American National Standard

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COMMITTEE DRAFT FOR VOTE

Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

Developed by
Association for the Advancement of Medical Instrumentation

Approved 200X by
American National Standards Institute, Inc.

Abstract: This standard specifies test methods appropriate to many interference frequencies, whether high or low, near or far field. The standard may specify performance limits or require disclosure of performance in the presence of electromagnetic emitters where appropriate. It provides manufacturers of electromagnetic emitters with information about the level of immunity to be expected from active implantable cardiovascular devices.

Keywords: test methodology, active implantable medical devices, electromagnetic compatibility, electromagnetic emitters, cardiovascular devices

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International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (NOTE—Documents are sorted by International designation.)

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

International designation	U.S. designation	Equivalency
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI VP20: 19941	Major technical variations
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:200x [1]	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161: 2000	ANSI/AAMI/ISO 14161:2000	Identical

[1] FDIS approved; being prepared for publication.

International designation	U.S. designation	Equivalency
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

Committee representation – *TO BE UPDATED by AAMI, if included in final document*

Association for the Advancement of Medical Instrumentation

CRMD (former Pacemaker) Committee

The AAMI ElectroMagnetic Compatibility (EMC) Task Force developed this standard under the auspices of the AAMI CRMD (former Pacemaker) Committee.

At the time this document was balloted, the AAMI CRMD (former Pacemaker) Committee had the following members:

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	Robert Founds, St. Jude Medical Inc.
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	Robert Founds, St. Jude Medical Inc.
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	Veronica Ivans, Medtronic Inc.
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	Richard Wessels, Guidant Corp.
	Donald Witters, U.S. Food and Drug Administration
	Robert Stevenson, Wilson-GreatBatch
	Wes Clement, Medtronic, Inc.
	Joseph Ballis, Medtronic, Inc.
	Josef Vock, St. Jude Medical, Inc.
	Roger Carrillo, MD, Mount Sinai Medical Center, Miami

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

This voluntary standard was developed by the ElectroMagnetic Compatibility (EMC) Task Force of the AAMI Pacemaker Committee. It is intended to apply to active implantable cardiovascular devices (pacemakers and implantable cardioverter defibrillators [ICDs]) and reflects the conscientious efforts of the task force to develop a standard for those performance levels that could be reasonably achieved at the present time.

As used within the context of this standard, “shall” indicates requirements to be followed strictly in order to conform to the standard; “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action is undesirable but not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the standard; “can” is used as a statement of possibility and capability; “must” is used only for those situations which cannot be otherwise, as in the example “Monday must follow Sunday.”

The concepts incorporated herein are not inflexible or static. They are reviewed periodically to assimilate new data and advances in technology. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the America National Standard, *Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators* (ANSI/AAMI PC69, second edition:200x), but it does provide important information about the development and intended use of the document.

Introduction

The number and the types of electromagnetic emitters to which patients with active implantable cardiovascular devices are exposed in their day-to-day activities have proliferated over the last two decades. This trend is expected to continue. The interaction between these emitters and active implantable cardiovascular devices (pacemakers and implantable cardioverter defibrillators [ICDs]) is an ongoing concern of patients, industry, and regulators, given the potential life-sustaining nature of these devices. The risks associated with such interactions include device inhibition or delivery of inappropriate therapy that, in the worst case, could result in serious injury or patient deaths.

Standard test methodologies allow manufacturers to evaluate product electromagnetic compatibility performance and demonstrate that the product achieves an appropriate level of electromagnetic compatibility in uncontrolled electromagnetic environments that patients may encounter.

It is important that manufacturers of transmitters and any other equipment producing electromagnetic fields (intentional or unintentional) understand that such equipment may interfere with the proper operation of pacemakers or implantable cardioverter defibrillators (ICDs).

It is important to understand that these interactions may occur despite conformance of the pacemaker or ICD to this standard and the conformance of emitters to the relevant human exposure safety standards and pertinent regulatory emission requirements, e.g. the US Federal Communications Commission.

Compliance with biological safety guidelines does not necessarily guarantee EM compatibility with pacemakers and ICDs. In some cases, the reasonably achievable electromagnetic immunity performance for pacemakers and ICDs falls below these biological safety limits.

The potential for emitter equipment to interfere with a pacemaker or ICD is complex and is dependent on the following factors:

— Frequency content of the emitter

— Modulation format

— Power of the signal

— Proximity to the patient

— Coupling factors

— Duration of exposure

Pacemakers and ICDs are life-sustaining devices designed to sense low-level physiological signals (as low as 0.1mV) that have frequency content up to several hundred Hertz. For patient safety and comfort these devices are small in size, offer many therapeutic features and have a long battery life. These highly desired features combined with the intrinsic functionality limit the size and number of components and thus place practical constraints on the capability to control EMI.

An emitter with a fundamental carrier frequency up to several hundred Hertz has the potential to directly be sensed by the pacemaker or ICD. Also, higher frequency carriers that are modulated up to several hundred Hertz with sufficient proximity and power may be sensed by the pacemaker or ICD.

Additional detail regarding this issue can be found in Annex M.

This standard addresses the electromagnetic compatibility of pacemakers and ICDs up to 3,000-MHz and is divided in several sections.

1) $0 \leq f < 450$ MHz

In the lower frequency bands (< 450 MHz), there are many EM emitters such as broadcast radio and television and a number of new technologies or novel applications of established technologies that may increase the likelihood of interaction between the emitters and patients' pacemakers and ICDs. A few examples are:

— electronic article surveillance (EAS) systems;

— access control systems (radio-frequency identification - RFID);

— new wireless service in the ultra high frequency (UHF) and very high frequency (VHF) bands;

— magnetic levitated rail systems;

— radio-frequency (RF) medical procedures such as high frequency surgery and ablation therapy;

— metal detectors; and

— magnetic resonance imaging.

— experimental use of transponders for traffic control.

2) 450 MHz ≤ f < 3,000 MHz

These are the frequencies (f) that are typically associated with personal handheld communication devices (e.g., wireless telephones and two-way radios).

Two decades ago, relatively few pacemaker patients used handheld transmitters or were exposed to EM fields from portable transmitters. Handheld, frequency-modulated (FM) transceivers for business, public safety, and amateur radio communications represented the predominant applications. However, the environment has changed rapidly during the last 15 years, with wireless phone systems becoming increasingly common as this technology matured and received widespread public acceptance. Thus, it is becoming increasingly likely that a large portion of the pacemaker and ICD patient population will be exposed to EM fields from portable wireless phone transmitters operated either by themselves or by others. Also, it should be expected that the wireless technology revolution would continue to evolve new applications using increasingly higher microwave frequencies.

Most electronic equipment, including external medical devices, has been designed for compatibility with relatively low-amplitude EM conditions. Recognizing the wide range of electromagnetic environments that patients could encounter, implantable devices have been designed to tolerate much higher amplitude EM conditions than most other electronic products. However, in some instances even this enhanced immunity is not sufficient to achieve compatibility with the complex electric and magnetic fields generated by low-power emitters located within a few centimeters of the implantable device. Mid-1990s studies demonstrated that some models of pacemakers and ICDs had insufficient immunity to allow unrestricted use when in close proximity to some handheld emitters (e.g., wireless telephones and two-way radios). While operating restrictions can avoid EM interaction with implantable devices, this approach is not viewed as an optimum long-term solution. Rather, improved EM compatibility is the preferred method for meeting patient expectations for using wireless services with minimal operating restrictions.

Some technological factors contributing to the expanding variety of emitters to which patients may be exposed now are:

— smaller wireless phones;

— the introduction of digital technology; and

— peak transmitter power.

Wireless phone size has now been reduced sufficiently so that it is possible for patients to carry a phone that is communicating or in standby mode in a breast pocket immediately adjacent to a pectorally implanted device.

Since 1994, reported studies have indicated that interference effects in pacemakers are more severe from digital phones than from analog phones. In February 2005, there were more than 175 million digital subscribers in the U.S (source CTIA website **www.ctia.org**, 25 February 2005).

The various wireless phone standards allow for a variety of power levels and modulation schemes. Most digital wireless phones are capable of producing greater peak transmitted power than analog phones are capable of producing. The above factors contribute to greater potential interactions with pacemakers and ICDs.

For frequencies of 450 MHz ≤ f ≤ 3,000 MHz the standard specifies testing at 120 mW net power into a dipole antenna to simulate a handheld wireless transmitter 15 cm from the implant. An optional characterization test is described that uses higher power levels to simulate a handheld wireless transmitter placed much closer to the implant. Claims that the manufacturer may wish to make based on the results of the optional characterization must be negotiated between the manufacturer and the appropriate regulatory authorities.

3) f ≥ 3,000 MHz

This standard does not require testing of devices above 3 GHz. The upper frequency limit chosen for this standard reflects consideration of the following factors: (1) the types of radiators of frequencies above 3 GHz, (2) the increased device protection afforded by the attenuation of the enclosure and body tissue at microwave frequencies, (3) the expected performance of EMI control features that typically must be implemented to meet the lower frequency requirements of this standard, and (4) the reduced sensitivity of circuits at microwave frequencies. Additional details can be found in Section 5 of the present standard.

In conclusion, it is reasonable to expect that patients with pacemakers and ICDs will be exposed to increasingly complex EM environments. Also, the rapid evolution of new technologies and their acceptance by patients will lead to growing expectations for unrestricted use. In view of the changing EM environment and customer expectations, manufacturers will need to evaluate their product designs to assess compatibility with the complex fields, a broad range of frequencies, and a variety of modulation schemes associated with existing and future applications.

Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators

1 Scope

This standard sets forth a comprehensive test methodology for the evaluation of the electromagnetic compatibility of active implantable cardiovascular devices (pacemakers and implantable cardioverter defibrillators).

The standard details test methods appropriate to the interference frequencies at issue. It specifies performance limits or requires disclosure of performance in the presence of EM emitters where indicated. In addition, it provides manufacturers of EM emitters with information about the level of immunity to be expected from active implantable cardiovascular devices.

This standard addresses the interaction of pacemakers and ICDs with EM emitters operating across the electromagnetic spectrum. It divides the EM frequency spectrum into the following three discrete segments:

0 Hz $\leq f <$ 450 MHz

450 MHz $\leq f \leq$ 3,000 MHz

$f >$ 3,000 MHz

2 Normative references –

The following documents contain provisions that, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to use the most recent editions of the documents indicated below. The Association for the Advancement of Medical Instrumentation maintains a register of currently valid AAMI/American National Standards.

IEEE C95.1: 1999, IEEE Standard for Safety Levels with Respect to Human Exposure to Radio-Frequency Electromagnetic Fields, 3 kHz to 300 GHz

IEEE C95.6: 2003, IEEE Standard for Safety Levels with Respect to Human Exposure to Electromagnetic Fields in the Frequency Range 0 - 3 kHz

1999/519/EC, Council Recommendation on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)

ICNIRP Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic fields (up to 300 GHz), Health Physics, April 1998, Volume 74, Number 4, p 494-522

EN 45502-2-1: 2003, Active implantable medical devices – Part 1: Particular requirements for devices intended to treat bradyarrhythmia

PrEN 45502-2-2: 2006, Active implantable medical devices – Part 2: Particular requirements for devices intended to treat tachyarrhythmia (includes implantable defibrillators)

3 Definitions, symbols, and abbreviations

3.1 Implantable pacemaker: Active implantable medical device intended to treat bradyarrhythmias, comprising an implantable pulse generator and leads.

3.2 Implantable cardioverter defibrillator (ICD): Active implantable medical device intended to detect and correct tachycardias and fibrillation by application of cardioversion/defibrillation pulses to the heart, comprising an implantable pulse generator and leads

3.3 Inhibition generator: Equipment that generates a simulated heart signal for pacemakers and ICDs

3.4 Harm: Physical injury or damage to the health of people, or damage to property and environment [ISO/IEC Guide 51: 1999, definition 3.6]

Table 1 contains a description of the acronyms and abbreviations used in this standard.

Table 1—List of acronyms and abbreviations

Acronym or Abbreviation	Description
A	atrial
AAMI	Association for the Advancement of Medical Instrumentation
ACA	antenna cable attenuation (+dB)
AdBm	power meter “A” reading (dBm)
ASIC	Application Specific Integration Circuit
ATP	antitachycardia pacing
BdBm	power meter “B” reading (dBm)
bpm	beats per minute
CW	continuous wave
dB	decibel
dBi	decibels above an isotropic radiator
dBm	decibels above a milliwatt
DCF	directional coupler forward port coupling factor (+dB)
DCR	directional coupler reflected port coupling factor (+dB)
DUT	device under test
ECG	electrocardiogram
EGM	electrogram
EM	electromagnetic
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EN	European Norm
ESMR	enhanced specialized mobile radio
f	frequency
FP	forward dipole power (mW)
FPdBm	forward dipole power (dBm)
ICD	implantable cardioverter defibrillator
ICNIRP	International Commission on Non-Ionizing Radiation Protection
IEEE	Institute of Electrical and Electronics Engineers
λ	wave length
NP	net dipole power (mW)
o.d.	outside diameter
Ωcm	measure of resistivity (Ohm-cm)
PCS	personal communication services
PVARP	post ventricular atrial refractory period
RF	radio frequency
RMS	root mean square
RP	reflected dipole power (mW)

Acronym or Abbreviation	Description
RPdBm	reflected dipole power (dBm)
SMA	subminiature “A”
T_{shs}	simulated heart signal interval
V	ventricular
VF	ventricular fibrillation
VSWR	voltage standing wave ratio
VT	ventricular tachycardia

NOTE Throughout the standard, DUT has been used to designate both pacemakers and ICDs. When a certain test, requirement, etc is applicable only to pacemakers or ICDs, these designations were used.

4 Test requirements for the frequency band—0 Hz ≤ f < 3,000 MHz

4.1 General

Implantable pacemakers and ICDs shall not cause any **harm** because of susceptibility to electrical influences due to external electromagnetic fields, whether through malfunction of the device, damage to the device, heating of the device, or by causing local increase of induced electrical current density within the patient.

Compliance shall be confirmed if after performing the appropriate procedures described in 4.2 to 4.8, the values of the characteristics when measured are as stated by the manufacturer specification of the **DUT**. All requirements shall be met for all settings of the **DUT**, except:

For pacemakers: those settings the manufacturer specifies in the accompanying documentation as not meeting the requirements of 4.4 and 4.5.1.1

For ICDs: those settings the manufacturer specifies in the accompanying documentation as not meeting the requirements of 4.5.1.2

NOTE 1 This does not mean that all combinations of settings are tested but at least the setting to which the device is pre-set by the manufacturer should be tested completely.

NOTE 2 If the case of the pulse generator is covered with an insulating material, the pulse generator (or part of it) should be immersed in a 9 g/l saline bath held in a metal container; the metal container should be connected directly to the test circuit as applicable in each test set up.

NOTE 3 Manufacturers that utilize Automatic Gain Control function (or similar feature) for sensing purpose should include a detailed test method.

4.2 Induced lead current

The **DUT** shall be constructed so that ambient electromagnetic fields are unlikely to cause hazardous local increases of induced electrical current density within the patient.

NOTE The following test is intended to address the compatibility of the intracardiac signal sensing. Any additional physiological sensors may be turned off during testing unless otherwise specified. Tests for these additional sensors are under consideration.

4.2.1 Pacemakers

Test equipment: Use the test set-up defined in Figure 2, tissue equivalent interface circuit defined by Figure D1and Table D1a; the low pass filter defined by Figure D4; two oscilloscopes, input impedance nominal 1 MΩ; and test signal generators, output impedance 50 Ω.

Test signal: Two forms of test **signal** shall be used.

Test **signal** 1 shall be a sinusoidal signal of 1 V peak-to-peak amplitude. The frequency, shall be either swept over the range 16.6 Hz to 20 kHz at a rate of one decade per minute, or applied at a minimum of four distinct, well-spaced frequencies per decade between 16.6 Hz and 20 kHz with an evenly distributed dwell time of at least 60 s per decade.

Test **signal** 2 shall be a sinusoidal carrier signal, frequency 500 kHz, with continuous amplitude modulation at 130 Hz (double sideband with carrier) [see Figure 1].

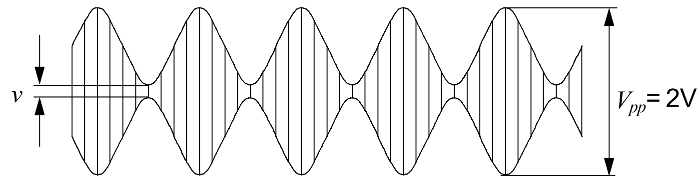

Figure 1 — Test signal 2

The maximum peak-to-peak voltage of the modulated signal shall be 2 V. The modulation index (M) shall be 95 percent, where:

$$M = \frac{V_{pp} - v}{V_{pp} + v} * 100$$

Test procedure: The test signal generator shall be connected through input C of the interface circuit as shown in Figure 2. The test **signal** shall be measured on the oscilloscope connected to monitoring point D.

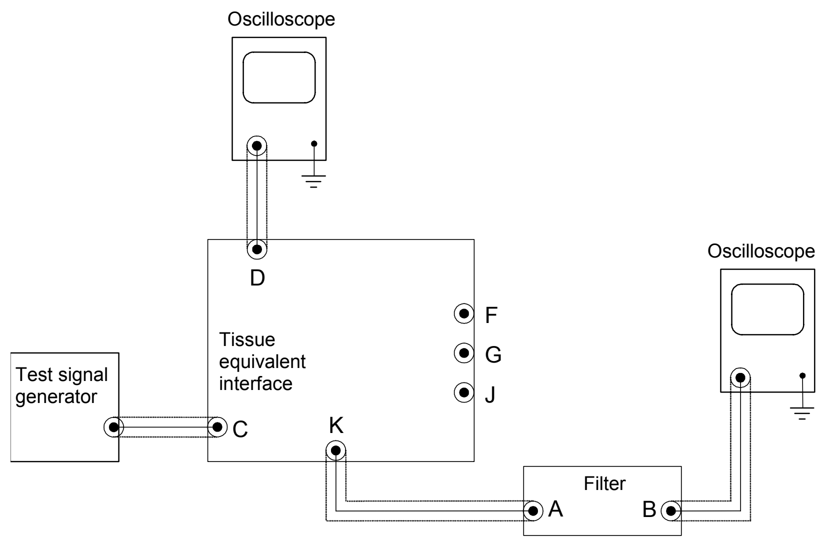

Figure 2 — Test set-up for measurement of induced current flow in pacemakers and ICDs

The induced electrical current is measured by the oscilloscope connected to test point K through the low pass filter (as defined in Figure D4) as shown in Figure 2. When the test **signal** 1 is being used, the low-pass filter shall be switched to bypass mode.

The capacitor Cx of the interface circuit [see Figure D1] shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator [see Annex E].

NOTE 1 It is not mandatory that a current measurement be made in the period from 10 ms preceding a stimulation **pulse** to 150 ms after the stimulation **pulse**.

The **pacemaker** shall be categorized into one or more of four groups as appropriate:

- single channel unipolar pacemakers shall be Group a);
- multichannel unipolar pacemakers shall be Group b);
- single channel bipolar pacemakers shall be Group c);
- multichannel bipolar pacemakers shall be Group d).

NOTE 2 The bipolar channel should be tested in unipolar and/or bipolar according to the programmability of the device and should be changed where applicable.

Any **terminal** of the **pacemaker** not being tested shall be connected to the channel under test through a resistor of value R $\geq$ 10 kΩ as specified by the manufacturer.

Group a) The **pacemaker** shall be connected to the coupled outputs F and G of the tissue equivalent interface (as shown in Figure 3), with output J connected to the case.

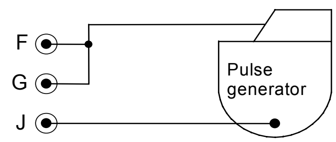

Figure 3 - Connection to a single channel unipolar pacemaker

Group b) Every input/output of the **pacemaker** shall be connected in turn to the coupled outputs F and G of the tissue equivalent interface [as shown in Figure 4], with output J connected to the case.

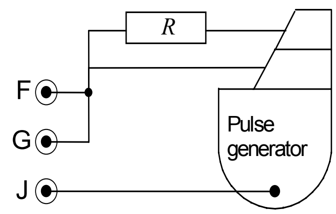

Figure 4 - Connection to a multichannel unipolar pacemaker

Group c) Common mode performance shall be tested with the **DUT** connected to the outputs F and G of the tissue equivalent interface [as shown in Figure 5], with output J connected to the case.

Differential mode performance shall be tested using the test signals reduced to one-tenth amplitude. The **pacemaker** shall be connected between the coupled outputs F and G and the output J of the tissue equivalent interface [as shown in Figure 6].

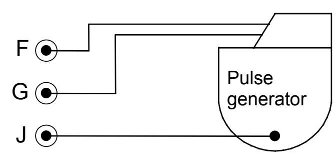

Figure 5 - Common mode connection to single channel bipolar pacemaker

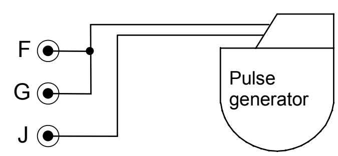

Figure 6 - Differential mode connection to single channel bipolar pacemaker

Group d) Common mode performance shall be tested by every input/output of the **pacemaker** being connected in turn to outputs F and G of the tissue equivalent interface [as shown in Figure 7], with output J connected to the case.

Differential mode performance shall be tested using the test signals reduced to one-tenth amplitude. Every input/output of the **pacemaker** shall be connected in turn between the coupled outputs F and G and the output J of the tissue equivalent interface [as shown in Figure 8].

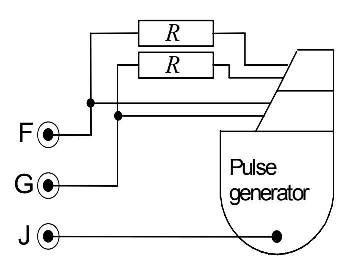

Figure 7 - Common mode connection to multichannel bipolar pacemaker

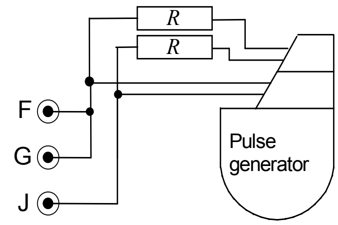

Figure 8 - Differential mode connection to multichannel bipolar pacemaker

The current (rms) shall be determined by dividing the peak-to-peak voltage reading on the oscilloscope, connected to test point K by 232 Ω for test signal 1. For test signal 2, the measurement will be taken with a true rms voltmeter connected to test point B (at the filter output) and divided by 82 Ω.

Compliance shall be confirmed if:

- for test signal 1 the measured current is not greater than that specified in Table 1A below; and
- for test signal 2 the current at modulating frequency of 130 Hz shall be not greater than 50 µA rms.

Table 1A - Spurious injection current limits for pacemakers

f	Current rms
16.6 Hz ≤ f ≤ 1 kHz	50 µA
1 kHz ≤ f ≤ 20 kHz	50 µA * f ⁄ 1kHz

4.2.2 ICD

***Test equipment*: Use the test set-up defined in Figure 2, tissue interface circuit defined in Figure D1 and either Table D1a or Table D1b; the low pass filter defined in Figure D4; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF; and test signal generators, output impedance of 50 Ω.**

Unless otherwise stated all resistors shall be of film type with low inductance, tolerance ± 2% rated 0.5 W and all capacitors shall be of the ceramic type, tolerance ± 5%.

Test signal: Two forms of test signal shall be used.

NOTE—Care must be taken that the test signal generator does not itself produce low frequency components (see Annex E).

Test **signal** 1 shall be a sinusoidal signal of 1 V peak-to-peak amplitude. The frequency, shall be either swept over the range 16.6 Hz to 20 kHz at a rate of one decade per minute, or applied at a minimum of four distinct, well-spaced frequencies per decade between 16.6 Hz and 20 kHz with an evenly distributed dwell time of at least 60 s per decade.

Test voltage 2 shall be a sinusoidal carrier signal, frequency 500 kHz with continuous amplitude modulation at 130 Hz (double sideband with carrier) (see Figure 1).

The maximum peak-to-peak voltage of the modulated signal shall be 2V. The modulation index (M) shall be 95 percent where:

$$M = \frac{V_{pp} - v}{V_{pp} + v} * 100$$

Test procedure: The test signal generator shall be connected through input C of the interface circuit as shown in Figure 2. The test voltage shall be measured on the oscilloscope connected to test point D.

The measuring oscilloscope shall be connected to test point K of the interface circuit through the low pass filter (see Figure D4) as shown in Figure 2. When the test signal 1 is being used, the low pass filter shall be switched to bypass mode.

The capacitor Cx of the interface circuit (see Figure D1) shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator (see Annex E).

NOTE—It is not mandatory that a current measurement be made in the period from 10 ms preceding a stimulation pulse to 150 ms after the stimulation pulse.

The ICD shall be set to the factory settings (nominal or as recommended by the manufacturer) during the test. The tachyarrhythmia therapy functions of the ICD shall be inactive during the test, and the high voltage capacitors, if any, shall not be charged.

CAUTION: Care must be taken to ensure that the high voltage capacitors are discharged. Failure to use safe laboratory practices may result in severe electrical shock resulting in personal injury or death to the persons handling the equipment or conducting the test. Also, damage to electrical equipment, particularly the tissue equivalent interface circuit, is likely.

4.2.2.1 Measurement of current injected through sensing/pacing terminals

Select the tissue equivalent interface circuit defined in Figure D1 and Table D1a. If the ICD offers multi-channel sensing/pacing, every input/output of the ICD shall be tested in turn. Any sensing/pacing terminal of the ICD not being tested shall be connected to the equivalent terminal of the channel under test through a resistor of value R $\geq$ 10 kΩ as specified by the manufacturer. (For safety, c/d terminals are loaded with high voltage 50 Ω, 25 W resistors RL).

Bipolar sense/pace ICDs shall be tested in two configurations:

Common mode performance shall be tested with the sensing/pacing terminals of the channel under test connected to the output F and G of the tissue equivalent interface (as shown in Figure 9) and the case connected to output J.

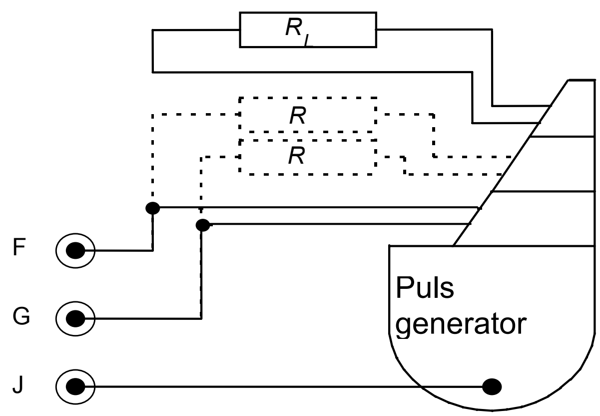

Figure 9 - Common mode connection to multichannel bipolar ICD

Differential mode performance shall be tested using test signals 1 and 2 reduced to one-tenth amplitude. The sensing/pacing terminals of the channel under test shall be connected between the coupled outputs F and G and the output J of the tissue equivalent interface (as shown in Figure 10).

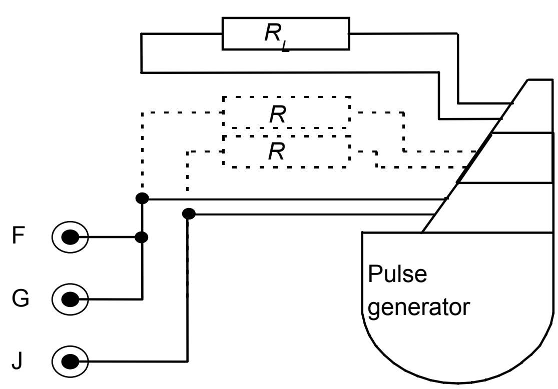

Figure 10 - Differential mode connection to multichannel bipolar ICD

The current (rms) shall be determined by dividing the peak-to-peak voltage reading on the oscilloscope connected to test point K via the low-pass filter (as shown in Figure D4 in by-pass mode) by 232 Ω for test signal 1. For test signal

2, the measurement will be taken with a true rms voltmeter connected to test point B (at the filter output in filter mode) and divided by 82 Ω.

Alternatively, a true rms voltmeter with input impedance ≥ 1 Mς may be used to determine the rms current. The reading shall be accurate to ± 10% within a bandwidth of the measured frequencies.

4.2.2.2 Measurement of current injected through cardioversion/defibrillation terminals

Select the tissue equivalent interface circuit defined in Figure D1 and Table D1b.

The sense/pace terminals shall be loaded with resistor(s) RL of 500 Ω ± 5%. For a multichannel sensing/pacing device, the sense/pace terminals shall be connected through resistors R of ≥ 10 kΩ as shown. The manufacturer shall be free to choose the value of the resistors that are appropriate for the device under test. If the ICD has more than two cardioversion/defibrillation terminals, the terminals not being tested shall be loaded with 50 Ω, 25 W resistors and connected to one of the terminals under test through a resistor R ≥ 10 kς.

If both of the cardioversion/defibrillation terminals under test are intended to be connected to endocardial leads, then the test signals shall be reduced to one-tenth amplitude. If one of both of the cardioversion/defibrillation terminals under test is intended to be connected to patches on the heart, the test signals shall be reduced to one-half amplitude. If any of the cardioversion/defibrillation terminals are intended to be connected to a subcutaneous patch, then the full test signal amplitude shall be used.

Common mode performance shall be tested with the cardioversion/defibrillation terminals connected to the outputs F and G of the tissue equivalent interface (as shown in Figure 11) and the case connected to output J.

NOTE—If the case of the ICD is an active terminal, no common mode test is required.

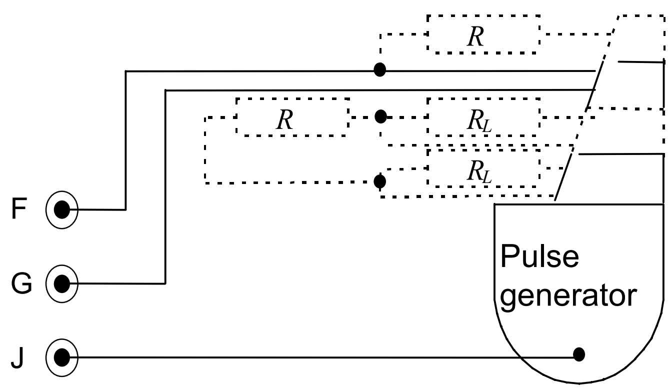

Figure 11 - Common mode connection for cardioversion/defibrillation terminals

Differential mode performance shall be tested with the cardioversion/defibrillation terminals connected between the coupled outputs F and G and the output J of the tissue equivalent interface (as shown in Figure 12).

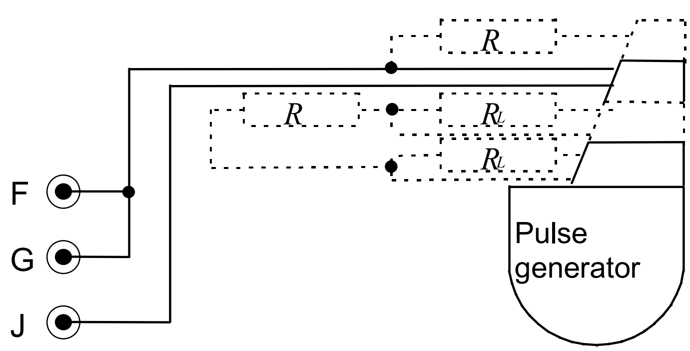

Figure 12 - Differential mode connection for cardioversion/defibrillation terminals

If the ICD has more than two cardioversion/defibrillation terminals, the test is performed on each pair of terminals in turn.

The current is determined by dividing the peak-to-peak voltage reading on the oscilloscope connected to test point K via the low-pass filter (as shown in Figure D4) by 133 Ω for test signal 1. For test signal 2, the measurement will be taken with a true rms voltmeter connected to test point B (at the filter output) and divided by 47 Ω.

Alternatively, a true rms voltmeter with input impedance ≥ 1 MΩ can be used to determine the rms current. The reading shall be accurate to ± 10% within a bandwidth of at least 20 kHz.

Compliance shall be confirmed if:

For test voltage 1, the current (rms) shall be no greater than that specified in Table 2 for sense/pace terminals and Table 3 for cardioversion/defibrillation terminals, and

For test voltage 2 the current at 130 Hz shall be no greater than 50 μA rms.

Table 2 - Spurious injection current limits for ICD sense/pace terminals

f	Current rms
16.6 Hz ≤ f ≤ 1 kHz	50 μA
1 kHz ≤ f ≤ 20 kHz	50 μA * f ⁄ 1kHz

Table 3 - Spurious injection current limits for ICD cardioversion/defibrillation terminals

f	Current rms
16.6 Hz ≤ f ≤ 1 kHz	50 μA
1 kHz ≤ f ≤ 20 kHz	50 μA * f ⁄ 1kHz

4.3 Protection from persisting malfunction due to continuous wave (CW) sources

The **DUT** shall be constructed so that ambient continuous wave electromagnetic fields are unlikely to cause malfunction of the **DUT** that persists after the removal of the electromagnetic field.

NOTE—The following test is intended to address the compatibility of the intracardiac signal sensing. Any additional physiological sensors may be turned off during testing unless otherwise specified. Tests for these additional sensors are under consideration.

4.3.1 Pacemakers

Test equipment: Use the test set-up in Figure 13, tissue equivalent interface circuit defined by Figure D2; two oscilloscopes, input impedance nominal 1 MΩ; and a test signal generator, output impedance 50Ω.

Test signal: The test **signal** shall be a continuous sinusoidal signal that shall be either, swept over the frequency range of 16.6 Hz to 140 kHz at a rate of one decade per minute, or, applied at a minimum of four distinct, well-spaced frequencies per decade with an evenly distributed dwell time of at least 60 s per decade. For common mode testing the following amplitudes shall be used: for frequencies, f, between 16.6 Hz and 20 kHz, the peak-to-peak amplitude, V_{pp}, shall be 1 V. For f between 20 kHz and 140 kHz, V_{pp} shall be 1 V increased by a factor m, where:

$$m = \frac{f}{20\,\mathrm{kHz}}$$

Differential mode performance shall be tested using test signal reduced to one-tenth amplitude.

***Test procedure*:** The test signal generator shall be connected through input C of the interface circuit (as defined in Figure D2) as shown in Figure 13. The test **signal** shall be measured on the oscilloscope connected to monitoring point D. The operation of the **pacemaker** is recorded on the oscilloscope connected to monitoring point K.

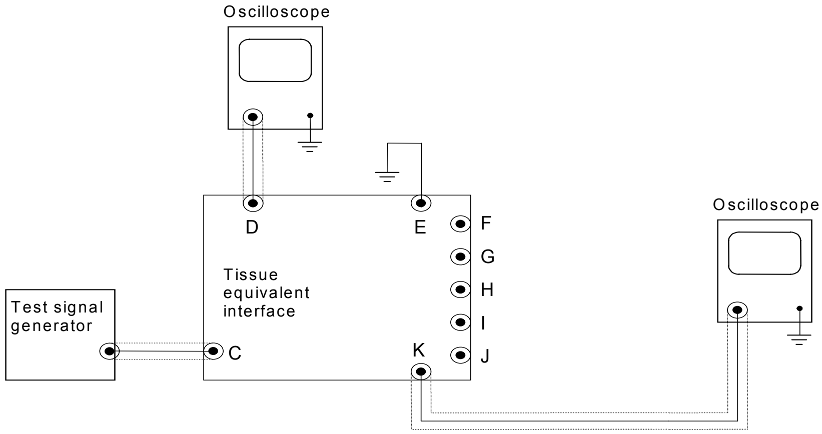

Figure 13 - Test set-up to check for induced malfunction

The **pacemaker** shall be categorized into one or more of four groups as appropriate:

Single channel unipolar **pacemakers** shall be Group a);

Multichannel unipolar **pacemakers** shall be Group b);

Single channel bipolar **pacemakers** shall be Group c);

Multichannel bipolar **pacemakers** shall be Group d).

NOTE—The bipolar channel should be tested in unipolar and/or bipolar according to the programmability of the device and should be changed where applicable.

Group a) The **pacemaker** shall be connected to the coupled outputs H and I of the tissue equivalent interface [as shown in Figure 14], with output J connected to the case.

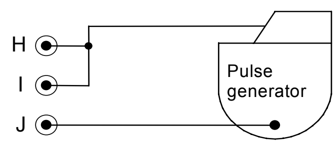

Figure 14 - Connection to a single channel unipolar pacemaker

Group b) Every input/output of the **pacemaker** shall be connected in parallel to the paired, coupled outputs F/G and H/I of the tissue equivalent interface [as shown in Figure 15], with output J connected to the case.

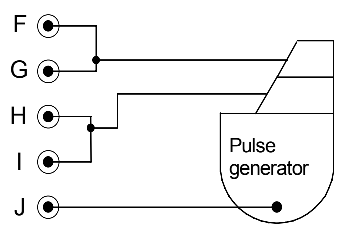

Figure 15 - Connection to a multichannel unipolar pacemaker

Group c) Common mode performance shall be tested with the **pacemaker** connected to the outputs H and I of the tissue equivalent interface [as shown in Figure 16], with output J connected to the case.

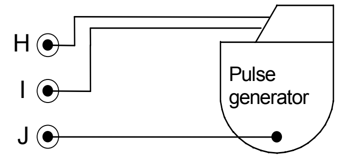

Figure 16 - Common mode connection to a single channel bipolar pacemaker

Differential mode performance shall be tested with the **pacemaker** shall be connected to the coupled outputs H/ I and the output J of the tissue equivalent interface [as shown in Figure 17].

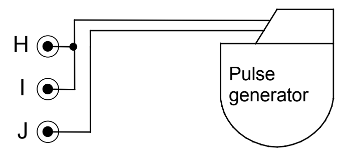

Figure 17 - Differential mode connection to a single channel bipolar pacemaker

Group d) Common mode performance shall be tested by every input/output of the **pacemaker** being connected to the outputs F, G, H and I of the tissue equivalent interface [as shown in Figure 18], with output J connected to the case.

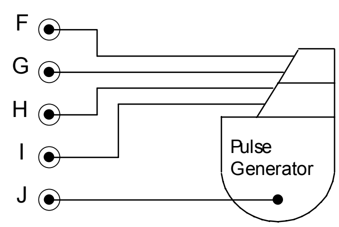

Figure 18 - Common mode connection to a multi channel bipolar pacemaker

Differential mode performance shall be tested with every input/output of the **pacemaker** shall be connected in turn between the coupled outputs H/ I and the output J of the tissue equivalent interface [as shown in Figure 19]

Any **terminal** of the **pacemaker** not being tested shall be connected to the equivalent **terminal** of the channel under test through a resistor of value R ≥10 kΩ.

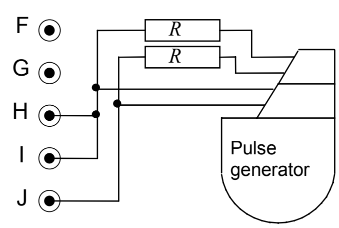

Figure 19 - Differential mode connection to a multi channel bipolar pacemaker

Compliance shall be confirmed if after application of the specified test signal, the **pacemaker** functions as prior to the test without further adjustment.

4.3.2 ICDs

Test equipment. Use the tissue equivalent interface circuits defined by Figure D2 and Figure D3; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF, the oscilloscope connected to test point D (in Figure 13 or 22) shall have an accuracy of ± 10% within a bandwidth of at least 30 MHz and a test signal generator output impedance of 50 Ω.

CAUTION: Good high frequency test procedures should be observed. Modification of the test circuits is allowed as long as electrical equivalence shall be maintained.

Test signal: The test **signal** is a continuous sinusoidal signal that shall be either, swept over the frequency range of 16.6 Hz to 140 kHz at a rate of one decade per minute, or, applied at a minimum of four distinct, well-spaced frequencies per decade with an evenly distributed dwell time of at least 60 s per decade. For common mode testing the following amplitudes shall be used: for frequencies, f, between 16.6 Hz and 20 kHz, the peak-to-peak amplitude, V_{pp}, shall be 1 V. For f between 20 kHz and 140 kHz, V_{pp} shall be 1 V increased by a factor m, where:

$$m = \frac{f}{20\,\mathrm{kHz}}$$

Differential mode performance shall be tested using test signal reduced to one-tenth amplitude.

The ICD shall be set to the factory settings (nominal or as recommended by the manufacturer) during the test. The tachyarrhythmia therapy functions of the implantable pulse generator shall be inactive during the test, and the high voltage capacitors, if any, are discharged.

CAUTION: Care must be taken to ensure that the high voltage capacitors are discharged. Failure to use safe laboratory practices may result in severe electrical shock resulting in personal injury or death to the persons handling the equipment or conducting the test. Also, damage to electrical equipment, particularly the tissue interface equivalent circuits, is likely.

4.3.2.1 Malfunction due to electrical interference on the sensing terminals.

Test procedure: Select the tissue equivalent interface circuit defined by D2. The test signal generator shall be connected through input C of the interface circuit as shown in Figure 13. The test voltage shall be measured on the oscilloscope connected to test point D of the interface circuit. The operation of the ICD is monitored by the oscilloscope connected to test point K.

The capacitor Cx of the interface circuit (see Figure D2) shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator (see Annex E).

Any sensing/pacing terminal of the ICD not being tested shall be connected to the equivalent terminal of the channel under test through a resistor of value R ≥ 10 kΩ as specified by the manufacturer. (For safety, cardioversion/defibrillation terminals are loaded with high voltage 50Ω, 25W resistors RL.)

Bipolar sense/pace ICDs shall be tested in two configurations.

Common mode performance shall be tested with the pairs of sensing/pacing terminals connected to the outputs F, G, H and I of the tissue equivalent interface (as shown in Figure 20) and the case connected to output J.

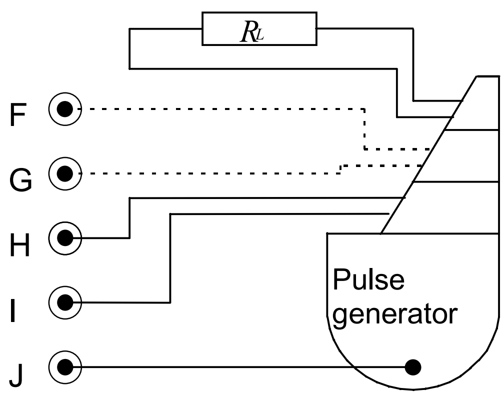

Figure 20 - Common mode connection for multichannel bipolar ICDs

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. Sensing/pacing channels shall be tested in turn. The sensing/pacing terminals of the channel under test shall be connected between the coupled outputs H/ I and the output J of the tissue equivalent interface (as shown in Figure 21).

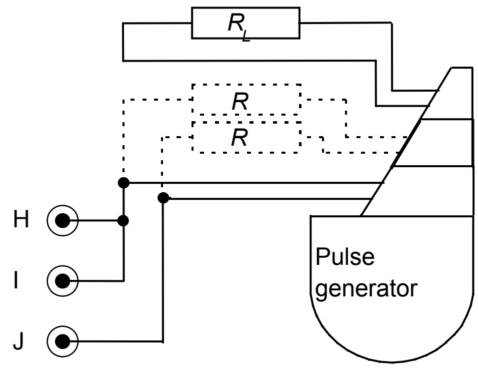

Figure 21 - Differential mode connection for multichannel bipolar ICDs

Compliance shall be confirmed if, after application of the specified test signals, the ICD functions as prior to the test without further adjustment of the ICD.

4.3.2.2 Malfunction due to electromagnetic interference on the cardioversion/defibrillation lead.

Test procedure: Select the tissue equivalent interface circuit defined by Figure D3. The test signal generator shall be connected through input C of the interface circuit as shown in Figure 22. The test voltage shall be measured on the oscilloscope connected to test point D.

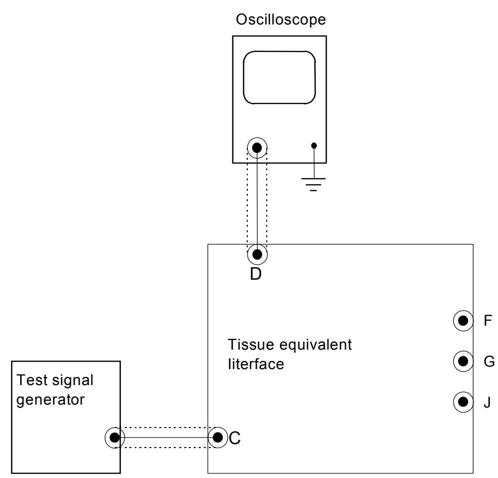

Figure 22 - Test setup to check for induced malfunction due to voltages induced on cardioversion/defibrillation leads in ICDs

The capacitor Cx of the interface circuit (see Figure D3) shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator (see Annex E).

The sense/pace terminals shall be loaded with resistor(s) RL of 500 Ω ± 5%. For a multi-channel sensing/pacing device, the sense/pace terminals shall be connected through resistors R of ≥ 10 kΩ as shown. The manufacturer shall be free to choose the value of the resistors that are appropriate for the device under test. If the ICD has more than two cardioversion/defibrillation terminals, the terminals not being tested shall be loaded with 50 Ω, 25 W resistors and connected to one of the terminals under test through a resistor R.

Common mode performance shall be tested with the cardioversion/defibrillation terminals connected to the outputs F and G of the tissue equivalent interface (as shown in Figure 23) and the case connected to output J.

NOTE If the case of the ICD is an active terminal, no common mode test is required, i.e. testing and one-tenth amplitude.

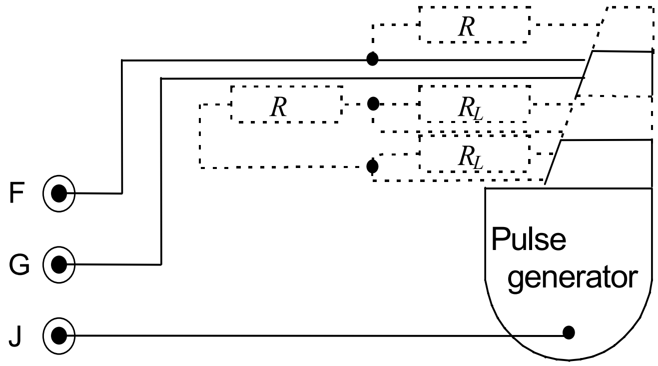

Figure 23 - Common mode connection for cardioversion/defibrillation terminals

Differential mode performance shall be tested with the cardioversion/defibrillation terminals connected between the coupled outputs F/ G and the output J of the tissue equivalent interface (as shown in Figure 24).

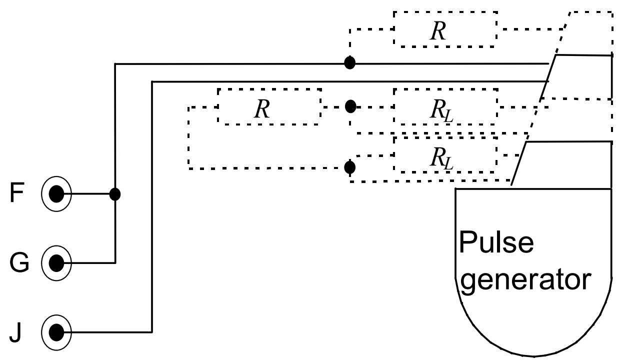

Figure 24 - Differential mode connection for cardioversion/defibrillation terminals

If the ICD has more than two cardioversion/defibrillation terminals, the tests shall be performed on each pair of terminals in turn.

Compliance shall be confirmed if, after application of the specified test signals, the ICD functions as prior to the test without further adjustment of the ICD.

4.4 Temporary response to continuous wave (CW) sources

NOTE The following test is intended to address the compatibility of the intracardiac signal sensing. Any additional physiological sensors may be turned off during testing unless otherwise specified. Tests for these additional sensors are under consideration.

4.4.1 Pacemakers

The pacemaker shall be constructed so that ambient continuous wave electromagnetic fields are unlikely to cause malfunction of the pulse generator during the exposure to the electromagnetic field.

***Test equipment*:** Use the tissue equivalent interface circuit defined by Figure D2; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF; the oscilloscope connected to test point D in Figure 25 shall have an accuracy of ± 10% within a bandwidth of at least 20 MHz, an inhibition signal generator, output impedance not greater than 1 kΩ which provides a simulated heart signal in the form defined by Figure J1; and a test signal generator, output impedance 50 Ω.

Test signal: The test **signal** shall be a continuous sinusoidal signal applied at a minimum of four distinct, well-spaced frequencies per decade between 16.6 Hz to 167 kHz. For common mode tests, at each selected frequency the test **signal** shall be slowly increased from zero to a maximum of 1 V peak-to-peak.

Differential mode performance shall be tested using test signal reduced to one-tenth amplitude.

***Test procedure*:** The test signal generator shall be connected through input C of the interface circuit as shown in Figure 25. The test **signal** shall be measured on the oscilloscope connected to monitoring point D of the interface circuit. The operation of the **pacemaker** is recorded on the oscilloscope connected to monitoring point K.

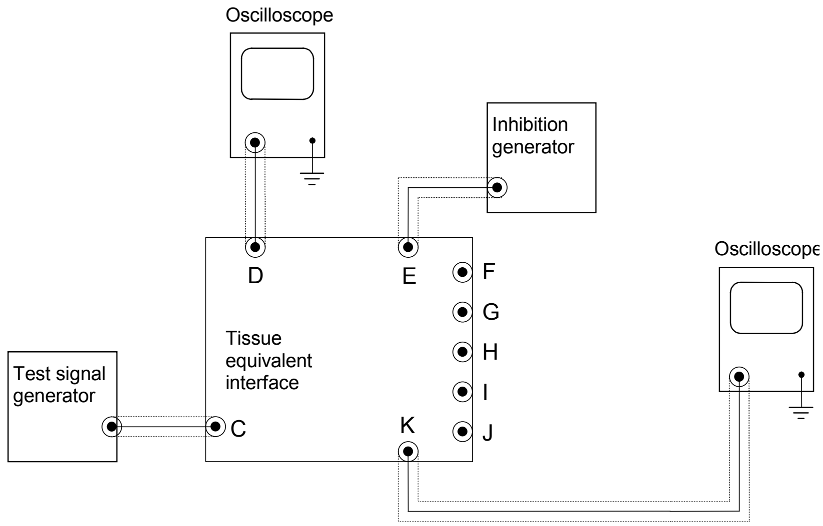

Figure 25 - Test set-up to characterize performance while subject interference for pacemakers and ICDs

The pacemaker shall be set to its highest sensitivity (most sensitive setting), unless the labeling of the pacemaker includes a clear warning that for given settings the pacemaker does not comply, in which case the pacemaker shall be set to its highest sensitivity for which the manufacturer claims compliance with this Standard. Other parameters shall be programmed to values that enable the person conducting the test to observe the point when the test signal is detected by the **pacemaker**. For with devices utilizing AGC, the manufacturer should provide details of the test method.

The test shall be performed with the pacemaker in the pacing mode and in a synchronized mode when it is not possible to distinguish between uninfluenced mode and interference mode of operation. The pacemaker shall be set in synchronized mode by a signal from the inhibition signal generator connected to test point E of the interface [as shown in Figure 25]. The amplitude shall be set at twice the value that just synchronizes the pacemaker under test and the interval shall be 800 ms or 90 percent of the programmed **basic pulse interval** as shipped, whichever is the shorter.

NOTE 1 When the pulse generator is synchronized by the inhibition signal generator, this should be set without the test signal being applied.

NOTE 2 Allow for testing in both AAI and VVI mode in lieu of DDD mode; ventricular pacing only must be verified. See Annex I for testing modes.

The **pacemaker** shall be categorized into one of four groups as required by 4.3.1 and connected to the tissue equivalent interface according to Figure 14, Figure 15, Figure 16 and Figure 17, Figure 18, or figure 19 as applicable. Only the ventricular channel need to be tested when the pulse generator is programmed to dual chamber operation and any other terminal of the pulse generator shall be connected to the equivalent terminal through a resistor of value $R \geq 10\ k\Omega$ as shown/specified by the manufacturer.

Compliance shall be confirmed if while the test conditions are varied as required, the **pacemaker** continues to operate as set or in its interference mode as characterized by the manufacturer.

If for some value of the test conditions, the pacemaker changes from its set mode to its interference mode, or vice versa, then no pause longer than twice the pre-set interval shall occur unless the change of mode is completed within a change by a factor of two in voltage of the test signal.

NOTE Interference mode is intended for short-term operation for periods of seconds and is not intended for routine long-term operation. Such short-term operation is recognized as being clinically acceptable with the risk of adverse events increasing with time of exposure. Therefore, interference mode should be considered necessary for unforeseen exposure but should not be depended on to support a patient exposed to intentional radiators.

4.4.2 ICDs

The manufacturer shall characterize the performance of the ICD in the presence of ambient continuous-wave electromagnetic fields.

The ICD shall be tested without simulated heart signal applied, unless the heart signal is needed to distinguish between uninfluenced mode and interference mode of operation.

Test equipment: Use the tissue equivalent interface circuit defined by Figure D2; two oscilloscopes, input impedance nominal 1 MΩ, the oscilloscope connected to test point D in Figure 25 shall have an accuracy of ± 10% within a bandwidth of at least 20 MHz, an inhibition signal generator, output impedance not greater than 1 kΩ which provides a simulated heart signal in the form defined by Figure J1 and a test signal generator, output impedance 50 Ω. The capacitor Cx of the interface circuit (in Figure D2) shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator (see Annex E).

***Test** signal*: The test **signal** shall be a continuous sinusoidal signal applied at a minimum of four distinct, well-spaced frequencies per decade between 16.6 Hz to 167 kHz. For common mode tests, at each selected frequency the test **signal** shall be slowly increased from zero to a maximum of 1 V peak-to-peak.

Differential mode performance shall be tested using test signal reduced to one-tenth amplitude.

NOTE The test voltage need not be increased further once the implantable pulse generator begins to detect the test signal.

Test procedure: The test signal generator shall be connected through input C of the interface circuit as shown in Figure 25. The test voltage shall be measured on the oscilloscope connected to test point D of the interface circuit.

The ICD shall be set to its highest sensitivity (most sensitive setting). Other parameters shall be programmed to values that enable the person conducting the test to observe the point when the test signal is detected by the implantable pulse generator.

The test shall be performed with the ICD in the pacing mode and in a synchronized mode when it is not possible to distinguish between uninfluenced mode and interference mode of operation.

For a multi-channel ICD, any sense/pace terminals not being tested are connected through resistors of ≥ 10 kΩ to the corresponding terminals of the channel under test. The manufacturer is free to choose the value of the resistors that is appropriate to the device under test. For safety reasons, the cardioversion/defibrillation terminals are loaded with high voltage 50 Ω (25 W) resistors. The operation of the ICD shall be monitored by the oscilloscope connected to test point K.

Bipolar sense/pace ICDs shall be tested in two configurations:

Common mode performance shall be tested with the sensing/pacing terminals connected to the outputs F, G, H and I (as shown in Figure 20) of the tissue equivalent interface (as shown in Figure D2) and the case connected to output J.

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sensing/pacing terminals of the channel under test shall be connected between the coupled outputs H and I and the output J (as shown in Figure 21) of the tissue equivalent interface (as shown in Figure D2).

For each predetermined test frequency and sensitivity setting, record the amplitude of the test signal (voltage) when the ICD begins to detect the test signal.

If the manufacturer's recommended sensitivity setting is less than the most sensitive setting, the ICD shall be reprogrammed to the recommended sensitivity setting, and the entire test sequence shall be repeated.

Compliance shall be established by completing testing per the above conditions and documenting the characterization of the ICD behavior in a formal report.

NOTE Interference mode is intended for short-term operation for periods of seconds and is not intended for routine long-term operation. Such short-term operation is recognized as being clinically acceptable with the risk of adverse events increasing with time of exposure. Therefore, interference mode should be considered necessary for unforeseen exposure but should not be depended on to support a patient exposed to intentional radiators.

4.5 Protection from sensing modulated electromagnetic interference (EMI) as cardiac signals

The **DUT** shall be constructed so that commonly encountered modulated electromagnetic fields are unlikely to change the therapeutic behavior of the **DUT**.

NOTE 1 The following test is intended to address the compatibility of the intracardiac signal sensing. Any additional physiological sensors may be turned off during testing unless otherwise specified. Tests for these additional sensors are under consideration.

NOTE 2 Dual chamber devices can be tested in VVI and AAI modes or in lieu of DDD mode.

Pacemakers

The **pacemaker** shall be set to its most sensitive setting in both unipolar and bipolar modes for which the manufacturer claims compliance with this standard. For frequencies above 1 kHz the least sensitive settings acceptable for compliance are 2.0 mV sensitivity in the unipolar sensing mode and 0.3 mV sensitivity in the bipolar sensing mode, or the **sensitivity** as shipped, whichever is the more sensitive.

The **pacemaker** shall be tested with and without a simulated heart signal. It is essential to determine when the device responds to electromagnetic interference (EMI). Therefore, device parameters shall be programmed so that it is possible to discriminate when the device is influenced by the EMI. When testing with the simulated heart signal, the generator output shall be set to amplitude of twice the value that just inhibits the pacemaker. The interval of the inhibition signal shall be 800 ms or 90% of the programmed basic pulse interval as shipped, whichever is shorter.

ICDs

The ICD shall be set to its most sensitive setting for which the manufacturer claims compliance with this standard. The arrhythmia detection interval shall be programmed to a value greater than the initial burst-to-burst interval of 350 ms ± 25 ms. For frequencies above 1 kHz the least sensitive settings acceptable for compliance is 0.3 mV sensitivity, or the **sensitivity** as shipped, whichever is the more sensitive.

CAUTION: These tests may produce high voltage shocks. Failure to use safe laboratory practices may result in severe electrical shock resulting in personal injury or death to the persons handling the equipment or conducting the test.

4.5.1 Protection from sensing electromagnetic interference (EMI) as cardiac signals in the frequency range 16.6 Hz – 150 kHz

4.5.1.1 Pacemakers

***Test equipment*:** Use the tissue equivalent interface circuit defined by Figure D2; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF, the oscilloscope to be connected to output D of the interface circuit having a bandwidth of at least 20 MHz; an inhibition signal generator, output impedance not greater than 1 kΩ, which provides a signal of the form defined by Figure J1; and a test signal generator, output impedance of 50 Ω.

***Test signal*:** The common mode test **signal** shall be a modulated signal, carrier frequency, f, between 16.6 Hz and 150 kHz. The carrier shall be switched at zero amplitude approximately 100 ms on, 600 ms off [see Figure 26]. The burst shall start and terminate at a zero crossings of the carrier and only complete carrier cycles shall be used.

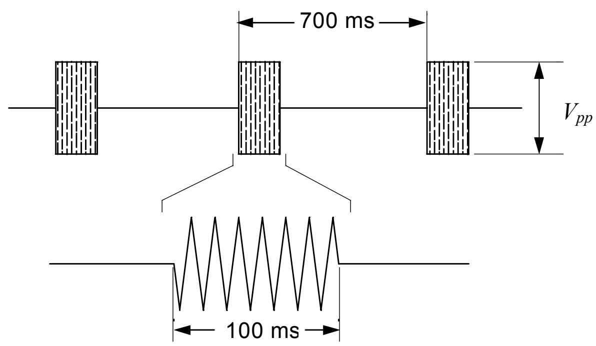

Figure 26 - Test signal for pacemaker testing of frequencies in the range 16.6 Hz - 150 kHz

The amplitude of the common mode test signal (V_{pp}) is defined as the peak-to-peak amplitude of the open circuit voltage driving the pacemaker at the outputs of the tissue interface. The amplitude of the test signal, V_{pp}, shall be a function of the carrier frequency f, as defined by Table 4.

Table 4 - Peak to peak amplitudes Vpp in the range 16.6 Hz to 150kHz

f	V_{pp}
16.6 Hz ≤ f ≤ 1 kHz	2 mV
1 kHz ≤ f ≤ 3 kHz	2 mV * $(f / 1\ kHz)^2$
3 kHz ≤ f ≤ 150 kHz	6 mV * f / 1 kHz

Differential mode performance shall be tested using test signal reduced to one-tenth amplitude.

Test procedure: The test signal generator shall be connected to the tissue equivalent interface circuit through input C as shown in Figure 25. The test **signal** shall be measured on the oscilloscope connected to monitoring point D. The operation of the **pacemaker** shall be recorded on the oscilloscope connected to monitoring point K.

NOTE 1 Two tests are performed, one with and one without simulated heart signal applied to input E.

The capacitor C_X of the interface circuit (see Figure D.2) shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator [see Annex E].

The modulated signal shall be applied at a minimum of four distinct, well-spaced frequencies per decade between 16.6 Hz and 150 kHz with an evenly distributed dwell time of at least 60 s per decade. (V_{pp} can be measured directly at connector D of the tissue interface.)

NOTE 2 Care must be taken that the interference generator does not itself produce low frequency components.

NOTE 3 When the **pacemaker** is synchronized by the inhibition signal generator, this should be set without the modulated test signal being applied.

If the **pacemaker** under test is a multi channel device, it shall be programmed to minimize the occurrence of possible cross talk between channels.

The **pacemaker** shall be categorized into one of four groups as required by 4.3.1 and connected to the tissue equivalent interface according to Figure 14, Figure 15, Figure 16, Figure 17, Figure 18, and Figure 19 as applicable.

Compliance shall be confirmed if the **pacemaker** at all times functions in its set mode, both with and without the simulated heart signal applied by the inhibition signal generator and irrespective of the application of the required modulated signal.

For those sensitivity settings of the **pacemaker** at which a change of pacing pattern occurs, compliance shall be confirmed if an appropriate warning is provided in the accompanying documentation.

4.5.1.2 ICDs

Test equipment: Use the tissue equivalent interface circuit defined by Figure D2; two oscilloscopes, input impedance nominal 1MΩ, < 30 pF, the oscilloscope connected to test point D in Figure D2 shall have an accuracy of ± 10% within a bandwidth of at least 20 MHz, an inhibition signal generator, output impedance not greater than 1 kΩ which provides a simulated heart signal in the form defined by Figure J1 and test signal generators, output impedance of 50 Ω.

The amplitude of the simulated heart signal shall be approximately twice the minimum value required for detection by the ICD. The simulated heart signal generator shall be connected through input E of the interface circuit.

The capacitor Cx of the interface circuit (see Figure D2) shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator (see Annex E).

Test signal: The test voltage for common mode shall be a modulated signal, carrier frequency, f, between 16.6 Hz and 150 kHz as in Table 5 below:

Table 5 - Peak to peak amplitudes Vpp in the range 16.6 Hz to 150 kHz

f	V_{pp}
16.6 Hz ≤ f ≤ 1 kHz	2 mV
1 kHz ≤ f ≤ 3 kHz	2 mV * (f / 1 kHz)^2
3 kHz ≤ f ≤ 150 kHz	6 mV * f / 1 kHz

The carrier shall be switched to create bursts of 100 ms. The burst-to-burst interval, T, shall be measured leading to leading edge (see Figure 27). The burst shall start and terminate at a zero crossings of the carrier, and only complete carrier cycles shall be used.

Differential mode performance shall be tested using a test signal reduced to 10% amplitude of the common mode test.

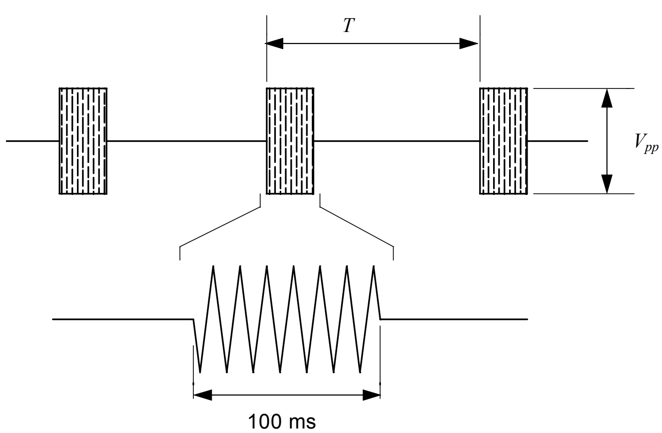

Figure 27 - Test signal for ICD testing for frequencies in the range 16.6 Hz - 150 kHz

Test procedure: Two possible disruptions of normal operation of the device by the interference are considered. A false positive in which case the EMI is mistaken for an arrhythmia that needs to be treated. And a false negative in which case the EMI prohibits the sensing of an arrhythmia and the needed therapy is withheld. The false positive case is tested with a burst-to-burst interference interval (T) simulating fibrillation and with both a simulated heart signal at a normal sinus rate (T_{shs}) and without a simulated heart signal. The false negative case need not be tested as sensing of interference signal is implicitly tested.

Test 1: Simulated heart signal applied with T_{shs}=800 ms (or 90% of basic pulse interval, whichever is less) and burst-to-burst interval of interference signal set to T=350 ±25 ms.

NOTE: The test setup of Test 1 seeks to determine if the modulated interference will influence the ICD during inhibited mode of operation. The burst-to-burst interval (T) is selected to simulate fibrillation.

Test 2: No simulated heart signal applied and burst-to-burst interval of interference signal set to T=350 ±25 ms.

NOTE: The test setup of Test 2 seeks to determine if the detection of the modulated interference will prevent the ICD from providing bradycardia therapy. The burst-to-burst interval (T) is selected to simulate fibrillation.

Any sense/pace terminals not being tested are connected through resistors of ≥ 10 kΩ to the corresponding terminals of the channel under test. The manufacturer is free to choose the value of the resistors that is appropriate to the device under test. For safety reasons, the cardioversion/defibrillation terminals are loaded with high voltage 50 Ω (25 W) resistors.

The operation of the ICD shall be monitored by the oscilloscope connected to test point K. The applicable tests described in paragraphs A), and B) below shall be performed at a minimum of four carrier frequencies per decade.

NOTE: Since the ICD may require that it detect several consecutive input signals before therapy is initiated, sufficient time must be allowed at each frequency tested for the device under test to react to the input interference.

A) Bipolar sense ICDs shall be tested in two configurations.

Common mode performance shall be tested with the sensing/pacing terminals connected to the outputs F, G, H and I (as shown in Figure 20) of the tissue equivalent interface (as shown in Figure D2) and the case connected to output J.

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sensing/pacing terminals of the channel under test shall be connected between the coupled outputs H and I and the output J (as shown in Figure 21) of the tissue equivalent interface (as shown in Figure D2).

NOTE: The ICD shall be programmed to prevent cross talk between different channels.

B) For an ICD which uses signals from both sense and cardioversion/defibrillation leads for arrhythmia detection, the manufacturer shall provide details of the test method.

Compliance shall be confirmed if:

While performing Test 1 above, the ICD is not influenced by the interference signal, i.e. does not exhibit any pacing pulses and does not deliver a tachyarrhythmia therapy

And

While performing Test 2 above the ICD is not influenced by the interference signal, i.e. does not exhibit any deviation in pace-to-pace interval that exceeds 10% of the programmed rate and does not deliver a tachyarrhythmia therapy

Compliance shall be confirmed if the manufacturer discloses in the accompanying documentation the maximum sensitivity setting or the maximum test signal amplitude for which compliance with this subclause is claimed.

4.5.2 Protection from sensing electromagnetic interference (EMI) as cardiac signals in the frequency range 150 kHz – 10 MHz

4.5.2.1 Pacemakers

Test equipment: Use the test equipment defined by Section 4.5.1.1 of this standard.

Test signal: The test **signal** shall be a modulated signal, carrier frequency, f, between 150 kHz and 10 MHz. The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst-to-burst interval, T, shall be measured leading to leading edge [see Figure 28].

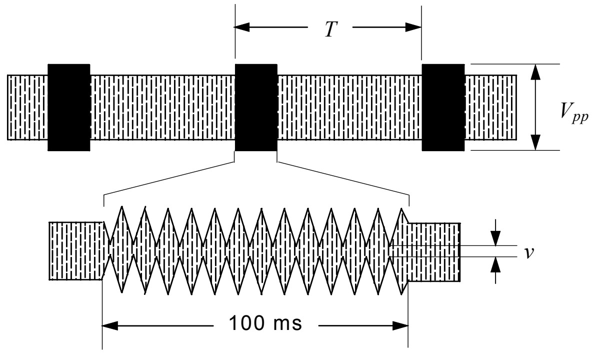

Figure 28 - Test signal for frequencies 150 kHz - 10 MHz

The modulation bursts shall start and terminate at zero crossings of the modulation signal (thus the envelope starts and terminates at a value of approximately 50 percent of the unmodulated carrier). The burst counts 13 complete modulation cycles. The modulation index shall M shall be 95 percent, where:

$$M = \frac{V_{pp} - v}{V_{pp} + v} * 100$$

The burst-to-burst interval (T) of the test signal shall be set to 700 ms ± 50 ms.

The amplitude of the test signal (V_{pp}) is defined as the peak-to-peak amplitude of the open circuit voltage driving the pacemaker at the outputs of the tissue interface. The amplitude of the test signal, V_{pp}, shall be a function of the carrier frequency f, as defined by Table 6.

Table 6 - Peak to peak test signal amplitudes V_{pp} in the range 150 kHz to 10 MHz, pacemakers

f	V_{pp}
150 kHz ≤ f ≤ 167 kHz	6 mV * f / 1 kHz
167 kHz ≤ f ≤ 1 MHz	1 V
1 MHz ≤ f ≤ 10 MHz	1 V * f / 1 MHz

Test procedure: The modulated signal shall be applied at a minimum of four distinct, well-spaced frequencies per decade between 150 kHz and 10 MHz with an evenly distributed dwell time of at least 60 s per decade. (V_{pp} can be measured directly at connector D of the tissue interface.) The test configuration and procedure shall be otherwise as required by 4.5.1.1.

Compliance shall be confirmed if the **pacemaker** at all times functions in its set mode irrespective of the application of the required modulated signal.

4.5.2.2 ICDs

Test equipment: Use test equipment defined in 4.5.1.2.

The amplitude of the simulated heart signal shall be approximately twice the minimum value required for detection by the ICD, and the interval shall be 90% of the programmed basic pulse interval as shipped. The simulated heart signal generator shall be connected through input E of the interface circuit.

The capacitor Cx of the interface circuit (see Figure D2) shall be bypassed unless required to eliminate spurious low frequency signals produced by the interference signal generator (see Annex E).

Test signal: The test voltage for common mode shall be a modulated signal, carrier frequency, f, between 150 kHz and 10 MHz as in Table 7 below:

Table 7 - Peak to peak test signal amplitudes Vpp in the range 150 kHz to 10 MHz, ICDs

f	V_{pp}
150 kHz ≤ f ≤ 167 kHz	6 mV * f / 1 kHz
167 kHz ≤ f ≤ 1 MHz	1 V
1 MHz ≤ f ≤ 10 MHz	1 V * f / 1 MHz

Differential mode performance shall be tested using a test signal reduced to 10% amplitude of the common mode test

The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst-to-burst interval, T, shall be measured leading to leading edge (see Figure 29).

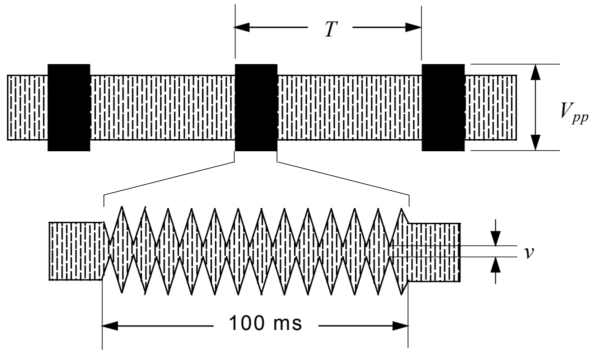

Figure 29 - Test signal for frequencies 150 kHz - 10 MHz

The modulation bursts shall start and terminate at zero crossings of the modulation signal (thus the envelope starts and terminates at a value of approximately 50 percent of the unmodulated carrier). The burst count is 13 complete modulation cycles. The modulation index (M) shall be 95 percent, where:

$$M = \frac{V_{pp} - v}{V_{pp} + v} * 100$$

The test signal generator shall be connected through input C of the interface circuit as shown in Figure 25. The test voltage shall be measured on the oscilloscope connected to test point D of the interface circuit.

Test procedure:. Two possible disruptions of normal operation of the device by the interference are considered, but only one is tested. A false positive in which case the EMI is mistaken for an arrhythmia that needs to be treated; and a false negative in which case the EMI prohibits the sensing of an arrhythmia and the needed therapy is withheld. The false positive case is tested with a burst-to-burst interference interval (T) simulating fibrillation and with both a simulated heart signal at a normal sinus rate (T_{shs}) and without a simulated heart signal. The false negative case need not be tested as sensing of interference signal is implicitly tested.

This setup tests for the detection of the modulated interference as an arrhythmia in the presence of a normal sinus rhythm (i.e., a false positive). The burst-to-burst interval (T) is selected to simulate a fibrillation, which can be detected by the device

Test 1: Simulated heart signal applied with T_{shs}=800 ms (or 90% of basic pulse interval, whichever is less) and burst-to-burst interval of interference signal set to T=350 ±25 ms.

NOTE: The test setup of Test 1 seeks to determine if the modulated interference will influence the ICD during inhibited mode of operation. The burst-to-burst interval (T) is selected to simulate fibrillation.

Test 2: No simulated heart signal applied and burst-to-burst interval of interference signal set to T=350 ±25 ms.

NOTE: The test setup of Test 2 seeks to determine if the detection of the modulated interference will prevent the ICD from providing bradycardia therapy. The burst-to-burst interval (T) is selected to simulate fibrillation. .

Any sense/pace terminals not being tested are connected through resistors of ≥ 10 kΩ to the corresponding terminals of the channel under test. The manufacturer is free to choose the value of the resistors that is appropriate to the device under test. For safety reasons, the cardioversion/defibrillation terminals are loaded with high voltage 50 Ω (25 W) resistors.

The operation of the implantable pulse generator shall be monitored by the oscilloscope connected to test point K. The applicable tests described in paragraphs A) and B) below shall be performed with the test signal either swept over the frequency range at a rate of one decade per minute, or, applied at a minimum of four distinct, well-spaced frequencies per decade with an evenly distributed dwell-time of at least 60s per decade.

NOTE Since the implantable pulse generator may require that it detect several consecutive input signals before therapy is initiated, sufficient time must be allowed at each frequency tested for the device under test to react to the input interference.

A) Bipolar sense ICDs shall be tested in two configurations.

Common mode performance shall be tested with sensing/pacing terminals connected to the outputs F, G, H and I (as shown in Figure 20) of the tissue equivalent interface (as shown in Figure D2) and the case connected to output J.

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sensing terminals of the channel under test shall be connected between the coupled outputs H and I and the output J (as shown in Figure 21) of the tissue equivalent interface (as shown in Figure D2).

NOTE The implantable pulse generator shall be programmed to prevent cross talk between channels.

B). For an ICD which uses signals from both sense and cardioversion/defibrillation leads for arrhythmia detection, the manufacturer shall provide details of the test method.

Compliance shall be confirmed if:

While performing Test 1 above, the ICD is not influenced by the interference signal, i.e. does not exhibit any pacing pulses and does not deliver a tachyarrhythmia therapy

And

While performing Test 2 above the ICD is not influenced by the interference signal, i.e. does not exhibit any deviation in pace-to-pace interval that exceeds 10% of the programmed rate and does not deliver a tachyarrhythmia therapy

Compliance shall be confirmed if the manufacturer discloses in the accompanying documentation the maximum sensitivity setting or the maximum test signal amplitude for which compliance with this subclause is claimed.

4.5.3 Protection from sensing electromagnetic interference (EMI) as cardiac signals in the frequency range 10 MHz – 450 MHz

4.5.3.1 Pacemakers

Test equipment: Use the tissue injection network defined by Figure D5; an oscilloscope, #1, input impedance 50 Ω, accuracy of ± 10% within a bandwidth of at least 450 MHz; an oscilloscope,#2, input impedance nominal 1 MΩ, an inhibition signal generator, output impedance not greater than 1 kΩ, which provides a simulated heart signal of the form defined by J1; a test signal generator, output impedance 50 Ω.

Test signal: The test signal shall be a modulated signal of the form defined by 4.5.2.1 [see Figure 28]. The modulated test signal shall be applied at a minimum of 6 distinct, well-spaced frequencies per decade, beginning at 10 MHz and ending at 450 MHz (i.e.10, 20, 40, 60, 80, 100, 200, 400, 450) with an evenly distributed dwell time of at least 60 s per decade. The amplitude of the test signal (V_{pp}) is defined as the peak-to-peak amplitude of the open circuit voltage driving the outputs (F, G) of the injection network. The amplitude of the test signal, V_{pp}, shall be 10 V.

NOTE: The peak-to-peak amplitude of the test signal, V_{pp}, cannot be measured directly at any connector of the injection network during the test. Therefore it must be calculated from the voltage at connector D, V_{osc}, by applying the calibration factor, *m*, of Annex F.

Test procedure: Prior to any testing, calibrate the setup using the procedure in Annex F. The test signal generator shall be connected to the injection network through input C as shown in Figure 30. The test signal generator shall be adjusted so that the test **signal** amplitude measured on the oscilloscope #1 connected to monitoring point D (V_{osc}) when multiplied by the calibration factor for the injection network, determined according to the method of Annex F, is equal to the required test signal amplitude, V_{pp}.

Two tests are performed, one with and one without the simulated heart signal applied through the inhibition signal generator to input E (E'). The interval of the inhibition signal T_{shs} shall be set to 800 ms or 90% of the programmed basic pulse interval as shipped, whichever is shorter. The burst-to-burst interval (T) of the modulated signal shall be set to 700 ms ± 50 ms.

NOTE: If an rms voltmeter is used during calibration procedure and testing at monitoring point D, then the test value shall be 53% of the calibration value, to provide a nominal modulated test amplitude of 10 Vpp (open circuit) at output F and G.

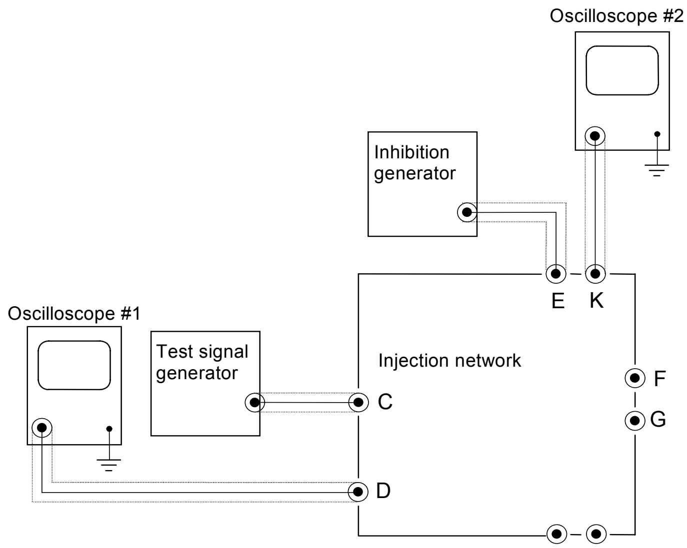

Figure 30 - Test set-up to check for malfunction at high frequency

Connections between outputs F and G and the **pacemaker** shall be by copper straps, width ≥ 5 mm, length ≤ 50 mm (not including the length of the standard connector pin inserted into the device header). Unused ports on the injection network shall be fitted with 50 Ω terminations.

Unipolar **pacemakers** shall be connected to output F of the injection network [as shown in Figure 31], using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L).

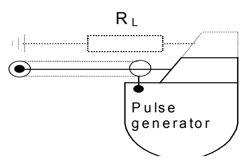

Figure 31 - Connection to a unipolar pacemaker

Bipolar **pacemakers** shall be connected to outputs F and G of the injection network [as shown in Figure 32], using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L).

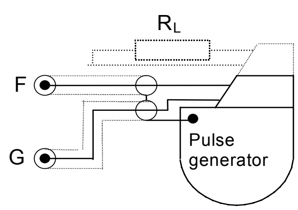

Figure 32 - Connection to a bipolar pacemaker

Compliance shall be confirmed if the **pacemaker** at all times functions in its set mode irrespective of the application of the required modulated signal.

4.5.3.2 ICDs

ICDs shall be tested per the sequence described in 4.5.3.1 of this standard, testing each channel in turn.

CD channels not being tested should be turned off and loaded with 50 Ohms.

Compliance shall be confirmed if the ICD at all times functions in its set mode irrespective of the application of the required modulated signal.

4.6 Protection from static magnetic fields of flux density up to 1 mT

The DUT shall not be affected by static magnetic fields of flux density of up to 1 mT.

4.6.1 Pacemakers

Test equipment: Use a test signal generator which provides a signal in the form defined by Figure J1; an oscilloscope; 51 kΩ ± 1% and 500 Ω ± 1% resistors; and a field coil, capable of generating a uniform magnetic field of flux density of up to 1 mT ± 0.1 mT in the region to be occupied by the **pacemaker**.

Test procedure: A 500 Ω ± 1% load resistor (R_L) is connected between terminals S and T [see Figure 33], with the monitoring oscilloscope connected to terminal S. The signal from the test signal generator shall be injected at terminal S through a 51 kΩ ± 1% feed resistor (R).

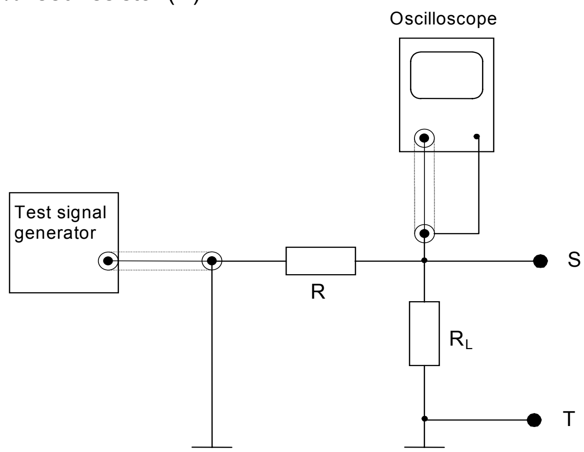

Figure 33 Test setup for magnetostatic measurements

For unipolar **pacemakers**, output S shall be connected to the **terminal** of the channel under test and output T to the **pacemaker** case.

For bipolar **pacemakers**, outputs S and T shall be connected to the **terminal**s of the channel under test. Channels not under test shall be loaded with 500 Ω ±1% resistors.

The **pacemaker** shall be set in synchronized mode by the signal from the test signal generator. The amplitude of the test signal shall be twice the amplitude that just synchronizes the **pacemaker** under test.

While remaining connected to the test equipment, the **pacemaker** shall be placed within the coil, centered in its field, and aligned so that the most sensitive axis of the **pacemaker** is parallel to the axis of the coil. The magnetic field shall be slowly increased from 0 to uniform field strength of flux density of up to 1 mT ± 0.1 mT in the region where the **pacemaker** is placed. The magnetic field shall be maintained for at least one minute.

NOTE 1: Care should be given to avoid wire-loops.

NOTE 2: The field shall be measured in the absence of the pacemaker.

Compliance shall be confirmed if the pacemaker remains inhibited while the magnetic field is applied.

4.6.2 ICDs

ICDs shall be tested per the sequence described in Section 4.6.1 of this standard.

Compliance shall be confirmed if no transition behavior is observed in the presence of the magnetic field.

4.7 Protection from static magnetic fields of flux density up to 50 mT

The DUT shall not remain functionally affected after exposure to static magnetic fields of flux density of up to 50 mT.

4.7.1 Pacemakers

Test equipment: Use a field coil, capable of generating a uniform magnetic field of flux density of up to 50 mT ± 5 mT, in the region to be occupied by the **pacemaker**.

Test procedure: The required field flux density shall be generated prior to placing the **pacemaker** in the field. Then the **pacemaker** shall be slowly placed in the center of the test coil. **After at least 15 seconds exposure to the magnetic field, the pacemaker shall be slowly removed from the field.**

Re-orientate the **pacemaker** so that a second orthogonal axis is aligned with the axis of the test coil and again subject the **pacemaker** to the required fields. Then repeat again with the third orthogonal axis aligned with the axis of the test coil.

Compliance shall be confirmed if after the magnetic field is removed the pacemaker functions as prior to the test without adjustment.

4.7.2 ICDs

ICDs shall be tested per the sequence described in section 4.7.1 of this standard.

Compliance shall be confirmed if after the magnetic field is removed the ICD functions as prior to the test without adjustment.

4.8 Protection from AC magnetic field exposure in the range 1 to 140 kHz

The **DUT** shall be constructed so that ambient time-variable magnetic fields are unlikely to cause any malfunction of the **DUT** that persists after removal of the magnetic field.

4.8.1 Pacemakers

Test equipment: Use a radiating coil, diameter $\geq$ 12 cm and exceeding the largest pulse generator linear dimension by 50 %, and a calibration coil, diameter $\leq$ 4 cm. The radiating coil shall be energized by a signal generator.

Test field: The test magnetic field, H, shall be modulated at a frequency, f, as defined by Table 8.

Table 8 — Modulated magnetic field strengths

f	H rms
1 kHz $\leq$ f $\leq$ 100 kHz	150 A/m
100 kHz $\leq$ f $\leq$ 140 kHz	150 A/m *100 kHz/f

Test procedure: Using the calibration coil, determine the signal levels applied to the radiating coil that produce the magnetic field, H, in the center of the radiating coil [see Figure 34]. Remove the calibration coil.

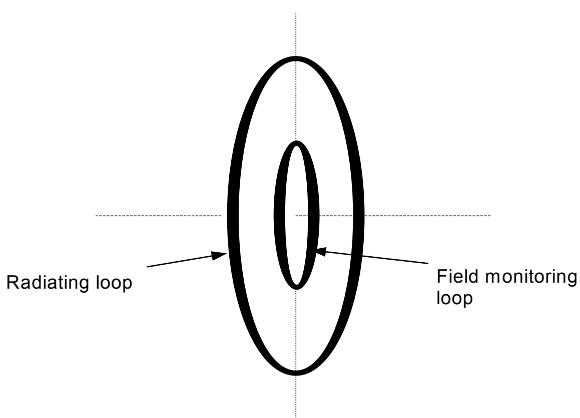

Figure 34 — Loop configuration for varying magnetic field test

Place the center of the **pacemaker** at the field intensity calibration point. Load the cardiac lead **terminals** of the **pacemaker** lead interface as specified by the manufacturer using care to minimize loop areas of connections. Generate the required fields by either sweeping the test signal over the required frequency range at a maximum rate of one decade per minute or by applying the test signal at four distinct, well spaced frequencies per decade with an evenly distributed dwell time of at least 60 seconds per decade.

NOTE: Observe care to slowly increase or decrease the field intensity when applying or removing the test signal.

Re-orientate the **pacemaker** so that a second orthogonal axis is aligned with the axis of the radiating loop and again subject the **pacemaker** to the required fields. Then repeat again with the third orthogonal axis aligned with the axis of the radiating loop.

Compliance shall be confirmed if after application of the specified test signal, the **pacemaker** functions as prior to the test without further adjustment.

4.8.2 ICDs

ICDs shall be tested per the sequence described in Section 4.8.1 of this standard.

CD terminals should be turned off and loaded as specified by the manufacturer, using care to minimize loop areas of connections.

Compliance shall be confirmed if after application of the specified test signal, the **ICD** functions as prior to the test without further adjustment.

4.9 Test requirements for the frequency range 450 MHz $\leq f \leq$ 3,000 MHz

4.9.1 General requirements

Tolerances for time and frequencies shall be ± 1%, unless otherwise specified.

NOTE The rationale for selecting specific test frequencies, modulation, power levels, and other test conditions is provided in Annexes A and B.

Lead configurations

Pacemakers shall be tested with both unipolar and bipolar lead systems when appropriate.

ICDs shall be tested with an appropriate lead system as recommended by the manufacturer.

4.9.2 Test setup

4.9.2.1 Test environment

Caution: Personnel performing the measurements defined in this document should not be exposed to radio-frequency electromagnetic fields that exceed the "Maximum Permissible Exposure" provisions of the IEEE C95.1 standard for controlled environments. Due to the nature of exposures that are likely to be encountered by persons performing the tests described herein, partial body exposures are possible. In these cases, the provisions of the "Relaxation of Power Density Limits for Partial Body Exposures" of the IEEE C95.1 standard can be utilized.

As good test practice, it is recommended that the test tank be placed in an electromagnetically shielded room in order to limit spurious emissions to the outside environment, for example, services licensed by the Federal Communications Commission (FCC). Relocation of the test setup within the shielded enclosure may affect the repeatability of this test.

4.9.2.2 Torso simulator in Annex G

The distance between the surface of the saline and the top surface of the device under test (DUT) and the dipole antenna heights shall be as specified in Table 9.

Table 9 - Requirements for the test setup

Parameter	Specification	Tolerance
Saline resistivity [a)]	375 Ωcm	± 15 Ωcm
Surface of the saline to top surface of the DUT	0.5 cm	± 1 mm
Dipole element axis centerline to saline surface	2.0 cm	± 1 mm
Dipole element axis centerline to device surface	2.5 cm	± 2 mm

[a)] The saline resistivity shall be measured at a low frequency (i.e., ≤ 1 kHz) and is the equivalent of 0.027 molar (1.8 g/l or 0.18%)

NaCl concentration, at 21° C,.

4.9.2.3 Device under test and lead positioning in torso simulator

The DUT is positioned on the bottom grid at the center of the torso simulator. The connector bore for a single-chamber pulse generator or the right ventricular bore of a multiconnector pulse generator shall be aligned with the X-axis (see Figure G1). The lead connector pin (TIP) contact in the pulse generator connector bore on the X-axis defines the DUT reference point. The DUT and its lead(s) rest on the upper surface of the bottom grid and are anchored with nonconducting string. The lead(s) is configured in a spiral extending approximately 5 cm (2 in) from the edge of the device or previous lead placements. The lead electrodes shall be oriented to facilitate DUT monitoring and signal injection.

With the bottom grid and DUT in place, the top grid is placed above it, with the center cutout area aligned over the center of the DUT. The DUT-to-antenna spacing can be adjusted by turning the threaded plastic legs that support the bottom grid. The saline depth over the device under test and the dipole antenna heights shall be adjusted according to Table 9.

4.9.2.4 Interference signal generation

a) Dipole antennas

A detailed description of the dipole antennas is given in Annex H.

b) Test frequencies and modulation

The carrier signal shall be a sinusoidal waveform at each of the following frequencies: 450; 600; 800; 825; 850; 875; 900; 930; 1,610; 1,850; 1,910; 2,450; and 3,000 MHz.

The signal shall be pulse modulated with the following characteristics: The carrier shall be gated on for 25 milliseconds (ms) at 500 ms intervals. Gating rise and fall time should be < 0.5 microseconds (μs).

4.9.2.5 Parameter programming

The DUT shall be programmed per the parameters listed in Annex I and at nominal values for those parameters not defined in the tables. The form of antitachycardia pacing (ATP), if applicable, shall be preprogrammed to avoid confusion with inappropriate bradycardia pacing as defined in 4.9.4.

NOTE: During testing with the simulated heart signal ON, dual-chamber devices may be tested in both AAI and VVI pacing modes in lieu of DDD(R) mode. In this standard, pacing modes are described using a generic code developed by the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG). The full code is explained in Annex C.

4.9.2.6 Monitoring of device activity

The DUT output signal will be detected by electrically monitoring a pair of plates (–X, +X) with monitoring equipment having a minimum input resistance of 1 MΩ (see Figure G2).

4.9.2.7 Simulated cardiac signal injection

A signal generator will be used to apply a simulated heart waveform (described in Annex J) to the second pair of plates, orthogonal to the plates utilized in 4.9.2.6.

4.9.3 Test procedure

4.9.3.1 Required test

Set up the test equipment in accordance with Figure G2. Verify electrical and dimensional requirements of torso simulator setup per Table 9.

Program the DUT and record parameters per Annex I.

a) X-axis testing, simulated heart signal off

Place the 450-MHz dipole antenna on the grid with the axis of the antenna elements parallel to the X axis, with the dipole reference point (see Annex H) centered over the DUT reference point as defined in 4.9.2.3, at the elevation specified in Table 9. The ECG signal shall be OFF.

Set the carrier frequency to 450 MHz. Set the dipole net RF power to 120 mW root mean square (RMS) (continuous wave). Record the forward and reflected power readings for documentation purposes. The net power calculation is presented in Annex K.

Set the RF signal generator for pulse modulation per 4.9.2.4 b).

Monitor and record the DUT performance during exposure to the modulated RF signal. Exposure duration:

— Devices intended to treat bradyarrhythmia (pacemakers)—minimum of 5 seconds (sec).

— Devices intended to treat tachyarrhythmia (including ICDs)—minimum of 15 sec.

(Or longer in either case if required for DUT detection algorithms to fulfill.)

b) X-axis testing, simulated heart signal on, bradycardia rate

Place the 450 MHz dipole antenna on the grid with the axis of the antenna elements parallel to the X axis, with the dipole reference point (see Annex H) centered over the DUT reference point as defined in 4.9.2.3, at the elevation specified in Table 9. The simulated heart signal shall be ON at the simulated bradycardia rate, per Annex J.

Set the carrier frequency to 450 MHz. Set the dipole net RF power to 120 mW RMS (continuous wave). The net power calculation is presented in Annex K.

Set the RF signal generator for pulse modulation per 4.9.2.4 b) and apply the simulated heart signal.

Monitor and record the DUT performance during simultaneous exposure to the modulated RF signal and the simulated heart signal. Exposure duration:

— Devices intended to treat bradyarrhythmia (pacemakers)—minimum of 5 sec.

— Devices intended to treat tachyarrhythmia (including ICDs)—minimum of 15 sec.

(Or longer in either case if required for DUT detection algorithms to fulfill.)

c) X-axis testing, simulated heart signal on, tachycardia rate (only for devices intended to treat tachyarrhythmia)

Place the 450-MHz dipole antenna on the grid with the axis of the antenna elements parallel to the X axis, with the dipole reference point (see Annex H) centered over the DUT reference point as defined in 4.9.2.3, at the elevation specified in Table 8. The simulated heart signal shall be ON at the simulated tachycardia rate, per Annex J.

Set the carrier frequency to 450 MHz. Set the dipole net RF power to 120 mW RMS (continuous wave). The net power calculation is presented in Annex K.

Set the RF signal generator for pulse modulation per 4.9.2.4 b).

Monitor and record the DUT performance during exposure to the modulated RF signal. Exposure duration: 15 sec or longer if required by DUT detection algorithms.

d) Y axis testing

Repeat 4.9.3.1 a) through c), except with the antenna elements parallel to the Y axis.

e) Testing at remaining frequencies

Repeat 4.9.3.1 a) through d) for all frequencies listed in 4.9.2.4 b) using the appropriate dipole antenna.

f) Post-test DUT verification

With the RF signal removed, verify that the programmed parameters of the DUT are the same as the pretest values.

4.9.3.2 Optional characterization testing

A manufacturer may perform the testing described in this subclause to demonstrate immunity to handheld transmitters that are operated without restrictions near the implanted pulse generator. See also Annex B: List of Common EM Emitters.

For optional DUT characterization, net dipole power is set to 8 watts RMS (continuous wave) for the frequency range 450 MHz $\leq f <$ 1,000 MHz and to 2 watts RMS (continuous wave) for the frequency range 1,000 MHz $\leq f \leq$ 3,000 MHz. The test setup and programming of the DUT are as specified in 6.4.1. Repeat 4.9.3.1 a) through f) for these power levels.

4.9.4 Performance criteria

4.9.4.1 Single-chamber pacing modes of antibradycardia devices or ICDs

a) Simulated heart signal OFF

During test exposure with the simulated heart signal OFF, the DUT shall not exhibit any deviation in pace-to-pace interval that exceeds 10% of the programmed rate.

At the completion of the testing or immediately prior to any reprogramming during test, the programmed parameters shall be unaltered from pre-exposure values.

b) Simulated heart signal ON

During test exposure with the simulated heart signal ON, the DUT shall not exhibit any pace pulse during application of ECG and RF signals.

At the completion of the testing or immediately prior to any reprogramming during test, the programmed parameters shall be unaltered from pre-exposure values.

4.9.4.2 Dual-chamber pacing modes of antibradycardia devices or ICDs

a) Simulated heart signal OFF

During test exposure with the simulated heart signal OFF, the DUT shall not exhibit any deviation in pace-to-pace interval that exceeds 10% of the programmed rate.

At the completion of the testing or immediately prior to any reprogramming during test, the programmed parameters shall be unaltered from pre-exposure values.

b) Simulated heart signal ON

During test exposure with the simulated heart signal ON, the DUT shall not exhibit any pace pulse(s) during application of ECG and RF signals.

At the completion of the testing or immediately prior to any reprogramming during test, the programmed parameters shall be unaltered from pre-exposure values.

4.9.4.3 Antitachyarrhythmia modes of ICDs

a) Simulated heart signal OFF

During test exposure with the simulated heart signal OFF, the DUT shall not exhibit either of the following characteristics:

— delivery of defibrillation or cardioversion pulse to the high voltage electrodes; or

— delivery of antitachycardia pacing to the pacing leads.

If either response occurs, then the RF signal shall be disabled for 30 sec, simultaneous with application of inhibition/synchronizing signal(s), if necessary to reset therapy in the ICD.

At the completion of the testing or immediately prior to any reprogramming during test, the programmed parameters shall be unaltered from pre-exposure values.

b) Simulated heart signal ON (tachycardia rate)

During exposure to RF and simulated heart, the DUT shall deliver an appropriate therapy to the high-voltage electrodes or exhibit evidence that such a pulse could be delivered.

At the completion of the testing or immediately prior to any reprogramming during test, the programmed parameters shall be unaltered from pre-exposure values.

5 Testing above 3,000 MHz frequency

This standard does not require testing of devices above 3 GHz. The upper frequency limit reflects consideration of the following factors: (1) the types of radiators of frequencies above 3 GHz, (2) the increased device protection afforded by the attenuation of the enclosure and body tissue at microwave frequencies, (3) the expected performance of EMI control features that typically must be implemented to meet the lower frequency requirements of this standard, and (4) the reduced sensitivity of circuits at microwave frequencies.

Electromagnetic fields at frequencies above 3 GHz are mostly directed beams that do not cause high intensity public exposure. Common applications include radar and microwave communication links that do not produce exposure to the main field beam. Patient exposures by such microwave field sources are typically due to lower intensity antenna pattern side-lobes and scattered fields. Anticipated future vehicular applications that may involve greater public exposure are not expected to be problematic because of low intensity and high microwave frequency.

Device circuitry is highly shielded against effects of microwave fields by the metallic enclosure. The principal EMI mode is by field energy coupled to electrical leads connecting the device to the heart. However, the amount of field energy coupled to leads decreases with increasing frequency in the microwave range due to greater field attenuation in over-lying body tissues. Coupled field energy that reaches the device terminal is further attenuated by EMI control features that typically must be implemented in the device to meet the radio frequency requirements of this standard.

6 Protection of pacemakers and ICDs from electromagnetic fields encountered in therapeutic environment

6.1 Protection of the device from damage caused by HF surgical exposure

The DUT shall be designed so that stray, high frequency currents from electrosurgical equipment flowing through the patient shall not permanently affect the device and the settings are recoverable through reprogramming , provided the DUT does not lie directly in the path between cutting and return (HF earth) electrodes.

6.1.1 Pacemakers

Test setup: Use an RF test signal generator, output impedance 50 Ω. Each DUT input and/or output terminal, as applicable, shall be connected through individual 170±2% Ω, 1W resistors (R_L) to ground [see Figure 35]. The case of the DUT shall be connected directly to the signal generator output, unless the case is covered with an insulating material.

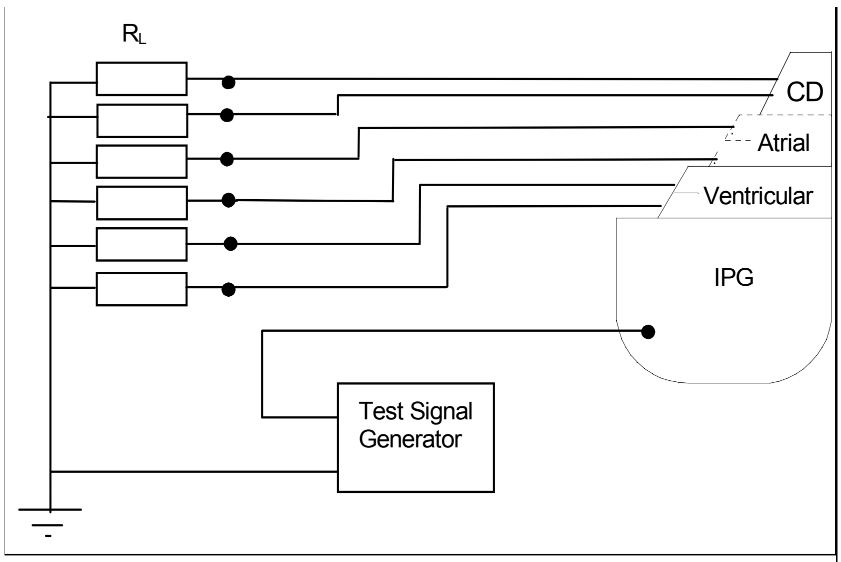

Figure 35 Test setup for protection of the device from high frequency currents caused by HF surgical equipment

Test signal: The test signal frequency shall be 500 kHz and the open loop test signal amplitude as shown in the Table 10 below.

Table 10 – Test signal characteristics

Test signal voltage	Waveform	Test period
36 Vpp	Continuous wave	30 seconds application

Test procedure: Apply the test signal above.

Compliance shall be confirmed if after completing the test procedure, the device is not permanently affected and the settings are recoverable through reprogramming.

6.1.2 ICDs

Test per section 6.1.1. In addition to that the c/d terminals should be loaded with R_L = 50ς.If possible, the ICDs shall be programmed with high voltage therapy OFF.

6.2 Protection of the device from damage caused by external defibrillators

The DUT shall be designed so that external defibrillation of the patient will not permanently affect the device, provided that the external defibrillator electrodes (e.g. paddles) are placed according to the DUT manufacturer's recommendations.

6.2.1 Pacemakers

<u>*Test 1*</u>

Test equipment: Use a defibrillation pulse generator providing a damped sinus waveform as in Figure 36 with the following characteristics T_p=1.5 to 2.5 ms, T_{w50}=3 to 5.5 ms, where T_p is the time interval from the start of the defibrillation pulse to the maximum voltage V_{test} and T_{w50} is the time interval during which the test voltage is above 50% of the maximum value (V_{test}).

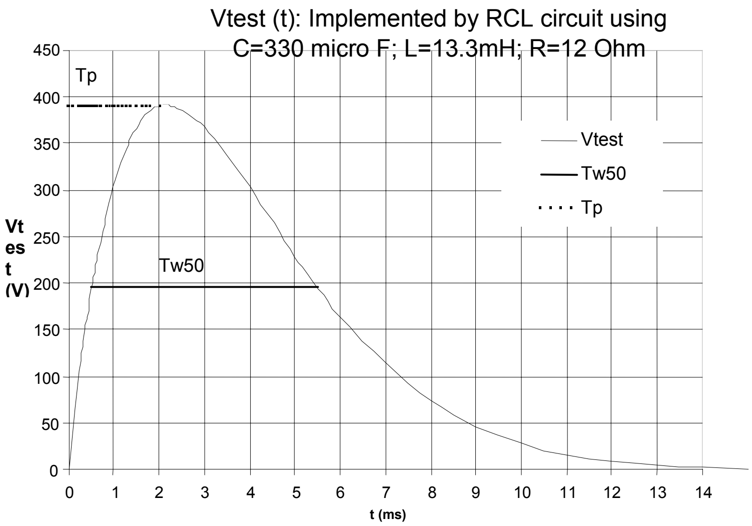

Figure 36 — Damped sinus waveform

Figure 37 illustrates an example schematic with: C = 330 µF ± 16,5 µF; L = 13,3 mH ± 0,13mH; R_L+ R_G = 15 Ω ± 0,3Ω

where R_L is the resistance of the inductance in ohms and R_G is the defibrillation pulse generator output resistance ohms.

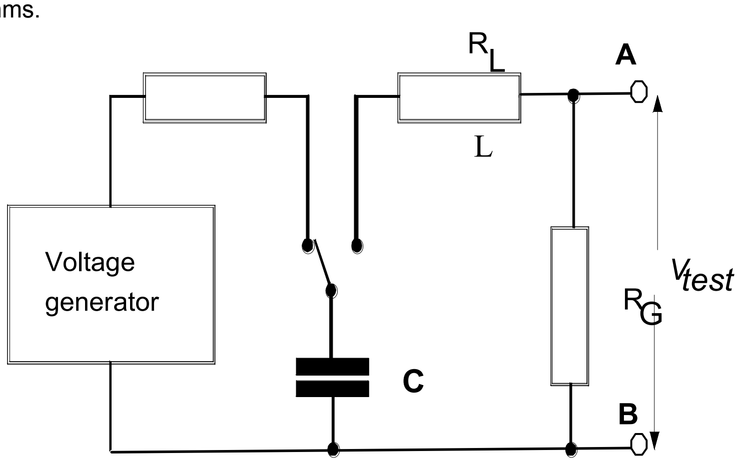

Figure 37 — RCL circuit for generating a damped sinus defibrillation waveform for Test 1

Test procedure for Test 1: Connect the output V_{test} to terminals A and B of the resistor network in Figure 40 (with parameters in Table 11, Test 1).

The pulse amplitude of the output voltage (V_{test}) at the output of the defibrillation pulse generator, across R_G, shall be 380 V+5% - 0%.

The **pacemaker** shall be categorized into one or more of four groups as appropriate and connected as indicated:

- single channel unipolar pacemakers shall be Group a); connect the Tip terminal to output D
- multichannel unipolar pacemakers shall be Group b); connect the Vtip to D and Atip to F
- single channel bipolar pacemakers shall be Group c); connect Vtip to D, Vring to E
- multichannel bipolar pacemakers shall be Group d); connect Vtip to D, Atip to F, Vring to E and Aring to G

Connect the case terminal of the pulse generator to output I of the resistor network (see Figure 40).
Test by applying a sequence of three voltage pulses of positive polarity at 20-25 s intervals. Then after an interval of 60 s minimum repeat the test with pulses of negative polarity (see Figure 38 below).

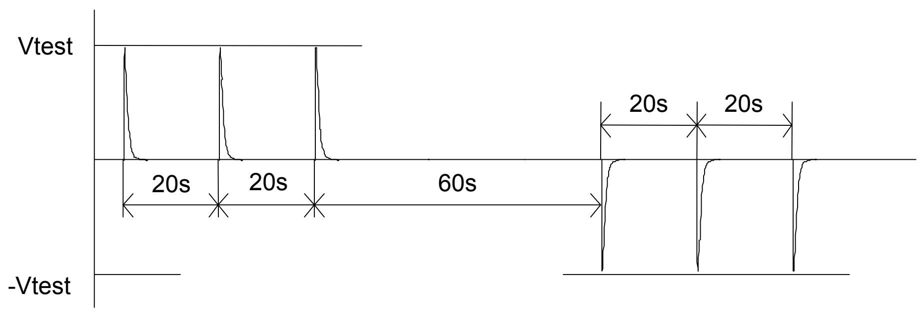

Figure 38 – Timing sequence used in Tests 1 and 2

Compliance shall be confirmed if after completing the test procedure, the device is not permanently affected and the settings are recoverable through reprogramming.

Test 2:

Test equipment: Use a test setup as shown in Figure 39 with C=150±50 μF and two coupled switches S1 and S2 and the resistive network in Figure 40 with the parameters defined in Table 11, Test 2.

Test signals: A monophasic, truncated exponential waveform with duration of Td = 10 ± 0.5 ms will be generated between outputs A and B activating the coupled switches S1 for a time period Td.

A biphasic, truncated exponential waveform is accomplished by changing the position of the coupled switches S2 during the ongoing pulse after a time of Td/2 (e.g. after 5 ms from upper position to lower position). The initial position of the coupled switches S2 determines the initial polarity of the output pulse.

The biphasic waveform is shown in Figure 41 with the following parameters: 1 μs < tr < 5 μs; tc ≤ 2 ms; 1 μs < tf < 5 μs.

Test procedure for Test 2: The pulse amplitude of the output voltage of the defibrillation generator shall be 270+5% -0% V between outputs A and B of the resistor network. Connect the pulse generator according to pacemaker category to the outputs C to G of the resistor network similar to the way described in test 1 above.

Test by applying a sequence of three monophasic voltage pulses of positive polarity at 20-25 s intervals. Then after an interval of minimum 60 s repeat the test with pulses of negative polarity (for timing sequence see Figure 38). Repeat the test using the biphasic test pulse in Figure 41.

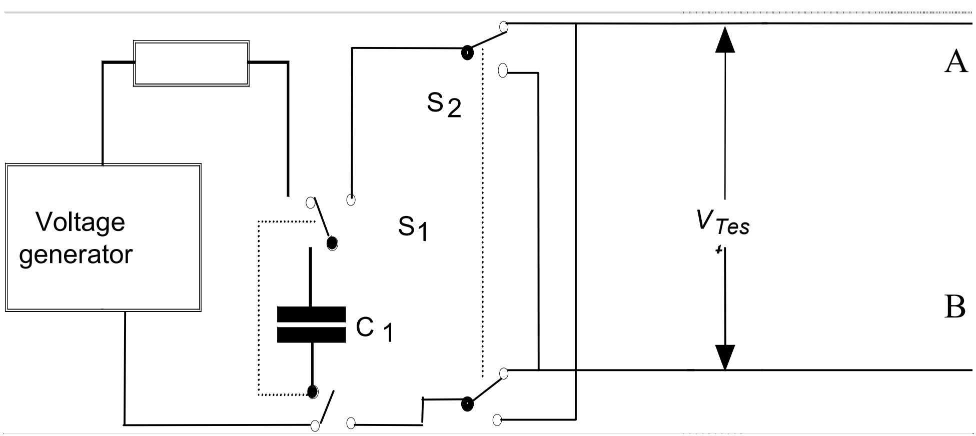

Figure 39 – Test setup for Test 2

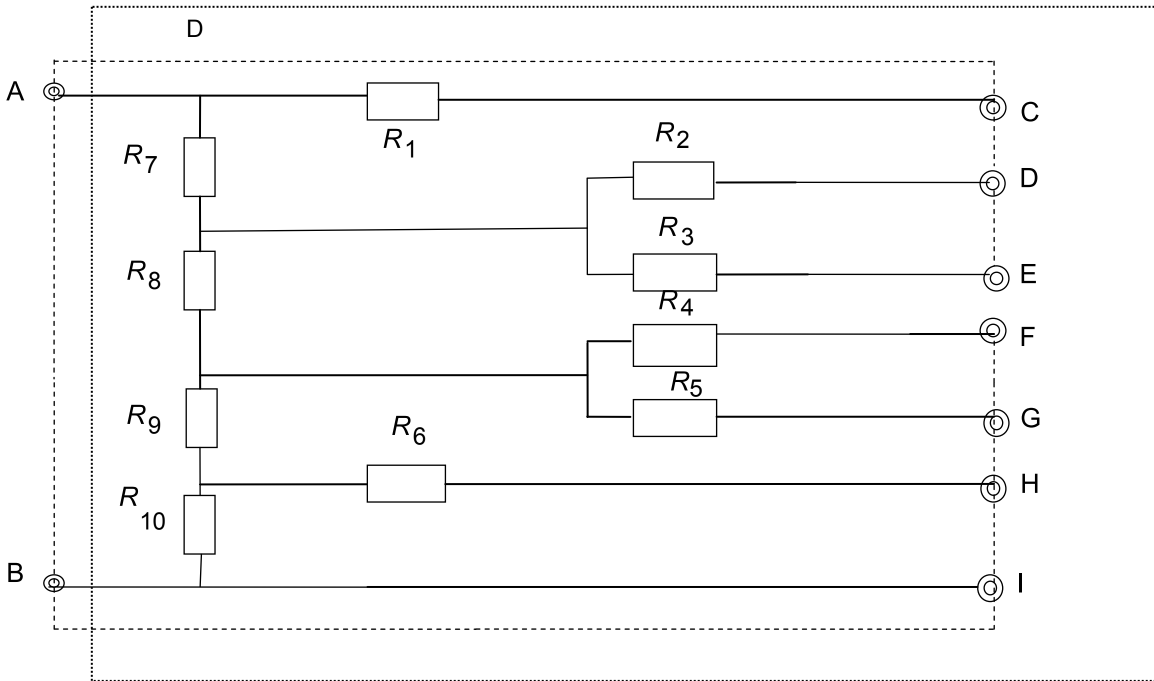

Figure 40 – Resistor network for Test 1 and Test 2

Table 11 – Resistor network parameters

Test	R1	R2	R3	R4	R5	R6	R7	R8	R9	R10
1	50 Ω	800 Ω	400 Ω	800 Ω	400 Ω	50 Ω	5 Ω	5 Ω	25 Ω	30 Ω
2	50 Ω	600 Ω	300 Ω	600 Ω	300 Ω	50 Ω	5 Ω	5 Ω	25 Ω	30 Ω

All resistors will be ±5%.

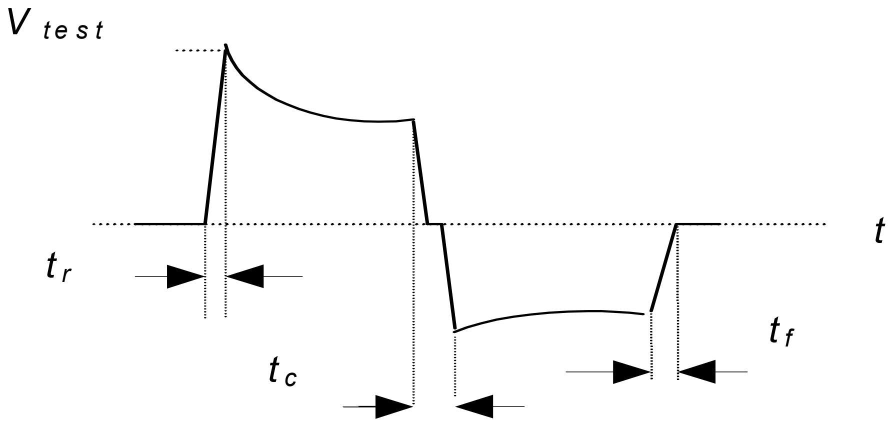

Figure 41 – Waveform for Test 2

Compliance shall be confirmed if after completing the test procedure, the device is not permanently affected and the settings are recoverable through reprogramming.

6.2.2 ICDs

Repeat test sequence in 6.2.1 with the following changes: in Figure 40 connect RV electrode to C and SVC electrode to H.

Annex A
(informative)

Rationale

This annex provides the rationale for certain provisions of this standard as useful background in reviewing, applying, and revising the standard. This rationale is directed toward individuals familiar with the subject of this document but who have not participated in its drafting. Remarks made in this annex apply to the relevant clause, subclause, or annex in this standard; the numbering may, therefore, not be consecutive.

A.1 Rationale for test requirements for the frequency band—0 Hz $\le f <$ 450 MHz

Exposure of a **pacemaker** to an electromagnetic field may:

induce currents from the **lead** into the heart, causing fibrillation or local heating;

induce voltages in the **lead** that damage the **DUT**;

induce voltages in the lead that prevent the **DUT** from correctly monitoring the intrinsic heart signal (ECG).

Additionally, **DUTs** incorporate magnetic control components (e.g. reed switches) that may be activated by magnetic fields. The magnetic control component or other circuit components of the **DUT** may be damaged by stronger magnetic fields

Hence some assurance is required that **DUTs** offer reasonable immunity to electromagnetic interference and from currents passing through the human body when the patient is in contact with domestic appliances.

The subclauses address:

protection from tissue damage or fibrillation caused by currents induced on the implanted **LEAD** directly or injected spuriously from the device (4.2);

protection from persisting malfunction of the device caused by voltages induced in the implanted **LEADS** (4.3);

protection from unacceptable transitions or operating modes of the device caused by voltages induced in the implanted **leads** (4.4);

protection from transient changes in therapeutic behavior of the device caused by voltages induced in the implanted **leads** (4.5);

protection from transient changes in therapeutic behavior of the device caused by weak (1 mT) static magnetic fields affecting any magnetically-sensitive components in the **DUT** (4.6);

protection from persisting malfunction of the device caused by stronger (10mT) static magnetic fields affecting any magnetically-sensitive components in the **DUT** (4.7);

protection from persisting malfunction of the device caused by time-varying magnetic fields applied to the **DUT** (4.8).

The EMI (Electromagnetic Interference) tests extend over a frequency range from 0 Hz (to include possible static magnetic environmental fields) to 3 GHz (to include radiation fields from mobile telephones).

The clause does not cover exposure to therapeutic and diagnostic treatments (with the exception of external defibrillation and electrosurgery), or to fields that occur in some occupational environments. Hence the device manufacturer may need to be consulted in case of uncertainty relating to occupational exposure to specific sources.

NOTE 1 The tests are not intended to cover any embedded telemetry antenna external to the electromagnetic shield of the DUT, unless such an antenna is an integral part of a lead. Electromagnetic susceptibility applicable to these parts is under consideration.

NOTE 2 In defining the tests, the setting of test **signal** equivalent to ambient electromagnetic fields required assumptions about the electrical characteristics of the DUT input and the layout of the implanted **lead**. These assumptions may not be valid for other than **LEADS** conducting an intracardiac signal to pacing/sensing terminals. Accordingly other physiological sensors (e.g. minute ventilation) are not covered by the tests of 4.2 through 4.5.3 and such additional sensors may be turned off during testing.

When considering the most appropriate sensitivity settings for the **DUT** under test, the working group considered both unipolar and bipolar configurations and concurred that **sensitivities** of 0.3mV (bipolar) and 2.0mV (unipolar) were appropriate for electromagnetic interference test frequencies above 1kHz. In arriving at these values, the group acknowledged that although state of the art **DUTs** provided settings, which were substantially more sensitive (e.g. 0.1mV), that such settings were primarily provided to aid the clinician in diagnostic testing. The working group considered that diagnostic programming at the more sensitive levels to be only temporary and that, in clinical practice, permanent programming of such values was usually avoided due to increased likelihood of far field sensing, myopotential sensing, and sensing of electromagnetic interference.

Consequently, an associated warning in the accompanying documentation was considered appropriate to alert the clinician that careful consideration should be given to patient exposure to electromagnetic interference etc, if programming **sensitivity** greater than 0.3mV (bipolar) and 2.0mV (unipolar).

It was acknowledged, however, that a few patients may require atrial **sensitivity** to be set to detect signals less than 0.3mV if atrial lead positioning was sub optimal or if sensed p-wave signals were often unusually low in amplitude (as in “single pass” VDD systems). For the majority of pacemaker patients however, settings more sensitive than 0.3mV (bipolar) and 2.0mV (unipolar) were considered to represent an increased risk from inappropriate far field and myopotential sensing, and from electromagnetic interference in those models which do not have immunity at the more sensitive settings.

The requirement to test at four distinct, well-spaced frequencies per decade may be normally met by following a f, 2 f, 4 f, 8 f, 16 f … sequence.

Electromagnetic fields may affect the **DUT** directly through its case or indirectly via induced currents and voltages in the implanted **leads**. In 4.2 to 4.5 currents and voltages induced in the implanted **leads** are the dominant effect, hence the requirement is tested by an injected voltage test at frequencies below 450 MHz and by a near field test of the **DUT** connected to its leads at frequencies above 450 MHz. The injected voltage tests use tissue interfaces (between 16.6 Hz and 10 MHz) or the injection network (between 10 and 450 MHz) to duplicate body tissues. These interfaces were developed in the 1980s as part of the work done for the development of the CENELEC standards EN 50061 Amendment 1 and EN 45502-2-1 (reference: T. Bossert, M. Dahme, Immunity to disturbance of cardiac pacemakers in RF fields of powerful radio transmitters, IRT Munich, Report, 1987). Additional work was done in the 1990s, reference: F. M. Landstorfer et alia, Development of a model describing the coupling between electrodes of cardiac pacemakers and transmitting antennas in their close vicinity in the frequency range from 50 Hz to 500 MHz, High Frequency Institute University of Stuttgart, Final Report, 1999.

In 4.6 to 4.8, there may be direct effects through the case of the device; hence the tests involve the field itself with no **LEAD** connected to the **DUT**.

Permitted human exposure to electromagnetic fields is limited by a number of national and international guidelines and recommendations from bodies such as ICNIRP, the European Commission, CENELEC, ANSI, IEEE and the IEC. Requirements in this clause take account of known sources of electromagnetic fields in the public environment. Requirements of 4.5 are based partly on Reference Levels for electro-magnetic fields in the European Recommendation 519 issued in 1999 (EC/519/99), under certain assumptions of field-to-voltage transfer functions. Reference Levels represent the most lenient test of acceptability of general public exposure to fields according to EC 519/99. Magnetic fields more than 20 times higher than the Reference Levels may comply with the Basic Restrictions of EC 519/99, especially for localized sources of electromagnetic fields at low frequencies. Accordingly, requirements of subclauses 4.3 and 4.7 are intended to prevent incompatibility with higher magnetic fields than the Reference Levels of EC Recommendation 519/99/EC.

In accordance with AIMD Directive 385/90/EC, clause 4 covers only fields of the order of magnitude likely to be encountered in the normal environment.

In an electromagnetic field, any implanted **lead** acts as an antenna. The voltages picked up by, and currents induced in this antenna depend upon the implantation site and upon the layout and characteristics of the **lead** as well as the frequency, polarization and direction of the electromagnetic field. The requirements in this clause are based on conservative assumptions about such coupling factors.

The frequency of the electromagnetic field influences the mechanism for induction of voltages and currents in the device and its leads, and also the transfer function expected between applied field strength and induced voltage. At low frequencies (below a few MHz) any lead and its return path (through the body for **unipolar leads**) form a closed conductive loop around which voltages are induced: the body has little screening effect on the fields, and the induced voltage is proportional to the frequency. As the frequency increases beyond this, body tissue starts to shield electromagnetic fields, and additionally the device leads act increasingly as dipole antennas. These effects are complex, and appropriate transfer functions are given in the German Draft Standard DIN VDE 0848-3-1:2003-10. At low frequencies, the effective induction loop area is considerably higher for **unipolar leads** than for bipolar, leading to higher induced voltages. Existing data indicates that for implants using present techniques, cross sectional areas are smaller than 200 cm^2 (typical) for pacemakers and 232 cm^2 (typical) for ICDs and the largest will not normally exceed 319 cm^2 (worst case), see Annex L for details.

The leads of multichannel unipolar **pacemakers** may act as multiple antennae. Thus each channel must be tested as if it were a single channel device. Care must be taken to avoid cross talk between channels, which could affect the result.

Bipolar leads induce differential voltages between tip and ring **electrodes**. The tests of bipolar **pacemakers** include a second procedure to cover this effect. Because of the close proximity of tip and ring **electrodes**, the applicable test **signal** is reduced to 10 percent of the common mode test signal amplitude.

<u>Selection of C_X</u>: The capacitor C_X in the tissue equivalent interface circuit serves to attenuate any spurious low frequency noise during burst and pulse amplitude modulation of the test signal carrier frequency. This spurious noise may incorrectly identify a **DUT** as sensitive to some or all of the test signals.

Spurious noise created by signal generators during periods of modulation generally has been found to be low frequency components independent of signal frequency which increase in amplitude with increasing signal amplitude. At the higher amplitudes, the spurious low frequency noise injected by the test signal generator may become significant, because of the necessary **sensitivity** of the **DUT** to the harmonic content with intra-cardiac signals. To attenuate these spurious signals the capacitor C_X in combination with a 68 Ω resistor forms a high-pass filter. The value of C_X is selected per the procedure of Annex E.

For burst-modulated signals, carrier frequencies of at least 1 kHz should be used when selecting C_X. The low-pass filter is used so that significant frequency components from burst modulated test signals are removed. Otherwise those components would be confused on the monitoring oscilloscope with any spurious low frequency components from the signal generator.

At low frequencies, the effect of C_X may be opposite to that desired. As an example, if the selection procedure sets C_X = 470 nF, the amplitude of the test signal at point C has to be increased if the test **signal** monitored at point D is not as required This increase in signal may increase the amount of spurious low frequency noise. Thus, the attenuation of the low frequency spurious noise by C_X may be more than offset by the increased amplitude injected. In this case, the use of C_X my cause an otherwise unaffected device to be affected by the test signal (corrupted by the spurious noise), and indicate false failure of the device. The use of C_X should be limited to cases where failure to comply may be caused by the test equipment. Compliance does not require C_X to be in-circuit, and, therefore, the use of C_X is optional at any frequency.

Sub clause 4.1 Because the tests of 4.2 through 4.8 might change permanently some electrical characteristics of the **DUT**, a final test against the manufacturer's electrical specifications is required.

Sub clause 4.2 Addresses the risk of demodulation products or currents picked up on the **leads** causing fibrillation or local tissue burns.

The fields experienced in the normal environment are not high enough to cause these effects even with a short circuit at the connector side of the lead. But touching some household appliances may cause currents sufficient to cause fibrillation. In addition, direct therapeutic treatment also may induce currents, which produce local tissue burns. If the therapeutic signals are modulated, demodulation in the circuitry of the **DUT** may cause fibrillation.

Data collected by Starmer and Watson indicate that the probability of inducing fibrillation with a 50 or 60 Hz rms current of 50 µA applied directly to the heart through **electrodes** with surface areas ranging from 1,25 to 2 mm^2 is 1%. Above 1 kHz the threshold current for fibrillation rapidly increases.

The test effectively checks that the **INPUT impedance** of the **DUT** is high enough to prevent dangerous currents. Test **signal** 1 stops at 20 kHz because above this frequency the loop impedance of the **electrode** plus body tissue naturally limits the current to acceptable levels. Test **signal** 2, at 500 kHz, commonly used for surgical diathermy, checks that any demodulation current is smaller than 50 µA. The requirement of this clause is compatible with IEC 60601-1.

The test cannot provide adequate safety in all situations and the required voltage of 2 V pp represents a first compromise in the absence of other data. During the treatment, the diathermy electrodes must always be placed in such a way that as little current as possible traverses the **DUT** and **lead**. Even with such precautions, neither risk of damage to the **DUT**, nor risk of fibrillation can be completely prevented.

The test procedures necessary to verify compliance with the requirements depend upon the type of **DUT** under test. Channels are tested in turn. The tissue interface provides two outlets for each channel.

If the channel under test is unipolar, both outlets of the tissue interface are connected in parallel to load the unipolar channel of the **DUT** with the full test signal being grounded at case of the device.

If the channel under test is bipolar, one outlet of the tissue interface is connected to the tip and one to the ring connector. So the bipolar channel of the **DUT** is loaded with the full test signal in a common mode circuit grounded at the case of the device, while tip and ring are isolated. Additionally the test is repeated in a differential mode, with the test signal provided between tip and ring. In this case the test **signal** is decreased by 90 %, since the antenna effect is smaller due to the decreased distance between tip and ring **electrodes**.

The test for the case using a C/D lead as the sense/pace indifferent was eliminated as currently there is no device with such a feature and it doesn't seem likely one would be designed. It was considered that the remainder of tests covers adequately the requirement.

Sub clause 4.3 Requirements to demonstrate that the device is neither damaged nor needs reprogramming after a reasonable interference overload had occurred at its **terminals**.

The categorization is similar to 4.2, but all channels are tested in parallel as in 4.4 and 4.5.

The test for the case using a C/D lead as the sense/pace indifferent was eliminated as currently there is no device with such a feature and it doesn't seem likely one would be designed. It was considered that the remainder of tests covers adequately the requirement.

Subsequent clauses address exposure of the device to fields that might be experienced for prolonged periods. However, higher fields might be experienced for short periods from localized sources of varying magnetic fields, such as metal detectors or anti-theft devices. Clause 4.3 addresses exposure to such fields over the limited frequency range over which these fields may induce voltages not covered by the other subclauses. Because exposure to such fields is expected to be of short duration, 4.3 checks for malfunction that persists beyond the removal of the exposure only.

The effects of high level localized alternating magnetic fields may be via voltages induced in the leads or by fields penetrating directly through the case of the implanted pulse generator. The direct effect is covered by 4.8.

At frequencies below a few kHz, the test in 4.3 covers voltages that may be galvanically (conductively) coupled into the DUT by a patient touching some household device.

Sub clause 4.4   Checks the therapeutic behavior as declared by the manufacturer in the presence of ambient continuous wave interference.

The categorization is similar to 4.2, but all channels are tested in parallel as in 4.3 and 4.5. The frequency band ends at 167 kHz since above this frequency the test of 4.5 covers the necessary requirement.

The test for the case using a C/D lead as the sense/pace indifferent was eliminated as currently there is no device with such a feature and it doesn't seem likely one would be designed. It was considered that the remainder of tests covers adequately the requirement.

As described earlier, the relevant fields are represented in this test as injected voltages. Because the frequency band overlaps the frequency band of physiological signals, as the voltage level is slowly increased, at some point a **DUT** may start to sense the interference. As the signal amplitude is further increased, one ore more changes in the therapeutic behavior may occur, due to small changes (or noise) in the sensed signal or stochastic phenomena in the sensing criteria.

This subclause checks at all voltages up to the maximum level specified. Therefore any isolated regions of influence and/or unacceptable uncertainty will be identified. A change in therapeutic behavior to a fixed-rate mode, as characterized by the manufacturer, is regarded as a clinically acceptable change provided the transition is completed within the permitted limits set by the compliance criteria of this subclause.

Sub clause 4.5   Checks for changes in therapeutic behavior caused by interference from modulated signals. The categorization required is similar to clause 4.2 but all channels are tested in parallel, as in clauses 4.3 and 4.4.

The modulation carried by the test interference signal has significant harmonic content overlapping that of ECG signals. DUTs may be sensitive to some of these frequency components for good and useful reasons. DUTs usually have a facility to ensure they provide pacing at a fixed rate, “interference mode”, rather than being inhibited by a large interference signal. The test in 4.5.1, therefore allows such a response if this is described in the physician’s manual.

Two different patterns of modulation are defined. At frequencies below 150 kHz, the modulation is pulsed because most interference sources are pulse modulated.

At frequencies above 150 kHz, the test signal simulates the lowest modulation frequency used with amplitude modulated broadcast transmitters, this being considered the most critical case for a **DUT**. The modulation frequency of the test signal is set to 130 Hz to avoid harmonics of both 50 Hz and 60 Hz mains supplies. The strongest effect occurs with full modulation. When testing, to avoid spurious effects from over modulation, the test modulation is set to 95 percent.

The curve of the test **signal** has several corner-points to take account of different considerations. In the frequency range from 3 kHz to 1 MHz, the voltage levels are derived from fields of the general public Reference Levels of European Recommendation EC/519/99. These give an indication of fields that may be experienced for long periods of time by the general public. For frequencies above 100 kHz the EC recommendation accepts increased peak values with respect to rms values. This is taken into account in 4.5 by assuming up to five simultaneous amplitude modulated signals that together match the rms Reference Level (i.e. up to a ratio of peak value over rms value not exceeding 5.6). Between 1 MHz and 10 MHz the test **signal** represents the type of exposure expected from radio transmitters. Above 10 MHz the test **signal** is limited to values considered as reasonable practical protection limits.

The requirement in the frequency range of 10 MHz to 450 MHz, 4.5.3, replaces the tissue equivalent interfaces used at lower frequencies by a 50 ohm injection network.

Sub clause 4.6   Ensures protection from exposure to weak magnetic fields. If the **DUT** contains a magnetic switch, this switch should not be activated by weak, static magnetic fields with which the patient may come in contact. An example is the magnetic strip used to seal refrigerator doors. Traditionally, this field limit has been set at 1 mT (10 gauss).

Sub clause 4.7   Defines protection from exposure to stronger (50 mT) static magnetic fields. These magnetic fields have the potential to permanently disrupt the operation of an **implantable pulse generator**. If the **DUT** contains a magnetic switch, the behavior of the device will probably be altered in the presence of the magnetic field. For example, telemetry could be activated or therapy could be deactivated. The manufacturer must assess the **hazard** to the patient that could result from the inadvertent closure of the magnetic switch as part of an overall risk assessment.

However, once the strong magnetic field is removed, the **DUT** must function as prior to the exposure without adjustment. Therefore, a change in **DUT** operation which could be resolved by programming would be considered a failure of this test.

Sub clause 4.8 Checks for persistent malfunction being caused by direct application of time-varying magnetic fields to the **DUT**.

Subclauses 4.2 to 4.5 assume that the major influence of applied time-varying electromagnetic fields is through induced voltages and currents in the **leads** of the device, which are therefore represented as injected current and voltage signals. The test of 4.8 ensures that time-varying magnetic fields to which the public may be exposed do not cause malfunction due to direct effects of the field on the internal circuitry or components of the device. In the general public environment, human exposure to magnetic fields is limited by a number of international standards and recommendations. At frequencies from a few kHz to 100 kHz, worldwide limits are generally set at a constant field level throughout the frequency band. For localized fields very close to magnetic field generating equipment this limit corresponds to about 100 to 150 A/m rms (for example the IEEE limit is 163 A/m). In this frequency range this will represent the most extreme field to which the implanted device is likely to be exposed. The field level of 150 A/m also corresponds closely to the voltage test levels of test 4.3. A field of 150 A/m rms applied to an induction loop of 200 cm^2 would induce peak-to-peak voltages of 1.33 V at 20 kHz increasing linearly with frequency, which is very similar to the levels used in 4.3. 150 A/m is also the field strength recommended as a generic test in ISO 14708-1. Above 100 kHz the field falls linearly to represent the likely fields from potential sources of interference. The test is terminated at 140 kHz since no significant sources resulting in public exposure exist above this frequency.

A.2 Rationale for test requirements for the frequency band—450 MHz $\le f \le$ 3,000 MHz

A.2.1 Rationale for DUT reference point

Electromagnetic fields of handheld transmitters operating in the frequency range covered by this standard affect implanted cardiac devices primarily through field-to-lead energy transfer at the connector of a pacemaker or ICD. The lead connector (TIP) pin contact in a single-chamber pulse generator or the right ventricular lead connector (TIP) pin contact of a multiconnector pulse generator is defined as the common reference point as this should encompass most devices. If a multiconnector pulse generator does not have a right ventricular port, the manufacturer must define and document the point in the connector that serves as the DUT reference point.

A.2.2 Rationale for the RF modulation

The principal RF interaction in implanted cardiac devices is spurious electromagnetic interference (EMI) signal generation through undesired demodulation of high-amplitude RF signals on pacing leads. Spurious EMI signals, which are similar to the pulsating cardiac signal sensed by the cardiac device, are most likely to cause interactions. The RF modulation for tests specified by this standard represents the worst case by using a rate and pulse width that simulates physiological signal characteristics and, as a result, lies within the implantable pulse generator's bandpass. Typical communications service signal modulations are less disturbing than the modulation specified by this standard.

A.2.4 Rationale for the optional characterization testing

The 120-mW power level described in this standard allows a high level of confidence that an implantable pulse generator will not be affected by electromagnetic interference from a handheld emitter at a 15-cm distance. A manufacturer may perform the optional characterization tests to demonstrate immunity without regard to the separation distance.

A.2.5 Rationale for test power levels

The dipole antenna power levels defined in the first edition of this standard were derived from measurements of RF signals coupled to an instrumented pulse generator can with leads installed. The chart in Figure A1 shows the result of experiments that measured dipole net power that induced the same peak voltage on pacing leads as was produced by cellular phones. Specially instrumented pacemaker cans and a spectrum analyzer were used to measure the EMI signal voltage induced on bipolar and unipolar pacing leads. The instrumented pacemaker can and pacing leads were placed in a saline tank according to the specifications of the dipole test protocol. The peak voltages induced on the pacing leads by wireless phones were measured using two phone orientations as each phone was moved along the X and Y axes to locate the point of maximum signal coupling. In one orientation, the phone was held at a 30-degree angle to the phone support grid with the antenna tip pressed against the grid. In the second orientation, the phone rested on the support grid or was elevated 5, 10, or 15 cm above the pacemaker can, and the antenna axis was parallel to the saline surface. Dipole antennas were located 2.5 cm from the pacemaker can and were moved along the X- and Y-axes to locate the point of peak voltage induction on the pacing leads. At the point of maximum coupling, dipole net power was adjusted to match the lead-induced voltage measured for a particular cellular phone and spacing.

These experiments indicated that a maximum of 12 mW net dipole power was required to match the highest induced voltage observed from cell phones that were spaced 15 cm from the pacemaker can. The specified test requirement of a 40-mw dipole net power level in the first edition is approximately three times this level. These experiments also demonstrated that the optional 8-watt and 2-watt dipole test levels produce higher lead voltages than are produced by wireless phones operated immediately adjacent to the pacemaker.

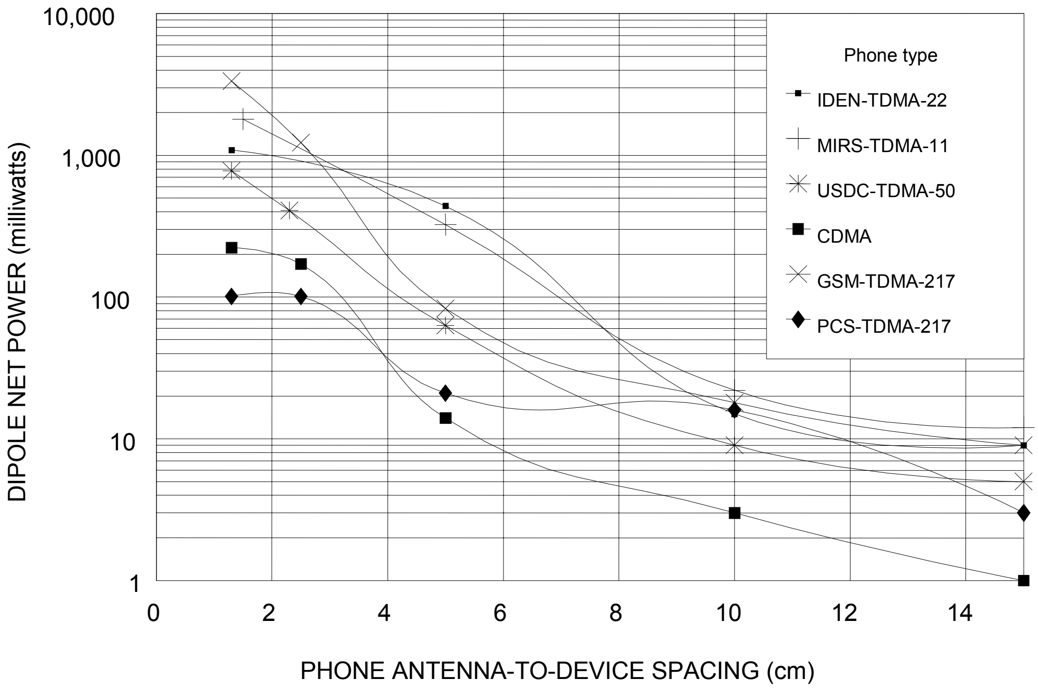

Figure A1 - Dipole net power measurements (dipole spacing = 2.5 cm) conducted for the first edition

The 40-mW dipole net power level specified in the first edition of this standard ensured compatibility of implanted cardiac devices with handheld wireless and personal communication services (PCS) phones (e.g., IDEN, MIRS, USDC [TDMA-50 at 800 MHz], CDMA [CDMA at 800 MHz], GSM [TDMA-217 at 900 MHz], PCS [TDMA-217 at 1,900 MHz]) and other similar power hand-held transmitters when the transmitter maintained a minimum of 15 cm from the implanted device.

At the time the 40 milliwatt testing requirement of the first edition of this standard was developed, cell phones were primarily voice devices and only had non-voice data streams during registration or network synchronization.

Over the last few years, GSM has replaced analog and older digital technologies in the cellular (850 MHz) band, and can transmit peak pulse powers in this lower band of 2 watts. While overall time-averaged transmit power levels may have generally decreased over time due to improved network density and migration of services to the upper (PCS) bands, the maximum possible (peak pulse) power levels in the cellular (850 MHz) band have significantly increased. Moreover, the incorporation of multiple transmitting antennas (to support WiFi, Bluetooth links), evolving form factors, higher bit rates to facilitate data and internet access, and the use of wireless headsets have resulted in a more complex and diverse pattern of use and exposure.

The GSM technology protocol specifies that registration, network synchronization, and information exchange can initially performed at peak pulse transmit power levels (albeit often only for a very short series of bursts). The user of a mobile phone has very little control of this transmission and exchange of data, and for pacemaker patients such emissions could represent a situation with significantly greater exposure than from older technology.

In addition, there has been a proliferation of new emitters in this same time period. WiMAX, UWB, and other technologies are rapidly being developed, and several RFID devices are on the market. For example, there are a number of fixed and portable RFID devices that transmit 3 watts or more effective radiated power in a number of frequency bands from 135 kHz to 5.875 GHz (one common RFID frequency is 915 MHz). These other transmitters require additional study and are to be a focus in the third edition of this standard.

During the development of the second edition, the AAMI EMC Task Force discussed the above factors and decided that a further increase to 120 mW might be prudent. This requirement is consistent with current industry practices when the transmitter is maintained a minimum of 15 cm from the implanted device for patient guidance and labeling of devices that are not designed for compatibility with close-proximity wireless phones.

The optional characterization test specified in 4.9.3.2 requires dipole net power levels of 8 watts in the frequency range 450 MHz $\le f <$ 1,000 MHz and 2 watts in the frequency range 1,000 MHz $\le f \le$ 3,000 MHz. The selected power levels are based on the maximum power levels likely to be encountered from the sources[1)] identified in Annex B Table B1. Experimental data show that dipole net power levels below 3,350 mW produced the voltage induction effect of 800- and 900-MHz wireless phones spaced 1.3 cm from the device. At the higher frequency band of the PCS phone, 101-mW dipole net power produced the voltage induction effect of the phone at 1.3-cm spacing. The power levels of the optional test are intended to ensure compatibility of implanted cardiac devices with handheld wireless phones and other similar power handheld transmitters that are operated without restrictions near the implanted pulse generator.

A.2.6 Rationale for lead configuration

The DUT lead configuration as illustrated in Figure G1 was selected because it fits the saline test tank and is easily repeatable. In vitro test studies have shown that the primary RF coupling to the DUT at these frequencies is through the device connector and therefore the layout of the lead is not critical at these test frequencies.

A.2.7 Rationale for device programmed parameters

Testing both VVI and AAI is added as an alternative to DDD(R) testing due to the difficulty of electrically isolating the ventricular and atrial chambers in the specified torso simulator. Additionally, the sense amplifiers, bandpass filtering, digital filtering and EMI filtering are identical whether testing VVI and AAI or DDD modes.

A.2.8 Rationale for sample size

The test outlined in this standard are to be seen as type tests and shall be performed on a sample of one device as being representative of the devices leaving volume production.

A sample size of one device is appropriate considering the fact that the observed spread or variation of the electromagnetic compatibility (EMC) characteristics from one device to another of a certain implantable pulse generator model is extremely small. Over the whole frequency range (d.c. to 3,000 MHz), the EMC of an implantable pulse generator is fully determined by the implementation of both the cardiac signal sensing filters and the EMI suppression filters. These filters consist of RF feedthrough filters, passive front-end filters (using only a few discrete components) and with all further signal filtering performed on-chip on one or more integrated circuits (ASIC). The tolerances of the off-chip components are small and the characteristics of the on-chip filter are basically identical from one device to another due to integrated circuit process control, digital filtering and/or on-chip trimmed filters, etc. Variances from device to device are smaller than the variances due to measurement uncertainties of the tests defined in this standard.

A.3 Rationale for test requirements in Clause 6

A.3.1 Protection of the device from damage caused by HF surgical exposure

The test frequency of 500 kHz was selected as typical of the majority of electrosurgical equipment, and the continuous wave test of 36 Vpp of the signal was selected based on results of work by the EMC Task Force. It should be noted that this test level may likely result in myocardial damage, even though it is technically possible in an in-vivo situation..

The requirement does not provide complete protection, since the voltages and currents induced in the DUT during exposure to electro surgery are dependent on distances between the electrosurgical electrodes and any conductive part of the **DUT** or its **leads**, and the surgeon may not be aware of the positioning of such parts.

A.3.2 Protection of the device from damage caused by external defibrillators

Testing is conducted using various types of external defibrillation waveforms that the patient may be subjected to.

Test 1 was designed to explore the ability of the pulse generators to withstand external defibrillation applied from units that have damped sinus monophasic waveforms, (such as Edmark, Lown, Pantrige waveforms) or a biphasic waveform (such as the Gurvich waveform). The test stresses the DUT with a high voltage.

Test 2 was designed to explore the ability of the pulse generators to withstand external defibrillation applied from units with monophasic or biphasic truncated exponential waveforms capabilities, employing very fast rise and fall time. This test stresses the DUT with a high voltage and high dV/dt.

The different test voltage levels are intended to align with the clinical experience documented in literature teaching that significantly lower defibrillation energy is needed when a truncated exponential waveform is used compared to a damped sinus waveform. References: Mittal et alia, PACE 1999' Volume 22 Number 4 p 739; Mittal et alia, PACE 1999, Volume 22 Number 6 A214; Bardy et al Circulation, 1996, Volume 94 pages 2506-2514.

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1) IRIDIUM phones were not tested when determining the maximum power for the optional characterization test.

Annex B
(informative)

Rationale for test frequencies

B.1 Test frequencies for the range 0 to 450 MHz

Table B.1—List of common EM emitters, 0 – 450 MHz

Frequency (MHz) port/base	Source	Modulation, if applicable
Static		
	Stereo Speaker Magnets	
	Name Tag Magnets	
	Magnetic Therapy	
	Video Display	
	MAGLEV Train (Japan)	
	EAS Tag Magnetizer	Pulse
	Stun Gun – conducted current	
	Electrolysis – conducted current	
Variable Low Frequency		
	Internal combustion engines (chain-saw, weed cutter, boat, yard tractor, snow mobile, portable generator, auto, etc.)	Pulse with variable repetition rate
	Electric fence – conducted current	
	Battery Powered Tools & Carts	
1 to 100 Hz		
16.6	Electrified Railroad	CW
60	Distribution Transformer (ground level)	CW
60	Distribution Line	CW
60	115 kV Transmission Line	CW
60	230 kV Transmission Line	CW
60	315 kV Transmission Line	CW
60	500 kV Transmission Line	CW
60	800 kV Transmission Line	CW
60	1100 kV Transmission Line	CW
60	Portable Generator	CW
60	Saw: hand-held, table	CW
60	Hand Drill	CW
60	Tape Head Demagnetizer	CW
60	Soldering Gun	CW
60	Arc Welding (300 amp)	Intermittent

Frequency (MHz) port/base	Source	Modulation, if applicable
60	Fluorescent Desk Lamp	CW
60	Fluorescent Fixtures	CW
60	Tanning Bed	CW
60	In Floor Resistive Heating	CW
60	Electric Range	CW
60	Microwave Oven	CW
60	Blender	CW
60	Can Opener	CW
60	Mixer (hand-held)	CW
60	Vacuum Cleaner	CW
60	Electric Blanket	CW
60	Hair Dryer: hand-held, table	CW modulated by movement
60	Electric Shaver	CW modulated by movement
60	Electric Tooth Brush	CW modulated by movement
60	Rotating Sign	CW
73	EAS	CW modulated by movement
0.1 to 1 kHz		
100	Metal Detector	CW modulated by movement
210-220, 218, 219	EAS	CW modulated by movement
400	Aircraft Power	
436	EAS	CW modulated by movement
450	EAS Tag Demagnetizer	Damped Sine Burst
500	Metal Detector	Pulsed
500, 534, 535	EAS	CW
850	EAS	Pulsed
862	EAS	CW
943, 950	EAS	Pulsed: 10 ms burst, 150 ms period, 2 or 3 bursts per gate activation
1 to 10 kHz		
1	Metal Detector	
2.5	EAS	Pulsed
3	EAS	CW
4	Metal Detector	Pulsed
5, 5.15	EAS	CW
7.65	EAS	CW
5 – 10	Walk-through Metal Detector	CW
10 to 100 kHz		
< 50	Walk-through Metal Detector	Pulsed 200 – 400 pps
10-100	Hand-held metal detectors	CW modulated by movement
	Video Displays	
	Slot Machines	

Frequency (MHz) port/base	Source	Modulation, if applicable
10-14	OMEGA	CW for 0.9-1.25
10	EAS	Pulsed
13.25	Hand-held Metal Detector	
13.5-14.5	EAS	CW
18	EAS	CW
20-50	Induction Range	CW
22.75	Hand-held Metal Detector	
39.5	EAS	Pulsed
50, 58, 58.6	EAS	Pulsed: 1.64 ms burst, 16.4 ms period
64	Hand-held Metal Detector	
80	EAS	
94.5	Hand-held Metal Detector	
0.1 to 1 MHz		
.1	LORAN (being phased out)	Pulsed @ 10 Hz
.115	Hand-held Metal Detector	
.1342	TIRIS Texas Instruments Registration and Identification System	
.148 to .283	European AM Radio	
.2 to .3	Hand-held metal detector	
.535 to .1605	US AM Radio	AM (Amplitude Modulation)
1 to 30 MHz		
1863	Hand-held Metal Detector	
2	EAS	Swept frequency
3.25	EAS	
5	EAS	
8, 8.2	EAS	Swept frequency
13.56	RFID	
3 to 30	Ham Radio	
27	Radio Control Toys (unlicensed)	
26 to 27	CB Radio	
30 to 450 MHz		
49	Radio Control Toys (unlicensed)	Part 15, Subpart C
151 to 154	Multi-Use Radio Service (MURS)	
218-219	218-219 MHz Band Radio Service Mobile Fixed	Part 95, Subpart F – 95.801
462 to 467	Family Radio Service (FRS) General Mobile Radio Service (GMRS) Mobile Fixed	Part 95, Subpart B – 95.191 Part 95, Subpart A – 95.1

Code of Federal Regulations (CFR) Title 47 – Telecommunication – FCC Rule Parts

Part 15 – Radio Frequency Devices
Part 18 – Industrial, Scientific and Medical (ISM) Equipment
Part 20 – Commercial Mobile Radio Services
Part 21 – Domestic Public Fixed Radio Services
Part 22 – Public Mobile Services
Part 24 – Personal Communication Services

Part 27 – Miscellaneous Wireless Communication Services
Part 90 – Private Land Mobile Radio Services
Part 95 – Personal Radio Services
Part 97 – Amateur Radio Services

CFR Web Addresses:
Regulations: www.access.gpo.gov/cgi-bin/cfrassemble-cgi?title=200347
Frequency Allocation Table: www.fcc.gov/oet/spectrum/table/fcctable.pdf

B.2 Test frequencies for the range 450 to 3,000 MHz

The test frequencies are selected to ensure thorough testing of the two main frequency bands for wireless phones. Additional test frequencies are specified to ensure comparable immunity performance for communications services that transmit at other frequencies within the 450 to 3,000 MHz frequency range (refer to Table B.2 for a list of sources known at this time).

Table B.2—List of common EM emitters, 450 – 3, 000 MHz

Transmit frequency (MHz) port/base	Service type	Service name
453–458 / 463–468	Analog cellular	NMT-450
462–467	Family radio	–
470–980	UHF television	–
800	Wireless modem	–
806–821 / 847–866	ESMR	MIRS/IDEN
806–824 / 851–869	Wireless data	ARDIS-RD-LAP
824–849 / 869–894	Cellular	AMPS (EIA/TIA-553) DAMPS (TIA/EIA-627) CDMA (IS-95) CDPD
868 / 864	Digital cordless	CT2
871–904 / 916–949	Analog cellular	ETACS
880–915 / 925–960	Digital cellular	GSM
896–902 / 935–941	Wireless data	RAM-MOBITEX
902–928	Wireless LAN	–
915	EAS	–
915–925 / 860–870	Analog cellular	NTACS
932 / 885	Cordless phone	CT1+
932–940	Two-way paging	–
935–960	Analog cellular	NMT-900
940–956 / 810–826	Digital cellular	PDC
948 / 944	Digital cordless	CT2+
959–960 / 914–915	Cordless	CT1
1240–1300	Ham radio	–
1335	Military radar	–
1477–1501 / 1429–1453	Digital cellular	PDC
1610–1616.5	Satellite phone	IRIDIUM
1710–1785 / 1805–1880	Digital cellular	DCS 1800

Transmit frequency (MHz) port/base	Service type	Service name
1850–1910 / 1930–1990	PCS	TDMA (J-STD-011) CDMA (J-STD-008) PCS 1900 (J0STD-007) WB CDMA PACS DCT-U
1880–1900	Digital cordless	DECT
1895–1918	Digital cordless	PHS
2390–2400	PCS	–
2450	Microwave ovens	–
2450 / 2712	Diathermy	–
2400–2483	Wireless data	IEEE 802.11
2470–2499	Wireless data	IEEE 802.11

Annex C
(informative)

Code for describing modes of implantable generators

C.1 The Code

The code is presented as a sequence of five letters. Tables C1 and C2 below give an outline of the basic concept of the pacemaker and ICD code.

Table C1 - NASPE/BPEG generic (NBG) Pacemaker code

Position	I	II	III	IV	V
Category	Chamber(s) paced	Chamber(s) sensed	Response to sensing	Rate modulation	Multisite pacing
	O=None	O=None	O=None	O=None	O=None
	A=Atrium	A=Atrium	T=Triggered	R=Rate modulating	A=Atrium
	V=Ventricle	V=Ventricle	I=Inhibited		V=Ventricle
	D=Dual (A+V)	D=dual (A+V)	D=Dual (T+I)		D=Dual (A+V)
Manufacturers' Designation Only	S=Single (A or V)	S=Single (A or V)			

Source: The Revised NASPE/BPEG Generic Pacemaker Code for Antibradycardia, Adaptive-Rate and Multisite Pacing, PACE, Vol. 25: pp 260–264, February 2002.

NOTE NASPE has changed its name to HRS – Heart Rhythm Society

The significance of the position of the code letter is as follows:

First letter: The paced chamber is identified by "V" for ventricle, "A" for atrium, "D" for dual (i.e., both atrium and ventricle), or "S" for single chamber (either atrium or ventricle).

Second letter: The sensed chamber is identified by either "V" for ventricle, "A" for atrium. An "O" indicates that the implantable pulse generator has no sensing function. "D" indicates dual (i.e., both ventricle and atrium), and "S" indicates single chamber (either atrium or ventricle).

Third letter: The mode of response is either "I" for Inhibited (i.e., an implantable pulse generator whose output is inhibited by a sensed signal), or "T" for Triggered (i.e., an implantable pulse generator whose output is triggered by sensed signal); "O" is used if the implantable pulse generator has no sensing functions, and "D" is used for a implantable pulse generator that can be inhibited and triggered.

Fourth letter: The fourth letter is used only to indicate the presence (R) or absence (O) of an adaptive-rate mechanism (rate modulation).

Fifth letter: This letter is used to indicate whether multisite pacing is present in (O) none of the cardiac chambers, (A) one or both of the atria, (V) one or both of the ventricles, or (D) any combination of A or V as just described.

Table C2 - NASPE/BPEG Defibrillator (NBD) code

Position	I	II	III	IV
	Shock chamber	Antitachycardia pacing chamber	Tachycardia detection	Antibradycardia pacing chamber
	O=None	O=None	E=Electrogram	O=None
	A=Atrium	A=Atrium	H=Hemodynamic	A=Atrium
	V=Ventricle	V=Ventricle		V=Ventricle
	D=Dual (A+V)	D=Dual (A+V)		D=Dual (A+V)

Source: The NASPE/BPEG Defibrillator Code, PACE, Vol. 16: pp 1776–1780, September 1993.

The significance of the position of the code letter is as follows:

Position I: Shock chamber – This position serves to distinguish among devices capable of delivering atrial (A), ventricular (V), and dual chamber (D) shocks. No details are given concerning incremental energy shock protocols. If the defibrillation function is programmed off, the shock chamber is designated as O (none) in Position I when specifying the current mode of operation.

Position II: Antitachycardia pacing chamber – This position identifies the location of antitachycardia pacing without specifying the pacing protocol (burst, ramp, etc.). The possible antitachycardia pacing configurations are designated as O (none), A (atrial), V (ventricular), and D (dual chamber). Where antitachycardia pacing capability is present, the capability of "tiered" therapy (antitachycardia pacing followed, if necessary, by shock) is assumed to exist.

Position III: Tachycardia detection – This position distinguishes devices that detect tachycardia by means of Electrogram signal processing (E) alone from those that sense one or more hemodynamic related variables (H) as well, such as blood pressure or transthoracic impedance. Position III is hierarchical in the sense that H implies E. *All* defibrillators are assumed to use Electrogram (EGM) sensing for tachycardia detection.

Position IV: Antibradycardia pacing chamber – This position identifies the location of antibradycardia pacing without specifying the mode of pacing. The possible antibradycardia pacing configurations are designated as O (none), A (atrial), V (ventricular), and D (dual chamber).

Annex D
(normative)

Interface circuits

CAUTION: Care must be taken in the construction of the tissue interface to prevent electrical crosstalk within the tissue interface circuit.

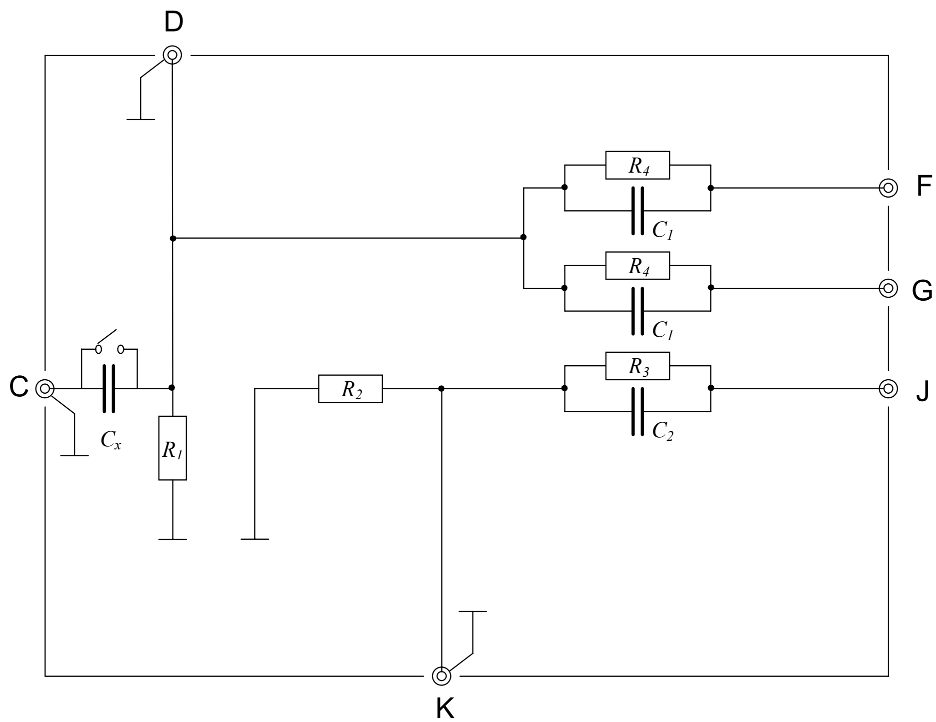


Figure D1 - Tissue equivalent interface circuit for current measurements in pacemakers and ICDs

C Input (test signal)
D Test point (test signal).
K Monitoring point

Table D1a - Component values for Figure D1

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 Annex E
R_4	560 Ω		

Table D1b - Component values for Figure D1

R_1	68 Ω (2W)	C_1	15 nF
R_2	47 Ω (1W)	C_2	180 pF
R_3	47 Ω	C_X	Refer to Annex E
R_4	33 Ω		

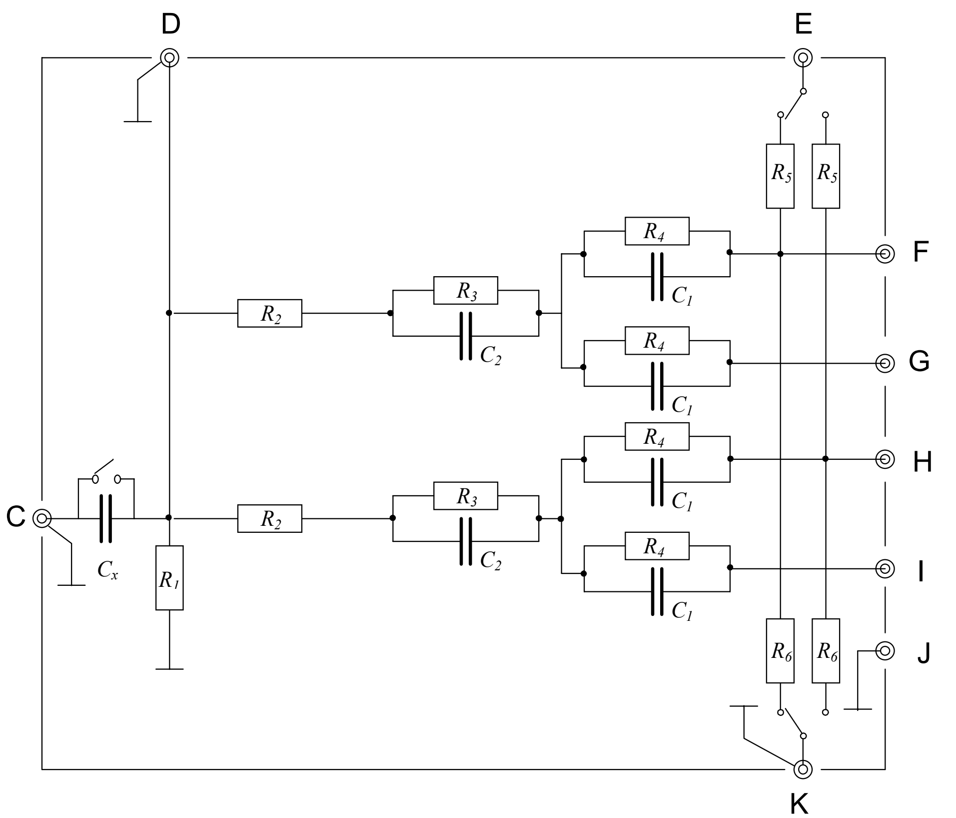


Figure D2 - Tissue equivalent interface circuit to check for malfunction

C	Input (test signal)	E	Input (inhibition generator).
D	Test point (test signal).	K	Monitoring point

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

Table D2 - Component values for Figure D2

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 Annex E
R_4	560 Ω		
R_5	56 kΩ		
R_6	1 MΩ		

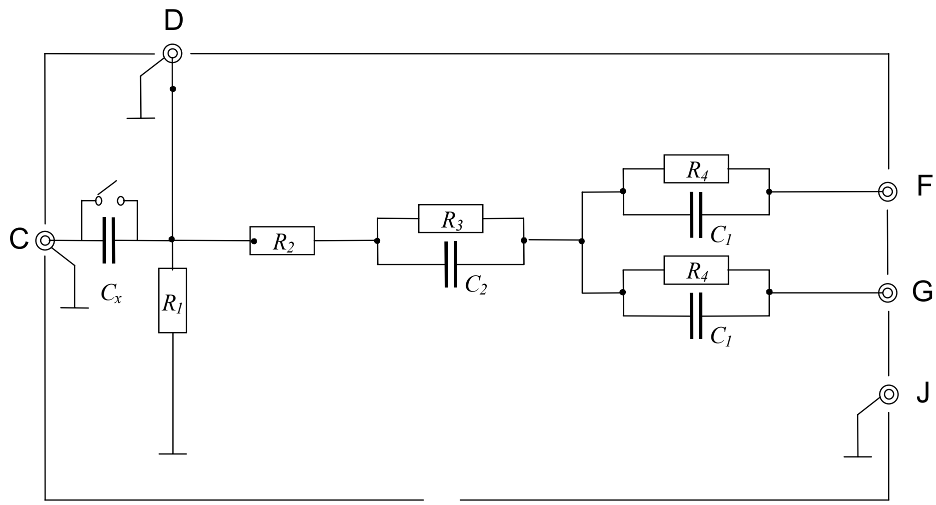


Figure D3 - Tissue equivalent interface circuit to check for induced malfunction due to voltages induced on cardioversion/defibrillation leads in ICDs

C Input (test signal)

D Test point (test signal).

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

Table D3 - Component values for Figure D3

R_1	68 Ω (2W)	C_1	15 nF
R_2	47 Ω	C_2	180 pF
R_3	47 Ω	C_X	Refer to Annex E
R_4	33 Ω		

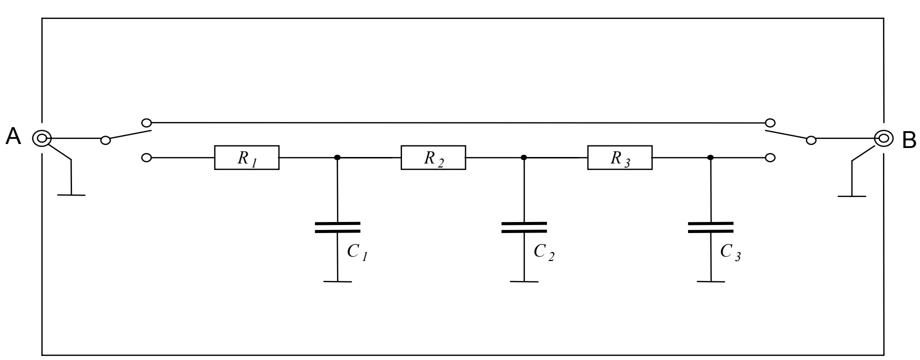
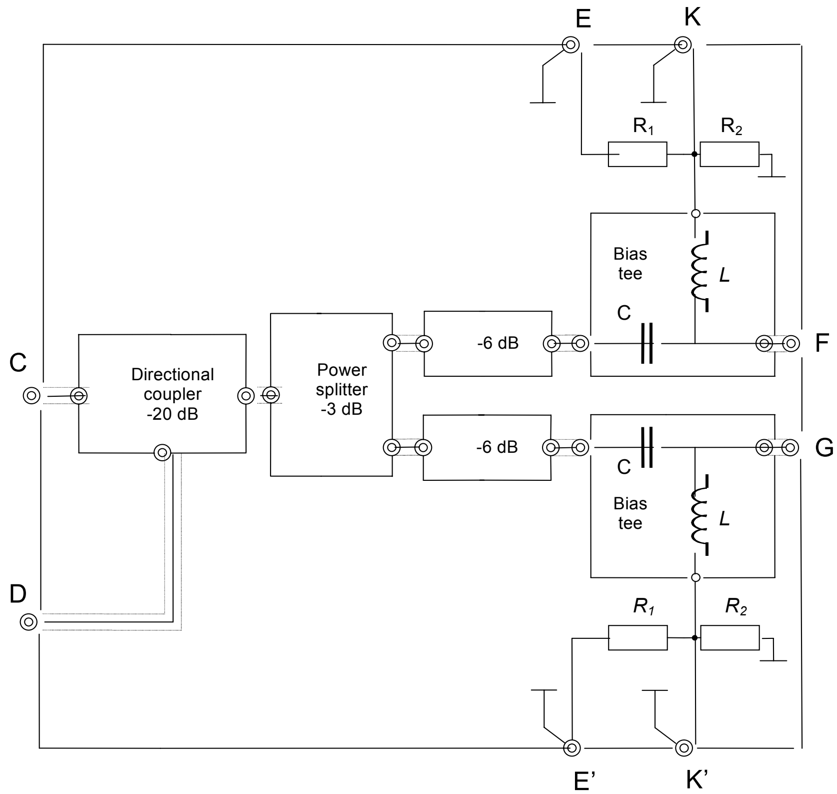


Figure D4 - Low pass filter used to attenuate the 500 kHz component of test signal

A Input Switch up: - bypass mode
B Output Switch down: - filter mode

Table D4 - Component values for Figure D4

R_1	4,7 KΩ	C_1	22 nF
R_2	15 kΩ	C_2	16,8 nF
R_3	47 kΩ	C_3	2,2 nF



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

Figure D5 - Injection network

Table D5 - Component values for Figure D5

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

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

The two bias tees shown in Figure GG104 shall provide a capacitor value of 120 pF ± 5 % and a minimum filter inductance of 0,5 mH.

NOTE: This recommendation eliminates potential testing variability at 20 MHz, the lowest test frequency, which can occur with an unspecified bias tee capacitor. This capacitor must be specified so that variability of network source impedance is eliminated at lower test frequencies. The prescribed calibration process of clause 4.5.3 does not adequately compensate bias tee capacitor effects occurring under pacemaker loads, since an unmodified bias tee and a pacemaker will have unequal impedances in a 50 Ohm system.

Annex E
(informative)

Selection of capacitor C_x

This annex describes a method for selecting capacitor C_X that is used in the tissue interface circuits described in Annex D. Capacitor C_X is used to reduce any spuriously injected low-frequency signals from the interference signal generator.

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 E1. For frequencies below 9 kHz, low-pass filter may require proper scaling.

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 E1. Adjust the test signal generator to provide the signal specified in the test procedure.

NOTE: When selecting C_X for burst modulated test signals, use only carrier frequencies above 1 kHz.

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

NOTE: A signal level of 0.2 mV can be sensed by pacemakers having high sensitivity settings. A signal level under 0.05 mV is needed for testing high sensitivity settings, but may be difficult to achieve in practice with standard test equipment.

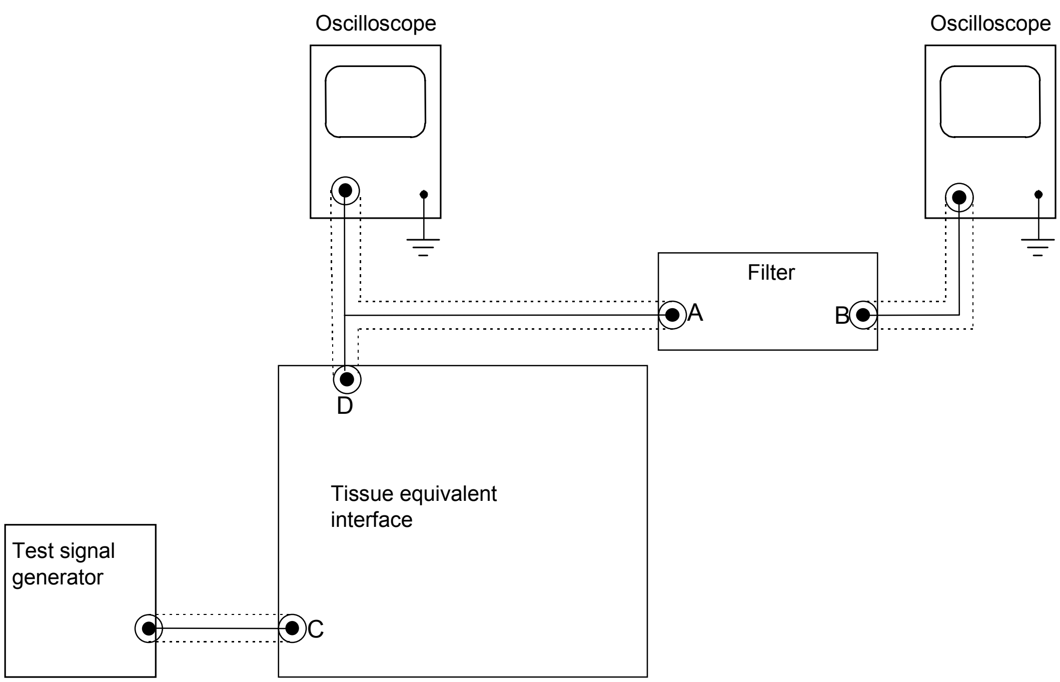


Figure E1 - Test to check for spurious low frequency noise and to determine the value of C_X

Annex F
(normative)

Calibration of the Injection Network, Figure D5

This annex describes the method for calibrating the injection network described in Annex D, Figure D5. The calibration factor, *m*, is the link between test voltage V_{ppr} and measured voltage of the oscilloscope #1 connected to test point D of the injection network, V_{osc}.

$V_{pp} = m * V_{osc}$

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 attenuation 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 must be determined as follows:

Calibration equipment. The configuration of Figure D5 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.

Calibration signal. The output from the test signal generator shall be unmodulated carrier.

Calibration procedure. The calibration signal shall be increased until the output voltage at the voltage meter reaches the peak-to-peak value indicated in the following table. Read the peak-to-peak voltage on the 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 F1 – Calibration Signal Amplitude

Frequency (MHz)	Output F (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

NOTE 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 shall be documented in the test report.

Annex G
(normative)

Torso simulator

This torso simulator is adapted from the “In Vitro Testing of Pacemakers for Digital Cellular Phone Electromagnetic Interference” (Paul Ruggera et al., Biomedical Instrumentation & Technology, July/August 1997, pp. 358–371).

G.1 Tank

The torso simulator consists of a plastic box, 28 quart (26.5 l), 20.1 x 14.17 x 5.51 in (51 x 36 x 14 cm) minimum filled with saline solution per Table 8. The dipole antenna rests on the “top grid” with the DUT resting on the “bottom grid.”

G.2 Top grid

The top grid is a piece of plastic grid cut from a fluorescent light fixture cover made of nonconductive, nonmetalized plastic. This is cut to fit the box’s opening such that the top grid’s top surface is no lower than the box’s top rim. The grid is constructed of 1/16" (0.0625 in, 0.1587 cm) wide, 11/32" (0.3437 in, 0.8731 cm) thick beams spaced 17/32" (0.5312 in, 1.349 cm) apart in two directions. This forms an array of square holes over the entire surface that are approximately 0.5 in (1.27 cm) on a side.

G.3 Cutout

A central area of the top grid having the dimensions of 4.5 x 5 in (11.43 x 12.7 cm) is removed so the DUT can be moved into the upper grid and the dipole antenna can be placed closer to the DUT. To provide a continuous surface on which the antenna is supported over this large central hole, nonconductive string (20-pound test monofilament fishing line) is laced over the central hole. This line was chosen because of its strength and the fact that it does not absorb water. This results in a dry, stable surface on which to place the dipole antenna. Each nonconductive strand is tied individually to the indents on opposite sides of the grid.

G.4 Bottom grid

A bottom grid made of the same material as the top grid is used to support the DUT inside the saline-filled box. The bottom grid has plastic legs threaded into nuts fastened to the bottom grid. By turning these legs, the bottom grid elevation is changed. This, in turn, varies the device’s depth of immersion in the saline-filled box.

G.5 Tank electrodes

Two pairs of stainless steel electrode plates placed along the X and Y axes are used to monitor and test the device while it is immersed in the saline. Each plate measures 1.97 x 1.97 x 0.0787 in (5 x 5 x 0.2 cm). Each plate is positioned at the middle of one of the inner walls of the torso simulator box. One pair of plates is placed on opposite walls of the torso simulator and allows monitoring of the DUT. The second pair allows electrocardiographic (ECG) simulation signals to be applied to the device lead(s) through the saline. An imaginary line connecting one pair of plates is perpendicular to the imaginary line connecting the other pair of plates. This minimizes the cross talk between injection and monitoring plates. Each plate has a threaded hole in its center, with a stainless steel screw threaded through the hole. The screw is forced through a small hole in the outer wall of the plastic box and is secured with a nut to form a watertight seal. The screw extends outside the box and forms an external electrical terminal. The device signal is detected by electrically monitoring a pair of plates with monitoring equipment having a minimum input resistance of 1 MΩ. A signal generator is used to apply simulated ECG waveforms to the second pair of plates. These signals produce voltages in the saline that mimic cardiac activity.

G.6 Illustrations

Figure G1 and Figure G2 illustrate all the features discussed above.

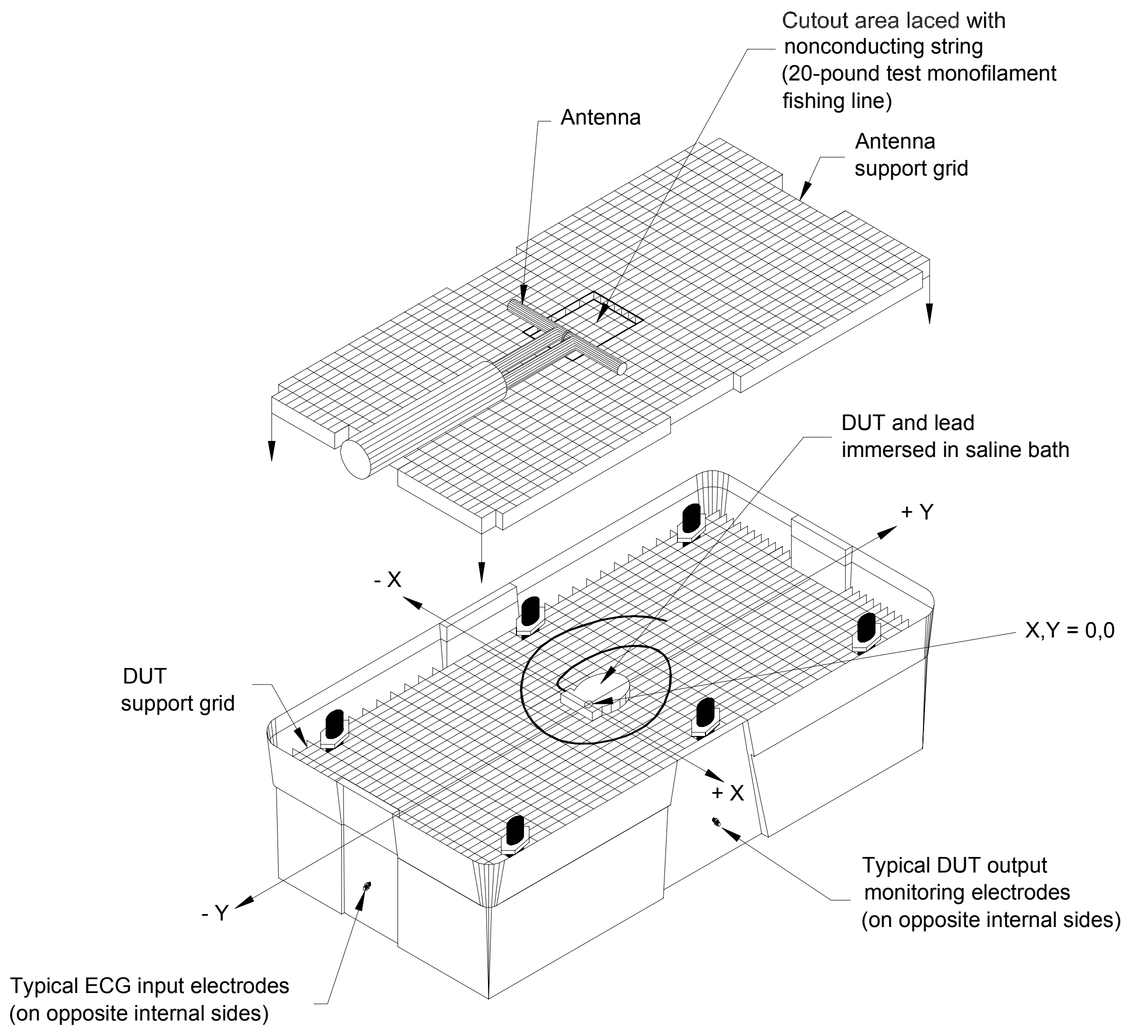


Figure G1 - Torso simulator

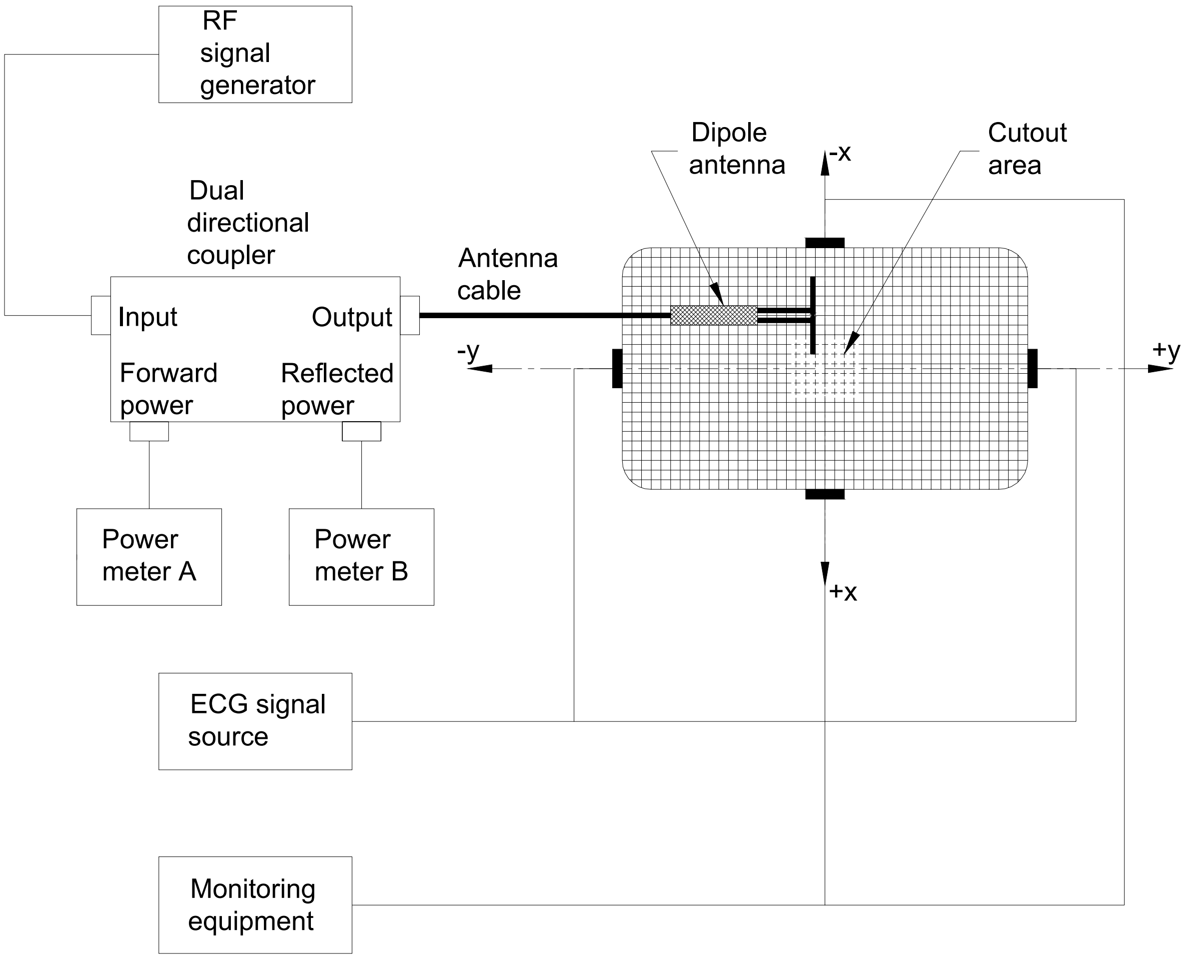


Figure G2 - Test setup

Annex H
(normative)

Dipole antennas

H.1 Resonant dipole

The dipoles to be used for these tests are tuned, half-wavelength, resonant dipoles with a series-parallel coaxial stub balun that meets the specification in Table H1. The coaxial balun is terminated into a suitable 50 Ω coaxial interface connector. See Figure H1 or ANSI C63.5-1988, appendix C, for examples of dipole antennas that can meet the specification in Table H1. See Table 8 for saline resistivity and spacing between the antenna and the saline during characterization of the antenna.

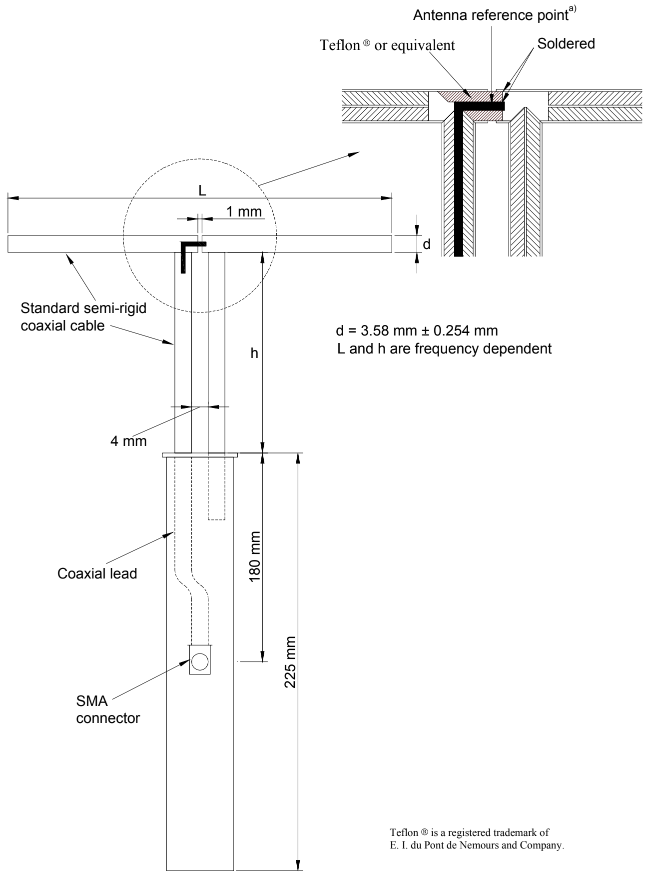
Table H1 - Dipole description

Test Frequencies	Defined in 4.5.7.2.4 b)
At each frequency, the following characteristics shall apply:	
Symmetry [a)]	± 0.5 dB up to $\lambda/8$ from the antenna reference point of the dipole
Internal loss [b)]	≤ 0.2 dB
Voltage standing wave radio (VSWR) (referenced to 50 Ω)	= 1.5:1 with the dipole tuned at 2 cm from the saline bath
Power rating	10 W minimum CW
Rod length symmetry	± 0.1 mm
Rod axis alignment [c)]	Offset of the dipole elements: 0.25 mm maximum. Offset to the flat edge at any point along the dipole elements: 1 mm maximum.
Rod diameter	3.58 mm ± 0.254 mm copper

[a)] Symmetry is defined as the H-field difference of the left and right dipole elements at any distance along the dipole from the dipole reference point.

[b)] Internal loss is measured by shorting the dipole at the antenna reference point and measuring the return loss with a network analyzer. An antenna with a measured internal loss exceeding 0.2 dB may be utilized, provided the loss exceeding 0.2 dB is added to antenna cable attenuation (ACA) for calculation of FORWARD dipole power (see F.1.1) and REFLECTED dipole power (see F.1.3).

[c)] The separation between the two elements of the dipole at the antenna reference point must be kept constant.



[a] The intersection of the axis of the antenna rod and the axis of the antenna support is the reference point for antenna location.

NOTE This drawing was developed by Schmid & Partner Engineering AG, Zurich, Switzerland, for IEEE C34 SC 2.

Figure H1 - Example of dipole antenna

Annex I
(normative)
Pacemaker/ICD programming settings

I.1 Introduction

This annex describes the programmable settings for the DUT.

I.2 Pacemaker

I.2.1 Parameters

Table I 1 - Pacemaker parameters

Parameter (where appropriate/available)	Single-chamber device	Dual-chamber device	Single pass lead
Bradycardia Mode (most comprehensive) [a), c)]	VVI (AAI), VVIR (AAIR)	DDD, DDDR [b)]	VDD [b)]
Sensing polarity	Unipolar & bipolar	Unipolar & bipolar	Unipolar & bipolar
Pacing polarity	Unipolar & bipolar	Unipolar & bipolar	Unipolar & bipolar
Pacing rate	Nominal	Nominal	Nominal
A/V blanking	Minimum	Minimum	Minimum
A/V refractory	Minimum	Minimum	Minimum
PVARP	–	Minimum	Minimum
A/V sensitivity	As specified in the test being conducted	As specified in the test being conducted	As specified in the test being conducted
Rate response	As specified in the test being conducted	As specified in the test being conducted	–
Hysteresis	Off (VVI/AAI)	Off (VVI)	–
Other parameters	As appropriate (nominal preferred)	As appropriate (nominal preferred)	As appropriate (nominal preferred)

[a)] Pacing modes are described using a generic code developed by the North American Society of Pacing and Electrophysiology and the British Pacing and Electrophysiology Group. The full code is explained in Annex C.

[b)] During testing with the ECG signal ON or during testing requiring injected signal, dual-chamber devices may be tested in both AAI(R) and VVI(R) modes in lieu of DDD(R) as listed above.

c) Applies to 4.9

I.2.2 Diagnostic settings

If certain features are strictly for diagnostic purposes and labeled as such by the manufacturer, these features shall be excluded when determining the settings for EMC testing.

I.3 ICD

I.3.1 Parameters

Table I 2 - Tachycardia device parameters

Parameter	Single-Chamber Device	Dual-Chamber Device
Mode (most comprehensive) [a]	VVI (AAI), VVIR	DDD, DDDR [b]
Bradycardia parameters	Nominal	Nominal
A/V blanking	Minimum	Minimum
A/V refractory	Minimum, if applicable	Minimum, if applicable
PVARP	–	Minimum
A/V sensitivity	As specified in the test being conducted	As specified in the test being conducted
Detection enable	ON	ON
Detection criteria	As specified in the test being conducted	As specified in the test being conducted
ICD ATP therapy[3]	OFF	OFF
VT/VF therapy #1	Lowest energy setting or appropriate monitoring means	Lowest energy setting or appropriate monitoring means
VT/VF therapy #2, . . . etc.	OFF, if possible	OFF, if possible
Rate response	As specified in the test being conducted	As specified in the test being conducted
Hysteresis	OFF (VVI/AAI)	OFF (VVI)
Other parameters	As appropriate (nominal preferred)	As appropriate (nominal preferred)

[a] Pacing modes are described using a generic code developed by the North American Society of Pacing and Electrophysiology and the British Pacing and Electrophysiology Group. The full code is explained in C.5.

[b] During testing with the ECG signal ON or during testing requiring injected signal (Clauses 4.9.3 b) and 4.9.4.2 b)), dual-chamber devices may be tested in both AAI(R) and VVI(R) modes in lieu of DDD(R) as listed above.

c) For ATP only devices, the feature shall be programmed on with other parameters set to nominal settings

I.3.2 Diagnostic settings

If certain features are strictly for diagnostic purposes and labeled as such by the manufacturer, these features shall be excluded when determining the settings for EMC testing.

I.4 Other operating modes or parameters not implied in this standard

For EMC testing of cardiac pacemakers or implantable cardioverter defibrillators with characteristics other than those listed in this annex, the DUT shall be placed in its most susceptible operating mode. For DUTs with several available operating modes (including software-controlled operational modes), a sufficient number of modes shall be tested such that all circuitry is evaluated. The DUT shall be monitored during testing for indications of degradation or malfunction. The monitoring circuitry shall not influence test results. During testing, the DUT shall not exhibit any malfunction, degradation of performance, or deviation from specified indications beyond the tolerances indicated in the individual device specifications.

Annex J
(normative)

Simulated cardiac signal

J.1 Heart simulated signal

The simulated waveform (Ref: Figure below) shall have the following characteristics:

— Leading edge is t = 2 ms and trailing edge is T = 13 ms;

— Total pulse width is 15 ms (see Figure J1).

The ECG simulated bradycardia rate must be 10% to 20% greater than the programmed pacing rate of the DUT. The ECG simulated tachycardia rate must be within the programmed tachycardia detection window of the DUT. The amplitude of the signal is raised from zero to a point where the DUT tracks the signal, and then the amplitude of the signal is doubled to ensure sufficient sensing. Tests with an ECG signal shall be performed with the ECG signal polarity that has the lower sensing threshold if the two thresholds are different.

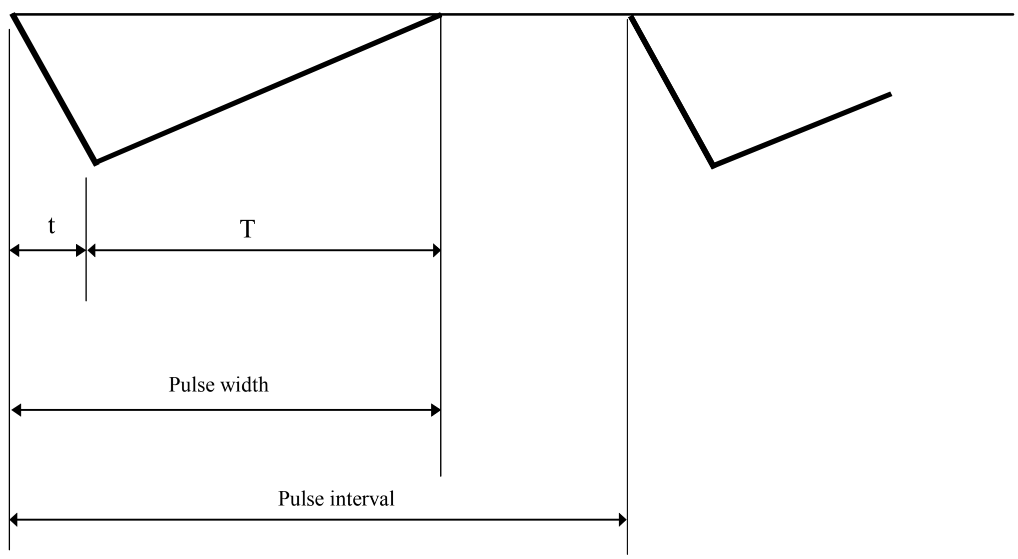


Figure J 1 - Simulated cardiac signal

Annex K

(normative)

Calculation of net power into dipole antenna

K.1 Calculation of net dipole power

The test setup shown in Figure K1 is used to measure net power into a dipole antenna for the test protocol specified in this standard. Net power into the dipole antenna is defined to be the forward power minus the reflected power at the cable terminal of the dipole antenna. Dipole net power is calculated from power measurements made at a dual-directional coupler using the calculations defined hereafter. Factors DCF, DCR, and ACA utilized in these expressions must be derived for each test frequency using the measurement methodology described herein, or an equivalent method with justification provided.

K.1.1 Calculation of FORWARD dipole power (dBm)

FPdBm = AdBm + DCF − ACA

Where: FPdBm forward dipole power (dBm)

AdBm power meter “A” reading (dBm)

DCF directional coupler forward port coupling factor (+dB)

ACA antenna cable attenuation (+dB)

K.1.2 Conversion of FORWARD dipole power from dBm to milliwatts

$FP = 10^{(FPdBm/10)}$

Where: FP forward dipole power (mW)

FPdBm forward dipole power (dBm)

K.1.3 Calculation of REFLECTED dipole power (dBm)

RPdBm = BdBm + DCR + ACA

Where: RPdBm reflected dipole power (dBm)

BdBm power meter “B” reading (dBm)

DCR directional coupler reflected port coupling factor (+dB)

ACA antenna cable attenuation (+dB)

K.1.4 Conversion of REFLECTED dipole power from dBm to milliwatts

$RP = 10^{(RPdBm/10)}$

Where: RP reflected dipole power (mW)

RPdBm reflected dipole power (dBm)

K.1.5 Calculation of NET dipole power (mW)

NP = FP − RP

Where: NP net dipole power (mW)

FP forward dipole power (mW)

RP reflected dipole power (mW)

K.2 Measurement of factors for net power calculations

The methodology described hereafter is recommended for measuring directional coupler factors and antenna cable attenuation.

K.2.1 DCF—Directional coupler forward port coupling factor

Configure the test equipment as shown in Figure K 2 with power meter B connected directly to the directional coupler output port. If an attenuator will be installed at the directional coupler forward power port during tests with the setup shown in Figure K 1, install the same attenuator at the forward power port for this measurement. The attenuator loss is embedded within the directional coupler coupling factor. At each test frequency, apply an unmodulated sine signal to the input port of the directional coupler using sufficient amplitude to provide > 20 dB signal-to-noise ratio at both power meters and record the power levels (dBm) at power meters A and B.

The directional coupler forward port coupling factor (DCF) is calculated at each test frequency by the expression:

DCF = BdBm - AdBm

Where: DCF directional coupler forward port coupling factor (dB)

BdBm power meter B reading (dBm)

AdBm power meter A reading (dBm)

K.2.2 DCR—Directional coupler reflected port coupling factor

Configure the test equipment as shown in Figure K 3 with power meter B connected directly to the directional coupler input port. If an attenuator will be installed at the directional coupler reflected power port during tests with the setup shown in Figure K 1, install the same attenuator at the reflected power port for this measurement. The attenuator loss is embedded within the directional coupler coupling factor. At each test frequency, apply an unmodulated sine signal to the output port of the directional coupler using sufficient amplitude to provide > 20 dB signal-to-noise ratio at both power meters and record the power levels (dBm) at power meters A and B.

The directional coupler reflected coupling factor (DCR) is calculated by the expression:

DCR = BdBm - AdBm

Where: BdBm power meter B reading (dBm)

AdBm power meter A reading (dBm)

K.2.3 ACA antenna cable attenuation

Configure the test equipment as shown in Figure K 4 with the antenna cable used in the Figure K 1 test setup connected between the directional coupler output port and power meter B. If an attenuator will be installed at the directional coupler forward power port during tests with the setup shown in Figure K 1, install the same attenuator at the forward power port for this measurement. At each test frequency, apply an unmodulated sine signal to the input port of the directional coupler using sufficient amplitude to provide > 20 dB signal-to-noise ratio at both power meters and record the power levels (dBm) at power meters A and B.

The antenna cable attenuation (ACA) is calculated by the expression:

ACA = AdBm + DCF - BdBm

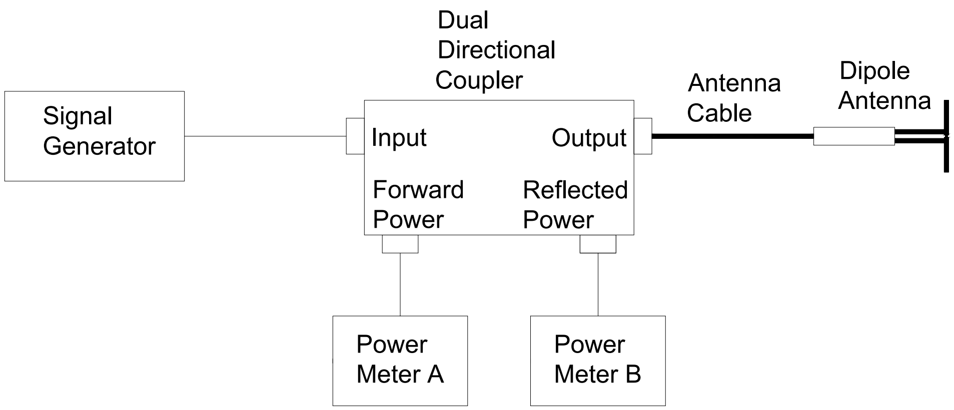
Where: ACA antenna cable attenuation (dB)

AdBm power meter A reading (dBm)

DCF directional coupler forward port coupling factor (+dB)

BdBm power meter B reading (dBm)

NOTE—Excess internal antenna losses (see Table) shall be added to ACA.



NOTES —

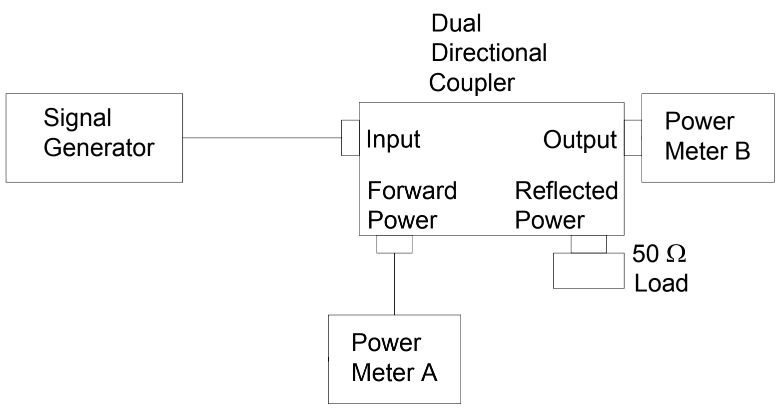
1) All RF interfaces are 50 Ω characteristic impedance.

2) An attenuator may be required at the directional coupler forward power and reflected power ports to reduce power levels to within the range of the power meter when conducting tests up to the 8-watt power level.

3) A single power meter can be used in lieu of dual power meters by moving the meter between ports and installing a 50 Ω termination at the unmetered port.

Figure K1 - Test setup

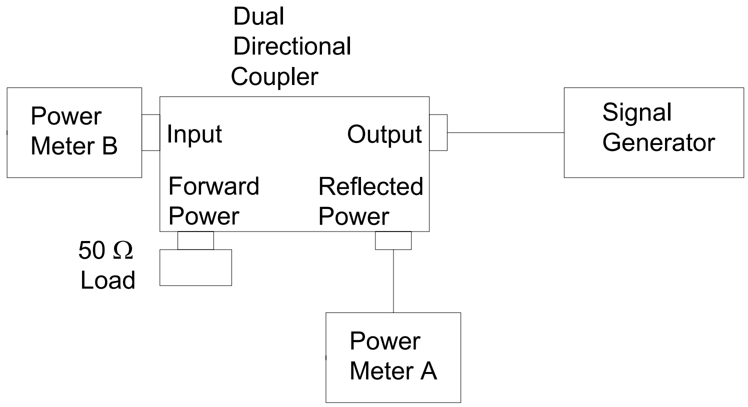
NOTES—



1) All RF interfaces are 50 Ω characteristic impedance.

2) A single power meter can be used in lieu of dual power meters by moving the meter between ports and installing a 50 Ω termination at the unmetered port.

Figure K2 - Directional coupler forward port coupling factor

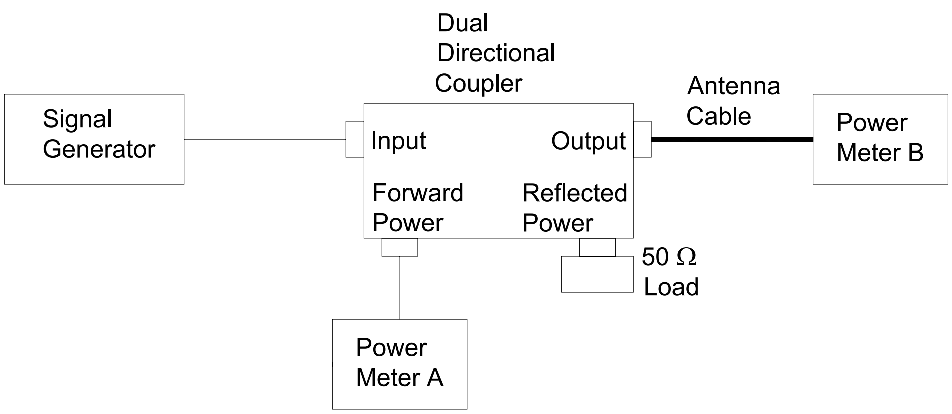


NOTES —

1) All RF interfaces are 50 Ω characteristic impedance.

2) A single power meter can be used in lieu of dual power meters by moving the meter between ports and installing a 50 Ω termination at the unmetered port.

Figure K3 - Directional coupler reverse port coupling factor



NOTES —

1) All RF interfaces are 50 Ω characteristic impedance.

2) A single power meter can be used in lieu of dual power meters by moving the meter between ports and installing a 50 Ω termination at the unmetered port.

Figure K4 - Antenna cable attenuation

Annex L
(informative)

Loop Area Calculations

L.1 Purpose

Initial evaluation of implanted lead area was done in the mid-1980s. Information was published (Irnich, Werner, & Barold, S. Serge, ed. Interference Protection, Modern Cardiac Pacing. Mount Kisco, NY: Futura Pub. Co.,1985. Chapter 38, page 847.), which indicated unipolar pacemakers with a semicircle lead configuration may form 570 cm^2 loop area.

Articles published in the 1990s indicated lower effective coupling areas: A. Scholte and J. Silny, The interference threshold of unipolar cardiac pacemakers in extremely low frequency magnetic fields, Journal of Medical Engineering & Technology, Vol. 25, No. 5, September/October 2001, pages 185-194; W. Irnich, Electronic security systems and active implantable medical devices, PACE, Vol. 25, No. 8, August 2002, pages 1235-1242.

As an understanding of realistic effective coupling areas is important for designing devices resistant to EMI and for defining test criteria for implantable cardiovascular medical device standards, the AAMI EMC Task Force considered the in-vivo evaluation of the effective loop areas an important step toward defining requirements.

As a result a study was conducted to evaluate the effective loop areas, in relation to electromagnetic interference susceptibility, of IPG and ICD lead systems, and to determine: 1) if a difference exists in the effective lead loop area for IPGs and ICDs; 2) correlate actual implanted systems to modeling done in various studies in Europe.

L.2 Procedure

X-rays from IPG and ICD patients were obtained and analyzed using a LASICO, Model L-30, planimeter to determine the two-dimensional lead area. Planimeter measurements were made on each lead from the device to the lead tip in the implanted ventricular and/or atrial transvenous lead systems. Additionally, planimeter measurements of the lead segment within a 5.275” diameter circle (approximately 22 in^2 [141 cm^2], a typical size for partial exposure) were made by placing the circle over the implanted system and keeping the center of the device within the circle.

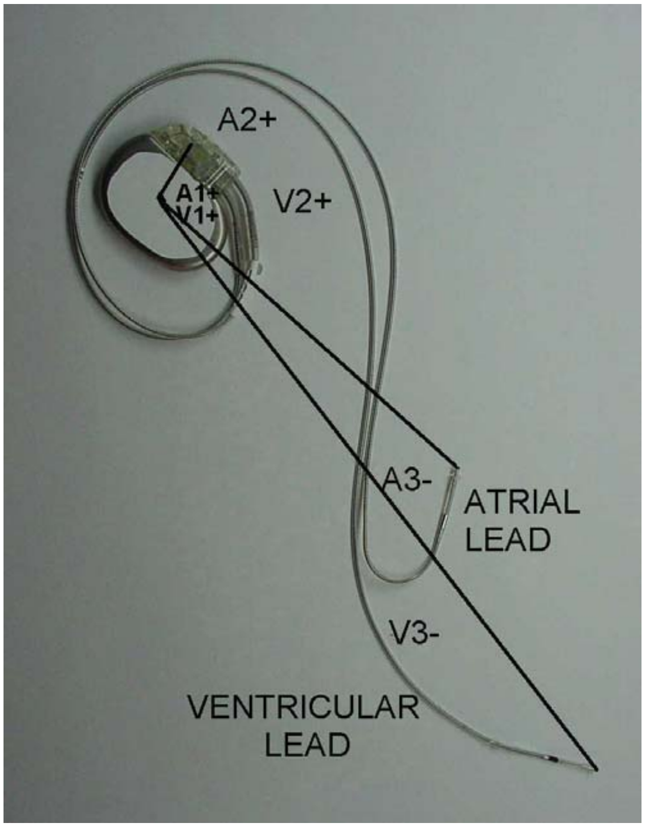


Figure L1 – Simulated Right Pectoral Dual Chamber Pacemaker X-Ray

Effective Atrial Area = A1 + A2 - A3
Effective Ventricular Area = V1 + V2 - V3

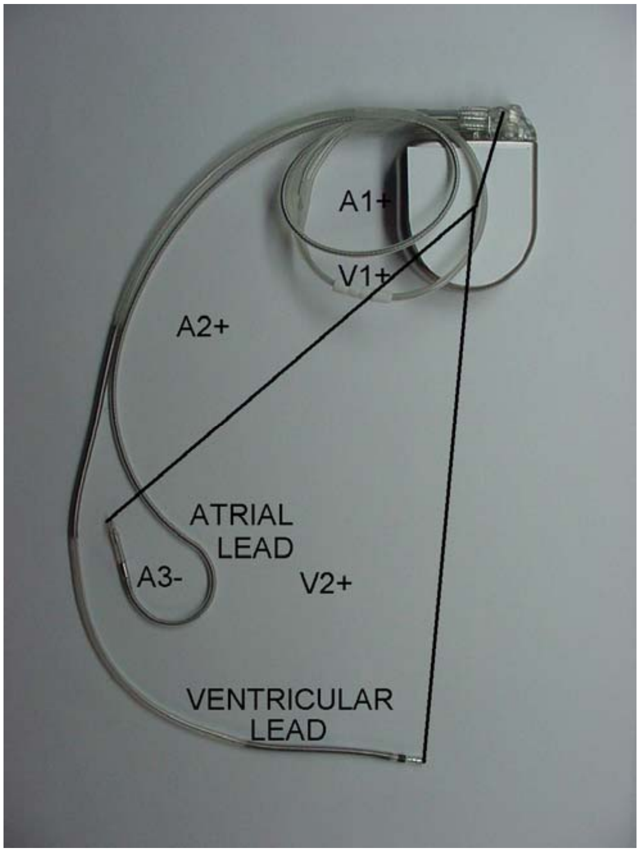


Figure L2 – Simulated Left Pectoral Dual Chamber ICD X-Ray

Effective Atrial Area = A1 + A2 - A3
Effective Ventricular Area = V1 + V2

L.3 Results

The mean effective coupling areas for a large loop (a person walking into an electromagnetic field) and for a small loop (a person with only a part of the body exposed to an electromagnetic field) are shown in Tables L1 (pacemakers, n=100 patients) and L2 ICDs, n=59 patients), below.

Each table is broken down by device and implant location: right pectoral (RP) or left pectoral (LP). Lead length and effective coupling areas are provided for the available frontal perspective of the atrial and ventricular leads, as well as the available lateral view. Also provided are large lead loop measurements; and small (5 inch diameter) lead loop measurements.

Table L1: Pacemaker Systems

IPG LOCATION AND QTY	STATISTICS	V LEAD LENGTH (CM)	A LEAD LENGTH (CM)	COUPLING AREA							
				Small loop				Large loop			
				V frontal	V lateral	A frontal	A lateral	V frontal	V lateral	A frontal	A lateral
47 Left pectoral	AVG	57	52	46	48	45	48	191	117	120	88
	MAX	65	57	88	70	83	80	314	187	166	154
	MIN	52	45	12	20	13	19	57	72	59	45
	SDEV	5	5	22	18	22	19	62	35	26	30
49 Right pectoral	AVG	55	46	70	57	73	58	68	117	95	91
	MAX	76	55	100	101	100	99	169	189	159	137
	MIN	48	37	8	42	43	40	6	62	45	63
	SDEV	5	4	19	16	15	16	31	31	25	19
4 Abdominal	AVG	54	53	28	33	-	34	91	109	58	83
	MAX	58	53	81	33	-	34	143	135	105	103
	MIN	52	53	8	33	-	34	42	80	11	62
	SDEV	3	-	35	-	-	-	45	39	67	29

A – atrial; V – ventricular

Table L2: ICD Systems

ICD LOCATION AND QTY	STATISTICS	V LEAD LENGTH (CM)	A LEAD LENGTH (CM)	COUPLING AREA							
				Small loop				Large loop			
				V frontal	V lateral	A frontal	A lateral	V frontal	V lateral	A frontal	A lateral
54 Left pectoral	AVG	65	52	57	40	57	35	232	108	137	66
	MAX	78	62	97	76	107	69	389	190	201	105
	MIN	55	42	13	23	20	20	91	23	79	20
	SDEV	5	5	19	14	20	13	51	38	28	25
3 Right pectoral	AVG	68	52	59	-	41	-	167	93	145	57
	MAX	75	53	80	-	56	-	233	93	147	57
	MIN	58	50	31	-	26	-	101	93	144	57
	SDEV	9	2	25	-	21	-	93	-	2	-
2 Abdominal	AVG	105	-	33	-	-	-	140	-	-	-
	MAX	105	-	42	-	-	-	167	-	-	-
	MIN	105	-	24	-	-	-	112	-	-	-
	SDEV	-	-	-	-	-	-	-	-	-	-

In summary for the Large Loop Areas (full lead system):

1) IPGs, 47 left pectoral implants and 49 right pectoral implants were analyzed (See Table L1)

2) ICDs, 54 left pectoral implants and 3 right pectoral implants were analyzed (See Table L2)

3) As seen when comparing Figure L1 to Figure L2, the left pectoral lead system results in larger loop areas as compared to the "Lazy S" orientation of the right pectoral leads. The right pectoral lead tends to have more effective loop area subtracted as shown in Figure L1

4) Left pectoral, frontal orientation of ventricular leads provided the largest effective loop areas, averages were: 191 cm^2 for IPGs and 232 cm^2 for ICDs (See Tables L1 and L2)

5) The maximum effective loop areas measured were 314 cm^2 for IPGs and 389 cm^2 for ICDs. (See Tables L1 and L2)

6) The difference in effective loop area can be attributed to the use of longer leads with ICD. The average left pectoral ventricular lead length was 65 cm for ICDs and 57 for IPGs. (See Tables L1 and L2)

In summary for the Small Loops Areas (partial lead system):

1) IPGs, 47 left pectoral implants and 49 right pectoral implants were analyzed (See Table L1)

2) ICDs, 54 left pectoral implants and 3 right pectoral implants were analyzed (See Table L2)

3) The left pectoral lead systems resulted in approximately the same effective loop area since the subtractive parts of the "Lazy S" orientation seen in right pectoral leads typically fell outside the 5 inch diameter area measured. Left pectoral, frontal orientation of ventricular leads resulted in average loop areas: 46 cm^2 for IPGs and 57 cm^2 for ICDs, while the right pectoral, frontal orientation of ventricular lead averaged 57cm^2 for IPGs and 59 cm^2 for ICDs. (See Tables L1 and L2)

4) The maximum effective loop areas measured were 88 cm^2 for right pectoral ventricular lead of an IPG and 107 cm^2 for an atrial left pectoral lead for an ICD. (See Tables L1 and L2)

L.4 Conclusion

This study found the average left pectoral geometric loop area for IPGs to be 191 cm^2, which confirms the previous use of 200 cm^2 in estimations of effective loop area. Measurement of ICD systems found average left pectoral loop areas of 232 cm^2. The difference between loop areas of 200 cm^2 and 232 cm^2 is essentially insignificant therefore the same loop area was applied to ICDs.

The geometric loop area is the area enclosed by leads and an imaginary straight line between the electrode TIP (RING) and the metallic CASE of the implanted pulse generator. The effective loop area, in particular for magnetic fields in the lower frequency range, is significantly smaller as shown above.

Annex M
(informative)

Correlation between levels of test voltages used in the standard and radiated fields strengths

An intentional or inadvertent emitter that produces field levels that are at or substantially below human safety exposure standards or national telecommunication regulations (such as EC 519/99, IEEE C95.1&C95.6, and FCC) could still interfere with the proper operation of an implantable pacemaker or ICD. These standards and regulations are intended to avoid biological effects from EMF (electromagnetic fields). They are not intended to ensure EMC (electromagnetic compatibility) between emitting equipment and pacemakers or implantable defibrillators. Implantable pacemakers and ICDs are particularly sensitive to peak signals. Emitted fields, whether intentional or not, with frequency components that are similar to those found in a cardiac signal (0 to 1kHz) can be particularly problematic. These emitted frequency components can be either from the carrier signal or modulation of the carrier signal. Implantable pacemakers and ICDs are designed to sense low-level cardiac electrogram signals (as low as 0.1 mV) in this frequency band. As such, the devices can be thought of as very sensitive receivers of low frequency signals.

The purpose of this Annex is to provide information to the manufacturers of devices that emit electromagnetic fields (EMF) with levels and modulation components that might adversely affect the operation of implantable pacemakers or ICDs. With this information, emitter manufacturers (intentional or inadvertent), can help minimize the electromagnetic interference (EMI) effects on implantable pacemakers or ICDs by one or more of the following actions: (1) avoiding certain frequencies, (2) reducing the EMF levels, (3) avoiding modulation formats which may be more problematic for the medical devices, or (4) limiting the exposure time to the interfering source.

The potential for interference with implantable pacemakers and ICDs is a complex topic and is dependent on a number of factors:

- Frequency of the emitted signal
- Modulation format
- Proximity to the patient
- Coupling factors
- Duration of exposure
- Power of the signal

For surgical implantation, the implanted medical devices must be small in size, lightweight, and provide a long battery life. These combined constraints limit the degree of filtering that can be incorporated into the devices to reject EMI sources, especially at the lower frequencies. As a result, it is beneficial to provide additional guidelines for the exposure of pacemaker and defibrillator patients in a certain range of frequencies, power levels and modulation formats (even though they are permitted by the human safety EMF exposure standards for the general population.)

When a pacemaker is subjected to electromagnetic interference it may exhibit one or more of the following adverse responses:

- Missed pacing beats / stop pacing (pacemaker inhibition)
- Stop sensing (noise reversion to asynchronous pacing)
- Fast pacing (tracking of the EMI by dual chamber devices)
- Current induced into the lead system that can trigger an arrhythmia
- Activation of the magnetic switch

When an ICD is subjected to electromagnetic interference it may exhibit one or more of the following adverse responses:

- High voltage shock (inappropriate delivery of therapy)
- Unable to identify the need for therapy (inability to properly detect cardiac tachyarrhythmia due to noise)
- Missed pacing beats/ stop pacing (oversensing that manifests itself as inhibition)
- Stop sensing (noise reversion to asynchronous pacing)
- Fast pacing (tracking of the EMI by dual chamber devices)
- Current induced into the lead system that can trigger an arrhythmia
- Activation of the magnetic switch, which suspends therapies or causes other changes, depending on the device model.

Many of the above responses may result in potentially life threatening situations for device dependent patients. For example, in a patient whose heart cannot beat on its own, if EMI from an emitter is sensed as cardiac activity, the pacemaker or implantable defibrillator may be inhibited (not pace the heart) and the heart may stop.

Correlation of pacemaker or ICD interference input voltages with radiated electric fields is a very complex subject that is beyond the scope of this Annex. Such RF input voltages depend upon coupling factors that vary in each frequency band. For example, lower frequency electric fields induce circulating currents in body tissue, which can be detected by pacemaker/ICD input circuits as voltage differentials. At higher frequencies, the leads can act as an antenna to EMI further complicated by standing waves from human body cavity resonance. At even higher frequencies (like cellular telephone bands), the EMI coupling is primarily into the short lead lengths of the pacemaker or implantable defibrillator header connector block (the rest of the lead wire system is decoupled due to its high impedance and the dampening effect of body tissue). Additionally, due to the reflection and absorption of body tissue frequencies above 3GHz are very unlikely to interfere with pacemakers or ICDs.

However, it is possible to estimate the induced input voltages that are the result of exposure to time varying magnetic fields. Emitter manufacturers typically measure the radiated output levels of their equipment in electromagnetic field strength units, The following is a correlation between the voltage test levels in Section 4.0 of this standard and electromagnetic field strength levels (amps/meter peak). This correlation uses Faraday's law and reflects an average lead implantation area of 200 square cm. It should be noted as discussed in Annex L that the largest implantation areas can exceed 300 square cm. for special cases, e.g. large patients or abdominally implanted systems.

While device filtering above 1 kHz can attenuate interference up to certain levels, it should be noted that high amplitude, modulated or pulsed signals may contain artifacts that fall within the bandpass of the implantable pacemaker/defibrillator and potentially be demodulated and detected, causing undesirable device operation. This latter behavior may be caused by a number of phenomena dependent on device design including voltage dependent linearity limitations in circuitry, which must be ahead of the filtering.

Device susceptibility closely follows the ICNIRP Reference Levels. Figure M1 shows the voltage at the input terminals of the device while Figure M2 shows the magnetic field that produces this voltage. This assumes the average pacemaker/ICD unipolar lead area of 200 square cm which may lead to an under estimation of the induced voltages in patients having lead loop areas greater than this. Figures M3 and M4 designate operations that may occur at levels above those shown in Figures M1 and M2.

1. Sensing Regions for Implantable Pacemakers and ICDs (Zone 1): This region is particularly sensitive for implantable pacemakers and ICDs. Fundamental frequencies and/or modulation formats in this region have a significantly greater likelihood to interfere with pacemakers and ICDs.

2. EMF Levels Below Filter Response (Zone 2): In this region, continuous exposure to an EMI source is unlikely to have an effect on implantable pacemaker or ICD operation and is of nominal concern for emitter manufacturers.

3. EMF Level Above Filter Response (Zone3a): In this region the EMI source may cause an ICD to deliver inappropriate high voltage therapy or reversion to asynchronous pacing in implantable pacemakers or implantable defibrillators. Asynchronous pacing at a fixed rate may result in competitive rhythms with intrinsic cardiac activity and long-term use of this modality is not always clinically appropriate. In general, the interfering signal should be unmodulated or the modulation frequency should not be in the range 1 – 1000 Hz (1kHz). Exposures to these levels should be infrequent and transient or short term, lasting a matter of seconds. While longer exposures of pacemakers are not necessarily unsafe, they may deny the patient the optimal therapy and such exposures should, therefore, be minimized. In the case of rate responsive pacemaker or implantable defibrillators, such exposures can cause the device to shift to the upper tracking rate. Further, in the case of ICDs an unwanted therapy may be delivered or a needed therapy may be withheld. The generally accepted advice for Zone 3a is for the patient to pass through the emitter field at a normal rate, without lingering in the field. Manufacturers of Zone 3a emitter equipment that is not readily recognizable by the public are encouraged to provide informational signage to inform pacemaker and ICD patients of the existence of an electromagnetic field to allow them to minimize their exposure time.

4. EMF Level Above Filter Response (Zone 3b): In this region the operation of the device is unknown, but no permanent malfunction will affect the implantable pacemakers or ICDs. In this region exposure should be infrequent and short term (lasting a matter of seconds). It should be noted that when the field is removed the device would function as prior to exposure without further adjustment of the device.

5. EMF Level Above Tested Limits (Zone 4): In this region the EMI levels are significantly above the maximum exposure levels to which pacemakers and ICDs are typically designed and tested. Thus, the device response is not generally known and there are no guarantees as to any level of performance. There is also a small but very real possibility that reprogramming or permanent damage to the implantable pacemaker or ICD could occur. Should such Zone 4 emitter systems exist, appropriate warning signage is recommended to inform pacemaker and ICD patients so they can take appropriate avoidance actions.

It is important to understand that pacemaker and ICD devices function by detecting peak voltages, which could result from a magnetic field coupling with the implanted lead system. The previously mentioned human safety EMF exposure guidelines may allow for duty cycle and RMS time averaging of the emitted signal. Pacemakers and ICD circuits are unable to handle these time-averaged large signals. To ensure the safety of pacemaker and ICD patients, it is recommended that their exposure be limited to the frequencies (either as a carrier or modulation) and power levels shown on Figures M1 and M2.

If it is not possible for an emitter manufacturer to avoid the frequencies and levels shown in Figures M1 and M2, then emitter manufacturers are strongly advised to consult with pacemaker and ICD manufacturers to determine the appropriate EMI mitigation steps that the emitter manufacturers can take to avoid the potential for interference with implantable pacemakers and ICDs.

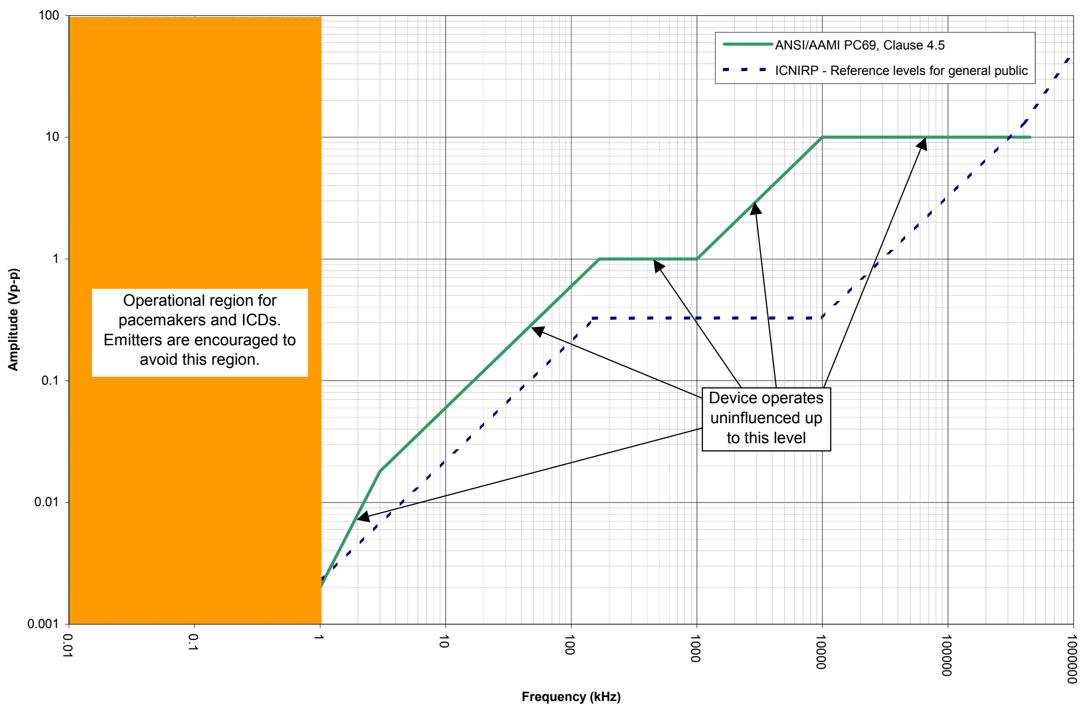


Figure M1 – Induced voltage test levels

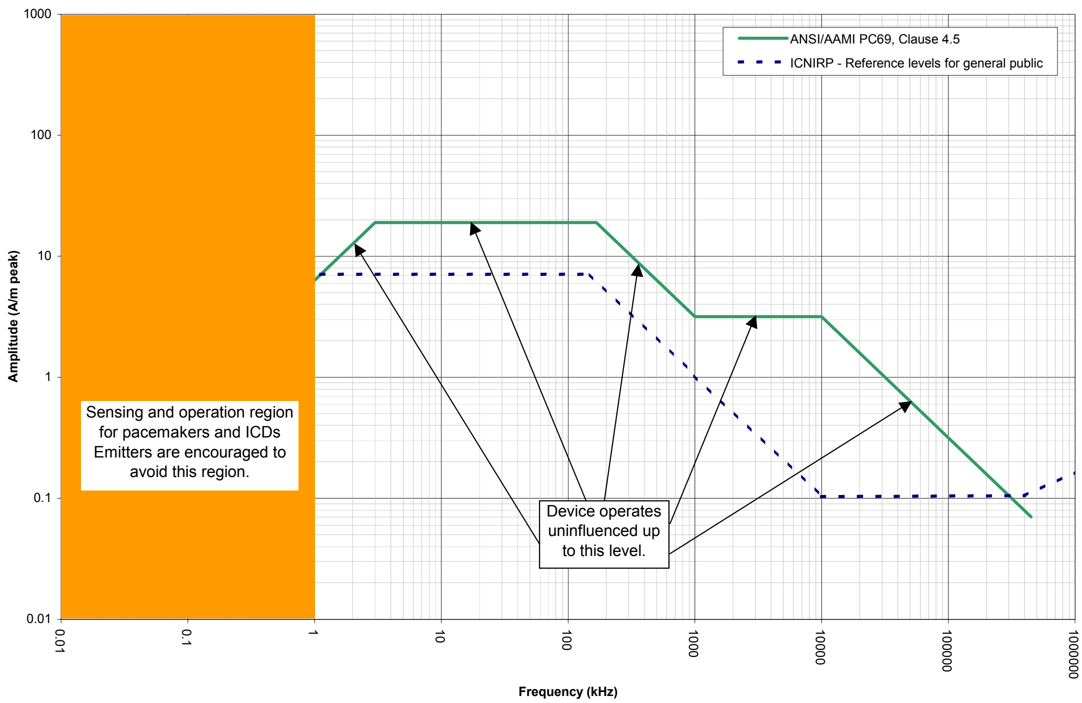


Figure M2 – Magnetic field amplitudes producing test limits

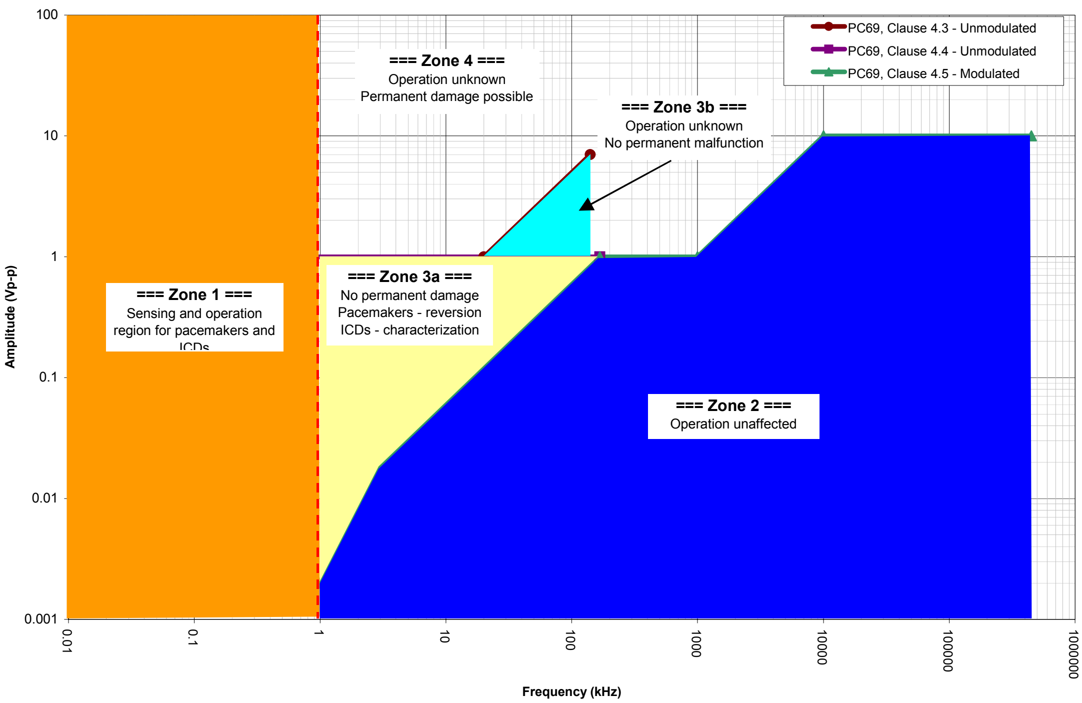


Figure M3 – Induced voltage zones

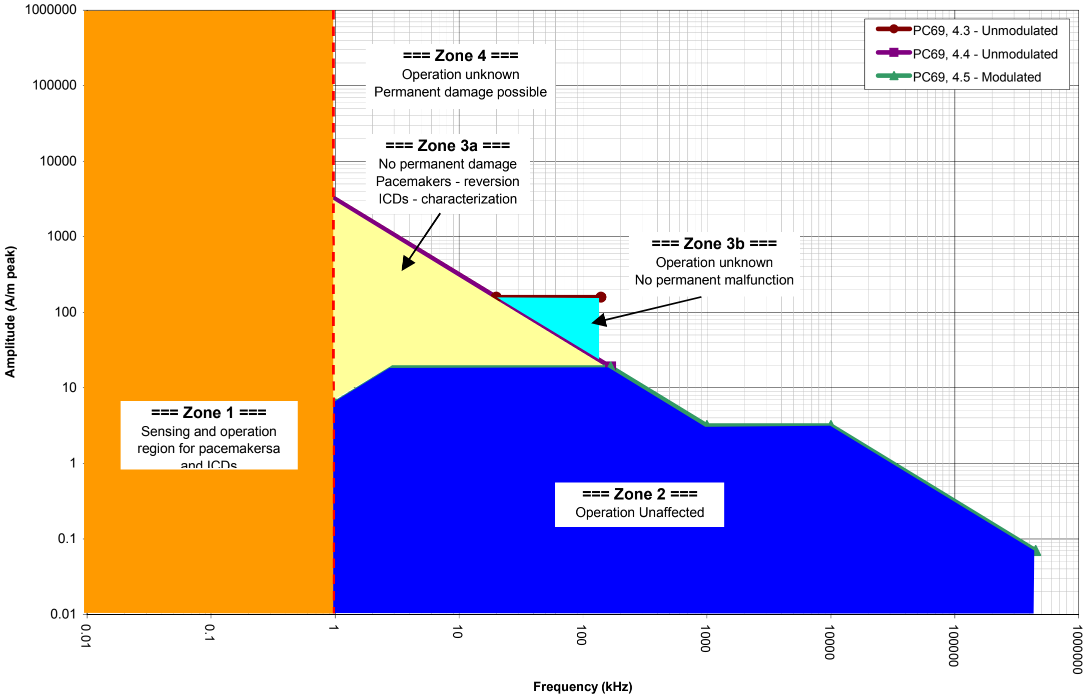


Figure M4 – Magnetic field zones

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