuity between the values of 10 cm and 15 cm, the 10 V/m was scaled linearly to 16 V/m between the lengths of 10 cm and 63 cm. In practice, 10 V/m is only used for 63 cm; shorter leads use an elevated E-field magnitude until at 10 cm a value of 16 V/m is attained.



Calculated electric field intensity in human model in a y-gradient coil in a coronal slice through the vertical center of the patient. Landmarks (center of RF coil) are indicated by the arrows. The maximal dB/dt on a cylinder of 20 cm radius is 100 T/s. Color bar is in V/m.



Calculated electric field in a phantom in a y-gradient coil. Landmarks (center of RF coil) are indicated by the arrows. The maximal dB/dt on a cylinder of 20 cm radius is 100 T/s. Color bar is in V/m.

Figure B.1 – Calculated E-field intensities in human model and phantom

B.3 Leads longer than 63 cm

For leads arranged along a circular path (see Figures B.2 and B.3) the area enclosed by the lead is calculated by Equation (B.4) for angles less than π radians and Equation (B.5) for angles greater than π radians.

Equation (B.3) constrains the radius of the circular path such that the lead length is constant for different sweep angles. Since the radius is constrained by the lead length, the maximum surface area occurs when the swept angle is π radians (refer to Figure B.4). Therefore, the tables are constructed using the area of a semi-circle, Equation (B.2).

Clause 20 includes calculations for different radii in the scanner bore, "compliance volume" r = 20 cm and "implant volume" r = 25 cm. To accommodate lead lengths that will exceed the volume's radii when placed in a semi-circular configuration, a half-ellipse model was utilized such that the semi-minor axis is forced to be either 20 cm or 25 cm. The lead length was calculated using Equation (B.6). The transition from a semi-circle to half-ellipse occurs for leads greater than 65cm for the "compliance volume" and greater than 80 cm for the "implant volume".

To calculate the induced EMF for different lead lengths, the swept area for either the semi-circle or half-ellipse was multiplied by a $\partial B/\partial t$ of 1 T/s. Therefore, to calculate the actual worst-case EMF generated, the table value should be multiplied by the expected $\partial B/\partial t$ exposure. A single $\partial B/\partial t$ is used for the "implant volume", instead of one for r = 0 cm to 20 cm and another for r = 20 cm to 25 cm. This was done to simplify the tables even though it results in a higher EMF than would be expected.

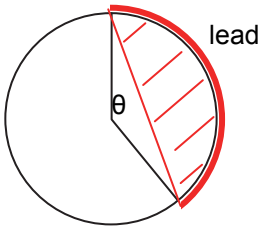


Figure B.2 – Area bounded by a lead arranged along a circular path for an angle < π radians with a straight line return path.

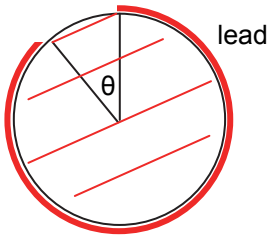


Figure B.3 – Area bounded by a lead arranged along a circular path for an angle > π radians with a straight line return path.

$$r = \frac{l}{\theta} \tag{B.3}$$

$$A = \frac{1}{2} r^2 (\theta - \sin\theta) = \frac{1}{2}\left(\frac{l}{\theta}\right)^2 (\theta - \sin\theta) \tag{B.4}$$

$$A = \pi r^2 - \frac{1}{2} r^2 (\theta - \sin\theta) = \pi\left(\frac{l}{\theta}\right)^2 - \frac{1}{2}\left(\frac{l}{\theta}\right)^2 (\theta - \sin\theta) \tag{B.5}$$

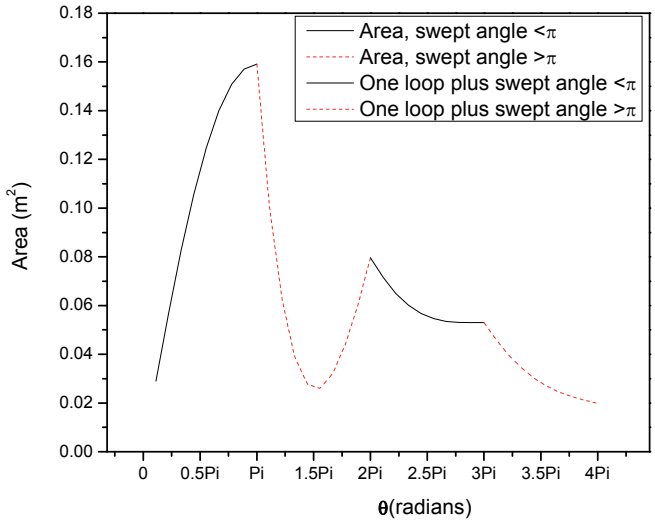


Figure B.4 – Area enclosed by a fixed lead length of 1m when placed along a circular path for different swept angles

$$Lead\ length = 2a\int_0^{\pi/2} \sqrt{1-\left(\frac{a^2-b^2}{a}\right)\left[\sin(\theta)\right]^2}\, d\theta \qquad \text{(B.6)}$$

where

a is the semi-major axis length;

b is the semi-minor axis length.

Some comments on further calculations that may be performed to improve the calculation of the induced EMF are as follows.

a) It is known that the $\partial B/\partial t$ is not spatially uniform. One may choose to include the spatial dependency in the calculations. For example, one may assume two different values for $\partial B/\partial t$; one for the “compliance volume” and another for the “implant volume”.

b) Since the curl of E is non-zero, E is a non-conservative field and the line integral is path dependent. One may simulate the $\partial B/\partial t$ or E and perform line integrals on more realistic lead paths.

Annex C
(informative)

Basic MR physics

C.1 Static magnetic field

The static magnetic field (SMF) of the magnet does not just produce a SMF inside the bore of the system. In the area around the system, the stray field of the magnet is also to be taken into account. Apart from exposure to the static magnetic field, in clinical practice the most severe accidents occur when ferromagnetic objects are brought into the vicinity of the magnet and become very dangerous missiles when attracted by the magnet of the system. Many incidents have been reported and clearly can only be avoided by careful procedures in the hospitals.

The values for the SMF (0 Hz) are in the range of 0,2 T up to 7 T for clinically available scanners and can be vertical (in the open MR scanners) or horizontal in the cylindrical magnets. For most high field MR scanners, the SMF is permanently present due to the superconductive magnets applied on 95 % of the scanners. The stray field of the magnet can be significant as a result of the fact that modern MR scanners apply shielded magnets, which implies that the magnetic field decays faster as a function of the distance away of the scanner, resulting in a lower field and thus less siting problems in the hospital environment. The stray field can have magnetic spatial gradient fields up to 12 T/m for a standard 1,5 T active shielded magnet just outside the bore opening of the magnet.

C.2 Gradient field

In addition to the SMF, switched gradient magnetic fields are applied during MR scanning in the frequency range between 0 Hz and 5 kHz. While the SMF is always present in and around the scanner, the switched gradient magnetic field is only present during scanning of the patient. The waveforms applied can have very different shapes and are certainly not always sinusoidal. The waveforms typically are also intermittent. For patients, it is well accepted that the limits for the gradients applied during scanning are set at values to avoid peripheral nerve stimulation, an effect well known and scientifically understood and well controlled on the MR scanners (via requirements spelled out in IEC 60601-2-33).

The strength of the gradient magnetic field is typically expressed in T/m or in T/m/s; the latter is referred to as the slew rate of the gradient system. It gives the relevant information about amplitude and switching times of the gradient magnetic fields. Currently, the high performance systems can have gradient outputs up to 400T/m/s or 200T/m. For testing of the AIMD safety, it is important to realize that the maximum values of the applied gradients vary a lot in the patient space inside the MR scanner and that the specification of the worst-case position and worst-case specification of the gradient performance is critical. The worst-case specification can be much higher than clinically applied for patients because of the peripheral nerve stimulation limitations.

C.3 RF field

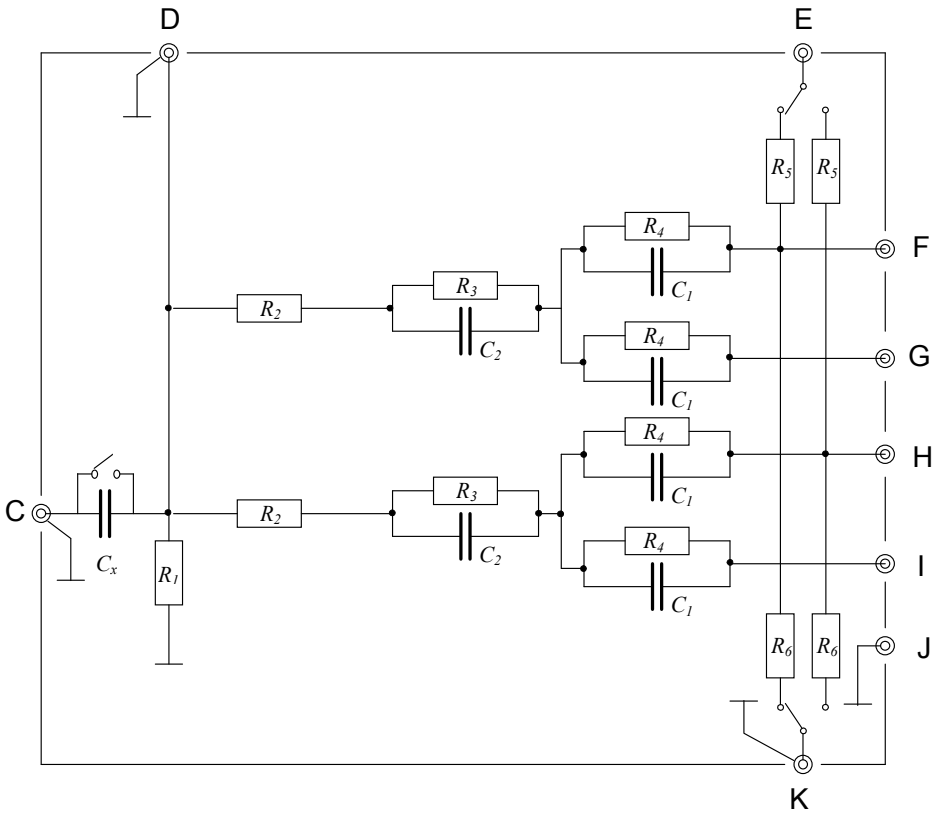
The third type of electromagnetic field is the pulsed radio frequency (RF) field. The RF waveform can be a modulated sinusoidal waveform (e.g. pulsed) or a block pulse and is also only applied during scanning. The frequency content of the RF pulse is specified around the Larmor frequency for the protons at the value of the static magnetic field and has a range of a few hundred kHz around the Larmor frequency. The amount of RF energy absorbed by the human body can be calculated. Much is known about the heating effect in human tissue as a result of this type of EMF exposure. For patients, the maximum allowed values of the RF energy are related to the maximum temperature rise accepted for the body of the patient. This limit is set at 1 °C for the patient (IEC 60601-2-33), which is a very conservative value.

The strength of the applied RF field is typically expressed in microTeslas. Depending on the dimensions of the transmit coil in the MR scanner, this transmit field can be as high 40 microTesla. The maximum allowed values for the amount of RF energy are controlled on the MR scanner via the specific absorption rate (SAR) value, a value which is calculated prior to each scan and which fulfils the requirements as specified additionally in IEC 60601-2-33.

Annex D
(informative)

Gradient injection network

D.1 General



Key
C Input (test signal)
D Test point (test signal)
E Input (inhibition generator)
K Monitoring point
F, G, H, I, J Device connection points

Figure D.1 – Tissue equivalent interface circuit for gradient malfunction

All resistors used should be of film type with low inductance, tolerance ±2 %, rated 0,5 watt. All capacitors are of the ceramic type, tolerance ±5 %, unless otherwise stated.

Table D.1 – Component values for Figure D.1

R_1 68 Ω (2W)	C_1 15 nF
R_2 82 Ω (1W)	C_2 180 pF
R_3 120 Ω	C_X Refer to D.2
R_4 560 Ω	
R_5 56 kΩ	
R_6 1 MΩ	

D.2 Method for selecting capacitor C_x

The following procedure describes a method for selecting capacitor C_X that is used in the tissue interface circuit of Figure D.1. Capacitor C_X is used to reduce any spuriously injected low-frequency signals from the interference signal generator.

For the procedure, use oscilloscopes, input impedance of 1 MΩ ± 10 %, < 30 pF, accurate to ± 10 % within a bandwidth of at least 30 MHz. For frequencies above 9 kHz, the low-pass filter should conform to Figure D.2. For frequencies below 9 kHz, low-pass filter may require proper scaling.

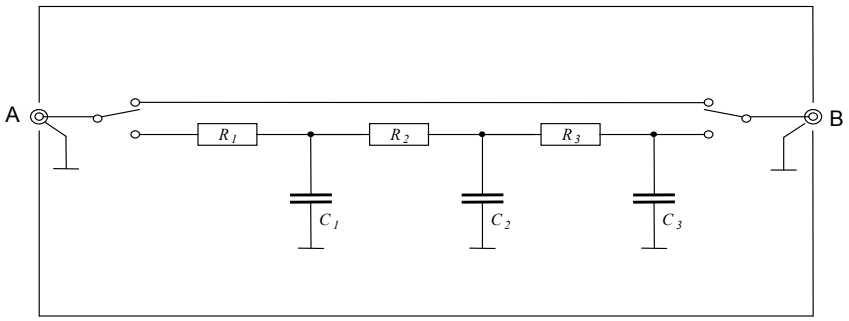


Figure D.2 – Low-pass filter used to attenuate the 500 kHz component of test signal

Table D.2 – Component values for Figure D.2

R1 4,7 KΩ	*C1* 22 nF
R2 15 kΩ	*C2* 16.8 nF
R3 47 kΩ	*C3* 2.2 nF

The test signal generator and tissue equivalent circuit to be used in the test procedure are connected to the oscilloscopes and low pass filter as shown in Figure D.3. Adjust the test signal generator to provide the signal specified in the appropriate test procedure in Clause 16 or Clause 20.

If feasible, select a value of C_X for a reading that is less than 0,05 mV, measured at test point B of the low-pass filter.

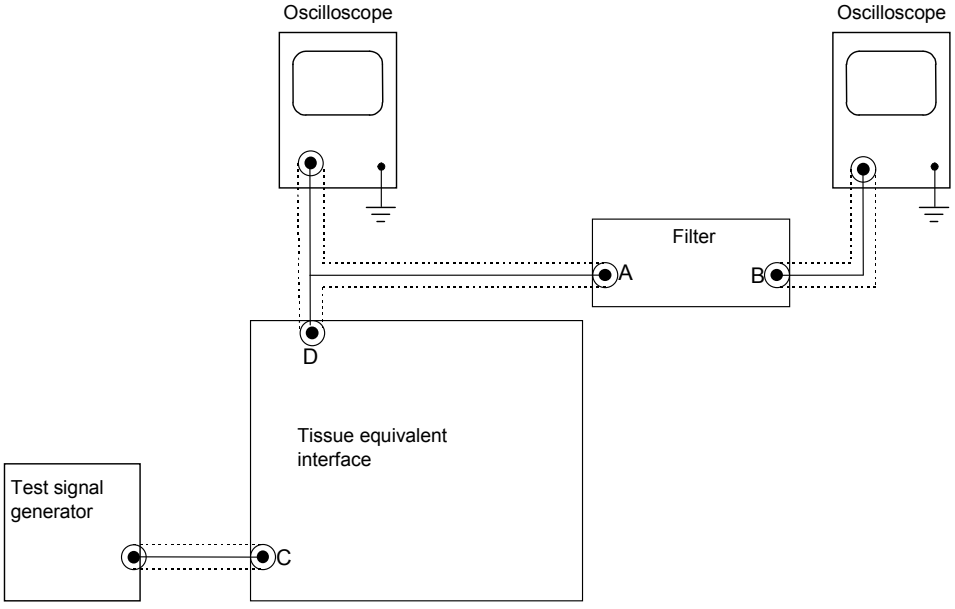


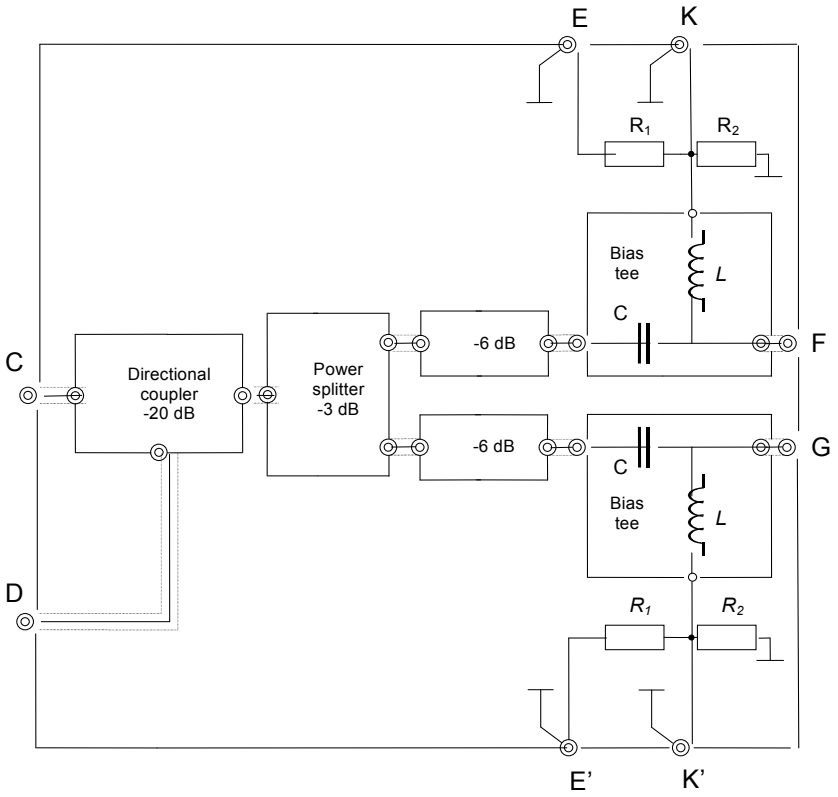
Figure D.3 – Test to check for spurious low frequency noise and to determine the value of C_X

Annex E
(informative)

RF injection network

E.1 General

Figure E.1 shows an RF injection network.



Key
C Input (test signal)
D Test point (test signal)
E Input (inhibition generator)
F Output to device
G Output to device
K Monitoring point (device)
E' Input or termination
K' Monitoring point (device) or termination

Figure E.1 – RF injection network

All resistors used should be of film type with low inductance, tolerance ± 2 %, rated 0,5 watt. All capacitors are of the ceramic type, tolerance ± 5 %, unless otherwise stated.

Table E.1 – Component values for Figure E.1

R_1	56 kΩ	R_2	500 Ω
Bias Tee	C = 120 pF, L = 0,5 mH		

The two bias tees shown in Figure E.1 should provide a capacitor value of 120 pF ± 5 % and a minimum filter inductance of 0,5 mH.

NOTE This recommendation eliminates potential testing variability, which can occur with an unspecified bias tee capacitor. This capacitor should be specified so that variability of network source impedance is eliminated at lower test frequencies. The calibration process (below) does not adequately compensate bias tee capacitor effects occurring under device loads, since an unmodified bias tee and a device will have unequal impedances in a 50 Ohm system.

The following procedure describes a method for calibrating the injection network of Figure E.1. The calibration factor, m, is the link between test voltage V_{PP} (measured at point F) and measured voltage of the oscilloscope #1 connected to test point D of the injection network, V_{OSC}.

$$V_{PP} = m \times V_{OSC}$$

If only high frequency components with specified low tolerances are used, the calibration factor can be calculated using the formula:

$$20 * \log (m) = - [a_{DC} + a_{PC} + a_{AT} + a_{BT}] + c_{DC} + 6\ dB$$

where

a_{DC} is the maximum insertion loss of the directional coupler in dB;

a_{PC} is the maximum insertion loss of the power splitter for each way in dB;

a_{AT} is the maximum insertion loss of the attenuator in dB;

a_{BT} is the maximum insertion loss of the bias tee in dB;

c_{DC} is the minimum coupling loss of the directional coupler in dB;

and coupler loss is entered as a positive value.

Otherwise the calibration factor is determined as follows.

E.2 Calibration equipment

The configuration of Figure E.1 is used. Output G is terminated by a 50 Ω terminator. Output F is connected to a calibrated high frequency voltage meter with an input impedance of 50 Ω, an accuracy of at least ±1 dB and a bandwidth of at least 450 MHz.

E.3 Calibration signal

The output from the test signal generator should be an unmodulated carrier.

E.4 Calibration procedure

The calibration signal should be increased until the output voltage at the voltage meter reaches the peak-to-peak value indicated in Table E.2. Read the peak-to-peak voltage on oscilloscope 1 connected to test point D of the injection network, V_{OSC}. The calibration factor, m, is equal to 10 V divided by V_{OSC}.

Table E.2 – Calibration signal amplitude scale

Frequency (MHz)	Output F (test voltage V_{PP})
10	2,58
20	3,85
30	4,38
40	4,62
50	4,75
60	4,82
70	4,87
80	4,90
90	4,92
100	4,93
150	4,97
200	4,98
300	4,99
400	5,00
450	5,00

Depending on available test equipment, these values may be converted to $V_{(RMS)}$. This is left to the discretion of the party performing the test. The calibration amplitudes and units should be documented in the test report.

Annex F
(informative)

Estimation of the temperature rise *in vivo* from determined energy deposition

F.1 General

The SAR or temperature increase measured in the test phantom is not directly related to the temperature increase in tissue, even for the same energy deposition, because the local thermal properties of tissue significantly deviate from those of the test phantom. Estimation of temperature increase in tissue, given the measured SAR or temperature increase in the test phantom, is possible with two additional steps:

a) translation of measured SAR or ΔT into local energy deposition;

b) transformation of local energy deposition into *in vivo* temperature changes.

In other words, the test phantom enables the determination of the energy deposition around the AIMD and the heating in a phantom. This is the basis for assessing the heating in a real patient geometry via thermal modelling.

Due to the different thermal properties, any location that is exposed to integrated energy deposition of -6dB of the peak integrated energy deposition should be evaluated.

This annex describes how the experimentally determined energy deposition around a test object can be used to estimate the maximum temperature increase in tissue. This annex also includes a multi-tier approach that allows the practitioner to choose from appropriate methods ranging from simple and conservative to more complex and with tighter safety margins.

The maximum temperature rise, which is typically observed at the interface between the implant and the surrounding tissue, falls off dramatically as a function of distance. Implanted objects, for example metal electrodes, cause a physiologic response resulting in the formation of a fibrotic capsule or scar tissue growth in the immediate vicinity of the implants. Formation of the scar tissue is a complex process depending on time and space. Detailed discussion on scar tissue can be found in Annex O. Depending on the particular AIMD and application, elevated temperatures within the scar tissue region surrounding an implant may not be clinically significant since scar tissue is not viable for electrical stimulation therapy (for example, cardiac pacing). In contrast, it is the temperature rise in viable tissue, which may be several millimetres away from the implanted device, which is the primary safety concern.

F.2 Outline of the five ΔT-Tier approach for assessment of *in vivo* temperature rise

It is always possible to skip lower tier validations and immediately perform a higher tier validation. All reported *in vivo* temperature rise estimates, regardless of the tier of analysis, require an accompanying uncertainty analysis, as described in F.3. Tier 5 is less well defined and only the basic requirements are provided without detail requirements regarding the uncertainty budget.

F.2.1 First ΔT-Tier

The most conservative estimation is:

$$T_{\text{incr,max}} = (S_{\text{max}}) \times t_{\text{exposure}} / c_{\text{min}}$$

where

S_{max} is the maximum local RMS SAR;

$t_{exposure}$ is the exposure time in the MR scanner;

c_{min} is the minimal heat capacity of any region in the heated area.

F.2.2 Second ΔT-Tier

Thermal simulations are performed in homogeneous phantoms with the previously assessed energy deposition distributions for the appropriate AIMD configuration(s). The worst-case thermal capacity and transfer parameters for any of the tissues in which >10 % of the deposited energy is absorbed should be used. For example, if energy is absorbed in three different tissue types in the anatomical region of interest, the ΔT estimation is the maximum ΔT simulated in homogeneous phantoms with worst-case thermal parameters for each of the three tissues.

F.2.3 Third ΔT-Tier

Thermal simulation is performed on a volume of tissue encompassing the peak energy deposition (SAR) around the AIMD and extending to within 1 % of the peak SAR value. Model parameters will be conservative with respect to thermal flux. All relevant geometries and anatomical targets are modelled and worst-case model parameters are assigned with respect patient variation, tissue scarring and thermoregulation. Modelling the implant is required only if significant energy is deposited within the implant. Otherwise, the implant can be excluded from the model and replaced by an isolating boundary condition at the tissue/implant interface.

F.2.4 Fourth ΔT-Tier

Thermal simulations are performed for a large domain encompassing the entire relevant heated region (all relevant geometries). Convective boundary conditions can be used at the surface or for internal cavities with airflow; however, worst-case convective coefficients should be assigned. If scar tissue can form next to the implant, all relevant scar tissue shapes should be modelled. Worst-case conditions should be assumed for all tissue parameters (solid-wise, variations due to scarring are not considered because scar tissue is modelled separately). The implant can either be modelled a) in detail (in this case, a detailed experimental validation of the implant model is required), b) as an isolating boundary condition (if perfectly shielded) or c) as a homogeneous solid with parameters corresponding to the worst-case component of the implant.

F.2.5 Fifth ΔT-Tier - Tissue temperature by direct measurement in animals

Temperature rise can also be assessed *in vivo* by using appropriate measurement protocols and instrumentations. It is a difficult assessment since many parameters are difficult to determine and therefore the uncertainty budget is difficult to assess, especially since not all uncertainty parameters can be considered independent. The following uncertainty budget should be provided, including strong support by validation:

— uncertainty budget with respect to the determined energy deposition in 10.7 in terms of magnitude and 3D distribution at location of the assessment;

— uncertainty budget for the thermal properties (heat capacity, conductivity, perfusion) during the measurements with respect to the worst-case human tissue.

F.3 Uncertainty budget of ΔT-Tier 1 to Tier 4

A comprehensive uncertainty budget is to be performed and reported. The uncertainty budget should include all of the following parameters:

— energy deposition (see 10.7);

— shape of tissues and implant at the energy deposition;

— thermal conductivity;

— density;

— perfusion rate;

— heat-induced changes of the metabolic heat generation rate;

— specific heat capacity;

— numerical uncertainties;

— boundary conditions;

— grid resolution;

— convergence;

— field interpolation.

The tolerance or uncertainties of these parameters with respect to the *in vivo* worst case should be treated as independent when possible and the uncertainty for the end point, i.e. the *in vivo* temperature rise in tissue determined. The RSS value can be treated as the uncertainty or as the offset in the final evaluation.

Annex G
(informative)

Methods of assessment of the temperature rise *in vivo*

G.1 Basics

The Pennes bioheat equation (PBE) may be used to transform energy deposition into temperature changes with given local tissue parameters:

$$\rho c \frac{\partial T}{\partial t}(\vec{x},t) = \nabla \cdot (k(\vec{x}) \nabla T(\vec{x},t)) + \rho Q + \rho S - \rho_{\mathrm{b}} c_{\mathrm{b}} \rho \omega (T - T_{\mathrm{b}}) \tag{G.1}$$

where

T is temperature;

k is thermal conductivity;

S is energy desposition;

ρ is density;

ω is perfusion rate;

Q is metabolic heat generation rate;

c is specific heat capacity;

T_{b} is basal metabolic temperature of blood.

The index, b, indicates a blood property. The energy deposition, S, can be obtained in the test phantom configuration at the relevant incident field strength (see F.2) by a detailed 3D SAR measurement scan with a spatial resolution of <1mm or EM simulations of the relevant AIMD location by point SAR measurements or EM and thermal simulations and point temperature measurements.

The index, b, indicates a blood property. Relevant boundary conditions are:

— the Dirichlet ($T = T_{amb}$);

— the Neumann ($k \frac{\partial T}{\partial n} = q$);

— and the mixed (convective) boundary condition [$k \frac{\partial T}{\partial n} = h(T_{amb} - T)$, where h is convection coefficient].

The boundary conditions can be expressed in a more general form as:

$$a \frac{\partial T}{\partial n} + bT = c \tag{G.2}$$

For moderate temperature increases, where the tissue parameters can be considered constant (e.g. no perfusion changes in response to deposited energy), the substitution T=T_{base}+T_{incr}, where T_{base} is temperature in absence of deposited energy, and T_{incr} is induced temperature increase as a result of deposited energy, can be performed and a new set of equations is obtained:

$$\rho c \frac{\partial T_{\text{incr}}}{\partial t}(\vec{x},t) = \nabla \cdot (k(\vec{x}) \nabla T_{\text{incr}}(\vec{x},t)) + \rho S - \rho_{\text{b}} c_{\text{b}} \rho \omega T_{\text{incr}} \tag{G.3}$$

and

$$a \frac{\partial T_{incr}}{\partial n} + b T_{incr} = 0$$

These equations describe the relevant temperature increase while avoiding the use of parameters, such as the metabolic heat generation rate, blood temperature and environmental temperature, thus reducing the number of variables.

G.2 Temperature modelling

In the case of homogeneous media, a Green's function approach may be used to determine the steady state temperature distribution based on energy deposition convoluted with the Green's function of Equation (G.3). The (spherically symmetric) steady state Green's function of Equation (G.3) in homogeneous material is:

$$G(R) = \frac{\rho}{4\pi\pi k} exp(-vR) \tag{G.4}$$

where

$$v = \sqrt{\frac{\rho_b c_b \omega}{(k \cdot c)}}$$

For non-homogeneous tissues, FE or FDTD-based modelling can be applied. Implementations that allow simulations of implant, tensorial and discrete vessel networks can also be applied to reduce the safety margin. Several validated commercial codes are available to perform these simulations. For any of the temperature-based evaluations, an extended uncertainty budget is required, including all parameters of F.3

Worst-case estimations are obtained when the following variables are minimal (at the lowest value featured in the population): ω, ρ, c, k, ρ_b, c_b; however, Q is to be be maximal (for example, increased metabolic activity under exposure should be considered).

G.3 *In vivo* confirmation

The assessment of heating due to RF fields may be confirmed using direct tissue temperature measurements in animals. Although particular approaches may vary due to specifics of AIMD design and anatomic target, animal validation studies will be composed of the following elements.

Compute the AIMD-associated tissue temperature rise in a suitable large animal numerical body model (pig, dog, sheep, etc.) that produces an E-field distribution over the AIMD that is nominally equivalent to the computed distribution in human body models in terms of phase and amplitude distribution. It should be demonstrated that the phase and amplitude diversity along the lead path are reasonably equivalent to the human. *In vivo* temperature rise will be computed for both head first and tail first orientations of relevant axial (landmarks) and radial (left, right) body positions with respect to the scanner patient table to account for the influence of elliptical B_1 polarization. The computational method and RF coil configuration will be identical to the one used for the human body E-field computations.

Measure the AIMD-associated tissue temperature rise in animals using identical B_1 RMS (or SAR), lead route and body position used in the computational methods. The number of animals used should be sufficient to capture the anatomical variability of the animal population with respect to the animal body model and the variation of the AIMD placements with respect to placement in the model. *In vivo* temperature measurements will be made using an AIMD instrumented with a fibre-optic (or equivalent) temperature probe with a well characterized measurement uncertainty. Probes should be placed on the AIMD in locations that produce the highest temperature rise.

Validate the AIMD model using appropriate statistical analysis. The total predicted temperature uncertainty should include the variability of the differences between the predicted and measured *in vivo* temperatures.

If the distribution of the differences of all individual differences are Gaussian and within the bounds of the combined uncertainty, the validation can be considered validated and the combined relative uncertainties should be considered as an additional bias in the evaluation.

Annex H
(informative)

Assessment of dielectric and thermal parameters

H.1 Dielectric measurements

H.1.1 General

This subclause describes the measurement of the dielectric properties of tissue-equivalent material by providing sufficient details to enable users to perform accurate measurements of the dielectric properties of liquid or solid materials including the corresponding uncertainties. Alternative methods may be used such as slotted lines, etc.

The open-end coaxial transmission line method is well suited for any highly homogeneous materials, such as liquids and some gel-like materials, for frequencies above 300 MHz. At lower frequencies, polarization effects should be carefully analysed.

The TEM transmission line method is a volume method and less sensitive to non-homogeneous distributions at the surface or frequency limitations, provided it is sufficiently long. This contribution intends to provide an overview of the TEM test methodology to perform dielectric property measurements of hand phantom material. The dielectric parameters to be determined are the complex relative permittivity $\varepsilon_r = \varepsilon_r' - j\sigma / \omega\varepsilon_0$ of the material.

H.1.2 Open-ended coaxial method for liquids and gels

Measurements are made by placing the probe in contact with the sample and measuring the admittance or reflection coefficient with respect to the open-circuit end, using a network analyser or equivalent instrumentation. Test procedures should specify the network analyser calibration and settings for the required frequency range. The application software should interpret the measured data to yield the dielectric properties of the sample as a function of frequency. To use this technique, a probe and a software package for the network analyser has to be developed or obtained from a commercial source. The methodology should specify the probe size and applicable frequency range, details of which are described in H.3.1 and H.3.2.

H.1.3 TEM transmission line method

The TEM transmission line method is based on the measurement of the complex transmission coefficient of a TEM-mode coaxial transmission line filled with the test sample. The measurement of transmission coefficient is performed using a vector network analyser to determine magnitude and phase of the scattering coefficient S_{21}. The measured data is then used to calculate the complex permittivity as a function of frequency. Details of this method are given in H.3.2.

H.1.4 Uncertainty budget of dielectric parameter measurements

Table H.1 — Example uncertainty template for dielectric constant (ε*r*′) or conductivity (σ) measurement at a specific frequency band

Uncertainty component	Tolerance/ uncertainty value (± %)	Probability distribution	Divisor	*ci*	Standard uncertainty (± %)	*vi* or *veff*
Repeatability (n repeats, mid-band)		N	1	1		n-1
Reference material ε*r*′		R	√3	1		∞
Reference material σ		R	√3	1		∞
Network analyser drift, linearity, etc.		R	√3	1		∞
Test-port cable variations		U	√2	1		∞
Dimensional accuracy of sensor system		N	1	1		∞
Homogeneity of the material		N	1	1		∞
Temperature of the material		R	√3	1		∞
Combined standard uncertainty						
NOTE Separate tables are usually needed for each ε*r*′ and σ.						

H.1.5 Uncertainty contributions

— Repeatability: measure the permittivity and conductivity of the material n times ($n \geq 5$) at the frequency of interest. Re-calibrate the network analyser between each measurement. Make sure that the temperature of the liquid is the same for each measurement. Calculate the repeatability as the standard deviation divided by the mean value.

— Reference material: uncertainty of the available reference data.

— Network analyser: drift, linearity and other contributions affecting the capability of measuring attenuation and phase at the specific frequency.

— Test-port cable variations: influence of cable variations on amplitude and phase measurement.

— Dimensional accuracy of the sensor system, e.g. in the case of the TEM line, the reference line is assumed to be a precision 50 ohm line with a section of air dielectric. The section of this line filled with the sample material should be well known in length, the dimensions of the line should not change, and the space should be filled without gaps at the inner or outer conductor.

— Temperature of the material: influence of changes in the dielectric properties of the sample, or reference material, caused by temperature.

H.2 Determination of thermal parameters

H.2.1 General

This subclause describes the measurement of the thermal properties (heat capacity, thermal conductivity) of tissue-equivalent material by providing sufficient details to enable users to perform accurate measurements of the thermal properties of liquid or solid materials, including the corresponding uncertainties.

The hot-wire method is well suited for the determination of the thermal conductivity of any homogeneous materials such as liquids and gel-like materials. It can also be used for solids and powders. The advantages of the hot-wire method are the short measuring times (steady-state methods often result in long measuring times) and that only relatively small samples are required.

The differential scanning calorimetry method is well suited for the determination of the heat capacity of any homogeneous materials such as liquids, solids and gel-like materials.

The third parameter to be determined is the viscosity of the liquid.

H.2.2 Measurement of thermal conductivity

A well suited method to determine thermal conductivity is the hot wire method. A thin wire is embedded into the sample to be investigated, simultaneously serving as a heating element and a temperature sensor. During the experiment, the wire is heated with a constant electrical power source. The temporal development of the increase in temperature at the hot wire is calculated from the resistance of the wire. This temperature increase is primarily dependent on the thermal conductivity of the sample. The thermal conductivity is determined by taking the thermal contact resistance between sample and wire as well as axial heat losses to the temporal temperature development into consideration and fitting an analytical solution. The sensitivity with respect to deviation from recipes should also be determined if the thermal conductivity is not measured for each batch. A comprehensive uncertainty budget should be provided as well.

H.2.3 Differential scanning calorimetry method for liquids and gels

The most common way of determining the specific heat capacity is differential scanning calorimetry. It can be used to determine specific heat capacity as a function of temperature as well as the location of phase transition temperatures (relevant for gels). During measurement, a sample and subsequently a reference material are subjected to a controlled temperature program with constant heating and cooling rates. At a constant heating rate, a temperature difference between the probe (or reference material) and its surroundings is caused due to their different heat capacities; the temperature difference is measured as a function of time. By calibrating the differential scanning calorimeter with the reference material, heat flows can be directly allocated to the temperature differences. The heat capacity can therefore be precisely and repeatedly determined as a function of temperature. The sensitivity with respect to deviation from recipes should also be determined if the heat capacity is not measured for each batch. A comprehensive uncertainty budget should be provided as well.

H.2.4 Estimation of viscosity parameters

Reliable temperature measurements can only be conducted if the Grashof number is sufficiently large, i.e. the viscosity of the medium or gel should be much larger than 1 Pa·s. An appropriate method for measurement of the viscosity needs to be selected, e.g. rheometers. The viscosity should be determined for the entire range of temperature, of which the lowest number should be used. The sensitivity with respect to deviation from recipes should also be determined if the viscosity is not measured for each batch. A comprehensive uncertainty budget should be provided as well.

Annex I
(normative)

Measurement system validation

I.1 Objective

The objective of this annex is to validate the exposure setup, the applied instrumentation, procedures and uncertainty budget.

I.2 Frequency

This validation should be repeated at least once per year or whenever there are personnel changes or setup or instrumentation changes, etc.

I.3 Validation with standard devices (S-AIMD)

The system may be validated using one of two highly characterized standard implants (S-AIMD).

S-AIMD 1: the FDA wire of I.8.1 which is a straight stainless steel wire of 1,5 mm diameter and 200 mm length with a 0,5 mm thick plastic insulation. 10mm at both ends of the wire are left non-insulated.

S-AIMD 2: rod of 3,175 mm diameter and 100 mm length, made of ASTM B348-5 titanium alloy.

I.4 Procedure

The procedure in Clause 10 shall be applied and the energy deposition shall be determined and normalized to 1 V/m. For this assessment, the uncertainty budget shall be computed as in 10.8.

I.5 Comparison

The results shall be compared to the values provided in Table I.3, Table I.4, Table I.7 and Table I.8. If the results are within the combined uncertainties of the computations and experimental assessment, the validation is successful.

I.6 Target results for validation with standard devices – S-AIMD1

I.6.1 General

The S-AIMD defined below is exposed to an incident E-field that has constant amplitude and phase. The electric and the thermal parameters of the wire and surrounding media are given in Table I.1 and

Table I.2. All results are normalized to a tangential incident E-field of 1V/m_{RMS} and valid neglecting thermal convection. Variation of dielectric parameters with temperature properties can be neglected (measured SAR and temperature increase shall be scaled to 1V/m_{RMS} assuming linear square dependency of the target values to the incident electrical field).

Table I.1 – Dielectric and thermal parameters of the wire

Relative permittivity (insulation)	3
Electrical conductivity (insulation)	0 S/m
Electrical conductivity (wire)	Infinity
Heat capacitance (insulation)	1 000 J/kg/K
Thermal conductivity (insulation)	0,2 W/m/K
Density (insulation)	1 400 kg/m^3
Heat capacitance (wire)	500 J/kg/K
Thermal conductivity (wire)	16 W/m/K
Density (wire)	8 000 kg/m^3

Table I.2 – Dielectric and thermal properties of the tissue simulant

Relative permittivity	78
Electrical conductivity	0,48 S/m
Heat capacitance	3 200 J/kg/K
Thermal conductivity	0,42 W/m/K
Density	1 000 kg/m^3

I.6.2 Simulations

I.6.2.1 Electromagnetic simulations

Electromagnetic simulations have been performed with the FDTD method implemented in the software SEMCAD X. The S-AIMD is embedded in a lossy background with the characteristics of the liquid given in

Table I.2. It is exposed to a plane wave propagating perpendicularly to its axis. The E-field component of the plane wave is aligned with the wire. Because of the small mesh step used in the wire region (0,2 mm), the total mesh size is 15 Mcells.

I.6.2.2 Thermal simulations

The E-field obtained after convergence of the simulation is used as a source for the thermal simulation (one hour of exposure). The wire is modelled using a special scheme for the simulation of thin, highly thermoconductive structures (see I.8.2). It couples the 3D simulation of the full domain to a 1D simulation of the wire using knowledge about the local temperature behaviour in the wire vicinity. The thermal properties used in the simulations are given in Table I.1 and

Table I.2. The same computational grid was used for both the EM and the thermal simulations.

I.6.3 Results

The SAR and temperature values are extracted along the axis of the wire and radially across the wire along lines at 2 mm and 5 mm from the tip end, as shown in Figure I.1. All extractions are done in the central plane of the wire.

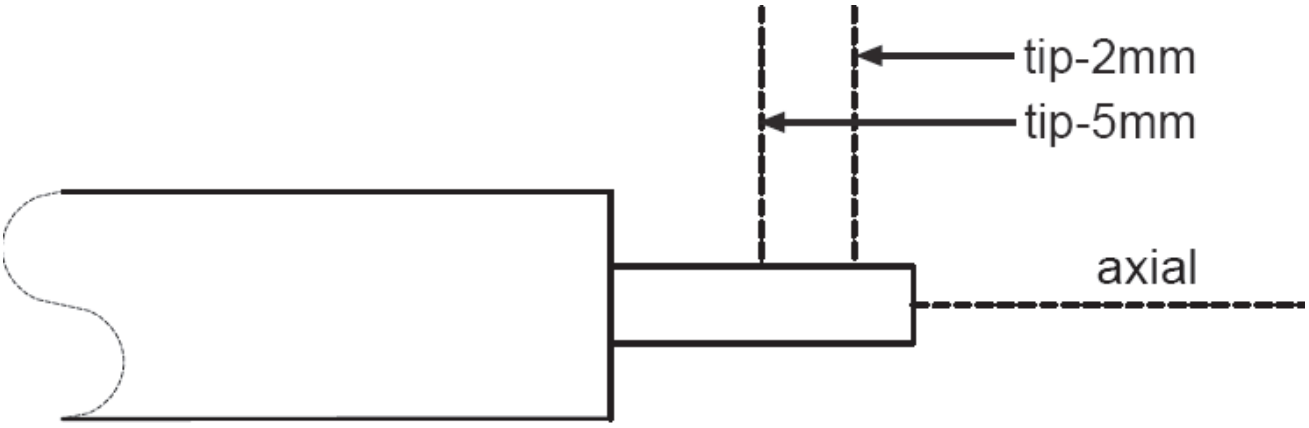


Figure I.1 – Sketch showing the extraction lines for the SAR and temperature simulations

Figure I.2 shows the normalized SAR in dB for the 3 extraction lines: radial at 2 mm from tip, radial at 5 mm from tip and axial. The uncertainty of the numerical assessment is 2 % (see I.8.3).

Figure I.3 shows the temperature after 1 h for the 3 extraction lines: radial at 2 mm from tip, radial at 5 mm from tip and axial. The uncertainty of the numerical assessment is 2,2 % (see I.8.3).

All results are given for an incident E-field of 1V/m_{RMS}.

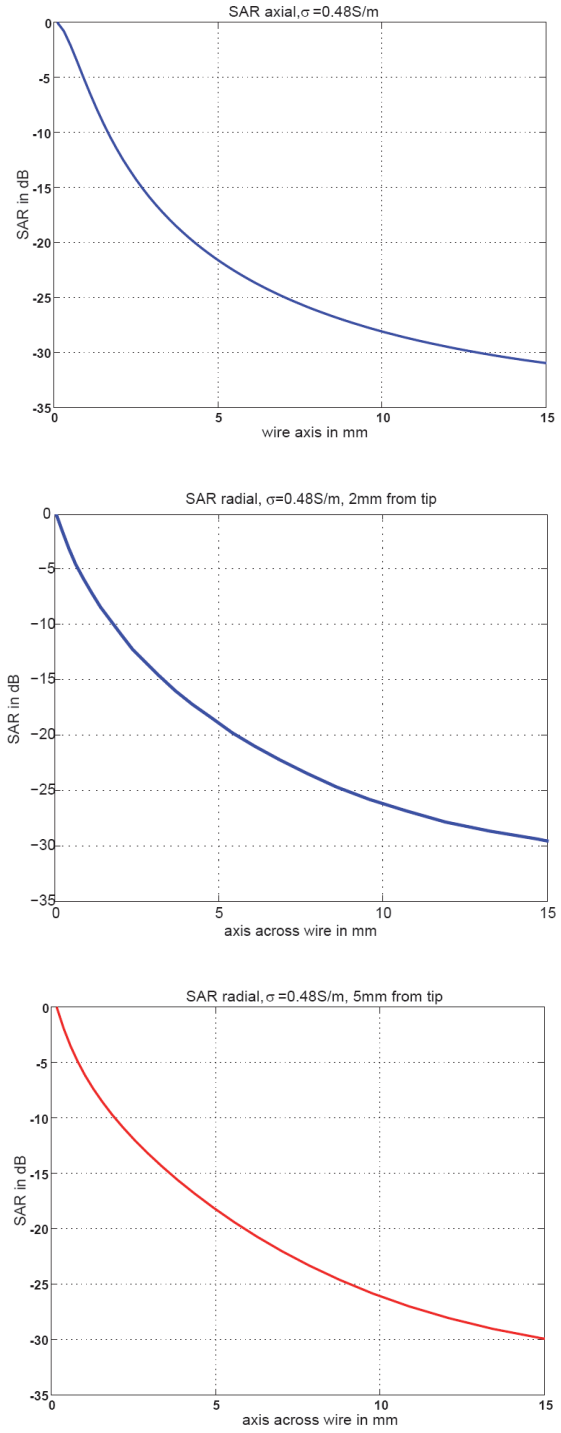


Figure I.2 – SAR distribution (0dB correspond to 1,6W/kg/(V/m)$_2$ (top), 1,1W/kg/(V/m)$_2$ (centre) and 0,9 W/kg/(V/m)$_2$ (bottom) (see I.8.3)

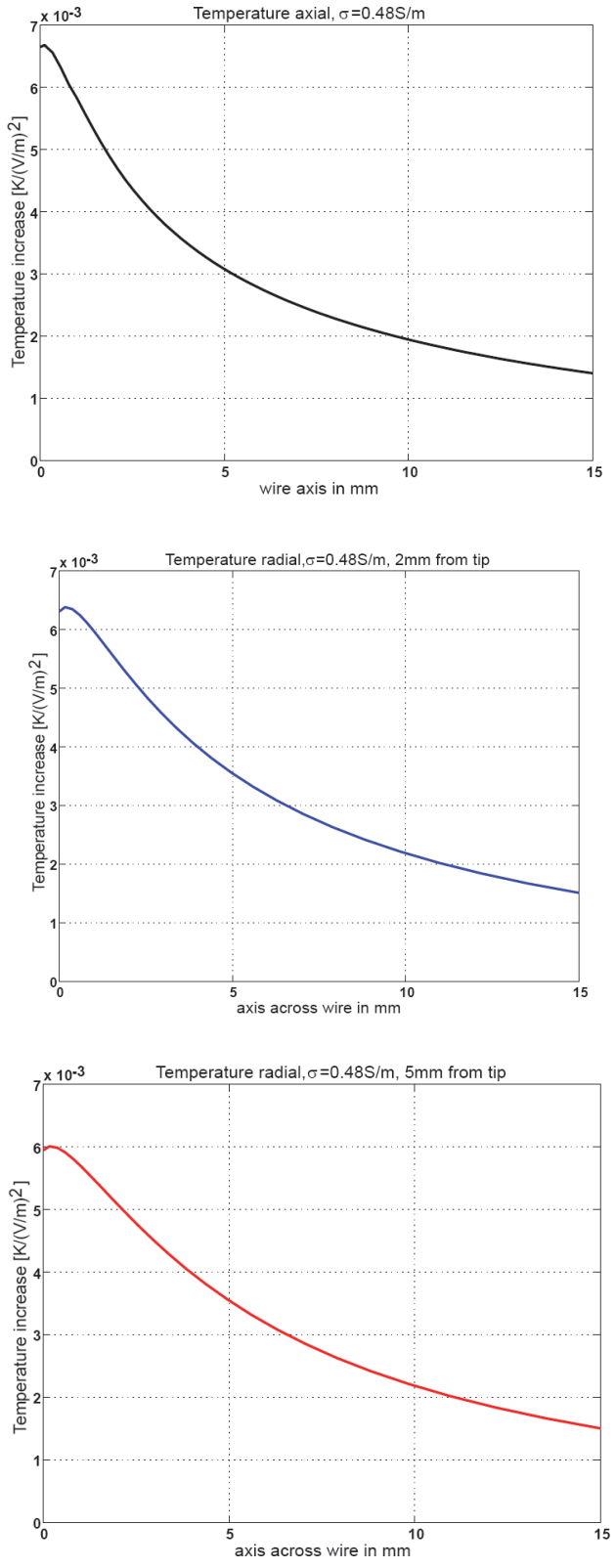


Figure I.3 – Temperature distribution (see I.8.3)

I.6.3.1 Numerical target values

Tabular values are given in Table I.3 and Table I.4.

Table I.3 – SAR distributions of S-AIMD1 axial and radial at 2 mm and 5 mm from the tip end (the uncertainty of the numerical assessment is 2 %) (see I.8.3)

Distance mm	SAR tip-2mm W/kg/(V/m)^2	SAR tip-5mm W/kg/(V/m)^2	SAR axial W/kg/(V/m)^2
0,2	1,11	0,89	1,5
0,4	0,71	0,57	1,2
0,6	0,49	0,40	0,85
0,8	0,35	0,29	0,60
1,0	0,26	0,22	0,41
1,3	0,19	0,16	0,27
1,5	0,14	0,12	0,18
1,8	0,11	0,10	0,12
2,2	0,081	0,073	0,082
2,5	0,060	0,056	0,056
2,9	0,045	0,043	0,039
3,4	0,034	0,032	0,028
3,8	0,025	0,024	0,020
4,4	0,019	0,018	0,015
4,9	0,014	0,014	0,011
5,6	0,010	0,010	0,008 4
6,3	0,007 8	0,007 5	0,006 4
7,0	0,005 8	0,005 5	0,005 0
7,8	0,004 4	0,004 1	0,003 9
8,8	0,003 3	0,003 1	0,003 1
9,8	0,002 5	0,002 3	0,002 5
10,9	0,002 0	0,001 8	0,002 1
12,1	0,001 5	0,001 4	0,001 7
13,4	0,001 2	0,001 1	0,001 5

Table I.4 – Temperature distributions of S-AIMD1 axial and radial at 2 mm and 5 mm from the tip end (the uncertainty of the numerical assessment is 2 %) (see I.8.3)

Distance mm	Temp tip-2 mm mK/(V/m)^2	Temp tip-5 mm mK/(V/m)^2	Temp axial mK/(V/m)^2
0,2	6,4	6,0	6,7
0,4	6,3	6,0	6,5
0,6	6,3	5,9	6,3
0,8	6,1	5,8	6,0
1,0	6,0	5,7	5,8
1,3	5,8	5,5	5,5
1,5	5,6	5,4	5,2
1,8	5,3	5,2	4,9
2,2	5,1	5,0	4,6
2,5	4,8	4,8	4,3
2,9	4,6	4,5	4,1
3,4	4,3	4,3	3,8
3,8	4,1	4,1	3,6
4,4	3,8	3,8	3,3
4,9	3,6	3,6	3,1
5,6	3,3	3,3	2,9
6,3	3,1	3,1	2,7
7,0	2,9	2,9	2,5
7,8	2,6	2,6	2,3
8,8	2,4	2,4	2,1
9,8	2,2	2,2	2,0
10,9	2,0	2,0	1,8
12,1	1,9	1,8	1,7
13,4	1,7	1,7	1,5

I.7 Target results for validation with standard devices – S-AIMD2

I.7.1 General

The S-AIMD defined below is exposed to an incident E-field that has constant amplitude and phase along its length. The electric and thermal parameters of the wire and surrounding media are given in Table I.5 and Table I.6. Results are normalized to a tangential incident E-field of 1V/m_{RMS}. The calculations do not consider thermal convection and variation of dielectric parameters with temperature.

Use of S-AIMD2 for determination of local SAR is described in ASTM F2182.

Table I.5 – Parameters for S-AIMD2

NOTE The implant is a rod made from grade 5 titanium (McMaster-Carr 89055K313[1]) with a diameter of 3,175 mm and a length of 10 cm.

Electrical conductivity (wire)	infinity
Heat capacitance (wire)	560 J/kg/Kpwd
Thermal conductivity (wire)	7,2 W/m/K
Density (wire)	4 420 kg/m^3

Table I.6 – Dielectric and thermal parameters of the tissue simulant for the calculation of temperature rise and SAR for S-AIMD2

Relative permittivity	78
Electrical conductivity	0,48 S/m
Heat capacitance	3 200 J/kg/K
Thermal conductivity	0,42 W/m/K
Density	1 000 kg/m^3

I.7.2 Simulations

I.7.2.1 Electromagnetic simulations

Electromagnetic simulations have been performed with the FDTD method implemented in a custom program. The S-AIMD is embedded in a lossy background with the characteristics of the liquid given in Table I.6 and it is exposed to two plane waves propagating perpendicularly to its axis in opposite directions, which yields a standing wave with rather uniform E-field in the vicinity of S-AIMD2. The E-field component of the plane wave is aligned with the wire. Because of the small mesh step used in the wire region (0,1mm), the total mesh size is 32M cells.

I.7.3 Thermal simulations

The E-field obtained by the FDTD simulation is used as a source for the thermal simulation (six minutes of exposure). A custom thermal solver that accounts for linear heat flow is used. The thermal properties used in the simulations are given in Table I.5 and Table I.6. The grid for calculation of the temperature rise extends 3 cm in all directions from the end of S-AIMD2.

I.7.3.1 Results

The SAR and temperature values are extracted along the axis of the wire and radially across the wire along lines at 2 mm and 5 mm from the tip end, as shown in Figure I.1. All extractions are done in the central plane of the wire.

The plots in Figure I.4 show the normalized SAR in dB for the three extraction lines: radial at 2 mm from tip radial at 5 mm from tip and axial. The uncertainty of the numerical assessment is estimated to be better than 5 %. The plots in Figure I.5 show the temperature after six minutes for the three extraction lines: radial at 2 mm from tip, radial at 5 mm from tip and axial. The uncertainty of the numerical assessment is estimated to be better than 5 %. All results are given for an incident E-field of 1V/m$_{RMS}$.

[1] McMaster-Carr 89055K313 (Cleveland, OH, USA) is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO or IEC of this product.

The left plot in Figure I.6 shows the temperature distribution around S-AIMD2 after 6 min with a background SAR of 1 W/kg (E_{RMS} = 45,64 V/m). The right plot in Figure I.6 shows the SAR in dB relative to the background SAR produced by the incident field with no implant.

Figure I.7 shows the calculated current distributions for S-AIMD1 and S-AIMD2.

NOTE 1 In principle, MRI could be used to determine the current and hence the local E-field.

Table I.7 and Table I.8 tabulate values for Figure I.4 and Figure I.5, respectively.

NOTE 2 Values presented here for S-AIMD2 will depend on the properties of the phantom material. For example, the temperature rise will be less if we assume the heat capacitance to be that of water.

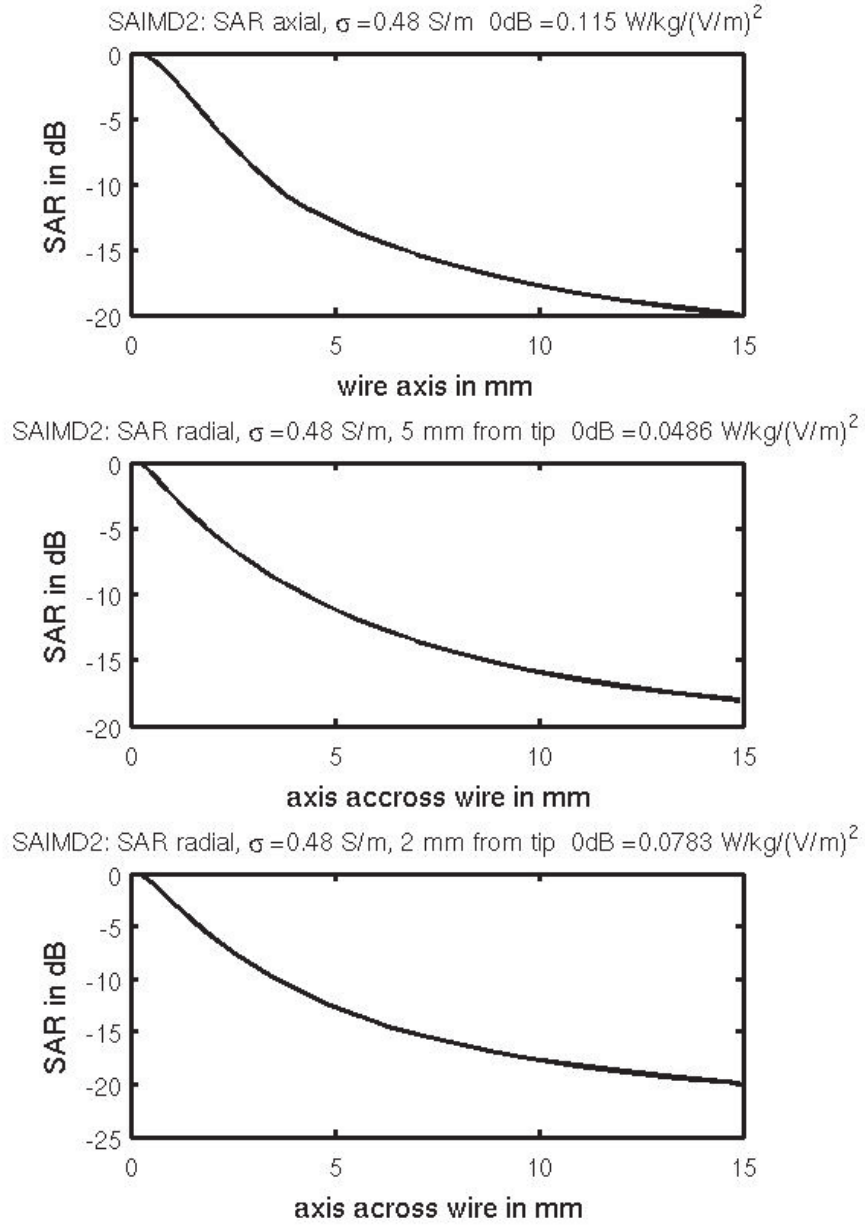


Figure I.4 – Calculated parameters for S-AIMD2 for E_{RMS} = 1V/m (the plot is SAR in dB relative to maximum indicated in titles)

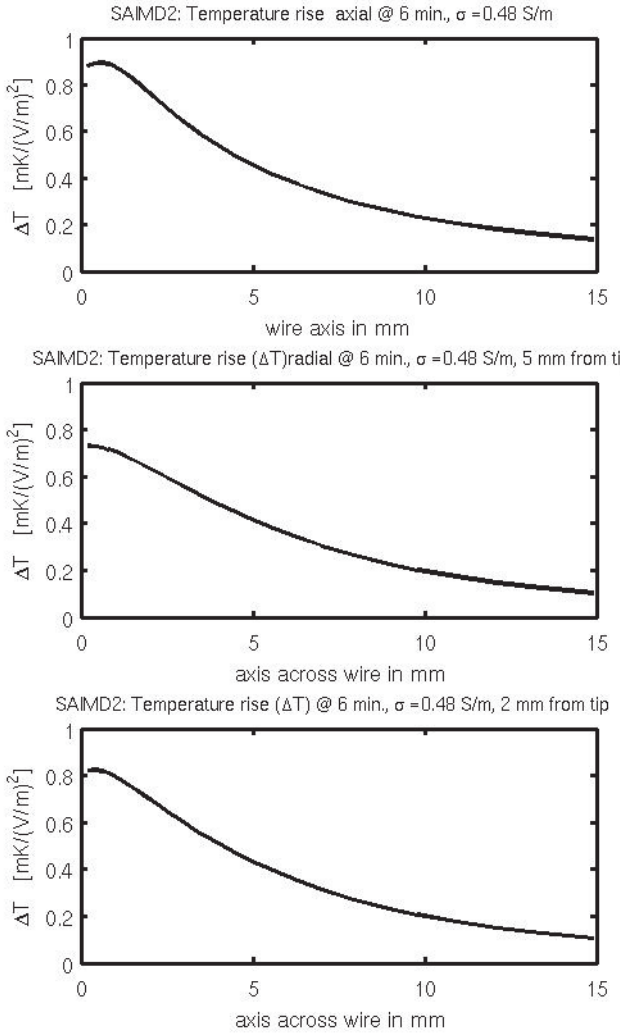
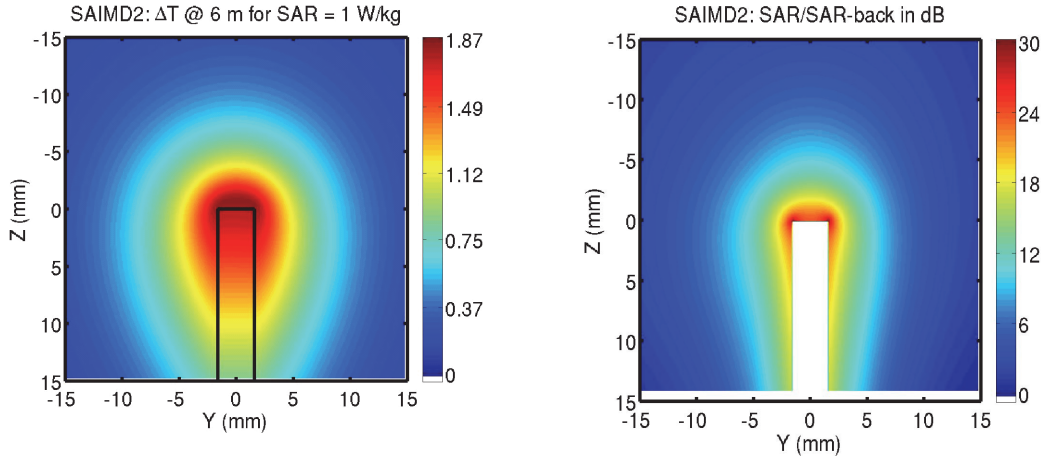


Figure I.5 — Calculated parameters for S-AIMD2 for ERMS = 1V/m (the plot is temperature rise after 6 min)



The left image is temperature distribution after 6 min power application with a background SAR of 1 W/kg (E_{RMS} = 45,64 V/m).
The right image is the SAR in dB relative to the background SAR.

Figure I.6 — SAIMD2

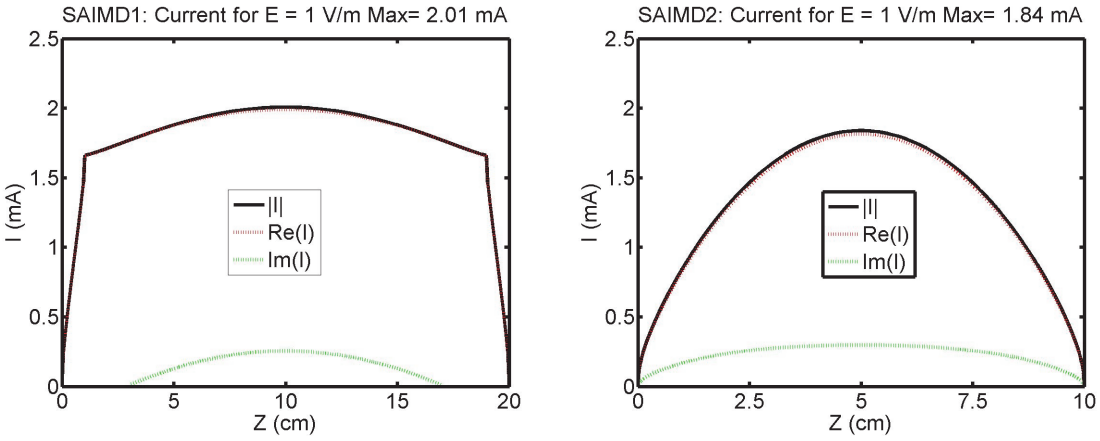


Figure I.7 — Current distributions in SAIMD1 (left) and SAIMD 2 (right) for an incident tangential E-field of 1 V/m

Table I.7 — SAR distributions of S-AIMD2 axial and radial at 2 mm and 5 mm from the tip end (RMS E-field is 1 V/m. The background SAR is then 0,48 mW/kg)

Distance mm	SAR tip-2mm mW/kg/(V/m)^2	SAR tip-5mm mW/kg/(V/m)^2	SAR axial mW/kg/(V/m)^2
0,2	78,3	48,6	115,2
0,4	69,8	43,5	109,0
0,6	59,7	37,6	99,3
0,8	50,4	32,1	87,8
1,0	42,5	27,5	75,8
1,3	33,1	22,1	59,4
1,5	28,3	19,3	50,1
1,8	22,5	15,9	38,7
2,2	17,1	12,5	27,8
2,5	14,1	10,6	22,0
2,9	11,1	8,7	16,5
3,4	8,5	6,9	12,0
3,8	6,9	5,8	9,5
4,4	5,3	4,6	7,3
4,9	4,4	3,8	6,0
5,6	3,4	3,1	4,8
6,3	2,8	2,5	4,0
7,0	2,3	2,1	3,3
7,8	2,0	1,8	2,8
8,8	1,6	1,5	2,3
9,8	1,4	1,3	2,0
10,9	1,2	1,1	1,7
12,1	1,0	1,0	1,5
13,4	0,9	0,9	1,3
14,9	0,8	0,8	1,2

Table I.8 — Calculated temperature rise after 6 min for S-AIMD2 (RMS E-field is 1 V/m)

Distance mm	Temp tip-2mm mK/(V/m)^2	Temp tip-5mm mK/(V/m)^2	Temp axial mK/(V/m)^2
0,2	0,822	0,731	0,878
0,4	0,823	0,729	0,892
0,6	0,818	0,723	0,895
0,8	0,807	0,714	0,889
1	0,793	0,703	0,876
1,3	0,767	0,684	0,848
1,5	0,748	0,670	0,825
1,8	0,719	0,648	0,788
2,2	0,678	0,617	0,736
2,5	0,647	0,593	0,698
2,9	0,608	0,562	0,650
3,4	0,561	0,524	0,595
3,8	0,525	0,494	0,555
4,4	0,476	0,452	0,502
4,9	0,439	0,419	0,462
5,6	0,392	0,377	0,414
6,3	0,350	0,339	0,373
7	0,314	0,305	0,337
7,8	0,278	0,270	0,301
8,8	0,239	0,233	0,264
9,8	0,206	0,201	0,233
10,9	0,177	0,172	0,204
12,1	0,150	0,146	0,179
13,4	0,126	0,123	0,157
14,9	0,105	0,102	0,136

Annex J
(informative)

Example of coil systems

Table J.1 — Example of a test coil system meeting the minimal requirements for the 1,5T RF transmit coil systems

Number of rungs	16
Length	650 mm ±5 %
Diameter	700 mm ± 5 %
Shield (diameter/length)	830/850 mm ±5 %
Larmor frequency	64 MHz ±5 %
RF power (peak)	10kW
Crest factor (peak to average power)	<10
Drift	<0,25 dB
Deviation from circular polarization at isocentre 20log(B1max/B1min2)	<1 dB

Annex K
(informative)

Current distribution on the AIMD as a function of the phase distribution of the incident field

K.1 Background

In general, the energy picked up by an antenna is maximum at resonance condition. This condition results in high electrical field strength at the tip. In a similar fashion this holds true for elongated AIMDs embedded in a tissue simulant, and gives rise to a high SAR and temperature at its ends. These conditions are generally evaluated assuming a constant phase distribution of the tangential component of the incident E-field along the AIMD. However, it has been shown that the local energy deposition near the ends of the AIMD can be further increased if the phase distribution of the tangential component of the incident electrical field is not uniform [see Equation (K.1)]. Therefore, the worst-case conditions of the tangential incident E-field depend not only on the length of the AIMD but also the phase distribution along the AIMD.

A change of the phase of the tangential component of the incident electrical field along the AIMD leads to an asymmetrical current distribution, which causes a comparatively steep gradient of the current at the exposed end of AIMD. This entails a concentration of charges at the end and, consequently, the electric flux and deposited power near the end will be increased. The conditions under which the deposited power is maximized can be approximated by a constant gradient of the phase of the incident field along the AIMD while keeping the amplitude of its tangential component constant [see Equations (K.1) and (K.2)].

The following clauses discuss these incident E-field conditions in lossy medium and theoretically demonstrate the effect of the phase on the temperature rise/deposited energy near the end of the AIMD.

K.2 Phase gradients in lossy dielectrics

In a homogeneous lossy dielectric, a constant phase gradient with constant amplitude of the tangential component of the incident field can only be fulfilled for inhomogeneous waves [see Equation (K.3)]. The electric and magnetic field vectors of the inhomogeneous waves can be written as:

$$\begin{Bmatrix} \vec{E} \\ \vec{H} \end{Bmatrix} \propto e^{-jk\vec{n}\cdot\vec{r}} \tag{K.1}$$

with k as the free space wave number of the dielectric and $\vec{r}$ as the position vector. In order to satisfy the scalar wave equation,

$$\Delta\Phi + k^2\Phi = 0 \tag{K.2}$$

the complex vector $\vec{r}$ should fulfil the following conditions:

$$\begin{aligned} \mathrm{Re}\{\vec{n}\}^2 - \mathrm{Im}\{\vec{n}\}^2 &= 1 \\ \mathrm{Re}\{\vec{n}\}\cdot\mathrm{Im}\{\vec{n}\} &= 0 \end{aligned} \tag{K.3}$$

which require that the real and the imaginary part of $\vec{n}$ be orthogonal. For constant amplitude and constant phase gradient of the E_y component in the *y*-direction, $\vec{n}$ can be written as:

$$\mathrm{Re}\{\vec{n}\} = \begin{pmatrix} \cosh\beta \\ 0 \\ 0 \end{pmatrix}$$

$$\mathrm{Im}\{\vec{n}\} = \begin{pmatrix} 0 \\ -\sinh\beta \\ 0 \end{pmatrix} \qquad \text{(K.4)}$$

β is an arbitrary real number, which determines the angle between the direction of maximum attenuation and the direction of the phase gradient. The phase gradient is a function of β.

The exposure of a lead to a field with constant phase gradient of the incident field can cause a significant increase of the E-field at one of its tips in comparison to, for example, exposure at its resonance length with constant phase. The worst-case phase gradient depends on the dielectric properties of the environment and on the electrical characteristics of the wire. Among these are, for example, insulation properties, wire diameter, pitch, etc. Therefore, the worst-case phase gradient needs to be determined for each lead in particular. At phase gradients other than the worst case, the E-fields at the tips can be lower than for exposure with constant phase.

Phase characteristics as those described above usually occur in the reactive near field of sources. Due to the nature of inhomogeneous waves, they decay rapidly when the distance from the source is increased. In lossy dielectrics, such as body tissue or tissue simulant, the attenuation of their amplitudes is even more pronounced. In the high field regions of homogeneous phantoms, the phase distribution of the tangential incident E-field is rather constant. It appears therefore difficult to generate a field distribution that is appropriate to account for the effects described above.

The phase gradients which lead to worst-case heating are a function of the electric lead characteristics and have to be determined for each lead.

As an alternative, worst-case scaling factors have been derived numerically which need to be applied when testing a lead with an incident field with constant phase (see Table 8).

K.3 Transfer function to determine induced heating

The temperature rise of the tissue surrounding the electrode at the end of an AIMD arises from an E-field induced by an MRI RF magnetic field and can be expressed as:

$$\Delta T = A\left|\int_0^L S(z)E_{tan}(z)dz\right|^2 \qquad \text{(K.5)}$$

where

A is a constant;

S is the E-field sensitivity function of the lead;

$E_{\tan}$ is the tangential component of the incident E-field;

z is the distance along the lead, which has a length, L, and z = 0 is at the electrode (see Reference [29]).

In Equation (K.5), $S(z)$ is a function of AIMD designs and electrical properties of surrounding tissues. $S(z)$ and $E_{\tan}(z)$ are complex quantities and thus can be written as:

$|S(z)|e^{i\omega\phi s(z)}$ and $|E_{\tan}(z)|e^{i\omega\phi E(z)}$, respectively. Then, Equation (K.5) becomes:

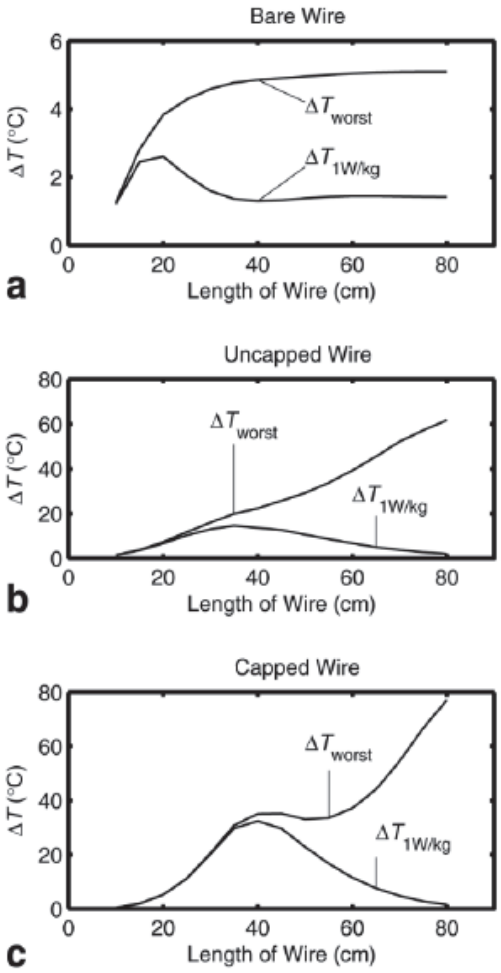
$$\Delta T = A\left|\int_0^L |S(z)||E_{tan}(z)|e^{i\omega(\phi_S(z)+\phi_E(z))}dz\right|^2 \quad \text{(K.6)}$$

From Equation (K.6), it is apparent the temperature rise at the electrode will depend on both magnitude and phase distributions of the incident field. Therefore, depending on $\phi S(z)$ and $\phi E(z)$, they can constructively or destructively add to each other. Furthermore, the worst case occurs when phase distributions of $S(z)$ and $E_{\tan}(z)$ are cancelling each other, or in other words $\phi_S(z) = -\phi_E(z)$. Then, the worst-case temperature rise becomes:

$$\Delta T_{worst} = A\left|\int_0^L |S(z)||E_{tan}(z)|dz\right|^2 \quad \text{(K.7)}$$

In the worst case, if the condition $\phi_S(z) = -\phi_E(z)$ is achieved, there is no resonance associated with a length of AIMD system. Figure K.1 (accepted from K.4.1) shows several examples.

As shown in Figure K.1, 80 cm capped wire in the worst-case phase distribution can heat more than twice of the resonant length in the uniform phase distribution. Thus, *in vitro* heating testing of an AIMD system that consists of a long lead should properly account for this phase effect.



NOTE Reproduced from Reference [29].

Figure K.1 — Temperature rises versus wire length for $E_{\tan}$ with intensity producing a SAR of 1 W/kg for uniform phase distribution ($\Delta T_{1W/kg}$) and worst-case phase distribution (ΔT_{Worst}) (material conductivity is 0,46 S/m and frequency is 64 MHz)

Annex L
(informative)

Recipe and rationale for tissue simulating materials

L.1 Rationale

The primary requirement for tissue simulating material is:

— provision of the means to quantify the worst-case energy deposited by the AIMD such that it can be accurately transformed into the worst-case temperature increase *in vivo*.

Secondary requirements, but important nonetheless, are:

— wide availability as a liquid or gel;

— ease of use;

— stability over time and temperature;

— easy adjustment of target parameters;

— being non-toxic to personnel;

— being non-toxic to the environment.

The tissue simulant inside the phantom impacts the following conditions of the test setup:

— loading of the RF coil by the phantom;

— amplitude and phase distribution in the phantom;

— resonance lengths of the AIMD;

— power picked up by the AIMD and deposition of power at specific locations, e.g. a tip.

The last two points are the most relevant since the results should be normalized to the induced fields at a constant amplitude and phase.

Since the length of the AIMDs is usually relatively short with respect to the wavelength, the test setup should provide maximum coupling for short AIMDs. As a result, the testing times will be significantly reduced.

For temperature measurements, an increased S/N ratio can be achieved for a given amplitude of the incident field by increasing the conductivity of the tissue simulant. As the induced fields per input power only depend on the conductivity to a minor degree, tissue-simulating material with high permittivity and high conductivity is the most obvious choice.

Based on experience with saline solutions, which meet the above specifications, the material in Table L.1 is suggested. However, alternative materials may also be used.

L.2 Recipes

Table L.1 – Examples of recipes for 64Mhz

	Wet-tissue (HCM)		Fat-tissue (LCM)
	Gel	**Liquid**	**Gel**
Recipe	97,812 % water 2 % HEC 0,188 % NaCl	99,71 % water 0,20 % NaCl	55% Triton 30% Castor Oil 13,5% water 1,5% NaCl
Relative dielectric permittivity	78	78	11,5
Conductivity [S/m]	0,47	0,47	0,045
Density [kg/m3]	993	1 000	To be determined
Thermal capacity [J/kg/K]	4 200	4 200	To be determined
Thermal conductivity k [W/m/k]	0,62	n.a.	To be determined
Viscosity		n.a.	To be determined

Annex M
(informative)

Generation of incident fields

M.1 General

The fields induced in the phantom are considerably different from the fields induced in the human. However, the phantoms are well suited to generate a well-controlled test environment that can be correlated to human situations. The objective is to obtain a uniform tangential E-field for E-field coupling and uniform B-field for inductive coupling.

M.2 ASTM Phantom

The ASTM phantoms are defined in M.4.1. The most uniform E-field coupling is achieved 10 mm above the phantom and 150 mm from the centre parallel to L1. L1 is on the right or left side, depending on the rotation of the excitation. Figure M.1 and Figure M.2 illustrate the E_z field distributions inside the phantom. The points PCL1, PTL1, PLL1 are marked corresponding to ±1dB excitation range.

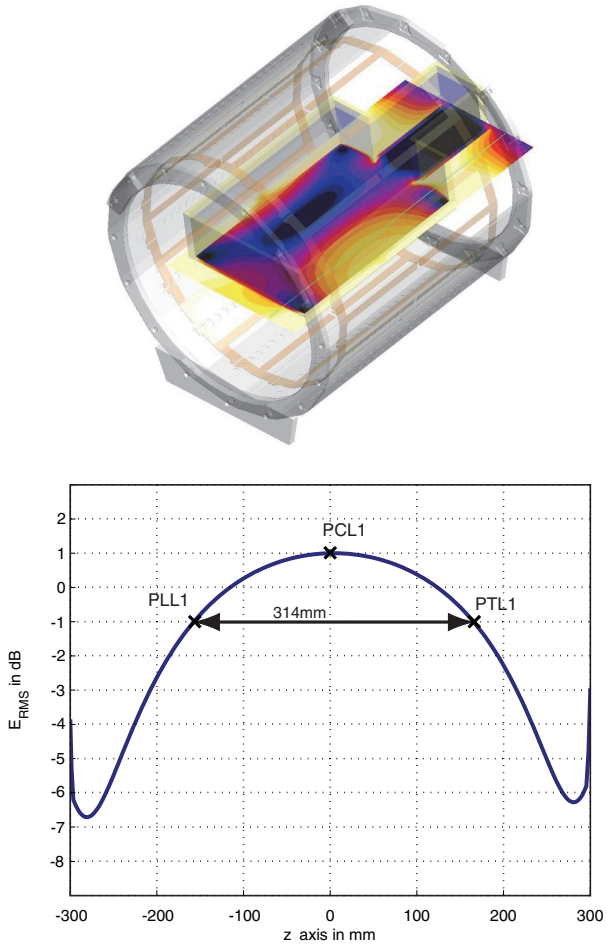


Figure M.1 – E_z -field induced in the ASTM phantom along line L1 (0 dB = 71V/uT)

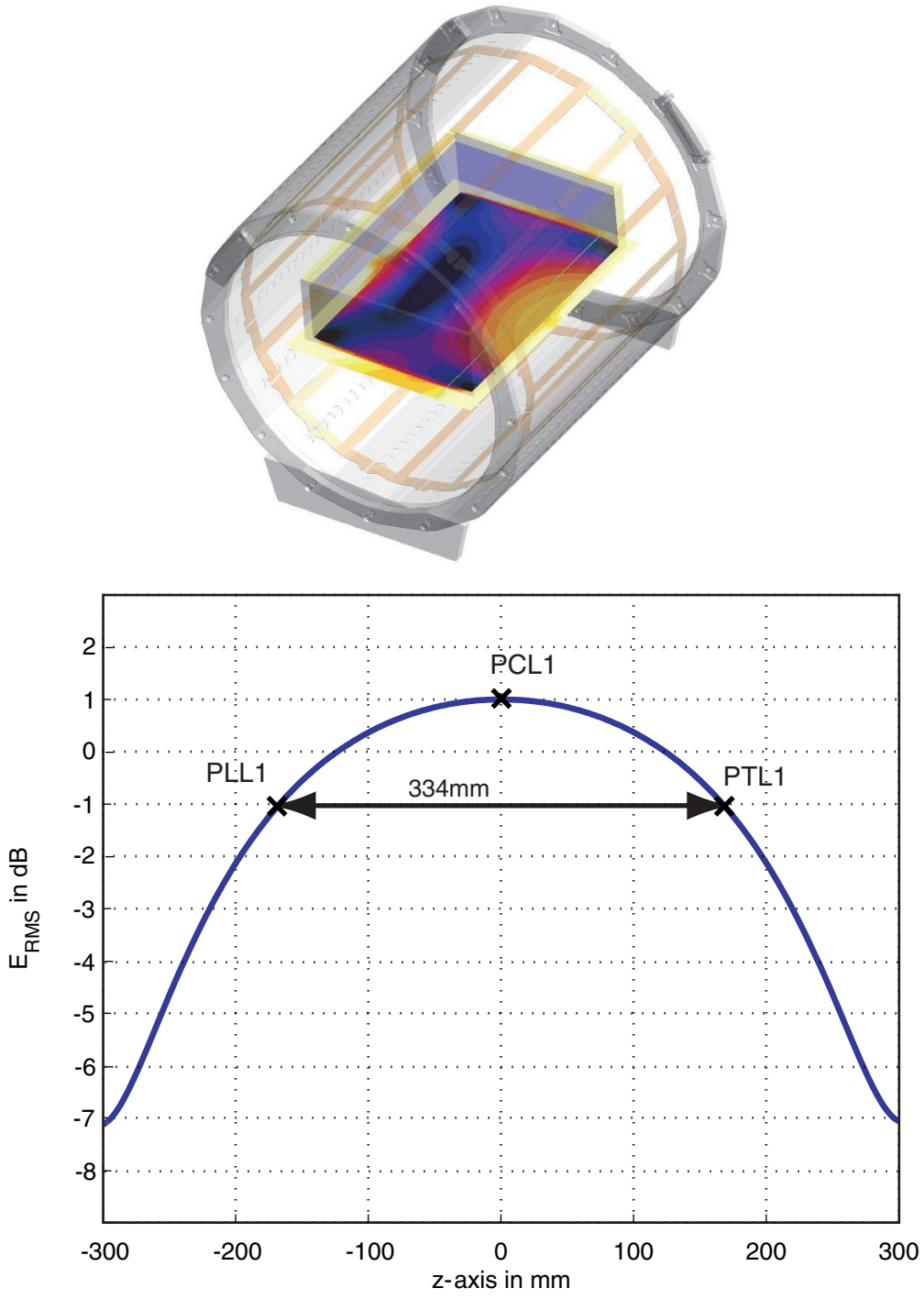


Figure M.2 — E_z-field induced in the brick phantom along line L1 (0 dB = 68V/uT)

M.3 Circular and elliptical phantoms

The cylindrical field in any thin cylindrical phantom that is small with respect to the wavelength is uniform with a constant phase. Similar conditions are obtained in moderately elliptical phantoms. Examples are shown in Figure M.3, M.4 and M.5.

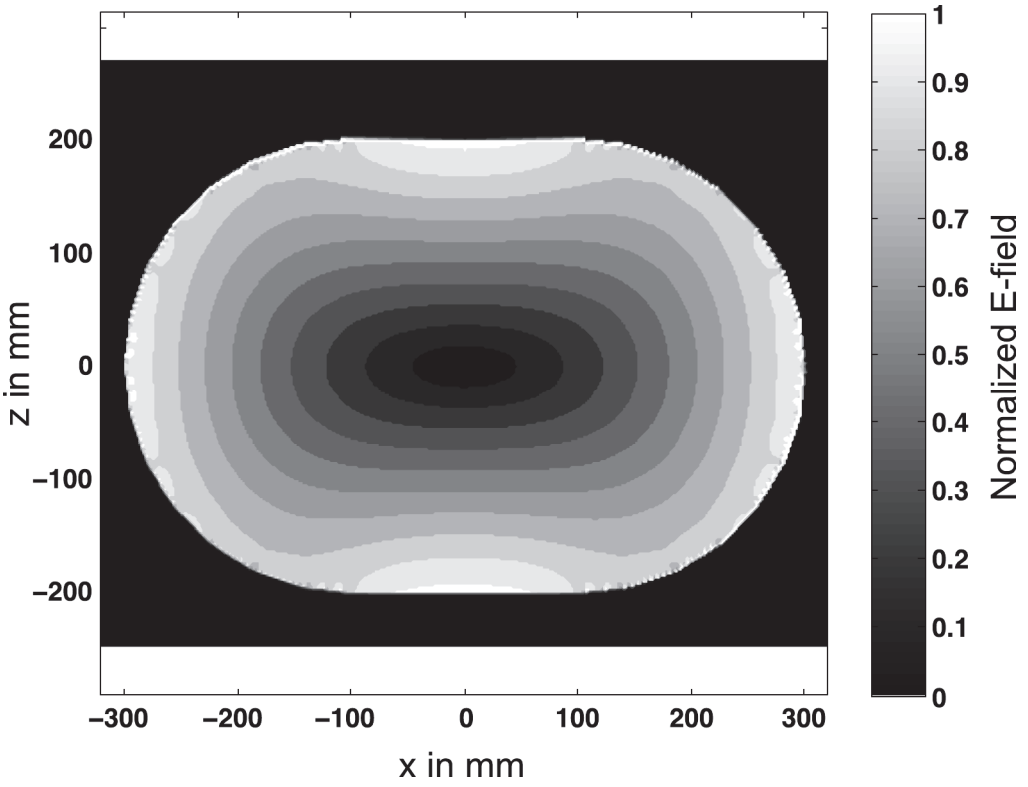


Figure M.3 — *E*-field in an elliptical phantom with a size of 600 mm × 400 mm, 200 mm radius, 90 mm liquid depth

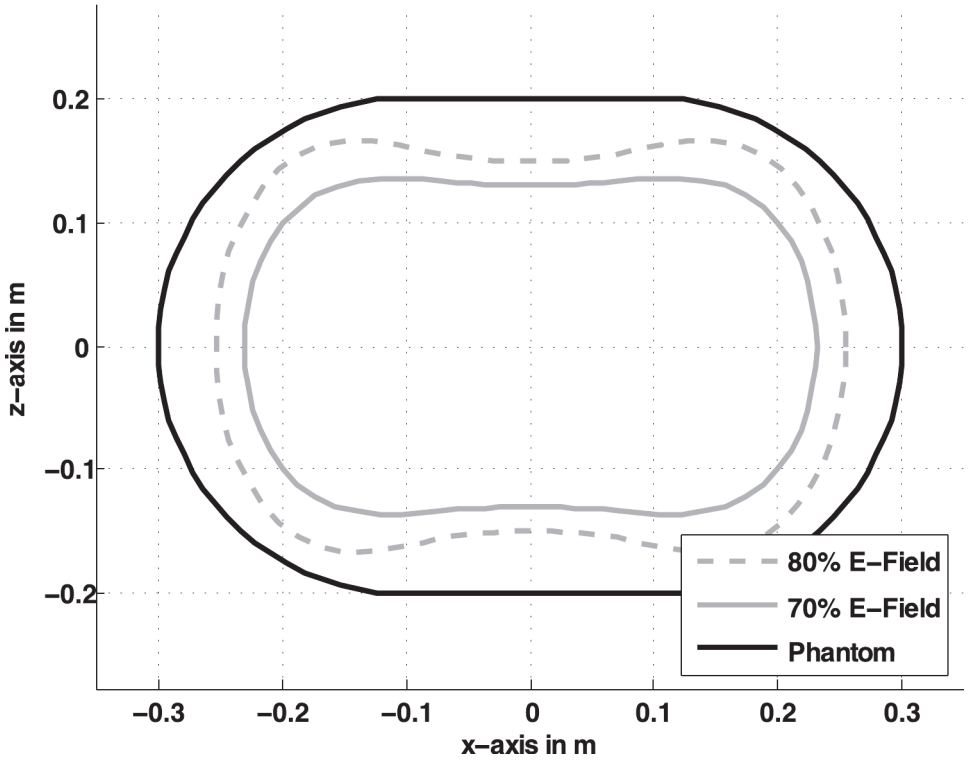


Figure M.4 — Elliptical phantom: lines of constant amplitude of the tangential *E*-field

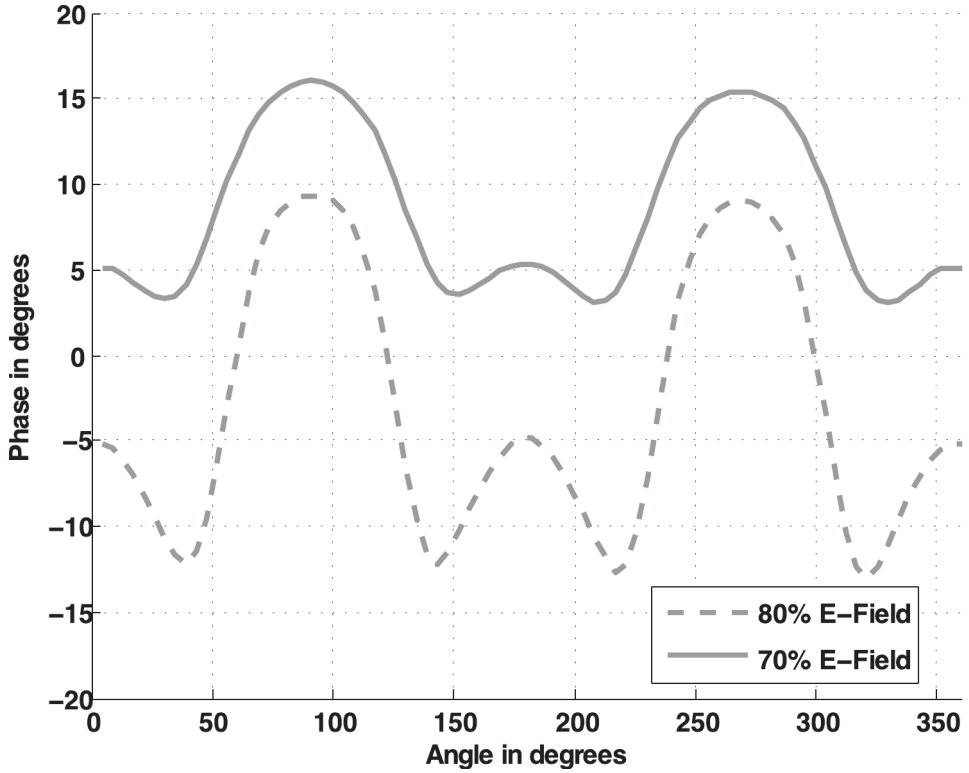


Figure M.5 — Elliptical phantom: phase change along the lines of constant tangential E-field amplitude

Annex N
(informative)

Dielectric parameters

Table N.1 — Dielectric parameters of body tissue (see Reference [19])

	64 MHz		128 MHz		Density	Specific heat capacity	Thermal conductivity	Perfusion rate
	ε_r	σ in S/m	ε_r	σ in S/m	kg/m^3	J/kg/K	W/m/K	ml/min/kg
Bladder	68,6	0,29	21,9	0,30	1 040	3 900	0,56	78
Blood	86,4	1,21	73,2	1,25	1 060	3 824	0,51	10 000
Bone cortical	16,7	0,06	14,7	0,07	1 990	1 289	0,40	22
Brain grey matter	97,4	0,51	73,5	0,59	1 039	3 675	1,13	671
Brain white matter	67,8	0,29	52,5	0,34	1 043	3 621	0,50	237
Cartilage	62,9	0,45	52,9	0,49	1 100	3 664	0,47	50
Cerebellum	116,4	0,72	79,7	0,83	1 040	3 640	0,53	560
Cerebrospinal fluid	97,3	2,07	84,0	2,14	1 007	4 191	0,60	0
Colon	94,7	0,64	76,6	0,71	1 044	3 653	0,56	752
Cornea	87,4	1,00	71,5	1,06	1 076	3 793	0,52	38
EyeSclera	75,3	0,88	65,0	0,92	1 032	3 000	0,40	38
Fat	6,5	0,035	5,9	0,037	916	2 524	0,25	27
Gall bladder	105,4	1,48	88,9	1,58	1 026	3 496	0,47	78
Heart	106,5	0,68	84,3	0,77	1 060	3 720	0,54	900
Kidney	118,6	0,74	89,6	0,85	1 044	3 745	0,52	4 161
Lens	60,5	0,59	53,1	0,61	1 090	3 664	0,40	38
Liver	80,6	0,45	64,3	0,51	1 050	3 600	0,51	1 007
Lung	75,3	0,53	63,7	0,58	655	3 625	0,44	400
Mucous membrane	76,7	0,49	61,6	0,54	1 050	1 006	0,03	0
Muscle	72,2	0,69	63,5	0,72	1 041	3 546	0,53	28
Nerve	55,1	0,31	44,1	0,35	1 038	3 664	0,46	549
Oesophagus	85,8	0,88	74,9	0,91	1 040	3 500	0,53	383
Ovary	106,8	0,69	79,2	0,79	1 048	3 600	0,53	3 059
Pancreas	73,9	0,78	66,8	0,80	1 045	3 452	0,49	625
Prostate	84,5	0,88	72,1	0,93	1 045	3 761	0,53	1 697
Skin dry	92,2	0,44	65,4	0,52	1 100	3 437	0,35	97
Small intestine	118,4	1,59	88,0	1,69	1 044	3 653	0,56	1 000
NOTE The uncertainty is estimated to be +/-20 %. The properties of scar tissues are provided in Annex O.								

Table N.1 — Dielectric parameters of body tissue according to the Italian National Research Council, Institute for Applied Physics (continued)

	64 MHz		128 MHz		Density	Specific heat capacity	Thermal conductivity	Perfusion rate
	ε_r	σ in S/m	ε_r	σ in S/m	kg/m^3	J/kg/K	W/m/K	ml/min/kg
Spinal chord	55,1	0,31	44,1	0,35	1 038	3 664	0,46	549
Spleen	110,6	0,74	82,9	0,84	1 054	3 603	0,54	1 142
Stomach	85,8	0,88	74,9	0,91	1 050	3 553	0,53	374
Tendon	59,5	0,47	51,9	0,50	1 110	3 500	0,50	50
Testis	84,5	0,88	72,1	0,93	1 044	3 746	0,53	93
Thymus	73,9	0,78	66,8	0,80	1 026	3 960	0,52	1 697
Tongue	75,3	0,65	65,0	0,69	1 041	3 546	0,53	28
Tooth	16,7	0,06	14,7	0,07	2 160	1 340	0,40	0
Uterus	92,1	0,91	75,4	0,96	1 052	3 580	0,50	38
Vitreous humor	69,1	1,50	69,1	1,51	1 009	3 932	0,59	0

Annex O
(informative)

Thermal and electrical properties of scar tissues

It can be shown that RF power density, which directly corresponds to heating of the tissues, falls off with a $1/r^4$ relationship where r is the distance away from the implant (see Reference [37]). Because of the possibility for highly localized RF energy absorption immediately adjacent to implanted medical devices (e.g. electrode surfaces), it is important to properly model the local *in vivo* environment when performing implant electromagnetic and thermal simulations. Thus, knowledge of the various tissues and fluids immediately adjacent to the implant is necessary, as well as an understanding of how these environments change over time.

All implanted objects elicit some type of physiologic “foreign body response”. The initial acute reaction for an endocardial pacing lead starts with focal mechanical trauma to the tissue at the electrode implantation site and is generally a few days to a week long. The acute response is then followed by localized peri-implant accumulations of macrophages and fibroblasts with lesser numbers of lymphocytes and foreign body giant cells (often surface morphology dependent.) Extracellular matrix (ECM) is deposited by a variety of localized mesenchymal cells; usually type I and type III collagens predominate, depending on time post implant. The ECM matures and eventually develops into an organized cross-linked fibrotic capsule surrounding the cardiac stimulation electrodes (see Reference [38]). This encapsulation further anchors the lead tip maintaining connection to the myocardium. The chronic fibrous encapsulation extends over the electrodes and onto the insulated portion of the leads (see References [39], [40], [41], [42], [43] and [44]). Human histological studies have been done showing that the encapsulation is not necessarily uniform in thickness and can be anywhere from 0,1 mm to 1,8 mm thick (see References [45] and [46]). Excessive peri-implant fibrosis and/or mineralization over time may occur.

Many factors can affect the fibrotic capsule formation: implant location and surroundings, local lead corticosteroid drug elution, contact force between implant and endocardium, implant material, texture, shape, stiffness and porosity. Of particular interest, no relation was found between the duration of chronic pacing lead implant and the extent (thickness) of encapsulation at the electrode (see References [45] and [46]). Typical steroid eluting atraumatic pacing leads have a minimum encapsulation of 0,1 mm to 0,15 mm thick. Other implants, particularly neurological implants with contact to CSF, may have thinner encapsulation.

Electromagnetic and thermal property values from the literature generally focus on normal, healthy tissues. Properties of encapsulating tissues may need to be estimated, based upon information for their constituents, such as the concentrations of water, lipids and/or collagen (see References [47], [48], [49], [50] and [51]). From the description of the chronic pacing lead capsule formation above, it would be reasonable to use properties of similar tissues containing collagen at *in vivo* temperatures and the corresponding MR scanner operation frequency. Examples of alternative tissues with known properties are the cartilage, tendon or sclera of the eye dielectric properties at 64 MHz (see Reference [52]) and connective tissue thermal properties at 37 °C (see Reference [53]).

It is recommended that a sensitivity analysis be performed to indicate how much the induced heating depends on the tissue properties and thickness.

Annex P
(informative)

Estimation of conservative B_1 and 10g averaged E-field values for Tier 1 for RF-induced heating and malfunction

P.1 Objective

The objective of this annex is to describe the methods used to determine conservative estimates of the maximum induced E_{RMS} field and the maximum incident B_{1RMS} for human exposure in 1,5 T body-coils to be applied in Tier 1 (see Table 6 and Table 15).

P.2 Methods

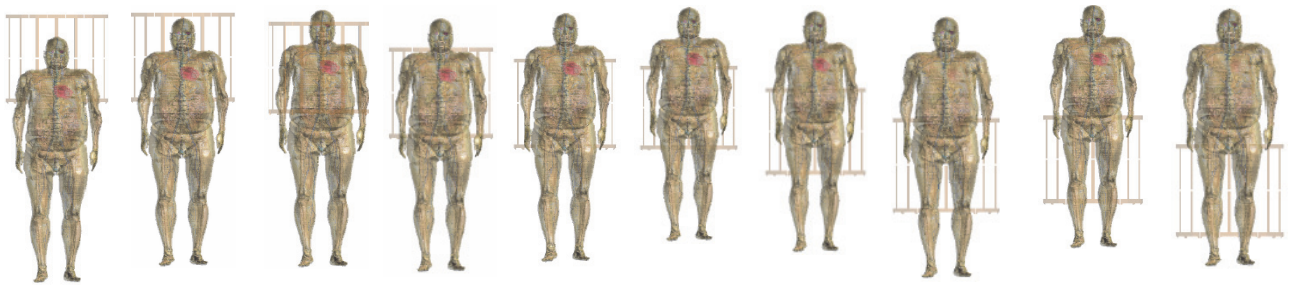
The maximum 10 g averaged E_{RMS} field (induced in the body) and the maximum B_{1RMS} field (incident at the isocentre) for the patient population have been determined by means of FDTD simulations involving four high resolution human models (DUKE, ELLA and LOUIS of the Virtual Family and FATS, the obese adult man) exposed to the RF fields of the birdcage defined in Annex J. The Virtual Family models are described in detail in P.5.1, and the FATS model is described in P.5.2.

NOTE SAR (W/kg) = $(\sigma|E_{RMS}|^2)/\rho$, where σ is conductivity (S/m), ρ is density (kg/m^3), and E_{RMS} is V/m.

The models are positioned with their arms along the sides of their bodies and the birdcage coil is moved in different landmarks along the axis of the bore (the z-axis). The reference point (i.e. z = 0) for all the models has been taken to be the centre of the heart. The fields have been obtained at 10 different positions for each model, representing the scanning landmarks for different clinical procedures.

The peak 10 g averaged E_{RMS} values have been extracted for each model and position in the head, trunk and limbs. Calculation of the peak 10 g average E_{RMS} is determined in accordance with IEEE C95.3 (see Reference [20]). At each voxel of the body model, a 10 g averaging volume in the shape of a cube is found by expanding the cube in all directions from the centre voxel until the mass is equal to 10 g. The densities of the different tissues are used in the determination of the size of the 10 g cube. For parts of the body with air boundaries, standardized methods in P.5.3 are used to determine the appropriate 10 g volume. All of the 10 g volumes are then scanned to find the highest value.

The peak E_{RMS} fields are normalized in two ways. They are normalized to B_{1RMS} incident in the isocentre of the coil, in units of (V/m)/μT. They are also normalized to the whole-body-average SAR limit or head-average SAR limit for the operating mode of the scanner, in units of V/m. From all the models, the maximum has been chosen.



z=-250mm z=-125mm z= 0 z=125mm z=250mm z=375mm z=500mm z=625mm z=750mm z=875mm

Figure P.1 – Positions of the FATS (obese adult male model) in the RF birdcage, translated along the bore axis

Table P.1 – Maximum incident B_1 and 10 g averaged induced E_{RMS} values for the Virtual Family models (DUKE, ELLA, LOUIS) and the obese male model (FATS) in the different landmarks inside the birdcage

FATS												
Position	E RMSmax, *in vivo* / B_1 RMSmax			B_1 RMSmax			E RMSmax, *in vivo* Normal mode			E RMSmax, *in vivo* First level mode		
	Head	*B*ody	Limbs	Normal mode	First level mode	Head	Head	Body	Limbs	Head	Body	Limbs
	V/m/µT	V/m/µT	V/m/µT	µT	µT	µT	V/m	V/m	V/m	V/m	V/m	V/m
z=-250	81	82	51	4,7	4,7	4,7	378	384	241	378	384	241
Z=-125	**91**	96	50	4,6	4,6	4,6	**421**	444	232	**421**	444	232
Z=0	84	93	70	4,1	5,6	4,1	344	379	287	344	519	393
Z=125	62	104	120	3,6	5,0	3,6	219	370	428	219	523	605
Z=250	30	131	164	3,4	4,8	3,4	102	443	555	102	626	784
z=375	10	**139**	**167**	3,6	5,1	3,6	36	**496**	**598**	36	**701**	**846**
Z=500	3,7	124	126	4,0	5,6	4,0	15	495	505	15	701	714
Z=625	3,1	81	84	4,7	6,6	4,7	14	380	392	14	537	555
Z=750	2,8	63	72	5,4	7,7	5,4	15	344	393	15	486	556
Z=875	2,7	45	75	6,5	9,2	6,5	18	290	488	18	411	690
NOTE The bold number provides the overall maximum values.												

Table P.1 — Maximum incident B_1 and 10 g averaged induced E_{RMS} values for the Virtual Family models (DUKE, ELLA, LOUIS) and the obese male model (FATS) in the different landmarks inside the birdcage (continued)

LOUIS												
Position	$E_{RMSmax,\ in\ vivo}$ / $B_{1\ RMSmax}$			$B_{1\ RMSmax}$			$E_{RMSmax,\ in\ vivo}$ Normal mode			$E_{RMSmax,\ in\ vivo}$ First level mode		
	Head	Body	Limbs	Normal mode	First level mode	Head	Head	Body	Limbs	Head	Body	Limbs
	V/m/µT	V/m/µT	V/m/µT	µT	µT	µT	V/m	V/m	V/m	V/m	V/m	V/m
z=-250	38,5	53,2	52,7	6,3	6,3	**6,3**	243	336	334	243	336	334
Z=-125	34,9	66,5	66,0	5,7	6,9	5,7	199	379	376	199	462	459
Z=0	28,6	68,4	62,4	4,6	6,6	4,6	133	317	289	133	449	409
Z=125	27,9	76,4	98,9	4,1	5,8	4,1	115	314	406	115	444	575
Z=250	18,2	67,3	77,8	4,0	5,7	4,0	73	271	313	73	383	443
z=375	5,1	76,4	98,9	4,3	6,1	4,3	22	329	426	22	466	603
Z=500	4,3	67,3	77,8	4,8	6,8	4,8	21	325	375	21	459	531
Z=625	3,3	49,0	60,9	5,5	7,8	5,5	19	272	338	19	385	478
Z=750	2,8	34,4	64,3	6,5	9,1	6,5	18	223	416	18	315	588
Z=875	2,7	34,5	58,2	**7,7**	**10,8**	**7,7**	20	264	445	20	373	630

ELLA												
Position	$E_{RMSmax,\ in\ vivo}$ / $B_{1\ RMSmax}$			$B_{1\ RMSmax}$			$E_{RMSmax,\ in\ vivo}$ Normal mode			$E_{RMSmax,\ in\ vivo}$ First level mode		
	Head	Body	Limbs	Normal mode	First level mode	Head	Head	Body	Limbs	Head	Body	Limbs
	V/m/µT	V/m/µT	V/m/µT	µT	µT	µT	V/m	V/m	V/m	V/m	V/m	V/m
z=-250	43,9	47,5	37,2	5,9	5,9	5,9	260	281	221	260	281	221
Z=-125	46,5	54,5	40,7	5,6	6,4	5,6	259	304	227	259	349	260
Z=0	41,8	55,7	66,0	4,5	6,4	4,5	188	251	298	188	355	421
Z=125	27,9	59,5	88,1	4,0	5,6	4,0	111	237	350	111	335	496
Z=250	12,2	61,8	97,4	3,9	5,5	3,9	47	241	380	47	341	537
z=375	4,4	76	85	4,2	5,9	4,2	18	320	355	18	452	502
Z=500	3,8	41,0	60,7	4,7	6,6	4,7	18	192	285	18	272	403
Z=625	3,9	21,6	58,1	5,4	7,6	5,4	21	116	312	21	164	441
Z=750	4,0	10,3	60,6	6,3	8,9	6,3	25	65	382	25	92	540
Z=875	4,1	7,1	54	7,5	10,7	7,5	31	54	410	31	76	579

Table P.1 — Maximum incident B_1 and 10 g averaged induced E_{RMS} values for the Virtual Family models (DUKE, ELLA, LOUIS) and the obese male model (FATS) in the different landmarks inside the birdcage (continued)

DUKE												
Position	$E_{RMS,\ max,\ in\ vivo}$ / $B_{1RMS,max}$			$B_{1RMS,max}$			$E_{RMS,\ max,\ in\ vivo}$ Normal mode			$E_{RMS,\ max,\ in\ vivo}$ First level mode		
	Head	Body	Limbs	Normal mode	First level mode	Head	Head	Body	Limbs	Head	Body	Limbs
	V/m/μT	V/m/μT	V/m/μT	μT	μT	μT	V/m	V/m	V/m	V/m	V/m	V/m
z=-250	46,2	62,5	36,9	6,1	6,1	6,1	281	379	224	281	379	224
Z=-125	36,9	73,3	39,2	4,7	6,6	4,7	173	344	184	173	487	260
Z=0	23,2	74,4	56,1	4,0	5,6	4,0	92	294	222	92	416	314
Z=125	12,4	76,1	77,5	3,6	5,1	3,6	45	274	279	45	387	395
Z=250	6,2	90,4	95,2	3,6	5,1	3,6	22	325	343	22	460	485
z=375	4,2	95,8	93,1	3,8	5,4	3,8	16	368	357	16	520	505
Z=500	4,0	93,1	70,8	4,2	6,0	4,2	17	393	298	17	555	422
Z=625	3,9	75,6	56,9	4,8	6,8	4,8	19	363	274	19	514	387
Z=750	3,9	49,3	59,9	5,7	8,1	5,7	23	283	343	23	400	486
Z=875	3,9	38,2	55,8	7,2	10,2	7,2	28	276	403	28	391	570

P.3 Results

Table P.1 presents four sets of data for each of the body models. The first set of data is the maximum 10 g averaged E_{RMS} values found in the head, trunk and limbs normalized to incident $B_{1\ RMS}$ in the isocentre (expressed in units of V/m/μT).

The second set of data is the incident $B_{1\ RMS}$ in the isocentre, at which the whole-body SAR limits are reached (see IEC 60601-2-33). The incident B_1 field is equal to the magnitude of the total B_1 field vector in the loaded RF coil (i.e. the RF coil in the presence of the body) minus the scattered B_1 field vector. The incident B_1 field therefore accounts for losses due to the presence of the body, but it does not include the B_1 field component (i.e. the B_1 component that is in the opposite circular polarization to the proton spin precession) that is of no use to imaging. In typical circularly polarized 1,5 T scanners, the B_1 component does not contribute significantly to the total B_1 field (the contribution is less than 5 %), so including or ignoring the B_1 component does not significantly change the result.

$B_{1\ max}$ is normalized to the averaged SAR limit for the head (3,2 W/kg), the body in normal mode (2 W/kg), or the body in first level mode (4 W/kg) found in IEC 60601-2-33. The head-averaged SAR and the body-averaged SAR are calculated separately. If the head-averaged SAR limit is exceeded at a lower B_1 level than the body-averaged SAR limit for normal mode, then the lower value is chosen for $B_{1\ max}$. The same is true for the other $B_{1\ max}$ values. In other words, the $B_{1\ max}$ values are defined as follows:

$B_{1\ max}$ (head) = min [$B_{1\ max}$ (head), $B_{1\ max}$ (normal mode)]

$B_{1\ max}$ (normal mode) = min [$B_{1\ max}$ (head), $B_{1\ max}$ (normal mode)]

$B_{1\ max}$ (first level mode) = min [$B_{1\ max}$ (head), $B_{1\ max}$ (first level mode)]

The third and fourth sets of data in Table P.1 are the peak 10 g averaged E_{RMS} fields normalized to the appropriate SAR levels. These values are calculated by multiplying $E_{RMSmax,\ in\ vivo}/B_{1\ max}$ (first set of data) by $B_{1\ max}$ (second set of data).

The highest values of the E and B fields in Table P.1 are then chosen for Tier 1 (Table 6 and Table 7). As expected, the highest induced E-fields per B_1 are induced in the FATS model, since his body occupies the largest volume inside the cage.

The theoretical maximum incident $B_{1\ RMS}$ for the two modes values will significantly increase for even smaller persons than LOUIS before the averaged SAR limits are reached. These maximum values will be far beyond what is achievable in commercial scanners. Therefore, it is recommended to test $B_{1\ RMS}$ coupling for the maximum achievable $B_{1\ RMS}$ of 7 µT in commercial scanners (see Table 7). Different values will be obtained for different birdcages and different sets of anatomies. However, the values given here are considered to be sufficiently conservative.

Table P.2 – Conservative induced incident E_{RMS} values for testing according to Tier 1

	Maximum induced field normalized to $B_{1\ RMS}$	**Normal mode**	**First level mode**
Body part	$E_{RMS\textit{in vivo}}$ / $B_{1\ RMSmax}$	$E_{RMS\textit{in vivo}}$	$E_{RMS\textit{in vivo}}$
Head	90 V/m/µT	420 V/m	420 V/m
Trunk	140 V/m/µT	500 V/m	700 V/m
Extremities	170 V/m/µT	600 V/m	850 V/m

NOTE 1 The E-field values for the normal mode and first level control mode shown in this table are conservative 10 g averaged E_{RMS} values. The 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 using four different anatomical models with a mass ranging from 50 kg to 120kg 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).

Table P.3 – Conservative induced incident $B_{1(RMS)}$ values for testing according to Tier 1

	$B_{1\ RMS\ \textit{in vivo}}$	$B_{1\ RMS\textit{in vivo}}$
Body part	**Normal mode**	**First level mode**
Head	7 µT	7 µT
Trunk	7 µT	7 µT
Extremities	7 µT	7 µT

NOTE 2 As the maximum $B_{1\ RMS}$ is not limited by the SAR limits but by the limitations of the commercial scanners, the $B_{1\ RMS}$ to be used for magnetic coupling is set to 7 µT.

P.4 Scaling of results for Tier 1 of RF-induced malfunction

For RF-induced malfunction in Clause 19, conservative values for the peak E-field in tissue are needed. For Tier 1, the worst-case values of $E_{RMS\textit{in vivo}}$ are calculated by scaling $E_{RMSmax,\ \textit{in vivo}}/B_{1\ RMSmax}$ of Table 6 by the maximum B_1 field. The highest B_1 field currently reported for commercial 1,5 T scanners is 30 µT (this is B_1+, the circularly polarized component in the same direction as the proton spin precession). Therefore, the values in Table 15 are calculated as follows.

For head:

$$E\ (\text{peak})_{\textit{in vivo}} = B_1\ (\text{peak}) \times \max\ (E_{RMSmax,\ \textit{in vivo}}/B1_{RMS})(\text{head})$$

$$= 30\ \mu\text{T} \times \max\ (90\ \text{V/m/}\mu\text{T}) = 2\ 700\ \text{V/m}$$

For trunk:

$$E\,(\text{peak})_{in\ vivo} = B_1\,(\text{peak}) \times \max\,(E_{\text{RMSmax, in vivo}}/B1_{\text{RMS}})(\text{trunk})$$

$$= 30\ \mu\text{T} \times \max\,(140\ \text{V/m/}\mu\text{T}) = 4\,200\ \text{V/m}$$

For extremities:

$$E\,(\text{peak})_{in\ vivo} = B_1\,(\text{peak}) \times \max\,(E_{\text{RMSmax, in vivo}}/B1_{\text{RMS}})(\text{extremities})$$

$$= 30\ \mu\text{T} \times \max\,(170\ \text{V/m/}\mu\text{T}) = 5\,100\ \text{V/m}$$

The tests of RF-induced malfunction use test signals according to the RF sequence of sequences described in 8.2. These signals are pulsed sinusoids.

Table P.4 — E-field level for Tier 1

Body part	Normal and first level mode E (peak) (V/m)
Head	2 700
Trunk	4 200
Extremities	5 100

Annex Q
(informative)

AIMD configurations

This includes combinations of the following configurations.

— If a system can include one or more mechanically or electrically connected components, each possible combination of system components constitutes an "AIMD configuration".

— If system components can exist within the patient in distinct geometrical environments, locations or patterns, each such disposition is an "AIMD configuration". Specific examples might include:

  — depth of implantation;

  — looping or bunching of components (e.g. strain-relief loops in leads);

  — anatomical locations;

  — shape, polarization or orientation of constituent components;

  — surrounding tissue characteristics (e.g. devices implanted within adipose tissue versus lean tissue versus the circulatory system).

— If a system can have multiple operating modes or settings, each state or combination of settings is an "AIMD configuration". Specific examples might include:

  — normal operating mode versus MR specific mode;

  — therapy enabled/disabled;

  — device on/off;

  — pump speed high/low;

  — output voltage high/low;

  — input filtering enabled/disabled;

  — fixed versus variable rate;

  — telemetry enabled/disabled.

NOTE Because there is a potentially infinite set of AIMD configurations for even the simplest device, it is neither expected nor intended that testing be done for all possible AIMD configurations. Rather, it is incumbent upon the manufacturer to clearly define and describe those AIMD configurations which represent potential for malfunction or patient harm based on device-specific design and performance considerations. Rationale regarding equivalency or supersedence of AIMD configurations under given test conditions should be used to reduce the set of required tests.

Annex R
(normative)

Uncertainty evaluation

R.1 General

This annex presents requirements for estimating the uncertainty of measurements or simulations of the procedures referred to in this Technical Specification. Each clause describes the dominant components of the uncertainty that shall be accounted for. A detailed uncertainty estimation is required in order to obtain a defined confidence interval or coverage of the assessment. The concept of uncertainty estimation is based on the general rules provided by ISO/IEC Guide 98-3. Nevertheless, the uncertainty estimation for complex measurements remains a difficult task and requires high-level and specialized engineering knowledge. The clauses in this annex provide a minimal list of parameters that shall be assessed and documented with respect to the assessment of uncertainty. The specific procedures used to estimate the uncertainty of each contributing component shall be justified.

Before calculating the combined standard uncertainty from the individual uncertainty components, the standard uncertainty of each term shall be converted from the term's statistical distribution to a normal (Gaussian) distribution. This requires dividing the standard deviation by the appropriate divisor, depending on the statistical distribution:

— N: normal (Gaussian) distribution with a coverage factor, k — Divisor = k.

— R: rectangular distribution — Divisor = √3

— T: triangular distribution — Divisor = √6

— U: U-Shaped distribution — Divisor = √2

The combined standard uncertainty of a measurement is determined from the root-sum-square (RSS) combination of the standard uncertainties of the individual components.

$$u_c = \sqrt{\sum_{i=1}^{m} c_i^2 \cdot u_i^2} \tag{R.1}$$

where

c_i is the sensitivity coefficient of each uncertainty component u_i, and

m is the number of influence quantities.

The interval around the assessed value providing a 95th percentile confidence corresponds to the assessed value plus the uncertainty for k=2 (2 × standard uncertainty).

R.2 Uncertainty budget of energy deposition using SAR or temperature probes

This clause describes the uncertainty budget to be applied for Clause 10.

Table R.1 — Measurement uncertainty evaluation template for experimental SAR and temperature evaluation *in vitro*

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Measurement system				
Probe and data acquisition uncertainty		N	1	
RF transmit coil and phantom				
Incident field E and B				
Medium parameters		N	1	
DUT related				
DUT position		N	1	
DUT holder uncertainty		N	1	
Data assessment evaluation				
Point measurement		R	√3	
3D-energy deposition reconstruction		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

a) The probe uncertainty includes at least the following parameters for SAR measurements:

— probe calibration for the specific tissue simulating material;

— linearity;

— isotropy;

— integration volume;

— distortion of the field;

— noise level.

b) The probe uncertainty includes at least the following parameters for temperature measurements:

— probe calibration for the specific temperature range;

— linearity;

— integration volume;

— EM field sensitivity;

— noise level;

— response time;

— distortion of the field and temperature distribution by the probe and probe fixture.

c) The incident field uncertainty includes at least the following parameters:

— uncertainty of target magnitude;

— uncertainty of targeted phase;

— deviation from target amplitude distribution;

— deviation from target phase distribution;

— drift of amplitude;

— drift of phase;

— distortion of DUT holder and probe fixture.

d) The uncertainty related to the phantom medium should include at least the following parameters:

— deviation from target permittivity, including variations by temperature;

— deviation from target conductivity, including variations by temperature;

— uncertainty of density;

— uncertainty of thermal conductivity (only for temperature measurement);

— uncertainty of heat capacity (only for temperature measurement);

— uncertainty of Grashof number, including variations by temperature;

— distortion of the scattered field by the holder and fixture.

e) The uncertainty of point measurement should include the following:

— precision of probe positioning with respect to DUT with respect to the local gradient;

— signal-to-noise ratio;

— distortion due to convection (temperature probe only);

— uncertainty due to measurement time.

f) The uncertainty related to the 3D extrapolation should take the following into consideration:

— it is recommended to use numerical data for the extrapolation such that only the uncertainty with respect of the numerical distribution shall be determined;

— the uncertainty with respect to determining the amplitude of the distribution that is different compared to that of the single point assessment.

R.3 Uncertainty budget for gradient-induced device heating

This clause describes the uncertainty budget to be applied for Clause 11.

The following uncertainty budgets are applied:

— Table R.2: uncertainty budget for Tier 2 (determine the magnetic field RMS *dB/dt* exposure requirement by computation).

— Table R.3: uncertainty budget for Tier 2 (determine the magnetic field RMS *dB/dt* exposure requirement by measurement using clinical MR scanner).

— Table R.4: uncertainty budget for *in vitro* temperature rise testing (DUT RMS *dB/dt* exposure measurement).

— Table R.5: uncertainty budget for *in vitro* temperature rise testing (DUT *in vitro* temperature rise measurements).

Table R.2 – Uncertainty budget for Tier 2 (determine the magnetic field strength by computation)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Simulation uncertainty				
Numerical reflections		R	√3	
Absorbing boundaries		N	1	
Simulation features		N	1	
Discretization		N	1	
Post-processing (e.g. averaging)		N	1	
Gradient coil design				
Field polarisation		R	√3	
Field uniformity		R	√3	
Body anatomy				
Body geometry		N	1	
Dielectric parameters		N	1	
Thermal parameters		N	1	
AIMD paths in body		N	1	
Body position in coil		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

Table R.3 — Uncertainty budget for Tier 2 (determine the magnetic field RMS *dB/dt* exposure requirement by measurement using a clinical MR scanner)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Magnetic field probe uncertainty				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Integration time		R	√3	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Probe position		R	√3	
Probe orientation		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

Table R.4 — Uncertainty budget for *in vitro* temperature rise testing (DUT RMS *dB/dt* exposure measurement)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Magnetic field probe uncertainty				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Integration time		R	√3	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Probe position		R	√3	
Probe orientation		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

Table R.5 — Uncertainty budget for *in vitro* temperature rise testing (DUT *in vitro* temperature rise measurements)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Temperature probe uncertainty				
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Integration time		R	√3	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Probe position		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

R.4 Uncertainty budget for gradient-induced vibration

This clause describes the uncertainty budget to be applied for Clause 12.

The following uncertainty budgets are applied:

— Table R.6: uncertainty budget for Tier 2 (determine the vector product gradient field $dB/dt \times B_0$ exposure requirement by computation).

— Table R.7: uncertainty budget for Tier 2 (determine the vector product gradient field $dB/dt \times B_0$ exposure requirement by measurement using clinical MR scanner).

— Table R.8: uncertainty budget for measurement of DUT vector product gradient field $dB/dt \times B_0$ exposure.

— Table R.9: uncertainty budget for measurement of DUT vibration.

Table R.6 — Uncertainty budget for Tier 2 (determine the vector product gradient field $dB/dt \times B_0$ exposure requirement by computation)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Simulation uncertainty				
Numerical reflections		R	√3	
Absorbing boundaries		N	1	
Simulation features		N	1	
Discretization		N	1	
Post-processing (e.g. averaging)		N	1	
Gradient coil design				
Field vector error in region of interest (ROI)		R	√3	
Field magnitude error in ROI		R	√3	
Static (B_0)coil design				
Field vector error in ROI		R	√3	
Field magnitude error in ROI				
Body anatomy				
Body geometry		N	1	
Thermal parameters		N	1	
AIMD position in body		N	1	
AIMD orientation in body		N	1	
Body position in coil		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

Table R.7 — Uncertainty budget for Tier 2 (determine the vector product gradient field $dB/dt \times B_0$ exposure requirement by measurement using clinical MR scanner)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Gradient magnetic field *dB/dt* probe uncertainty				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Integration time		R	√3	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Probe position		R	√3	
Probe orientation		R	√3	
Static magnetic field probe uncertainty				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Probe position		R	√3	
Probe orientation		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

Table R.8 — Uncertainty budget for measurement of DUT vector product gradient field $dB/dt \times B_0$ exposure

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Gradient magnetic field *dB/dt* probe uncertainty				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Integration time		R	√3	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Probe position uncertainty		R	√3	
Probe orientation uncertainty		R	√3	
Static magnetic field probe uncertainty				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Probe position uncertainty		R	√3	
Probe orientation uncertainty		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

Table R.9 — Uncertainty budget for measurement of DUT vibration

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Acceleration uncertainty				
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Directivity		R	√3	
Calibration uncertainty		N	1	
DUT position		R	√3	
DUT orientation		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

R.5 Uncertainty budget for B_0-induced malfunction

This clause describes the uncertainty budget to be applied for Clause 18.

Table R.10 — Uncertainty budget for B_0 static field test

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
B_0 source related uncertainty				
Amplitude deviation from 1,5 T		N	1	
Deviation from spatial uniformity		R	√3	
Drift over measurement time	e.g. 5%	R	√3	2,9 %
Magnetic field probe uncertainty				
Noise		N	1	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
DUT related				
DUT position		R	√3	
Combined standard uncertainty		RSS		Sqrt of sum of sqrs
Expanded uncertainty (95% confidence interval)		2 x RSS		2X standard number

R.6 Uncertainty budget for RF-induced malfunction

R.6.1 Injected immunity

This clause describes the uncertainty budget to be applied for 19.2.

The following uncertainty budgets are applied:

— Table R.11 for the determination of the incident E-field;

— Table R.12 for the exposure to the field with HCM/LCM;

— Table R.13 for the measurement of induced voltage;

— Table R.14 for the injected immunity test.

Table R.11 — Uncertainty budget for Tier 2 and Tier 3, Step 1 (determine incident test E-field)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Simulation uncertainty				
Numerical reflections		R	√3	
Absorbing boundaries		N	1	
Simulation features		N	1	
Discretization		N	1	
Post-processing (e.g. averaging)		N	1	
RF coil design				
Field polarisation		R	√3	
Field uniformity		R	√3	
Body anatomy				
Body geometry		N	1	
Dielectric parameters		N	1	
Thermal parameters		N	1	
AIMD paths in body		N	1	
Body position in coil		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95% confidence interval)				

Table R.12 — Uncertainty budget for Tier 1 to Tier 3, Step 2 (expose to field with HCM/LCM)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Source uncertainty				
RF amplifier stability		N	1	
Deviation from spatial uniformity		R	√3	
***E*-field probe uncertainty**				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Integration time		R	√3	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Phantom related				
Permittivity measurement		N	1	
Conductivity measurement		N	1	
Permittivity agreement with target values		R	√3	
Conductivity agreement with target values		R	√3	
Phantom shape		R	√3	
DUT related				
DUT position		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

Table R.13 — Uncertainty budget for Tier 1 to Tier 3, Step 3 (measure induced voltage)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Voltage monitor				
Influence of monitor on field distribution		N	1	
Influence of communication on field distribution		N	1	
Stability over time		R	√3	
Noise		N	1	
Component values		N	1	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

Table R.14 — Uncertainty budget for injected immunity test

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Injection network				
Component values		N	1	
Lead lengths		R	√3	
Source uncertainty				
RF amplifier stability		N	1	
Drift over measurement time		R	√3	
Voltage monitor				
Influence of monitor on field distribution		N	1	
Influence of communication on field distribution		N	1	
Stability over time		R	√3	
Noise		N	1	
Component values		N	1	
Combined standard uncertainty		**RSS**		
Expanded uncertainty (95 % confidence interval)				

R.6.2 Radiated immunity

This subclause describes the uncertainty budget to be applied for 19.3.

The following uncertainty budgets are applied:

— Table R.15 for the determination of the incident test E-field;

— Table R.16 for the radiated immunity test.

Table R.15 — Uncertainty budget for Tier 2 and Tier 3, Step 1 (determine incident test E-field)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Simulation uncertainty				
Numerical reflections		R	√3	
Absorbing boundaries		N	1	
Simulation features		N	1	
Discretization		N	1	
Post-processing (e.g. averaging)		N	1	
RF coil design				
Field polarisation		R	√3	
Field uniformity		R	√3	
Body anatomy				
Body geometry		N	1	
Dielectric parameters		N	1	
Thermal parameters		N	1	
AIMD paths in body		N	1	
Body position in coil		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

Table R.16 — Uncertainty budget for radiated immunity test

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Source uncertainty				
RF amplifier stability		N	1	
Deviation from spatial uniformity		R	√3	
***E*-field probe uncertainty**				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Integration time		R	√3	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Phantom related				
Permittivity measurement		N	1	
Conductivity measurement		N	1	
Permittivity agreement with target values		R	√3	
Conductivity agreement with target values		R	√3	
Phantom shape		R	√3	
DUT related				
DUT position		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

R.7 Uncertainty budget for gradient-induced malfunction

R.7.1 Injected immunity

This clause describes the uncertainty budget to be applied for 20.2.

The following uncertainty budgets are applied:

— Table R.17 for the determination of the incident magnetic field strength;

— Table R.18 for the injected immunity test.

Table R.17 — Uncertainty budget for Tier 2 and Tier 3, Step 1 (determine magnetic field strength)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Simulation uncertainty				
Numerical reflections		R	√3	
Absorbing boundaries		N	1	
Simulation features		N	1	
Discretization		N	1	
Post-processing (e.g. averaging)		N	1	
Gradient coil design				
Field polarisation		R	√3	
Field uniformity		R	√3	
Body anatomy				
Body geometry		N	1	
Dielectric parameters		N	1	
Thermal parameters		N	1	
AIMD paths in body		N	1	
Body position in coil		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

Table R.18 — Uncertainty budget for injected immunity test

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Injection network				
Component values		N	1	
Lead lengths		R	√3	
Source uncertainty				
RF amplifier stability		N	1	
Drift over measurement time		R	√3	
Voltage monitor				
Influence of monitor on field distribution		N	1	
Influence of communication on field distribution		N	1	
Stability over time		R	√3	
Noise		N	1	
Component values		N	1	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

R.7.2 Radiated immunity

This subclause describes the uncertainty budget to be applied for 20.3.

The following uncertainty budgets are applied:

— Table R.19 for the determination of the incident magnetic field strength;

— Table R.20 for the radiated immunity test.

Table R.19 — Uncertainty budget for Tier 2, Step 1 (determine magnetic field strength)

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Simulation uncertainty				
Numerical reflections		R	√3	
Absorbing boundaries		N	1	
Simulation features		N	1	
Discretization		N	1	
Post-processing (e.g. averaging)		N	1	
Gradient coil design				
Field polarisation		R	√3	
Field uniformity		R	√3	
Body anatomy				
Body geometry		N	1	
Dielectric parameters		N	1	
Thermal parameters		N	1	
AIMD paths in body		N	1	
Body position in coil		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

Table R.20 — Uncertainty budget for radiated immunity test

Description	Uncertainty value +/- %	Probability distribution	Divisor	Standard uncertainty
Source uncertainty				
RF amplifier stability		N	1	
Deviation from spatial uniformity		R	√3	
Magnetic field probe uncertainty				
Spherical isotropy		R	√3	
Noise		N	1	
Sensor displacement		R	√3	
System detection limits		R	√3	
Readout electronics		N	1	
Response time		R	√3	
Integration time		R	√3	
Directivity		R	√3	
Spatial resolution		N	1	
Calibration uncertainty		N	1	
Phantom related				
Permittivity measurement		N	1	
Conductivity measurement		N	1	
Permittivity agreement with target values		R	√3	
Conductivity agreement with target values		R	√3	
Phantom shape		R	√3	
DUT related				
DUT position		R	√3	
Combined standard uncertainty		RSS		
Expanded uncertainty (95 % confidence interval)				

Annex S
(informative)

Guidance on gradient field interactions and test methods for pacemakers

S.1 Pacemaker-specific MR gradient hazards

Pacemaker patients are subject to several potential hazards due to MRI gradient field. These hazards arise from induced voltage along patient cardiac pacing leads and internal circuitry, as well as eddy current induction in the pulse generator case and internal conductive components. Potential hazardous effects, the intended evaluation methods and associated requirements are detailed in Table S.1.

The second column in Table S.1 lists the effects of gradient-induced hazards. The severity of hazards varies. For example, gradient-induced noise might result in the failure to sense cardiac signals properly, which could cause temporary inhibition of pacing. More severe is gradient-induced cardiac stimulation, which might result in inappropriate high-rate pacing and/or induced arrhythmia which could be life threatening.

Table S.1 — Pacemaker gradient effects and test methods

Mechanism	Effect	Evaluation method	Requirement
Gradient-induced lead voltage	Unintended cardiac stimulation (without rectification)	1. Measure *in vivo* lead capture threshold: Q_{min}, $I_{rheobase}$. 2. Measure pulse generator charge and current injection due to gradient-induced EMF: Q_{PG_EMF}, I_{PG_EMF}	Lead capture threshold > gradient-induced PG lead interface pulse current or pulse charge: $Q_{min} > Q_{PG\_EMF}$ $I_{rheobase} > I_{PG\_EMF}$
	Unintended cardiac stimulation (with rectification)	1. Measure *in vivo* lead capture threshold: Q_{min}, $I_{rheobase}$. 2. Measure pulse generator charge & current injection due to max gradient-induced EMF: Q_{PG_EMF}, I_{PG_EMF}	Lead capture threshold > gradient-induced PG lead interface pulse current or pulse charge: $Q_{min} > Q_{PG\_EMF}$ $I_{rheobase} > I_{PG\_EMF}$
	Failure to sense bio-electric signals	1. Scanner 2. Bench simulation of MRI gradient field environment	Meets applicable manufacturer sensing specifications during MRI gradient field exposure
	Inhibition of pacing therapy	1. Scanner 2. Bench simulation of MRI gradient field environment	Deliver specified pacing therapy during exposure to MRI gradient field exposure
	Distortion of pace pulses	1. Scanner 2. Bench simulation of MRI gradient field environment	Deliver specified pacing therapy during exposure to MRI gradient fields
	Device malfunction during MRI	1. Bench test, exposure of device to maximum gradient field-induced lead voltages 2. Expose device and leads to MR scanner gradient magnetic fields	Meets operating requirements per device labelling during and after exposure to actual or simulated MRI gradient fields
	Device overstress damage	1. Exposure to MR scanner gradient magnetic fields 2. Bench stress test by injecting signal equivalent to gradient-induced lead voltage	Meets manufacturer specifications following exposure

Table S.1 — Pacemaker gradient effects and test methods (*continued*)

Mechanism	Effect	Evaluation method	Requirement
Eddy currents induced in device by MR gradient magnetic fields	Device heating	Measure pulse generator case surface temperature rise during exposure to worst-case gradient field amplitude and pulse sequence	1. Case heating does not result in pocket tissue damage or discomfort 2. Device meets manufacturer specifications following exposure
	Vibration (patient)	MR scanner	Vibration does not result in patient tissue damage or discomfort
	Vibration (device)	1. MR scanner 2. Shaker table profile validated to at least equal *in vivo* clinical conditions	Device meets manufacturer specifications following vibration
Static field	Force	MR scanner using ASTM F2052 or an equivalent method	Force < 1G (ASTM). Or IPG manufacturer specific safe pressure limit (kg/cm^2)
	Torque	MR scanner using ASTM F2213 or an equivalent	Torque < product of 1G and IPG longest torque arm (ASTM). Or IPG manufacturer specific safe torque limit

The most serious pacemaker patient safety risks associated with MRI-gradient magnetic fields are those resulting in unintended cardiac stimulation. There are two types of unintended cardiac stimulation.

The first type is caused by gradient-induced lead voltage waveforms being mistaken for sensed cardiac EGM signals. If the pacemaker has a demand pacing feature that is enabled, the gradient noise may cause pacing to be inhibited. In this case, the patient will not receive pacing support. Additionally, if the pacemaker is programmed to DDD mode, atrial over-sensing gradient noise may cause ventricular pacing at the maximum tracking rate.

The second type is caused by gradient-induced lead voltages large enough to cause cardiac stimulation. The effects of gradient-induced cardiac stimulation will depend upon the nature of the gradient pulse sequence and the resulting cardiac stimulation rate. If the stimulation occurs at a very high rate, it will emulate ventricular tachycardia (VT) or ventricular fibrillation (VF) and result in haemodynamic collapse. At lower stimulation rates, the patient safety risk is induction of a sustained arrhythmia if the stimulation occurs during the vulnerable period associated with the relative refractory portion of the cardiac cycle. Either of these outcomes could be fatal if the arrhythmia is not corrected promptly.

The MRI gradient magnetic field could also cause the pacemaker device to malfunction due to conducted or radiated EMI. The outcome of malfunctions could also be a patient safety risk.

S.2 Determining pacemaker-specific MR gradient magnetic field requirements

S.2.1 General

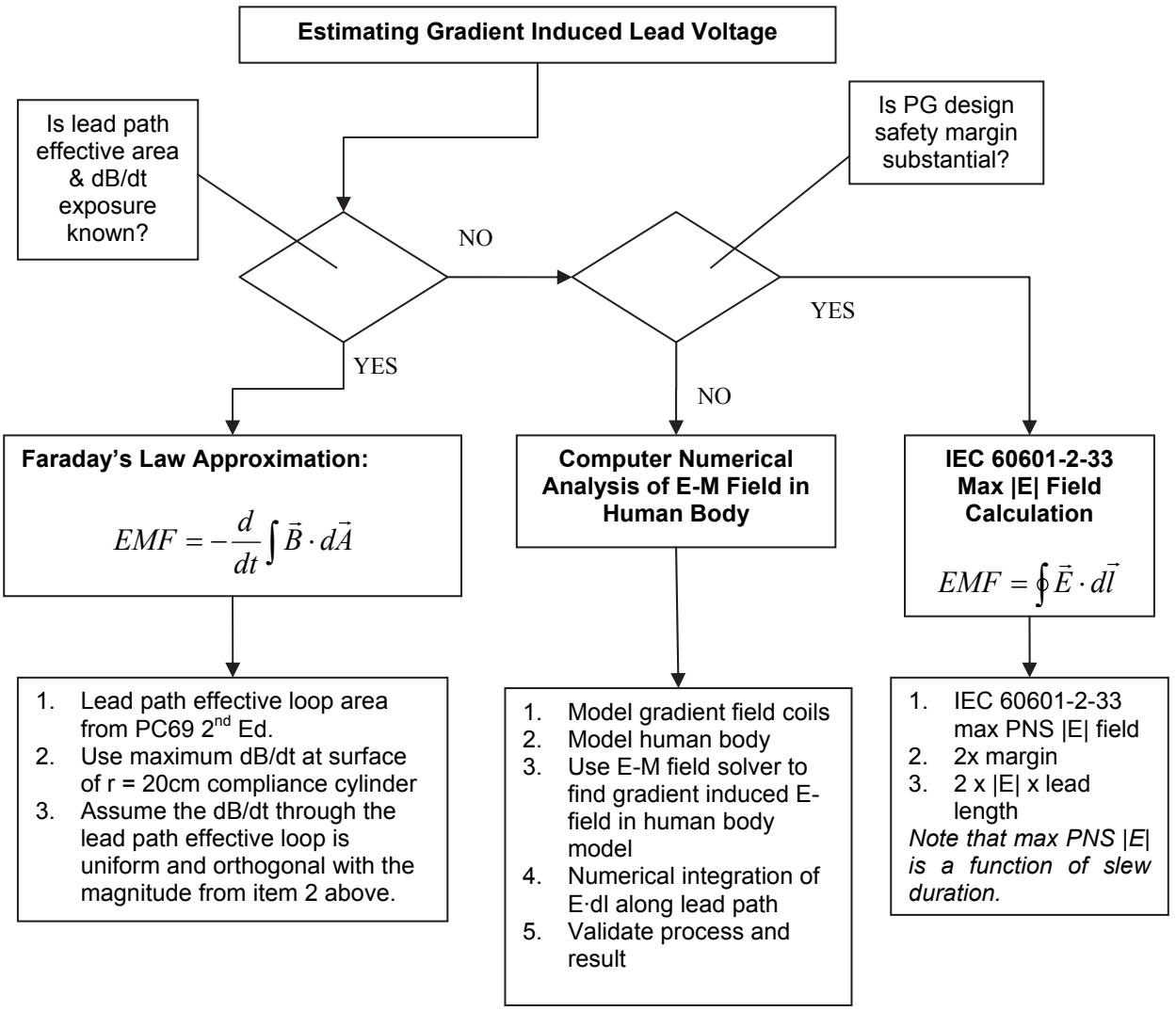
This clause describes the general considerations associated with pacemaker hazards during MRI scans and methods for estimating key parameters such as induced EMF along leads, lead stimulation threshold, device input impedance (Q_{PG_EMF}), and patient vibration limits.

S.2.2 Gradient-induced voltage along patient leads

In the typical pacemaker implant, the pulse generator (PG) is implanted subcutaneously in the pectoral region and pacing/sensing leads are routed transvenously to the heart. This configuration results in an effective loop in which voltage induction may occur when time-varying MR gradient fields are present. Significant common mode EMF may develop between the distal end of the lead and the pacemaker can. In addition, smaller differential voltages may appear between the tip of one lead (e.g. right atrium) and another (e.g. right ventricle) due to dissimilarities in lead trajectory and loop area such as might occur when excess lead is coiled in the pocket.

NOTE This decision tree provides guidance when selecting a method for calculating gradient-induced lead voltage.

Figure S.1 shows several methods for determining gradient-induced voltage along the patient leads. The most appropriate method will depend on design margin, knowledge of lead path and dB/dt exposure, and numerical modeling capability.



NOTE This decision tree provides guidance when selecting a method for calculating gradient-induced lead voltage.

Figure S.1 — Gradient-induced voltage estimation method decision tree

S.2.3 Unintended cardiac stimulation

S.2.3.1 General considerations

If the pacemaker and lead system allows charge flow during MRI gradient field exposure, there may be unintentional stimulation. If unintended cardiac stimulation occurs, there is a risk the patient will experience haemodynamic collapse due to ventricular high-rate asynchronous stimulation or an induced arrhythmia.

A process for evaluating the risk of gradient-induced cardiac stimulation is shown in Figure S.2.

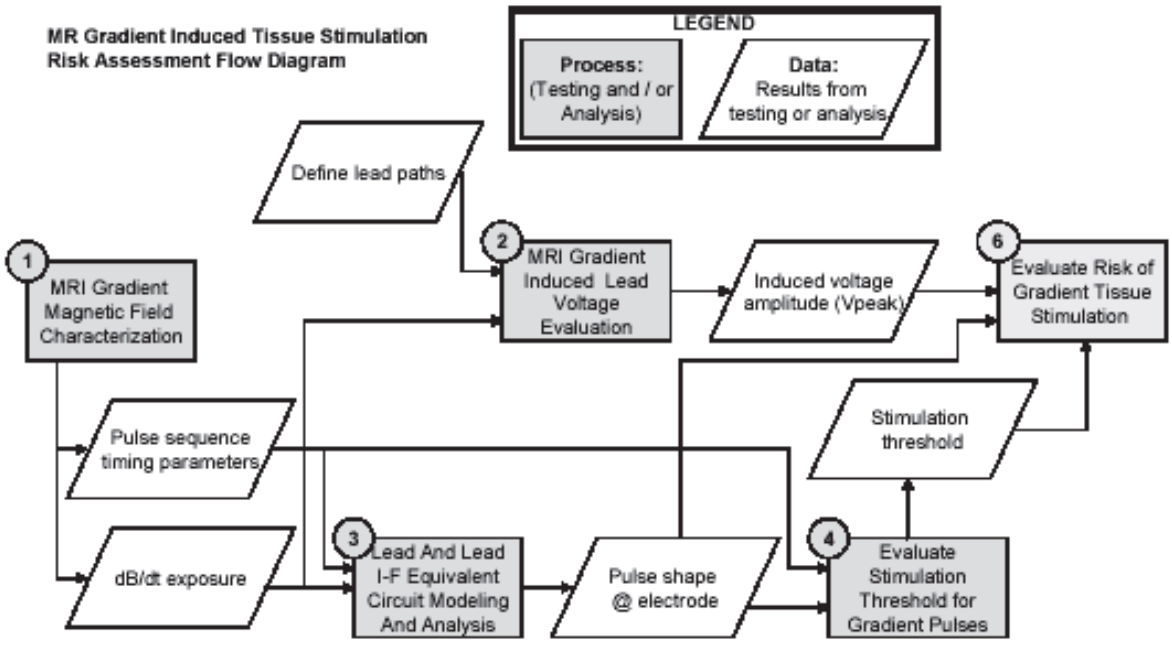
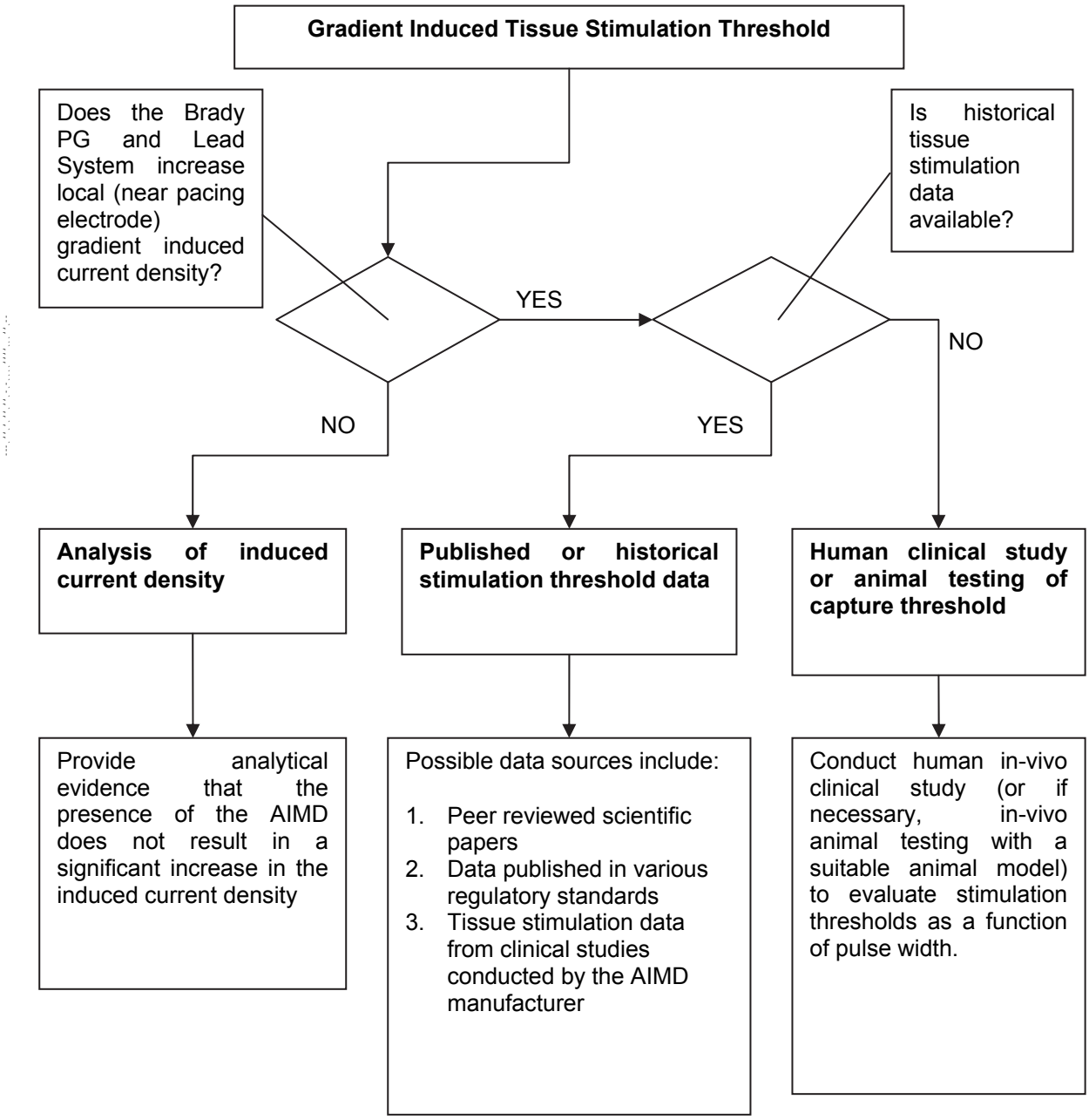


Figure S.2 — A process for evaluating the risk of gradient-induced cardiac stimulation for pacemaker patients

S.2.3.2 Cardiac stimulation threshold

There is a minimum charge in which cardiac capture will occur for a particular lead electrode.

Figure S.3 describes the process of determining this lead electrode minimum cardiac stimulation threshold, Q_{min}.



NOTE The capture threshold is a function of the effective width of the gradient-induced current pulse. The gradient-induced current waveform may differ from that of the EMF and is to be considered.

Figure S.3 — Methods for determining the minimum lead electrodes cardiac stimulation threshold

S.2.3.3 Gradient-induced PG charge injection, internal circuit impedance

The pacemaker's finite input impedance permits charge flow during MRI gradient field exposure. An EMI filter is used to suppress external RF interference from sources such as cell phones, keyless entry systems, and theft prevention monitors. The EMI filter provides a low impedance path between lead terminals and the PG CAN for RF inference. In the presence of gradient-induced voltage, these capacitors charge rapidly (<10uS) to the external EMF potential. This charge flows through the pacing lead electrode(s) into the cardiac tissue as it returns to the PG CAN and the proximal end lead terminals. The pacemaker patient lead interface circuit may also contribute to charge injection. Depending on the magnitude of the total charge injection, Q_{PG_EMF}, and the stimulation threshold of the lead, Q_{min}, cardiac stimulation may occur.

The potential circuit paths for currents flowing as a result of MR gradient-induced lead voltage are illustrated in Figure S.4 for a dual chamber pacemaker with unipolar (single electrode) pacing leads. For each path the current is required to flow through the pulse generator in order to complete the circuit.

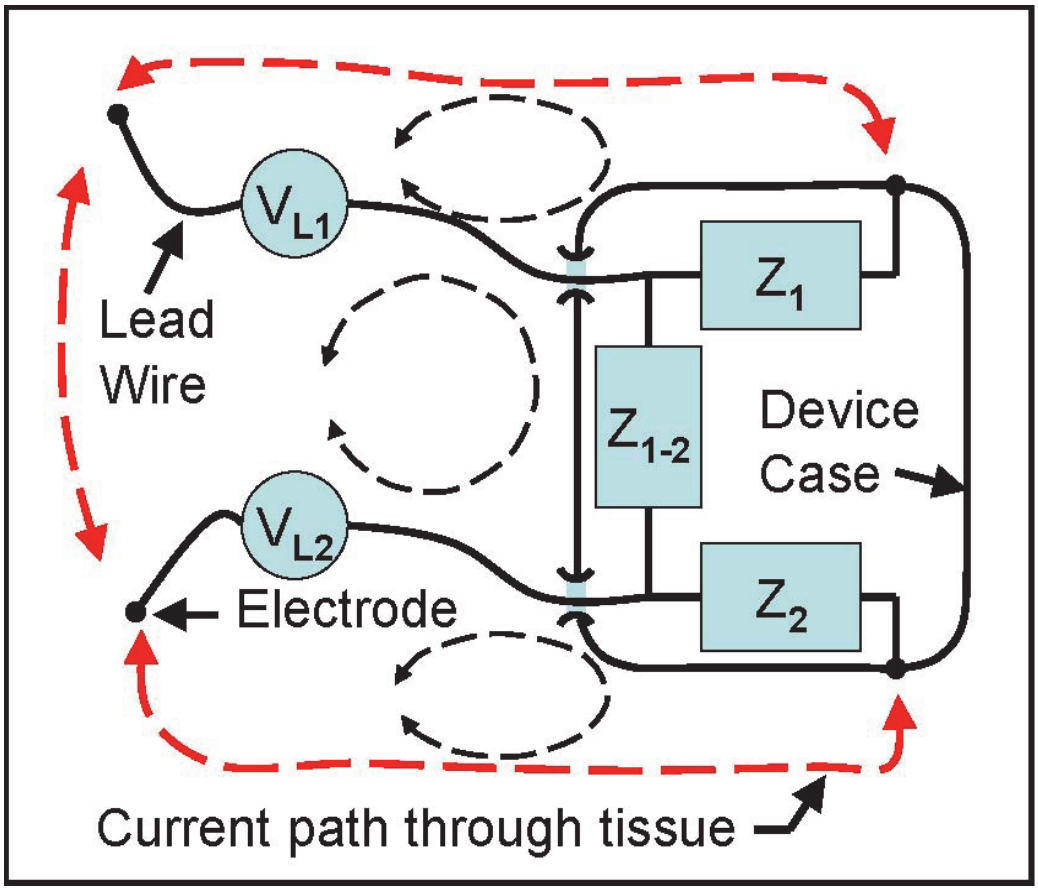


Figure S.4 — Illustration of gradient-induced current paths in a dual chamber pacemaker using unipolar (single electrode) pacing leads

The behaviour of the IPG and lead interface circuit in response to gradient-induced lead voltages can be most easily understood by considering the case of a single chamber IPG with a single unipolar (single electrode) pacing lead. The equivalent circuit for this simple pacing system is shown in Figure S.5.

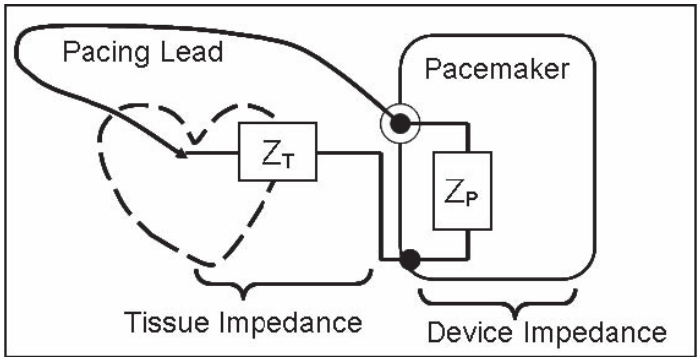
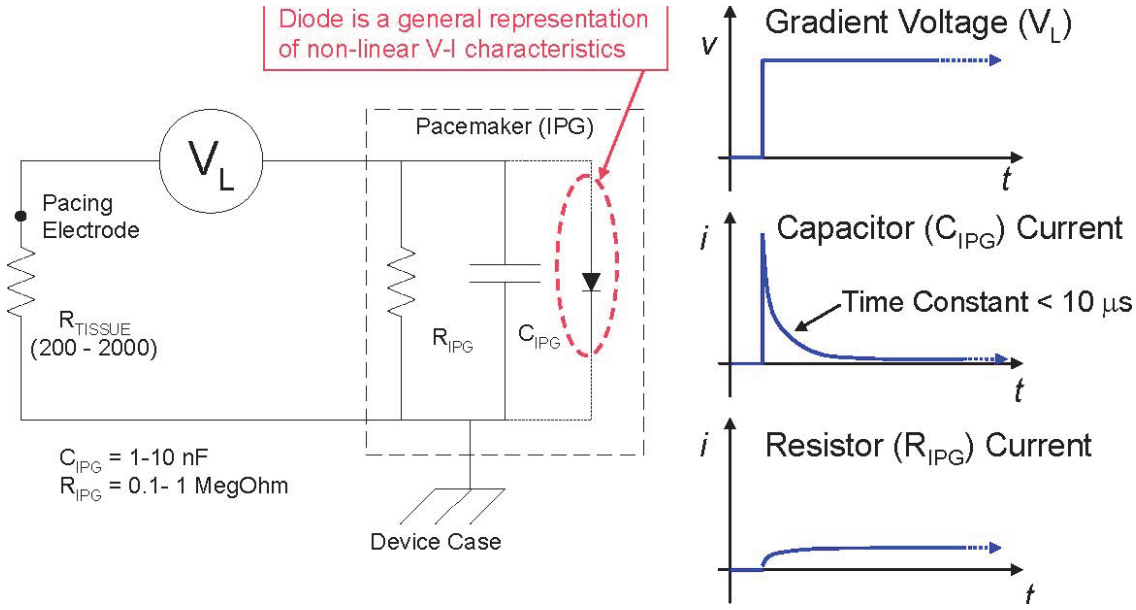


Figure S.5 — Simplified equivalent circuit for gradient-induced current flowing through the pacing electrode in a single chamber IPG with unipolar lead

The equivalent circuit for a dual chamber pacing system with bipolar leads is more complex. However, the basic principles are the same, and behaviour in the presence of gradient-induced lead voltage is similar. Once

the behaviour of the simpler single chamber unipolar lead configuration is understood, it can be extended to more complex systems.



NOTE Electrode current will be the sum of the resistive and capacitive currents that are illustrated qualitatively to the right.

Figure S.6 — Illustration of a simplified equivalent circuit for electrode current resulting from MR gradient field-induced lead voltage

Figure S.6 provides a qualitative picture of the shape of pulses (voltage and current) that would be applied to tissue adjacent to the pacing electrode during MR scanning if the IPG lead interface equivalent circuit is a parallel R-C combination and maintains linear operation over the full dynamic range of the gradient-induced lead voltage. The current through the electrode would be the summation of the capacitive component and the resistive component.

The diode in Figure S.6 represents the possibility of non-linear operation that could occur if the gradient-induced lead voltage becomes large enough to trigger over-voltage, ESD, or other types of protection circuits. Over-voltage breakdown of low voltage circuitry or other mechanisms might also cause non-linear increases in electrode current.

The amplitude, pulse shapes and pulse repetition pattern (related to the gradient pulse sequence) present at the pacing electrode need to be known in order to evaluate the risk of gradient-induced cardiac stimulation.

S.2.3.4 Q_{min}, $_{QPG\_EMF}$ comparison

To determine patient safety, the minimum lead charge stimulation threshold, Q_{min}, is compared to the pacemaker's gradient-induced charge injection, Q_{PG_EMF}. Figure S.7 illustrates the determination of Q_{min} and Q_{PG_EMF} as well as the associated risk evaluation.

NOTE Q_{min} is a conservative limit. Higher IPG gradient-induced charge injection might be acceptable for moderate and long pulse durations, depending on lead capture characteristics.

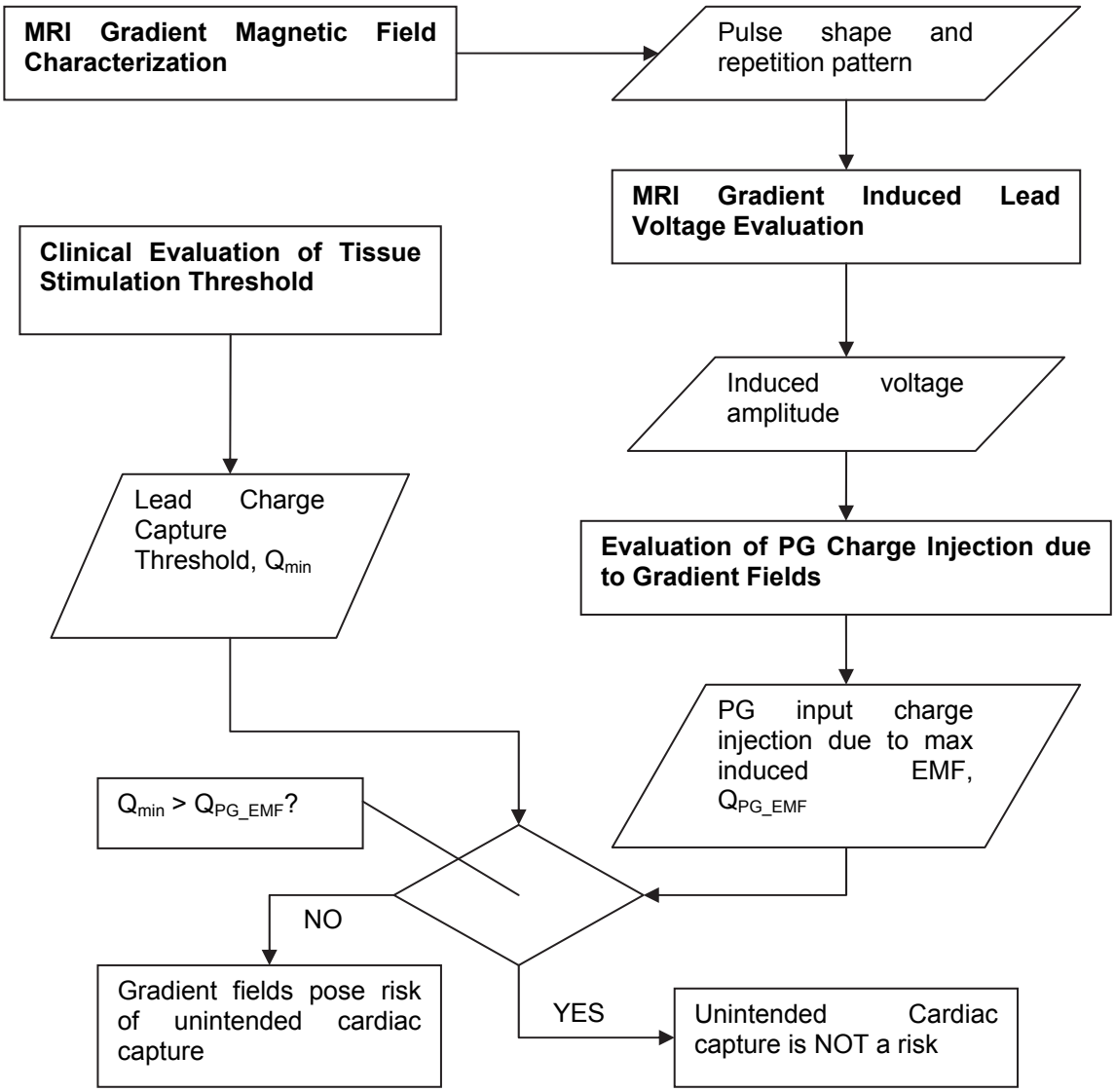


Figure S.7 — Evaluation process for unintended cardiac charge stimulation risk

S.2.3.5 $I_{rheobase}$, I_{PG_EMF} comparison

To determine patient safety for long current pulses, the minimum lead current stimulation threshold, $I_{rheobase}$, is compared to the pacemaker's gradient-induced current injection, I_{PG_EMF}. Figure S.8 illustrates the determination of $I_{rheobase}$ and I_{PG_EMF} as well as the associated risk evaluation.

NOTE $I_{rheobase}$ is a conservative limit. Higher IPG gradient-induced current injection might be acceptable for short and moderate pulse durations, depending on lead capture characteristics.

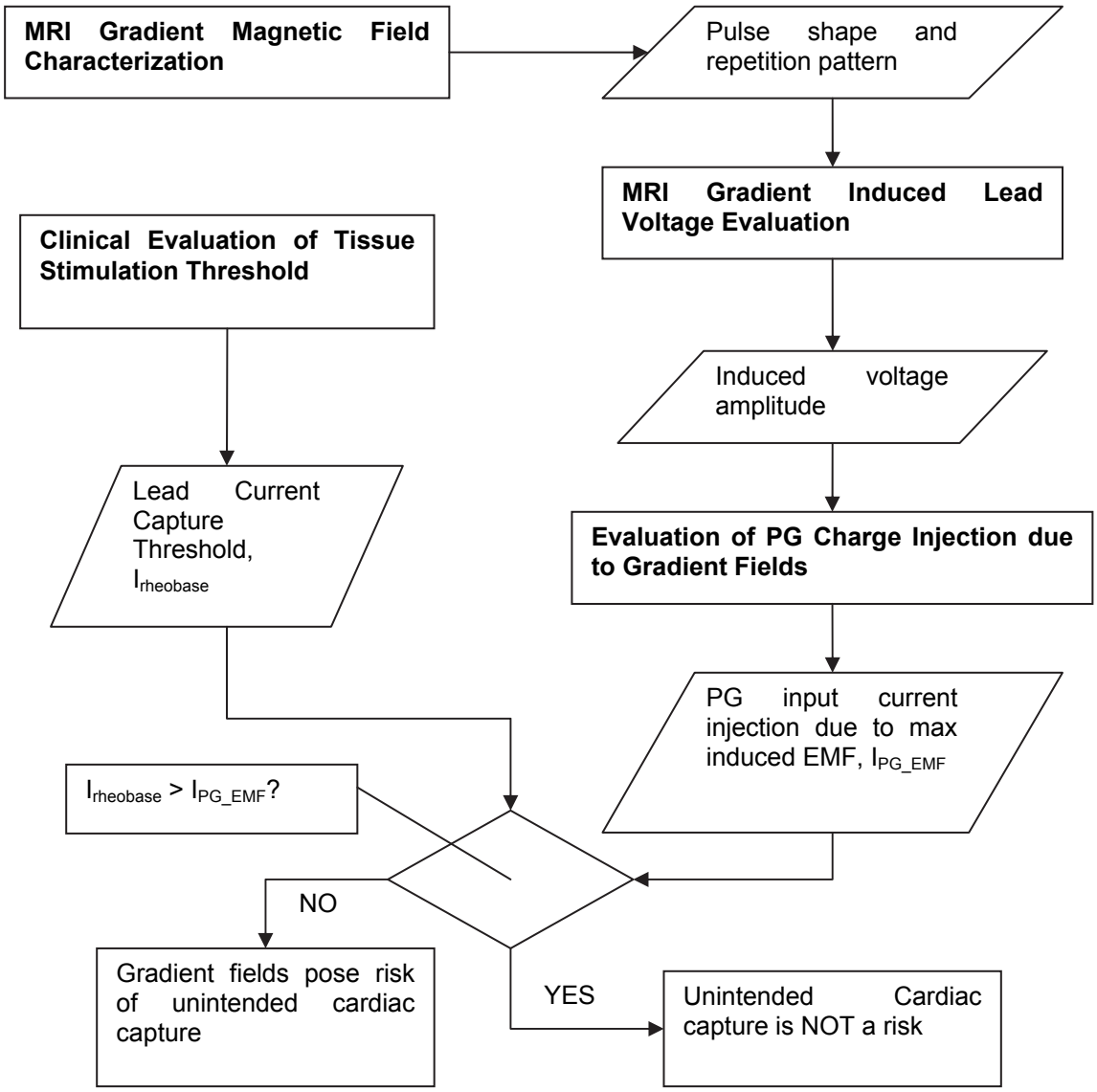


Figure S.8 — Evaluation process for unintended cardiac current stimulation risk

S.2.4 Failure to sense cardiac signals

Interference generated by MRI clinical scan gradient pulse sequences may be sensed by the cardiac sensing circuitry of the device. Over-sensing may cause pace inhibition (no pacing therapy) or improper atrial tracking and inappropriate high rate ventricular pacing in a dual chamber pacemaker. Cardiac sensing may be turned off to mitigate this hazard. If pacemaker sensing is enabled during MRI, EMC testing should be performed to evaluate this hazard for a wide variety of pulse sequence types and settings.

S.2.5 Therapeutic output pace pulse distortion

Gradient-induced lead voltages along long leads can distort delivered pace pulses. Pulse distortion might result in ineffective pace therapy delivery. Unipolar pacing along the common mode induction path between tip and CAN are particularly vulnerable to distortion. Bipolar pacing vectors involve a much smaller loop area and are much less susceptible to distortion. Longer pulse widths and/or higher pacing output voltages may be used to mitigate this hazard. Figure S.9 illustrates pulse distortion for a typical implant exposed to a moderate gradient system.

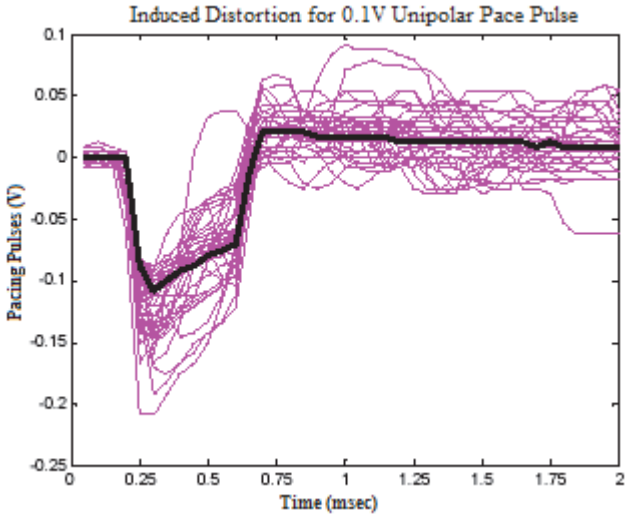


Figure S.9 — Gradient-induced pace pulse distortion example

Pacing output performance during MRI exposure can be tested in an MR scanner. The device and lead path should be placed in an ASTM phantom. The device, lead path and phantom should be positioned such that the induced voltage amplitude is ≥ the maximum expected in patients. The pacing output should be monitored while the scanner is operating and compared to the manufacturer's specification.

Pacing output performance can also be tested on the bench using injected signals that simulate gradient-induced lead voltage and a resistor network that approximates the patient's body tissues. The gradient-induced lead voltage is primarily a common mode signal.

S.2.6 Device malfunction during MRI gradient field exposure (EMC)

A variety of device malfunctions can occur in the presence of MRI fields. Potential issues resulting from the exposure of the device to MR gradient and B_0 fields include:

— false magnet detection;

— internal circuit malfunction;

— suspension of intended pacing therapy;

— program mode and/or memory state retention;

— device reset;

— false battery status or end of life indicator.

An MR Conditional labelled pacemaker should be designed to avoid these and similar operating faults. Comprehensive EMC testing should be performed to verify that the PG operates as specified and labelled during and after MRI exposure. The gradient-induced EMI signal injected into the lead interface can be defined (amplitude, pulse width, and pulse sequence) using some of the methods described above. The conducted EMI test requirements should be coordinated with the requirements for gradient-induced cardiac stimulation.

S.2.7 Device damage due to electrical overstress (EMC)

Pacemakers may be permanently damaged by exposure of MR gradient and B_0 fields. Potential damage may include:

— EMI filter damage (high currents);

— lead interface component stress;

— B_0 residual magnetization effects (reed switch, magnet sensors, etc.);

— internal circuitry (EMF developed along long loops and sensitive circuits, e.g. inductive telemetry coil).

EMC stress testing should be performed to verify that the device meets manufacturer specifications following MRI exposure. The EMC stress should be designed to cover the cumulative labelled scan time and MRI electrical and magnetic field intensity exposure. Refer to Clauses 16, 17, 18, 19 and 20 of this Technical Specification for additional information regarding EMC testing.

S.2.8 MR gradient-induced heating

Gradient-induced eddy current will flow in the pacemaker can, battery and internal circuitry. This eddy current flow will result in the heating of conductive surfaces. Pacemaker design should be evaluated to ensure the temperature rise due to eddy current heating does not exceed tissue safety limits.

The induced eddy current magnitude is related to:

— PG case radius, r, (proportional r^4; greatest power deposition will occur along the outer perimeter of the IPG Can);

— conductivity (directly proportional);

— material thickness (directly proportional).

The maximum dB/dt exposure orthogonal to the largest surfaces of the PG CAN should be determined to set the dB/dt needed from either an MRI gradient system or a lab gradient field simulator (high power coil set and driving amplifiers). The worst-case gradient sequence with respect to PG heating should also be defined in terms of slewing duty ratio or RMS value of gradient slewing.

S.2.9 MR gradient-induced device vibration

Gradient-induced eddy current will flow in the pacemaker can, internal battery and circuitry. The eddy currents give rise to a net magnetic moment that attempts to align with the B_0 field, causing torque and vibration. The pacemaker design should be evaluated for potential device and patient tissue damage. Figure S.10 illustrates the gradient-induced vibration risk assessment.

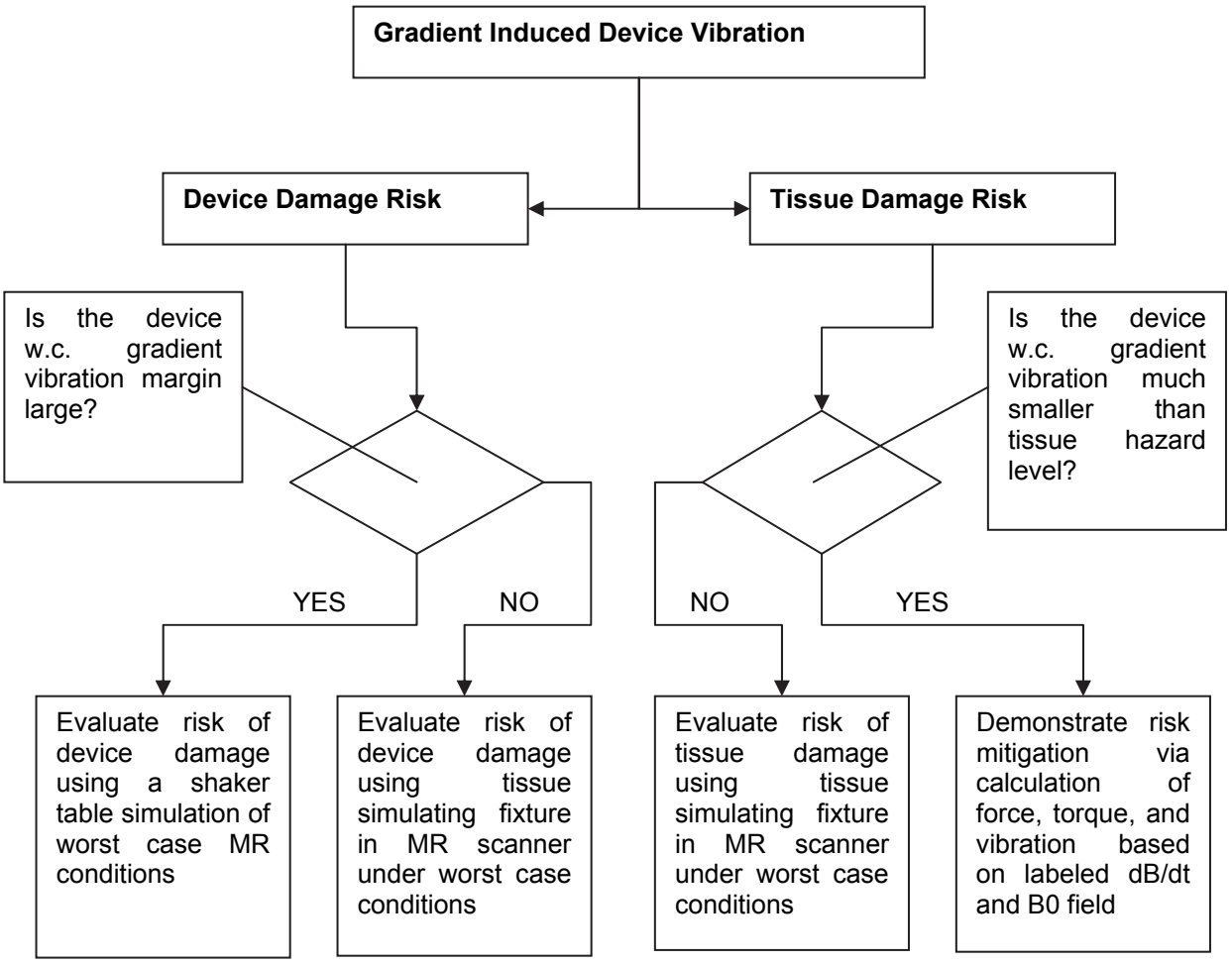


Figure S.10 — Gradient-induced vibration evaluation method

If a shaker table is used to simulate gradient vibration when a pacemaker patient is MR scanned, the shaker table power spectral density (PSD) should be ≥ the PSD measured in an MR scanner under worst-case conditions. The structural resonances of the PG should be determined. The resonance frequencies should be the focus of gradient vibration testing.

S.3 Operating requirements and operating mode during MR scanning

In order to avoid the MRI gradient field or other EMC hazards, the pacemaker manufacturer may provide special device operating mode(s) to be selected by the device programmer or other means before subjecting the patient to the MRI scan. The AIMD manufacturer may specify reduced performance and feature availability during MR scanning. Normal condition MRI safety risk testing should be conducted with PG modes and settings per MR Conditional label instructions. The PG should be evaluated against the requirements applicable during MRI. Safety risk testing should also be done with the AIMD programmed to typical/default modes and settings.

S.3.1 Operating specification during MR imaging

The pacemaker manufacturer should specify the MR Conditional modes of the device and perform adequate testing to verify intent, effectiveness and safety.

S.3.2 Pacemaker programmed as specified by the MR Conditional labelling instructions

Gradient MRI field testing of the pacemaker should be performed in the MRI Conditionally safe mode(s) of the device.

S.3.3 Pacemaker in normal operating mode

The pacemaker manufacturer should consider the effect(s) of MRI gradient exposure as part of the formal hazard analysis. Additional gradient field testing of the pacemaker outside of the conditionally safe mode to quantify effects and patient hazards is recommended.

S.4 Pacemaker-specific MR gradient magnetic field safety testing

S.4.1 Unintended cardiac tissue stimulation

The purpose of this testing is to verify that gradient-induced voltages do not cause unintended tissue simulation.

S.4.1.1 Minimum stimulation charge threshold, Q_{min}

S.4.1.1.1 General

The purpose of this test is to determine the minimum lead electrode charge capture threshold, Q_{min}.

S.4.1.1.2 Test environment

In vivo, preclinical and clinical lead study.

S.4.1.1.3 Test condition

Lead capture threshold studies with charge injection waveform consistent with that resulting from MR gradient-induced voltage. Lead stimulation should be conducted with a voltage pulse generator connected in series with a source impedance representing the gradient-induced EMF and pulse generator input impedance, such that the resulting lead current waveform matches that of the waveform produced under the influence of the MRI gradient field.

S.4.1.1.4 Test method

MR Conditional lead clinical and/or preclinical studies should be conducted to measure Q_{min} over a statistically significant sample of implants to 95 % confidence 99 % reliability level.

To conduct the Q_{min} study, a voltage generator should be connected to the proximal side of the lead through source impedance, simulating the IPG input impedance, and the return side to the patient through an appropriate IPG can model at the implant site. Adjust the pulse amplitude of the voltage source to determine the capture threshold of the lead. Q_{min} can then be calculated from the minimum capturing pulse amplitude and source impedance.

NOTE Compare Q_{min} to Q_{PG_EMF} to determine the safety margin (see S.4.1.2). The voltage difference between the minimum capturing pulse amplitude and the maximum induced PG lead system EMF may also serve as an adjunct measure of safety margin.

S.4.1.2 Maximum gradient-induced PG input charge injection, Q_{PG_EMF}

S.4.1.2.1 General

The purpose of this test is to determine the maximum pulse generator input charge injection.

S.4.1.2.2 Test environment

This test can be performed using readily available electronic test equipment in a non-MRI environment.

S.4.1.2.3 Test condition

A voltage waveform simulating worst-case gradient-induced voltage (EMF induced by greatest dB/dt allowed by MR Conditional labelling) is applied to the device under test.

S.4.1.2.4 Test method

Apply a square wave voltage through a series sensing capacitor (C_{sense} ~ 0,2uF) with the amplitude set to worst-case gradient field EMF with period of $2x T_{rise}$ where T_{rise} is equal to the minimum labeled slew time for a maximum amplitude gradient pulse. Measure voltage across the sensing capacitor just before the square wave transition event and determine the input charge injection, Q_{PG_EMF}.

S.4.1.2.5 Requirement

The pulse generator input charge injection, Q_{PG_EMF}, should not exceed Q_{min}.

S.4.1.3 Alternative method – Minimum capture E-field

S.4.1.3.1 General

The purpose of this test is to verify that the gradient-induced E-field across the lead electrode/tissue interface does not exceed the minimum required for capture. The following test establishes a reference E-field waveform necessary to capture tissue. The E-field reference waveform is compared to those produced when subjecting the device and lead system to an external gradient field to determine safety margin.

S.4.1.3.2 Test environment

Bench testing. MR Conditional PG and lead system immersed in saline solution approximating tissue impedance. Gradient coil capable of generating maximum labeled dB/dt, and E-field probes placed to measure E-field signature of distal electrode(s) (see Annex U).

Before collecting E-field waveforms from the gradient field challenge, a function generator in series with appropriate PG source impedance should be used to establish the minimum capture E-field reference waveform.

S.4.1.3.3 Test condition

Source impedance required to replicate the lead current waveform produced under the influence of the MR gradient field. The source impedance is selected to suitably model the IPG input impedance.

The pulse amplitude used during the E-field study to establish the minimum capture E-field reference waveform should equal the minimum voltage required for stimulation (as determined during the MR Conditional lead Q_{min} preclinical study).

Worst-case dB/dt according to MR Conditional labelling should be applied to device and lead system during gradient challenge testing.

S.4.1.3.4 Test method

Place the MR Conditional lead in a saline solution which approximates the tissue impedance. Using appropriately positioned E-field probes, measure the E-field signature at the distal electrode(s) while applying pulse amplitude equal to the minimum stimulation voltage through the PG input impedance model. This E-field signature corresponds to the Q_{min} specification of the MR Conditional lead.

Position the lead system within saline solution for worst-case voltage induction. Determine the E-field signature at distal electrode(s) when the maximum labelled gradient field is applied to the device and lead system.

Compare this worst-case E-field signature to the E-field signature corresponding to the Q_{min} specification.

S.4.1.3.5 Requirement

Gradient-induced lead E-field measurements should not exceed the minimum capture E-field reference waveform.

S.4.1.4 Minimum stimulation current threshold, I_{rheobase}

S.4.1.4.1 General

The purpose of this test is to determine the rheobase capture current of the lead and its associated electrodes, I_{rheobase}.

S.4.1.4.2 Test environment

In vivo, preclinical and clinical lead study.

S.4.1.4.3 Test condition

Lead capture threshold studies conducted with a rectangular current pulse, modelling the current flow through IPG input conductance under the influence of MR gradient-induced voltage. Rheobase is evaluated by successively increasing pulse width while reducing stimulation current level until the capture threshold can no longer be reduced.

S.4.1.4.4 Test method

MR Conditional lead clinical and/or preclinical studies should be conducted to measure I_{rheobase} over a statistically significant sample of implants to 95 % confidence 99 % reliability level.

To conduct the I_{rheobase} study, a current generator should be connected to the proximal side of the lead. The return side should be connected to the patient through an appropriate IPG can model at the implant site. Adjust the pulse amplitude to determine the lead capture threshold at successively longer pulse widths until the stimulation threshold cannot be reduced. Alternatively, rheobase current may be determined using a voltage generator and knowledge of the lead impedance.

NOTE Compare I_{rheobase} to $I_{\text{PG\_EMF}}$ to determine the safety margin (refer to S.4.1.2). The difference between the rheobase and the maximum induced IPG current injection amplitude may also serve as an adjunct measure of safety margin.

S.4.1.5 Maximum gradient-induced PG input current injection, $I_{\text{PG\_EMF}}$

S.4.1.5.1 General

The purpose of this test is to determine the maximum pulse generator input current injection.

S.4.1.5.2 Test environment

This test can be performed using readily available electronic test equipment in a non-MRI environment.

S.4.1.5.3 Test condition

A supply voltage simulating worst-case gradient-induced voltage (EMF induced by greatest dB/dt allowed by MR Conditional labelling) is applied to the device under test.

S.4.1.5.4 Test method

Apply a DC voltage equal to worst-case gradient EMF through a series sensing resistor (R_{sense} ~ R_{input}/10). Measure voltage across the sense resistor and determine input current injection, I_{PG_EMF}.

S.4.1.5.5 Requirement

The pulse generator input current injection, I_{PG_EMF}, should not exceed $I_{rheobase}$.

S.4.2 Failure to sense cardiac signals

S.4.2.1 General

The purpose of this testing is to verify that the pacemaker's electrical sensing will perform as specified in the presence of MR gradient magnetic field-induced noise on signals generated by electrodes in electrical contact with tissue. Common mode (present on both tip electrode and ring electrode signals) and differential mode (present between tip electrode and ring electrode) noise should be considered. The methods described in ANSI/AAMI PC69 may be adapted for this testing.

S.4.2.2 Test environment

Bench testing. A signal generator will be used to simulate gradient-induced voltage (noise). Refer to ANSI/AAMI PC69.

S.4.2.3 Test condition

Signal amplitude and waveform and/or spectral content should be derived from characteristics of the allowed gradient field exposure, gradient pulse sequence and lead path.

S.4.2.4 Test method

Refer to ANSI/AAMI PC69.

S.4.2.5 Requirement

AIMD meets applicable manufacturer sensing specifications in the presence of MR gradient-induced noise.

S.4.3 Failure to deliver intended electrical therapy

S.4.3.1 General

The purpose of this testing is to verify that the pacemaker will continue to deliver appropriate pacing therapy in the presence of gradient-induced voltage on lead wires.

S.4.3.2 Test environment

A bench and signal generator to inject simulated gradient-induced voltage between device and pacing load.

S.4.3.3 Test condition

A signal amplitude and time domain pulse train and/or spectral content derived from gradient field characteristics, lead path, and gradient pulse sequence. Both unipolar and bipolar pacing modes should be evaluated by testing and analysis.

S.4.3.4 Test method

Simulated gradient-induced lead voltages should be applied between the device and the load. The therapeutic electrical output should be monitored to verify that it meets the specified performance.

S.4.3.5 Requirement

During exposure to simulated gradient-induced lead voltage, the pacing output signal should meet the performance specified by the manufacturer.

S.4.4 Device overstress or malfunction

S.4.4.1 General

The purpose of this test is to verify that the device will not be affected (malfunction, over-stress, etc.) by gradient-induced lead voltage appearing at the lead connector terminals of a pacemaker. The methods described in ANSI/AAMI PC69 should be applied with using test waveforms simulating MR gradient-induced lead voltages and currents.

S.4.4.2 Test environment

For bench testing, a signal generator should be used to apply a simulated gradient-induced lead voltage to the device (see ANSI/AAMI PC69).

S.4.4.3 Test conditions

The voltage signal amplitude should be indicative of the maximum gradient-induced lead voltages as determined using one of the methods detailed in S.2.2.

a) Test waveforms: one or more induced voltage waveforms should be defined based on the range of gradient pulse sequences used clinically for MR imaging.

b) Simulated tissue impedance: the signal generator should be connected with series impedance to simulate the tissue in the *in vivo* current path (see ANSI/AAMI PC69).

S.4.4.4 Test method

The device should be placed in the prescribed operating mode(s) and device settings. Test signals simulating MR gradient-induced lead voltages and currents should be applied to the device using methods described in ANSI/AAMI PC69.

S.4.4.5 Requirement

The device should meet operational requirements during and after testing. Operational requirements and/or performance during testing may be different (reduced) compared to normal operation.

S.4.5 Device heating

S.4.5.1 General

The purpose of this test is to verify that case heating does not exceed the safe level for tissue in contact with the device case.

S.4.5.2 Test environment

Purpose-built magnetic field generating equipment (e.g. Helmholtz coil) or a suitable MR scanner gradient system should be used to provide a magnetic field capable of producing the *dB/dt* levels and pulse repetition rates characteristic of the worst-case MR gradient magnetic fields that the pacemaker will be exposed to during patient scans.

S.4.5.3 Test condition

The DUT should be subjected to a gradient magnetic field time rate of change (*dB/dt*) equal to 50T/s RMS.

NOTE 50T/s RMS is selected so that the heating may be measured and scaled appropriately for the gradient exposure contained in the manufacturer's MR Conditional labelling.

The device should be oriented such that the gradient magnetic field is orthogonal to the surface of the device with the largest area.

If the MR Conditional labelling provided for the device restricts the maximum allowed continuous scan time, the duration of magnetic field exposure should be set equal to this time. If not, the magnetic field should be applied until the case temperature rise relative to the solution temperature has stabilized.

S.4.5.4 Test method

The DUT should be immersed in a gelled solution or other medium that either simulates or can be correlated to the thermal and electrical properties of the *in vivo* environment. To prepare for this test, a survey of the device surface should be conducted to find the location of greatest temperature rise. Note that some internal components, such as batteries, may be heated significantly by gradient-induced eddy currents. The effect of internal component heating on device reliability should be considered. In addition, this heat may be transferred to the device case and produce hot spots in unexpected locations.

Additional temperature probes should be used to monitor the solution away from the device case so that temperature rise above background can be measured. Once established, the locations of temperature probes both on the device and in the solution should be specified and controlled so that the measurements give repeatable results. When a gelled solution is used, care is needed to make sure that the solution in which the device is immersed returns to a homogeneous temperature between tests when test runs are repeated. Stirring the solution between test runs may be helpful, particularly if a gelled solution is used.

NOTE If thermocouples are used to measure temperature, care should be taken that the thermocouple wires, the device case, and the measurement instrumentation do not form low impedance loops that could circulate large induced currents when the magnetic field is operating.

S.4.5.5 Requirement

The temperature versus time profile of the hottest area of the device case should stay below the threshold of clinically significant thermal damage. The maximum allowed temperature rise will depend on the maximum scan time allowed by MR Conditional labelling. Table S.2 details safe temperature/time exposure.

Table S.2 — Acceptable time/temperature exposure relationships

Temperature (°C)	Time (min)
39	1 960
40	480
41	120
42	30
43	15
44	7,5
NOTE This table is based on the discussion of the relationship between temperature rise and tissue damage in ISO 14708-6:2010, Annex CC.	

S.4.6 MR gradient-induced device vibration

S.4.6.1 General

The purpose of this test is to verify that device vibration during pulsing magnetic gradient fields will not cause device or tissue damage.

S.4.6.2 Test environment

A gradient coil and B_0 field capable of producing static and time-varying magnetic fields consistent with MR Conditional labelling. This environment may be produced using a commercial scanner, or suitable research equipment.

S.4.6.3 Test environment

Purpose-built equipment capable of generating vibratory forces equivalent in magnitude and frequency to those which would be produced in the AIMD and an MR scanner with static and time-varying magnetic fields consistent with AIMD MR Conditional labelling.

A resonance study of the PG should be conducted using an appropriate bench test setup (e.g. shaker table). This study should cover the frequency bandwidth representative of MR gradients (DC through 6 kHz). Vibration testing should account for the structural resonances of the PG and the appropriate shaker table input or gradient pulse sequence (intensity, frequency, dwell, etc.) to produce significant spectral power at the PG structural resonance frequencies.

S.4.6.4 Test condition

Worst-case MRI conditions with regard to vibratory forces (largest dB/dt and B_0 field allowed by MR Conditional labelling). The most appropriate means of imparting these vibratory forces may be to use an MR scanner.

NOTE Gradient-induced eddy currents can only develop in conductive parts. Therefore gradient-induced vibratory forces will be applied selectively to conductive parts. This might 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 shake table.

The test duration should at least be equal to the maximum cumulative scan time identified by labelling (product of the maximum continuous scan time and maximum number of scans as dictated in the MR Conditional labelling for the device).

S.4.6.5 Test method — Gradient coil evaluation of device damage

Mount PG in a tissue simulator (fixture allowing degrees of freedom consistent with device implant and simulating the mechanical properties of implant pocket) within the gradient coil and B_0 field. Ballistics gel may provide an appropriate simulation of the mechanical properties of implant pocket. Alternately, a fixture restricting all case movement may be more representative of the worst case.

The AIMD should be placed where dB/dt is perpendicular to B_0 and where both dB/dt and B_0 are known. The magnitudes of dB/dt and B_0 should be consistent with AIMD labelling. The AIMD should 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.

Expose the device to worst-case MR conditions with regard to vibration. The exposure sequence should account for the intensity, frequency and dwell, along with other unique frequencies revealed during the device resonance study. Test duration should be no less than the maximum cumulative scan time identified in the device's MR Conditional labelling.

It is recommended that manufacturers employ the overstress method to ensure that the device is margin tested to the intended labelling. Overstress may be accomplished by testing at higher B_0 or dB/dt fields than identified in the MR Conditional labelling.

S.4.6.6 Test method — Bench evaluation of device damage

Mount PG to linear shaker table according to the requirements and guidance given in IEC 60068-2-47. Challenge the device with a random vibration test according to IEC 60068-2-64, Test Fh, under the following conditions.

a) Test frequency range: 100 Hz to 6kHz.

b) Acceleration spectral density: <provided by manufacturer> $(m/s^2)^2/Hz$.

c) Shape of acceleration spectral density curve: flat horizontal ± <provided by manufacturer>, 100 Hz to 6 kHz.

d) Test duration: maximum cumulative scan identified by labelling.

Repeat the test with the device oriented in each of three mutually perpendicular axes.

NOTE The acceleration spectral density is device dependent.

S.4.6.7 Requirements — Device damage

Monitor the performance of the device throughout the testing. Evaluate the device specification performance following the testing. The device should satisfy the following criteria:

— the pacemaker performs as specified during vibration exposure;

— the device conforms to values stated in the manufacturer's specification after completing the test procedure.

S.4.6.8 Test method — Gradient coil evaluation of tissue damage

Mount PG within gradient coil and B_0 field. Expose the device to worst-case dB/dt and B_0 identified in MR Conditional labelling and a pulse sequence that encompasses the unique frequencies identified in the resonance study. Confirm that the resulting RMS acceleration is less than the guidelines established in the gradient clause of this Technical Specification.

S.4.6.9 Requirement

Gradient-induced vibrations should not cause clinically significant tissue damage. RMS acceleration should be less than the guidelines established in Clause 12.

NOTE Tissue damage testing may be avoided by confirming a large tissue safety margin through analysis. The analysis should consist of torque/acceleration calculations based on the eddy current evoked by the labeled dB/dt and B_0 field. Compare analytical results to guidelines established in Clause 12.

S.4.7 Device translation

S.4.7.1 General

The purpose of this test is to verify that in the presence of the B_0 field there is no risk of tissue damage or device migration.

S.4.7.2 Test environment

An MR scanner capable of generating the largest B_0 field spatial gradients allowed by MR Conditional labelling.

S.4.7.3 Test condition

The largest B_0 field spatial gradient allowed by MR Conditional labelling. The device should be positioned in the scanner such that the AIMD is subject to the maximum spatial gradient for the labelled scanner type.

S.4.7.4 Test method

ASTM F2052 or equivalent load/force transducer should be used to measure the maximum force on the AIMD. If a maximum pressure criterion is to be relied upon, appropriate CAD modelling should be performed to determine the maximum device edge pressure.

S.4.7.5 Requirement

The device should satisfy one or both of the following criteria:

— the device translation force should be less than the mass of the device;

— the maximum edge pressure should not exceed the level provided by the manufacturer, in Pascals, which has been shown to not cause clinically significant tissue damage or device migration.

S.4.8 Device torque due to MR static magnetic field

S.4.8.1 General

The purpose of this test is to verify that the alignment torque exerted on devices in the presence of the MR B_0 field does not result in tissue damage.

S.4.8.2 Test environment

An MR scanner capable of generating the largest static magnetic field identified by MR Conditional labelling.

S.4.8.3 Test condition

The largest B_0 field allowed by MR Conditional labelling. The device should be positioned in the scanner or bench setup such that the AIMD is subject to the maximum static field.

S.4.8.4 Test method

The torque exerted on the device should be evaluated as described in ASTM F2213.

S.4.8.5 Requirement

The device torque should not exceed the product of the device mass and longest torque arm.

Annex T
(informative)

Characterization of lead port interface impedance for evaluating gradient-induced extrinsic electric potential effects

T.1 General

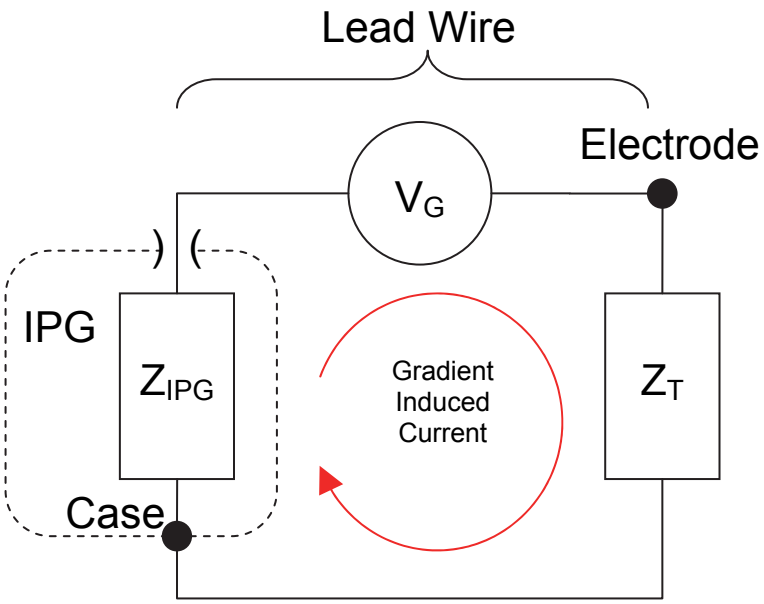
When patients with AIMDs are imaged using MR scanners, the gradient magnetic fields may cause hazardous effects related to the presence of the AIMD. For AIMDs incorporating long lead wires (e.g. pacemakers, implantable cardio-verter defibrillators, and neuro-modulators) one potentially hazardous effect is the induction of voltage on the lead wires.

The MR gradient magnetic fields to which patients are exposed during an MR exam are time varying. They are most typically pulsed on and off repetitively or in a pulsed manner. While less common, there are also imaging sequences that vary the gradient field's amplitude using a sinus shaped waveform having some variation in amplitude and frequency as image data is acquired as outlined in T.4.1. The operating frequency range for the gradient magnetic fields is approximately in the range from less than 1 Hz up to a few kHz. Some harmonic content may extend to higher frequencies. Because they vary in time, the gradient fields will induce an E-field in a patient's body and the AIMD. Consequently, a gradient-induced extrinsic electric potential will be developed between the distal and proximal ends of an implanted AIMD lead wire. This electric potential is frequently called a gradient-induced lead voltage, the terminology that will be adopted here.

The potentially hazardous effects of gradient-induced lead voltage should be considered when evaluating the safety of AIMDs labelled to allow MR scanning of implanted patients. The currents that flow through AIMD lead wire electrodes as a result of induced lead voltage may be large enough to cause unintended electrical stimulation of adjacent tissue. The type and degree of hazard presented by unintended tissue stimulation will depend upon the type of AIMD being considered. As an example, while documented clinical occurrences are rare, unintended cardiac stimulation is a potential patient safety risk when pacemaker patients are MR scanned. The most serious pacemaker patient safety risk is high-rate asynchronous stimulation of the right ventricle (RV). This condition could mimic or induce VT or VF and patient harm can result if stimulation persists or an induced self sustaining VT/VF episode is not terminated.

Other types of AIMDs having long lead wires with electrodes at the distal end, e.g. neuro-modulators or deep brain stimulators, entail the risk of stimulating other types of tissue. The unintended tissue stimulation patient safety risk of the AIMD will have to be evaluated on a case-by-case basis to determine a suitable test method and compliance criteria.

The simple example of a pacemaker with a single lead wire is shown in Figure T.1. Some AIMDs, such as dual chamber pacemakers, may have multiple lead wires with dissimilar trajectory and lead length. This will result in different gradient-induced E-field exposure for each lead. In these cases, the potential difference between the electrode(s) at the distal end of one lead wire versus those at the end of another and the possible patient safety implications of current flow between distal end electrodes should also be considered.



Key

Z_{IPG} internal impedance between the lead wire terminal and the IPG (implantable pulse generator) case

V_G gradient-induced lead voltage

Z_T impedance through tissue

Figure T.1 — Simplified illustration of the circuit for the current that can flow through a pacemaker lead electrode as a result of gradient field-induced lead voltage

T.2 Lead port interface impedance

If the following conditions apply:

a) the currents that flow through the electrodes of long AIMD lead wires when patients are exposed to MR scanner gradient fields are potentially hazardous, and

b) those currents are limited by the AIMD electronic module (e.g. the implantable pulse generator for a pacemaker system),

then the impedance characteristics that the AIMD electronic module presents between lead ports, and between lead ports and the device case, play an essential role in AIMD safety during MR scanning. The term lead interface will be used to denote the electrical characteristics the AIMD electronic module presents to the attached lead wires. The electronic module circuitry may have a non-linear relationship between input and applied voltage. The non-linearity may be due to forward biasing a diode or parasitic p-n junction, exceeding the stand-off voltage of low voltage integrated circuits, or activation of over-voltage protection circuits. The lead interface impedance characteristics should therefore be evaluated dynamically using a test voltage ≥ the maximum expected gradient-induced lead voltage. It is strongly recommended that the lead interface impedance test be conducted using pulses similar to those induced in the lead wires by MR gradient fields. The voltage pulses will have an amplitude at least equal to the expected worst-case (maximum) gradient-induced voltage. It is also recommended that the test voltage include an additional margin above the expected maximum.

Because the purpose of the bench testing described here is measurement of electronic module lead interface electrical characteristics, it is not necessary that the voltage pulse waveform exactly simulate a gradient-induced lead voltage waveform. A pulse width and repetition rate that falls within the range of values present in MR pulse sequences and selected to suit the purpose of the measurements may be chosen.

T.3 Laboratory test method

In this clause, test methods for implants using test equipment in a laboratory are specified. Voltages, time-varying magnetic fields and vibrations are applied with laboratory equipment to simulate the stresses that the AIMD experiences during MRI. These types of tests are sometimes referred to as “bench-top” tests.

The test methods in this clause are intended for a generic AIMD. These tests may need to be adapted for a specific AIMD type (see Annex S).

Potential advantages of the bench-top tests compared to tests in an MR system are as follows.

a) Bench-top tests may be capable of application of greater stress (simulated induced voltage or gradient magnetic field dB/dt) than is possible in an MR system.

b) Bench-top tests are potentially less costly, since an expensive MR system is not used. However, there is a cost associated with the equipment acquisition and set-up for bench-top tests. For a limited number of tests, it is likely that it will be less costly to do the tests in an MR system.

A disadvantage of a bench-top test is that it may not be possible to simulate all of the conditions that a device experiences in an MR system. It may be advisable to do a few tests in an MR system to confirm the findings of the bench-top tests.

Voltage is applied with a function generator to simulate the voltage that the AIMD will experience from the induced gradient voltage. Figure T.2 illustrates the technique. The electrodes are shorted together and voltage is applied between the electrodes and device case with a function generator. The implant is immersed in saline, but the electrode is in air. Connections are made at the header block to measure voltage across the EMI capacitor.

The signal V_P applied by the function generator will be a square wave with amplitude as specified in AIMD specific requirements and a nominal frequency 1 kHz. Test voltage amplitude as a function of lead length and gradient field dB/dt exposure is specified in 20.2.1 to 20.2.3. Any of Tier 1 to Tier 3 as described in the sub-clauses may be used to determine the minimum amplitude requirement. The amplitude is expected to exceed the worst-case gradient-induced voltage.

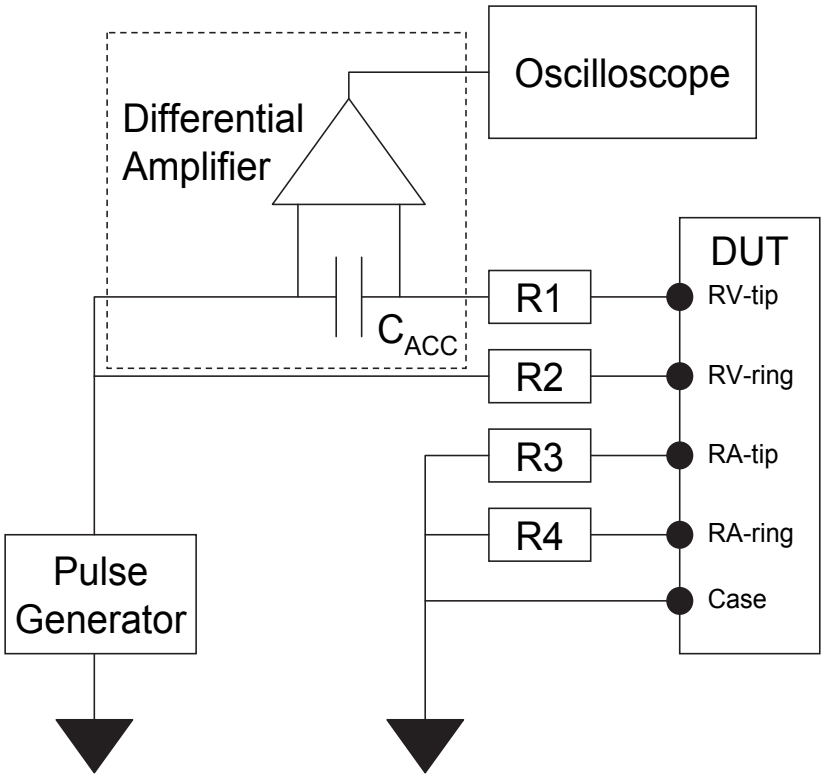
The capacitor in Figure T.2 is used to measure the pulse charge moved through the AIMD. The values are selected so that most of V_P will appear across the AIMD input capacitance.

$$C_{ACC} \rangle 10 C_{INPUT}$$

where C_{INPUT} is the input capacitance of the electronic module. It may be necessary to connect a large value resistance across C_{ACC} to prevent small DC leakage currents from accumulating a charge on the capacitor. R1 to R4 are set to the nominal value of the respective *in vivo* electrode-tissue interface resistance. For the test, record the voltage versus time, ΔV, VF, and the voltages V_P and C_{ACC}.

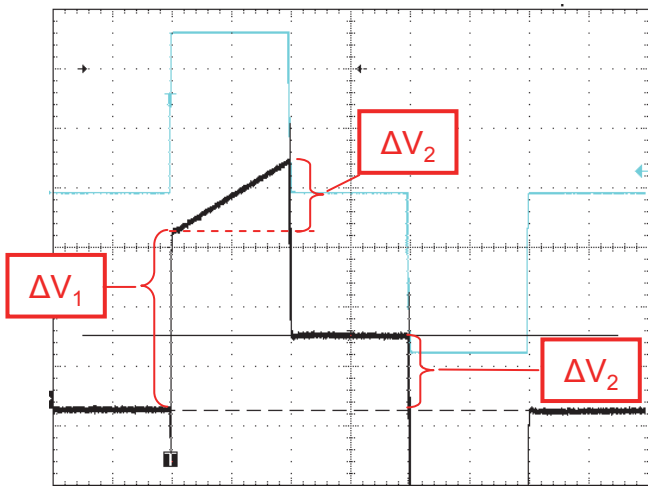
NOTE A floating differential measurement is required for the voltages across R_T and C_T.

An alternative to using the accumulator capacitor to measure pulse charge is to monitor current through the AIMD using a current probe. If the oscilloscope has math function computing capability, the current waveform can be integrated to find pulse charge or the applied voltage waveform can be divided by the AIMD current waveform to obtain a dynamic impedance measurement. The measurement method and data collected will depend on the nature of the applicable AIMD test criteria.



NOTE A current probe may be an alternative to the accumulator capacitor and differential amplifier. The measurement method is consistent with the compliance criteria for the AIMD type.

Figure T.2 – Example method for measuring the impedance characteristics of an AIMD lead interface using the example of a pacemaker



Key

ΔV_1 charge accumulated during charging of the device lead interface capacitance.

ΔV_2 charge corresponding to the energy dissipated in lead interface resistance.

NOTE The time scale is 0,5 ms per division.

Figure T.3 — Illustration of the pulse voltage (V_P) applied to the DUT (top trace) and the resulting waveform across the accumulator capacitor (bottom trace)

Annex U
(informative)

Method for *in vitro* measurement of gradient-induced E-field

U.1 General

This non-destructive bench-top test evaluates MR-induced E-fields, measures the E-field (E) immediately surrounding distal tips of leads of an AIMD during exposure to simulated MR gradient fields. The purpose of this test is to determine whether stimulation level voltages can be induced by MR gradient fields in AIMD leads while exposed to MR imaging gradient fields. The test compares the waveform and timing of the maximum magnetically-induced E-field to the E-field induced at the same location by the AIMD's stimulating pulse generator. The comparison is performed at the same location and time with various pulse generator settings. This test method is primarily intended to evaluate the maximum vector magnitude of magnetically-induced E-fields at tips of stimulating leads. This evaluation is done by comparison with the magnitude of the E-field produced by a pulse generator voltage on the lead (intentional stimulation). However, this method can be used to evaluate magnetically induced voltages near sensing leads.

U.2 Summary of method

This is a technique for evaluating the E-field induced by a gradient magnetic field in a saline tank model. A ratiometric comparison is made between the amplitude and timing of the E-field intentionally induced for stimulation by the pulse generator of an AIMD with the magnetically induced E-field of a simulated MRI gradient field. The E-fields are measured at locations where the magnetically induced E-field is known to be highest. The locations of the maxima of the intended and induced field are usually the same (at the distal tip of stimulation leads, very close to the electrodes of the leads). Background information is provided in U.12.

U.3 Test equipment

A patient simulator comprises a saline-filled, clear acrylic plastic cylinder with an outer diameter of 24 cm, wall thickness of 0,8 cm and depth of 24 cm. The saline is 0,6 % and is 18 cm deep in the tank.

A plastic support grid (see Figure U.1) is mounted horizontally, 9 cm above the bottom of the saline tank. A plastic grid is cut from a fluorescent light fixture cover made of non-conductive, non-metalized plastic, which is cut to fit the tank's opening so that the grid's top surface is placed 9 cm above the bottom of the tank on four plastic 1,27 cm threaded bolts screwed into plastic bolts glued to the grid.

The grid is constructed of beams 0,12 cm wide, 1,25 cm thick and spaced 1,36 cm apart. The grid walls are 1,36 cm on each side. This grid is used for testing pacemakers for electromagnetic interference in ANSI/AAMI PC69. The leads and pulse generator rest on this grid. A cutout on one location at the outer edge of the grid removes all plastic from the immediate proximity of the distal tip of a lead under test.

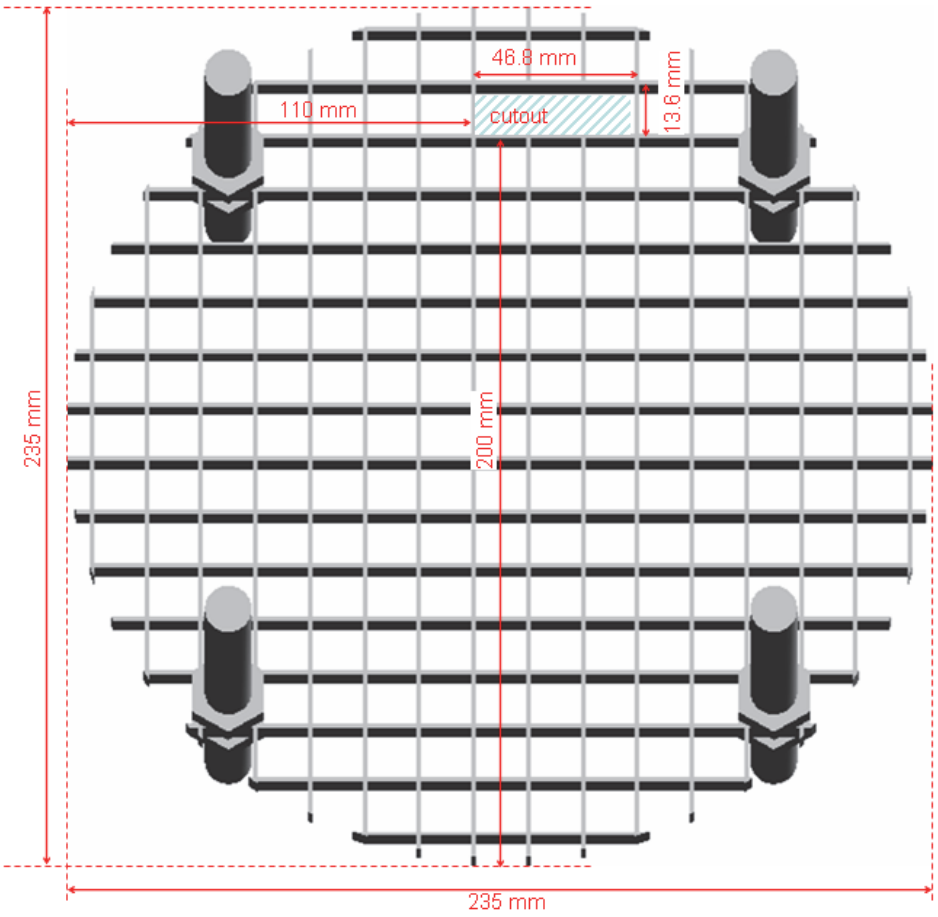


Figure U.1 — Plastic support grid

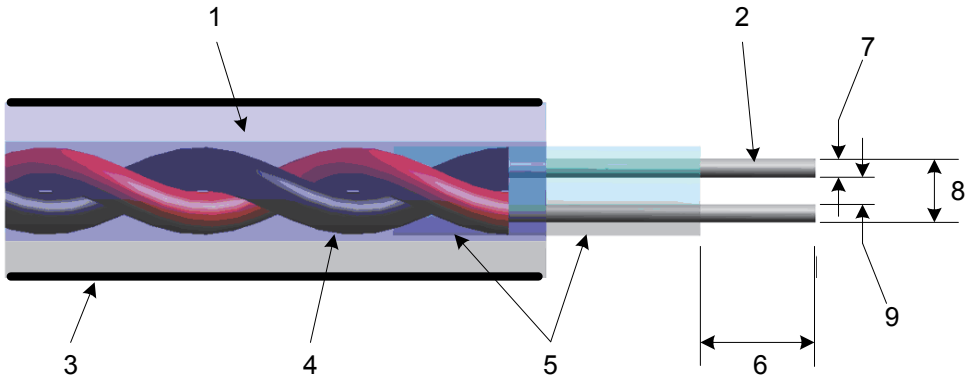
U.4 Gradient field simulator

A Helmholtz coil with an outer diameter of 41,6 cm is used to produce a 1 kHz sinusoidal magnetic field, uniform within ± 5 % throughout a 24 cm diameter by 24 cm deep cylindrical volume centred inside the coil. Uniformity is measured with this volume empty. This coil can be driven by a suitable high power audio amplifier. If necessary, high power, low value resistors and high current non-polarized polycarbonate capacitors can be placed in series with the coil to match impedances.

NOTE If the Helmholtz coil has many turns, then the E-field produced by the coil may interfere with signals carried on probe cables and nearby instrumentation.

U.5 E-field probe system

The system comprises a two-electrode probe with straight electrodes of 0,5 mm diameter, constructed from a tightly twisted pair of insulated solid conductor copper wire (AWG 32 gauge) as shown in Figure U.2. This is housed in a tube made from a disposable plastic standard-tip serological 10 mL graduated pipette (length 225 mm, inner diameter 2,5 mm, outer diameter 4,5 mm). Voltage from the distal tip of the probe electrodes is carried from the proximal end of the pipette via a twisted pair of wires to a high input impedance differential amplifier (greater than 10 megohms). The bandwidth is nominally 300 Hz to 3 000 Hz but can be broader. Wires should be vertical (parallel to the B field) for at least 1 m above the saline tank and Helmholtz coil to avoid magnetic field pickup. Alternatively, an analogue fibre-optic link with differential high input impedance can be used.



Key

1	pipette	6	3,5 mm
2	bare wires	7	0,2 mm
3	foil shield	8	0,9 mm
4	insulated wires	9	0,5 mm
5	silicone		

Figure U.2 — E-field **probe construction**

U.6 Probe positioner

A 3-axis linear translation stage with 0,2 mm resolution and 30 cm or more of motion along each axis is used, for example an XZ adapter[2]. It may be manually or motor driven (Figure U.3). All metal on this assembly should be greater than 30 cm from the saline tank and Helmholtz coil. This should be mounted on a wooden or other support assembly above and directly over the saline tank. A wooden or plastic block larger than 3 cm × 3 cm cross section and 5 cm long with a hole in its centre should be mounted on the vertical travel axis of the positioner. The probe should be mounted in the block with non-conducting thumbscrew. Wires exiting from the probe should be kept 2 cm from any metal of the positioner. The probe should be placed with its long axis oriented vertically. The wires exiting from it are supported by a plastic or wooden structure to keep them vertically oriented, parallel to the B field near the Helmholtz coil (Figure U.4).

[2] Velmex XZ Adapters are an example of a suitable product available commercially (http://www.velmex.com/manual_xz_adapters.html). This information is given for the convenience of users of this document and does not constitute an endorsement by ISO or IEC of this product.

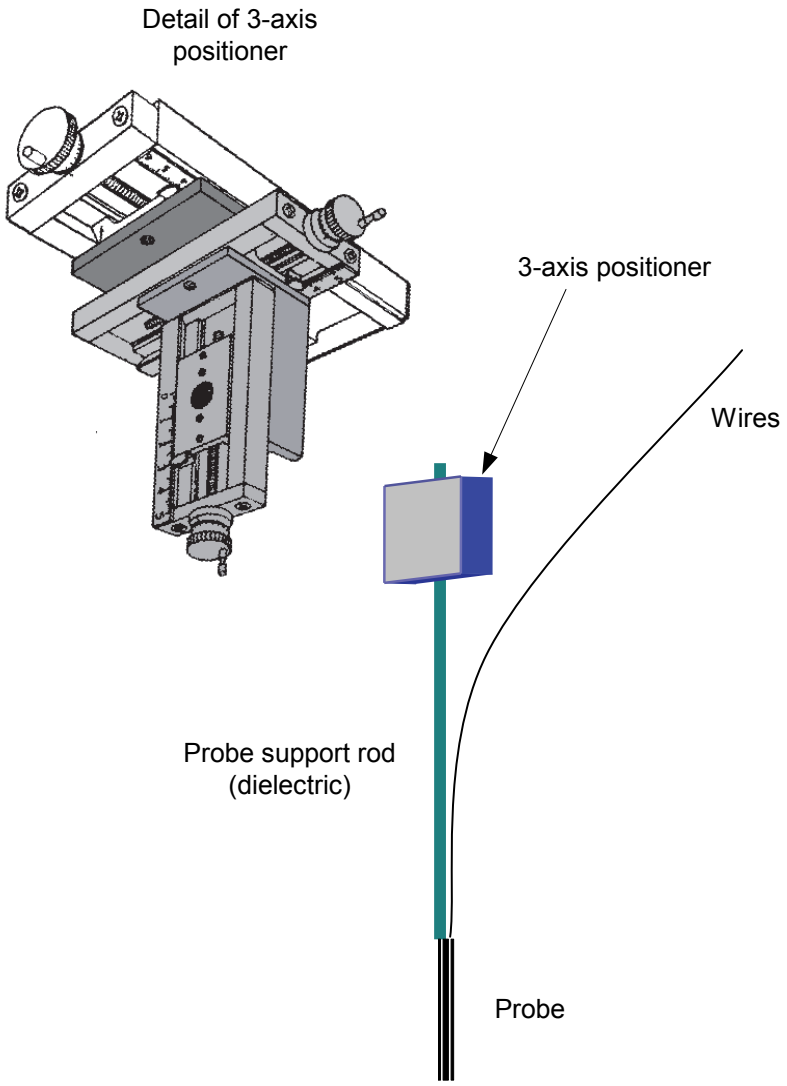


Figure U.3 — 3-axis probe positioner

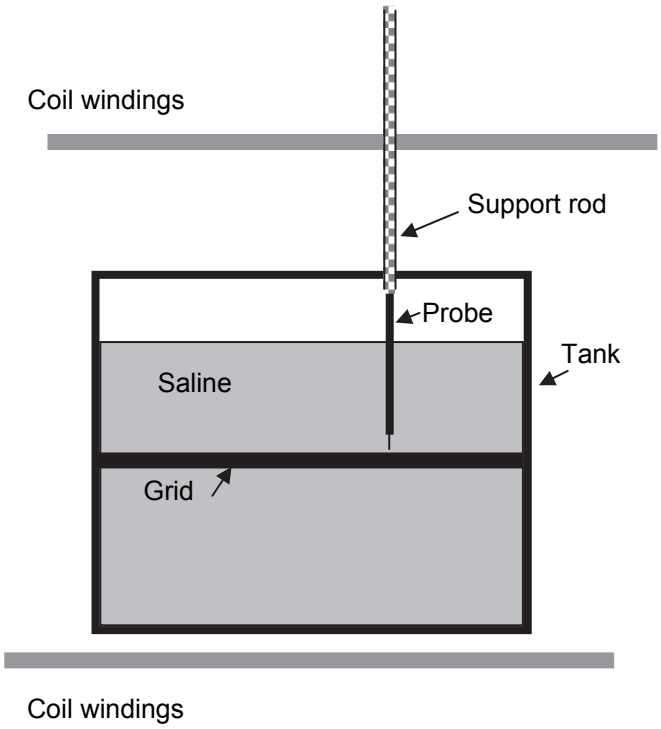


Figure U.4 — Side view of saline tank and Helmholtz coil

U.7 Device under test

The AIMD, consisting of a pulse generator and leads, should be connected together in the configuration prescribed by the manufacturer. It should be programmed and tested separately for each stimulation configuration of interest (e.g. bipolar and unipolar pacing of each cardiac chamber).

U.8 Test set-up

U.8.1 Magnetic field setup and calibration

A linearly polarized magnetic field at 1 kHz with a flux density, B, of 1,2 Gauss RMS = (1 T/s dB/dt) should be generated using a Helmholtz coil. With no saline in the tank, uniformity of B should be measured and demonstrated to be ± 5 % throughout the volume occupied by the saline tank. This should be done while the metallic probe positioner and all other test system components are in place. These measurements should be made with a commercially available instrument or search coil with a diameter of no more than 4 cm.

U.8.2 Placement of device under test

The pulse generator and leads are placed on the top surface of the plastic grid in the saline tank. The lead is configured in a circular loop, 1cm ± 0,2 cm away from the inner vertical wall of the saline tank (Figure U.5). The distal tip of the lead is placed in the cutout portion of the grid with the lead parallel to the log axis of the cutout. The gap between the distal tip of the lead and any portion of the pulse generator and proximal end of the attached lead should be greater than 5 cm. If the lead is too long to allow this gap to exist, the pulse generator and proximal end of the lead can be moved closer to the centre.

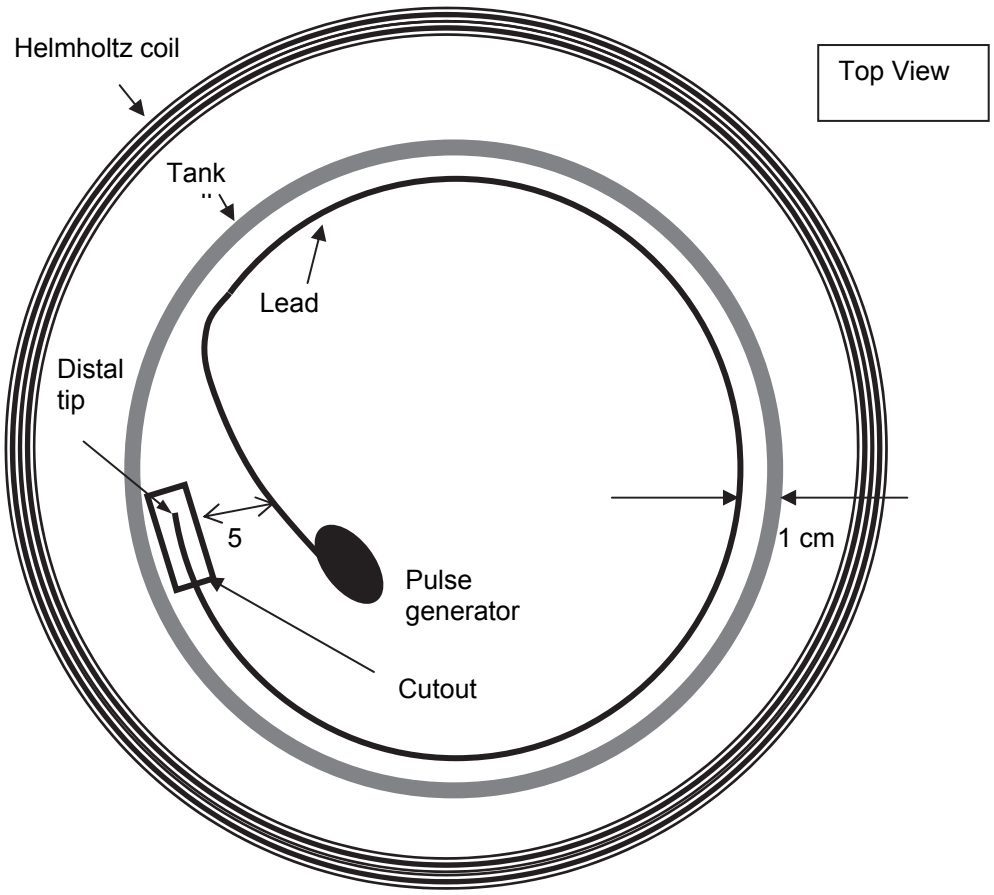


Figure U.5 — Placement of device and lead under test

U.8.3 Placement and orientation of E probe

The probe is placed at several locations in the saline tank for different measurements. For measurements at locations not in the centre of the tank, the probe tips can be oriented in either the radial or tangential orientation with respect to the circular tank geometry. These orientations are illustrated in Figure U.6.

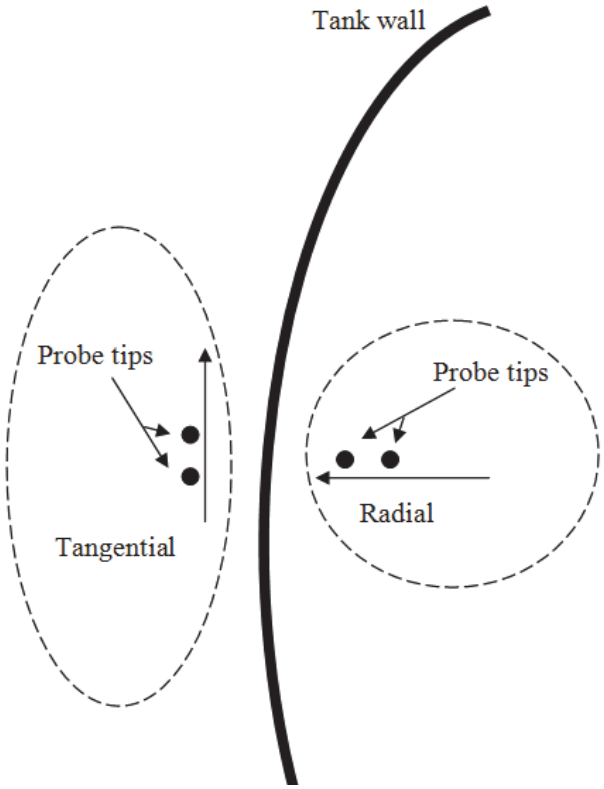


Figure U.6 — E-field **probe tip orientations**

U.9 Verification and background noise immunity of the probe system

U.9.1 Centre of tank – No device

With no objects in the tank, except for saline, the probe is placed 1 cm above the grid in the geometric centre of the tank. A voltage waveform measurement is made on a digital storage oscilloscope or data acquisition system. Measurements are made for both no magnetic field on and with the field on. This is repeated after the probe is rotated 90 degrees about its long axis. The data from this measurement are compared with data taken at the outer edge of the tank (U.9.2).

U.9.2 Outer edge – No device

The probe is placed 1 cm above the grid in saline. The centreline of the probe tips is placed 1 cm from the inner wall of the tank. No stimulating device pulse generator or lead is placed in the saline tank. A voltage waveform measurement is made on a digital storage oscilloscope or data acquisition system with no magnetic field on. A measurement is made with the field on. The measurements are made for the probe tips in the radial orientation and are repeated with the probe rotated 180 degrees. The probe tips are placed in the tangential orientation and measurement is made. The measurement is repeated with the probe rotated 180 degrees. The maximum voltage at the edge of the tank is induced in the tangential orientation. This value is compared with the voltage in the centre of the tank. If the voltage in the centre is greater than 10 % of the maximum edge voltage, there is erroneous pickup voltage in the E-probe leads, and measurements cannot be made until this problem is corrected.

U.9.3 Device-induced fields – Measurements of stimulating and magnetically-induced E-fields

The stimulating device under test is placed in the saline tank. This is usually a pulse generator and one or more stimulating leads. These are placed on the top surface of the grid. The E-field probe is placed at a prescribed location very close to the device's stimulation electrodes. The distal tip of the lead is placed in the cutout as discussed previously. With the device under test in place, the probe is placed sequentially at various measurement locations. For each measurement location, the closest portion of the tip of the probe is at a distance of 1,5 mm to 5 mm from the distal tip of each of the stimulating electrodes of the device under test. The exact distance will depend on the typical clinical location of the target tissues from the stimulating electrode for a specific device modality. The probe tips are placed at a depth that aligns them 0,5 mm below the centreline of the device's electrode under test as shown in Figure U.7. The same specific electrode (#1) of the pair of probe electrodes should always be placed nearest to the stimulating electrode. This is necessary since small asymmetries exist between the probe electrodes.

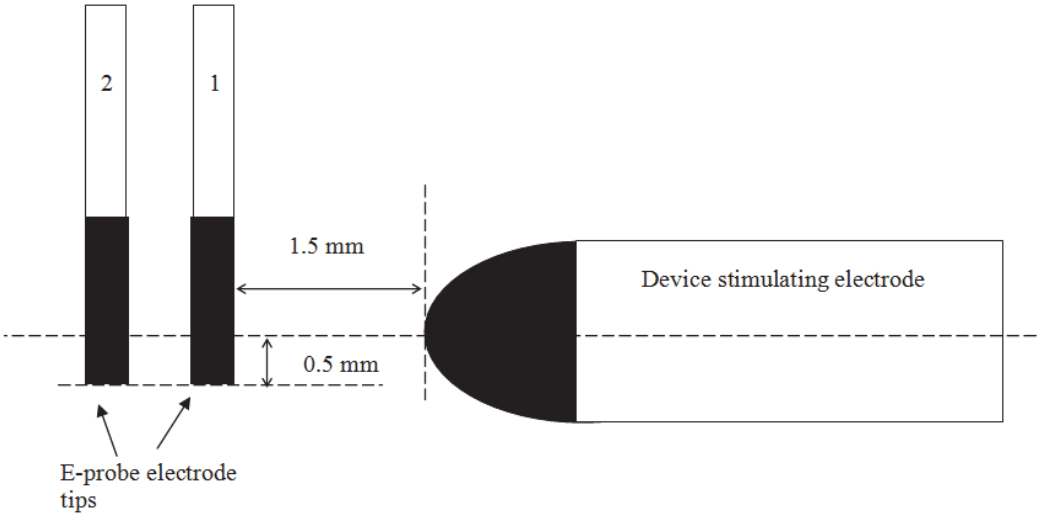


Figure U.7 — Probe tip placement

U.10 Measurement procedures

Measurement of the magnetically induced E-fields should be made at every device electrode. This is done even if the pulse generator setting does not apply voltage pulses to a particular device electrode for a specific device setting. A voltage waveform measurement is made on a digital storage oscilloscope or data acquisition system. All possible E-field measurements of interest are made at each location of interest, with the probe in a single orientation and position before relocating the probe. This is done before any repositioning of the probe to another location is performed. This is necessary because very steep spatial variations in E exist near the stimulating device lead. If the probe is moved a fraction of a millimetre and data is taken again, significant changes in the data will be observed due to the spatial variations. Waveforms should be recorded to observe the magnetically induced sinusoid for the time interval immediately before, during and after the device stimulation pulse as shown in Figure U.8.

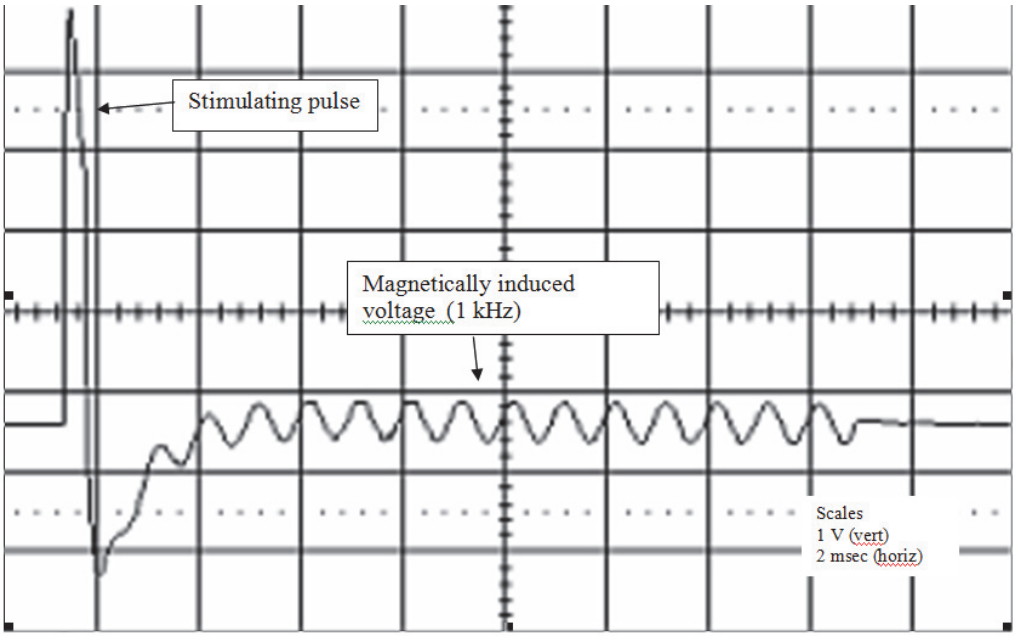


Figure U.8 — E-field measurements adjacent to stimulating lead tips from stimulating device and magnetic field

The following measurements should be made at each single fixed location, with and without magnetic field turned on, with the probe positioned at each point of interest. The pulse generator output is set for a maximum stimulation level for one configuration (e.g. bipolar, unipolar). The E-field probe tips are oriented in the radial orientation with respect to the surface of the stimulating electrode. With no magnetic field present, a voltage waveform measurement is made. This set of measurements is repeated with the magnetic field turned on. Waveform measurements from the probe are saved for later analysis.

Measurements are made with the E-field probe tips oriented in the tangential orientation with respect to the surface of the stimulating electrode. The pulse generator output is set for a maximum stimulation level for one configuration (e.g. bipolar, unipolar). First the B field is turned off and data are recorded. Then the B field is turned on and the data are recorded.

U.11 Evaluation of the test results

At each location of the probe with respect to a stimulating electrode, determine the ratio of the peak amplitude and timing of the gradient field-induced E-field to the intended stimulation E-fields. Scaling of the results should be performed to assess the magnetically induced signal at 30 T/s and 100 T/s. This is done by multiplying data obtained at 1 T/s by a factor of 30 and 100 respectively.

It is important to evaluate the duration and temporal relationship of the magnetically induced waveform with respect to the intended stimulation waveform of the AIMD. This is needed to take into account the strength-duration issues of the stimulation of electrically excitable tissues. For example, alteration of the intended stimulation waveform by the magnetically induced (gradient) waveform is to be considered. For an example, see S.2.5. Since this E-field test method uses a continuous sinusoid, it simulates the worst-case situation where the gradient pulse occurs all of the time.

U.12 Background information

U.12.1 Basic theory of magnetically induced E-field near a lead

A conductive path formed by an AIMD's lead, pulse generator and the tissue of a patient form a loop. In a simplified case, this loop is in a single plane. If a uniform magnetic field is perpendicular to this loop, the induced current is maximized. The following simplified equation calculates the RMS magnitude of the E-field at any point in the saline induced by a sinusoidally varying B field (see U.13.1).

$$E = \pi \times F \times r \times B$$

where

E is the E-field at a point (V/m) in the saline;

F is the frequency (Hz) of the magnetic field;

B is the magnetic flux density (T);

r is the radial distance (m) from centre of saline.

When a conducting wire is added to a saline tank and the tank is exposed to a magnetic field, a current is induced in the saline and the wire. If the tip of the wire is not insulated, this will produce an additional E in volume of saline that is greatest very close to the tip of the wire. The current density, J, at any point in the surrounding saline is equal to the conductivity, σ, times E:

$$J = \sigma E$$

The E-field and current density in the vicinity of the lead tip are greatest at the boundary of the tissue and the lead tip. The local E-field is inversely proportional to the surface area of the lead tip at this boundary. The E vector is normal to the surface of the conducting tip (Figure U.9). The E-field falls off exponentially as distance from this boundary increases. This makes positioning of an E-field probe critical. If the E-field is measured by a two-electrode probe, then the voltage measured between the electrodes representing the spatial average of the E-field between the electrodes is averaged over this region.

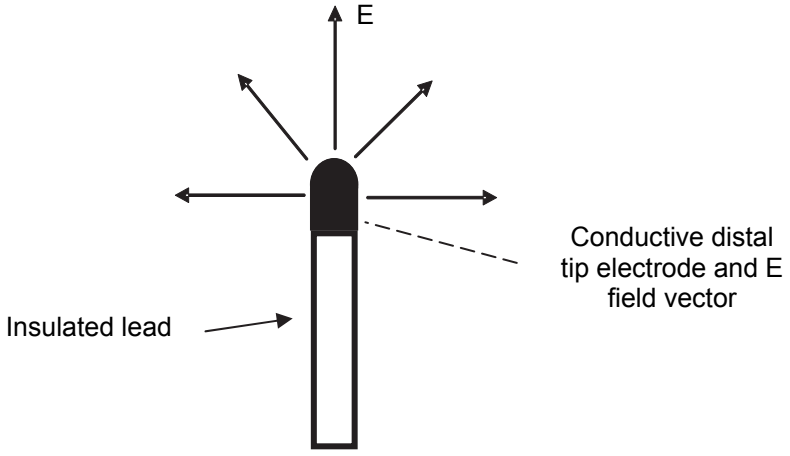


Figure U.9 — E-fields surrounding a unipolar lead

U.12.2 Electrical circuit of an AIMD in a conducting body

An AIMD with a lead placed in a conducting body (patient or saline model) forms a closed loop electrical circuit as shown in Figure U.10. If a lead is connected to the internal circuitry of the pulse generator, an electrical path with an internal impedance, Z, exists through the pulse generator's stimulating and/or sensing

circuit to the outer case "Can" and to the saline. The impedance of this path in the pulse generator is variable and depends on the instantaneous state of the AIMD's circuitry. If the AIMD is a cardiac pacemaker delivering a stimulating pulse in the unipolar mode, the impedance is not high (compared to the impedance of the rest of the loop) during the delivery of the pulse. After the pulse is delivered, the impedance is usually high compared to the rest of the loop. However, in practice, the impedance Z is intentionally kept low for a short period after the pulse is delivered. For a bipolar lead, the impedance between each electrode and the case of the pulse generator depends on the circuit design of the pulse generator.

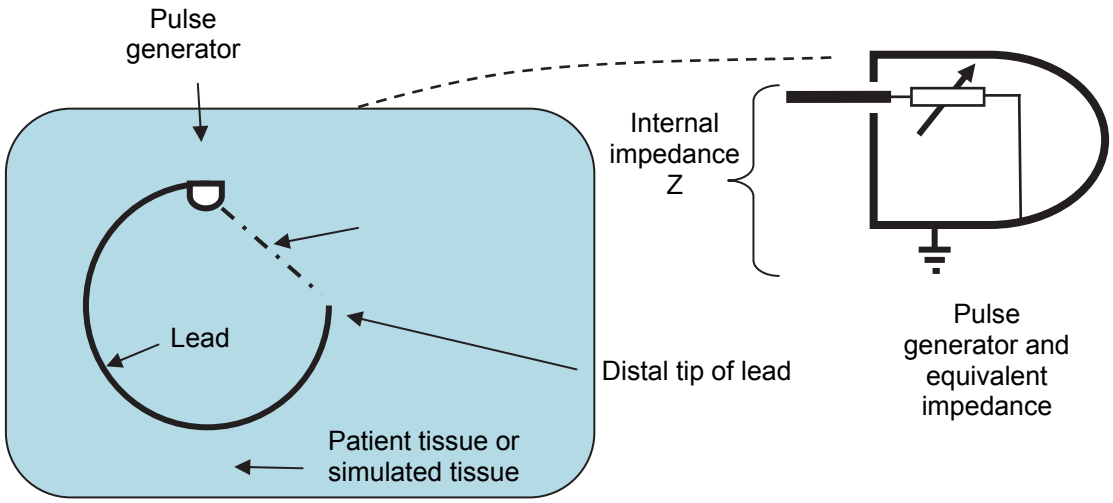


Figure U.10 — Closed loop electrical circuit

Annex V
(informative)

Basic physics and interactions of gradient magnetic fields with AIMDs

V.1 General

The gradient field output of the MR scanner can produce induced voltages in the leads or other components of the AIMD. The induced voltages are a function of the dimension and shape of the AIMD and associated electrical leads (loop size), the position of the patient (and thus the AIMD) in the scanner bore and the scan protocol applied for the specific patient. The induced voltages might cause damage to or interfere with the functionality of the device, such as sensing errors in a cardiac pacing system or pulse width changes of a neurostimulator, or cause overstimulation due to induced extrinsic electric potential. Another key issue is the increased possibility of nerve stimulation. MRI scan sequences are programmed to avoid painful nerve stimulation. The presence of a metallic implant, active or passive, will result in the concentration of induced currents and hence an enhanced possibility of nerve stimulation. In contrast to PNS (see Table V.1), which generally occurs near the outer surface of the body, the presence of an implant could cause stimulation to internal structures, including the heart and the brain.

V.2 Background information

Table V.1 provides a list of symbols, abbreviations, terminology, definitions and notation conventions relevant to the gradient magnetic fields. General MRI definitions are included in the main body of this Technical Specification.

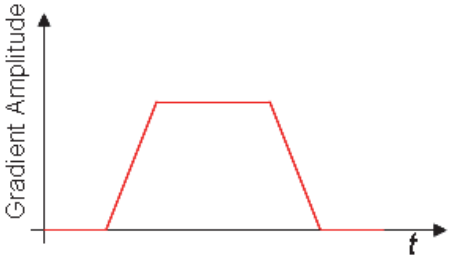
Table V.1 — Symbols, abbreviations, terms and definitions

Symbol or abbreviation	Term	Definition
B_x, B_y, B_z	Gradient magnetic field (i.e. magnetic flux density)	Time-varying magnetic fields that provide spatial and temporal perturbations of the static field in the imaging region of the scanner.
	MAGNETIC RESONANCE SYSTEM (MR SYSTEM)	Ensemble of MR EQUIPMENT, ACCESSORIES including means for display, control, energy supplies, and the CONTROLLED ACCESS AREA, where provided.
	WHOLE BODY MAGNETIC RESONANCE EQUIPMENT (WHOLE BODY MR EQUIPMENT)	MR EQUIPMENT of sufficient size to allow whole body MR-EXAMINATION and partial body MR-EXAMINATION of adult PATIENTS. It may be equipped with VOLUME RF TRANSMIT COILS, LOCAL RF TRANSMIT COILS and with a SPECIAL PURPOSE GRADIENT SYSTEM.
	WHOLE BODY GRADIENT SYSTEM	A gradient system suitable for use in WHOLE BODY MR EQUIPMENT.
	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.

Table V.1 — Symbols, abbreviations, terms and definitions (*continued*)

Symbol or Abbreviation	Term	Definition
	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.
	COMPLIANCE VOLUME	Area of PATIENT-accessible space in which compliance of GRADIENT OUTPUT is inspected in MR EQUIPMENT with a cylindrical WHOLE BODY MAGNET, the COMPLIANCE VOLUME is a cylinder with its axis coinciding with the magnet axis and with a radius of 0,20 m.
	Isocentre	Centre of the gradient coil system in an MR system.
$\lvert dB/dt \rvert_{max}$	Maximum dB/dt	Maximum magnitude of the gradient field time rate of change (a vector entity). The value of gradient field $\lvert dB/dt \rvert_{max}$ is restricted as a function of T_{seff} to prevent peripheral nerve stimulation.
EPW	Effective pulse width	EPW is defined as the pulse area divided by peak amplitude.
FOV	Field of view	The distance spanned by the image.
GA	Gradient amplitude	The spatial variation in gradient field G_x, G_y or G_z intensity at "gradient" isocentre. The units most commonly used for gradient amplitude are mT/m.
S	Gradient slew rate	Manufacturer's gradient system performance specification with unit Tesla/metre/second (T/m/s).
G_x, G_y, G_z	Gradient(s), physical gradient(s)	Terminology and symbols used as an inclusive general reference to the gradient hardware (amplifier, coil, etc.) and fields. SI units on the G quantities are T/m.
PNS	Peripheral nerve stimulation	Stimulation of nerves on the periphery of the patient's body due to E-fields generated in the patient's body by time-varying gradient magnetic fields.
EPI	Echo planar imaging	MRI pulse sequence in which the entire image is formed in single repetition time.
EMI Cap	Electro-magnetic interference filter capacitor	Capacitor in a generator to protect circuitry from electromagnetic voltage induced in the lead.
	Search coil	A planar wire coil used to measure dB/dt based on Faraday's Law of Induction. For a more detailed description, see IEC 60601-2-33:2002, 51.105.2 b).

Table V.1 — Symbols, abbreviations, terms and definitions (*continued*)

Symbol or Abbreviation	Term	Definition
	SPECIAL PURPOSE gradient system	An example of a SPECIAL PURPOSE gradient system is a gradient system that can be incorporated into MR EQUIPMENT to allow special examination of the head of the PATIENT.
	Trapezoidal gradient pulse 	A gradient pulse that changes gradient field strength (amplitude) from the starting value to the new value at a constant rate of change, holds constant at the new value for the programmed time, then transitions from the new value to the next value also at a constant rate of change. The rate of change is constant over the duration of any one change, but in general may vary from one amplitude transition to another. In the most basic example, the starting value and the next value are both zero, and the rate of change has the same magnitude but opposite sign for the transitions.
$t_{s,eff}$	Effective stimulus duration or effective slew duration	This terminology and symbol is used in the IEC standard for discussion of gradient field-induced PNS. A trapezoidal gradient pulse, $t_{s,eff}$ is equal to the slew duration. For other pulse shapes, the effective slew time is defined in IEC 60601-2-33:2002. See Figure V.4.
GSR	Maximum gradient slew rate	The 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.
dB/dt	TIME RATE OF CHANGE OF THE MAGNETIC FIELD	Rate of change of the magnetic flux density with time (T/s).

V.3 Purpose and characteristics of MR gradient magnetic fields

V.3.1 Gradient description

Figure V.1 illustrates a cylindrical whole body MRI coil, depicting coils for producing the gradient, the RF and the static magnetic fields. The gradient fields produced by this system provide spatial (varying as a function of location) and temporal (varying as a function of time) perturbation of the static magnetic field. Gradient fields allow 2-D and 3-D images to be constructed from the received RF signal. The gradient fields are used to

a) spatially select the portion of the patient in which the protons will be in resonance (slice select),

b) spatially alter the phase relative to some reference (phase encode),

c) spatially vary the frequency of the protons while the time-varying flux is being measured by the receiver coil (frequency encode). Assuming B_0 is in the z-direction, the gradient coils produce the x, y, and z field gradients $G_x = \partial B_z/dx$, $G_y = \partial B_z/dy$, and $G_z = \partial B_z/dz$, respectively.

Figure V.2 illustrates the winding pattern for a transverse gradient coil for production of the y-gradient. The arrows in the figure represent the magnitude and direction of the magnetic field produced by the coil current. The x-coil is similar to the y-coil, except there is a 90° rotation along the z-axis between the two coils. The maximal magnetic field intensity for the x- and y-gradient coils is the transverse component at a distance of about 30 cm from bore centre (isocentre). For some scanners with shorter static field magnets and bore

lengths, and/or reduced field of view along the z axis, the maximal field intensity may occur closer to the bore centre (isocentre).

Similarly, Figure V.3 illustrates the winding pattern and magnetic field directions for a z-gradient coil. The z-gradient coil produces a longitudinal magnetic field that has greatest intensity about 35 cm on either side of the bore centre (isocentre). Again, for some scanners with shorter static field magnets and bore lengths, and/or reduced field of view along the z axis, the maximal field intensity may occur closer to the bore centre (isocentre).

Figure V.4 shows a trapezoidal gradient waveform and defines the timing parameters. The waveform shown is for the gradient amplitude, which is proportional to the current in the coil.

NOTE 1 The voltage induced in the patient is proportional to the time derivative of the waveform.

The gradient pulse sequences used for clinical MR scanning can be quite complex. For orthogonal image slices, each of three gradient functions typically designated as slice select, phase encode, and frequency encode or readout, can be mapped with any one of the three gradient channels (G_x, G_y, and G_z). If the image slice orientation is oblique or double oblique, a weighted sum of two or three gradient functions will be applied to two or three gradient channels. Detailed information about the nature of the various pulse sequence types used in clinical images can be found in textbooks on the subject.

The technical specification sheet provided by the MR manufacturer provides the maximal slew rate S in units of T/m/s. The maximal dB/dt on the axis of the bore in units of T/s will be approximately 0,3 S, with S in units of T/m/s. This approximation arises from the fact that the maximal dB/dt will occur about 30 cm from isocentre. The maximal dB/dt on the surface of the 20 cm radius compliance volume will be about 10 % greater than the on-axis value for the z-coil and about 50 % greater for the transverse coils.

NOTE 2 These values are representative and approximate.

Table V.2 lists some gradient parameters provided by manufacturers. Note that the values in the table are hardware limits. Gradient waveforms produced by the MR system will be constrained by these limits. In addition, thermal limits of the gradient system may constrain the sustained performance.

Table V.2 — Sample values of gradient parameters from MR Compatibility data sheets

Gradient system	Siemens[a] 3T Tim 102 x 8	Philips[b] 3,0T Achieva	GE[c] 3,0 T
Maximum amplitude	45 mT/m	40 mT/m	50 mT/m
Min. rise time to max. amplitude	225 µs	200us	267 µs
Max. slew rate	200 T/m/s	200 T/m/s	150 T/m/s

[a] Siemens parameters are from Magnetom System Owner Manual MR compatibility data sheet Verio (3/2008).

[b] Philips parameters are from Intera, Achieva, and Panorama Technical Description, Philips No. 452213268821.

[c] GE parameters are from 2381696-100 Rev. 5 (2/2007).

V.3.2 Slew rate and *dB/dt*

The technical specification for the MR system provides the maximal gradient slew rate. This quantity has units of T/m/s and is defined at isocentre. Another relevant parameter for gradient interactions is the minimal ramp time from zero current in the coil to maximal positive or negative gradient amplitude. The time-varying magnetic field dB/dt at some point in the scanner will be proportional to the slew rate. Consider for example dB_y/dt. This may be expressed as

$$\frac{dB_y}{dt} = f_{yx}(x,y,z)S_x(t) + f_{yy}(x,y,z)S_y(t) + f_{yz}(x,y,z)S_z(t) \quad \text{(V.1)}$$

where the f parameters are functions of position (x,y,z) in the scanner and the dynamical slew rates S_x, S_y and S_z are functions of time during the pulse sequence. Extending to the three coordinate axes, the time magnetic fields are expressed as:

$$\begin{pmatrix} \frac{dB_x}{dt} \\ \frac{dB_y}{dt} \\ \frac{dB_z}{dt} \end{pmatrix} = \begin{pmatrix} f_{xx} & f_{xy} & f_{xz} \\ f_{yx} & f_{yy} & f_{yz} \\ f_{zx} & f_{zy} & f_{zz} \end{pmatrix} \begin{pmatrix} S_x \\ S_y \\ S_z \end{pmatrix} \tag{V.2}$$

From Equation (V.2), the f terms in Equation (V.1) on the axis of the bore in the imaging region are

$$f_{xx}(0,0,z)=f_{yy}(0,0,z)=f_{zz}(0,0,z)=z \text{ (in imaging regions)} \tag{V.3}$$

Other terms in the f matrix in the imaging region are negligible.

Note that, assuming similar coil lengths, the terms of the f matrix for a practical whole body MR system will be similar inside the compliance volume. Thus relatively simple modelling using generalized gradient coils, such as shown in Figure V.2 and Figure V.3, can be used to obtain the f matrix in the compliance volume. Outside the compliance volume, and especially near the wall of the bore, the terms of the f matrix may depend on the details of the gradient coil design (e.g. shielded versus unshielded) and the radial placement of the gradient coil.

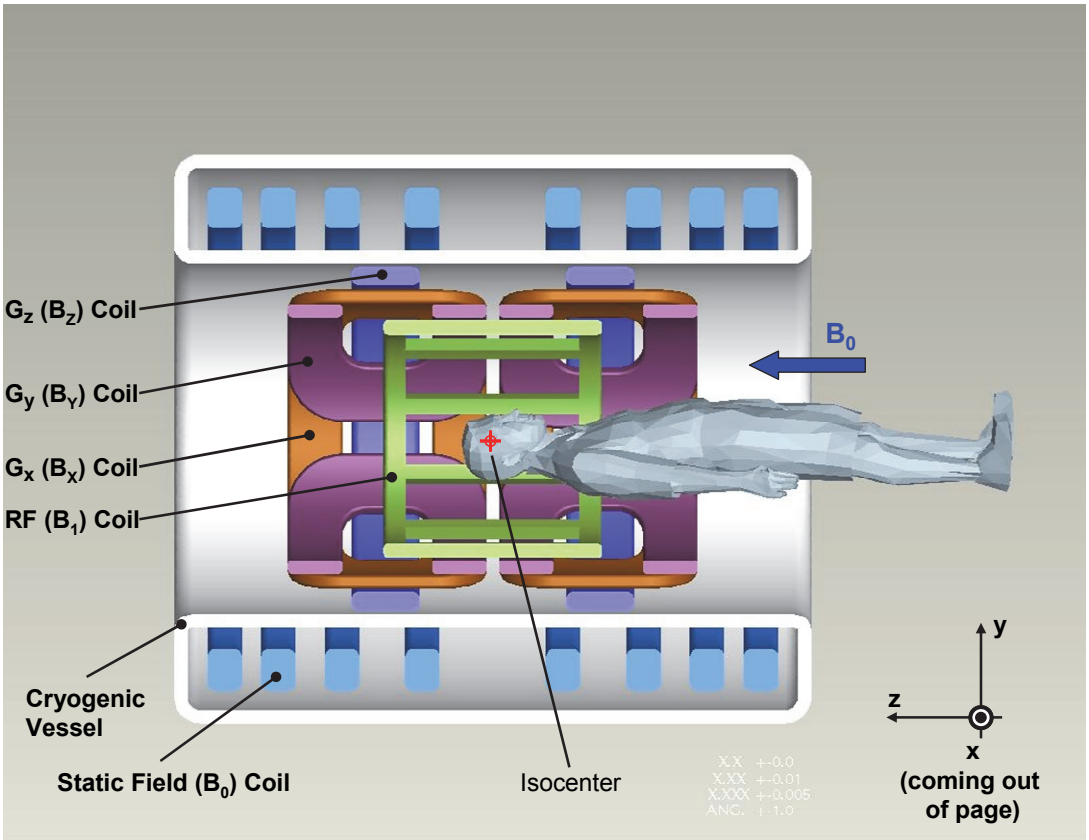
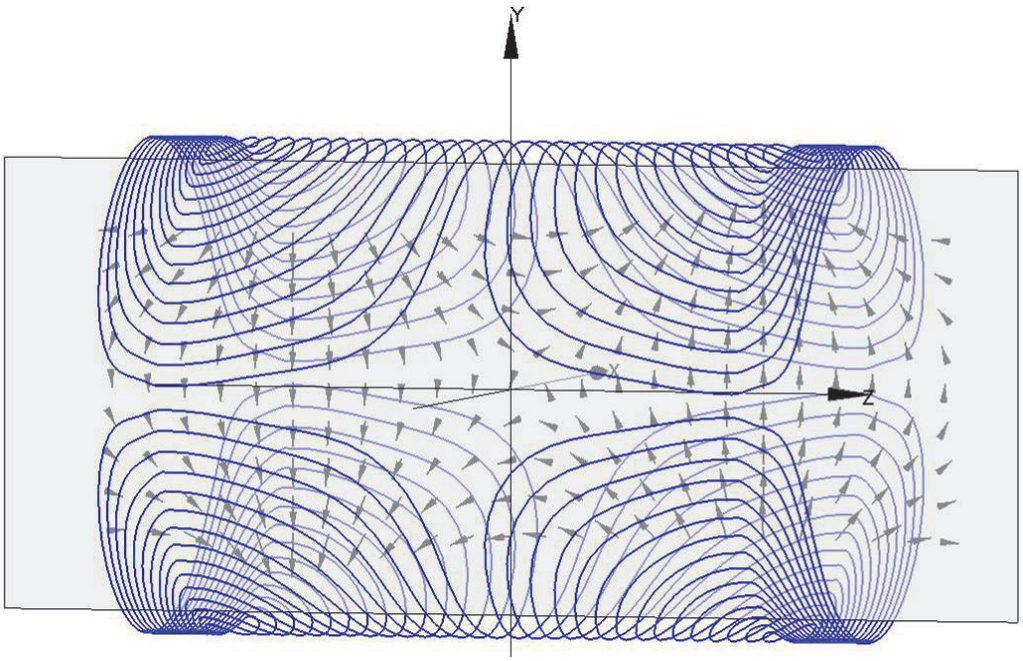
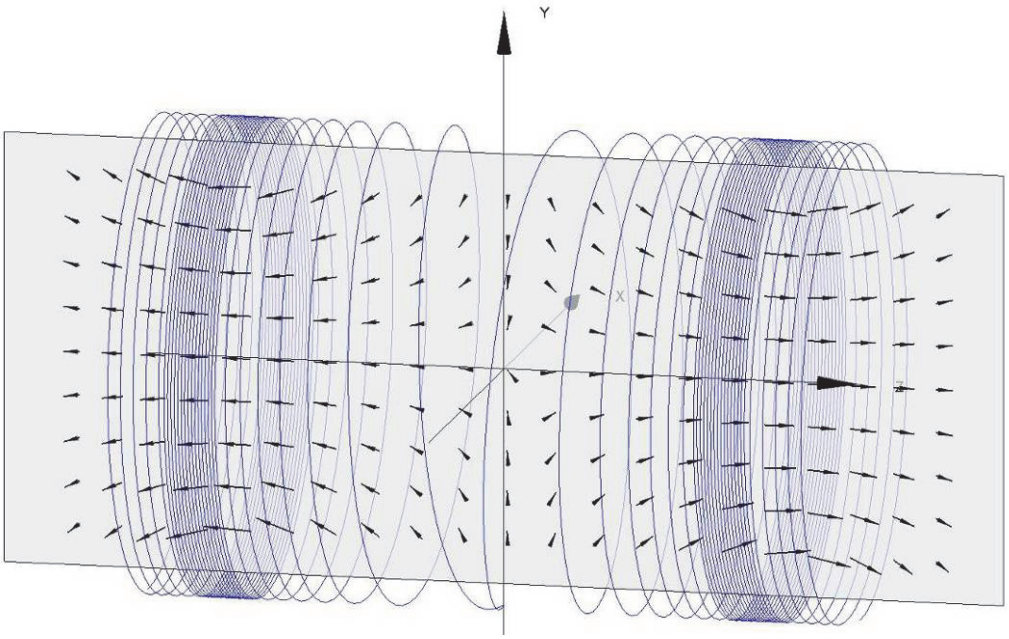


Figure V.1 — Illustration of the coils used in cylindrical bore MRI scanners and the reference coordinate system used when discussing the fields and their effects



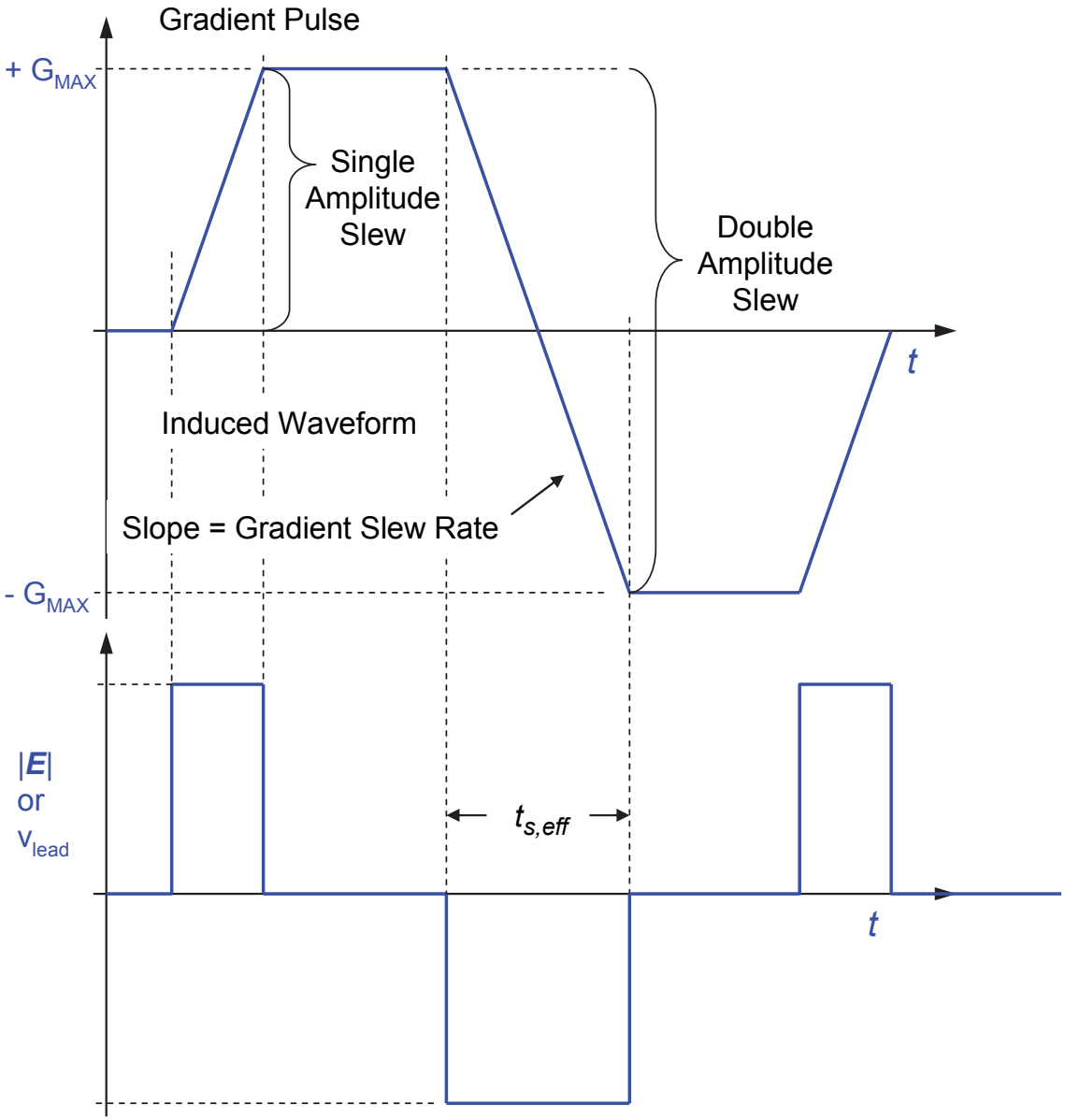
NOTE The pattern in the y = 0 plane for B_x will be the same; there is a 90° rotation about the z-axis.

Figure V.2 — Winding pattern for a y-gradient coil and the magnetic field pattern (B_y) produced in the x = 0 plane



NOTE This field has radial symmetry. Because the field has radial symmetry, the pattern will be the same in any plane that passes through the z axis of the reference coordinate system.

Figure V.3 — Winding pattern for a z-gradient coil and the magnetic field pattern (B_z) produced in the x = 0 plane



NOTE 1 The plot at the top illustrates the variation of gradient field magnitude versus time at a point within the bore.

NOTE 2 The plot on the bottom illustrates the magnitude of the induced E-field.

NOTE 3 The time scale has been distorted relative to actual gradient pulses for the purpose of illustrating waveform features.

Figure V.4 — Trapezoidal gradient pulse and associated induced E-field, which has the same path as the voltage induced along the lead path

V.4 E-fields and induced voltages

The gradient coil produces a time-varying magnetic field dB/dt, which then induces an E-field in the patient. The induced E-field E may be expressed as

$$E = -\partial \mathrm{A}/dt - \nabla\Phi \qquad \text{(V.4)}$$

where A is the magnetic vector potential and Φ is the electrostatic potential (see V.7.1). For the pulsed gradients, the frequency is sufficiently low that both the wavelength in air and the skin depth in tissues are large compared to body dimensions. Thus, to an excellent approximation, $\partial \mathrm{A}/\partial t$ is due to the time-varying current in the gradient coil and $\nabla\Phi$ is from the electric charge that accumulates at interfaces between tissue and the surrounding air and between tissues with different conductivities.

Equation V.4 shows that there are two ways of producing an E-field:

— a time-varying magnetic field;

— electrostatic charge.

For a patient with an implant in a gradient coil, electro-static charge of significance is present in four places.

a) The metal of the coil. This produces an E-field external to the body of the patient.

b) On the surface of the body of the patient. This charge tends to shield the patient from the external E-field. These charges also force the normal component of current density on the surface of the body to be zero.

c) Inside the body on interfaces between tissues of different conductivity. This contributes to local "hot spots" inside the body.

d) On the surface of metal implants inside the body. If the charges are on an electrode, then there will be a strong local field near the surface of the electrode.

The E-field induced in the body or a phantom can be calculated with several computational methods, such as FEM, FDTD, and impedance (see V.7.2). Figure V.5 shows sample calculated E-field intensity distributions (without vector direction information) in the human body and Figure V.6 shows the E-fields in a phantom. Note that the induced E-field in the body or phantom will depend on the time rate of change of the gradient coil current, type of gradient coil (x, y or z), the landmark, and to a lesser extent, the specifics of the gradient coil design. Nonetheless, we expect that for a cylindrical bore imager, gradient coils of different designs will induce similar E-field patterns in the patient.

Nema Standard MS11-2006 (V.7.3) describes a probe for measurement of gradient-induced E-fields in a phantom.

As a result of the induced E-field, there will be a voltage induced between the electrodes of elongated conductors and the case of an AIMD system. The induced voltage ΔV is the line integral of the E-field between the electrode and the IPG

$$\Delta \mathrm{V} = -\int_{\text{electrode}}^{\text{IPG}} E \bullet dl \qquad \text{(V.5)}$$

where dl is an element of line length. For an AIMD path that is approximately closed, ΔV may be approximated by the product of dB/dt and the (effective) loop area.

Figure V.7, which shows E-field magnitude and direction, illustrates the calculation of the induced voltage. An implantable pulse generator (IPG), lead path and the lead path effective loop area have been superimposed on the phantom and E-field pattern to aid in visualizing coupling to the pacing lead. The lead path and the vectors involved in finding the voltage induced along the lead path are shown to the right in the figure. Note that the E-field pattern is representative of a phantom location where the middle of the torso is near the axial location with greatest dB/dt. The E-field pattern will vary as a function of phantom location relative to isocentre along the z axis. Note also that the induced electrode voltage will vary with time unless dB/dt remains constant.

The induced voltage as calculated by integrating the magnetic flux over the loop area may be greater or less than the true value as expressed in Equation (V.5). Appendix L of ANSI/AAMI PC69 discusses loop area for implanted cardiac pacing systems.

The circuit path for currents induced by gradient magnetic fields is shown pictorially on the left. The simplified equivalent circuit for gradient-induced current flowing through the pacing lead tip electrode is shown on the right. A single chamber IPG with unipolar lead has been illustrated for simplicity. The IPG internal impedance (Z_{IPG}) has been shown as a capacitor, which models an AIMD where the lead interface impedance is dominated by capacitance. The tissue impedance (Z_{tissue}) has been shown as a resistance because the tissue impedance is dominated by resistance in the frequency range of interest for MRI gradient-induced signals.

Figure V.8 illustrates the current flow in the AIMD due to the gradient voltage. The amplitude of the gradient-induced voltage v_{grad} between the pacing electrode at the lead tip and the IPG case is dependent upon the lead path and the gradient field dB/dt the lead path is exposed to. The gradient-induced voltage will cause a current to flow between the tip electrode and the IPG case. The E-field may cause current flow and charge accumulation near the electrode, enhancing the possibility of tissue stimulation.

It is customary for IPG designs to employ an EMI capacitor between the lead and the IPG case in order to reduce electromagnetic interference (EMI). The induced voltage will appear across the capacitor because the width of the dB/dt pulse will generally exceed the time constant of the current path equivalent circuit. The maximal charge transfer, Q, through the EMI capacitor as the result of a gradient pulse is expressed as

$$Q = C_E \Delta V \tag{V.6}$$

where C_E is the equivalent value of the EMI capacitor and any other capacitance connecting the lead electrode to the IPG case. The time constant τ associated with the charge transfer is:

$$\tau = R_E C_E \tag{V.7}$$

where R_E is the equivalent electrode resistance, which includes the impedance of the tissue at both the lead electrode and the IPG can interface. The value of τ is typically of the order of μs, much less than the effective duration of a gradient pulse, as well as the tissue stimulation chronaxie.

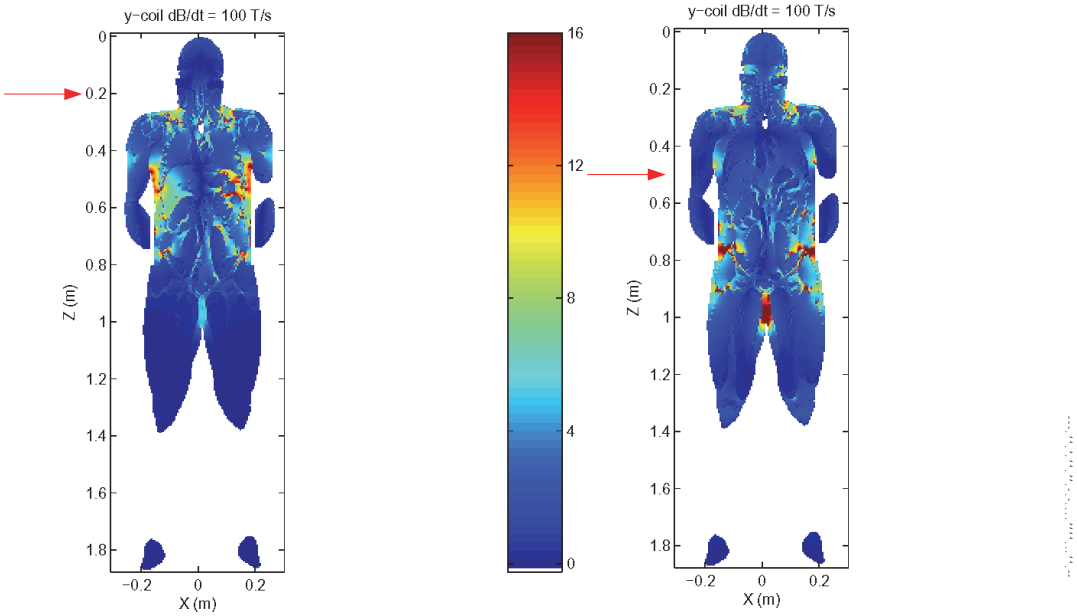
There may also be charge transfer through circuitry other than the equivalent capacitance, including a component due to the leakage between the lead connection and the surrounding tissue. Lead insulation integrity, IPG lead barrel connector seals, and header set screw seals should be considered in the design of the IPG.

If the impedance between the lead input at the header and the metallic case of the generator is purely resistive, then the current flow through the electrode has the same waveform as the gradient pulse. The current I_E during the gradient pulse is then expressed as

$$I_E = \frac{\Delta V}{R_E + R_L + R_H + R_T} \tag{V.8}$$

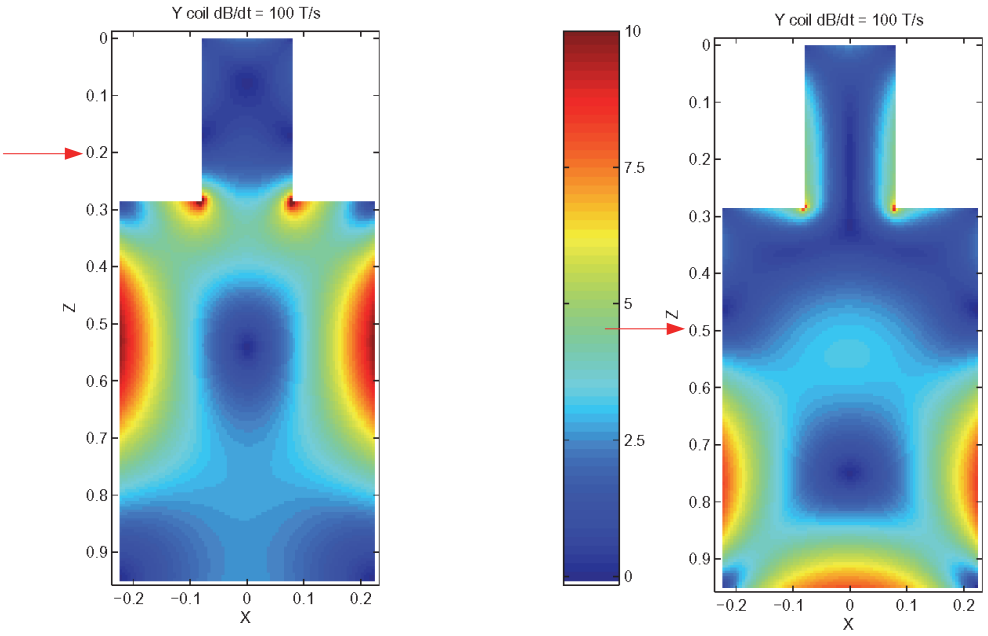
where ΔV is the voltage induced between the electrode and the IPG, R_E is the electrode resistance, R_L is the lead body resistance, R_H is the resistance between the header block and the IPG and R_T is the resistance between the IPG case and the tissue.

There may be an EMI capacitor between the header block and the IPG case. Furthermore, the IPG may contain electronic protection circuitry or parasitic diode junctions. If the voltage induced on the lead is large enough it may activate protection circuits or forward bias parasitic diodes. Appropriate circuit analysis is required if there are reactive or active components in the electrical path between the electrode and the tissue surrounding the IPG.



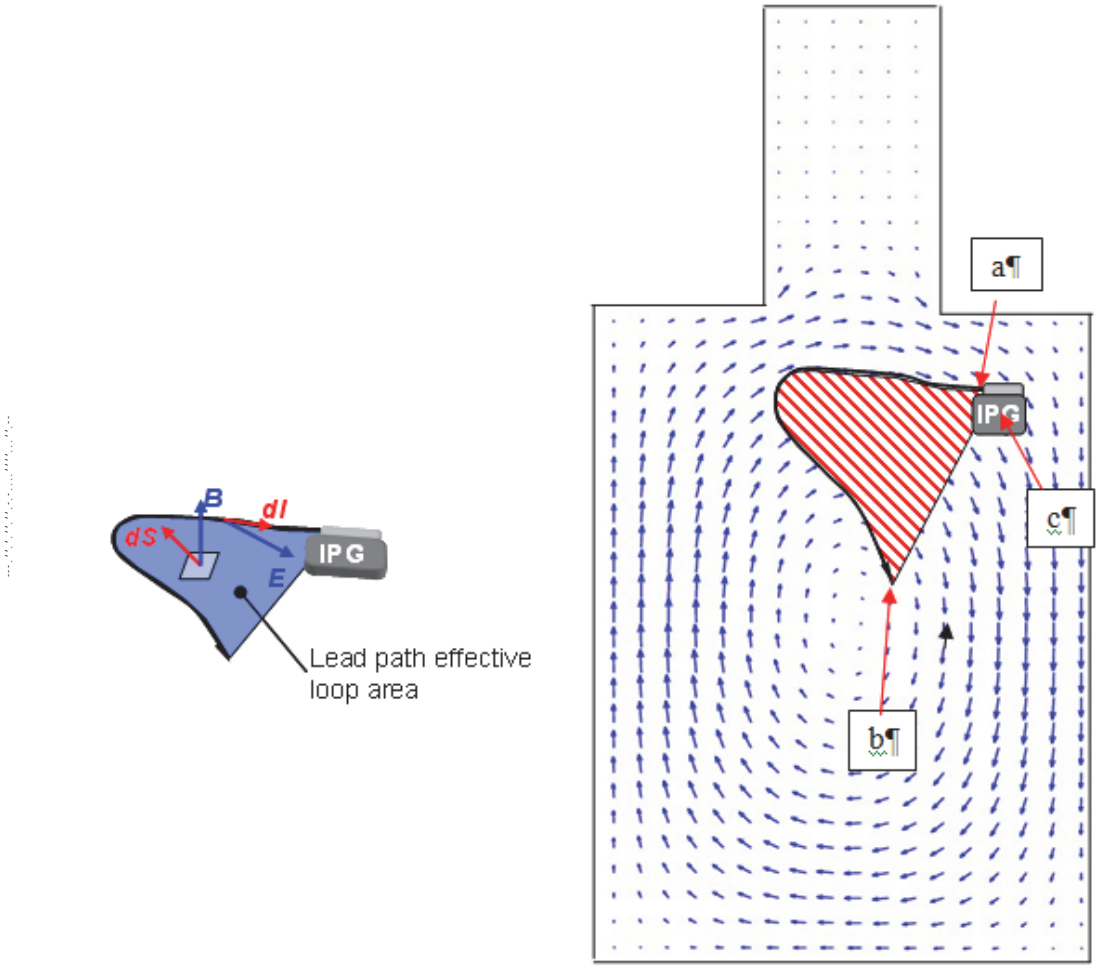
NOTE The left image is for a landmark (centre of RF coil) 20 cm below the top of the head and the right image is for a landmark 50 cm below the top of the head. Landmarks (centre of RF coil) are indicated by the arrows. The maximal *dB/dt* on a cylinder of 20 cm radius is 100 T/s. The colour bar is in V/m.

Figure V.5 — Calculated *E*-field intensity in human model in a y-gradient coil in a coronal slice through the vertical centre of the patient



NOTE The left image is for a landmark (centre of RF coil) 20 cm below the top of the head and the right image is for a landmark 50 cm below the top of the head. Landmarks (centre of RF coil) are indicated by the arrows. The maximal *dB/dt* on a cylinder of 20 cm radius is 100 T/s. The colour bar is in V/m.

Figure V.6 — Calculated *E*-field in a phantom in a y-gradient coil



NOTE 1 The arrows show the gradient-induced E-field in the ASTM phantom.

NOTE 2 The voltage ΔV between the case and the tip is the line integral of the E-field between proximal side of the IPG and electrode of the path of the lead.

[a] Proximal side of lead at the IPG header.

[b] Distal side of the lead at the tip electrode.

[c] Return path to the IPG case for current flow for a unipolar system.

Figure V.7 — Evaluation of induced voltage

The voltage differential,v_1, between electrode and the IPG is:

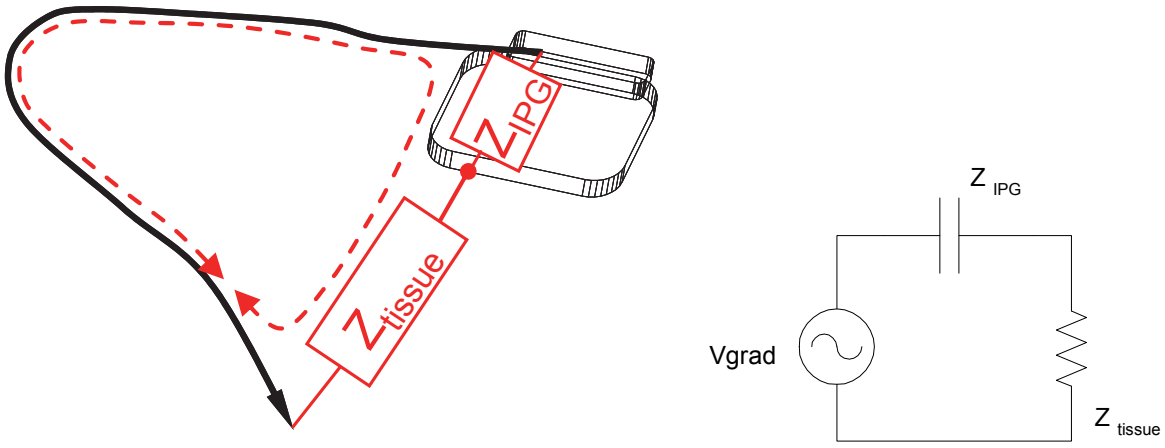
$$\Delta V = -\int_{A(\text{electrode path})}^{B} E \bullet dl \qquad \text{(V.9)}$$

where the integration path is along the lead and E is the background E-field that would exist with no implant. The voltage ΔV is the true voltage that would appear across an open circuit between the lead at the header block and the generator. An estimate for the induced voltage is obtained by integrating the magnetic flux over the loop area.

$$\Delta V_{\text{loop\_area}} = \int_{\text{surface}} \frac{\partial B}{\partial t} \bullet ds = -\int_{A(\text{electrode path})}^{B} \mathrm{E} \bullet \mathrm{dl} - \int_{B(\text{return path})}^{A} \mathrm{E} \bullet \mathrm{dl} \qquad \text{(V.10)}$$

The voltage as assessed with loop area differs by the true voltage by the line integral of E-field along the return path.

$$\Delta V_{\text{loop\_area}} = \Delta V - \int_{B(\text{return\_path})}^{A} \mathrm{E} \bullet \mathrm{dl} \qquad \text{(V.11)}$$



The circuit path for currents induced by gradient magnetic fields is shown pictorially on the left. The simplified equivalent circuit for gradient-induced current flowing through the pacing lead tip electrode is shown on the right. A single chamber IPG with unipolar lead has been illustrated for simplicity. The IPG internal impedance (Z_{IPG}) has been shown as a capacitor, which models an AIMD where the lead interface impedance is dominated by capacitance. The tissue impedance (Z_{tissue}) has been shown as a resistance because the tissue impedance is dominated by resistance in the frequency range of interest for MRI gradient-induced signals.

Figure V.8 — Circuit path for currents induced by gradient magnetic fields

V.5 Gradient-induced vibration and heating

A metallic implant will carry eddy currents in a conductive case and other conductive internal surfaces that are induced by dB/dt. The induced currents are a function of the electrical conductivity and dimensions of the surfaces. The instantaneous power deposited by eddy currents on a cylindrical disc is given by the following equation.

$$P = \sigma T \pi \frac{R^4}{8} \left(\frac{\mathrm{dB}}{\mathrm{dt}} \cos\beta \right)^2 \qquad \text{(V.12)}$$

where P is instantaneous power deposited on a disc of radius R, thickness T, conductivity σ, dB/dt 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 dB/dt RMS value of the MRI sequence(s), as well as the integral of the exposure across all conducting material of the IPG should 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).

Another gradient interaction is the torque of an implant that is produced by interaction of the induced gradient currents and the static magnetic field. A dB/dt perpendicular to its surface induces currents in the implant case. These currents produce a magnetic moment perpendicular to the surface. The component of the static field in

the plane of the implant interacts with the magnetic moment to produce a torque. As for heating, torque is greatest for implants with a large surface area and high electrical conductivity (including internal components such as ground planes, batteries, etc.). The gradient torque is manifested as a vibration and can be qualitatively assessed by running a sequence that produces an intense y-gradient and holding the implant with the normal of the large area of the device perpendicular to B_0 at a distance of about 30 cm from isocentre.

V.6 Risks to the patient with an implanted AIMD

The AIMD could be exposed to a high level of gradient field dB/dt when the MRI gradient fields are slewing from one pulse amplitude to another. Typically, gradient systems with larger gradient slew rates (units T/m/s) will expose the patient to higher levels of dB/dt. A partial list of patient safety risks associated with the MRI gradient magnetic fields follows.

— Stimulation of cardiac or other tissue when AIMDs have long lead wires with electrodes at the distal end of the lead.

— Eddy current heating of the device case and internal device components, such as batteries or high voltage defibrillation capacitors (in implantable defibrillators).

— Disruption of, for example, pacing therapy when patients are scanned (pacing inhibited, pacing at a very high rate, pacing pulse degraded) due to the gradient-induced E-field in the patient's body and the associated noise voltage coupled through the pacing leads to internal components of the IPG.

— Vibration due to gradient-induced device eddy currents interacting with the static magnetic field.

— Device malfunction or failure due to the gradient field-induced voltages at the proximal end of the lead or the gradient field coupling to device internal circuitry.

Cardiac stimulation is a potential safety risk when pacemaker patients are MR scanned (see V.7.4). The most serious patient safety risk is the result of high-rate asynchronous gradient-induced stimulation of the right ventricle (RV). This condition could mimic or induce VT or VF with repetitive high-rate stimulation occurring just as the ventricle leaves the refractory period and can result in haemodynamic collapse. If the gradient stimulation rate is low, the impact of less frequently induced ventricular contractions on haemodynamic efficiency may be less pronounced. When this is the case, the safety risk is reduced to the possibility of inducing a self-sustaining arrhythmia by stimulating during the vulnerable period associated with the myocardium relative refractory period following systole.

Other types of AIMDs having long lead wires, for example neuromodulators or deep brain stimulators with electrodes at the distal end will have the risk of stimulating other types of tissue. The safety risk of each type of AIMD will have to be evaluated on a case-by-case basis. Implant design to minimize the gradient-induced current from the electrodes will mitigate the possibility of unintended stimulation.

Some AIMDs, such as dual chamber pacemakers or multi-channel neurostimulators, may have multiple lead wires with dissimilar trajectories and lead lengths which will result in different E-field exposures. In these cases, the potential difference between the electrode(s) at the distal end of one lead wire versus the other and the possible patient safety implications of significant current flow between electrodes should also be considered. As in the case of the simple system illustrated above, the electrical impedance the IPG presents between the proximal end connections of the lead wires has a role in determining electrode current. While multiple lead wires and multiple electrodes add some complexity to the evaluation, the same basic principles apply. In the case of dual chamber pacemakers using endo-cardial lead wires, the induced voltage between electrodes in the right atrium (RA) and right ventricle (RV) will need to be evaluated.

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