INTERNATIONAL STANDARD

ISO 14117

First edition
2012-07-15

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

Dispositifs médicaux implantables actifs — Compatibilité électromagnétique — Protocoles d'essai EMC pour pacemakers cardiaques implantables, défibrillateurs implantables et dispositifs de resynchronisation cardiaque

Reference number
ISO 14117:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 14117 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

ISO 14117 is based on ANSI/AAMI PC69:2007. The relationship between the documents is addressed in A.2.4.

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.

In recent years, other active implantable cardiovascular devices have emerged, most notably devices that perform the function of improving cardiac output by optimizing ventricular synchrony, in addition to performing pacemaker or ICD function.

Although these devices can deliver an additional therapy with respect to pacemakers and ICD devices, most of their requirements concerning EM compatibility are similar so that, in most cases, the concepts that apply to pacemakers also apply to CRT-P devices, and the appropriate way to test a CRT-P device is similar to the way pacemakers are tested. Similarly, the concepts that apply to ICD devices mostly apply to CRT-D devices as well, so the appropriate way to test a CRT-D device is similar to the way ICD devices are tested.

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 active implantable cardiovascular devices.

It is important to understand that these interactions may occur despite the conformance of the device to this International 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 (FCC).

Compliance with biological safety guidelines does not necessarily guarantee EM compatibility with active implantable cardiovascular devices. In some cases, the reasonably achievable EM immunity performance for these devices falls below these biological safety limits.

The potential for emitter equipment to interfere with active implantable cardiovascular devices 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.

Devices within the scope of this International Standard are life-sustaining and 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 details regarding this issue can be found in Annex M.

This International Standard addresses the EM compatibility of pacemakers and ICDs up to 3 000 MHz and is divided in several sections.

a) 0 Hz ≤ f < 450 MHz

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

— 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;

— 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 centimetres of the implantable device. Studies in the mid-1990s 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. As of September 2010, there were more than 5 billion digital subscriptions worldwide.

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 $\leq f \leq$ 3 000 MHz, this International 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 are to be negotiated between the manufacturer and the appropriate regulatory authorities.

c) $f \geq$ 3,000 MHz

This International Standard does not require testing of devices above 3 GHz. The upper-frequency limit chosen for this International 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 are implemented to meet the lower-frequency requirements of this International Standard, and

4) the reduced sensitivity of circuits at microwave frequencies.

Additional details can be found in Clause 5.

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.

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

1 Scope

This International Standard specifies test methodologies for the evaluation of the electromagnetic compatibility (EMC) of active implantable cardiovascular devices that provide one or more therapies for bradycardia, tachycardia and cardiac resynchronization.

It specifies performance limits of these devices, which are subject to interactions with EM emitters operating across the EM spectrum in the two following ranges:

0 Hz $\leq f <$ 450 MHz;

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

This International Standard also specifies requirements for the protection of these devices from EM fields encountered in a therapeutic environment and defines their required accompanying documentation, providing manufacturers of EM emitters with information about their expected level of immunity.

2 Normative references

There are currently no standards normatively referenced within this International Standard. However, future editions are likely to include normative references as new emitters or test methods are identified.

NOTE It is also expected that future revisions of the related product standards ISO 14708-2 and ISO 14708-6 will normatively reference this standard.

3 Terms and 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 DUT 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 DUT and leads

3.3
implantable cardiac resynchronization therapy pacing device
CRT-P
active implantable medical device intended to provide improved ventricular activation to optimize cardiac output, comprising an implantable DUT and leads

3.4
implantable cardiac resynchronization therapy/defibrillator device
CRT-D
active implantable medical device intended to detect and correct tachycardias and fibrillation by application of cardioversion/defibrillation pulses to the heart, and to provide improved ventricular activation to optimize cardiac output, comprising an implantable DUT and leads

3.5
inhibition generator
equipment that generates a simulated heart signal for devices within the scope of this International Standard

3.6
harm
physical injury or damage to the health of people, or damage to property and environment

[ISO/IEC Guide 51:1999, definition 3.3]

3.7
maximum permanently programmable sensitivity
condition where the sensing channels of an ICD or pacemaker are set, either automatically by the device or programmed by a clinician, to detect the lowest amplitude signals

NOTE 1 These settings are intended for use without direct medical supervision.

NOTE 2 Sensitivity settings are usually expressed in terms of the minimum voltage that can be sensed. Therefore, a sensitivity of 1mV is actually more sensitive than a setting of 2mV.

NOTE 3 An AIMD may have settings, including those for sensitivity, that by design of the device or its software, are only temporarily available for use during diagnostic testing (such as during manufacture) or for testing at the time of implantation. Such settings are therefore unavailable for use by patients when not under immediate medical care and are not intended to be encompassed by the testing herein.

Table 1 shows acronyms and abbreviations used in this International 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
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

Table 1 *(continued)*

Acronym or abbreviation	Description
EM	electromagnetic
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EN	European Norm
ESMR	enhanced specialized mobile radio
f	frequency
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	wavelength
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 this International Standard, DUT has been used to designate all devices within the scope of this International Standard. When a certain test or requirement applies only to a specific type of device, that designation is used.

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

4.1 General

Implantable pacemakers, ICDs and CRT devices 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, 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 4.9, 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 as follows.

— For pacemakers and CRT-P devices: those settings that the manufacturer specifies in the accompanying documentation as not meeting the requirements of 4.4 and 4.5.2.1.

— For ICDs and CRT-D devices: those settings that the manufacturer specifies in the accompanying documentation as not meeting the requirements of 4.5.2.2.

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 DUT is covered with an insulating material, the DUT (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.

NOTE 4 Some of the tests described in the following sections may require modifications of the testing fixtures to allow for the tests to be applied to devices having three or more channels, e.g. CRT-P and CRT-D.

NOTE 5 The following tests are generally 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 Induced lead current

4.2.1 General considerations

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.

4.2.2 Pacemakers and CRT-P devices

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).

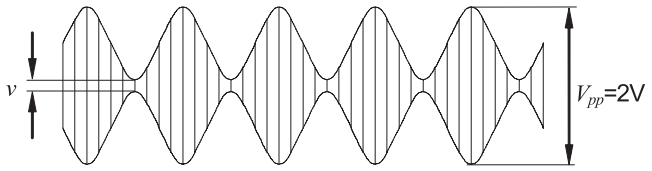


Figure 1 — Test signal 2

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.

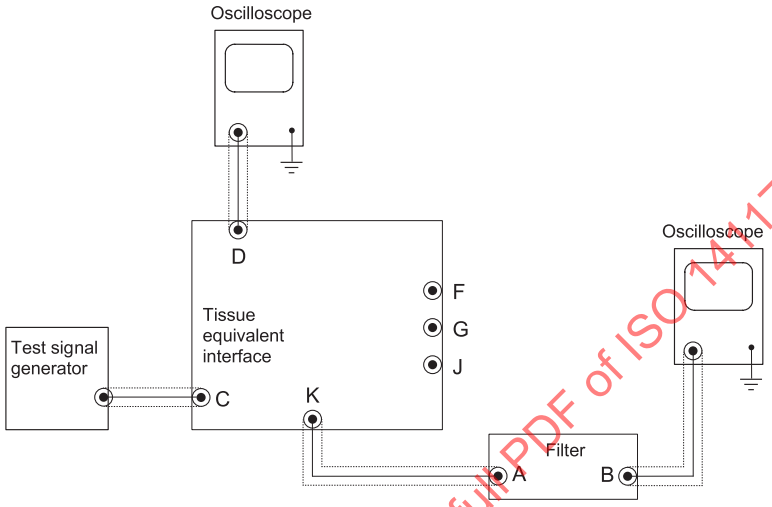


Figure 2 — Test setup for measurement of induced current

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 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 or CRT-P shall be categorized into one or more of four groups as appropriate:

— single-channel unipolar devices shall be Group a);

— multichannel unipolar devices shall be Group b);

— single-channel bipolar devices shall be Group c);

— multichannel bipolar devices 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 DUT not being tested shall be connected to the channel under test through a resistor of value $R \geq 10$ kΩ, as specified by the manufacturer.

Group a): the DUT 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.

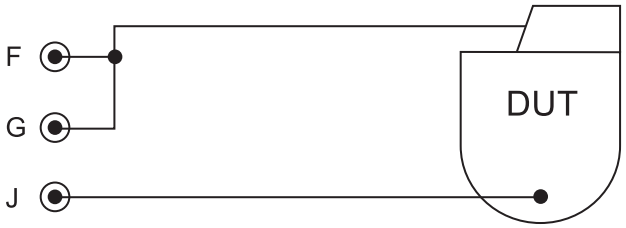


Figure 3 — Connection to a single-channel unipolar device

Group b): every input/output of the DUT shall be connected, in turn, to the coupled outputs F and G of the tissue-equivalent interface (as shown in Figure 4), with output J connected to the case.

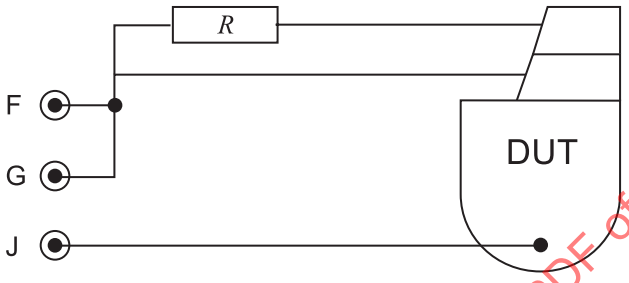


Figure 4 — Connection to a multichannel unipolar device

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.

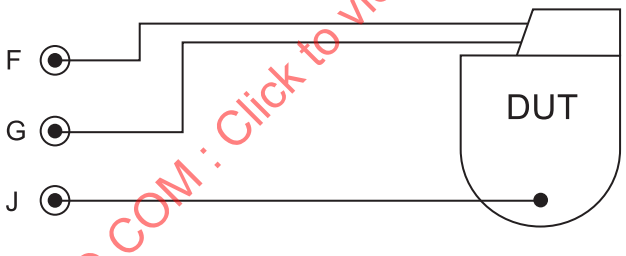


Figure 5 — Common mode connection to single-channel bipolar device

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 device

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.

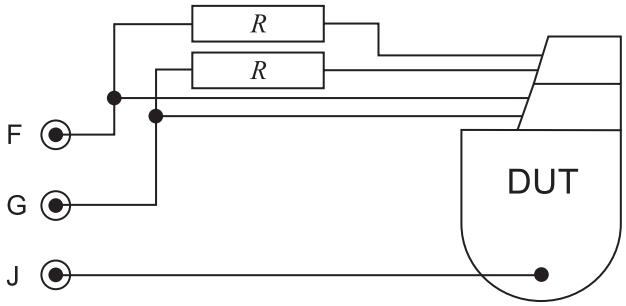


Figure 7 — Common mode connection to multichannel bipolar device

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).

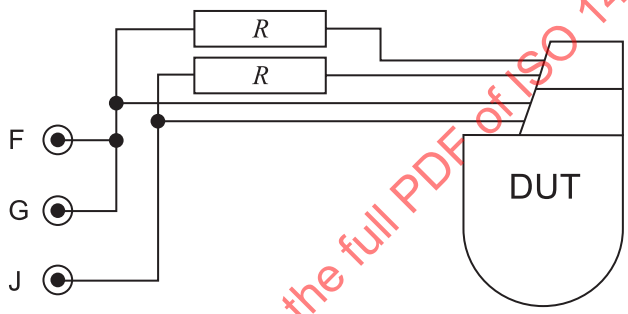


Figure 8 — Differential mode connection to multichannel bipolar device

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

f	Current rms
16,6 Hz ≤ f ≤ 1 kHz	50 μA
1 kHz ≤ f ≤ 20 kHz	50 μA × f/1kHz

4.2.3 ICDs and CRT-D devices

4.2.3.1 Test requirements

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.

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

NOTE 1 Care needs to 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.

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

CAUTION — Take care 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.

4.2.3.2 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 DUT offers multichannel sensing/pacing, every input or output of the ICD shall be tested in turn. Any sense/pace terminal of the DUT 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 DUTs 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.

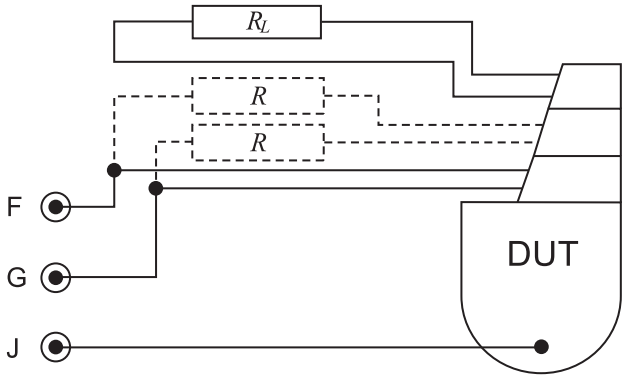


Figure 9 — Common mode connection to multichannel bipolar device

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).

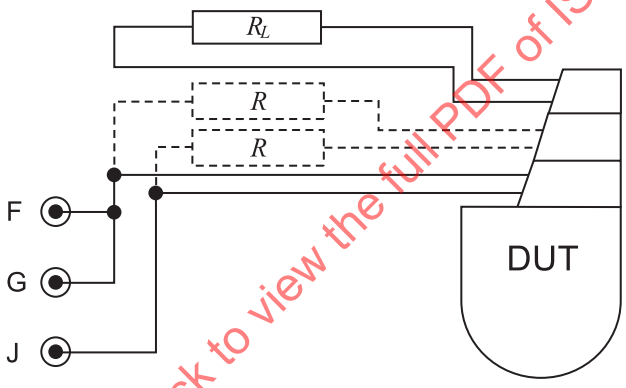


Figure 10 — Differential mode connection to multichannel bipolar device

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.

4.2.3.3 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 $R \geq 10$ 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 DUT is an active terminal, no common mode test is required.

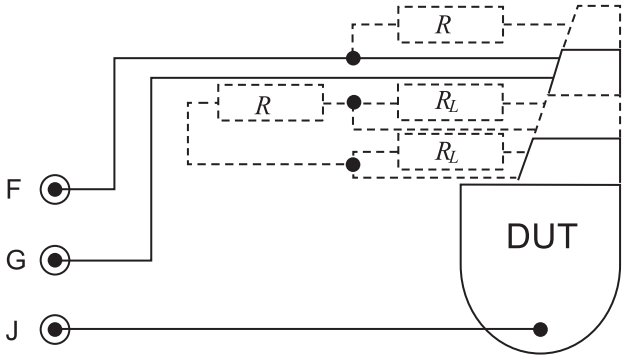


Figure 11 — Common mode connection for cardioversion/defibrillation terminals

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

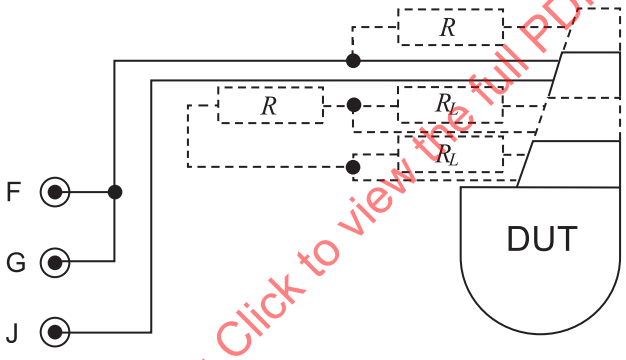


Figure 12 — Differential mode connection for cardioversion/defibrillation terminals

If the DUT 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 3a) for sense/pace terminals and Table 3b) for cardioversion/defibrillation terminals; and

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

Table 3a) — Spurious injection current limits for sense/pace terminals

f	Current rms
16,6 Hz ≤ f ≤ 1 kHz	50 µA
1 kHz ≤ f ≤ 20 kHz	50 µA × (f / 1kHz)

Table 3b) — Spurious injection current limits for 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 ambient electromagnetic fields

4.3.1 General requirements

The DUT shall be constructed so that ambient 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.

4.3.2 Pacemaker and CRT-P devices

4.3.2.1 Malfunction due to electromagnetic interference in the frequency range of 16,6 Hz to 10 MHz

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 10 MHz 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.

The test signal amplitude for unipolar and common mode test shall be as shown in Table 4.

Table 4 — Peak to peak amplitudes V_{pp} in the range 16,6 Hz to 10 MHz

f	V_{pp}
16,6 Hz ≤ f ≤ 20 kHz	1 V
20 kHz ≤ f ≤ 140 kHz	1V * (f/20 kHz)
140 kHz ≤ f ≤ 10 000 kHz	7V * (f/140 kHz) ^{0,1624}

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

Test procedure: The test signal generator shall be connected through input C of the interface circuit (as defined in Figure D.2), and as shown in Figure 13. The test signal shall be measured on the oscilloscope connected to monitoring point D. The operation of the DUT can be recorded on the oscilloscope connected to monitoring point K.

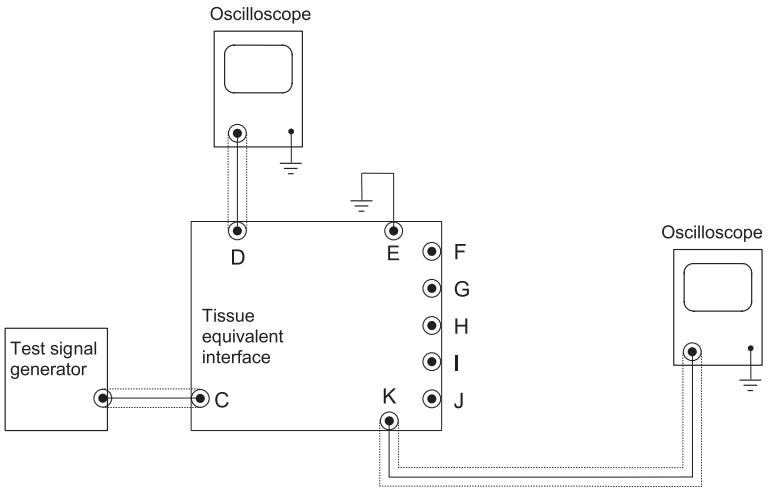


Figure 13 — Test setup to check for induced malfunction

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

— single-channel unipolar devices shall be Group a);

— multichannel unipolar devices shall be Group b);

— single-channel bipolar devices shall be Group c);

— multichannel bipolar devices shall be Group d).

NOTE A bipolar channel should be tested in all possible modes (unipolar, bipolar, or both), according to the programmability of the device.

Group a): the DUT 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 device

Group b): every input and output of the DUT 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.

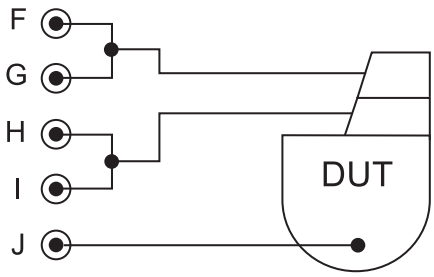


Figure 15 — Connection to a multichannel unipolar device

Group c): common mode performance shall be tested with the DUT connected to the outputs H and I of the tissue-equivalent interface (as shown in Figure 16), with output J connected to the case.

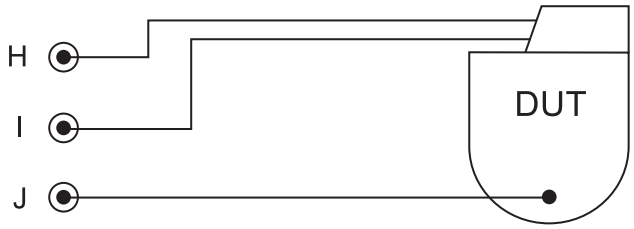


Figure 16 — Common mode connection to a single-channel bipolar device

Differential mode performance shall be tested with the DUT 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 device

Group d): common mode performance shall be tested by every input and output of the DUT 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.

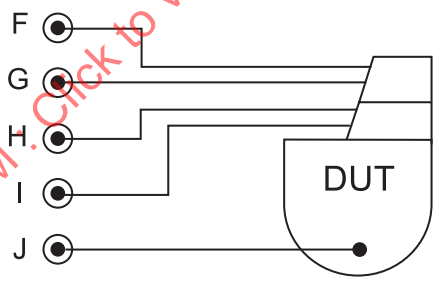


Figure 18 — Common mode connection to a multichannel bipolar device

Differential mode performance shall be tested with every input and output of the DUT 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 DUT not being tested shall be connected to the equivalent terminal of the channel under test through a resistor of value $R \geq 10\ \text{k}\Omega$.

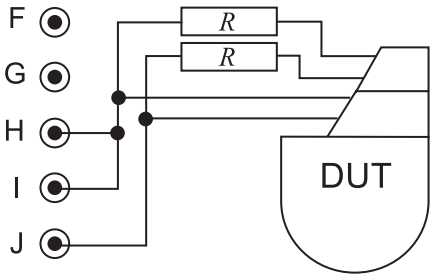


Figure 19 — Differential mode connection to a multichannel bipolar device

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

4.3.2.2 Malfunction due to electromagnetic interference in the frequency range of 10 MHz to 450 MHz

Test equipment: Use the test setup shown in Figure 21; the tissue injection network defined by Figure D.5; an oscilloscope (#1), input impedance 50 Ω, accuracy of ± 10 % within a bandwidth of at least 450 MHz; and a test signal generator, output impedance 50 Ω.

Test signal: The test signal shall be a modulated signal of the form as shown in Figure 20 . The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst-to-burst interval, T, shall be measured from leading edge to leading edge (see Figure 20). The burst-to-burst interval, T, of the modulated signal shall be set to 700 ms ± 50 ms.

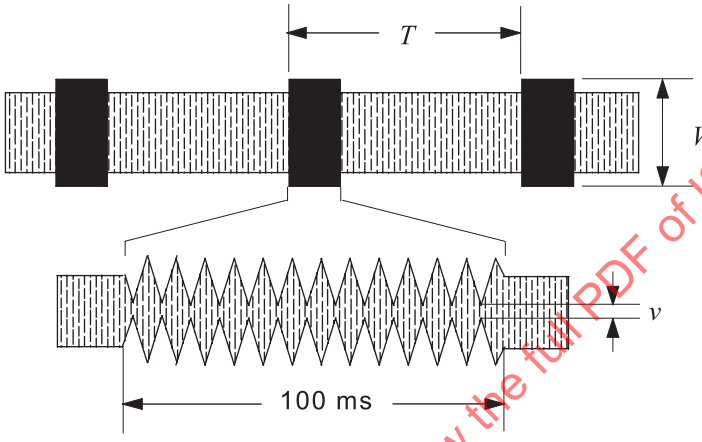


Figure 20 — Test signal for frequencies between 10 MHz and 450 MHz

The modulation bursts shall start and terminate at zero crossings of the modulation signal, thus the envelope starts and terminates continuously. The burst count is 13 complete modulation cycles. The modulation index, M, shall be 95 %, where:

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

NOTE 1 The peak-to-peak amplitude of the test signal, V_{pp}, cannot be measured directly at any connector of the injection network during the test. Therefore, it is calculated from the voltage at connector D, V_{osc}, by applying the calibration factor, m, of Annex F.

Test procedure: Prior to any testing, calibrate the setup using the procedure in Annex F. The test signal generator shall be connected to the injection network through input C as shown in Figure 21. The test signal generator shall be adjusted so that the test signal amplitude measured on oscilloscope #1 connected to monitoring point D (V_{osc}) when multiplied by the calibration factor for the injection network, determined according to the method of Annex F, is equal to the required test signal amplitude, V_{pp}.of 14 V.

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

NOTE 2 If an rms voltmeter is used during calibration procedure and testing at monitoring point D, then the test value shall be 53 % of the calibration value, to provide a nominal modulated test amplitude of 14 V_{pp} (open circuit) at outputs F and G.

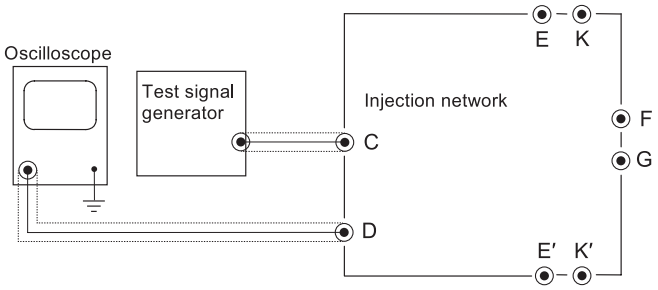


Figure 21 — Test setup to check for malfunction at high frequency

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

Unipolar devices shall be connected to output F of the injection network (as shown in Figure 22), using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn, and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L).

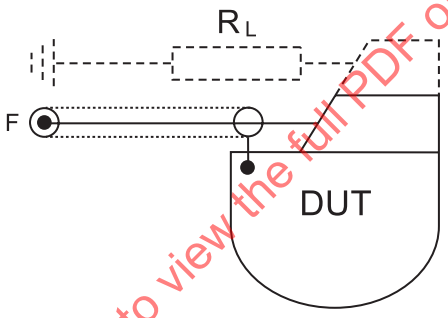


Figure 22 — Connection to a unipolar device

Bipolar devices shall be connected to outputs F and G of the injection network (as shown in Figure 23), using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn, and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L).

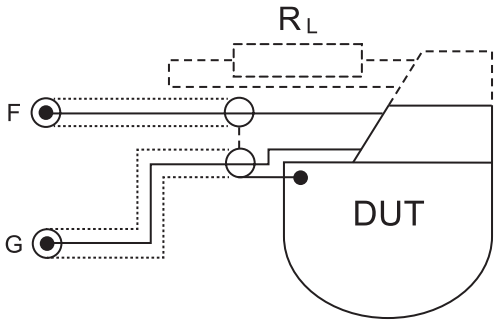


Figure 23 — Connection to a bipolar device

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

4.3.2.3 Malfunction due to electromagnetic interference in the frequency range of 450 MHz to 3000 MHz

Test: The DUT shall be subjected to the test procedure of 4.9.3.2 "optional characterization" of this International Standard (without device monitoring and recording of DUT performance, which is not required for this test).

Compliance shall be confirmed if the DUT functions as it did before the test without further adjustment.

4.3.3 ICDs and CRT-D devices

4.3.3.1 Malfunction due to electromagnetic interference in the frequency range of 16,6 Hz to 10 MHz

4.3.3.1.1 Test equipment and signal

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 Figure 26) 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 shall be a continuous sinusoidal signal that shall be either swept over the frequency range of 16,6 Hz to 10 MHz 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.

The test signal amplitude for common mode test shall be as shown in Table 5 below:

Table 5 — Peak to peak amplitudes V_{pp} in the range 16,6 Hz to 10 MHz

f	V_{pp}
16,6 Hz ≤ f ≤ 20 kHz	1 V
20 kHz ≤ f ≤ 140 kHz	1V * (f/20 kHz)
140 kHz ≤ f ≤ 10 000 kHz	7V * (f/140 kHz) ^{0,1624}

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

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

CAUTION — Take care 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.

4.3.3.1.2 Malfunction because of electrical interference on the sense or pace 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 can be 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 DUT 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).

A DUT with bipolar sensing/pacing 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 24) and the case connected to output J.

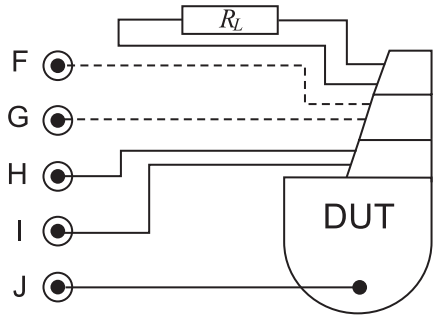


Figure 24 — Common mode connection for multichannel bipolar devices

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 25).

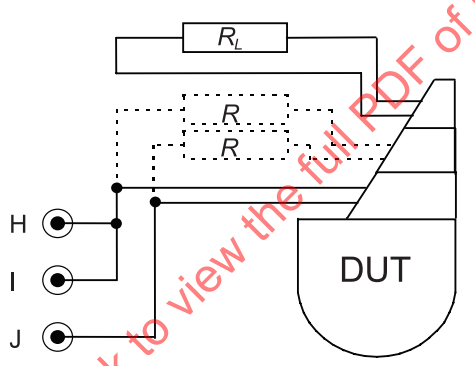


Figure 25 — Differential mode connection for multichannel bipolar devices

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

4.3.3.1.3 Malfunction because of electromagnetic interference on the cardioversion/defibrillation terminals

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 26. The test voltage shall be measured on the oscilloscope connected to test point D.

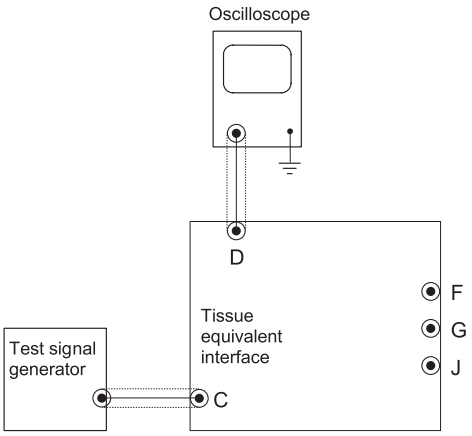


Figure 26 — Test setup to check for induced malfunction attributable to voltages induced on cardioversion/defibrillation terminals

The capacitor C_X of the interface circuit (see Figure D.3) shall be bypassed unless required to eliminate spurious low-frequency signals produced by the interference signal generator (see Annex E).

The sense/pace terminals shall be loaded with 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 DUT has more than two cardioversion/defibrillation terminals, the terminals not being tested shall be loaded with 50 Ω, 25 W resistors and connected to one of the terminals under test through a resistor R.

Common mode performance shall be tested with the cardioversion/defibrillation terminals connected to the outputs F and G of the tissue-equivalent interface (as shown in Figure 27) and the case connected to output J.

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

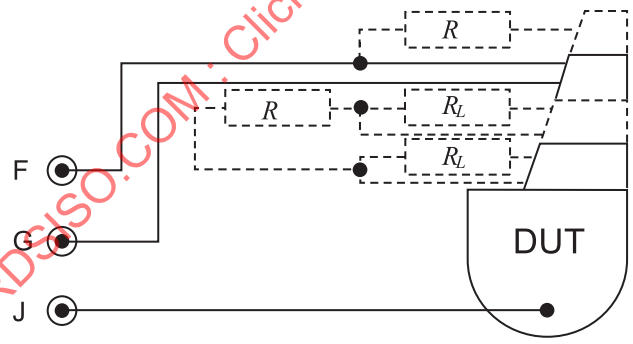


Figure 27 — Common mode connection for cardioversion/defibrillation terminals

Differential mode performance shall be tested with the cardioversion/defibrillation terminals connected between the coupled outputs F and G and output J of the tissue-equivalent interface (as shown in Figure 28).

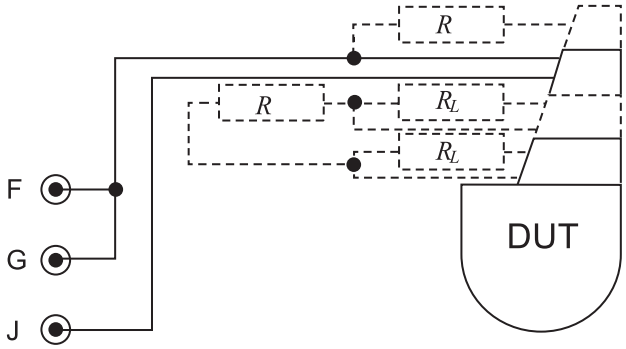


Figure 28 — Differential mode connection for cardioversion/defibrillation terminals

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

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

4.3.3.2 Malfunction due to electromagnetic interference in the frequency range of 10 MHz to 450 MHz

4.3.3.2.1 Test equipment and signal

Test equipment: Use the test setup as shown in Figure 30, using the tissue injection network defined by Figure D.5; an oscilloscope (#1), input impedance 50 Ω, accuracy of ± 10 % within a bandwidth of at least 450 MHz; and a test signal generator, output impedance 50 Ω.

Test signal: The test signal shall be a modulated signal of the form as shown in Figure 29. The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst-to-burst interval, T, shall be measured leading to leading edge (see Figure 29). The burst-to-burst interval, T, of the modulated signal shall be set to 700 ms ± 50 ms.

NOTE 1 The peak-to-peak amplitude of the test signal, V_{pp}, cannot be measured directly at any connector of the injection network during the test. Therefore, it is calculated from the voltage at connector D, V_{osc}, by applying the calibration factor, m, of Annex F.

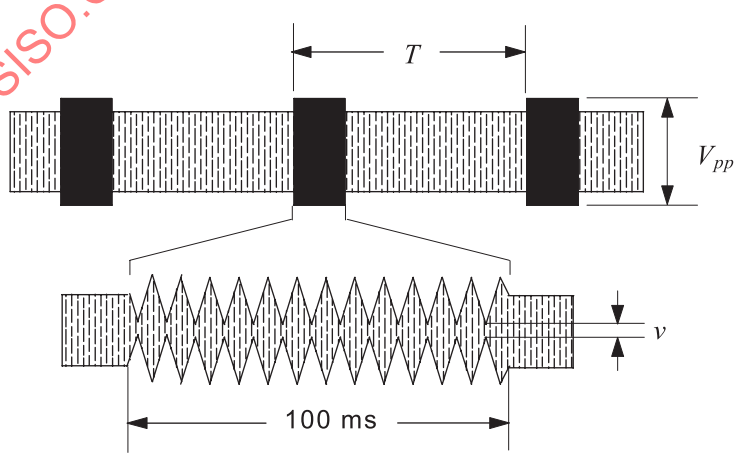


Figure 29 — Test signal for frequencies between 10 MHz and 450 MHz

The modulation bursts shall start and terminate at zero crossings of the modulation signal, thus the envelope starts and terminates continuously. The burst count is 13 complete modulation cycles. The modulation index, M, shall be 95 %, where:

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

The amplitude of the test signal (V_{pp}) is defined as the peak-to-peak amplitude of the open circuit voltage driving the implantable DUT at the outputs (F, G) of the injection network. The amplitude of the test signal, V_{pp}, shall be 14 V. Prior to testing the test set-up has to be calibrated using the procedure in Annex F.

4.3.3.2.2 Malfunction because of electrical interference on the sense or pace terminals

Test procedure: Prior to any testing, calibrate the setup using the procedure in Annex F. The test signal generator shall be connected to the injection network through input C as shown in Figure 30. The test signal generator shall be adjusted so that the test signal amplitude measured on the oscilloscope connected to monitoring point D (V_{osc}) when multiplied by the calibration factor for the injection network, determined according to the method of Annex F, is equal to the required test signal amplitude, V_{pp}, of 14 V. The test signal shall be applied at a minimum of six distinct, well-spaced frequencies per decade, beginning at 10 MHz and ending at 450 MHz (i.e.10, 20, 40, 60, 80, 100, 200, 400, 450) with an evenly distributed dwell time of at least 60 s per decade.

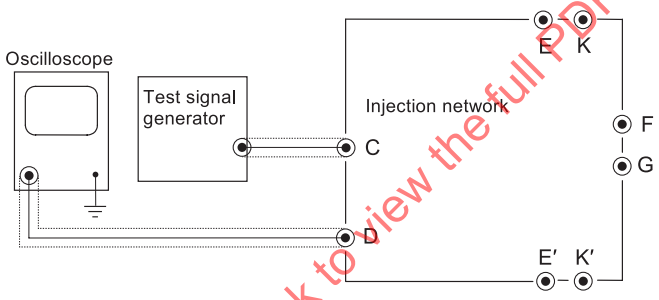


Figure 30 — Test set-up to check for induced malfunction at high frequency

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

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

a) A DUT with bipolar sensing/pacing shall be connected to outputs F and G of the injection network (as shown in Figure 31), using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L). For safety, cardioversion/defibrillation TERMINALS are loaded with high-voltage 50Ω, 25 W resistors, R_L as required by the HV therapy configuration.

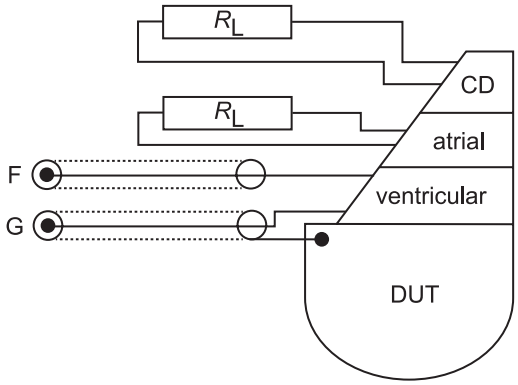


Figure 31 — Connection of the DUT

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

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

4.3.3.2.3 Malfunction because of electromagnetic interference on the cardioversion/defibrillation terminals

***Test procedure**:* Testing is performed as specified in 4.3.3.2.2 with the CARDIOVERSION/DEFIBRILLATION TERMINALS under test connected to the output F and G of the injection network (instead of the pacing/sensing TERMINALS, as shown in Figure 31). Any sensing/pacing channel shall be loaded with 500 Ω load resistors (R_L) and any CARDIOVERSION/DEFIBRILLATION TERMINALS not under test shall be loaded with high-voltage 50 Ω, 25 W resistors, R_L.

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

4.3.3.3 Malfunction due to electromagnetic interfernce in the frequency range of 450 MHz to 3 000 MHz

Test: the DUT shall be subjected to the test procedure of 4.9.3.2 "optional characterization" of this International Standard (without device monitoring and recording of DUT performance which is not required for this test).

Compliance shall be confirmed if the DUT functions as it did before the test without further adjustment.

4.4 Temporary response to continuous wave sources

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

4.4.1 Pacemakers' and CRT-P devices' response to temporary continuous wave sources in the frequency range 16,6 Hz to 167 KHz

Pacemakers and CRT-P devices that provide pacing therapy shall be constructed so that temporary exposure to ambient CW EM fields is unlikely to cause malfunction of the pacing therapy provided by the DUT.

Test equipment: Use the tissue-equivalent interface circuit defined by Figure D.2 and two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF, with the oscilloscope connected to test point D in Figure 32 shall have an accuracy of ± 10 % within a bandwidth of at least 20 MHz; an inhibition signal generator, output impedance not greater than 1 kΩ that provides a simulated heart signal in the form defined by Figure J.1; and a test signal generator, output impedance 50 Ω.

Test signal: The test signal shall be a continuous sinusoidal signal applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz to 167 kHz. For bipolar common mode and unipolar mode tests, at each selected frequency, the test signal shall be slowly increased from zero to a maximum of 1 V peak to peak.

Bipolar differential mode performance shall be tested using the test signal reduced to one-tenth amplitude (maximum of 0,1 V peak to peak).

NOTE 1 The test frequencies of 16,6 Hz, 50 Hz, 60 Hz and 100 Hz should be included in the set of predetermined test frequencies.

***Test procedure*:** The test signal generator shall be connected through input C of the interface circuit as shown in Figure 32. The test signal shall be measured on the oscilloscope connected to monitoring point D of the interface circuit. The operation of the pacemaker is recorded on the oscilloscope connected to monitoring point K. If the DUT is programmable to both unipolar and bipolar sensing polarity, the device shall be tested in both sensing polarities.

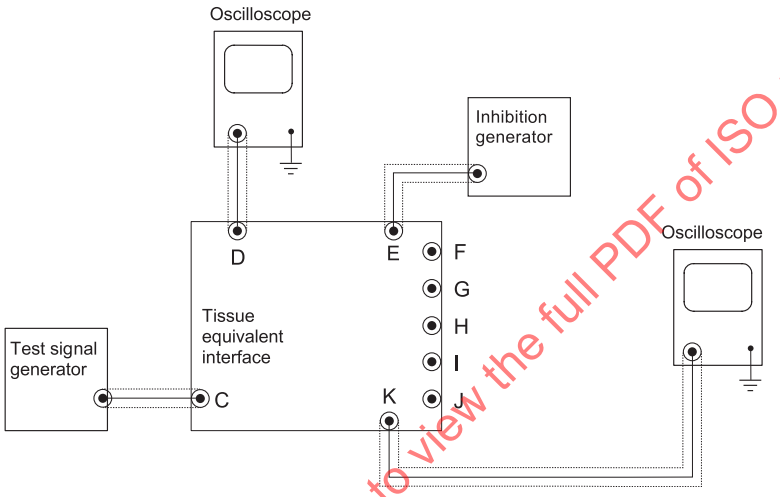


Figure 32 — Test setup to characterize DUT performance while subject to interference

Devices may allow for a number of fixed pacing sensitivity settings. For this subclause, the manufacturer may perform the test using one or multiple sensitivity settings, and in any order. However, the testing shall be used to identify any PERMANENTLY PROGRAMMABLE SENSITIVITY settings not meeting the conformity criteria of this subclause. Those settings that result in non-conforming test results shall be disclosed in accordance with 7.1.

For devices that use automatic gain control, the manufacturer should provide details of the test method.

Other parameters shall be programmed to values that enable the person conducting the test to observe the point when the test signal is detected by the DUT.

The test shall be performed with the DUT in the pacing mode and in a synchronized mode when it is not possible to distinguish between the uninfluenced and interference modes of operation. If testing is performed in synchronized mode, the DUT shall be synchronized by a signal from the inhibition signal generator connected to test point E of the interface (as shown in Figure 32). The amplitude of the inhibition signal shall be set at twice the value that just synchronizes the DUT under test and the interval shall be 800 ms or 90 % of the programmed basic pulse interval as shipped, whichever is the shorter. While determining the required amplitude for the inhibition signal, the test signal shall not be applied.

NOTE 2 Testing in both AAI and VVI mode in lieu of DDD mode is allowed; when testing in DDD mode, ventricular pacing only is to be verified. See Annex I for testing modes.

The pacemaker shall be categorized into one of four groups as required in 4.3.2 and connected to the tissue-equivalent interface according to Figure 14, Figure 15, Figure 16 and Figure 17, Figure 18 or Figure 19, as applicable. Only the ventricular channel needs to be tested when the DUT is programmed to dual-chamber operation; any other terminal of the DUT shall be connected to the equivalent terminal through a resistor of value $R \geq 10\ \text{k}\Omega$, as shown or specified by the manufacturer.

Compliance shall be confirmed when:

a) the pacemaker continues to operate as set while the test conditions are varied as required; or

b) for pacing devices incorporating a defined interference mode:

   if, while increasing the test signal amplitude, the device leaves its set mode, then the interference mode of the device shall be established when the test signal amplitude is increased by no more than 6dB. When such an increase in applied, test voltage would result in a value exceeding the maximum required test amplitude (1 Volt for bipolar common mode/unipolar mode; 0,1 Volt for bipolar differential mode); the transition to interference mode does not need to be verified;

c) for all PERMANENTLY PROGRAMMABLE SENSITIVITY settings for which conformity criteria (a) or (b) cannot be achieved, the manufacturer shall provide a warning in accordance with 7.1.

NOTE 3 Interference mode is intended for short-term operation for periods of seconds and is not intended for routine long-term operation. Such short-term operation is recognized as being clinically acceptable, with the risk of adverse events increasing with time of exposure. Therefore, interference mode should be considered necessary for unforeseen exposure but should not be depended on to support a patient exposed to intentional radiators.

4.4.2 ICDs and CRT-D devices

The manufacturer shall characterize the performance of ICDs and CRT-D devices in the presence of ambient CW EM fields.

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

Test equipment: Use the tissue-equivalent interface circuit defined by Figure D.2; two oscilloscopes, input impedance nominal 1 MΩ, with the oscilloscope connected to test point D in Figure 32 shall have an accuracy of ± 10 % within a bandwidth of at least 20 MHz; an inhibition signal generator, output impedance not greater than 1 kΩ, that provides a simulated heart signal in the form defined by Figure J.1; and a test signal generator, output impedance 50 Ω. The capacitor C_x of the interface circuit (in Figure D.2) shall be bypassed unless required to eliminate spurious low-frequency signals produced by the interference signal generator (see Annex E).

Test signal: The test signal shall be a continuous sinusoidal signal applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz to 167 kHz. For common mode tests, at each selected frequency the test signal shall be slowly increased from zero to a maximum of 1 V peak to peak.

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude (maximum of 0,1 V peak to peak)

NOTE 1 The test voltage need not be increased further once the DUT begins to detect the test signal.

NOTE 2 The test frequencies of 16,6 Hz, 50 Hz, 60 Hz and 100 Hz should be included in the set of predetermined test frequencies.

Test procedure: The test signal generator shall be connected through input C of the interface circuit, as shown in Figure 32. The test voltage shall be measured on the oscilloscope connected to test point D of the interface circuit.

The DUT shall be set to its MAXIMUM PERMANENTLY PROGRAMMABLE SENSITIVITY. Other parameters shall be programmed to values that enable the person conducting the test to observe the point at which the test signal is detected by the implantable DUT.

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

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

A DUT with bipolar sensing/pacing shall be tested in two configurations.

Common mode performance shall be tested with the sense/pace terminals connected to the outputs F, G, H, and I (as shown in Figure 24) of the tissue-equivalent interface (as shown in Figure D.2) and the case connected to output J.

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sense/pace terminals of the channel under test shall be connected between the coupled outputs H and I and the output J (as shown in Figure 25) of the tissue-equivalent interface (as shown in Figure D.2).

For each predetermined test frequency, record the amplitude of the test signal (voltage) when the DUT begins to detect the test signal.

NOTE 3 Allow for testing in both AAI and VVI mode in lieu of DDD mode; see Annex I for testing modes.

If the manufacturer's nominal (as shipped) sensitivity setting is less sensitive than MAXIMUM PERMANENTLY PROGRAMMABLE SENSITIVITY, the DUT shall be reprogrammed to the nominal sensitivity setting, and the entire test sequence shall be repeated. A report containing the results of the characterization testing defined in this section shall be prepared.

Compliance shall be confirmed by inspection of the manufacturer's test report.

NOTE 4 Interference mode is intended for short-term operation for periods of seconds and is not intended for routine long-term operation. Such short-term operation is recognized as being clinically acceptable, with the risk of adverse events increasing with time of exposure. Therefore, interference mode should be considered necessary for unforeseen exposure but should not be depended on to support a patient exposed to intentional radiators.

4.5 Protection from sensing EMI as cardiac signals

4.5.1 General considerations

The DUT shall be constructed so that commonly encountered EM fields are unlikely to change the therapeutic behaviour of the DUT.

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

Sensitivity settings during test (all device types): the DUT may allow for a number of fixed sensitivity settings. Where both unipolar and bipolar sensing are available, both modes should be tested. For this section, the manufacturer may perform the test using one or multiple sensitivity settings, and in any order. However, the testing shall be used to identify any PERMANENTLY PROGRAMMABLE SENSITIVITY settings that do not, or would not, meet the conformity criteria of this subclause.

For devices that have automatic gain control in addition to fixed programmed sensitivities, testing of the automatic gain control mode shall be optional. Where only automatic gain control is available, that mode shall be tested and the manufacturer shall provide details of the test method.

Pacemakers and CRT-Ps: For frequencies above 1 kHz, the least sensitive settings acceptable for compliance are 2,0 mV sensitivity in the unipolar sensing mode and 0,3 mV sensitivity in the bipolar sensing mode, or the sensitivity as shipped, whichever is the more sensitive.

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

ICDs and CRT-Ds: The arrhythmia detection interval shall be programmed to a value greater than the initial burst-to-burst interval of 350 ms ± 25 ms. For frequencies above 1 kHz, the least sensitive setting acceptable for compliance is 0,3 mV sensitivity, or the sensitivity as shipped, whichever is the more sensitive.

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

4.5.2 Protection from sensing EMI as cardiac signals in the frequency range of 16,6 Hz to 150 kHz

4.5.2.1 Pacemakers and CRT-P devices

Test equipment: Use the tissue-equivalent interface circuit defined by Figure D.2; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF, with the oscilloscope connected to output D of the interface circuit shall have a bandwidth of at least 20 MHz; an inhibition signal generator, output impedance not greater than 1 kΩ, that provides a signal of the form defined by Figure J.1; and a test signal generator, output impedance of 50 Ω.

Test signal:

Test signal 1: the test signal shall be a continuous sinusoidal wave, with a frequency, f, between 16,6 Hz and 1 kHz with peak-to-peak amplitude as shown in Table 6.

NOTE 1 The test frequencies of 16,6 Hz, 50 Hz, 60 Hz and 100 Hz should be included in the set of predetermined test frequencies.

Test signal 2: the test signal shall be a modulated signal, carrier frequency, f, between 1 kHz and 150 kHz with peak-to-peak amplitudes as shown in Table 6.

For test signal 2, one of the alternative modulations (modulation 1 or modulation 2) specified below shall be used as specified by the manufacturer.

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

Table 6 — Peak-to-peak amplitudes V_{pp} in the range of 16,6 Hz to 150kHz

f	V_{pp}
16,6 Hz ≤ f ≤ 1 kHz	2 mV
1 kHz ≤ f ≤ 3 kHz	2 mV × (f/1 kHz)^2
3 kHz ≤ f ≤ 150 kHz	6 mV × f/1 kHz

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

***Modulation 1**: the carrier shall be switched to create bursts of approximately 100 ms duration. The burst-to-burst interval, T, shall be measured leading to leading edge (see* Figure 33*). The burst shall start and terminate at a zero crossings of the carrier, and only complete carrier cycles shall be used (true gated signal). The burst-to-burst interval, T, shall be set to 700 ms ± 50 ms.*

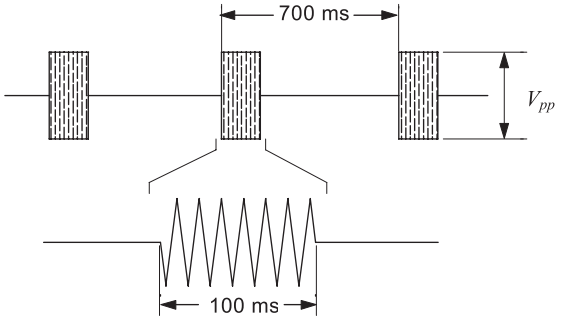


Figure 33 — Test signal 2: Modulation 1 in the range of 1kHz to 150 kHz

Modulation 2 (preferred): the test signal 2 is a sinusoidal carrier switched smoothly to create bursts with a duration of nominally 100 ms. The envelope of the burst has rise and fall times of nominally 10 ms with linear slopes. The burst duration, 100 ms, as well as the burst–to-burst interval T, shall be measured at half the amplitude of the leading slope of the envelope (see Figure 34). The burst-to-burst interval, T, shall be set to 700 ms ± 50 ms.

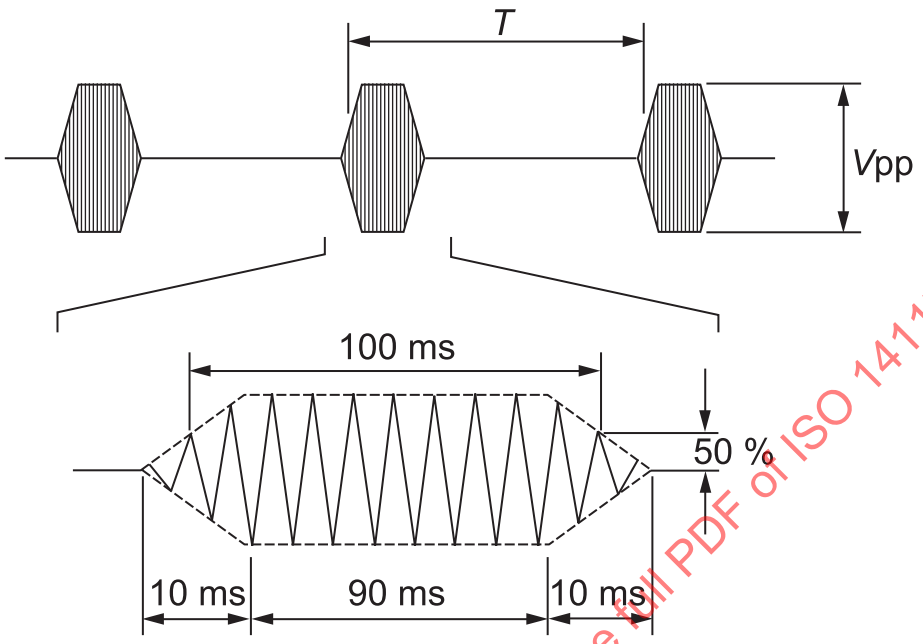


Figure 34 — Test signal 2 : Modulation 2 (preferred) in the range of 1kHz to 150 kHz

Test procedure: The test signal generator shall be connected to the tissue-equivalent interface circuit through input C, as shown in Figure 32. The test signal shall be measured on the oscilloscope connected to monitoring point D. The operation of the DUT shall be recorded on the oscilloscope connected to monitoring point K.

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

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

The test signals as defined above shall be applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz and 150 kHz, with an evenly distributed dwell time of at least 60 s per decade. (V_{pp} can be measured directly at connector D of the tissue interface.)

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

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

If the DUT is a multichannel device, it shall be programmed to minimize the occurrence of possible cross-talk between channels.

The DUT shall be categorized into one of four groups, as required in 4.3.2, and connected to the tissue equivalent interface according to Figures 14 to 19, as applicable.

For each tested frequency, the operation of the DUT shall be observed and recorded as either functioning in its set mode or not.

Compliance for the sensitivity tested shall be confirmed if the DUT at all times functions in its set mode, both with and without the simulated heart signal applied by the inhibition signal generator and irrespective of the application of the required test signal.

For those sensitivity settings of the DUT for frequencies up to 1 kHz, at which a change of pacing pattern occurs, compliance shall be confirmed if an appropriate warning and disclosure is provided according to 7.1.

4.5.2.2 ICDs and CRT-D devices

***Test equipment*:** use the tissue-equivalent interface circuit defined by Figure D.2; two oscilloscopes, input impedance nominal 1 MΩ, < 30 pF, with the oscilloscope connected to test point D in Figure D.2 shall have an accuracy of ± 10 % within a bandwidth of at least 20 MHz; an inhibition signal generator, output impedance not greater than 1 kΩ, that provides a simulated heart signal in the form defined by Figure J.1; and test signal generators, output impedance of 50 Ω.

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

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).

Test signal:

Test signal 1: the test signal shall be a continuous sinusoidal wave, with a frequency, f, between 16,6 Hz and 1 kHz with peak-to-peak amplitude as shown in Table 7.

NOTE 1 The test frequencies of 16,6 Hz, 50 Hz, 60 Hz and 100 Hz should be included in the set of predetermined test frequencies.

Test signal 2: the test signal shall be a modulated signal, carrier frequency, f, between 1 kHz and 150 kHz with peak-to-peak amplitudes as shown in Table 7.

For test signal 2, one of the alternative modulations (modulation 1 or modulation 2) specified below shall be used as specified by the manufacturer.

The amplitude of the common mode test signal, V_{pp}, is defined as the peak-to-peak amplitude of the open-circuit voltage driving the pacemaker at the outputs of the tissue interface. The amplitude of the test signal, V_{pp}, shall be a function of the carrier frequency, f, as defined by Table 7.

Table 7— Peak-to-peak amplitudes V_{pp} in the range of 16,6 Hz to 150 kHz

f	V_{pp}
16,6 Hz ≤ f ≤ 1 kHz	2 mV
1 kHz ≤ f ≤ 3 kHz	2 mV × (f/1 kHz)^2
3 kHz ≤ f ≤ 150 kHz	6 mV × f/1 kHz

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

Modulation 1: the carrier shall be switched to create bursts of approximately 100 ms duration. The burst-to-burst interval, T, shall be measured leading edge to leading edge (see Figure 35). The burst shall start and terminate at zero crossings of the carrier, and only complete carrier cycles shall be used (true gated signal).

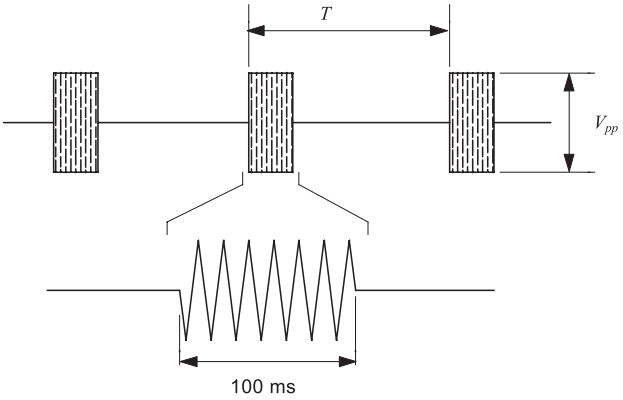


Figure 35 — Test signal 2: Modulation 1 in the range of 1kHz to 150 kHz

Modulation 2 (preferred): test signal 2 is a sinusoidal carrier switched smoothly to create bursts with a duration of nominally 100 ms. The envelope of the burst has rise and fall times of nominally 10 ms with linear slopes. The burst duration, 100 ms, as well as the burst–to-burst interval, T, shall be measured at half the amplitude of the leading slope of the envelope (see Figure 36).

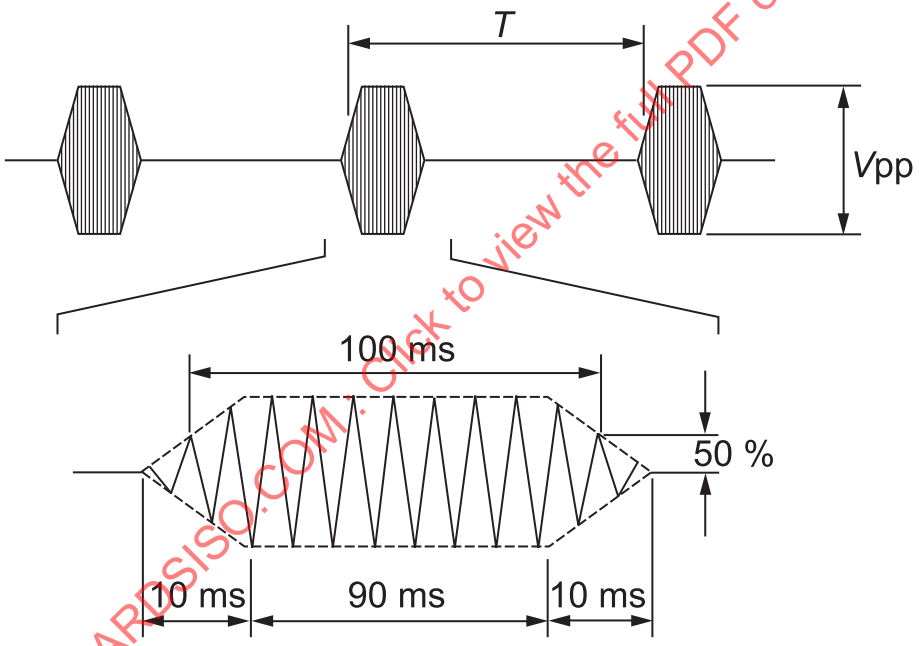


Figure 36 — Test signal 2 : Modulation 2 (preferred) in the range of 1kHz to 150 kHz

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

The test signals defined above shall be applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz and 150 kHz with an evenly distributed dwell time of at least 60 s per decade. (V_{pp} can be measured directly at connector D of the tissue interface.)

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

NOTE 2 The test setup of Test 1 seeks to determine if the modulated interference will influence the ICD during inhibited mode of operation. The burst-to-burst interval, T, is selected to simulate fibrillation.

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

NOTE 3 The test setup of Test 2 seeks to determine if the detection of the modulated interference will prevent the ICD from providing bradycardia therapy. The burst-to-burst interval, T, is selected to simulate fibrillation.

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

The operation of the DUT shall be monitored by the oscilloscope connected to test point K. The applicable tests described in list items a) and b) below shall be performed at a minimum of four carrier frequencies per decade.

NOTE 4 Since the DUT may require that it detect several consecutive input signals before therapy is initiated, sufficient time is to be allowed at each frequency tested for the device under test to react to the input interference.

a) DUTs with bipolar sensing shall be tested in two configurations, as follows.

Common mode performance shall be tested with the sense/pace terminals connected to the outputs F, G, H, and I (as shown in Figure 24) of the tissue-equivalent interface (as shown in Figure D.2) and the case connected to output J.

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sense/pace terminals of the channel under test shall be connected between the coupled outputs H and I and the output J (as shown in Figure 25) of the tissue-equivalent interface (as shown in Figure D.2).

NOTE 5 The DUT shall be programmed to prevent cross-talk between different channels.

b) For DUTs that use signals from both sense and cardioversion/defibrillation leads for arrhythmia detection, the manufacturer shall provide details of the test method.

For each tested frequency, the results of Test 1 and Test 2 shall be observed and recorded as influenced or not.

Compliance for the sensitivity being tested shall be confirmed if:

— while Test 1 is performed, the ICD is not influenced by the interference signal (i.e. it does not exhibit any pacing pulses and does not deliver a tachyarrhythmia therapy); and

— while Test 2 is performed, the ICD is not influenced by the interference signal (i.e. it does not exhibit any deviation in pace-to-pace interval that exceeds 10 % of the programmed rate and does not deliver a tachyarrhythmia therapy).

For those sensitivity settings of the DUT for frequencies up to 1 kHz at which influenced behaviour is observed, compliance shall be confirmed if an appropriate warning and disclosure is provided according to 7.1.

4.5.3 Protection from sensing EMI as cardiac signals in the frequency range of 150 kHz to 10 MHz

4.5.3.1 Pacemakers and CRT-P devices

Test equipment: use the test equipment defined in 4.5.2.1 of this International Standard.

Test signal: the test signal shall be a modulated signal, carrier frequency f, between 150 kHz and 10 MHz. The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst-to-burst interval, T, shall be measured leading edge to leading edge (see Figure 37).

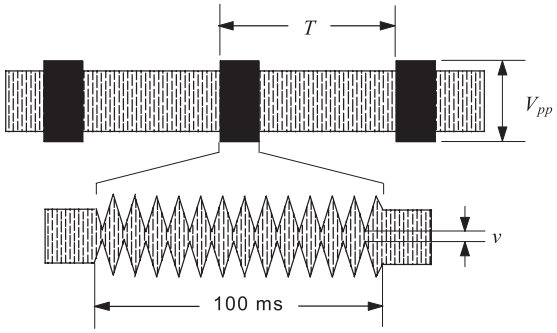


Figure 37 — Test signal for frequencies 150 kHz to 10 MHz

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

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

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

The amplitude of the test signal (V_{pp}) is defined as the peak-to-peak amplitude of the open circuit voltage driving the pacemaker at the outputs of the tissue interface. The amplitude of the test signal, V_{pp}, for unipolar test and bipolar common mode test shall be a function of the carrier frequency, f, as defined by Table 8.

Table 8 — Peak-to-peak test signal amplitudes V_{pp} in the range of 150 kHz to 10 MHz

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

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

Test procedure: the modulated signal shall be applied at a minimum of four distinct, well-spaced frequencies per decade between 150 kHz and 10 MHz, with an evenly distributed dwell time of at least 60 s per decade. (V_{pp} can be measured directly at connector D of the tissue interface.) The test configuration and procedure shall be otherwise as required in 4.5.2.1.

Compliance for the sensitivity being tested shall be confirmed if the DUT at all times functions in its set mode, irrespective of the application of the required modulated test signal.

4.5.3.2 ICDs and CRT-D devices

***Test equipment*:** use test equipment defined in 4.5.2.2.

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).

***Test signal*:** the test voltage for common mode shall be a modulated signal, carrier frequency, f, between 150 kHz and 10 MHz, as in Table 9.

Table 9 — Peak-to-peak test signal amplitudes V_{pp} in the range of 150 kHz to 10 MHz,

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

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

The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst-to-burst interval, T, shall be measured leading edge to leading edge (see Figure 38).

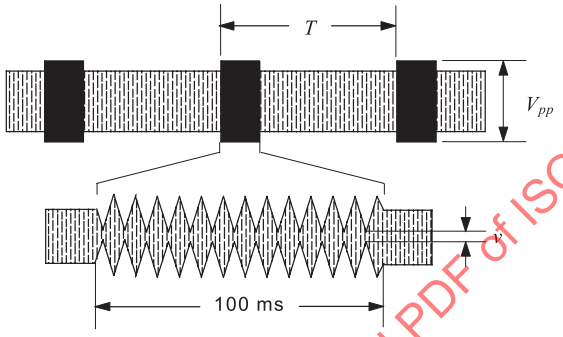


Figure 38 — Test signal for frequencies 150 kHz to 10 MHz

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

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

The test signal generator shall be connected through input C of the interface circuit as shown in Figure 21. The test voltage shall be measured on the oscilloscope connected to test point D of the interface circuit.

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

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

Test 1: Simulated heart signal applied with T_{shs} = 800 ms (or 90 % of basic pulse interval, whichever is less) and burst-to-burst interval of interference signal set to T = 350 ± 25 ms. The amplitude of the simulated heart signal shall be approximately twice the minimum value required for detection by the DUT. The simulated heart signal generator shall be connected through input E of the interface circuit.

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

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

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

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

The operation of the implantable DUT shall be monitored by the oscilloscope connected to test point K. The applicable tests described in list items a) and b) shall be performed with the test signal either swept over the frequency range 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.

Since the implantable DUT may require that it detect several consecutive input signals before therapy is initiated, sufficient time is to be allowed at each frequency tested for the DUT to react to the input interference.

a) DUTs with bipolar sensing shall be tested in two configurations, as follows.

   Common mode performance shall be tested with sense/pace terminals connected to the outputs F, G, H, and I (as shown in Figure 24) of the tissue-equivalent interface (as shown in Figure D.2) and the case connected to output J.

   Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sense terminals of the channel under test shall be connected between the coupled outputs H and I and the output J (as shown in Figure 25) of the tissue-equivalent interface (as shown in Figure D.2).

   The implantable DUT shall be programmed to prevent cross-talk between channels.

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

   For each carrier frequency, the results of Test 1 and Test 2 shall be observed and recorded as uninfluenced or not.

Compliance for the sensitivity being tested shall be confirmed if:

— while Test 1 is performed, the ICD is not influenced by the interference signal (i.e. it does not exhibit any pacing pulses and does not deliver a tachyarrhythmia therapy); and

— while Test 2 is performed, the ICD is not influenced by the interference signal (i.e. it does not exhibit any deviation in pace-to-pace interval that exceeds 10 % of the programmed rate and does not deliver a tachyarrhythmia therapy).

4.5.4 Protection from sensing EMI as cardiac signals in the frequency range of 10 MHz to 450 MHz

4.5.4.1 Pacemakers and CRT-P devices

Test equipment: use the tissue injection network defined by Figure D.5; an oscilloscope (#1), input impedance 50 Ω, accuracy of ± 10 % within a bandwidth of at least 450 MHz; an oscilloscope (#2), input impedance nominal 1 MΩ; an inhibition signal generator, output impedance not greater than 1 kΩ, which provides a simulated heart signal of the form defined by J1; and a test signal generator, output impedance 50 Ω.

Test signal: the test signal shall be a modulated signal of the form defined by 4.5.3.1 (see Figure 37). The modulated test signal shall be applied at a minimum of six distinct, well-spaced frequencies per decade, beginning at 10 MHz and ending at 450 MHz (e.g. 10, 20, 40, 60, 80, 100, 200, 400, 450), with an evenly distributed dwell time of at least 60 s per decade. The amplitude of the test signal (V_{pp}) is defined as the peak-

to-peak amplitude of the open-circuit voltage driving the outputs (F, G) of the injection network. The amplitude of the test signal, V_{pp}, shall be 10 V.

NOTE 1 The peak-to-peak amplitude of the test signal, V_{pp}, cannot be measured directly at any connector of the injection network during the test. Therefore, it is calculated from the voltage at connector D, V_{osc}, by applying the calibration factor, m, of Annex F.

Test procedure: Prior to any testing, calibrate the setup using the procedure in Annex F. The test signal generator shall be connected to the injection network through input C as shown in Figure 39 . The test signal generator shall be adjusted so that the test signal amplitude measured on oscilloscope #1 connected to monitoring point D (V_{osc}) when multiplied by the calibration factor for the injection network, determined according to the method of Annex F, is equal to the required test signal amplitude, V_{pp}.

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

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

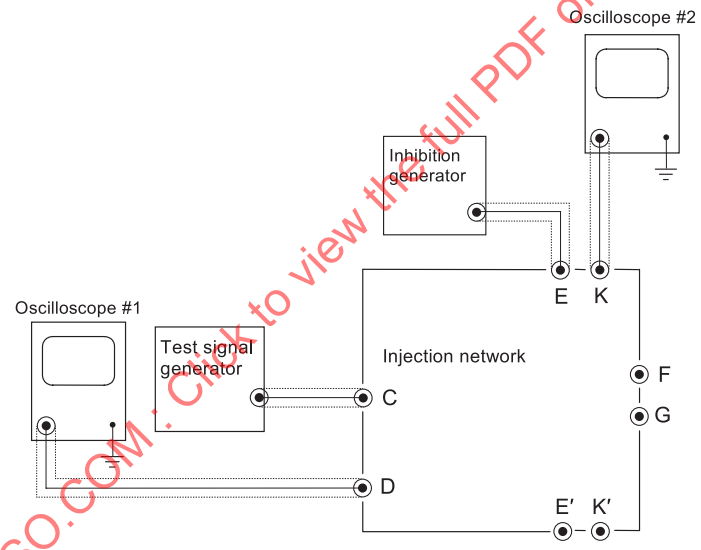


Figure 39 — Test setup to check for malfunction at high frequency

Connections between outputs F and G and the pacemaker shall be by copper straps, width ≥ 5 mm, length ≤ 50 mm (not including the length of the standard connector pin inserted into the device header). Unused RF ports (F and G) on the injection network shall be fitted with 50 Ω terminations ; in addition E' and K' shall be terminated with impedances equivalent to ports E and K, respectively, to keep the network balanced.

Unipolar pacing devices shall be connected to output F of the injection network (as shown in Figure 40), using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn, and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L).

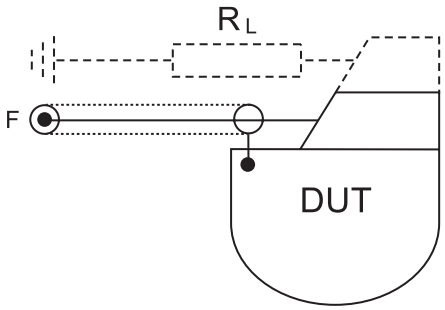


Figure 40 — Connection to a unipolar device

Bipolar devices shall be connected to outputs F and G of the injection network (as shown in Figure 41), using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn, and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L).

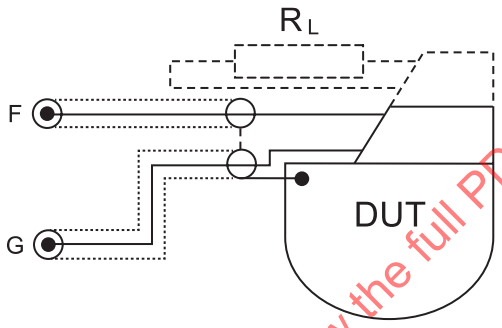


Figure 41 — Connection to a bipolar device

Compliance for the sensitivity being tested shall be confirmed if the DUT at all times functions in its set mode irrespective of the application of the required modulated signal.

4.5.4.2 ICDs and CRT-D devices

The DUT shall be tested in accordance with the sequence described in 4.5.4.1, testing each channel in turn.

DUT sensing/pacing channels not being tested should be turned off and loaded with 500 Ω. For safety, cardioversion/defibrillation TERMINALS are loaded with high-voltage 50 Ω, 25 W resistors. Compliance for the sensitivity being tested shall be confirmed if the DUT at all times functions in its set mode irrespective of the application of the required modulated signal.

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

4.6.1 General considerations

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

4.6.2 Pacemakers and CRT-P devices

Test equipment: use an inhibition generator that provides a signal in the form defined by Figure J.1; an oscilloscope; 51 kΩ ± 1 % and 500 Ω ± 1 % resistors; and a field coil that is capable of generating a uniform magnetic field of flux density of up to 1 mT ± 0,1 mT in the region to be occupied by the DUT.

Test procedure: A 500 Ω ± 1 % load resistor (R_L) is connected between terminals S and T (see Figure 42), with the monitoring oscilloscope connected to terminal S. The signal from the inhibition generator shall be injected at terminal S through a 51 kΩ ± 1 % feed resistor (R).

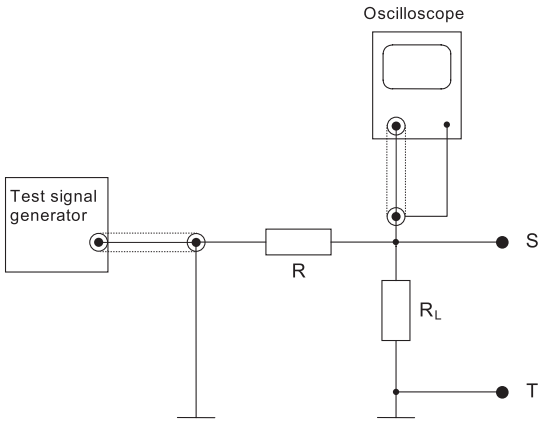


Figure 42 — Test setup for magnetostatic measurements

For unipolar devices, output S shall be connected to the terminal of the channel under test and output T to the DUT case.

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

The DUT shall be set in synchronized mode by the signal from the inhibition generator. The amplitude of the inhibition signal shall be twice the amplitude that just synchronizes the DUT.

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

NOTE Care should be taken to avoid wire-loops.

The field shall be measured in the absence of the DUT.

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

4.6.3 ICDs and CRT-D devices

The DUT shall be tested according to the sequence described in 4.6.2.

NOTE Synchronization through an inhibition generator and monitoring with an oscilloscope might not be needed when testing an ICD or CRT-D device.

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

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

4.7.1 General considerations

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

4.7.2 Pacemakers and CRT-P devices

Test equipment: use a field coil that is capable of generating a uniform magnetic field of flux density of up to 50 mT ± 5 mT in the region to be occupied by the DUT.

Test procedure: the required field flux density shall be generated before placing the DUT in the field. Then the DUT shall be slowly placed in the centre of the test coil. After at least 15 s of exposure to the magnetic field, the DUT shall be slowly removed from the field.

Reorient the DUT so that a second orthogonal axis is aligned with the axis of the test coil, and again subject the DUT to the required fields. Then repeat again with the third orthogonal axis aligned with the axis of the test coil.

Compliance shall be confirmed if, after the magnetic field is removed, the DUT functions as it did before the test without adjustment.

4.7.3 ICDs and CRT-D devices

The DUT shall be tested per the sequence described in 4.7.2.

Compliance shall be confirmed if, after the magnetic field is removed, the DUT functions as it did before the test without adjustment.

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

4.8.1 General considerations

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

4.8.2 Pacemakers and CRT-P devices

Test equipment: use a radiating coil (for example a Helmholtz coil), diameter ≥ 12 cm and exceeding the largest linear dimension of the DUT by 50 %, and a calibration coil, diameter ≤ 4 cm. The radiating coil shall be energized by a signal generator.

Test field: the test magnetic field, H, shall be modulated at a frequency, f, as defined by Table 10.

Table 10 — Sinusoidally modulated magnetic field strengths

f	H rms
1 kHz ≤ f ≤ 100 kHz	150 A/m
100 kHz ≤ f ≤ 140 kHz	150 A/m × 100 kHz/f

Test procedure: Using the calibration coil, determine the signal levels applied to the radiating coil that produce the magnetic field, H, in the centre of the radiating coil (see Figure 43). Remove the calibration coil.

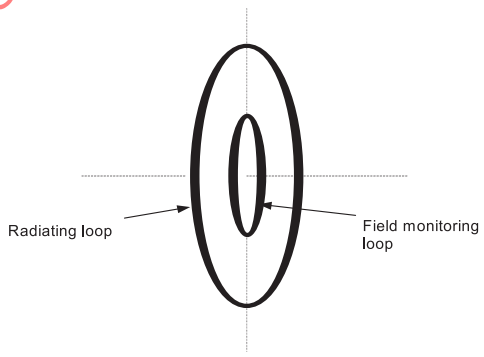


Figure 43 — Loop configuration for varying magnetic field test

Place the centre of the DUT at the field intensity calibration point. Load the cardiac lead terminals of the DUT lead interface as specified by the manufacturer, using care to minimize loop areas of connections. Generate the required fields by either sweeping the test signal over the required frequency range at a maximum rate of

1 decade per minute or by applying the test signal at four distinct, well-spaced frequencies per decade with an evenly distributed dwell time of at least 60 s per decade.

NOTE Care should be taken to increase or decrease the field intensity slowly when applying or removing the test signal.

Reorient the DUT so that a second orthogonal axis is aligned with the axis of the radiating loop, and again subject the pacemaker to the required fields. Then repeat again with the third orthogonal axis aligned with the axis of the radiating loop.

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

4.8.3 ICDs and CRT-D devices

The DUT shall be tested per the sequence described in 4.8.2.

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

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

4.9 Test requirements for the frequency range of 450 MHz ≤ *f* ≤ 3 000 MHz

4.9.1 General requirements

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

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

Lead configurations are as follows:

— pacemakers and CRT-P devices shall be tested with both unipolar and bipolar lead systems when appropriate;

— ICDs and CRT-D devices shall be tested with an appropriate lead system as recommended by the manufacturer.

4.9.2 Test setup

4.9.2.1 Test environment

CAUTION — Personnel performing the measurements defined in this International Standard should not be exposed to RF EM fields that exceed the "Maximum Permissible Exposure" provisions of the IEEE C95.1 standard for controlled environments. Because of 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 used.

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

4.9.2.2 Torso simulator in Annex G

The distance between the surface of the saline and the top surface of the DUT and the dipole antenna heights shall be as specified in Table 11.

Table 11 — Requirements for the test setup

Parameter	Specification	Tolerance
Saline resistivity[a]	375 Ωcm	±15 Ωcm
Surface of the saline to top surface of the DUT	0,5 cm	±1 mm
Dipole element axis centerline to saline surface	2,0 cm	±1 mm
Dipole element axis centerline to device surface	2,5 cm	±2 mm

[a] The saline resistivity shall be measured at a low frequency (i.e. ≤ 1 kHz) and is the equivalent of 0,027 molar (1,8 g/L or 0,18 %) NaCl concentration, at 21 °C.

4.9.2.3 Device under test and lead positioning in torso simulator

The DUT is positioned on the bottom grid at the centre of the torso simulator. The connector bore for a single-chamber DUT or the right ventricular bore of a multiconnector DUT shall be aligned with the X-axis (see Figure G.1). The lead connector pin (tip) contact in the DUT connector bore on the X-axis defines the DUT reference point. The DUT and its lead (or leads) rest on the upper surface of the bottom grid and are anchored with non-conducting string. The lead 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 centre cutout area aligned over the centre 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 11.

4.9.2.4 Interference signal generation

a) Dipole antennas: a detailed description of the dipole antennas is given in Annex H.

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

   The signal shall be pulse modulated with the following characteristics: the carrier shall be gated on for 25 ms at 500 ms intervals. Gating rise and fall time should be < 0,5 microseconds (μs).

4.9.2.5 Parameter programming

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

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

4.9.2.6 Monitoring of device activity

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

4.9.2.7 Simulated cardiac signal injection

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

4.9.3 Test procedure

4.9.3.1 Required test

Set up the test equipment in accordance with Figure G.2. Verify electrical and dimensional requirements of torso simulator setup as specified in Table 11.

Program the DUT and record parameters in accordance with Annex I.

a) X-axis testing, simulated heart signal off.

Place the 450 MHz dipole antenna on the grid with the axis of the antenna elements parallel to the X-axis, with the dipole reference point (see Annex H) centred over the DUT reference point, as defined in 4.9.2.3, at the elevation specified in Table 12. The electrocardiogram (ECG) signal shall be off.

Set the carrier frequency to 450 MHz. Set the dipole net RF power to 120 mW rms (CW). Record the forward and reflected power readings for documentation purposes. The net power calculation is presented in Annex K.

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

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

— devices intended to treat bradyarrhythmia (pacemakers) — minimum of 5 s;

— devices intended to treat tachyarrhythmia (including ICDs) — minimum of 15 s.

Exposure duration may be longer in either case if required for DUT detection algorithms to fulfill their tasks.

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

Place the 450 MHz dipole antenna on the grid with the axis of the antenna elements parallel to the X-axis, with the dipole reference point (see Annex H) centred over the DUT reference point as defined in 4.9.2.3, at the elevation specified in Table 11. The simulated heart signal shall be ON at the simulated bradycardia rate, specified in Annex J.

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

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

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

— devices intended to treat bradyarrhythmia (pacemakers and CRT-P devices) — minimum of 5 s;

— devices intended to treat tachyarrhythmia (including ICDs and CRT-D devices)—minimum of 15 s.

Exposure duration may be longer in either case if required for DUT detection algorithms to fulfill their tasks.

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

Place the 450 MHz dipole antenna on the grid with the axis of the antenna elements parallel to the X-axis, with the dipole reference point (see Annex H) centred over the DUT reference point as defined in 4.9.2.3, at the elevation specified in Table 11. The simulated heart signal shall be on at the simulated tachycardia rate, in accordance with Annex J.

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

Set the RF signal generator for pulse modulation as specified in 4.9.2.4 b).

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

d) Y-axis testing.

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

e) Testing at remaining frequencies.

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

f) Post-test DUT verification.

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

4.9.3.2 Optional characterization testing

A manufacturer may perform the testing described in this subclause to demonstrate immunity to hand-held transmitters that are operated without restrictions near the implanted DUT. See also Annex B.

For optional DUT characterization, net dipole power is set to 8 W rms for the frequency range 450 MHz $\leq f <$ 1 000 MHz and to 2 W rms (CW) 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 4.9.3.1. Repeat 4.9.3.1 a) to f) for these power levels.

4.9.4 Performance criteria

4.9.4.1 Single-chamber pacing modes

a) Simulated heart signal off.

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

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

b) Simulated heart signal on.

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

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

4.9.4.2 Multi-chamber pacing modes

a) Simulated heart signal off.

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

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

b) Simulated heart signal on.

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

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

4.9.4.3 Antitachyarrhythmia modes

a) Simulated heart signal off.

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

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

— delivery of antitachycardia pacing to the pacing leads.

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

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

b) Simulated heart signal on (tachycardia rate).

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

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

5 Testing above frequency of 3 000 MHz

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

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

The device circuitry is highly shielded against the effects of microwave fields by the metallic enclosure. The principal EMI mode is by field energy coupled to electrical leads connecting the device to the heart. However, the amount of field energy coupled to the leads decreases with increasing frequency in the microwave range because of greater field attenuation in overlying body tissues. Coupled field energy that reaches the device terminal is further attenuated by EMI control features that typically have to be implemented in the device to meet the RF requirements of this International Standard.

6 Protection of devices from EM fields encountered in a therapeutic environment

6.1 Protection of the device from damage caused by high-frequency surgical exposure

6.1.1 General considerations

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

NOTE If the case of the DUT is covered with an insulating material, the DUT (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.

6.1.2 Pacemakers and CRT-P devices

Test setup: Use an RF test signal generator, output impedance 50 Ω. Each DUT input and output terminal, as applicable, shall be connected through individual 170 Ω ± 2 %, 1 W resistors (R_L) to ground (see Figure 44). The case of the DUT shall be connected directly to the signal generator output, unless the case is covered with an insulating material.

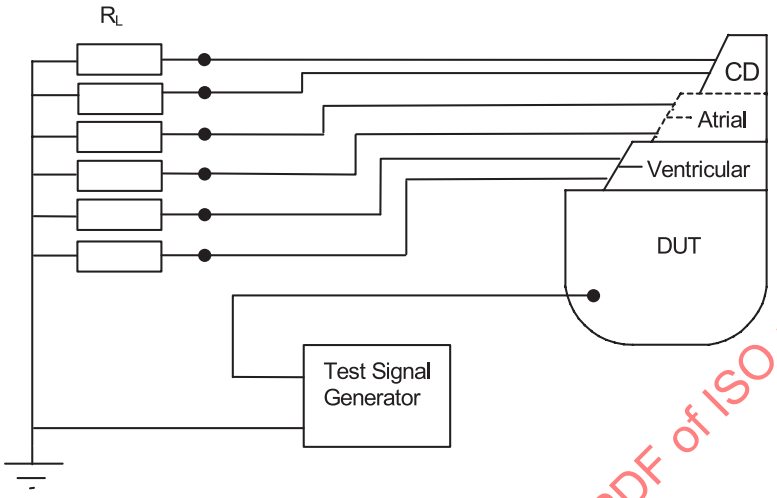


Figure 44 — Test setup for protection of the device from high-frequency currents caused by high-frequency surgical equipment

Test signal: The test signal frequency shall be 500 kHz, and the open-loop test signal amplitude shall be as shown in Table 12.

Table 12 — Test signal characteristics

Test signal voltage	Waveform	Test period
36 V_{pp}	Continuous sinusoidal	30 s

***Test procedure*:** Apply the test signal above.

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

6.1.3 ICDs and CRT-D devices

Test as specified in 6.1.2. In addition, the cardioversion/defibrillation terminals should be loaded with $R_L = 50\Omega$. If possible, the DUT shall be programmed with high-voltage therapy off.

6.2 Protection of the device from damage caused by external defibrillators

6.2.1 General considerations

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

NOTE If the case of the DUT is covered with an insulating material, the DUT (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.

Manufacturers may also use actual defibrillation equipment or programmable waveform generators provided that the applied V_{test} waveform applied to terminals A and B of the network in Figure 49 has the same characteristics as shown in Test 1 and Test 2.

6.2.2 Pacemakers and CRT-P devices

Test 1

Test equipment: Use a defibrillation test voltage generator providing a damped sinus waveform, as in Figure 45, with the following characteristics: T_p = 1,5 to 2,5 ms, T_{w50} = 3 to 5,5 ms, where T_p is the time interval from the start of the defibrillation pulse to the maximum voltage V_{test} and T_{w50} is the time interval during which the test voltage is above 50 % of the maximum value (V_{test}).

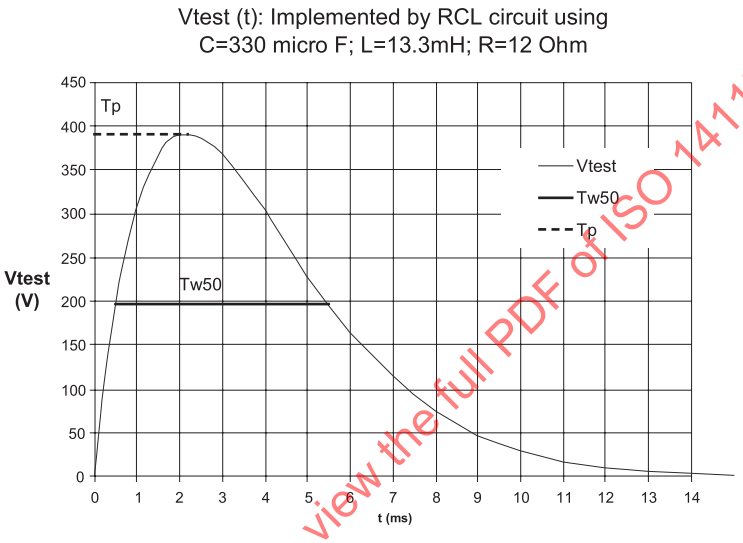


Figure 45 — Damped sinus waveform

Figure 46 illustrates an example schematic with C = 330 MF ± 16,5 μF; L = 13,3 mH ± 0,13 mH; R_L + R_G = 15 Ω ± 0.3 Ω, where R_L is the resistance of the inductance in ohms and R_G is the output resistance ohms of the defibrillation test voltage generator.

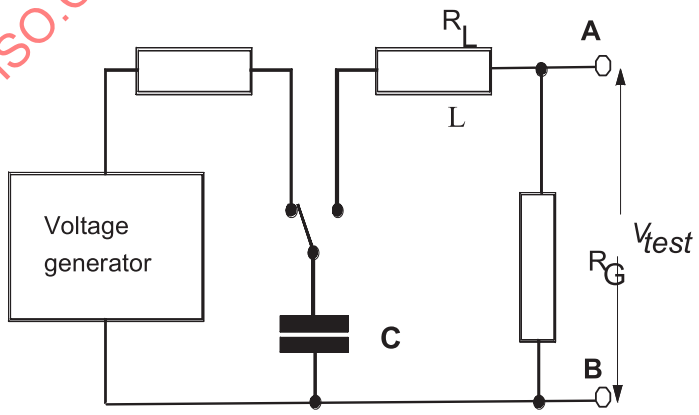


Figure 46 — Circuit for generating a damped sinus defibrillation waveform for Test 1

***Test procedure*:** Connect the output V_{test} to terminals A and B of the resistor network in Figure 49 (using the parameters in Table 12, Test 1).

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

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

— single-channel unipolar devices shall be Group a) — connect the tip terminal to output D;

— multichannel unipolar devices shall be Group b) — connect the V_{tip} terminal to output D and the A_{tip} terminal to output F;

— single-channel bipolar devices shall be Group c) — connect the V_{tip} terminal to output D, and the V_{ring} terminal to output E; and

— multichannel bipolar devices shall be Group d) — connect the V_{tip} terminal to output D, the A_{tip} terminal to output F, the V_{ring} terminal to output E and the A_{ring} terminal to output G.

Connect the case terminal of the DUT to output I of the resistor network (see Figure 49).

Test by applying a sequence of three voltage pulses of positive polarity at intervals of 20 s to 25 s. Then, after an interval of 60 s (minimum), repeat the test with pulses of negative polarity (see Figure 47).

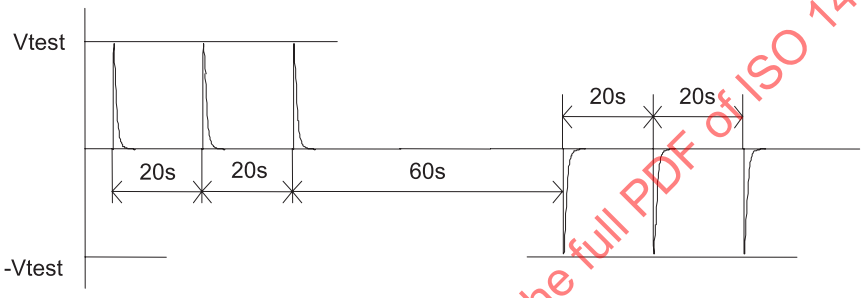


Figure 47 — Timing sequence used in Tests 1 and 2

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

Test 2

Test equipment: Use a test setup as shown in Figure 48 with C = (150 ± 50) μF and two sets of coupled switches, S1 and S2, and the resistive network in Figure 49 using the parameters defined in Table 13, Test 2.

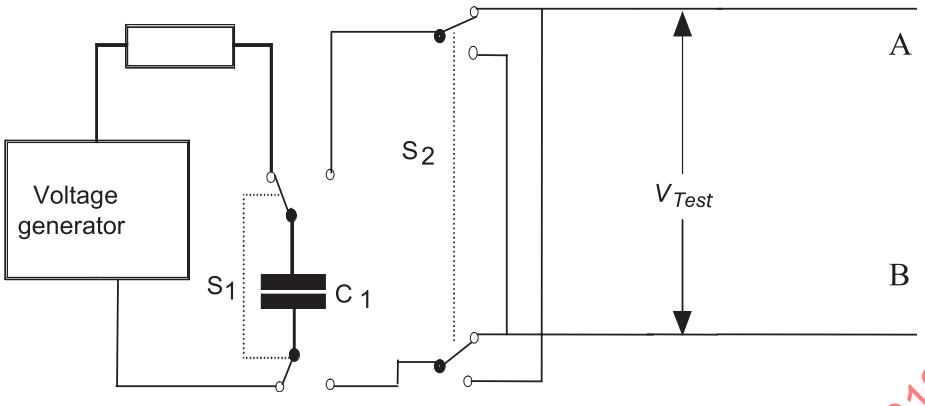
Test signals: A monophasic, truncated exponential waveform with duration of Td = (10 ± 0,5) ms will be generated between outputs A and B, activating coupled switches S1 for a time period Td; the waveform will have an exponential decay with a nominal time constant of 9,75 ms [based on the above capacitance of (150 ± 50) µF and the load of 65 Ω].

A biphasic, truncated exponential waveform is accomplished by changing the position of coupled switches S2 during the ongoing pulse after a time of $Td/2$ ± 0,5 ms [e.g. after (5 ± 0,5) ms, change from upper position to lower position]. The initial position of coupled switches S2 determines the initial polarity of the output pulse.

The biphasic waveform is shown in Figure 50 with the following parameters: 1 μs < tr < 5 μs; tc ≤ 2 ms; 1 μs < tf < 5 μs.

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

Test by applying a sequence of three monophasic voltage pulses of positive polarity at intervals of 20 s to 25 s. Then, after an interval of 60 s (minimum), repeat the test with pulses of negative polarity (for timing sequence, see Figure 47). Repeat the test using the biphasic test pulse in Figure 50.



NOTE Resistor Rp is optional and is used to protect the voltage generator during capacitor charging.

Figure 48 — Test setup for Test 2 (using a truncated exponential defibrillation waveform)

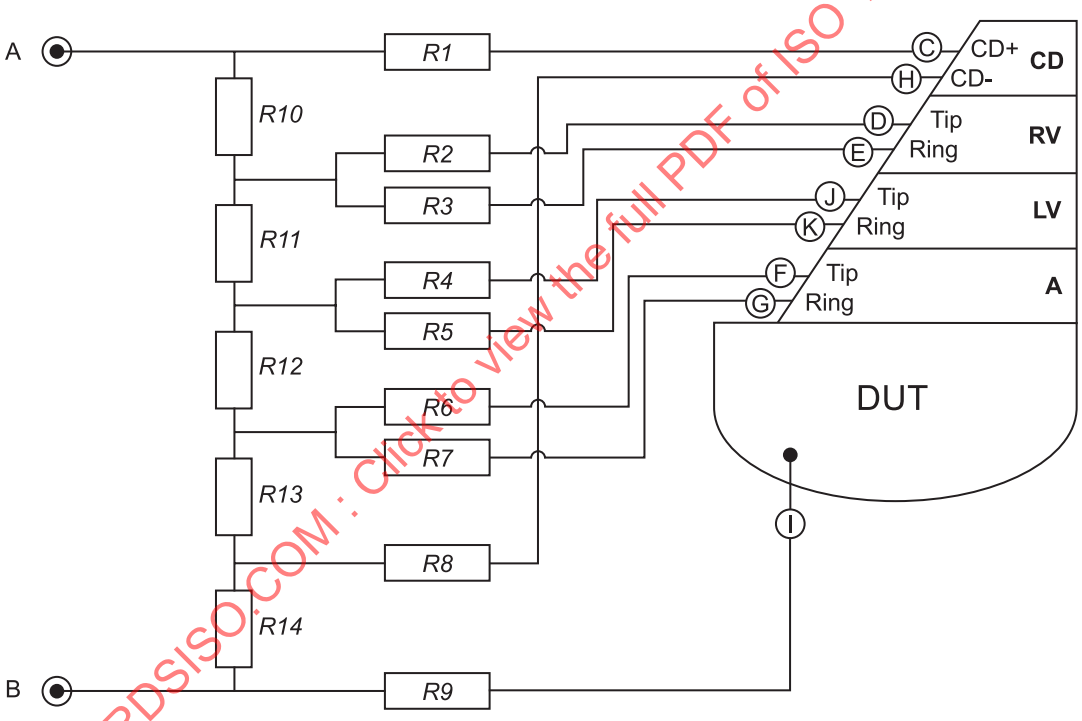


Figure 49 — Resistor network for Tests 1 and 2

Table 13 — Resistor network parameters

Test	R1 Ω	R2 Ω	R3 Ω	R4 Ω	R5 Ω	R6 Ω	R7 Ω	R8 Ω	R9 Ω	R10 Ω	R11 Ω	R12 Ω	R13 Ω	R14 Ω
1	50	800	400	800	400	800	400	50	50	5	5	5	20	30
2	50	600	300	600	300	600	300	50	50	5	5	5	20	30
NOTE All resistors will be ± 5 %; resistors R1 and R8 to R15 will be 25W.														

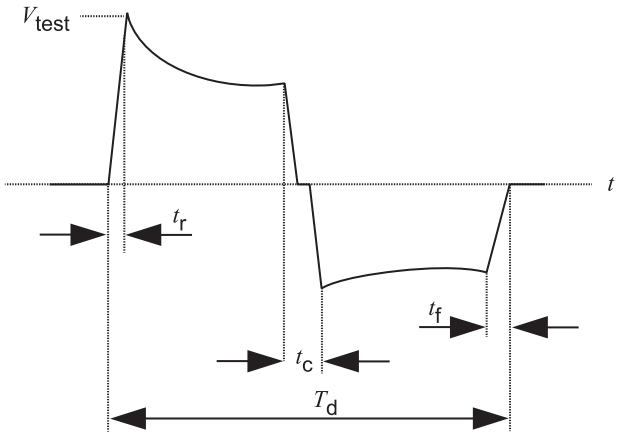


Figure 50 — Biphasic defibrillation waveform for Test 2

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

6.2.3 ICDs and CRT-D devices

Repeat the test sequence in 6.2.2 with the following changes: in Figure 49, connect the cardioversion/defibrillation terminals to the outputs C and H.

7 Additional accompanying documentation

7.1 Disclosure of permanently programmable sensitivity settings

If the DUT has permanently programmable sensitivity settings for which the continuous wave interference requirements of 4.4.1 or 4.5.2 are not met, then the accompanying documentation shall disclose these settings with a clear warning indicating that their use may result in a higher risk to the patient due to electromagnetic interference.

Compliance shall be confirmed by inspection.

7.2 Descriptions of reversion modes

The accompanying documentation for the DUT shall include descriptions of the reversion modes, such as magnet mode and operation during electromagnetic interference, if applicable.

Compliance shall be confirmed by inspection.

7.3 Known potential hazardous behaviour

The accompanying documentation for the DUT shall include information on known potential hazardous behaviour, if observed, as a result of the characterization test conducted under 4.4.2 .

Compliance shall be confirmed by inspection.

Annex A
(informative)

Rationale

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

A.1 Rationale for test requirements for the frequency band 0 Hz $\leq f <$ 450 MHz (see 4.1 to 4.8)

Exposure of the DUT to an electromagnetic field may

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

— induce voltages in the lead that damage the DUT; and

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

In addition, DUTs incorporate magnetic control components (e.g. reed switches) that may be activated by magnetic fields. The magnetic control component or other circuit components of the DUT may be damaged by stronger magnetic fields. Hence, some assurance is required that DUTs offer reasonable immunity to electromagnetic interference and from currents passing through the human body when the patient is in contact with domestic appliances.

The subclauses address:

— protection from tissue damage or fibrillation caused by currents induced on the implanted lead directly or injected spuriously from the device (4.2),

— protection from persisting malfunction of the device caused by voltages induced in the implanted leads (4.3),

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

— protection from transient changes in therapeutic behaviour of the device caused by voltages induced in the implanted leads (4.5),

— protection from transient changes in therapeutic behaviour of the device caused by weak (1 mT) static magnetic fields affecting any magnetically sensitive components in the DUT (4.6),

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

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

The EMI tests extend over a frequency range from 0 Hz (to include possible static magnetic environmental fields) to 3 GHz (to include radiation fields from mobile telephones). The frequency of 16,6 Hz is specifically called out to include possible environmental fields from some European railways.

Clause 4 does not cover exposure to therapeutic and diagnostic treatments (with the exception of external defibrillation and electrosurgery) or to EM fields that occur in some occupational environments. Hence,

the device manufacturer may need to be consulted in case of uncertainty relating to specific treatments or occupational exposure to specific sources.

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

NOTE 2 In definition of the tests, the setting of test signals equivalent to ambient EM fields required assumptions about the electrical characteristics of the DUT input and the layout of the implanted lead. Those assumptions may not be valid for cardiac leads other than leads conducting an intracardiac signal to pacing or sensing terminals. Accordingly, other physiological sensors (e.g. minute ventilation) are not covered by the tests given in 4.2 to 4.5.4, and such additional sensors may be turned off during testing.

When considering the most appropriate sensitivity settings for the DUT, the working group took into account both unipolar and bipolar configurations and concurred that sensitivities of 0,3 mV (bipolar) and 2,0 mV (unipolar) were appropriate for EMI test frequencies above 1 kHz. In arriving at these values, the group acknowledged that although state-of-the-art DUTs provided settings that were substantially more sensitive (e.g. 0,1 mV), such settings were primarily provided to aid the clinician in diagnostic testing. The working group considered that diagnostic programming at the more sensitive levels to be only temporary and that, in clinical practice, permanent programming of such values was usually avoided because of the increased likelihood of far-field sensing, myopotential sensing, and sensing of EMI.

In this International Standard, the requirements for warnings concerning the use of permanently programmable sensitivity settings that are found not to meet the basic requirements of 4.4.1 or 4.5.2 have been clarified. The warning(s), consisting of disclosure of non-conforming sensitivity settings, and cautionary statements similar to that given here, are required for pacing devices that are found not to perform safely during specified transient CW interference below 167 KHz, or sustained CW interference below 1 KHz.

Consequently, an associated warning in the accompanying documentation was considered appropriate, to alert the clinician that careful consideration should be given to patient exposure to EMI, if programming sensitivity greater than 0,3 mV (bipolar) and 2,0 mV (unipolar).

An appropriate warning statement could read as follows:

“Careful consideration should be given to patient exposure to external electromagnetic interference if programming a setting more sensitive than 0,3mV in a bipolar sense configuration setting, and more sensitive than 2,0 mV in a unipolar sense configuration setting. More sensitive settings than 0,3mV (bipolar) and 2,0mV (unipolar) are considered to represent an increased risk from sensing either inappropriate physiologic signals (e.g. far field R waves on the atrial channel, T waves on the ventricular channel, myopotentials in the unipolar sensing configuration or diaphragmatic myopotentials in the bipolar sensing configuration) or non-physiologic electromagnetic interference from external sources. These more sensitive settings should therefore be programmed only for those patients requiring such sensitivity parameters rather than routine programming without further evaluation.”

It was acknowledged, however, that a few patients may require atrial sensitivity to be set to detect signals of less than 0,3 mV if atrial lead positioning was suboptimal or if sensed P-wave signals were often unusually low in amplitude (as in “single pass” VDD systems). For the majority of pacemaker patients, however, settings more sensitive than 0,3 mV (bipolar) and 2,0 mV (unipolar) were considered to represent an increased risk from inappropriate far-field and myopotential sensing and from EMI in those models that do not have immunity at the more sensitive settings.

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

EM fields may affect the DUT directly through its case or indirectly through induced currents and voltages in the implanted leads. In 4.2 to 4.5, currents and voltages induced in the implanted leads are the dominant effect; hence, the requirement is tested by an injected voltage test at frequencies below 450 MHz and by a near-field test of the DUT connected to its leads at frequencies above 450 MHz. The injected voltage tests use tissue interfaces (between 16,6 Hz and 10 MHz) or an injection network (between 10 MHz and 450 MHz) to duplicate body tissues. Those interfaces were developed in the 1980s as part of the work done for the development of the CENELEC (European Committee for Electrotechnical Standardization) standards EN 50061 Amendment 1 and EN 45502-2-1 (Bossert and Dahme, 1987[2]). Additional work was done in the 1990s (Landstorfer, et al., 1999[5]).

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

Permitted human exposure to EM fields is limited by a number of national and international guidelines and by recommendations from bodies such as the International Commission on Non-Ionizing Radiation Protection (ICNIRP), the European Commission, CENELEC, ANSI, the IEEE, and the IEC. Requirements in Clause 4 take account of known sources of EM fields in the public environment. The requirements of 4.5 are based partly on reference levels for EM fields in the European Commission Recommendation 519, issued in 1999 (EC 519/99), under certain assumptions of field-to-voltage transfer functions. Reference levels represent the most lenient test of acceptability of general public exposure to fields according to EC 519/99. Magnetic fields more than 20 times higher than the reference levels may comply with the basic restrictions of EC 519/99, especially for localized sources of EM fields at low frequencies. Accordingly, the requirements of 4.3 and 4.7 are intended to prevent incompatibility with higher magnetic fields than the reference levels of EC 519/99.

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

In an EM field, any implanted lead acts as an antenna. The voltages picked up by and the currents induced in this antenna depend on the implantation site and on the layout and characteristics of the lead as well as the frequency, polarization and direction of the EM field. The requirements in Clause 4 are based on conservative assumptions about such coupling factors.

The frequency of the EM field influences the mechanism for induction of voltages and currents in the device and its leads, as well as the transfer function expected between applied field strength and induced voltage. At low frequencies (below a few MHz), any lead and its return path (through the body for unipolar leads) form a closed conductive loop around which voltages are induced: the body has little screening effect on the fields, and the induced voltage is proportional to the frequency. As the frequency increases beyond a few MHz, body tissue starts to shield EM fields and the device leads act increasingly as dipole antennas. These effects are complex, and appropriate transfer functions are given in DIN VDE 0848-3-1:2003-10[14]. At low frequencies, the effective induction loop area is considerably higher for unipolar leads than for bipolar ones, leading to higher induced voltages. Existing data indicate that for implants using present techniques, cross-sectional areas are smaller than 200 cm^2 (typical) for pacemakers and 232 cm^2 (typical) for ICDs, and the largest will not normally exceed 319 cm^2 (worst case); see Annex L for details.

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

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

Selection of C_x. The capacitor C_x in the tissue-equivalent interface circuits described in Annex D serves to attenuate any spurious low-frequency noise during burst and pulse amplitude modulation of the test signal carrier frequency. This spurious noise may incorrectly identify a DUT as sensitive to some or all of the test signals.

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

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

At low frequencies, the effect of C_x may be opposite to that desired. As an example, if the selection procedure sets $C_x = 470$ nF, the amplitude of the test signal at point C has to be increased if the test signal monitored at point D is not as required. This increase in signal may increase the amount of spurious low-frequency noise.

Thus, the attenuation of the low-frequency spurious noise by C_X may be more than offset by the increased amplitude injected. In this case, the use of C_X may cause an otherwise unaffected device to be affected by the test signal (corrupted by the spurious noise) and may indicate false failure of the device. The use of C_X should be limited to cases where failure to comply may be caused by the test equipment. Compliance does not require C_X to be in-circuit, and, therefore, the use of C_X is optional at any frequency.

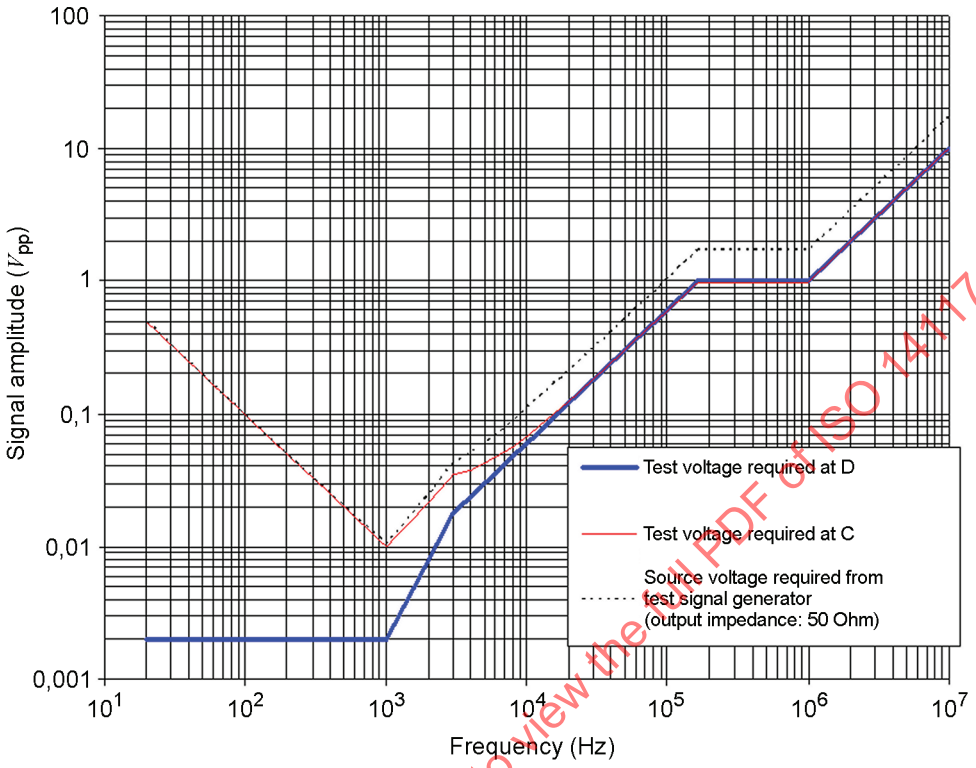


Figure A.1 — Example amplitude at point D and C of the tissue interface (C_X selected for 5 000 Hz corner frequency)

The shunt resistor R_1 of the tissue interfaces of Annex D has three functions: it provides a galvanic connection between terminals F, G, H and I to case (terminal J); it restricts the input resistance of the tissue interface to the value of R_1 (68 Ω) in case the device under test provides high impedance at its inputs; and it is part of the high-pass filter together with C_X.

The appropriate value of capacitor C_X depends upon the signal generator used and upon the carrier frequency. Experience shows that in most cases it would be practical to use three different capacitors in the range 16,6 Hz to 10 MHz:

16,6 Hz to 150 kHz: 10 000 nF

150 kHz to 1 MHz: 270 nF

1 MHz to 10 MHz: 27 nF

The load of the device under test is in parallel to the shunt resistor R_1 limiting test levels achievable by the signal generator. Increasing the shunt resistor to 200 Ω (for example 150 Ω in series with the input of an oscilloscope with 50 Ω), the following capacitors may be practical:

16,6 Hz to 150 kHz: 4 700 nF

150 kHz to 1 MHz: 150 nF

1 MHz to 10 MHz: 15 nF

The capacitor C_x should not be an electrolytic type but the tolerance does not matter.

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

Subclause 4.2 This addresses the risk of demodulation products or currents picked up on the leads causing fibrillation or local tissue burns.

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

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

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

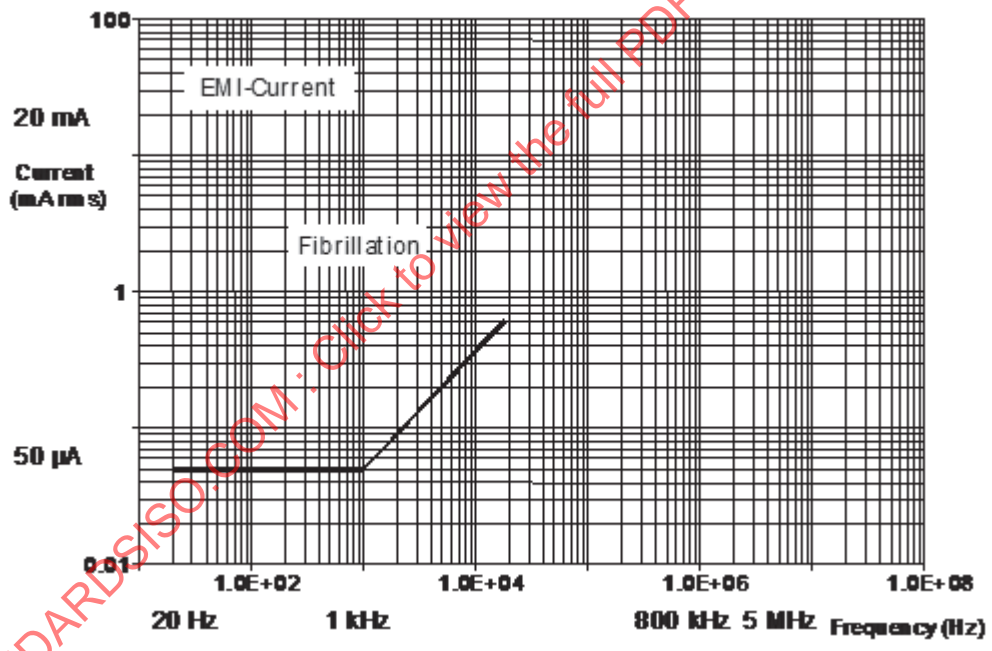


Figure A.2 — Maximum allowed current when injected to the heart (subclause 4.2)

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

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

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

If the channel under test is bipolar, one outlet of the tissue interface is connected to the tip and one to the ring connector. So the bipolar channel of the DUT is loaded with the full test signal in a common mode circuit grounded at the case of the device, while the tip and ring are isolated. In addition, the test is repeated in

a differential mode, with the test signal provided between the tip and ring. In this case, the test signal is decreased by 90 %, since the antenna effect is smaller owing to the decreased distance between the tip and ring electrodes.

The test for using a cardioversion/defibrillation lead as the sense/pace indifferent electrode was eliminated because currently there is no device with such a feature and it does not seem likely one will be designed. It was considered that the remainder of the tests adequately cover the requirement.

Subclause 4.3 specifies requirements to demonstrate that the device is neither damaged nor needs reprogramming after a reasonable interference overload occurs at its terminals.

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

The test for using a cardioversion/defibrillation lead as the sense/pace indifferent was eliminated because currently there is no device with such a feature and it does not seem likely one will be designed. It was considered that the rest of the tests adequately cover the requirement.

Subsequent clauses address exposure of the device to fields that might be experienced for prolonged periods. However, higher fields might be experienced for short periods from localized sources of varying magnetic fields, such as metal detectors or antitheft devices. Because exposure to such fields is expected to be of short duration, 4.3 checks for malfunctions that persist beyond the removal of the exposure only.

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

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

Subclause 4.4 checks the therapeutic behaviour as declared by the manufacturer in the presence of ambient CW interference.

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

The test for using a cardioversion/defibrillation lead as the sense/pace indifferent was eliminated because currently there is no device with such a feature and it does not seem likely that one will be designed. It was considered that the rest of the tests adequately cover the requirement.

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

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

In this International Standard, the requirement that the device transition to its interference mode within a specified time frame has been eliminated. The rationale for this is twofold: the rate of change of the test signal is not specified so as to allow freedom of choice on the part of manufacturers in structuring their testing, and secondly, the mode switch, when it occurs, is controlled by firmware in state-of-the-art devices, and this occurs within milliseconds, far shorter than the cardiac cycle.

Subclause 4.5 checks for changes in therapeutic behaviour caused by interference from modulated signals. The categorization required is similar to that in 4.2, but all channels are tested in parallel, as in 4.3 and 4.4.

Concerning frequencies up to 1 kHz, the majority of environmental fields encountered in this range are continuous wave in nature, not intentionally modulated. Therefore the test signals are continuous sinusoidal wave. These test signals reside in the sensed frequency band of the devices under test.

The modulation carried by the test interference signal has significant harmonic content overlapping that of ECG signals. DUTs may be sensitive to some of these frequency components for good and useful reasons. DUTs usually have a facility to ensure that they provide pacing at a fixed rate, “interference mode”, rather than being inhibited by a large interference signal. The test in 4.5.2 therefore allows such a response if interference mode is described in the physician’s manual.

For test signals with a carrier frequency between 1 KHz and 150 KHz: two alternative patterns of modulation are defined, both being pulsed because most interference sources are pulse modulated. The modulation is a true gated signal, or switched on and off smoothly. The bursts are provided with an envelope rise and fall time of 10 ms to decrease the inherent base band components.

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

The curve of the test signal has several corner points to take account of different considerations. In the frequency range from 3 kHz to 1 MHz, the voltage levels are derived from fields of the general public reference levels of EC/519/99. These give an indication of fields that may be experienced for long periods of time by the general public. For frequencies above 100 kHz, the European Commission recommendation accepts increased peak values with respect to rms values. This is taken into account in 4.5 by assuming up to five simultaneous amplitude modulated signals that together match the rms reference level (i.e. up to a ratio of peak value over rms value not exceeding 5,6). Between 1 MHz and 10 MHz, the test signal represents the type of exposure expected from radio-transmitters. Above 10 MHz, the test signal is limited to values considered as reasonable practical protection limits.

The requirement in the frequency range of 10 MHz to 450 MHz, 4.5.4, replaces the tissue-equivalent interfaces used at lower frequencies by a 50 Ω injection network.

Above 450 MHz injected voltage tests are less appropriate, and a radiated test method is preferred. This covers the range used by most mobile phone systems.

It is widely acknowledged that a suitable method for eliminating the effects of high-frequency interference is to use appropriate feed-through capacitors where the lead connections pass through the DUT case. Accordingly, compliance with 4.5.4 can be achieved by proving that suitable components have been used for all through-shield circuit interfaces.

Other design strategies may also be suitable, in which case a radiated test is required. The DUT together with all its leads is placed in a saline solution, which represents body tissue and its screening properties, and exposed to the near field of an electric dipole. Two levels of exposure are tested. The lower radiation level guarantees uninfluenced function of the DUT when exposed to mobile phones of 2 W output power at a distance of 15 cm. Compliance with this test is mandatory. The optional, higher radiation level guarantees compatibility even at distances of 2 cm, which represents a mobile phone situated directly against the surface of the human body and is not required for compliance. The test signal is modulated in order that it may not be confused with heart beats.

The test also guarantees compatibility in the far field (i.e. outside any exclusion fences) on the site of high-power transmitters such as mobile phone base stations. As in the other subclauses, 4.5.4 requires checking for any change of therapeutic behaviour, including transitions to fixed-rate interference mode.

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

Subclause 4.7 defines protection from exposure to stronger (50 mT) static magnetic fields. These magnetic fields have the potential to permanently disrupt the operation of an implantable DUT. If the DUT contains a magnetic switch, the behaviour of the device will probably be altered in the presence of the magnetic field. For example, telemetry could be activated, or therapy could be deactivated. The manufacturer should assess the hazard to the patient that could result from the inadvertent closure of the magnetic switch as part of an

overall risk assessment. However, once the strong magnetic field is removed, the DUT should function as it did before the exposure without adjustment. Therefore, a change in DUT operation that could be resolved by programming would be considered a failure of this test.

Subclause 4.8 checks for persistent malfunction being caused by direct application of time-varying magnetic fields to the DUT.

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

A.2 Rationale for test requirements for the frequency band 450 MHz $\leq f \leq$ 3 000 MHz *(see 4.9)*

A.2.1 Rationale for DUT reference point

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

A.2.2 Rationale for the RF modulation

The principal RF interaction in implanted cardiac devices is spurious 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 International Standard represents the worst case by using a rate and pulse width that simulates physiological signal characteristics and, as a result, lies within the bandpass of the implantable DUT. Typical communications service signal modulations are less disturbing than the modulation specified by this International Standard.

A.2.3 Rationale for the optional characterization testing

The 120 mW power level described in this International Standard allows a high level of confidence that an implantable DUT will not be affected by EMI from a hand-held emitter at a distance of 15 cm. A manufacturer may perform the optional characterization tests to demonstrate immunity without regard to the separation distance.

A.2.4 Rationale for test power levels

This International Standard is based on ANSI/AAMI PC69:2007[15] (second edition). The rationale below provides the background for the minimum and optional power levels to which legacy devices were tested prior to publication of the second edition and is retained for the purpose of informing users of this International Standard's evolution.

The dipole antenna power levels defined in ANSI/AAMI PC69:2000 (first edition) were derived from measurements of RF signals coupled to an instrumented DUT 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 analyser 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°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 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 120 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 dipole net power level of 40 mW in the first edition is approximately three times this level. These experiments also demonstrated that the optional 8 W and 2 W dipole test levels produce higher lead voltages than are produced by wireless phones operated immediately adjacent to the pacemaker.

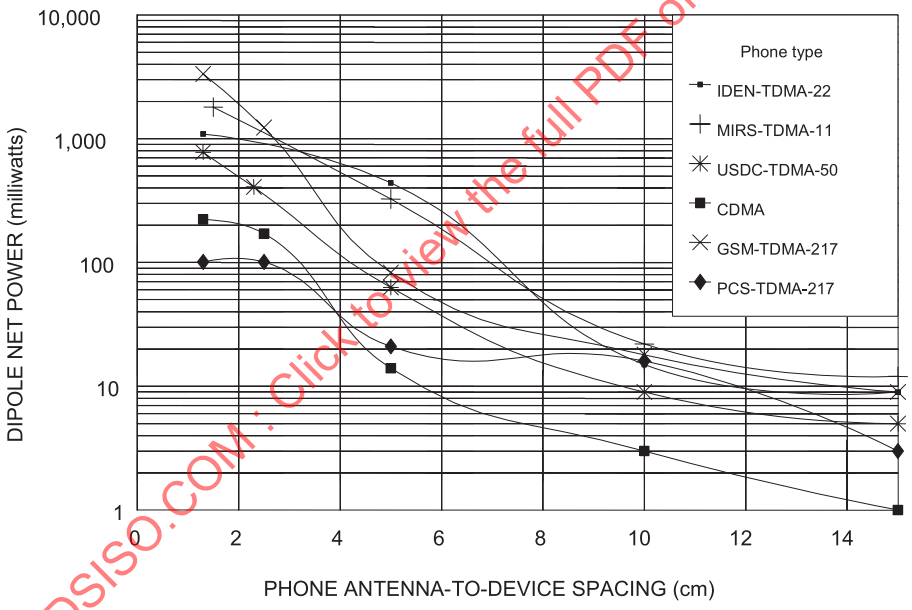


Figure A.3 — Dipole net power measurements (dipole spacing = 2,5 cm) conducted for the first edition

The 40 mW dipole net power level specified in ANSI/AAMI PC69:2000 ensured the compatibility of implanted cardiac devices with hand-held wireless and personal communication services (PCS) phones [e.g. IDEN, MIRS, USDC (TDMA-50 at 800 MHz), CDMA (CDMA at 800 MHz), GSM (TDMA-217 at 900 MHz), PCS (TDMA-217 at 1 900 MHz)] and other similar-power hand-held transmitters when the transmitter maintained a minimum of 15 cm from the implanted device.

At the time that the 40 mW testing requirement of ANSI/AAMI PC69:2000 was developed, cell phones were primarily voice devices and only used data streams during registration or network synchronization.

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

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

In addition, there has been a proliferation of new emitters in this same time period. WiMAX, UWB, and other technologies are developing rapidly, and several RFID devices are on the market. For example, there are a number of fixed and portable RFID devices that transmit 3 W or more effective radiated power in a number of frequency bands from 135 kHz to 5,875 GHz (one common RFID frequency is 915 MHz). These other transmitters require additional study and are to be a focus in the third edition of ANSI/AAMI PC69.

During the development of ANSI/AAMI PC69:2007[15], the AAMI Electromagnetic Compatibility (EMC) Task Force discussed the factors mentioned here and decided that a further increase to 120 mW might be prudent. This requirement is consistent with current industry practices when the transmitter is maintained a minimum of 15 cm from the implanted device for patient guidance and labelling of devices that are not designed for compatibility with close-proximity wireless phones.

The optional characterization test specified in 4.9.3.2 requires dipole net power levels of 8 W in the frequency range 450 MHz $\leq f <$ 1 000 MHz and 2 W in the frequency range 1 000 MHz $\leq f \leq$ 3 000 MHz. These power levels were selected on the basis of the maximum power levels likely to be encountered from the sources[1)] identified in Annex B, Table B.2. Experimental data show that dipole net power levels below 3 350 mW produced the voltage induction effect of 800 MHz and 900 MHz wireless phones spaced 1,3 cm from the device. At the higher-frequency band of the PCS phone, dipole net power of 101-mW produced the voltage induction effect of the phone at a distance of 1,3 cm. The power levels of the optional test are intended to ensure the compatibility of implanted cardiac devices with hand-held wireless phones and other similar-power hand-held transmitters that are operated without restrictions near the implanted DUT. Therefore 4.3 of this International Standard applies these optional power levels in order to demonstrate as a mandatory requirement that the DUT can withstand exposure to these levels without permanent effects or damage to the device.

A.2.5 Rationale for lead configuration

The DUT lead configuration illustrated in Figure G.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 and therefore the layout of the lead is not critical at these test frequencies.

A.2.6 Rationale for device programmed parameters

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

The programming specifically requested by Table I.1 and Table I.2 in Annex I, plus the high sensitive setting specified in many tests, could lead to sensing of the atrial spike by the ventricle(s), resulting in a behaviour known as “safety pacing”, essentially a shortening of the A-V delay.

This behaviour is not related to interference from external EM fields, does not modify the ventricular refractory period, shortens the total atrial refractory period (TARP = A-V delay + PVARP) and is not a reason to classify a device as non-conforming to this International Standard. Tolerating this behaviour is an alternative to testing with one active chamber at a time as allowed by Table I.1, footnote c or Table I.2, footnote b.

A.3 Rationale for sample size

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

A sample size of one device is appropriate considering that the observed spread or variation of the EMC characteristics from one device to another of a certain implantable DUT model is extremely small. Over the whole frequency range (d.c. to 3 000 MHz), the EMC of an implantable DUT is fully determined by the

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

implementation of both the cardiac signal sensing filters and the EMI suppression filters. These filters consist of RF feedthrough filters and passive front-end filters (using only a few discrete components), with all further signal filtering performed on-chip on one or more integrated circuits (ASIC). The tolerances of the off-chip components are small, and the characteristics of the on-chip filter are basically identical from one device to another because of integrated circuit process control, digital filtering or on-chip trimmed filters, and other factors. Variances from device to device are smaller than the variances caused by measurement uncertainties in the tests defined in this International Standard.

A.4 Rationale for test requirements in Clause 6

A.4.1 Protection of the device from damage caused by high-frequency surgical exposure

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

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

A.4.2 Protection of the device from damage caused by external defibrillators

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

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

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

The different test voltage levels are intended to align with the clinical experience documented in the literature, which teaches that significantly lower defibrillation energy is needed when a truncated exponential waveform is used compared with the energy needed when using a damped sinus waveform (Mittal, et al., 1999[6], 2000[7]; Bardy, et al., 1996[1]).

The resistive ladder in Figure 49 has been designed to present the same total impedance of 65 Ω to the defibrillation pulse generator (as the impedance used in ANSI/AAMI PC69:2007[15]).

Annex B
(informative)

Rationale for test frequency ranges

NOTE Tables B.1 and B.2 provide a summary of common emitters and their operating frequencies. The tables are provided for illustrative purposes only, and are not intended to imply compatibility under all circumstances of use between these sources and the devices tested within the scope of this International Standard.

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

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

Frequency port/base	Source	Modulation, if applicable
Static		
	Stereo speaker magnets	
	Name tag magnets	
	Magnetic therapy	
	Video display	
	MAGLEV train (Japan)	
	EAS tag magnetizer	Pulse
	Stun gun, conducted current	
	Electrolysis, conducted current	
Variable low frequency		
	Internal combustion engines (chain saw, weed cutter, boat, yard tractor, snowmobile, portable generator, auto, etc.)	Pulse with variable repetition rate
	Electric fence, conducted current	
	Battery-powered tools and carts	
1 Hz to 100 Hz		
16,6 ; 50	Electrified railroad	CW
50 ; 60	Distribution transformer (ground level)	CW
50; 60	Distribution line	CW
50; 60	115 kV transmission line	CW
50; 60	230 kV transmission line	CW
50;60	315 kV transmission line	CW
50;60	500 kV transmission line	CW
50;60	800 kV transmission line	CW
50;60	1 100 kV transmission line	CW
50;60	Portable generator	CW
50;60	Saw (hand-held, table)	CW
50;60	Hand drill	CW
50;60	Tape head demagnetizer	CW
50;60	Soldering gun	CW
50;60	Arc welding (300 A)	Intermittent
50;60	Fluorescent desk lamp	CW

Table B.1 *(continued)*

Frequency port/base	Source	Modulation, If applicable
50;60	Fluorescent fixtures	CW
50;60	Tanning bed	CW
50;60	In-floor resistive heating	CW
50;60	Electric range	CW
50;60	Microwave oven	CW
50;60	Blender	CW
50;60	Can opener	CW
50;60	Mixer (hand-held)	CW
50;60	Vacuum cleaner	CW
50;60	Electric blanket	CW
50;60	Hair dryer (hand-held, table)	CW modulated by movement
50;60	Electric shaver	CW modulated by movement
50;60	Electric toothbrush	CW modulated by movement
50;60	Rotating sign	CW
73	EAS	CW modulated by movement
0,1 kHz to 1 kHz		
100	Metal detector	CW modulated by movement
210–220, 218, 219	EAS	CW modulated by movement
400	Aircraft power	
436	EAS	CW modulated by movement
450	EAS tag demagnetizer	Damped sine burst
500	Metal detector	Pulsed
500, 534, 535	EAS	CW
850	EAS	Pulsed
862	EAS	CW
943, 950	EAS	Pulsed: 10 ms burst, 150 ms period, two or three bursts per gate activation
1 kHz to 10 kHz		
1	Metal detector	
2,5	EAS	Pulsed
3	EAS	CW
4	Metal detector	Pulsed
5 and 5,15	EAS	CW
7,65	EAS	CW
5 to 10	Walk-through metal detector	CW
10 kHz to 100 kHz		
< 50	Walk-through metal detector	Pulsed 200 pps to 400 pps
10 to100	Hand-held metal detectors	CW modulated by movement
	Video displays	
	Slot machines	
10 to14	OMEGA	CW for 0,9 to 1,25
10	EAS	Pulsed
13,25	Hand-held metal detector	
13,5 to 14,5	EAS	CW

Table B.1 *(continued)*

Frequency port/base	Source	Modulation, If applicable
18	EAS	CW
20 to 50	Induction range	CW
22.75	Hand-held metal detector	
39.5	EAS	Pulsed
50, 58 and 58,6	EAS	Pulsed: 1,64 ms burst, 16,4 ms period
64	Hand-held metal detector	
80	EAS	
94,5	Hand-held metal detector	
0,1 MHz to 1 MHz		
0,1	LORAN (being phased out)	Pulsed: 10 Hz
0,115	Hand-held metal detector	
0,134 2	TIRIS Texas Instruments Registration and Identification System (RFID)	
0,148 to 0,283	European AM radio	
0,2 to 0,3	Hand-held metal detector	
0,535 to 0,160 5	US. AM radio	AM (amplitude modulation)
1 MHz to 30 MHz		
1 863	Hand-held metal detector	
2	EAS	Swept frequency
3,25	EAS	
5	EAS	
8 and 8,2	EAS	Swept frequency
13,56	RFID	
3 to 30	Ham radio	
27	Radio control toys (unlicensed)	
26 to 27	CB radio	
30 MHz to 450 MHz		
49	Radio control toys (unlicensed)	Part 15, Subpart C
151 to 154	Multiuse radio service (MURS)	
218 to 219	218 MHz to 219 MHz band radio service Mobile Fixed	Part 95, Subpart F, 95.801
462 to 467	Family radio service (FRS) General mobile radio service (GMRS) Mobile Fixed	Part 95, Subpart B, 95.191 Part 95, Subpart A, 95.1

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

Part 15—Radio Frequency Devices

Part 18—Industrial, Scientific, and Medical (ISM) Equipment

Part 20—Commercial Mobile Radio Services

Part 21—Domestic Public Fixed Radio Services

Part 22—Public Mobile Services

Part 24—Personal Communication Services

Part 27—Miscellaneous Wireless Communication Services

Part 90—Private Land Mobile Radio Services

Part 95—Personal Radio Services

Part 97—Amateur Radio Services

CFR Web Addresses:

Regulations: http://www.fcc.gov/searchtools.html#rules

Frequency allocation table: http://transition.fcc.gov/oet/spectrum/table/fcctable.pdf

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

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

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

Transmit frequency (MHz) port/base	Service type	Service name
453 to 458/463 to 468	Analog cellular	NMT-450
462 to 467	Family radio	—
470 to 980	UHF television	—
800	Wireless modem	—
806 to 821/847 to 866	ESMR	MIRS/IDEN
806 to 824/851 to869	Wireless data	ARDIS-RD-LAP
824 to 849/869 to 894	Cellular	AMPS (EIA/TIA-553) DAMPS (TIA/EIA-627) CDMA (IS-95) CDPD
868/864	Digital cordless	CT2
871 to 904/916 to 949	Analog cellular	ETACS
880 to 915/925 to 960	Digital cellular	GSM
896 to 902/935 to 941	Wireless data	RAM-MOBITEX
902 to 928	Wireless LAN	—
915	EAS/RFID	—
915 to 925/860 to 870	Analog cellular	NTACS
932/885	Cordless phone	CT1+
932 to 940	Two-way paging	—
935 to 960	Analog cellular	NMT-900
940 to 956/810 to 826	Digital cellular	PDC
948/944	Digital cordless	CT2+
959 to 960/914 to 915	Cordless	CT1
1 240 to 1 300	Ham radio	—
1 335	Military radar	—
1 477 to 1 501/1 429 to 1 453	Digital cellular	PDC

Table B.2 *(continued)*

Transmit frequency (MHz) port/base	Service type	Service name
1 610 to 1 616,5	Satellite phone	Iridium
1 710 to 1 785/1 805 to 1 880	Digital cellular	DCS 1800
1 850 to 1 910/1 930 to 1 990	PCS	TDMA (J-STD-011) CDMA (J-STD-008) PCS 1900 (J0STD-007) WB CDMA PACS DCT-U
1 880 to 1 900	Digital cordless	DECT
1 895 to 1 918	Digital cordless	PHS
2 390 to 2 400	PCS	—
2 450	Microwave ovens	—
2 450/2 712	Diathermy	—
2 400 to 2 483	Wireless data	IEEE 802.11
2 470 to 2 499	Wireless data	IEEE 802.11

Annex C
(informative)

Code for describing modes of implantable generators

C.1 The code

The code is presented as a sequence of five letters. Table C.1 and Table C.2 provide an outline of the basic concept of the pacemaker and ICD code.

Table C.1 — NASPE/BPEG generic (NBG) pacemaker code

Position	I	II	III	IV	V	
Category	Chamber(s) paced	Chamber(s) sensed	Response to sensing	Rate modulation	Multisite pacing	
	O = none	O = none	O = none	O = none	O = none	
	A = atrium	A = atrium	T = triggered	R = rate modulating	A = atrium	
	V = ventricle	V = ventricle	I = inhibited		V = ventricle	
	D = dual (A + V)	D = dual (A + V)	D = dual (T + I)		D = dual (A + V)	
Manufacturers' designation only	S = single (A or V)	S = single (A or V)				

Source: The Revised NASPE/BPEG Generic Pacemaker Code for Antibradycardia, Adaptive-Rate and Multisite Pacing. PACE 25: 260–264, February 2002[16].

NOTE NASPE has changed its name to HRS, the Heart Rhythm Society.

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

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

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

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

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

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

Table C.2 — NASPE/BPEG defibrillator (NBD) code

Position	I	II	III	IV
	Shock chamber	Antitachycardia pacing chamber	Tachycardia detection	Antibradycardia pacing chamber
	O = none	O = none	E = electrogram	O = none
	A = atrium	A = atrium	H = haemodynamic	A = atrium
	V = ventricle	V = ventricle		V = ventricle
	D = dual (A + V)	D = dual (A + V)		D = dual (A + V)
Source: The NASPE/BPEG Defibrillator Code. PACE16:1776–1780, September 1993[17].				

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

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

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

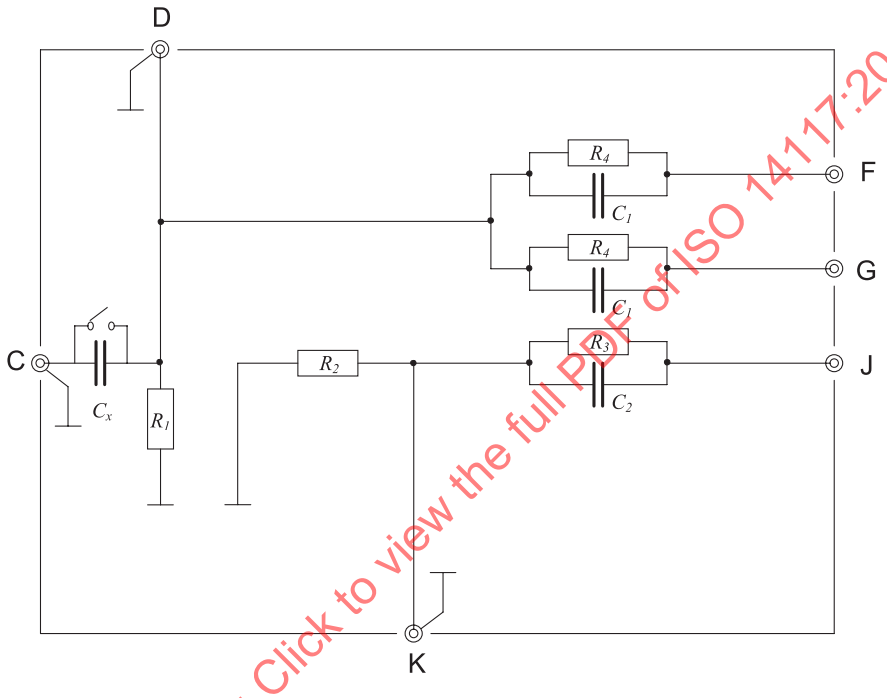
— Position III: Tachycardia detection — This position distinguishes devices that detect tachycardia by means of electrogram signal processing (“E”) alone from those that sense one or more haemodynamic-related variables (“H”) as well, such as blood pressure or transthoracic impedance. Position III is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

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

Annex D
(normative)

Interface circuits

CAUTION — Take care in the construction of the tissue interface in order to prevent electrical cross-talk within the tissue interface circuit.



Key:

C input (test signal)

D test point (test signal)

K monitoring point

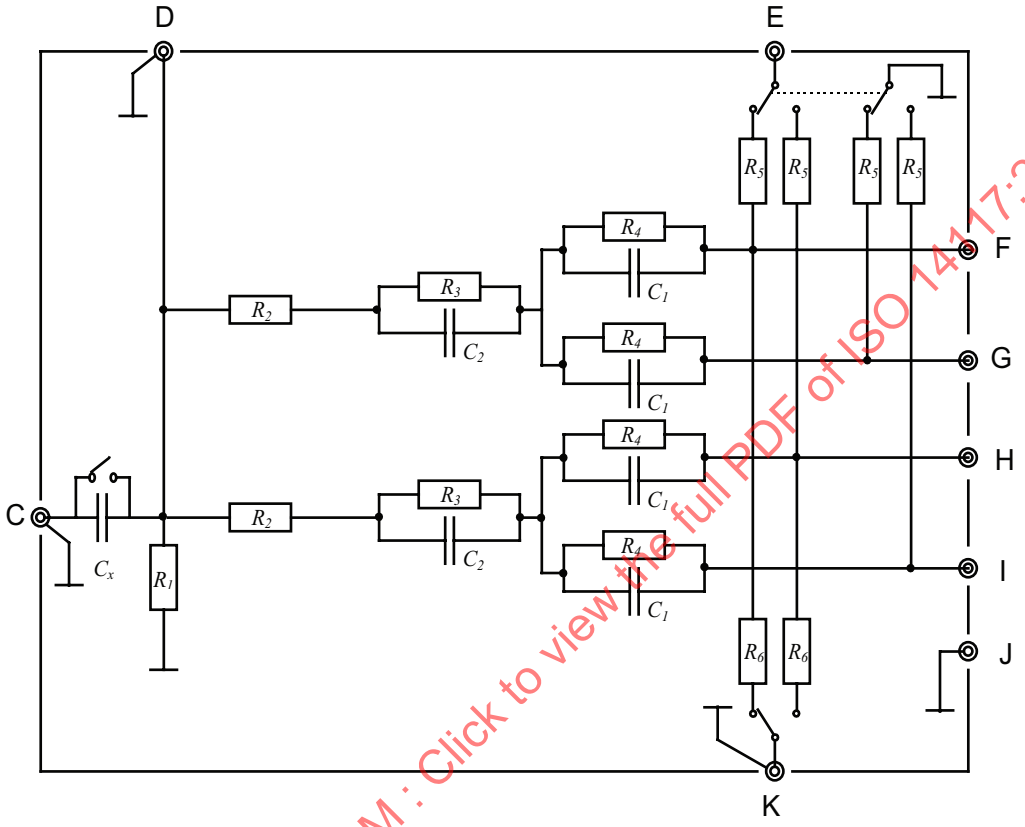
Figure D.1 — Tissue-equivalent interface circuit for current measurements

Table D.1a — Component values for Figure D.1

R_1	68 Ω (2 W)	C_1	15 nF
R_2	82 Ω (1 W)	C_2	180 pF
R_3	120 Ω	C_x	Refer to Annex E
R_4	560 Ω		

Table D.1b — Component values for Figure D.1

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



Key:

C input (test signal)
D test point (test signal)
E input (inhibition generator)
K monitoring point

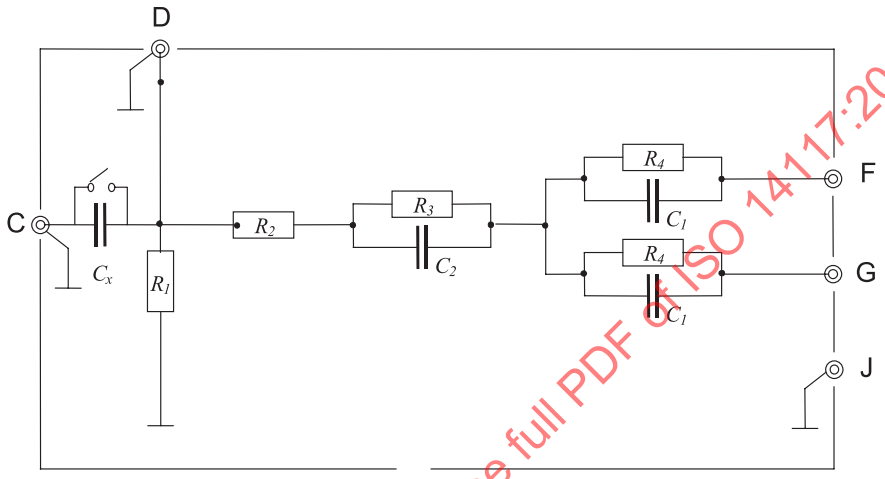
Figure D.2 — Tissue-equivalent interface circuit to check for malfunction

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

For testing CRT-P and CRT–D devices, the manufacturer shall modify the resistor network in D.2 to provide equivalent voltages and impedances for additional channels, as needed.

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

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



Key:

C input (test signal)

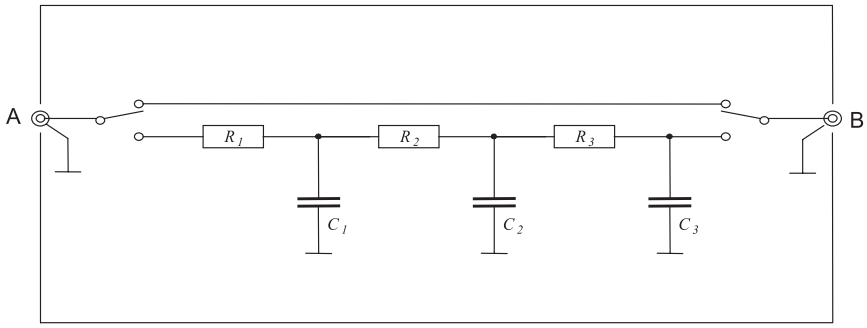
D test point (test signal)

Figure D.3 — Tissue-equivalent interface circuit to check for malfunction caused by voltages induced on cardioversion/defibrillation terminals

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

Table D.3 — Component values for Figure D.3

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



Key:

A input

B output

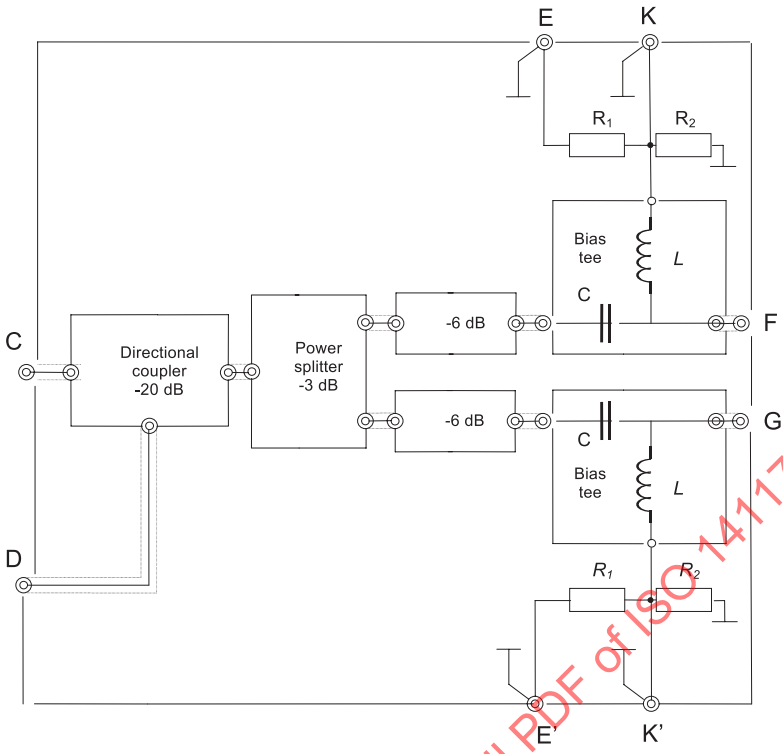
switch up: bypass mode

switch down: filter mode

Figure D.4 — Low-pass filter used to attenuate the 500 kHz component of a test signal

Table D.4 — Component values for Figure D.4

R_1	4,7 kΩ	C_1	22 nF
R_2	15 kΩ	C_2	6,8 nF
R_3	47 kΩ	C_3	2,2 nF



Key:

C input (test signal)
D monitoring point (test signal)
E input (inhibition generator)
E' input or termination
F output to implanted DUT
G output to implanted DUT
K monitoring point (implanted DUT)
K' monitoring point (implanted DUT) or termination

Figure D.5 — Injection network

Table D.5 — Component values for Figure D.5

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

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

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

This recommendation eliminates potential testing variability at 20 MHz, the lowest test frequency, which can occur with an unspecified bias tee capacitor. This capacitor shall be specified so that variability of network source impedance is eliminated at lower test frequencies. The prescribed calibration process of 4.5.4 does not adequately compensate for bias tee capacitor effects occurring under pacemaker loads, since an unmodified bias tee and a pacemaker will have unequal impedances in a 50 Ω system.

Annex E
(informative)

Selection of capacitor C_x

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

***Procedure*:** Use oscilloscopes, input impedance of 1 MΩ ± 10 %, < 30 pF, accurate to ± 10 % within a bandwidth of at least 30 MHz.

For frequencies above 9 kHz, the low-pass filter should conform to Figure D.4. For frequencies below 9 kHz, the low-pass filter may require proper scaling.

The test signal generator and tissue-equivalent circuit to be used in the test procedure are connected to the oscilloscopes and low-pass filter as shown in Figure E.1. Adjust the test signal generator to provide the signal specified in the test procedure.

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

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

NOTE 2 A signal level of 0,2 mV can be sensed by pacemakers that have high-sensitivity settings. A signal level under 0,05 mV is needed for testing high-sensitivity settings but may be difficult to achieve in practice with standard test equipment.

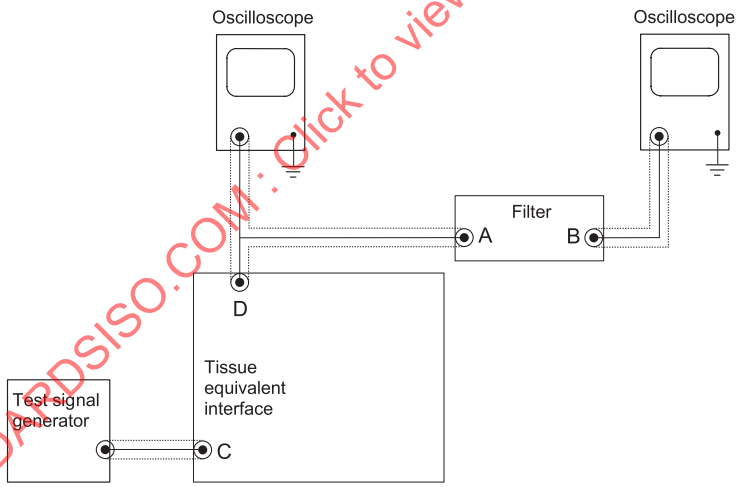


Figure E.1 — Test to check for spurious low-frequency noise and to determine the value of C_x

Annex F
(normative)

Calibration of the injection network (Figure D.5)

This annex specifies the method for calibrating the injection network described in Figure D.5. The calibration factor, m, is the link between the test voltage V_{pp} and the measured voltage of oscilloscope #1, connected to test point D of the injection network, V_{osc}.

$$V_{pp} = m \times V_{osc}$$

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

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

where a_{DC} is the maximum insertion loss of the directional coupler in dB, a_{PC} is the maximum insertion loss of the power splitter for each way in dB, a_{AT} is the maximum insertion loss of the attenuator in dB, a_{BT} is the maximum insertion loss of the bias tee in dB, c_{DC} is the minimum coupling loss of the directional coupler in dB, and coupler loss is entered as a positive value.

Otherwise the calibration factor shall be determined as follows:

Calibration equipment: The configuration of Figure D.5 is used. Output G is terminated by a 50 Ω terminator. Output F is connected to a calibrated high-frequency voltage meter with an input impedance of 50 Ω, an accuracy of at least ±1 dB and a bandwidth of at least 450 MHz.

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

Calibration procedure: The calibration signal shall be increased until the output voltage at the voltage meter reaches the peak-to-peak value indicated in Table F.1. Read the peak-to-peak voltage on the oscilloscope #1 connected to test point D of the injection network, V_{osc}. For 4.5.4, the calibration factor, m, is equal to 10 V divided by V_{osc} . The calibration factor, m, for 4.3.2.2 and 4.3.3.2 is equal to 14 V divided by V_{osc}.

Table F.1 — Calibration signal amplitude

Frequency (MHz)	Output F (V_{pp}) Subclauses 4.3.2.2 and 4.3.3.2	Output F (V_{pp}) Subclause 4.5.4
10	3,61	2,58
20	5,39	3,85
30	6,13	4,38
40	6,47	4,62
50	6,65	4,75
60	6,75	4,82
70	6,82	4,87
80	6,86	4,90
90	6,89	4,92
100	6,90	4,93
150	6,96	4,97
200	6,97	4,98
300	6,99	4,99
400	7,00	5,00
450	7,00	5,00
Depending on available test equipment, these values may be converted to V_{rms}. This decision is left to the discretion of the party performing the test. The calibration amplitudes and units shall be documented in the test report.		

Annex G
(normative)

Torso simulator

NOTE This torso simulator is adapted from Reference [8].

G.1 Tank

The torso simulator consists of a plastic box, 28 quart (26,5 l) capacity, measuring at least 51 cm × 36 cm × 14 cm (20,1 in × 14,17 in × 5,51 in) filled with saline solution per Table 10. The dipole antenna rests on the top grid, with the DUT resting on the bottom grid.

G.2 Top grid

The top grid is a piece of plastic grid cut from a fluorescent light fixture cover made of nonconductive, non-metalized plastic, which is cut to fit the box's opening so that the top grid's top surface is no lower than the box's top rim. The grid is constructed of 0,158 7 cm (0,062 5 in) wide, 0,873 1 cm (0,343 7 in) thick beams spaced 1,349 cm (0,531 2 in) apart in two directions. This configuration forms an array over the entire surface of square holes that are approximately 1,27 cm (0,5 in) on each side.

G.3 Cutout

A central area of the top grid with dimensions of 11,43 cm × 12,7 cm (4,5 in × 5 in) is removed so that 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, non-conductive 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. Hence, it results in a dry, stable surface on which to place the dipole antenna. Each non-conductive strand is tied individually to the indents on opposite sides of the grid.

G.4 Bottom grid

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

G.5 Tank electrodes

Two pairs of stainless steel electrode plates placed along the X and Y axes are used to monitor and test the device while it is immersed in the saline. Each plate measures 5 cm × 5 cm × 0,2 cm (1,97 in × 1,97 in × 0,078 7 in). 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 ECG simulation signals to be applied to the device leads 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 the injection and monitoring plates. Each plate has a threaded hole in its centre, 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 that has a minimum input resistance of 1 MΩ. A signal generator is used to apply simulated ECG waveforms to the second pair of plates. These signals produce voltages in the saline that mimic cardiac activity.

G.6 Illustrations

Figure G.1 and Figure G.2 illustrate all the features discussed above.

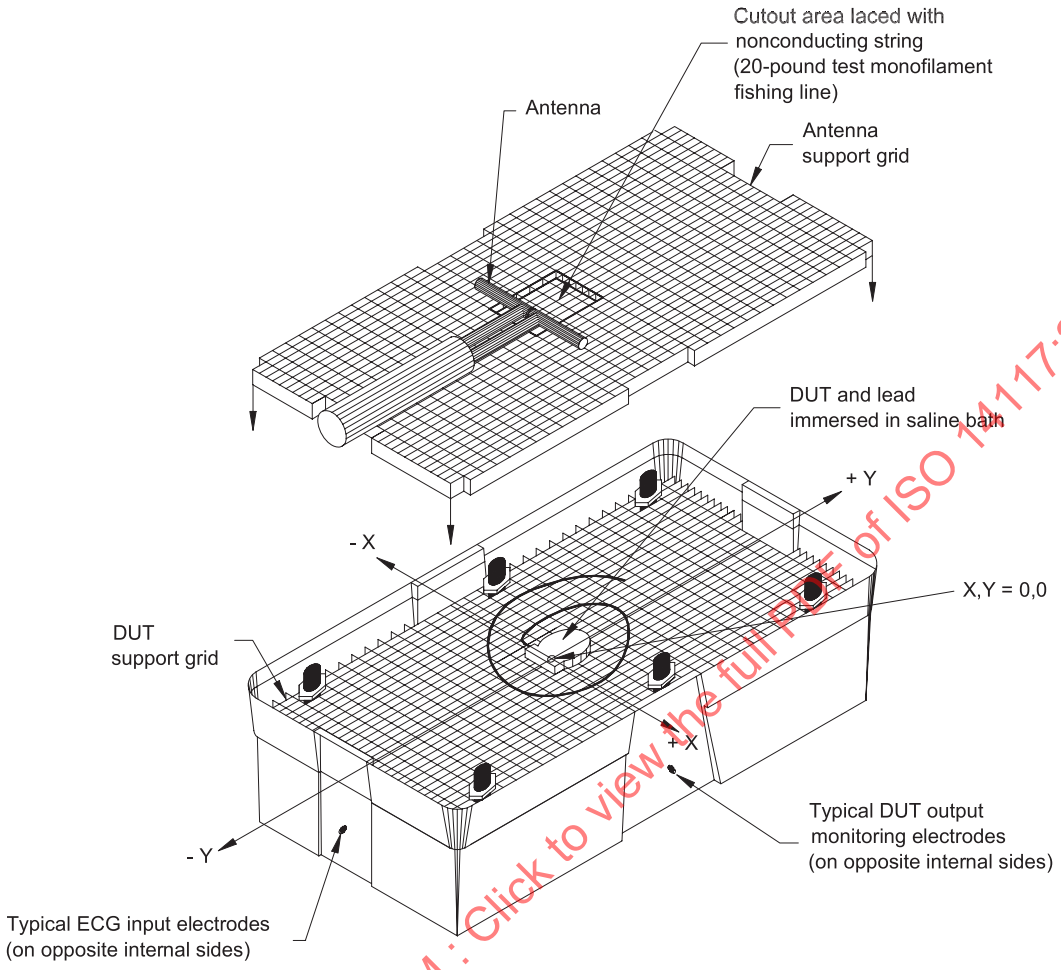


Figure G.1 — Torso simulator

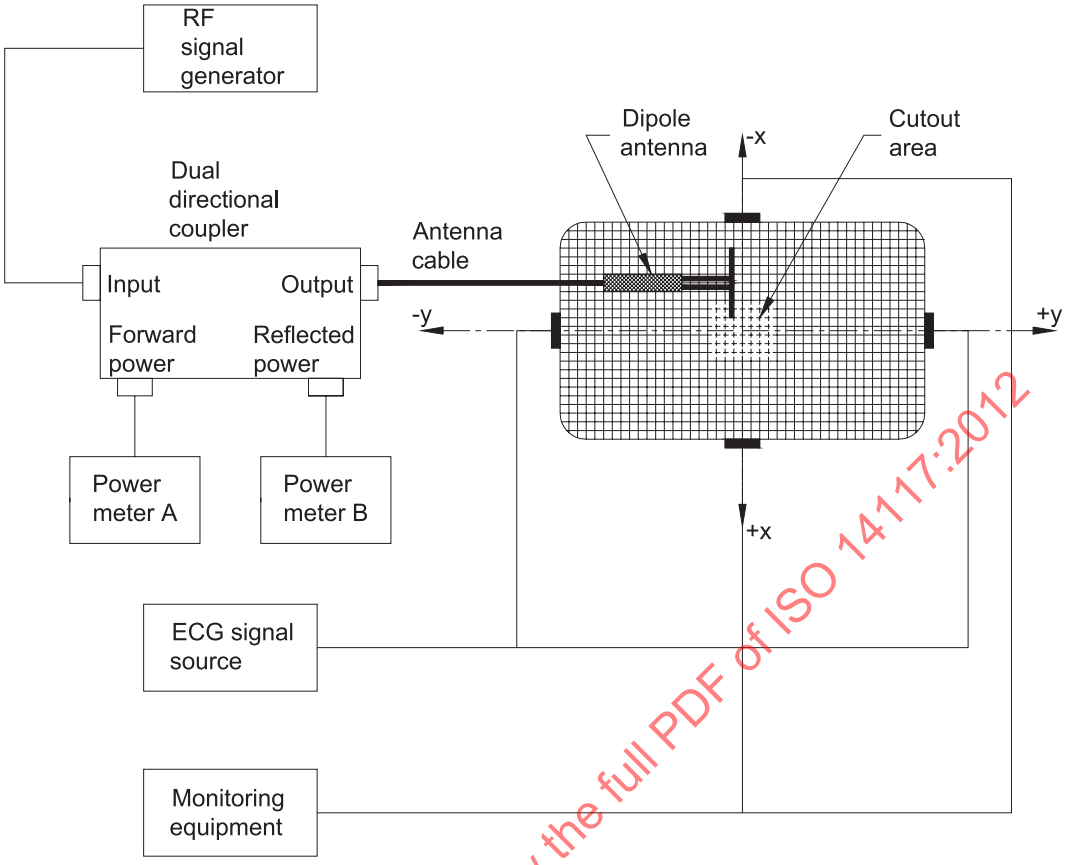


Figure G.2 — Test setup

Annex H
(normative)

Dipole antennas

H.1 Resonant dipole

The dipoles to be used for these tests are tuned, half-wavelength, resonant dipoles with a series-parallel coaxial stub balun that meet the specifications in Table H.1. The coaxial balun is terminated into a suitable 50 Ω coaxial interface connector. See Figure H.1 or ANSI C63.5-1988, Appendix C, for examples of dipole antennas that can meet the specification in Table H.1. See Table 10 for saline resistivity and spacing between the antenna and the saline during characterization of the antenna.

Table H.1 — Dipole description

Test frequencies	**Defined in 4.5.7.2.4 b)**
At each frequency, the following characteristics shall apply:	
Symmetry [a]	±0,5 dB up to $\lambda/8$ from the antenna reference point of the dipole
Internal loss [b]	≤ 0,2 dB
Voltage standing wave radio (VSWR) (referenced to 50 Ω)	= 1,5:1 with the dipole tuned at 2 cm from the saline bath
Power rating	10 W minimum CW
Rod length symmetry	±0,1 mm
Rod axis alignment [c]	Offset of the dipole elements: 0,25 mm maximum; offset to the flat edge at any point along the dipole elements: 1 mm maximum
Rod diameter	3,58 mm ± 0,254 mm copper

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

[b] Internal loss is measured by shorting the dipole at the antenna reference point and measuring the return loss with a network analyser. An antenna with a measured internal loss exceeding 0,2 dB may be used, provided that 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 shall be kept constant.