American National Standard

ANSI/AAMI PC69:2007

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

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Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

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American National Standard

ANSI/AAMI PC69:2007
(Revision of ANSI/AAMI PC69:2000)
Corrected Copy: 25 July 2008

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 12 April 2007 by
American National Standards Institute, Inc.

Abstract: This standard specifies test methods appropriate to many interference frequencies, whether high or low, near or far afield. 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 device

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

International designation	U.S. designation	Equivalency
IEC 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical

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International designation	U.S. designation	Equivalency
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007	ANSI/AAMI/ISO 15223-1:2007	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

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Committee representation

Association for the Advancement of Medical Instrumentation

Cardiac Rhythm Management Device (CRMD) Committee (former Pacemaker Committee)

The AAMI Cardiac Rhythm Electromagnetic Compatibility Task Force, under the auspices of the AAMI CRMD Committee, developed this standard. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Cardiac Rhythm Management Device Committee** had the following members:

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Foreword

This voluntary standard was developed by the Electromagnetic Compatibility Task Force of the AAMI Cardiac Rhythm Management Device (CRMD) Committee. It is intended to apply to active implantable cardiovascular devices (pacemakers and implantable cardioverter defibrillators) 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.

The major differences between the first edition of PC69 and this edition are: a test requirement and test method for the 0 Hz to 450 MHz range, including static magnetic fields, was added; the test requirement in the 450 MHz to 3 GHzrange was raised from 40 mW to 120 mW; a section on immunity above 3 GHz was added; and test requirements and test methods for two therapeutic environments (external defibrillation and electrosurgery) were included. In addition, there are two new annexes: Annex L provides a summary of the loop area calculations for EMC testing, including evaluation of X-rays and the effective loop area, and Annex M provides correlation information between levels of test voltages used in the standard and radiated magnetic field strengths.

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 that 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 five 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 American National Standard *Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators* (ANSI/AAMI PC69:2007), but it does provide important information about the development and intended use of the document.

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Introduction

The number and the types of electromagnetic (EM) emitters to which patients with active implantable cardiovascular devices are exposed in their day-to-day activities have proliferated over the past two decades. This trend is expected to continue. The interaction between these emitters and active implantable cardiovascular devices (pacemakers and implantable cardioverter defibrillators, or 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 death.

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

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

It is important to understand that these interactions may occur despite the 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., those of the U.S. Federal Communications Commission, or FCC).

Compliance with biological safety guidelines does not necessarily guarantee EM compatibility with pacemakers and ICDs. In some cases, the reasonably achievable EM 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 depends on the following factors:

— frequency content of the emitter,

— modulation format,

— power of the signal,

— proximity to the patient,

— coupling factors, and

— duration of exposure.

Pacemakers and ICDs are life-sustaining devices that are designed to sense low-level physiological signals (as low as 0.1 mV) that have frequency content up to several hundred hertz. For patient safety and comfort, these devices are small, 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 electromagnetic interference (EMI).

An emitter with a fundamental carrier frequency up to several hundred hertz has the potential to be sensed directly by the pacemaker or ICD. Also, higher-frequency carriers that are modulated up to several hundred hertz and that have 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 EM compatibility of pacemakers and ICDs up to 3,000 MHz and is divided in several sections.

a) $0\ \text{Hz} \leq f < 450\ \text{MHz}$

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:

— electronic article surveillance (EAS) systems;

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

— new wireless service in the ultra-high-frequency and very-high-frequency bands;

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— magnetic levitation rail systems;

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

— metal detectors;

— magnetic resonance imaging; and

— experimental use of transponders for traffic control.

b) 450 MHz ≤ f < 3,000 MHz

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

Two decades ago, relatively few pacemaker patients used hand-held transmitters or were exposed to EM fields from portable transmitters. Hand-held, frequency-modulated transceivers for business, public safety, and amateur radio communications represented the predominant applications. However, the environment has changed rapidly during the past 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 will 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 EM 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 hand-held emitters (e.g., wireless telephones and two-way radios). Although operating restrictions can help prevent 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 are contributing to the expanding variety of emitters to which patients may now be exposed:

— 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 United States.[1)]

The various wireless phone standards allow for a range 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. Those 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 hand-held wireless transmitter 15 cm from the implant. An optional characterization test is described that uses higher power levels to simulate a hand-held wireless transmitter placed much closer to the implant. Claims that the manufacturer may wish to make on the basis of the results of the optional characterization must be negotiated between the manufacturer and the appropriate regulatory authorities.

[1] CTIA, www.ctia.org, 25 February 2005.

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c) $f \geq$ 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 this 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, broad range of frequencies, and variety of modulation schemes associated with existing and future applications.

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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 (EM) compatibility of active implantable cardiovascular devices (pacemakers and implantable cardioverter defibrillators, or ICDs).

The standard details test methods appropriate for 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 EM spectrum. It divides the EM frequency spectrum into three discrete segments:

0 Hz $\leq f <$ 450 MHz;

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

$f >$ 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 that are 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*, 74(4): 494–522, 1998.

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)

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3 Definitions, symbols, and abbreviations

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

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)
BPEG	British Pacing and Electrophysiology Group
bpm	beats per minute
CENELEC	European Committee for Electrotechnical Standardization
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
EAS	electronic article surveillance
ECG	electrocardiogram
EGM	electrogram
EM	electromagnetic
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EN	European Norm
ESMR	enhanced specialized mobile radio
f	frequency

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Table 1 (continued)

Acronym or Abbreviation	Description
FCC	Federal Communications Commission
FP	forward dipole power (mW)
FPdBm	forward dipole power (dBm)
ICD	implantable cardioverter defibrillator
ICNIRP	International Commission on Non-Ionizing Radiation Protection
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
λ	wave length
NASPE	North American Society of Pacing and Electrophysiology
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
RFID	radio-frequency identification
rms	root mean square
RP	reflected dipole power (mW)
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 or requirement applies 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 EM fields, whether through malfunction of the device, damage to the device, or heating of the device or by causing local increase of induced electrical current density within the patient.

Compliance shall be confirmed if, after performance of 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 that the manufacturer specifies in the accompanying documentation as not meeting the requirements of 4.4 and 4.5.1.1.

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

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NOTE 1—This does not mean that all combinations of settings are tested, but at least the setting to which the device is preset 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 use an automatic gain control function (or similar feature) for sensing purposes should include a detailed test method.

4.2 Induced lead current

The DUT shall be constructed so that ambient EM 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 setup defined in Figure 2; the tissue-equivalent interface circuit defined in Figure D.1 and Table D.1a; the low-pass filter defined by Figure D.4; 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 1 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).

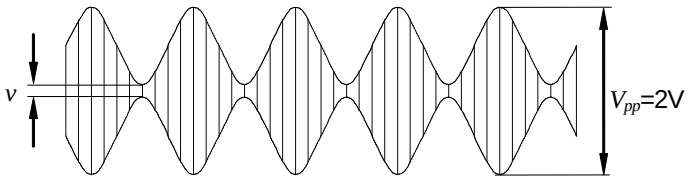


Figure 1—Test signal 2

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

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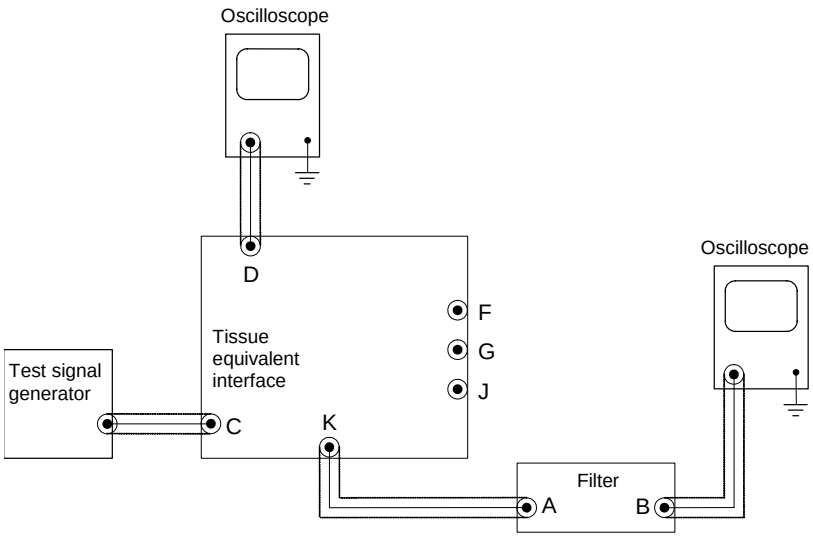


Figure 2—Test setup for measurement of induced current flow in pacemakers and ICDs

The induced electrical current is measured by the oscilloscope connected to test point K through the low-pass filter (as defined in Figure D.4) 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 C_x of the interface circuit (see Figure D.1) 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 milliseconds (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); and
- multichannel bipolar pacemakers shall be Group d).

NOTE 2—The bipolar channel should be tested in unipolar or bipolar mode or both 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 ≥ 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.

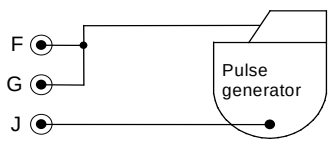


Figure 3—Connection to a single-channel unipolar pacemaker

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.

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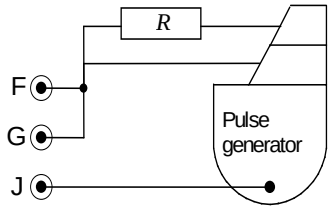


Figure 4—Connection to a multichannel unipolar pacemaker

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.

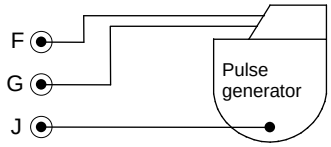


Figure 5—Common mode connection to single-channel bipolar pacemaker

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).

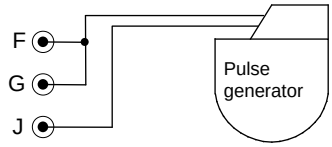


Figure 6—Differential mode connection to single-channel bipolar pacemaker

Group d) Common mode performance shall be tested by every input and 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.

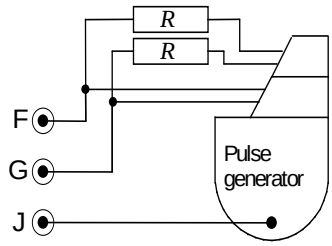


Figure 7—Common mode connection to multichannel bipolar pacemaker

Differential mode performance shall be tested using the test signals reduced to one-tenth amplitude. Every input and 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).

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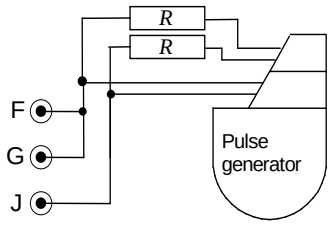


Figure 8—Differential mode connection to multichannel bipolar pacemaker

The current (root mean square, or 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 2, and
— for test signal 2, the current at modulating frequency of 130 Hz is not greater than 50 μA rms.

Table 2—Spurious injection current limits for pacemakers

f	Current rms
16.6 Hz $\leq f \leq$ 1 kHz	50 μA
1 kHz $\leq f \leq$ 20 kHz	50 μA × f/1kHz

4.2.2 ICDs

Test equipment: Use the test setup defined in Figure 2; the tissue interface circuit defined in Figure D.1 and in either Table D.1a or Table D.1b; the low-pass filter defined in Figure D.4; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF; and test signal generators, output impedance 50 Ω.

Unless otherwise stated, all resistors shall be of film type with low inductance, tolerance of ± 2 %, and rating of 0.5 W, and all capacitors shall be of the ceramic type, with tolerance of ± 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 1 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 % 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.

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The measuring oscilloscope shall be connected to test point K of the interface circuit through the low-pass filter (see Figure D.4) 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 C_x of the interface circuit (see Figure D.1) 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 sense/pace terminals

Select the tissue-equivalent interface circuit defined in Figure D.1 and Table D.1a. If the ICD offers multichannel sensing/pacing, every input or output of the ICD shall be tested in turn. Any sense/pace 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, cardioversion/defibrillation terminals are loaded with high-voltage 50 Ω, 25 W resistors R_L).

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

Common mode performance shall be tested with the sense/pace 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.

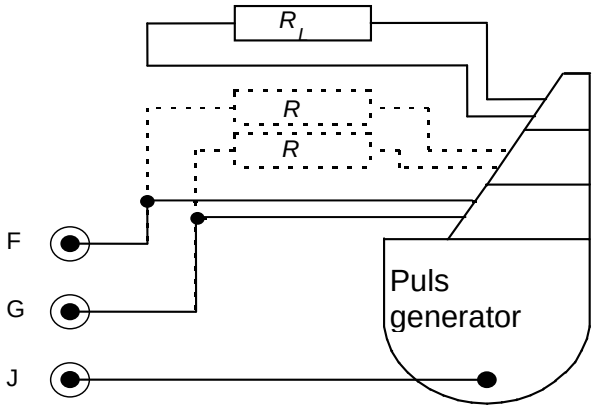


Figure 9—Common mode connection to multichannel bipolar ICD

Differential mode performance shall be tested using test signals 1 and 2 reduced to one-tenth amplitude. The sense/pace 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).

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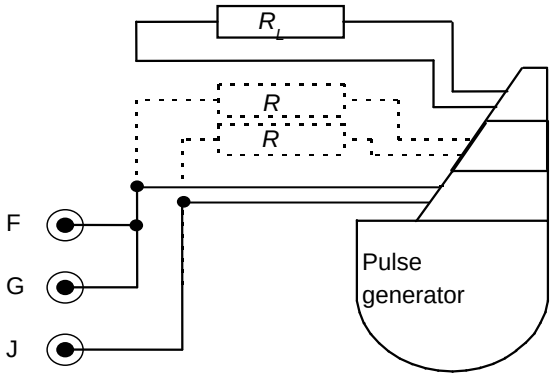


Figure 10—Differential mode connection to multichannel bipolar ICD

The current (rms) shall be determined by dividing the peak-to-peak voltage reading on the oscilloscope connected to test point K through the low-pass filter (as shown in Figure D.4 in bypass 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 MΩ 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 D.1 and Table D.1b.

The sense/pace terminals shall be loaded with resistors R_L 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 kΩ.

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 or both of the cardioversion/defibrillation terminals under test are 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.

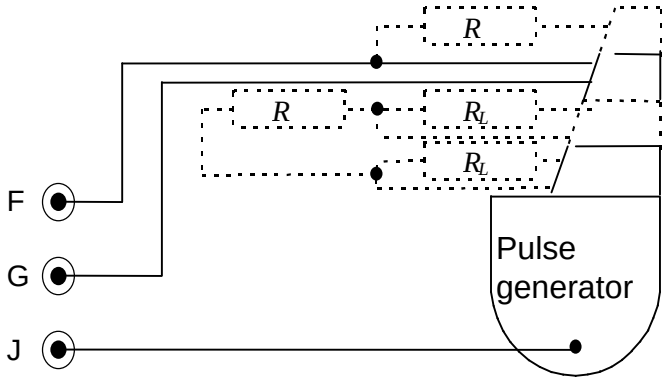


Figure 11—Common mode connection for cardioversion/defibrillation terminals

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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).

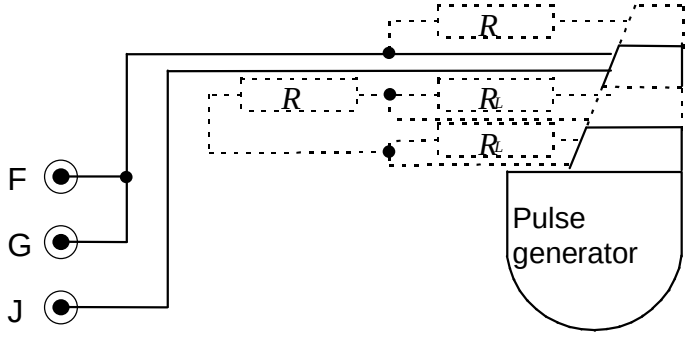


Figure 12—Differential mode connection for cardioversion/defibrillation terminals

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 through the low-pass filter (as shown in Figure D.4) 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 3 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 3—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 4—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 attributable to continuous wave sources

The DUT shall be constructed so that ambient continuous wave (CW) EM fields are unlikely to cause malfunction of the DUT that persists after the removal of the EM 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.

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4.3.1 Pacemakers

Test equipment: Use the test setup in Figure 13, the tissue-equivalent interface circuit defined by Figure D.2; 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 1 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, between 16.6 Hz and 20 kHz, the peak-to-peak amplitude, V_{pp}, shall be 1 V. For frequencies between 20 kHz and 140 kHz, V_{pp} shall be 1 V increased by a factor m, where

$$m = \frac{f}{20\ \text{kHz}}$$

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 D.2), 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.

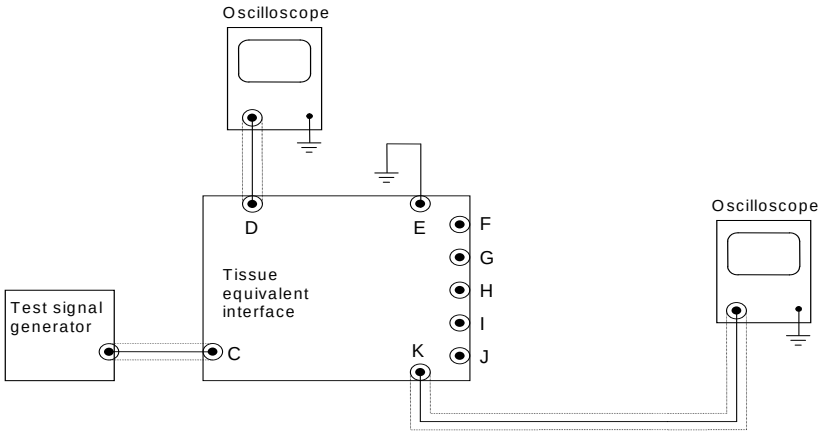


Figure 13—Test setup to check for induced malfunction

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); and

— Multichannel bipolar pacemakers shall be Group d).

NOTE—The bipolar channel should be tested in unipolar or bipolar mode, or both, 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.

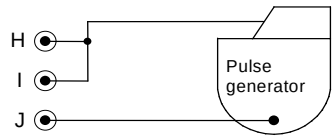


Figure 14—Connection to a single-channel unipolar pacemaker

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

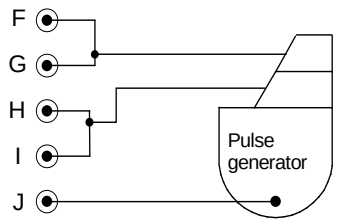


Figure 15—Connection to a multichannel unipolar pacemaker

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.

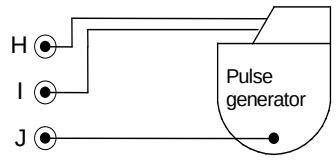


Figure 16—Common mode connection to a single-channel bipolar pacemaker

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

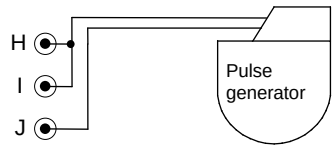


Figure 17—Differential mode connection to a single-channel bipolar pacemaker

Group d) Common mode performance shall be tested by every input and 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.

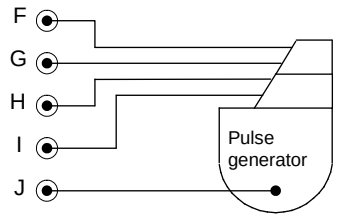


Figure 18—Common mode connection to a multichannel bipolar pacemaker

Differential mode performance shall be tested with every input and output of the pacemaker being connected, in turn, between the coupled outputs H and 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.

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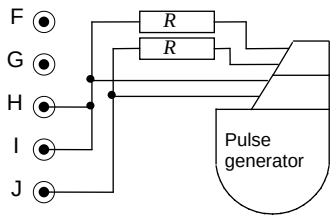


Figure 19—Differential mode connection to a multichannel bipolar pacemaker

Compliance shall be confirmed if, after application of the specified test signal, the pacemaker functions as it did before the test without further adjustment.

4.3.2 ICDs

Test equipment: Use the tissue-equivalent interface circuits defined by Figure D.2 and Figure D.3; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF, with 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 50 Ω.

CAUTION—Good high-frequency test procedures should be observed. Modification of the test circuits is allowed but 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 1 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 between 16.6 Hz and 20 kHz, the peak-to-peak amplitude, V_{pp}, shall be 1 V; for frequencies between 20 kHz and 140 kHz, V_{pp} shall be 1 V increased by a factor m, where

$$m = \frac{f}{20\ \text{kHz}}$$

Differential mode performance shall be tested using the 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, shall be 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-equivalent interface circuits, is likely.

4.3.2.1 Malfunction because of electrical interference on the sense terminals

Test procedure: Select the tissue-equivalent interface circuit defined by Figure D.2. 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 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).

Any sense/pace 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 50 Ω, 25 W resistors R_L.)

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

Common mode performance shall be tested with the pairs of sense/pace 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.

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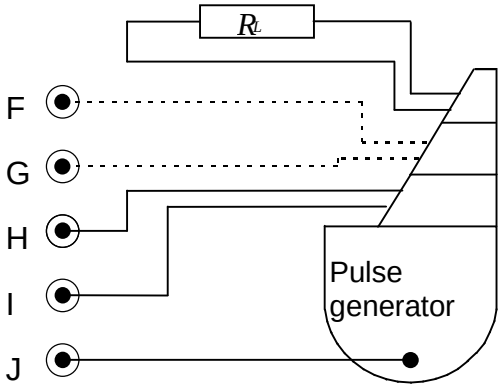


Figure 20—Common mode connection for multichannel bipolar ICDs

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

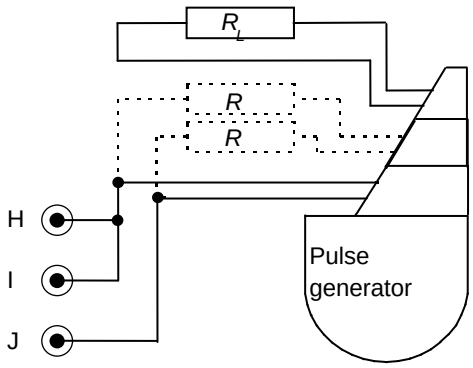


Figure 21—Differential mode connection for multichannel bipolar ICDs

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

4.3.2.2 Malfunction because of electromagnetic interference on the cardioversion/defibrillation lead

Test procedure: Select the tissue-equivalent interface circuit defined by Figure D.3. 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.

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