List of Titles

American National Standard

ANSI/AAMI PC69:2000

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

AAMI Association for the Advancement of Medical Instrumentation

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American National Standard ANSI/AAMI PC69:2000

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 3 May 2000 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 devices

List of Titles

AAMI Standard

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Glossary of equivalent standards

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 VP20:1994	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

Association for the Advancement of Medical Instrumentation

Pacemaker Committee

The AAMI Pacemaker Electromagnetic Compatibility Task Force developed this standard under the auspices of the AAMI Pacemaker Committee.

At the time this document was balloted, the **AAMI Pacemaker Committee** had the following members:

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	Doris J. W. Escher, MD, Montefiore Medical Center
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	Lee Hudson, Sulzermedica
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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Acknowledgment

The AAMI Pacemaker Electromagnetic Compatibility Task Force and AAMI Pacemaker Committee gratefully acknowledge the contributions of Robert Stevenson (Maxwell Technologies) and Don Heirman (Lucent Technologies) to the writing of this document.

Foreword

This voluntary standard was developed by the Pacemaker 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 PC69:2000), 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.

This standard is being developed in phases. The initial phase deals with near-field interference from emitters operating in the 450-MHz to 3,000-MHz band. These are the frequencies (f) that are typically associated with personal handheld communication devices (e.g., wireless telephones and two-way radios). This initial effort is intended to deal with an area not presently covered by any U.S. or international standard. It is the intent of the committee to publish the proposed standard as modified at the conclusion of each phase. Subsequent phases will address the interaction of pacemakers and ICDs with electromagnetic (EM) emitters operating in the remaining bands.

Phase I—450 MHz $\leq f <$ 3,000 MHz

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 10 years, with wireless phone systems becoming increasingly common as this technology matured and received widespread public acceptance. Wireless industry estimates indicate that wireless subscribers have increased from approximately 10 million worldwide in 1990 to more than 93 million in the United States alone in 2000. The wireless industry projected a worldwide wireless subscriber population in excess of 1.26 billion by the year 2005. 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.

Existing engineering standards for evaluating the electromagnetic compatibility (EMC) of implantable devices and other types of electronic equipment generally do not adequately address environments close to transmitters and the associated compatibility issues. 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.

For the past two decades, pacemakers and ICDs for the U.S. market typically have been evaluated for EM compatibility according to requirements of a 1975 draft AAMI pacemaker standard. The 1975 draft standard requires *in vitro* testing of pacemakers in a pulsating 450-MHz field, up to a peak intensity of 200 volts/meter, for demonstration of adequate immunity in radio-frequency interference environments. That test level in the 1975 draft standard was intended to simulate emissions from a distant radar source. Individual manufacturers may have, at their discretion, performed additional tests to provide further characterization of pacemaker and ICD EM immunity.

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 1999, there were more than 38 million digital subscribers in the U.S.

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.

This standard for frequencies of 450 MHz $\leq f \leq$ 3,000 MHz specifies testing at 40 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.

Subsequent Phases

While interaction with personal communications devices has been of recent concern, the number and types of EM emitters in the other parts of the frequency spectrum have also proliferated. In the lower frequency bands (< 450 MHz), there are many EM emitters such as broadcast radio and television. Now, there are 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);

— 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.

Some low-frequency emitters are designed to be compatible with biological safety guidelines. However, 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.

Innovative applications for frequencies in the microwave bands (> 3,000 MHz) may increase the likelihood that patients with pacemakers and ICDs may come into close proximity with emitters producing relatively high EM fields. Three examples are:

— marine radar used on pleasure craft;

— aviation transponders on small aircraft; and

— experimental use of transponders for traffic control.

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.

List of Titles

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 four discrete segments:

— 0 Hz ≤ f < 30 MHz[1)]

— 30 MHz ≤ f < 450 MHz

— 450 MHz ≤ f ≤ 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.

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

2.2 EN 50061:1988, *Safety of Implantable Pacemakers*.

3 Symbols (and abbreviated terms)

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

Table 1—List of acronyms and abbreviations

Acronym	Description
A	atrial
AAMI	Association for the Advancement of Medical Instrumentation
ACA	antenna cable attenuation (+dB)

[1)] EMC testing in this frequency band is presently covered by European Standard EN 50061/A1.

Acronym	Description
AdBm	power meter “A” reading (dBm)
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
ESMR	enhanced specialized mobile radio
f	frequency
FP	forward dipole power (mW)
FPdBm	forward dipole power (dBm)
ICD	implantable cardioverter defibrillator
λ	wave length
M	molar
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)
RPdBm	reflected dipole power (dBm)
SMA	subminiature “A”
V	ventricular
VF	ventricular fibrillation
VSWR	voltage standing wave ratio
VT	ventricular tachycardia

4 Test requirements for the frequency band—0 Hz ≤ f < 30 MHz

Under development.

5 Test requirements for the frequency band—30 MHz ≤ f < 450 MHz

Under development.

6 Test requirements for the frequency band—450 MHz ≤ f ≤ 3,000 MHz

6.1 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 annex A.

6.2 Sample size and configuration

A minimum of three samples of a particular device shall be tested. Devices shall be from initial production units, lots, or batches, or equivalent with justification of use provided. Devices shall be equivalent to implantable grade product.

6.3 Test setup

6.3.1 Test environment

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.

6.3.2 Torso simulator

The torso simulator is described in annex B. 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 2.

Table 2—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 M (1.8 g/l or 0.18%) NaCl concentration, at 21° C, measured at 1 kHz.

6.3.3 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 B.1). The lead connector pin 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 2.

6.3.4 Interference signal generation

6.3.4.1 Dipole antennas

A detailed description of the dipole antennas is given in annex C.

6.3.4.2 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).

6.3.5 Parameter programming

The DUT shall be programmed per the parameters listed in annex D. The form of antitachycardia pacing (ATP), if applicable, shall be preprogrammed to avoid confusion with inappropriate bradycardia pacing as defined in 6.5.

NOTE—During testing with the ECG 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 D.5.

6.3.6 Monitoring of device activity

The DUT output signal will be detected by electrically monitoring a pair of plates with monitoring equipment having a minimum input resistance of 1 MΩ (see Figure B.2).

6.3.7 Simulated cardiac signal injection

A signal generator will be used to apply a simulated electrocardiogram (ECG) waveform (described in annex E) to the second pair of plates, orthogonal to the plates utilized in 6.3.6.

6.4 Test procedure

6.4.1 Required test

Set up the test equipment in accordance with Figure B.2. Verify electrical and dimensional requirements of torso simulator setup per Table 2.

Program the DUT and record parameters per annex D.

6.4.1.1 X-axis testing, ECG 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 C) centered over the DUT reference point as defined in 6.3.3, at the elevation specified in Table 2. The ECG signal shall be OFF.

Set the carrier frequency to 450 MHz. Set the dipole net RF power to 40 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 F.

Set the RF signal generator for pulse modulation per 6.3.4.2.

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.)

6.4.1.2 X-axis testing, ECG 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 C) centered over the DUT reference point as defined in 6.3.3, at the elevation specified in Table 2. The ECG signal shall be ON at the simulated bradycardia rate, per annex E.

Set the carrier frequency to 450 MHz. Set the dipole net RF power to 40 mW RMS (continuous wave). The net power calculation is presented in annex F.

Set the RF signal generator for pulse modulation per 6.3.4.2.

Monitor and record the DUT performance during exposure to the modulated RF 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.)

6.4.1.3 X-axis testing, ECG 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 C) centered over the DUT reference point as defined in 6.3.3, at the elevation specified in Table 2. The ECG signal shall be ON at the simulated tachycardia rate, per annex E.

Set the carrier frequency to 450 MHz. Set the dipole net RF power to 40 mW RMS (continuous wave). The net power calculation is presented in annex F.

Set the RF signal generator for pulse modulation per 6.3.4.2.

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.

6.4.1.4 Y axis testing

Repeat 6.4.1.1 through 6.4.1.3, except with the antenna elements parallel to the Y axis.

6.4.1.5 Testing at remaining frequencies

Repeat 6.4.1.1 through 6.4.1.4 for all frequencies listed in 6.3.4.2 using the appropriate dipole antenna.

6.4.1.6 Post-test DUT verification

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

6.4.2 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 A.3.4 and A.3.5.

For optional DUT characterization, antenna 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 6.4.1.1 through 6.4.1.6 for these power levels.

6.5 Performance criteria

6.5.1 Single-chamber pacing modes of antibradycardia devices or ICDs

6.5.1.1 ECG signal OFF

During test exposure with the ECG 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.

6.5.1.2 ECG signal ON

During test exposure with the ECG 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.

6.5.2 Dual-chamber pacing modes of antibradycardia devices or ICDs

6.5.2.1 ECG signal OFF

During test exposure with the ECG 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.

6.5.2.2 ECG signal ON

During test exposure with the ECG 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.

6.5.3 Antitachyarrhythmia modes of ICDs

6.5.3.1 ECG signal OFF

During test exposure with the ECG 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.

6.5.3.2 ECG signal ON (tachycardia rate)

During exposure to RF and ECG, 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.

7 Test requirements for the frequency band—f > 3,000 MHz

Under development.

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 is, therefore, not consecutive.

A.1 Rationale for test requirements for the frequency band—0 Hz ≤ f < 30 MHz

Under development.

A.2 Rationale for test requirements for the frequency band—30 MHz ≤ f < 450 MHz

Under development.

A.3 Rationale for test requirements for the frequency band—450 MHz ≤ f ≤ 3,000 MHz

A.3.1 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 pin contact in a single-chamber pulse generator or the right ventricular lead connector 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.3.2 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 DUT's passband. Typical communications service signal modulations are less disturbing than the modulation specified by this standard.

A.3.3 Rationale for test frequencies

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 A.1 for a list of sources known at this time).

Table A.1—List of common EM emitters

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

Transmit frequency (MHz) port/base	Service type	Service name
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
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

A.3.4 Rationale for the optional characterization testing

The 40-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.3.5 Rationale for test power levels

The dipole antenna power levels defined in this standard are derived from measurements of RF signals coupled to an instrumented pulse generator can with leads installed. The chart in Figure A.1 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 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.

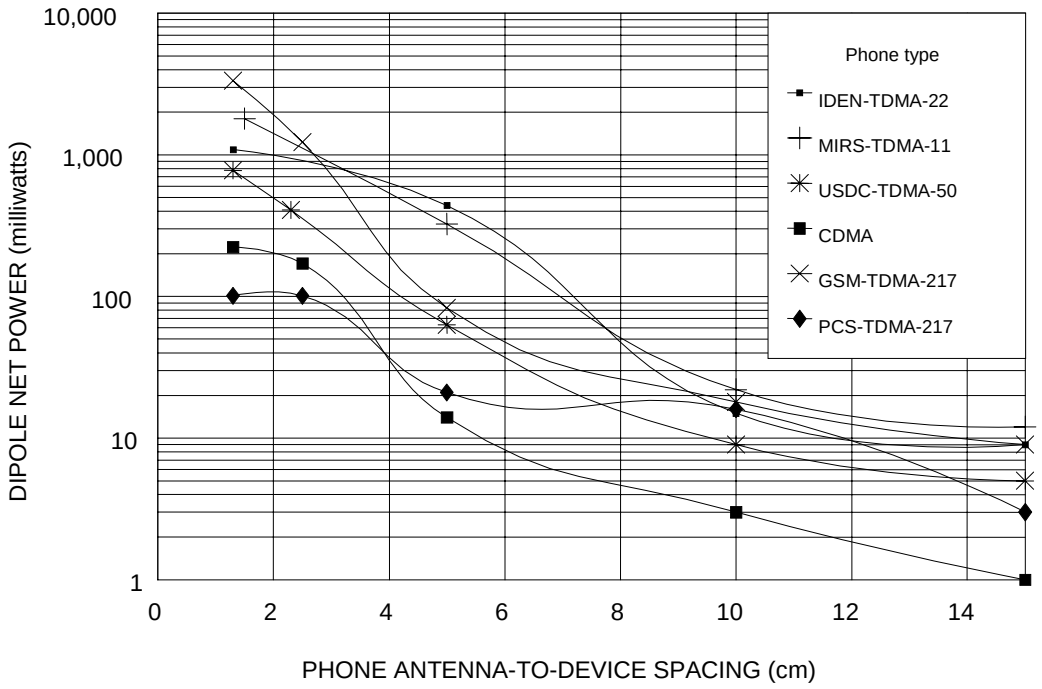


Figure A.1—Dipole net power measurements (dipole spacing = 2.5 cm)

The 40-mW dipole net power level specified in 6.4.1 ensures 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 is maintained a minimum of 15 cm from the implanted device. This requirement is consistent with current industry practices for patient guidance and labeling of devices that are not designed for compatibility with close-proximity wireless phones.

The optional characterization test specified in 6.4.2 requires dipole net power levels of 8 watts in the frequency range 450 MHz $\leq f <$ 1,000 MHz and 2 watts in the frequency range 1,000 MHz $\leq f \leq$ 3,000 MHz. The selected power

levels are based on the maximum power levels likely to be encountered from the sources[1)] identified in Table A.1. 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.3.6 Rationale for lead configuration

The DUT lead configuration as illustrated in Figure B.1 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.

A.3.7 Rationale for device program parameters

VVI coupled with AAI testing 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.

A.3.8 Rationale for sample size

The sample size for the number of each individual model to be tested is based on a desire to insure that the testing is truly representative of the performance of the model balanced against a practical concern of placing a reasonable limit on the amount of testing required by the protocol. Thus, a sample of one was dismissed based on the inability to be assured that this sample would be representative. A sample of two fails to allow for a determination of the true performance should there be a difference in the test results of the units. A sample size of three or more would allow for such discrimination. However, samples of four or more would significantly increase the amount of testing required and the time necessary to complete it, yet provide no assurance that additional useful information will be acquired. Thus, it is the consensus of the task force that a sample of three is both adequate and appropriate.

A.4 Rationale for test requirements for the frequency band—$f > 3{,}000$ MHz

Under development.

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

Annex B
(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).

B.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 2. The dipole antenna rests on the "top grid" with the DUT resting on the "bottom grid."

B.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.

B.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.

B.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.

B.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.

B.6 Illustrations

Figures B.1 and B.2 illustrate all the features discussed above.

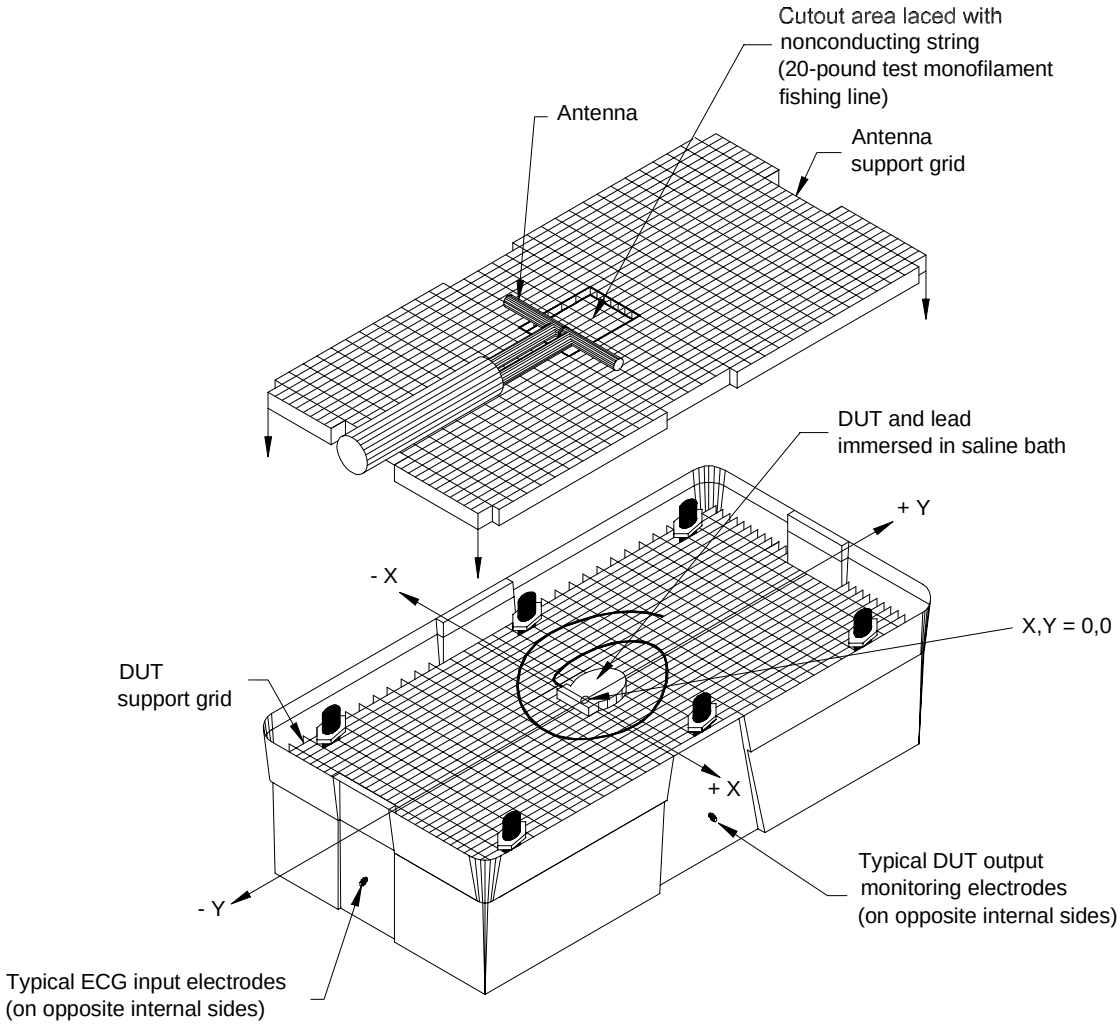


Figure B.1—Torso simulator

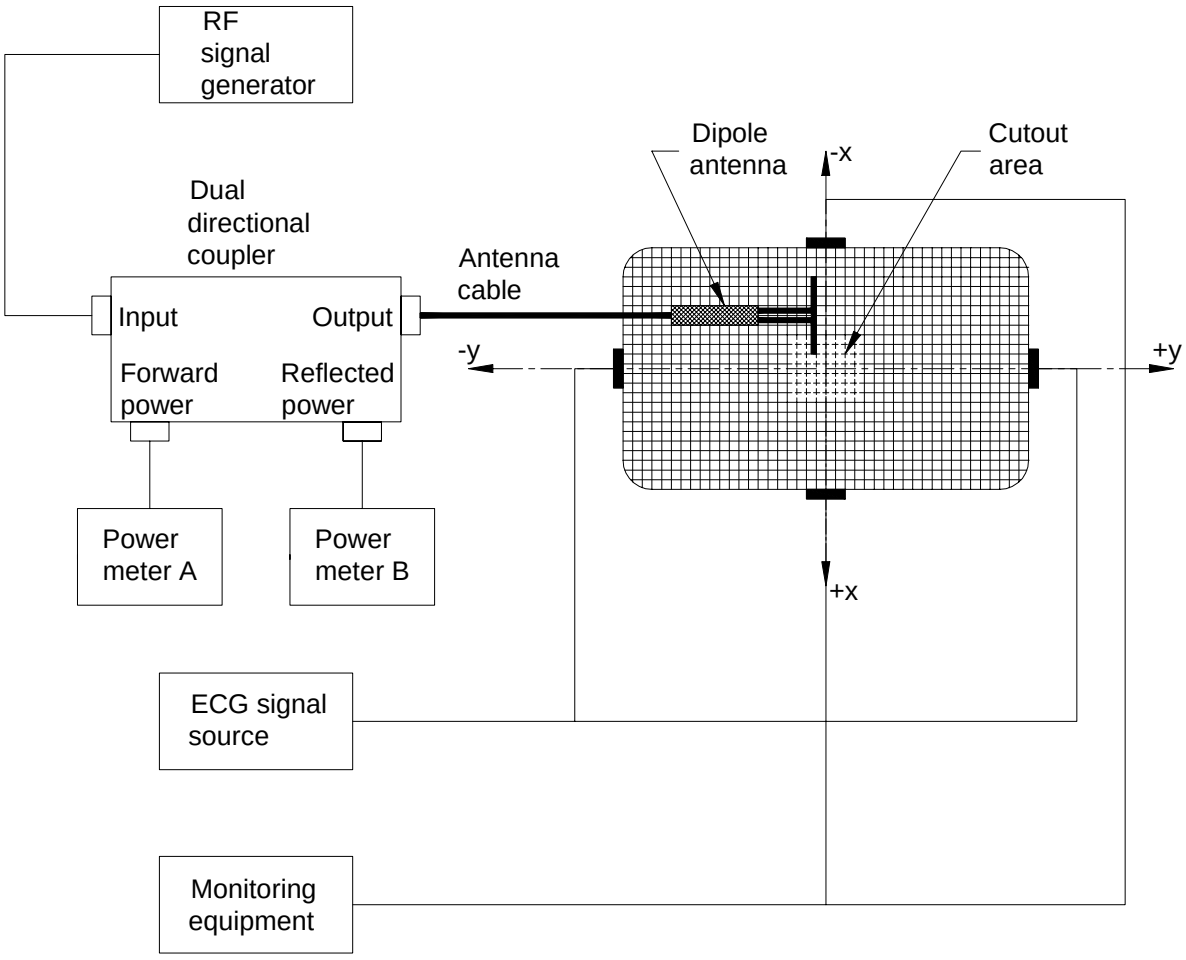


Figure B.2—Test setup

Annex C
(normative)

Dipole antennas

C.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 C.1. The coaxial balun is terminated into a suitable 50 Ω coaxial interface connector. See Figure C.1 or ANSI C63.5-1988, appendix C, for examples of dipole antennas that can meet the specification in Table C.1. See Table 2 for saline resistivity and spacing between the antenna and the saline during characterization of the antenna.

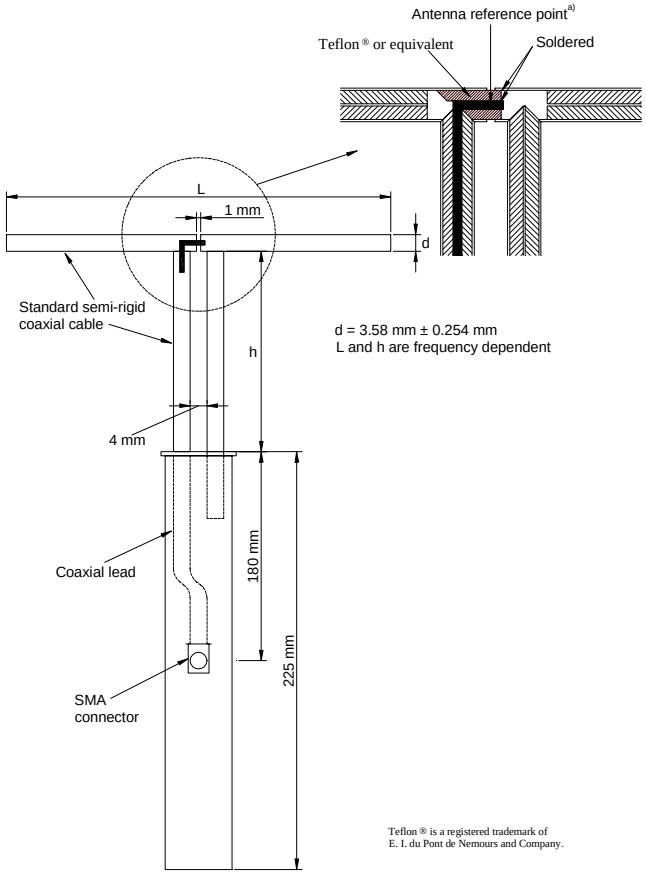
Table C.1—Dipole description

Test Frequencies	**Defined in 6.3.4.2**
At each frequency, the following characteristics shall apply:	
Symmetry [a)]	± 0.5 dB up to λ/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 C.1—Example of dipole antenna

Annex D
(normative)

Pacemaker/ICD programming settings

D.1 Introduction

This annex describes the programmable settings for the DUT.

D.2 Pacemaker

D.2.1 Parameters

Table D.1—Pacemaker parameters

Parameter (where appropriate/available)	Single-chamber device	Dual-chamber device	Single pass lead
Mode (most comprehensive) [a)]	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	Maximum	Maximum	Maximum
Safety pacing	On	On	–
Rate response	On (VVIR/AAIR)	On (DDDR)	–
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 D.5.

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

D.2.2 Lead configurations

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

D.2.3 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.

D.3 ICD

D.3.1 Parameters

Table D.2—Defibrillator 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	Maximum, if applicable	Maximum, if applicable
Detection enable	ON	ON
Detection criteria	Most likely to detect	Most likely to detect
ATP therapy	OFF	OFF
VT/VF therapy #1	Lowest energy setting	Lowest energy setting
VT/VF therapy #2, . . . etc.	OFF, if possible	OFF, if possible
Rate response	ON (VVIR/AAIR)	ON (DDDR)
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 D.5.

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

D.3.2 Lead configurations

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

D.3.3 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.

D.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.

D.5 The NASPE/BPEG generic (NBG) pacemaker code

Table D.3—NASPE/BPEG generic (NBG) pacemaker code

Position	I	II	III	IV	V
Category	Chamber(s) paced	Chamber(s) sensed	Response to sensing	Programmability, rate modulation	Anti-tachyarrhythmia
	O=none	O=none	O=none	O=none	O=none
	A=atrium	A=atrium	T=triggered	P=simple programmable	P=pacing
	V=ventricle	V=ventricle	I=inhibited	M=Multi-programmable	S=shock
	D=dual (A+V)	D=dual (A+V)	D=dual (T+I)	C=communicating	D=dual (P+S)
				R=rate modulating	
Manufacture designation only	S=single (A or V)	S=single (A or V)			

Source: The NASPE/BPEG Generic Pacemaker Code for Antibradyarrhythmia and Adaptive-Rate and Antitachyarrhythmia Devices, PACE 10: 794–799, 1987.

Annex E
(normative)

Simulated cardiac signal

E.1 ECG signal

The simulated waveform (Ref: Figure C3 of EN 50061) shall have the following characteristics:

— Rise time is t = 2 ms and fall time is T = 13 ms;

— Total pulse width is 15 ms (see Figure E.1).

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, 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.

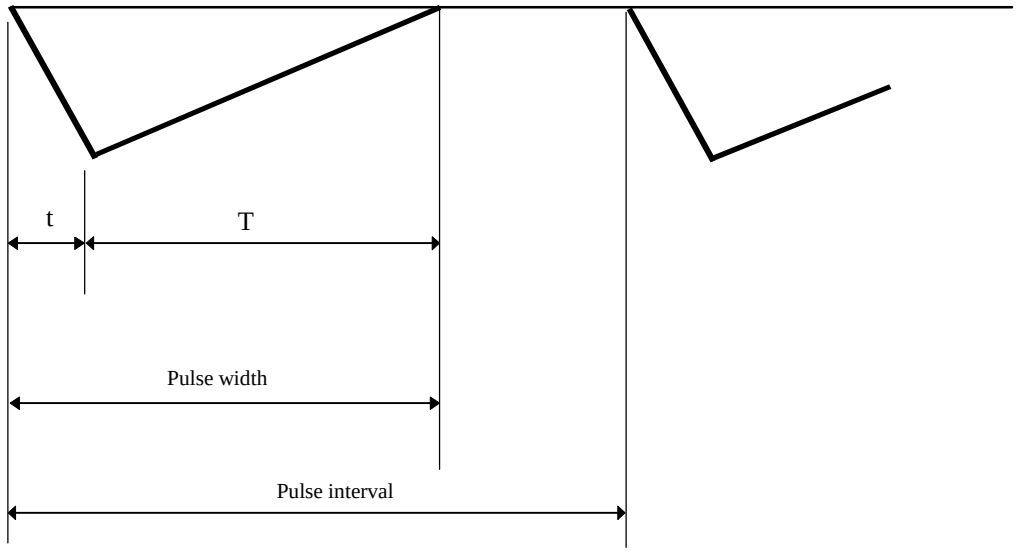


Figure E.1—Simulated cardiac signal

Annex F
(normative)

Calculation of net power into dipole antenna

F.1 Calculation of net dipole power

The test setup shown in Figure F.1 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.

F.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)

F.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)

F.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)

F.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)

F.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)

F.2 Measurement of factors for net power calculations

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

F.2.1 DCF—Directional coupler forward port coupling factor

Configure the test equipment as shown in Figure F.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 F.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)

F.2.2 DCR—Directional coupler reflected port coupling factor

Configure the test equipment as shown in Figure F.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 F.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: DCR directional coupler reflected port coupling factor (dB)

BdBm power meter B reading (dBm)

AdBm power meter A reading (dBm)

F.2.3 ACA antenna cable attenuation

Configure the test equipment as shown in Figure F.4 with the antenna cable used in the Figure F.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 F.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

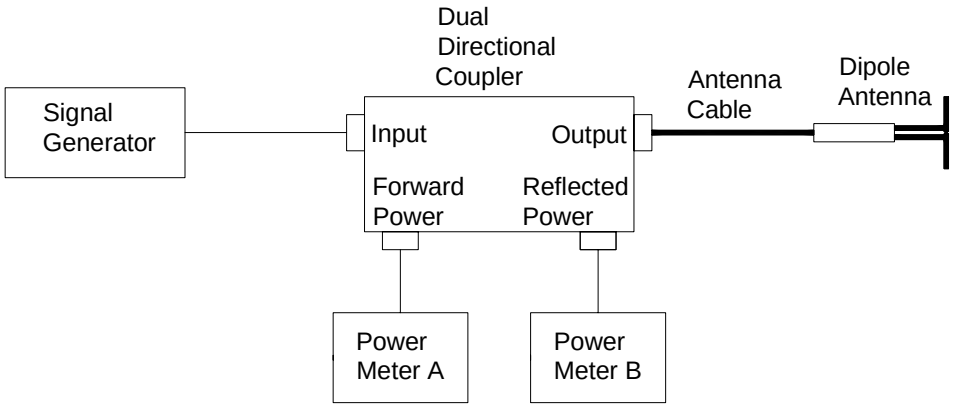
Where: ACA antenna cable attenuation (dB)

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 C.1) shall be added to ACA.



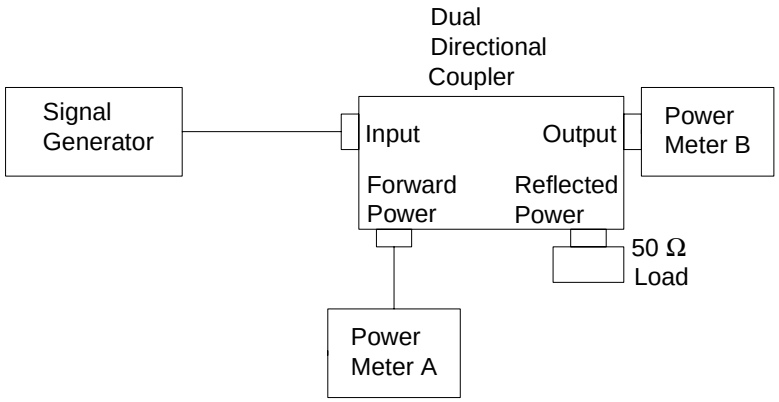
NOTES—

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 F.1—Test setup

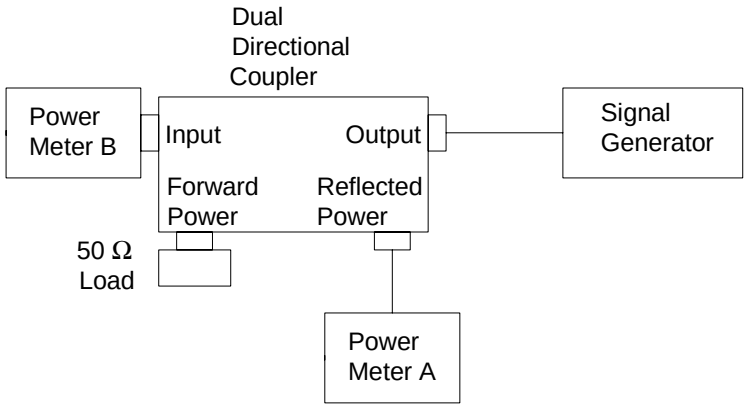


NOTES—

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 F.2—Directional coupler forward port coupling factor

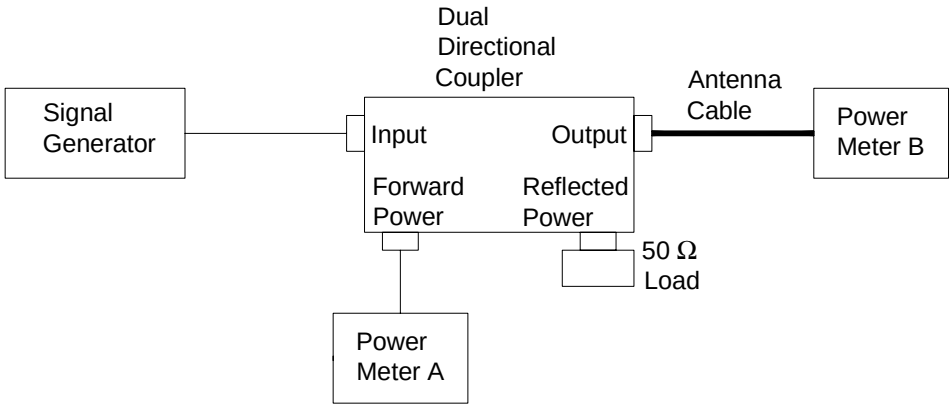


NOTES—

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 F.3—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 F.4—Antenna cable attenuation