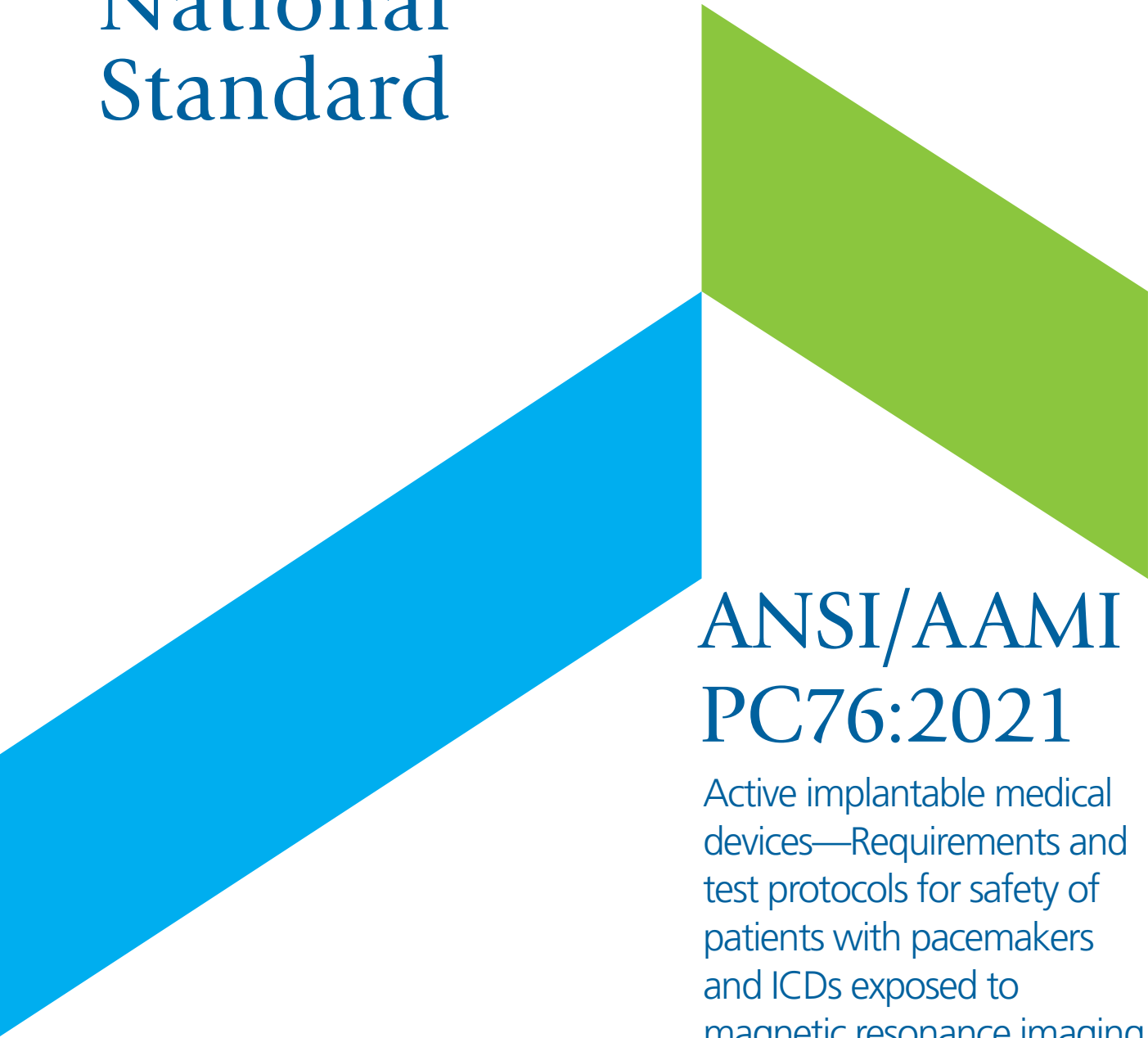


American National Standard



ANSI/AAMI PC76:2021

Active implantable medical
devices—Requirements and
test protocols for safety of
patients with pacemakers
and ICDs exposed to
magnetic resonance imaging

Active implantable medical devices—Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging

Approved 11 February 2021 by
AAMI

Approved 06 April 2021 by
American National Standards Institute, Inc.

Abstract: Provides requirements and test protocols for implantable pacemakers and ICDs exposed to magnetic resonance imaging. Physicians are increasingly using magnetic resonance imaging as tool for differential diagnostic, thus exposing pacemakers and ICD patients to such equipment. Current product standards for implantable pacemakers and ICDs do not include requirements and test protocols for implantable pacemakers and ICDs, which would ensure patient safety during such procedures.

Keywords: implantable medical devices, testing, pacemakers, ICDs, magnetic resonance, imaging

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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Pacemaker & MRI Compatibility Working Group

This AAMI American National Standard (ANS) was developed and approved by the AAMI Pacemaker & ICD MRI Compatibility Working Group.

At the time this document was published, the **AAMI Pacemaker & MRI Compatibility Working Group** had the following members:

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<i>Members:</i>	Jonathan Edmonson, Medtronic Inc Campus Mitchell Shein, CPR Consulting, LLC Shiloh Sison, Abbott Laboratories Paul Stadnik, Micro Systems Engineering Inc Bob Stevenson, Integer Johan van den Brink, Philips Ingmar Viohl, FDA/CDRH
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NOTE Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI PC76, *Active implantable medical devices - Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging* (AAMI PC76:2021), but it does provide important information about the development and intended use of the document.

Active implantable medical devices—Requirements and test protocols for safety of patients with pacemakers and ICDs exposed to magnetic resonance imaging

1 Scope

This document is applicable to transvenous pacemaker, ICD, and CRT systems intended to be used in patients who undergo a magnetic resonance scan in 1.5 T, cylindrical (circular or elliptical cross-section) bore, whole body magnetic resonance (MR) scanners operating at approximately 64 MHz with whole body coil excitation.

The tests that are specified in this document characterize interactions with the magnetic and electromagnetic fields associated with an MR scanner. The tests can be used to demonstrate device operation according to its MR Conditional labelling. The tests are not intended to be used for the routine testing of manufactured products. Some of the tests are type tests whereas others require sample size justification.

The scope of this document is limited to:

- systems that do not use sensing functions or that are programmed not to use sensing functions to affect therapy delivery during an MR scan;
- systems which have high voltage therapy disabled during an MR scan;
- devices which are implanted in the pectoral region of patients.

Requirements for non-implantable parts are outside the scope of this document.

The requirements of this document supplement or modify those of AAMI/ISO TIR10974.

NOTE 1 The document might provide useful guidance for newer therapies such as subcutaneous ICD systems, leadless pacemakers, and loop recorders, but their requirements are outside the scope of this document.

NOTE 2 Safety requirements for MR scanners can be found in IEC 60601-2-33.

2 Normative references

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

AAMI/ISO TIR10974, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*

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

ASTM F2052-15, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM F2213-17, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*

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

ASTM F2182, *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*

3 Terms and definitions

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

3.1

active implantable medical device

AIMD

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

Note 1 to entry: For the purposes of this document, an AIMD is a system consisting of a set of one or more fully introduced implantable components (e.g., device and leads).

[SOURCE: ISO 14708-1:2014, 3.2]

3.2

B₀

static magnetic field of the MR scanner, taken as 1.5 T in this document, unless otherwise stated

3.3

B_{1+rms}

root mean square (rms) of B₁₊

$$B_{1+rms} = \sqrt{\frac{\int_0^{t_x} [B_{1+}(t)]^2 dt}{t_x}}$$

where t is time, and t_x is the integration time, which shall be the highest average value for any 10 s period over the duration of the entire sequence

Note 1 to entry: B₁₊ is derived from the flip angle averaged over an adjustment volume, which is typically represented by the axial central slab wherein MR signal is generated.

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.201]

3.4

B₁₊

component of the RF field in the rotating frame that is effective for tilting of the nuclear magnetization

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.244]

3.5

B_{1+peak}

peak amplitude of B₁₊

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.245]

3.6

birdcage coil

radiator which generates the RF portion of the magnetic field

Note 1 to entry: This usually refers to a bench-top coil used to simulate the operation of a scanner's volume RF transmit coil.

3.7

cardiovascular implantable electronic device

CIED

totally introduced transvenous pacemaker, ICD, or CRT systems

3.8

compliance volume

patient-accessible space in which compliance of gradient output is inspected

Note 1 to entry: 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 and with a length equal to the gradient coil. In all other MR equipment, the compliance volume is the volume where any part of a patient body can be properly located according to the intended use of the MR equipment.

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.202]

3.9

$|dB/dt|_{rms}$

root mean square (rms) of the magnitude of the time rate of change of the gradient magnetic field

$$\left| \frac{dB}{dt} \right|_{rms} = \sqrt{\frac{\int_0^{t_x} \left| \frac{dB}{dt} \right|^2 dt}{t_x}}$$

where t is time, and t_x is the integration time.

3.10

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 1 to entry: Definition and validation of physiological stress is defined in the absence of additional sources that can cause or enhance stress factors (like AIMDs).

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.208, modified — the term “may” in Note 1 to entry has been replaced to “can”.]

3.11

G

spatial encoding magnetic field gradient expressed in units of T/m

Note 1 to entry: G_x introduces a spatial field 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.

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, Table 201.101]

3.12

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

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.209]

3.13

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

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.210]

3.14

intended use/intended purpose

use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

[SOURCE: ISO 14971:2007, 2.5]

3.15

isocentre

<MR equipment> null point of the spatially encoding gradients

Note 1 to entry: Typically, this also corresponds to the region of highest magnet homogeneity.

Note 2 to entry: Typically, this corresponds to the position in the system targeted for imaging.

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.214, modified]

3.16

lead

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

[SOURCE: ISO 14708-1:2014, 3.13]

3.17

lead port

insulated AIMD receptacle or port providing electrical and mechanical connection between an AIMD and a lead

3.18

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

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.218]

3.19

MR scanner/magnetic resonance scanner

see 3.18

Note 1 to entry: In this document, the term “MR scanner” is often used instead of “MR equipment”.

3.20

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

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.222, modified.]

3.21

MR Conditional

item with demonstrated safety in the MR environment within defined conditions, including conditions for the static magnetic field, the switched gradient magnetic field and the radiofrequency fields

Note 1 to entry: Additional conditions, including specific configurations of the item, may be required.

[SOURCE: ASTM F2503, 3.1.11, modified — The first and second sentences have been merged.]

3.22

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

Note 1 to entry: Definition and validation of physiological stress is defined in the absence of additional sources that can cause or enhance stress factors (like AIMDs).

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.224, modified — The term “may” in Note 1 to entry has been replaced to “can”.]

3.23

search coil

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

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.230]

3.24

specific absorption rate (SAR)

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

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.233]

3.25

dB/dt/time rate of change of the magnetic field

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

Note 1 to entry: The time rate of change of the magnetic field dB/dt is assumed to be evaluated in a suitably low frequency range (e.g. < 5 kHz) to disregard effects of switching amplifier ripple.

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.234]

3.26

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 to entry: 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).

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.236]

3.27

whole body gradient system

gradient system suitable for use in whole body MR equipment

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.237]

3.28

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

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.239]

3.29

whole body SAR

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

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.241]

3.30

partial body SAR

SAR averaged over the mass of the body that is exposed by the volume RF transmit coil and over a specified time

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.225]

3.31

local SAR

SAR averaged over any 10 g of tissue of the body and over a specified time

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.216]

3.32

head SAR

SAR averaged over the mass of the head and over a specified time

[SOURCE: IEC 60601-2-33:2010+AMD1: 2013+AMD2: 2015, 201.3.212]

4 Symbols and abbreviated terms

B_G gradient magnetic field magnitude

DUT device under test

RF radio frequency

rms root-mean-square

TEM transverse electromagnetic

5 General requirements for non-implantable parts

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

6 Global malfunction

The CIED is expected to operate in accordance with its intended use and should not create an unacceptable risk to the patient.

Table 1 consolidates the test criteria for the malfunction tests listed.

Table 1—Malfunction test and corresponding clause, and MR fields causing the assessed hazard

Malfunction test	B_0	$G_{x,y,z}$	B_1	Clause
B_0 malfunction	x	-	-	14
Gradient malfunction (injected/radiated)	-	x	-	16
RF malfunction (injected/radiated)	-	-	x	15
Gradient vibration malfunction (MR scanner/shaker)	x	x	-	10
MR combined fields	x	x	x	17

The whole malfunction assessment consists of three steps:

- Step 1: Monitoring during exposure.
- Step 2: Functional verification right after exposure.
- Step 3: Final verification.

Step 1 allows assessing that the CIED behaves as intended during exposure to the MR field(s).

Step 2 allows assessing that the CIED behaves as intended right after the exposure to the MR field(s) (i.e., that no unwanted transient malfunction occurs). This step only applies to MR combined fields and B_0 malfunction tests. This is not intended as a parametric test.

Step 3 allows assessing that the CIED operates in accordance with its intended use after exposure to the MR field(s).

Table 2 details the assessments to be performed for each step, for both radiated and injected malfunction tests. The difference in the assessment is that injected test environments allow for better monitoring and a better measurement than the radiated test environment.

Table 2—Assessments to be performed for both injected and radiated malfunction tests

Step	Radiated Tests	Injected Tests
Step 1: Monitoring during exposure ¹⁾		
Pacing Monitoring	According to 6.2 ^{6), 9)}	Ensure Capture ⁷⁾ No Missed Beats Allowed ²⁾
Step 2: Functional Verification right after exposure		
Maximum waiting time	30 min ⁵⁾	N/A
Telemetry Check ³⁾	Y ^{5), 8)}	N/A
MRI Mode	Y ^{5), 8)}	N/A
Reset (POR)	Y ^{5), 8)}	N/A
Revert Normal Mode	Y ^{5), 8)}	N/A
HV charge (if applicable)	Y ^{5), 8)}	N/A
Magnet Mode	Y ^{5), 8)}	N/A
Step 3: Final verification ⁴⁾		
The CIED operates in accordance with its intended use and should not create an unacceptable risk to the patient.	Y	

¹⁾ Only applicable if the CIED system supports cardiac pacing during MR-scan per its MR Conditional labelling.

²⁾ Injected test environments allow for better monitoring and a better measurement.

³⁾ Telemetry check is self-implied when interrogating device.

⁴⁾ It is preferable to perform the Final Verification soon after the exposure; a maximum delay of 14 days is allowed to the manufacturer.

⁵⁾ This step only applies to MR Combined Fields and B0 malfunction tests. Check should start within 30 minutes from end of exposure.

⁶⁾ For Gradient Vibration Malfunction test, the pacing shall be monitored for Hayes criteria [1] only the first and last 5 minutes of exposure.

⁷⁾ The voltage × duration product shall meet a safety factor above that requirement, to ensure capture during MRI exposure (e.g., 2.5 V × ms, in the case of a 2x safety factor).

NOTE Pacing threshold follows a well-accepted strength duration curve, which is a linear relationship between charge and pulse width. Charge at a given pulse is required to stimulate the cardiac tissue. A good approximation of Charge is a Current × pulse width, which for a fixed pacing impedance can also be Voltage × pulse width. To ensure capture, MR Conditional labelling defines the patient’s threshold prior to entering the MRI mode (e.g., ≤ 2.5V × 0.5ms or 1.25 V × ms). Therefore, we can define a voltage × duration product for the DUT to meet, while in MRI mode, during the exposure to still ensure capture.

⁸⁾ If the device does not automatically revert out of MRI Mode after a timeout, this assessment can be deferred to Step 3.

⁹⁾ Radiated Gradient Malfunction pacing monitoring only applicable if Injected Gradient Malfunction test is omitted.

6.1 Pacing monitoring in radiated environment

If the CIED system supports cardiac pacing during MR-scan per its MR Conditional labelling, the CIED pacing activity shall be evaluated during the radiated exposure as it follows:

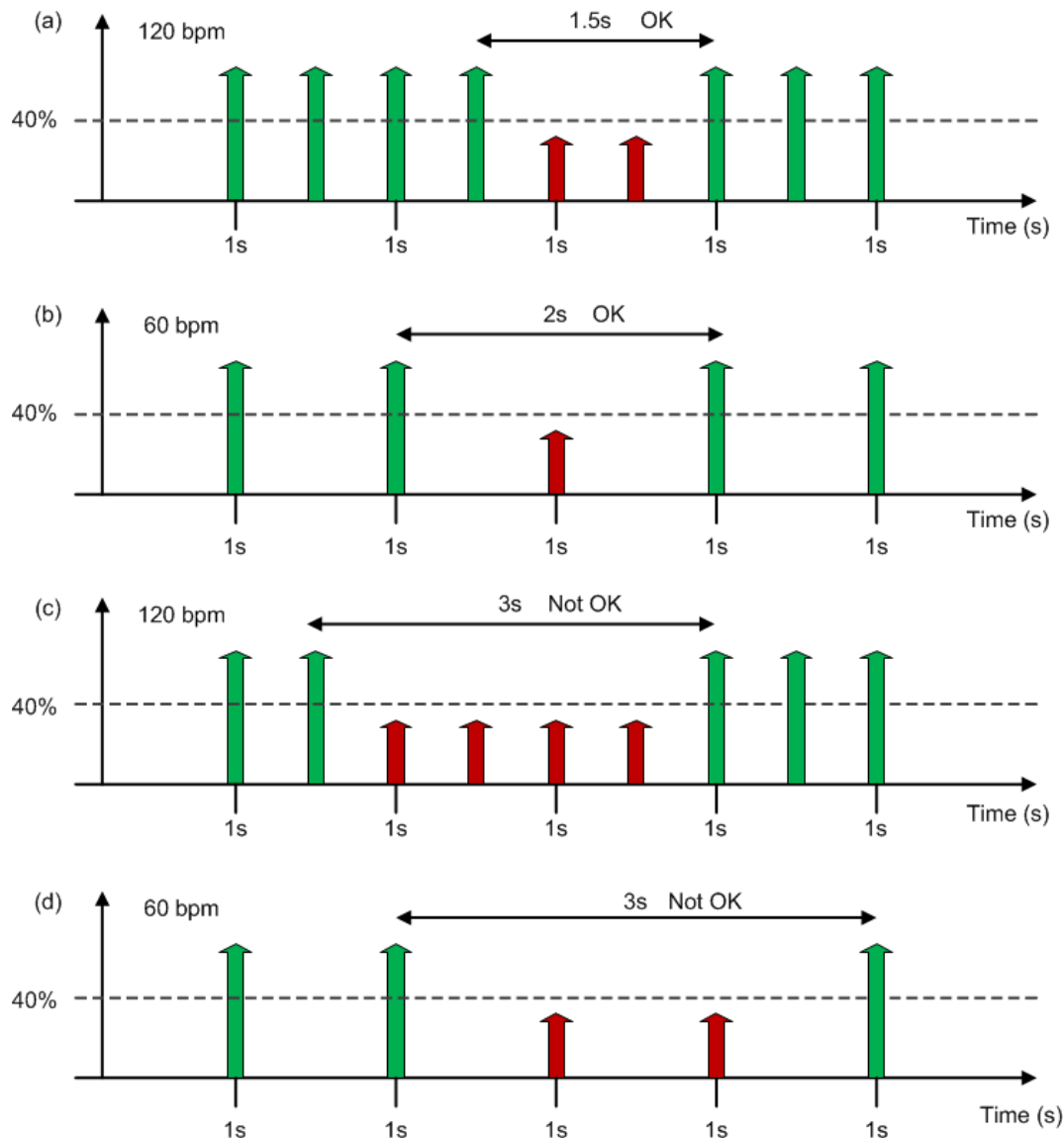
- No clinically significant loss of pacing signal (see NOTE 1) is detected during the whole monitoring time (see NOTE 2).

NOTE 1 Loss of pacing is defined as peak pace amplitude below 40 % of the programmed value (e.g., 2V for programmed value of 5V). Manufacturer may propose a different threshold for LV chamber upon justification.

NOTE 2 Based on [1], [2], a loss of pacing of more than 2 consecutive seconds is considered clinically significant, as illustrated in Figure 1.

A loss of pacing up to 2 seconds is considered not clinically significant; such an event is allowed as follows:

- During the MR combined fields test, once at each landmark shown in Table 22. For multiple scan protocols at one landmark, only one loss of pacing up to 2 seconds is allowed. This criterion is sufficient to meet the requirements of the B_0 Test for Class 0 devices (as defined in Table 12) as well.
- During the B_0 Test for Class 1 and Class 2 devices (as defined in Table 12), once during each orientation exposure.
- During the Gradient Vibration Test, once during the first 5 minutes and once during the last 5 minutes of exposure.
- During the Gradient Radiated Test, once during the whole radiated exposure.



Key

- a) 120 bpm, the interval is 1.5 s, hence not clinically significant.
- b) 60 bpm, the interval is 2 s, hence not clinically significant.
- c) 120 bpm, the interval is 2.5 s, hence clinically significant.
- d) 60 bpm, the interval is 3 s, hence clinically significant.

NOTE In the figure, "OK" indicates a not clinically significant interval, "Not OK" indicates a clinically significant interval.

Figure 1—Diagram showing the interval between two valid pacing amplitudes in different situations

7 General considerations for application of the tests of this document

Several clauses include the concept of Tiers (e.g., Tier 1, Tier 2, ..., Tier n) where each Tier represents an alternative test method. The lowest numbered Tier (Tier 1) represents the least complex test method, produces the least accurate result, but is conservative to ensure safety. AIMDs using the lower tiers require considerable margin to be able to accommodate the conservative assumptions.

As the tier number increases, the test method becomes more complex and is more difficult to implement but provides a more accurate result. The use of the higher tiers reduces the need for excess design margin because the test result is closer to clinical reality.

Several clauses use the Tier concept. The manufacturer may select an appropriate tier for each test and different tiers may be used for different tests. It is not required to use more than one tier for each test.

8 Protection from harm to the patient from lead electrode heating

8.1 General

This MRI RF-induced lead electrode heating assessment is derived from AAMI/ISO TIR10974 and is based on Clause 8, Tier 3, from the second edition. At the present time this is the only tier that is relevant and applicable for traditional transvenous cardiac pacemaker, ICD, and CRT systems.

Patient harm due to RF induced lead electrode heating is a function of absolute temperature, duration of the temperature, and individual implant considerations. RF induced heating of tissues surrounding the lead electrodes may result in local tissue temperature rises, leading to tissue damage or a reduction in the ability of the implanted device to deliver therapy. Both of these shall be evaluated to assess patient safety. Determining the rise in local tissue temperature due to interaction of a cardiac lead with the RF field of an MR scanner is a complex process that depends on device design, lead design, MR scanner technology (RF coil and pulse sequence design), patient size, anatomy, position, device location, lead path, and tissue properties. This complex environment can produce *in vivo* temperature variation spanning several orders of magnitude.

Two components are necessary to assess the safety of RF induced lead electrode heating.

- a) The first component is the RF lead modelling framework, which includes: a set of RF birdcage coil models representative of the targeted MR system scanner platforms, a set of human body models representative of the target population, RF models of the implantable cardiac leads, and a set of lead paths that include the extremes of clinical practice. This modelling framework is described in detail in Clause 8.3. The output of the RF lead modelling framework is a set of computer simulation results that define a probability distribution function of the power deposition at the lead to tissue interface.
- b) The second component assesses the impact of the power deposition on the associated tissue. The two methods for evaluating the tissue impact are described briefly below and in more detail in Clauses 8.6 through 8.8.
 1. CEM43 is a temperature versus time methodology that has been used to assess tissue damage in a variety of tissues throughout the human body.
 2. A change in pacing capture threshold (ΔPCT) has been correlated to cardiac tissue damage in the vicinity of the lead tip electrode.

The probability distribution function of power is combined with the chosen tissue damage evaluation method to predict the probability of tissue damage.

8.2 Hotspot determination

In this document hotspots are defined as the pace/sense electrodes for the pacemakers and cardiac resynchronization applications. For a typical ICD lead the high voltage electrodes have been demonstrated not to be a hot spot and therefore can be excluded. Furthermore, if the ring electrode electromagnetic model, obtained from a validated method, predicts a 99th percentile *in vitro* equivalent temperature rise or RF power deposition <1/4 of the 99th percentile validated *in vitro* equivalent tip temperature rise or RF power deposition, then the ring electrode can be excluded as a hotspot. Finally, for a cardiac resynchronization with left sided leads with multiple electrodes, each electrode is considered a hotspot.

Each hotspot requires a validated electromagnetic model and an *in vivo* power deposition analysis.

8.3 MRI RF lead modelling framework

The objective of the RF lead modelling framework is to define all required components of the modelling environment and the range of attributes that shall be considered for each component.

8.3.1 RF birdcage coils and excitation

The MR system market contains a variety of RF coil designs as described in Annex J of AAMI/ISO TIR10974. A thorough RF lead electrode heating analysis shall include a complete analysis of all potential coil types and field rotation that are allowed per the MR Conditional labelling.

8.3.1.1 Coil types

Early 1.5T MR systems used low pass coil designs which have capacitors at the center of each rung of the birdcage coil. Modern 1.5T MR systems use high pass coil designs which have capacitors on the end rings between the rungs of the coil. A small number of modern scanners use bandpass coil designs which have capacitors at the center of each rung and capacitors on the end rings between the rungs. Elliptical or oval shaped MRI birdcage coils have also begun to emerge. These different coil designs will definitely produce different electric field profiles within the human body models. These different electric field profiles may or may not have an impact on the lead heating profile. It is the responsibility of the implant manufacturer to either include the different types of whole-body birdcage coils in the composite simulation data set or perform an analysis that indicates a particular coil type does not impact the lead heating profile.

In addition to coil type, there are also variations in size. The most obvious size difference comes from scanners with either a 60 cm diameter or a 70 cm diameter patient aperture. It is important to note that the birdcage coil will be several centimeters larger than the patient aperture. In addition, each bore diameter also has a variety of different coil lengths. The length of the coil will impact the whole-body SAR (wbSAR) to B1+rms ratio and will also have an impact on the lead heating profile. The implant manufacturer shall either simulate with a range of coil lengths and diameters or perform a separate analysis that identifies the worst-case coil type to be used for the lead heating evaluation.

Annex J in AAMI/ISO TIR10974 was used to provide useful birdcage coil information that can be used to derive the number and types of coils in Table 3.

For cylindrical bore, circularly polarized (CP), MR Conditional labelling, the coils in Table 3 are considered representative of the clinical environment. Therefore, modelling these coils is considered sufficient for RF heating analysis.

Table 3—RF coil geometry for in-vivo simulations

Aperture diameter (Tol=5 %)	Length (Tolerance=10 %)	Comment
60	55	feed in the rings
60	70	"
70	55	"
70	70	"
70	38	"
60	55	feed in the rungs

8.3.1.2 Coil excitation

At present all 1.5T scanners use a coil excitation method that produces a CP RF magnetic field. The most common form of excitation is quadrature drive as describe in Annex J of AAMI/ISO TIR10974.

3T scanners have begun to use an excitation technology that is called multi-transmit or parallel transmit. This technology is not currently used at 1.5T and does not need to be evaluated.

The excitation level used in the simulations shall be consistent with the MR Conditional labelling. At present it would be acceptable to label for Normal Operating Mode, First Level Controlled Operating Mode, fixed wbSAR levels that differ from Normal Operating Mode or First Level Controlled Operating Mode, or a fixed B_{1+rms} level.

8.3.1.3 Field rotation

The CP birdcage coil can have a clockwise (CW) or counterclockwise (CCW) rotation. The direction of rotation of the B1 field is related to the direction of current flow in the super conducting magnet that generates the B0 field; i.e., is the

north pole at the front of the machine or at the rear. The B0 magnets can and are ramped in different directions in the clinical environment; therefore, the B1 field can be CW or CCW.

CW and CCW B1 fields induce different electric fields within the patient's body in the region of the cardiac implant. As a result, the lead heating analysis shall contain both CW and CCW excitations. CW and CCW is equivalent to performing simulations headfirst and feetfirst.

8.3.2 Human body library

At present, there is no peer reviewed published literature relative to the impact of body size (height, weight, girth) on lead heating. It is well understood that larger bodies and bodies with a higher percentage of muscle will be subjected to higher wbSAR levels for a given B_1 . Lead heating is a complex phenomenon because of the RF phase effects, but in general it is proportional to the electric field magnitude in the vicinity of the lead.

It is necessary to evaluate lead heating over a library of human body models that span the body mass index (BMI) and genders specified in Table 4 which represent the population of implanted cardiac systems. This can be met using the virtual family [2] models plus an obese model.

Table 4—Virtual body models

Gender	BMI Range (kg/m ²)
Male or Female	>35
Male	20 to 30
Female	20 to 30
Male	10 to 20
Female	10 to 20

8.3.3 Body position in bore (landmark)

Maximum RF coupling will occur when the lead path is central to the RF birdcage coil in the z-axis direction. It is desirable to produce a clinically relevant probability density function (pdf) without artificially skewing the result by including scans of body regions that produce no heating. Landmarks shall include the region between head (eye level) and hips but shall not go past the knees at isocenter in 10 cm maximum steps.

8.3.4 Lead pathways

The lead pathway is defined as the three-dimensional (3D) path that the lead follows from the proximal connection at the device header to the distal end in one of the chambers of the heart. This results in complex phase effects that can produce very low lead heating (cancellation) or very high lead heating (phase enhancement), depending on the amplitude and phase of the electric field tangential to the lead.

Variation in the lead pathway produces considerable variation in RF heating as a result of E_{tan} variation and the phase effects. Therefore, it is necessary to use a sufficient number of diverse yet clinically relevant lead paths in the simulation data set. At present device locations are constrained to the left and right pectoral regions.

8.3.4.1 Device locations

The lead heating analysis shall include lead paths that span the extremes of the allowed device implant locations within the pectoral region of the chest.

8.3.4.2 Lead tip locations

The right atrium (RA) is rather small so there is not much variation in lead path that can be realized by defining more than 1 RA location. Therefore, pathways with one atrial pacing site are sufficient.

The right ventricle (RV) is much larger with a greater degree of freedom for lead tip locations. The RV apex has been a popular implant site for years because of the ease of hitting it. In more recent years, implanting in various positions on the side wall has gained in popularity. A minimum of 2 RV tip locations (apex and 1 sidewall) shall be used to define RV tip locations.

There is a lot of variability in the venous structure of the veins that feed the coronary sinus (CS) for access in pacing the left ventricle (LV). At least three cardiac veins (Anterior, Lateral, Posterolateral or Posterior) at two locations in each vein shall be considered.

8.3.4.3 Lead pathway definition

The lead pathways used in simulations are defined by a 3D path from the device header with a smooth path to the vasculature, following the vasculature to the appropriate chamber of the heart, and ending with the tip implant locations defined in 8.3.4.2 for the RA, RV, and LV as applicable.

The MRI RF magnetic field will induce electric field around an implantable pulse generator (IPG) can. Since the IPG is made of conductive material the E-field near the can is normal to the device surface and the tangential component is zero. Therefore, any excess lead shall be assumed to be near the device case, where the tangential electric field is set to zero.

8.3.5 RF electrical lead model

There are a number of different methods for generating an RF electrical model of the cardiac lead. While concepts for developing a lead model have been published [5], [6], there have not been any publications that provide a detailed “how to” recipe. Specific methods have been developed by AIMD manufacturers, but the details are considered trade secrets and are highly guarded.

This document does not need or intend to define methods for generating an RF electrical model of a cardiac lead. The accuracy of the lead model will be determined during the lead model validation and an appropriate error term will be applied in the required uncertainty analysis.

An RF electrical lead model shall be created for each hotspot and each length of a lead model, unless model to model equivalency can be justified by lead design analysis and confirmed by radiated measurement across a variety of pathways. If model to model equivalency can be confirmed for one lead length, this could also be used to justify equivalency of the other lengths.

An important attribute of multi-chamber systems is that the leads run in parallel, in close proximity, for a considerable portion of the lead path. Lead heating would be less than a single lead when a second lead is in close parallel proximity over their entire length [4]. Therefore, power deposition assessment with a single lead is conservative. This rationale also applies to more than two leads.

Moisture content inside a lead varies by design of the lead. While the outer insulator (polymer) will reach saturation level by moisture absorption, the outer lumen will remain free of fluid. Saturation can be achieved with a 10-day soak of the lead.

For leads without a blood seal at the tip, the inner lumen will be filled with fluid due to the positive pressure of the heart versus the pocket. The percentage of ingress shall be determined by the AIMD manufacturer applying a nominal right sided heart pressure to the lead. This fluid ingress inner lumen with a saturated outer lumen shall be evaluated for power deposition.

Leads with a blood seal at the tip are designed to keep fluid out of inner lumen. However, blood seal design may allow some fluid ingress over time. The percentage of ingress shall be determined by the AIMD manufacturer using a prospective seal integrity test. A fluid free inner lumen with a saturated outer lumen shall be evaluated for power deposition. In addition, if the seal integrity test so indicates, a fluid ingressed lumen with a saturated outer lumen shall also be evaluated for power deposition.

8.4 Model validation

Many of the elements of the larger modelling framework have been around for years and have been validated for other uses. Various simulation tools have been used by MR system manufacturers, the cell phone industry, and other RF related industries for years. Human body models with unique RF tissue properties (σ and ϵ_r) have also been used by the cell phone and MR system industries for years and in particular they have been used to evaluate RF power deposition. In addition, cardiac AIMD manufacturers have been studying and evaluating transvenous cardiac lead paths for reliability and fatigue purposes for decades. In all cases, simulation tools have modeled RF energy propagating

through space, impinging on a human body, and analyzing the impact of RF induced currents within the body on associated tissues.

The derivation of the RF electrical model of the cardiac lead and analyzing the coupling and propagation of RF energy on the lead using a non in-situ E_{tan} is complex. In addition, this is a slightly different application of previous validated tools.

It is necessary to validate the individual RF model of the lead(s) and to also validate the combination of the overall modelling framework components working together in unison. The following sections describe the methods that shall be used for both validations.

8.4.1 *In-vitro* lead model validation

The primary reason for using modelling is to properly account for the amplitude and phase effects that occur on elongated structures such as cardiac pacing and defibrillation leads. As a result, the primary purpose of the lead model validation is to verify the model's ability to represent the amplitude and phase effects. Therefore, the model validation data set shall include a diverse set of incident electric fields that will result in amplitude and phase effect heating enhancement and cancellation.

The model validation effort involves the following steps:

1. Define the data set, which is a set of lead paths and optional landmark variants that expose the lead to a variety of tangential electric fields (magnitude and phase) that result in enhancement and cancellation due to the amplitude and phase effect.
2. Simulate each unique condition (lead path and landmark).
3. Measure each unique condition.
4. Compare the simulated and measured results using a least squares linear regression analysis.
5. Quantify the uncertainty in the model.

8.4.1.1 Phantom selection

ASTM F2182 defines two phantoms. The simple phantom is a rectangular box that represents the human torso. A more complex version of the phantom is created by adding a second rectangular box that represents the head and neck. Refer to ASTM F2182 for phantom dimensions.

AAMI/ISO TIR10974, Annex M also describes circular and oval/elliptical shaped phantoms, which can also be used for the model validation effort. In addition, Annex M describes different RF coil drive configurations and the resulting electric field distributions for a variety of phantoms.

The model validation data set shall include at least one of any of the ASTM phantoms described in ASTM F2182 or any of the phantoms described in AAMI/ISO TIR10974, Annex M.

8.4.1.2 Tissue simulating medium (TSM)

Because of the rapid decay of RF fields in tissues surrounding a transvenous cardiac lead, tissues closest to the lead body and electrode dominate the lead's RF performance. AAMI/ISO TIR10974 specifies TSM dielectric properties be generally representative of the permittivity and conductivity of the dominant tissues in the immediate surroundings of the implanted system. Implanted transvenous cardiac leads are generally surrounded by blood, muscle, vein wall and fibrotic connective/scar tissue along their length. These surrounding tissues are all relatively high-water-content and considered high permittivity (HPM) as defined in AAMI/ISO TIR10974.

NOTE The manufacturer can develop and validate RF heating models using TSM formulations shown to be appropriate for the AIMD under test using one of the three Tiers described. Alternatively, manufacturers can use data collected under the historical TSM selection criteria in AAMI/ISO TIR10974:2018. The committee has determined that the historical selection criteria result in TSM formulations that satisfy the essential requirements of 8.4.1. However, use of the current selection Tiers is recommended because

modelling and experimental techniques used to define appropriate TSM have improved since the publication of AAMI/ISO TIR10974:2018.

TSM Selection Tier 1: Evaluate a range of HPM TSM conductivities representative of the tissues surrounding the lead and choose the conductivity leading to the highest *in vivo* prediction results.

To determine a conservative HPM TSM conductivity, RF performance models for the lead surrounded by different uniform TSM conductivities are created. These models are then used to predict the *in vivo* performance of the lead. The conservative TSM conductivity is the conductivity corresponding to the lead model with highest *in vivo* prediction results.

Based on the tissues typically surrounding implanted cardiac leads, the HPM TSM conductivity evaluation shall include 0.47 S/m (representing connective/scar tissue and vein wall as well as a whole-body average), 0.68 S/m (representing heart, muscle) and 1.2 S/m (representing blood) as defined in AAMI/ISO TIR10974. These TSM properties are considered generally representative with the understanding that the electrical properties of human tissues continue to evolve since they vary significantly and are not known with a high degree of precision. AAMI/ISO TIR10974 Annex L provides formulation recommendations for HPM TSM solutions with these conductivities.

Alternatively, the transfer function model of a lead electrode under test shall be derived in a homogeneous HPM TSM whose conductivity matches that of the tissue that it is expected to be in contact with it in clinical use. Specifically, the transfer function model of the tip electrode of a cardiac lead that is expected to be in intimate contact with the myocardium shall be derived in a homogeneous HPM TSM whose conductivity matches that of the myocardium ($\sigma = 0.68$ S/m).

The above guidance is based on studies [8] that show that conductivity of the medium that is in intimate contact with the electrode has a strong influence on the magnitude of RF power deposition or temperature rise. This study also shows that, in contrast, the conductivity of the medium surrounding the insulated lead body has a weak influence on the RF power deposition; it is conditional upon the insulation being sufficiently thick.

The lead insulation thickness regulates RF power loss along the lead body. Leads with thick insulation enable low loss transmission of RF energy collected by the lead wires to the lead electrodes. On the other hand, leads with thin insulation form lossy transmission lines due to capacitive coupling of the lead wires with the surrounding conductive medium. In this case, increasing the conductivity of the medium surrounding the insulated lead body increases the RF power loss along the lead and effectively decreases the RF power deposited at the electrode. Bottomley et al [7] have shown that the rate of increase in electrode RF power deposition significantly declines beyond insulation thickness of 250 μm . In other words, the conductivity of the medium surrounding the lead body has a weak influence on the electrode RF power deposition when the insulation thickness exceeds 250 μm . Note that this also implies that testing under the assumption of thick insulation is conservative.

TSM Selection Tier 2: Electromagnetic Modelling

When one representative TSM conductivity is to be applied for *in vivo* prediction, instead of sweeping a range of conductivities, the conductivity of a suitable homogeneous TSM can be determined via electromagnetic (EM) modelling of an AIMD in both homogeneous and heterogeneous tissue environments.

Step 1: A homogeneous TSM is selected as an initial choice, the relative dielectric permittivity and the electrical conductivity values can be determined based on the tissue types surrounding the AIMD.

Step 2: Develop an equivalent EM model(s) of the AIMD and the associated confidence interval (uncertainty budget). Methods of developing the model are the responsibility of the implant manufacturer. The output of the model is an estimate of the local spatial integral of the local *in vivo* power deposition at each hotspot, P_{hotspot} , along the AIMD with a known uncertainty.

Step 3: The *in vitro* electromagnetic model of the AIMD, i.e., the AIMD EM model in the homogeneous TSM from Step 1, is validated for prediction of power deposition in homogeneous media/tissue by satisfying the requirements defined in 8.4.1.

Step 4: For a selected AIMD pathway (or location) in a human body, the tissues surrounding it can be determined by assessing the tissue properties along and around the AIMD. A tissue block, composed by the tissue property information extracted along and around the AIMD, can be developed. The size of the tissue block shall be sufficiently large such that the prediction of power deposition is converged, i.e., increasing the tissue block size does not change the prediction.

Step 5: Select the human body models of interest, select the pathways of interest, generate the corresponding *in vivo* tissue blocks. For each body model, the pathways shall be selected to cover clinically relevant implant locations. For each tissue block, an *in vivo* AIMD EM model can be created by placing the validated *in vitro* model into the selected tissue block.

Step 6: This step describes the calculation of *in vitro* and *in vivo* TF deviation terms. The *in vitro* AIMD EM model and the *in vivo* AIMD EM models can be applied to create the transfer functions (Annex K.3 of AAMI/ISO TIR10974) to predict power deposition. Take the *in vitro* transfer function (TF) and one of the *in vivo* transfer functions, both in their complex number form, calculate the difference between the two TFs at each data point; this complex data set is defined as ΔTF . Assume an incident tangential electric field (E_{tan}) of unit magnitude and conjugate phase with respect to each ΔTF . Combining the E_{tan} with the respective ΔTF will produce a term which describes the deviation in TF predictions between the *in vitro* and *in vivo* TFs. This term is defined as $\Delta Prediction_{TSM_vs_Tissue}$.

Next, assume a conjugate phase E_{tan} with unit magnitude for the *in vivo* TF, calculate the TF prediction by combining this E_{tan} with the *in vivo* TF. This term is $Prediction_{Tissue}$. Calculate the Deviation as ratio of $\Delta Prediction_{TSM_vs_Tissue}$ to $Prediction_{Tissue}$ terms as shown in Equation 1. The Deviation will indicate the percentage difference between the *in vitro* and *in vivo* TF predictions. For a homogeneous TSM to be considered as a suitable choice, statistical analysis should be conducted on the distribution of deviation terms to show that the deviations fall within a pre-defined uncertainty bound. Otherwise, the procedure circles back to the Step 1.

$$\text{Deviation} = \frac{\Delta Prediction_{TSM_vs_Tissue}}{Prediction_{Tissue}} \% \quad (1)$$

TSM Selection Tier 3: *In vivo* validation

An animal (canine or swine) study shall be performed to verify the selected TSM for the RF electrical lead model. The animal study shall be conducted in an acute phase with a lead instrumented with a fiber optic temperature probe at the tip electrode to measure the *in vivo* heating within an animal during MRI exposure. The fiber optic temperature probe serves as a surrogate to the power deposition at the lead to tissue interface. The *in vivo* verification of a selected TSM includes the following steps.

Step 1: Instrument a lead with a fiber optic temperature probe positioned at a known location close to the hot spot of the lead electrode.

Step 2: Determine the mean perfusion factor, being the ratio between the animal *in vivo* heating in the presence of perfusion versus the *in vitro* heating with no perfusion for a known power deposition at the lead to tissue interface. Methods for determining this factor may rely on an additional animal study using an RF injection method similar to that used for deriving the ΔPCT response or may rely on thermal modelling based on studies of cardiac perfusion rates.

Step 3: Implant the animal with the instrumented lead, taking care that the fiber optic temperature probe remains intact after the implant.

Step 4: Conduct a CT or MRI scan of the animal such that a 3D model for the animal and the lead routing can be generated.

NOTE 1 CT imaging is recommended for extraction of the lead routing within the animal, however MRI can be suitable for generation of the tissue model within the subject.

Step 5: Scan the animal in the MRI at a known B_{1+rms} , conduct temperature measurements for scans performed at a variety of landmark positions as well as animal positions within the scanner.

Step 6: Recreate the MRI scan setup via simulations using the CT data to generate a 3D model of the animal with at least the muscle, blood, fat, and bone tissues represented in the animal model.

Step 7: Conduct simulations of each unique MRI scan that was conducted, scaling the fields produced in the animal to the field exposure present during the MRI scan.

Step 8: Extract the tangential E-field at the positions where the lead was routed within the animal.

Step 9: Determine the predicted power deposition using the RF lead electrical model generated for the particular TSM being evaluated.

Step 10: Convert the measured *in vivo* heating to a measured estimate of RF power deposition at the lead to tissue interface, taking the mean perfusion factor into account.

Step 11: Demonstrate that the predicted RF power deposition using the particular TSM RF electrical lead model predicts the measured power deposition based on a sum of least squares regression analysis of the measured vs predicted power deposition.

NOTE 2 The correlation coefficient for the measured versus predicted RF power deposition can be significantly less than the typical correlation coefficients from *in vitro* validation of the RF electrical lead model. This can occur due to many reasons including significant variation in perfusion factors from animal to animal, uncertainty of the temperature probe position with respect to lead electrode hot spot after implant, and uncertainty in precise animal position and lead routing within the MR system.

8.4.1.3 RF coil and excitation

There are a large number of different designs for whole body RF birdcage coils in clinical use. In addition, there are laboratory whole body RF birdcage coils that possess field characteristics consistent with clinical practice. As a result, it is not necessary, desirable, or practical to standardize on the use of a single RF birdcage coil for the model validation procedure. The coil shall meet the constraints listed in Table 5.

Table 5—RF coil constraints

Characteristic	Requirement
Construction	≥16 rung high pass coil
Diameter range	60 cm to 75 cm
Coil length	55 cm to 75 cm
Frequency	64 MHz ± 5 %
RF Polarization	Circular or Linear

It is advantageous from a signal to noise (SNR) perspective to use the maximum birdcage power while maintaining temporal power stability, i.e., avoid RF coil component heating. However, excessive DUT and TSM heating will produce nonlinearities in temperature measurements that shall be avoided. Therefore, the RF power should be selected to maximize SNR for low heating paths or to prevent excessive heating for high heating lead paths. Therefore, keeping the total temperature below 40 °C as specified in ASTM F2182 is recommended.

8.4.1.4 Lead paths

A primary purpose of model validation is to demonstrate that the model behaves appropriately when there is both phase enhancement and phase cancellation. Lead paths that cause enhancement due to phase effects and lead paths that cause cancellation due to phase shall be included in the data set. The lead body construction has a significant impact on which paths produce cancellation and which paths produce enhancement. Therefore, it is not possible to define a single set of lead paths that is optimal for all lead designs. A set of lead paths shall be developed along with rationale that demonstrates that the set of lead paths produces cancellation, enhancement, and variation in between as well as assessment of model impact due to coupling between segments of the lead body. The minimum number of unique E_{tan} excitations shall be 25 with diversity of amplitude and phase along the lead pathway. These unique E_{tan} excitations can be achieved by varying the lead path, by varying the phantom position and/or adjusting the RF sources.

8.4.1.5 Phantom landmarks

It is possible and sometimes desirable to vary the landmark (phantom position in the birdcage coil) as a means of generating different tangential electric fields. However, there are other methods for creating electric field variation and testing at different landmarks is allowed but not required.

8.4.1.6 In-vitro lead model validation data and analysis

The model validation data set is all combinations of lead path (see 8.4.1.4) and landmark (see 8.4.1.5) that define the incident electric fields.

8.4.1.6.1 Simulations

The simulation involves providing an RF electrical excitation signal to the RF birdcage coil, containing one of the phantoms described in 8.4.1.1, filled with the TSM described in 8.4.1.2, and generating the 3D electric field (magnitude and phase) within the volume of the phantom.

The lead path in conjunction with the 3D electric field in the phantom is used to define the electric field (magnitude and phase) tangential to the lead. A second simulation applies the tangential electric field to the lead model and calculates the lead electrode power or temperature levels. The simulations are performed on each element of the simulation data set defined in 8.4.1.6.

8.4.1.6.2 Measurements

Measurements are made on each element of the simulation data set defined in 8.4.1.6. Measurement of energy deposition shall be performed using SAR probes or temperature probes. In general, the measurement probe(s) should be as small as possible to provide sufficient spatial resolution and should have minimal metallic content to avoid perturbing the electric field. Anything that perturbs the electric field can also degrade the model validation score, which can result in a larger uncertainty that shall be accounted for in the final result.

8.4.1.6.3 Data comparison and analysis

The simulation and measurement tools may provide results in different units, e.g., the simulation result could be in power and the measurement result could be in temperature. If necessary, the simulation and measurement result shall be converted to a common unit for comparison purposes.

The data comparison and analysis procedure shall include the following.

- An evaluation of the radiated electromagnetic field test environment uncertainty.

The uncertainty of the AIMD local deposited power determined using the radiated electromagnetic test apparatus shall be quantified. The *in vitro* test uncertainty, u_{exp} , represents the total uncertainty of the AIMD local deposited power due to variations in the test and measurement system including but not limited to the uncertainty of the incident tangential electric field, tissue simulating medium properties, AIMD placement, and deposited power measurement method (e.g., SAR or temperature).

- An evaluation of the AIMD model uncertainty.

Determine the AIMD model uncertainty, $u_{predict}$. This represents the uncertainty and variability associated with the numerical, analytical, and/or experimental methods used to derive and implement the AIMD model.

NOTE See 8.5.4 for additional information on uncertainty.

- A quantification of the AIMD model error.

Perform a linear least square regression and compute the error between the measured and computed deposited RF power.

The total error, e_{total} , is computed from the difference between the predicted and measured deposited power values from the model validation data set using appropriate statistical methods. When replicate measurements corresponding to a single model prediction are included, the total error can be composed into two components,

e_{model} and e_{random} . The e_{random} error term represents random measurement error relative to the mean value of all replicate measurements. The e_{model} error term relates the mean value of replicate measurements to the model predicted value and therefore provides an estimate of the model lack of fit or prediction error. Since the total error, e_{total} , includes both random error (e_{random}) and prediction error (e_{model}) contributions, it may be used as a conservative estimation of model prediction error, e_{model} .

- Evaluate validation criteria and compute the combined *in vitro* prediction uncertainty.

The purpose of model validation is to show that the model is acceptable for the intended use.

8.5 Human RF hotspot power prediction

The RF lead modelling framework described in 8.3 shall be used to predict the power deposition of each hotspot identified in 8.2 by:

$$P_{\text{hotspot}} = A \left| \int_0^L S_{\text{hotspot}}(z) E_{\text{tan}}(z) dz \right|^2 \quad (2)$$

where

P_{hotspot} is the local power deposition of the AIMD at a hotspot (W).

A is a constant (W/(V/m)²).

L is the length of the AIMD (m).

z is the position along the AIMD (m).

S_{hotspot} is the complex validated model of the AIMD (1/m).

E_{tan} is the local *in vivo* electric field determined in 8.5.2 (V/m).

8.5.1 Human body simulations

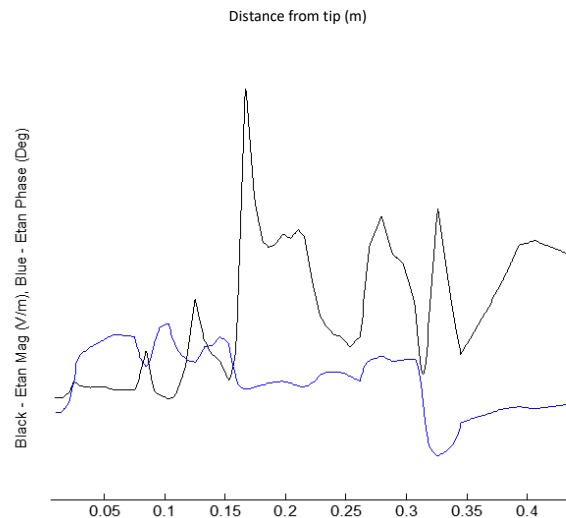
Each human body defined in 8.3.2 shall be:

- simulated within the RF birdcage coil(s) defined in 8.3.1.1;
- with both CW (clockwise) and CCW (counterclockwise) rotations as defined in 8.3.1.3;
- with a CP excitation and scaled to match the MR Conditional labelling;
- at human body landmark positions defined in 8.3.3.

Each human body simulation above produces a 3D electric field in the body. Each combination of attributes described above produces a unique human body 3D electric field that shall be called the human body simulation set.

8.5.2 E_{tan} extraction

E_{tan} is defined as the amplitude and phase of the electric field that is tangential to the lead pathway as defined in 8.3.4.3. An E_{tan} data set shall be created for each lead pathway defined in 8.3.4.3 and for each of the unique human body 3D electric field defined by the human body simulation set in 8.5.1. The E_{tan} data set contains the magnitude and phase of the tangential electric field along the entire length of the lead.



Key
 Blue Line is E_{tan} Phase (Deg)
 Black Line is E_{tan} Magnitude (V/m)

Figure 2—Example E_{tan} magnitude and phase

8.5.3 Lead model simulation and pdf

The E_{tan} data sets extracted in 8.5.2 are applied to all lead models defined in 8.3.5. The result of this simulation is the power delivered to the hotspot. The number of individual simulation results will range from tens of thousands to millions, depending on the number of elements in the human body simulation set, the number of birdcage coil models, and the number of lead pathways.

The combination of all of the results defines a probability distribution function (pdf or histogram) of the power delivered to the hotspot. Each lead length of a given model shall have an independent pdf.

8.5.4 Uncertainty analysis

The model prediction uncertainty, $u_{predict}$ and the radiated test system uncertainty, u_{exp} , shall be determined. Additional guidance on measurement error and uncertainty can be found in [9][10][11][12][13].

NOTE 1 Human body electromagnetic simulations are used to determine AIMD electric field exposures. The simulation space should represent the relevant patient population, and transmit RF coils, polarizations, and patient postures specified in the MR Conditional labelling. If a reduced set of simulations is used with limited variation of a particular parameter(s), additional uncertainty analysis may be used to account for the expected variation in the simulation space.

NOTE 2 AIMD location, orientation, and lead pathways that span the clinical use cases identified in the proposed MR Conditional labelling are required. Uncertainty analysis does not apply to these parameters.

8.6 Physiologic response

The output of 8.5 is a probability distribution of power levels expected over a broad range of clinical use conditions. To complete the RF lead induced tissue heating analysis the impact of the power deposition shall be quantified. The impact can be quantified using CEM43 as described in 8.6.1 or using the change in pacing capture threshold (ΔPCT) as described in 8.6.2.

A unique attribute of cardiac lead heating is that the hotspot spatial temperature distribution resembles that of a point source. The temperature drops very rapidly as a function of distance from the source. In addition, the normal lead implant process, healing response, and foreign body response produces scar tissue around the lead tip. The viable cardiac tissue that is responsible for initiating a cardiac contraction is at a reduced temperature because it is some

distance from the hotspot. The steep temperature profile and the distance to viable cardiac tissue should be included when analyzing cardiac tissue heating in the vicinity of the hotspots. Therefore, the spatial distribution of the hot spot for either CEM43 or Δ PCT should match the radiated exposure. In addition, for the CEM43 method, temperature of interest is at the viable cardiac tissue and not immediately at the hotspot.

8.6.1 CEM43 (cumulative equivalent minutes at 43 °C)

CEM43 $\leq$ 120 min (45 °C for 30 min) is the safe limit from chronic damage to cardiac tissue. See Annex C for rationale and references.

8.6.2 Change in pacing capture threshold (Δ PCT)

Cardiac cells in the vicinity of the lead tip electrodes are very sensitive to temperature. At temperature T_1 the cardiac cells are stunned and temporarily cease to initiate a contraction. The increased distance from the pacing electrode to the nearest viable cell increases, which produces an increase in PCT. These stunned cells recover with time and the pacing capture threshold returns to its original value.

There is a second higher temperature T_2 that produces permanent tissue necrosis. The body's healing response will replace the damaged cardiac cells with scar tissue. The permanent increase in the distance to the nearest viable cardiac tissue produces a permanent increase in PCT.

Staying below T_1 is completely safe because the nearest viable cardiac cells are never affected by excessive temperature. Exceeding temperature T_1 but staying below temperature T_2 will temporarily stun some cardiac cells and produce an increase in PCT. This condition is also safe provided the pacing system is capable of pacing at a high enough level to provide sufficient pacing safety margin until the PCT returns to baseline (days to weeks).

8.6.2.1 Acute versus chronic insult response

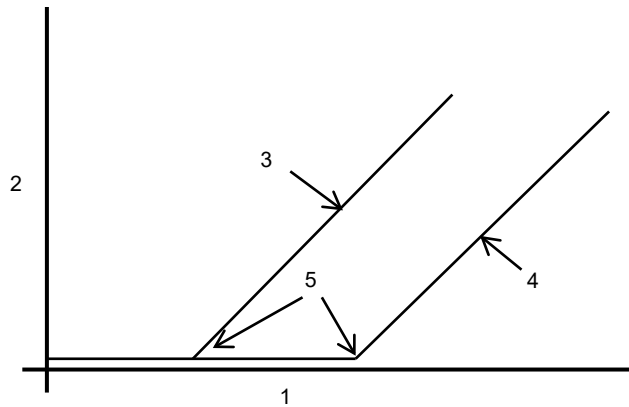
An animal (canine or swine) study is performed to develop the relationship between power deposition and the change in pacing capture threshold (Δ PCT). The animal study can be designed to look at the short term (acute insult response) change in PCT or the short term and the long term (chronic insult response) change in PCT.

The short-term change in PCT is always required because it determines the short term (immediately after MRI) safety profile of the patient. The long-term change in PCT determines if there has been any tissue necrosis, which is undesirable. Since the long-term response PCT change is always less than the short-term change, a safety analysis could be based solely on the more conservative short-term change. Alternatively, if the pacing system is capable of pacing at a high enough level to provide sufficient pacing safety margin until the PCT returns to baseline, the long-term response can be used for the safety analysis.

8.6.2.2 Δ PCT versus power data set

Figure 3 illustrates ideal Δ PCT versus power plots for the acute (short term) insult response and the chronic (long term) insult response. For low power levels (to the left of the first inflection point) there is no observable change in PCT. As the power level is increased above the first inflection point, there is sufficient heating to stun the viable cardiac tissue closest to the lead tip. This tissue stunning causes an increase in PCT that will recover over time. Increasing the power above the second inflection point produces a permanent change in PCT which is an indication of tissue necrosis.

The PCT recovery takes place over a period of hours to weeks. Some recovery can be noticed fairly quickly, but a complete recovery may exceed 4 weeks [14]. Waiting a longer period of time produces a more accurate assessment of tissue necrosis and the long-term impact which is the patient safety concern. The tradeoff is the overall length of the animal study versus a small incremental improvement in the result. A waiting period of 1 to 2 weeks is practical; however, this document places no limitation on the waiting period to assess the chronic insult response. In fact, the practitioner is free to use only acute insult response data in their safety assessment.



Key

1. X-axis = power
2. Y-axis = Δ PCT
3. Acute insult response
4. Chronic insult response
5. Inflection points

Figure 3— Δ PCT versus power

There is a significant variation in the physiologic response (Δ PCT) as a function of power between different individuals and pacing sites. For a given Δ PCT level (e.g., 0.5 or 1 V change), and across many animals, each injected power level will have a probability level ranging from 0 to 1. The probability of a Δ PCT will approach 1 as the power level increases. The plot of probability of Δ PCT vs. power will look similar to Figure 3, except the y-axis (2) will be probability and the different curves will be the Δ PCT changes (3 or 4), where the lower power inflection point corresponds to the lower Δ PCT.

The number of power levels and the spacing between the power levels is up to the discretion of the practitioner. It is worth noting that data points below the inflection point are non-events, i.e., they do not contribute to determining the location of the inflection point or the slope of the line. Likewise, excessive power levels do not provide a lot of valuable information.

8.6.2.2 Power level determination

The simulation results from 8.5 provide power deposition. It is essential that pre-clinical study data be collected also in terms of power deposition. The pre-clinical study can be performed using either standard leads or custom designed power delivery devices (PDD) implanted in a suitable animal model. The RF power deposited at the Tip assembly shall be validated no matter which devices are used for RF power injection by verifying that injected RF power produces an equivalent normalized spatial SAR or Δ T distribution as the radiated case: SAR or Δ T measurements shall be made at several locations in the axial and radial directions. The measurement locations for each direction shall be chosen to include the maximum and to encompass the 50 % of maximum and 25 % of maximum locations. The injected and radiated spatial distributions are considered equivalent if the measured differences are within the previously established measurement uncertainty.

8.6.2.2.1 Standard leads

Standard leads may be used for RF power injection in the pre-clinical study.

The methods described in Annex A shall be followed for the RF power delivery, because at frequencies significantly below 64 MHz propagation phase effects can be ignored. Alternatively, manufacturers may use data collected with the historical method described in Annex B, because at 64 MHz, the sensitivity to surrounding dielectric materials (tissues) and flexure along the lead body cannot be ignored.

8.6.2.2.2 Custom power delivery devices

Rather than using a standard lead, a custom PDD can be designed. In order to provide similar RF power distribution around the electrode, the distal assembly of the custom PDD containing the tissue contacting electrodes shall be

identical to the standard lead. The body of the PDD contains a uniform coaxial or other type of waveguide conductor to minimize RF loss and also reduce sensitivity to surrounding dielectric materials and flexure when implanted. The tip to tissue delivered power of the custom PDD is equal to the forward power into the PDD proximal end connector minus any RF losses along the PDD body. The power delivered can be measured using calorimetry or other techniques. The RF power delivered to the tip assembly shall be validated.

The distal end impedance and lead length *in vitro* shall approximately match the *in vivo* scenario with any expected impedance variation accounted for in the uncertainty analysis. Additionally, the common mode and impedance mismatch shall be accounted for in the uncertainty analysis.

8.6.2.2.3 Power delivery signal loss

When the termination impedance is not equal to the characteristic impedance, the power delivery lead will have some amount of signal loss due to shield currents. There are propagation modes between lead conductors and the surrounding TSM or biologic tissue which can represent an unaccounted signal loss. The effects of any signal loss shall be quantified and taken into account when determining the lead electrode delivered power if injecting at 64 MHz.

8.7 Combining simulated power profile with physiologic response

The modelling and simulation environment provide a probability distribution function (pdf) of power covering a wide range of clinically relevant use conditions. CEM43 or Δ PCT versus power animal studies are used to assess the physiologic impact of the delivered power.

CEM43 has the benefit of being much easier because it takes advantage of thermal damage research performed by others. Δ PCT versus power is relatively new and there is nothing published that could be used directly. However, Δ PCT versus power provides a much more accurate assessment of cardiac tissue damage and will allow high power levels to be tolerated. The downside is expensive and time-consuming animal studies to collect the required data.

The following subclauses describe methods for combining the simulation results with the chosen physiologic response model to determine the safety of a cardiac lead.

8.7.1 CEM43

The simulation output is the PDF of power in the *in vitro* environment. The deposited power can be directly transferred to the *in vivo* environment. The deposited power is an input to a thermal model of the *in vivo* environment with hot spot geometry, material properties of the lead, thermal properties of the heart muscle, thickness of scar tissue relevant to implant site, thermal properties of scar tissue, and convective properties of blood. Annex N of AAMI/ISO TIR10974 contains these parameters. The output of the thermal model is the *in vivo* temperature at the viable tissue adjacent to the hotspot.

8.7.2 Δ PCT

The result of the simulations from 8.5 is in power and the animal study provides Δ PCT versus power, so no unit conversion is required.

The result of the simulations define a power deposition probability distribution function. A preclinical study may be designed to provide the probability of a change in PCT as a function of power deposition. The two probability functions can be combined to estimate (or bound) the probability of observing a change in PCT as a result of getting an MRI (e.g., the clinical Δ PCT distribution). For example, each predicted power value in the human simulation pdf can be mapped to measured Δ PCT(s) found at the same power level in the animal study. Separate probabilities can be derived for the acute insult response and the chronic insult response if the animal study is designed to collect both.

8.8 Requirement

8.8.1 CEM43

CEM43 $\leq$ 120 min (45 °C for 30 minutes) is the safe limit from chronic damage to cardiac tissue. See to Annex C for rationale and references.

8.8.2 Δ PCT

There are two requirements, one for the acute insult response (as measured within 2-hours post power injection) and another for the chronic insult response.

8.8.2.1 Acute insult response requirement while in MRI mode

The requirement for the acute insult response is that there should be no patient harm resulting from a loss of capture (LOC). The risk assessment per the quality system will determine the acceptable level for probability associated with a loss of capture (P_{LOC}). Note that this acute requirement applies only to an RV lead as RA or LV LOC will not result in critical harm. The assessment assumes that MR Conditional labelling requires a capture threshold check post-MRI, if this post check is not required then justification for safety after reverting out of MRI mode is necessary.

Methodology:

1. Choose an acceptable P_{LOC} .
2. Select the Pacing amplitude and duration from the MRI mode pacing amplitude (MRIMPA).
3. Adjust MRIMPA to the prescan threshold duration $MRIMPA_{prescan}$ by applying the strength duration relationship $V_{pace} = b \times \left(1 + \frac{c}{d}\right)$ where b is rheobase and c is chronaxie and d is the pulse width.
4. Determine the pacing threshold rise (Δ PCT) clinical distribution as defined in 8.7.2.
5. Determine the post scan PCT (i.e., $PCT_{post\ scan}$) distribution by combining the patient population pre-scan PCT distribution, with the Δ PCT distribution from Step 4.
6. Compare Δ PCT ($@P_{LOC}$) to acceptance criteria for Method 1 or compare $PCT_{post\ scan} (@P_{LOC})$ to acceptance criteria for Method 2.

Acceptance criteria (select one method):

1. Method 1: A simple approach assumes that all patients have the maximum allowed pre-scan threshold requirement per MR Conditional labelling of PreMRIThreshold. If the following condition is met, then loss of capture will not occur at the P_{LOC} with a safety margin:

$$\Delta PCT (@P_{LOC}) < (MRIMPA_{prescan} / \text{safety factor}) - (\text{PreMRIThreshold}) \quad (3)$$

2. Method 2: Extract from the $PCT_{post\ scan}$ distribution the PCT associated with P_{LOC} which is called $PCT_{post\ scan} (@P_{LOC})$. If the following condition is met, then loss of capture will not occur at the P_{LOC}

$$PCT_{post\ scan} (@P_{LOC}) < MRIMPA_{prescan} / \text{safety factor} \quad (4)$$

Example:

1. Choose P_{LOC} of 1:10,000
2. MRIMPA Pacing amplitude and duration is 5V @ 1.0 ms.
3. Adjust MRIMPA to the pre-scan threshold duration (e.g., 5V @ 1 ms is same efficacy as 7.5V @ 0.5 ms) $MRIMPA_{0.5}$ by applying the strength duration relationship $V_{pace} = b \times \left(1 + \frac{c}{d}\right)$ where b is rheobase and c is chronaxie (assume 1 ms for this example) and d is the pulse width.
4. Apply an amplitude safety factor of 1.5x by dividing $MRIMPA_{0.5}$ by 1.5 (e.g., 7.5 @ 0.5 ms / 1.5 = 5V @ 0.5 ms). Therefore, a threshold up to 5V @ 0.5 ms compared to the MRIMPA of 5V @ 1 ms would still have charge safety factor of 2x before capture is lost. Hence MRIMPA will ensure capture up to that threshold.

NOTE For many years it was common clinical practice to program the pacing amplitude using a 3x or higher safety factor, i.e. pace using an amplitude level 3 times greater than required to capture the heart. This was due to the margin covering all variation between the 6 month or yearly office visits.

The use of automatic pacing amplitude adjustments based on daily PCT measurements has typically reduced the safety factor to 2x [15], [16]. This is acceptable because the time period of normal variation is reduced to a day or less.

The time period from MRI Mode programmed on to post scan check is even shorter, on the order of hours. Therefore, a safety factor of at least 1.5x in pace amplitude assuming a fixed pulse width is used.

5. Determine the pacing threshold rise (Δ PCT) clinical distribution.

6. Acceptance criteria using Method 1:

Using a fixed PreMRIThreshold of 2.5V @ 0.5 ms, if Δ PCT (@ 1:10,000) is less than 2.5V (e.g., 5V @ 0.5 ms - 2.5V @ 0.5 ms) then the acceptance criteria is met.

7. Acceptance criteria using Method 2:

Using prescan PCT distribution combined with the Δ PCT distribution = PCT_{post scan} distribution, if PCT_{post scan} (@ 1:10,000) is less than 5 @ 0.5 ms then the acceptance criteria is met.

8.8.2.2 Chronic insult response requirement

For the right atrium or right ventricle, it is acceptable to have up to 0.5V Δ PCT due to MRI at an occurrence rate of 1:100.

It is acceptable to have $0.5V < \Delta$ PCT $\leq 1V$ due to MRI at an occurrence rates of 1:100 provided the impact to longevity is assessed.

For the left ventricle, it is acceptable to have up to 1V Δ PCT due to MRI at an occurrence of 1:100.

8.9 Cumulative effect

The cumulative effect refers to multiple RF exposures (MRIs) eventually resulting in tissue damage or a change in PCT. Numerous cumulative effect animal studies have been performed and have demonstrated that there is no cumulative effect for cardiac tissue. Therefore, there is no need for any additional study of the cumulative effect [1].

9 Protection from harm to the patient from device heating

Device heating is defined as heating of the can tissue interface from gradient eddy current flow, RF heating from local SAR enhancement near the can, or heating from the injected RF from the leads.

9.1 Test equipment

The device heating test shall be performed with an RF source, a gradient source, and temperature measurement system as defined in AAMI/ISO TIR10974 Clauses 8.3 and 9.

9.2 Test method

There are three (3) independent heating mechanisms for the IPG enclosure (CAN).

1. Gradient heating from eddy currents.
2. Heating from injected RF from the leads.
3. RF heating of the tissue near the can from local SAR concentrations (without a lead).

Each heating mechanism requires a test method for its assessment.

9.2.1 Gradient induced temperature rise due to eddy currents on the device surface (without leads)

For the gradient induced temperature rise, the data will be either measured or scaled to 42 T/s RMS from Table 4 in Clause 9 of AAMI/ISO TIR10974, based on an implant radius of 20 cm. Similarly, the peak dB/dt value shall be either measured or scaled to $[\sqrt{2} \times 89.9]$ 127 T/s from Table A.2 in Annex A of AAMI/ISO TIR10974. A waveform that satisfies the peak and RMS values is shown in Figure 4 with $T_{off}(T3) = 3.2$ ms, $T_{dwell} = 0$ ms, $t_{slew}(T1) = 0.2$ ms.

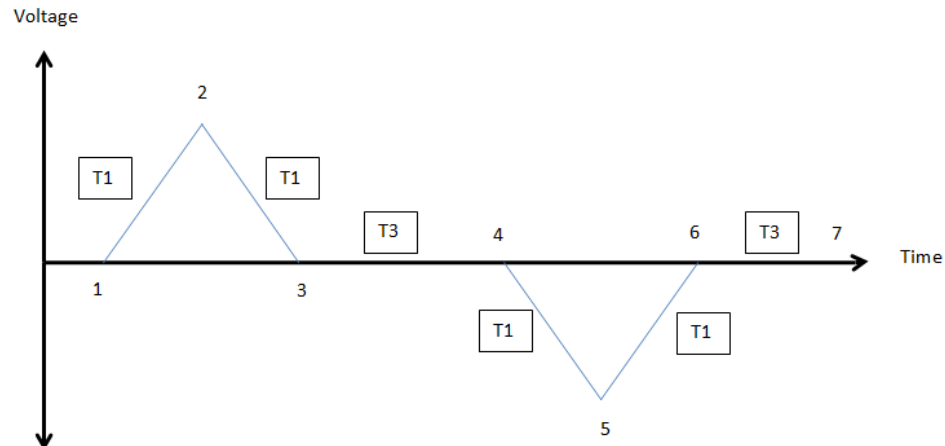


Figure 4—Gradient heating waveform with a peak value of 127 T/s, RMS value of 42 T/s, T1= 0.2 ms, T3= 3.2 ms to be used for gradient can heating assessment

9.2.1.1 Tier 1: Temperature measurement in TSM

Step 1: The purpose of this step is to determine the location of the hotspot while exposing the device to a radiated dB/dt level to produce sufficient thermal SNR. Record the location of hotspot within an accuracy of ± 10 mm.

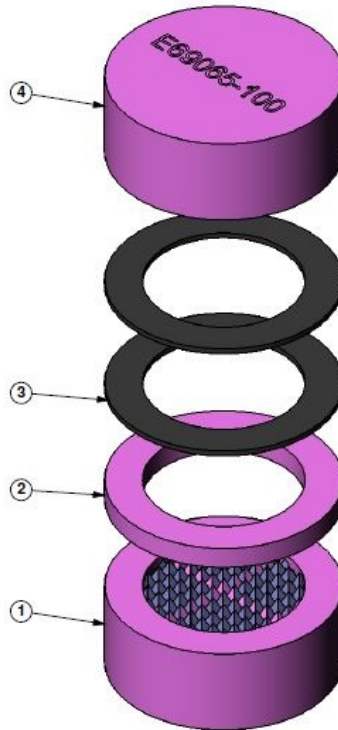
Step 2: Place the device into the gel and wait for 10 min to arrive at thermal equilibrium. Submerge the device without leads (ports plugged) under a minimum of 2.2 cm gelled Saline (e.g., PAA or HEC) as specified in ASTM F2182-11a section X1.2.3. Expose the device while submerged to the radiated dB/dt level with the appropriate RMS value, while measuring the temperature rise at the gradient hot spot. The test duration is 15 min as specified in ASTM F2182 X1.9.1. No further assessment is required if the acceptance criteria is met. If the criterion is not met proceed to Tier 2.

9.2.1.2 Tier 2: Power method

Step 1: The purpose of this step is to determine the location of the hotspot while exposing the device to a radiated dB/dt level to produce sufficient thermal SNR. Record the location of hotspot L1 within an accuracy of ± 10 millimeters.

Step 2: Measure the heating at the hot spot(s) due to radiated gradient field, denoted $T_{\text{radiated}}(t)$. Place the device (without leads), with temperature probes mounted at hot spot(s) determined in Step 1, into a thermally insulating container. An example of a thermally insulating container is shown in Figure 5. Place the container, with the device and probes, into the gradient coil in a region of uniform gradient field. While recording the temperature at the hot spot(s), expose the device to a radiated gradient field with the appropriate RMS dB/dt level for four minutes.

NOTE This duration has been determined to be sufficient to capture the maximum rate of temperature rise.



Key

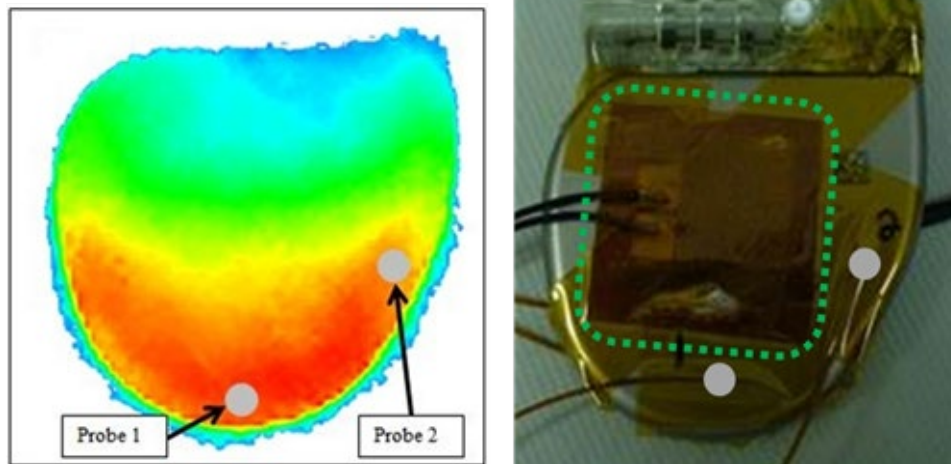
- 1) base (1)
- 2) mid-section
- 3) gaskets
- 4) solid cover

NOTE The container is constructed from foam insulation and is 130.18 mm in diameter by 114 mm tall. The device is placed on the base in the hollow space of the mid-section. Gaskets (3) are placed between the sections. The assembly is held together using tape or another adhesive.

Figure 5—Example of thermally insulating container

Step 3: Measure the heating at the hot spot(s) due to power applied through a resistive heater, denoted $T_{\text{resistive}}(t)$. Mount resistive heater(s) on both sides of the device, covering the majority of the surface but avoiding contact with the temperature probes located at the hot spot(s). An example setup is shown in Figure 6. Place the device, with temperature probes and resistive heaters into the insulating container of Step 2. In a benchtop setup outside the gradient coil, connect the heaters to a power supply and apply a constant power to the resistive heaters for four minutes (duration should be same as Step 2). Record the time-temperature profile at the hot spot(s), $T_{\text{resistive}}(t)$, and the applied power, $W_{\text{resistive}}$, throughout the heating duration. Compute the steady state $dT_{\text{resistive}}(t)/dt$ associated with each level of $W_{\text{resistive}}$ tested.

It is recommended that Step 3 be performed at three power levels with replicates so that the relationship between $dT_{\text{resistive}}(t)/dt$ and $W_{\text{resistive}}$ can be reliably established for use in Step 4. It is recommended that the power levels selected produce similar heating as measured in Step 2.



NOTE The resistive heater is enclosed by the green dashed line (at right); the probes are placed at the hotspots identified by the IR thermal map (at left). Note that the heater does not contact the probes. If the resistive heater covers the device hotspot, the probe can be conservatively placed at the edge of the device.

Figure 6—Example setup with resistive heaters placed on one side of a device

Step 4: Compute the gradient field induced surface power flux, Φ .

- 4a) Compute the steady state $dT_{\text{radiated}}(t)/dt$ over the duration of radiated gradient field exposure.
- 4b) Compute the nominal $dT_{\text{resistive}}(t)/dt/W_{\text{resistive}}$ over the range of applied power.
- 4c) Compute the radiated field induced power on the device:

$$W_{\text{radiated}} = W_{\text{resistive}} / dT_{\text{resistive}}(t)/dt \times dT_{\text{radiated}}(t)/dt$$

- 4d) Compute the gradient field induced surface power flux:

$$\Phi = W_{\text{radiated}} / A_{\text{PG}}$$

where A_{PG} is the surface area of the device.

Step 5: Estimate the *in vivo* tissue temperature rise, $\Delta T_{\text{in vivo}}$, using the following relationship (described in Annex D):

$$\Delta T_{\text{in vivo}} \approx 0.000266 \times \Phi^2 + 0.0632 \times \Phi \quad (5)$$

9.2.2 RF induced temperature rise from injected RF

Step 1: Perform radiated RF testing as specified in Clause 8 of AAMI/ISO TIR10974 while submerged in phantom filled with gelled Saline as specified in ASTM F2182 (matches the diffusivity and heat capacity of the body) with leads, in every port, in a pathway that generates sufficient SNR and a known injected level, and such that the E-field at the CAN is negligible (e.g., the corners or center of the ASTM phantom). The injected RF level (Level_{RF}) at each RF entry port can then be quantified with either measurements or models.

Step 2: Find the location of maximum heating (RF_{inject}) hot spot. This location may be found from multiple temperature probes placed around the device. The purpose of this step is to identify the location of the hottest spot but not necessarily its amplitude.

Step3: Repeat testing in Step 1 while recording temperature rise RF_{inject} for 15 minutes.

Step 4: If the found hot spot is associated with the position of a single RF_{entry} port, scale the measured temperature rise at RF_{inject} hot spot to the 90th percentile RMS power level for that particular RF_{entry} port. However, if the hot spot cannot be associated with the position of a single RF_{entry} point, scale the measured temperature rise at RF_{inject} hot spot to the 90th percentile RMS average or total power level from all the RF_{entry} ports. RMS levels are determined as specified in Clause 15 of AAMI/ISO TIR10974.

9.2.3 RF Induced Temperature Rise from local E-field at the CAN

Step 1: Identify the 90th percentile E-field value at the CAN for the MR Conditional labelled SAR. This is obtained by either by doing a statistical analysis on the average E_{tan} of the proximal 10 cm lead segment or doing a Tier 2 analysis of the CAN location. For normal operating mode this is 110 V/m RMS.

Step 2: Generate an E-field magnitude in a gelled Saline phantom to obtain sufficient SNR. Align the long dimension of the CAN with the generated E_{tan} . For example, this can be obtained midline near the edge of the ASTM phantom, where field magnitude is high and uniform.

Step 3: Find the location of maximum heating (RF_{pocket}) hot spot. This location should be found from multiple temperature probes placed around the device. The purpose of this step is to identify the location of the hottest spot but not necessarily its amplitude.

Step 4: Measure temperature rise for a ≥ 15 min exposure at the RF_{pocket} .

Step 5: Scale to the 90th percentile E-field value from Step 1.

9.2.4 Reporting the results from injected and radiated test

The AIMD manufacturer shall report the temperature rise due to gradient, local E-field RF and Injected RF separately.

9.3 Requirement

The acceptance criteria are listed in Table 6. The references and rational can be found in Annex C.

Table 6—Acceptance criteria for pocket tissue

Tissue Type	Safe Temperature limit (°C)	Duration (min)	CEM43 Equivalent
Skin Pain	≤ 44	Any	N/A
Skeletal Muscle Damage	45	30	120
NOTE Skeletal muscle is the worst-case tissue type for damage when considering start temperatures (see CEM43 in Annex C).			

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

This test applies the MR-induced vibrations test method from AAMI/ISO TIR10974 to the CRM devices covered by this standard. The potential for patient discomfort is acknowledged but does not require evaluation. The patient can halt the MR scan at any time if discomfort is experienced. The potential for induced vibration of a cardiac lead, while theoretically possible, does not require evaluation. A cardiac lead does not contain conductive planes large enough to generate measurable vibration, and therefore no testing is required in accordance with AAMI/ISO TIR10974.

10.1 Test Method

The MR-induced vibration test of AAMI/ISO TIR10974, Clause 10, is applicable and modified as shown in Figure 7. The test provides two Tiers (pathways) for evaluating MR-induced vibration. Tier 1 uses a direct scanner application and carries a heavy test burden, whereas Tier 2 uses conservative approximations to reduce test burden.