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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

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 14117:2012), which has been technically revised.

The main changes compared to the previous edition are as follows:

— new definitions added for *interference mode* and *transient exposure*;

— the breakpoint between injected voltage testing and radiated testing reduced from 450 MHz to 385 MHz to account for new wireless services;

— modification and clarification of 4.4, temporary exposure to CW sources;

— new 4.10 concerning *transient exposure* to low-frequency magnetic field sources;

— recognition of multiple electrode leads such as those with IS-4 and DF-4 connectors;

— new 7.4 explicitly requiring separation distance warning when applicable;

— elimination of the table of emitters and frequencies from Annex B;

— addition of new informative Annex N describing generic nomenclature for multi-port, multi-electrode systems;

— addition of new informative Annex O to provide a sample test method for evaluation of transient exposure;

— overall language clarifications, corrections to minor use issues from edition 1, and updated rationale.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 (*pacemaker*s and *implantable cardioverter defibrillator*s, or *ICD*s) 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* functions.

Although these devices can deliver an additional therapy with respect to *pacemaker*s and *ICD* devices, most of their requirements concerning EM compatibility are similar so that, in most cases, the concepts that apply to *pacemaker*s also apply to *CRT-P* devices, and the appropriate way to test a *CRT-P* device is similar to the way *pacemaker*s 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 might encounter.

It is important that manufacturers of transmitters and any other equipment that produces EM fields (intentional or unintentional) understand that such equipment can interfere with the proper operation of active implantable cardiovascular devices.

It is important to understand that these interactions can occur despite the conformance of the device to this document 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.

See Annex M for rationale concerning the use of ICNIRP 1998 levels. See Annex M for rationale applicable to emitters above 10 MHz.

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.

An emitter with a fundamental carrier frequency up to 1 kHz has the potential to be sensed directly by the *pacemaker* or *ICD*. Also, higher-frequency carriers that have baseband modulation rates below 500 Hz and that have sufficient proximity and power might be sensed by the *pacemaker* or *ICD*.

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

This document addresses the EM compatibility of *pacemaker*s and *ICD*s up to 3 000 MHz and is divided in several subclauses.

a) 0 Hz ≤ f < 385 MHz

In the lower-frequency bands (<385 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 can increase the likelihood of interaction between the emitters and patients' *pacemaker*s and *ICD*s. A few examples:

— electronic article surveillance (EAS) systems;

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

— new wireless services 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;

— experimental use of transponders for traffic control;

— wireless charging systems for electric or hybrid vehicles.

b) 385 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 *pacemaker*s and *ICD*s 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 might now be exposed:

— smaller wireless phones;

— the introduction of digital technology;

— 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.

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 *pacemaker*s and *ICD*s.

For frequencies of 385 MHz ≤ f ≤ 3 000 MHz, this document 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.

c) f ≥ 3 000 MHz

This document does not require testing of devices above 3 GHz. The upper-frequency limit chosen for this document reflects consideration of the following factors:

— the types of radiators of frequencies above 3 GHz;

— the increased device protection afforded by the attenuation of the enclosure and body tissue at microwave frequencies;

— the expected performance of EMI control features that typically are implemented to meet the lower-frequency requirements of this document; and

— 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 *pacemaker*s and *ICD*s 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.

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

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

1 Scope

This document 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 in conjunction with transvenous lead systems.

NOTE This document was designed for pulse generators used with endocardial leads or epicardial leads. At the time of this edition, the authors recognized the emergence of technologies that do not use endocardial leads or epicardial leads for which adaptations of this part will be required. Such adaptations are left to the discretion of manufacturers incorporating these technologies.

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 ≤ f < 385 MHz;

— 385 MHz ≤ f ≤ 3 000 MHz

This document 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

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 14708-2:2019, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

ISO 14708-6:2019, *Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

3 Terms, definitions, symbols and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1:2014, ISO 14708-2:2019, ISO 14708-6:2019 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1.1
pacemaker
implantable pacemaker
active implantable medical device intended to treat bradyarrhythmias, comprising an implantable DUT and leads

[SOURCE: ISO 14708-2:2019, 3.3, modified — "DUT" substituted for "pulse generator", and the admitted term" implantable pacemaker" added.]

3.1.2
ICD
implantable cardioverter defibrillator
active implantable medical device comprising an implantable DUT and lead(s) that is intended to detect and correct tachycardias and fibrillation by application of cardioversion/defibrillation pulse(s) to the heart

[SOURCE: ISO 14708-6:2019, 3.2, modified — "DUT" substituted for "pulse generator".]

3.1.3
CRT-P
implantable cardiac resynchronization therapy pacing device
active implantable medical device intended to provide improved ventricular activation to optimize cardiac output, comprising an implantable DUT and leads

[SOURCE: ISO 14708-2:2019, 3.7, modified — "DUT" substituted for "pulse generator".]

3.1.4
CRT-D
implantable cardiac resynchronization therapy/defibrillator device
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

[SOURCE: ISO 14708-6:2019, 3.34, modified — "DUT" substituted for "pulse generator".]

3.1.5
inhibition generator
equipment that generates a simulated heart signal for devices within the scope of this document

3.1.6
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 to entry: These settings are intended for use without direct medical supervision.

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

Note 3 to entry: An AIMD can 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.

3.1.7
interference mode
where asynchronous pacing is delivered in response to detected interference

3.1.8
transient exposure
exposure of the implanted DUT and leads for a period of less than 15 seconds

Note 1 to entry: 15 seconds is considered to be a reasonably foreseeable maximum exposure duration for persons walking past a stationary emitter.

3.2 Acronyms and abbreviations

Table 1 shows acronyms and abbreviations used in this document.

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
CIED	Cardiac Implantable Electronic Device
CRT	cardiac resynchronization therapy
CRT-P	*implantable cardiac resynchronization therapy pacing device*
CRT-D	*implantable cardiac resynchronization therapy/defibrillator device*
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
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*
NOTE Throughout this document, DUT has been used to designate all devices within the scope of this document. When a certain test or requirement applies only to a specific type of device, that designation is used.	

Table 1 *(continued)*

Acronym or abbreviation	Description
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 document, DUT has been used to designate all devices within the scope of this document. 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 requirements for all devices

Implantable pacemakers, *ICDs* and CRT devices shall not create an unacceptable risk for patients 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.

In 4.2 through 4.9, connections between the DUT and a tissue-equivalent interface circuit are illustrated using generic DUT symbols with a layered stacking of connection points on the DUT to indicated additional lead ports. These drawings were initially created for simple unipolar or bipolar ports intended to connect to leads with either a single or, at most, two electrodes. With the advent of leads having more than two electrodes (e.g. IS-4 or DF-4), these interconnection drawings become considerably more complex. In addition, the number and combination of port types for a given DUT can vary widely between manufacturers. Therefore, the connection drawings, even as given, should be treated as guidance, and engineering judgement should be applied to determine the set of connections necessary for a given DUT and type of test. To assist users of this document, Annex N has been prepared which illustrates a generic DUT with a reasonable worst case number of ports and electrodes. Annex N further discusses how such a complex DUT should be treated with respect to interconnection to an appropriate tissue-equivalent interface.

In 4.2 through 4.5, the test procedures specify the optional use of a coupling capacitor C_x. If this capacitor is used to demonstrate compliance with the requirements of the related subclause, then the value of C_x can be determined according to the method described in Annex E.

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. Physiologic sensors should be considered as part of the risk assessment required by 5.5 of ISO 14708-1:2014.

The tests outlined in this document 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.

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 *pacemaker*s and *CRT-P* devices: those sensitivity settings that the manufacturer specifies in the accompanying documentation as not meeting the requirements of 4.4 and 4.5.2.1.

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

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.

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 that use an automatic gain control function (or similar feature) for sensing purposes should include a detailed test method.

4.2 Induced lead current

4.2.1 General requirements

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 specified in Figure 2; the tissue-equivalent interface circuit specified in Figure D.1 and Table D.1a); the low-pass filter specified in 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).

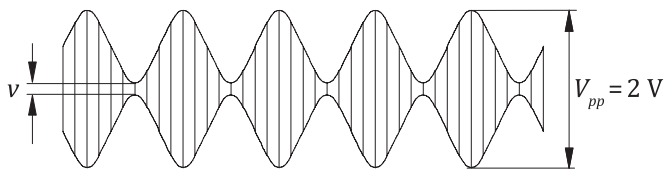
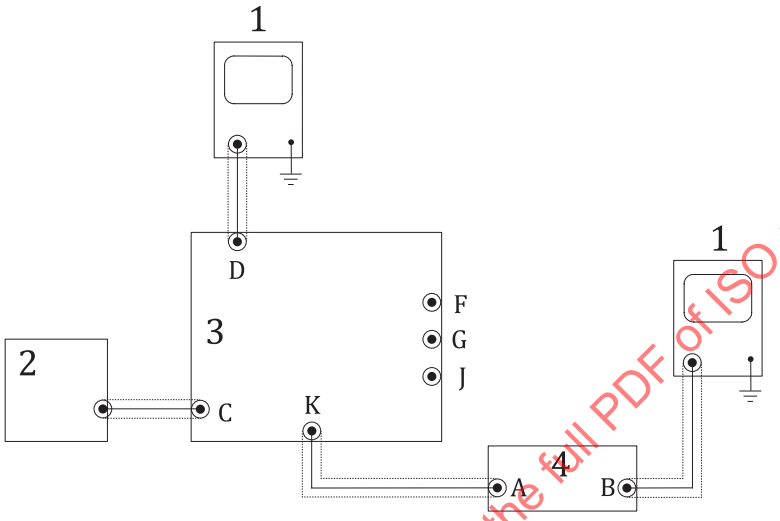


Figure 1 — Test signal 2

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

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

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.



Key

1 oscilloscope
2 test signal generator
3 tissue equivalent interface
4 filter

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 specified 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).

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 $R \geq 10\ k\Omega$, 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.

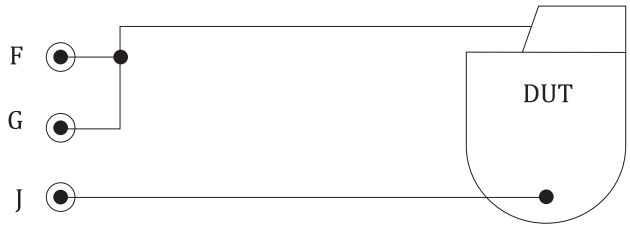


Figure 3 — Connection to a single-channel unipolar device

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.

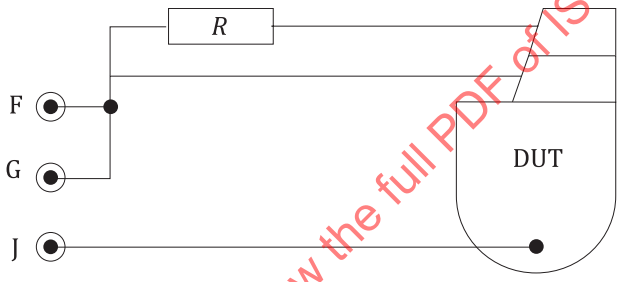


Figure 4 — Connection to a multichannel unipolar device

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.

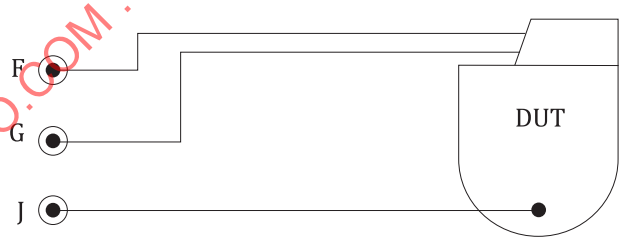


Figure 5 — Common mode connection to single-channel bipolar device

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.

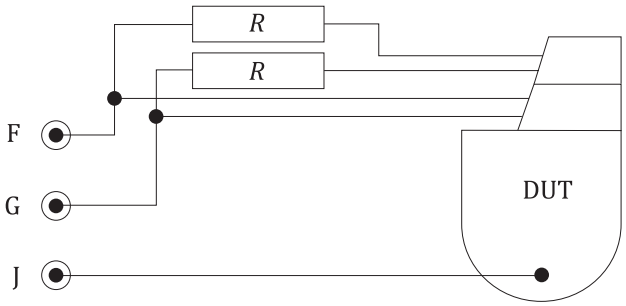


Figure 7 — Common mode connection to multichannel bipolar device

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).

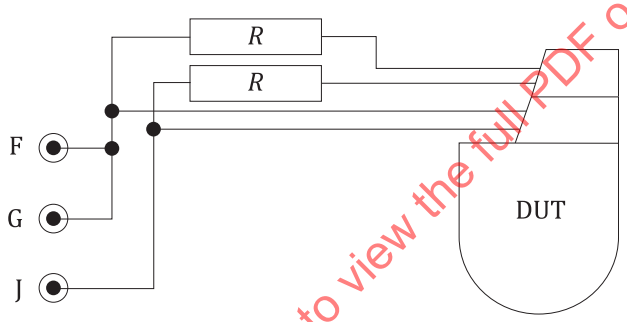


Figure 8 — Differential mode connection to multichannel bipolar device

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 shall be taken at test point B (filter output) using either an oscilloscope that has rms measurement capabilities, or a true rms voltmeter. The measurement shall be divided by 82 Ω to arrive at a value for current.

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 ≤ ƒ ≤ 1 kHz	50 µA
1 kHz ≤ ƒ ≤ 20 kHz	50 µA × (f/1 kHz)

4.2.3 *ICDs* and *CRT-D* devices

4.2.3.1 Test requirements

Test equipment: Use the test setup specified in Figure 2; the tissue-equivalent interface circuit specified in Figure D.1 and in either Table D.1a) or Table D.1b); the low-pass filter specified 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.

Care should 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

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

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 monitoring 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).

Current measurement is not required 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 can 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 specified in Figure D.1 and Table D.1a). If the DUT offers multichannel sensing/pacing, then every input or output of the DUT 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.

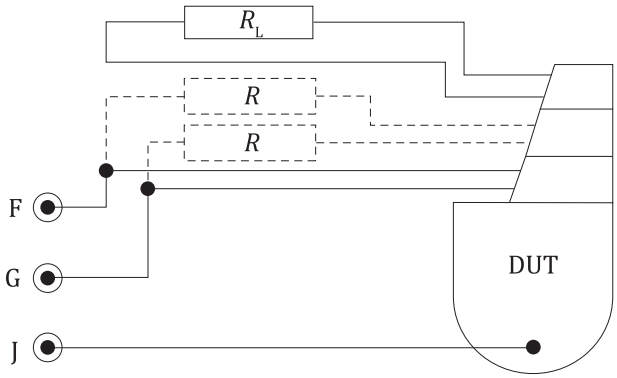


Figure 9 — Common mode connection to multichannel bipolar device

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).

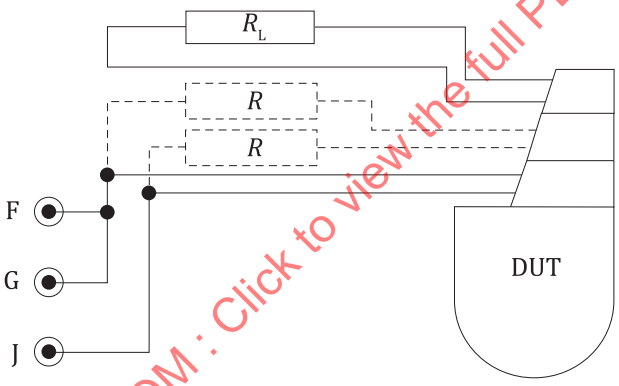


Figure 10 — Differential mode connection to multichannel bipolar device

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 shall be taken at test point B (filter output) using either an oscilloscope that has rms measurement capabilities, or a true rms voltmeter. The measurement shall be divided by 82 Ω to arrive at a value for current. .

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 specified 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 DUT has more than two cardioversion/defibrillation terminals, the terminals not being tested shall be connected to one of the terminals under test through a resistor R ≥ 10 kΩ as specified by the manufacturer.

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.

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

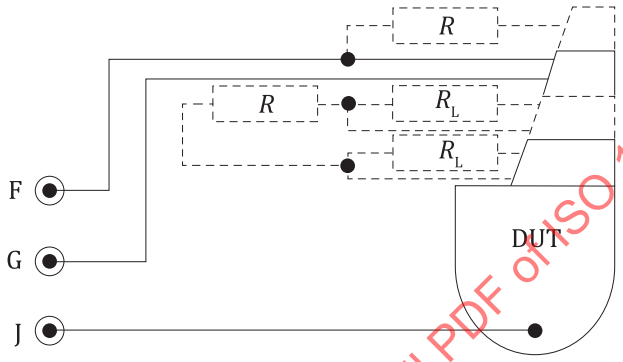


Figure 11 — Common mode connection for cardioversion/defibrillation terminals

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).

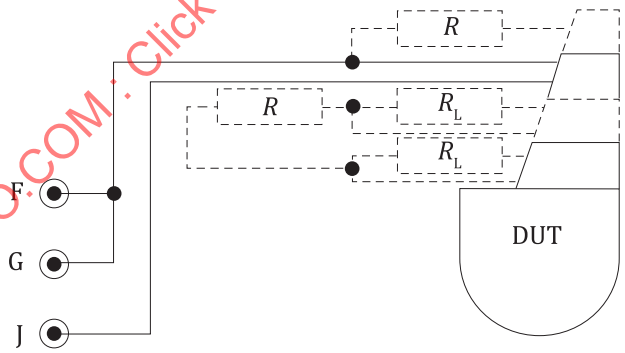


Figure 12 — Differential mode connection for cardioversion/defibrillation terminals

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 shall be taken at test point B (filter output) using either an oscilloscope that has rms measurement capabilities, or a true rms voltmeter. The measurement shall be divided by 47 Ω to arrive at a value for current..

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/1 kHz)

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/1 kHz)

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.

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 specified by Figure D.2; two oscilloscopes, input impedance nominal 1 MΩ; and a test signal generator, output impedance 50 Ω.

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.

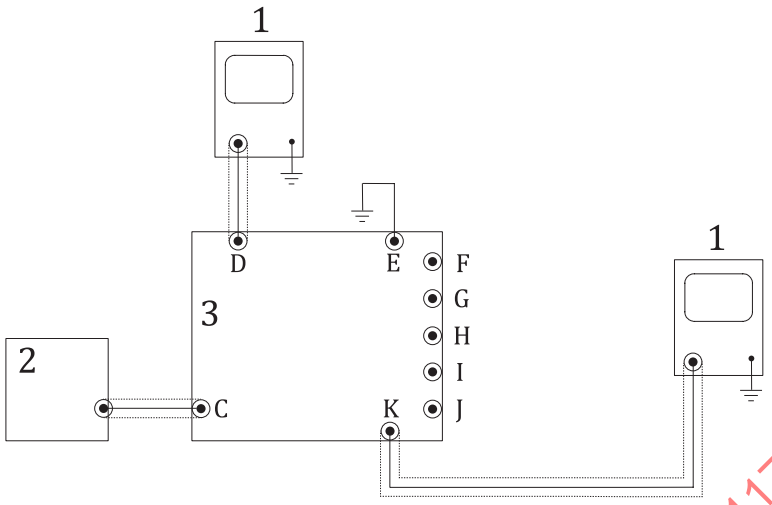
The test signal amplitude for unipolar and common mode test shall be as shown in Table 4.

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	1 V × (f / 20 kHz)
140 kHz ≤ f ≤ 10 000 kHz	7 V × (f / 140 kHz)$^{0,162\,4}$

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

Test procedure: The test signal generator shall be connected through input C of the interface circuit (as specified 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.



Key

1 oscilloscope
2 test signal generator
3 tissue equivalent interface

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).

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.

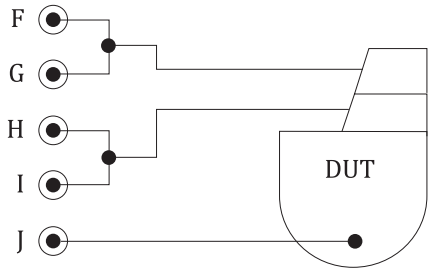


Figure 15 — Connection to a multichannel unipolar device

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).

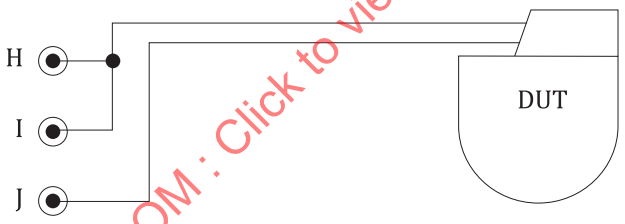


Figure 17 — Differential mode connection to a single-channel bipolar device

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.

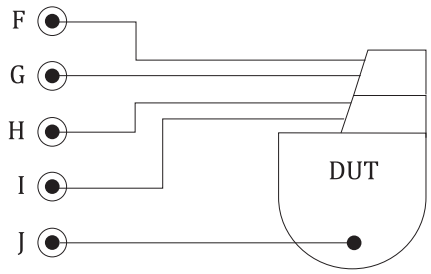


Figure 18 — Common mode connection to a multichannel bipolar device

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 $R \geq 10$ kΩ as specified by the manufacturer.

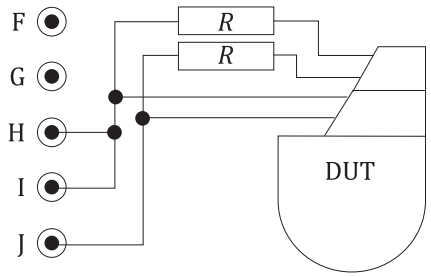


Figure 19 — Differential mode connection to a multichannel bipolar device

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 385 MHz

Test equipment: Use the test setup shown in Figure 21; the injection network specified by Figure D.5; an oscilloscope (#1), input impedance 50 Ω, accuracy of ±10 % within a bandwidth of at least 385 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.

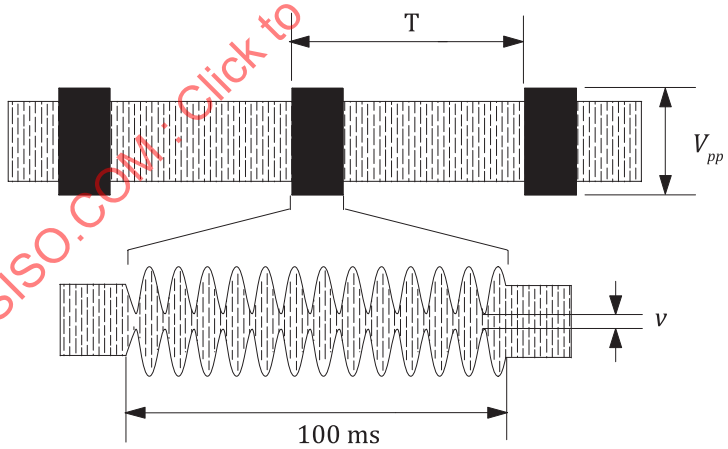


Figure 20 — Test signal for frequencies between 10 MHz and 385 MHz

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:

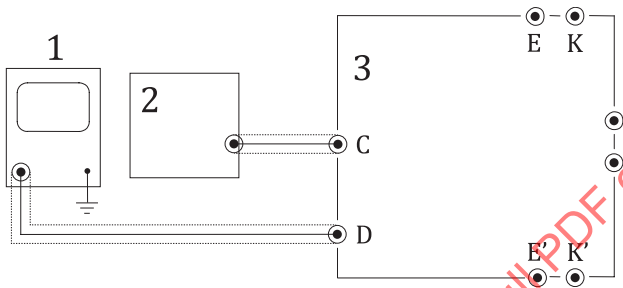
$$M = \frac{V_{\mathrm{pp}} - v}{V_{\mathrm{pp}} + v} \times 100$$

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 385 MHz (e.g. 10, 20, 40, 60, 80, 100, 200, 385), 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 If an rms voltmeter is used during calibration procedure and testing at monitoring point D, then the test value is 53 % of the calibration value, to provide a nominal modulated test amplitude of 14 V_{pp} (open circuit) at outputs F and G.



Key

1 oscilloscope
2 test signal generator
3 injection network

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).

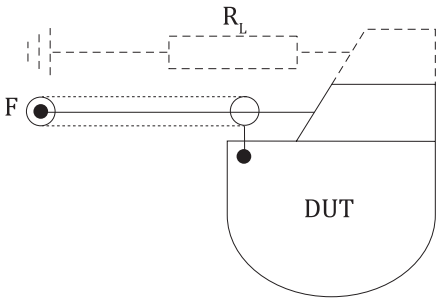


Figure 22 — Connection to a unipolar device

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).

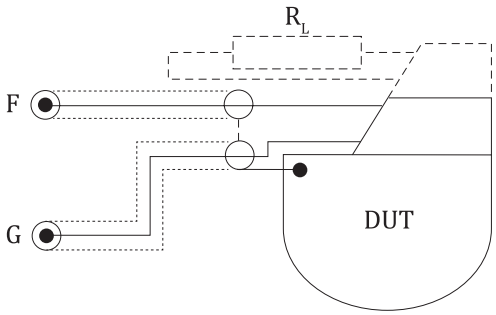


Figure 23 — Connection to a bipolar device

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 385 MHz to 3 000 MHz

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

The test levels specified in 4.9.3.2 are mandatory for this subclause.

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 as specified in Annex D, Figure D.2 and Figure D.3; two oscilloscopes, input impedance nominal 1 MΩ, <30 pF. 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	1 V × (f / 20 kHz)
140 kHz ≤ f ≤ 10 000 kHz	7 V × (f / 140 kHz)$^{0,162\,4}$

Differential mode performance shall be tested using the test signal reduced to one-tenth 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 can 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 specified 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 DUT 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.

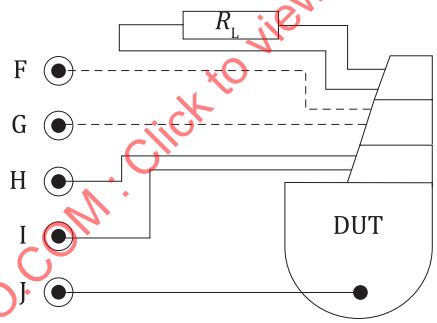


Figure 24 — Common mode connection for multichannel bipolar devices

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).

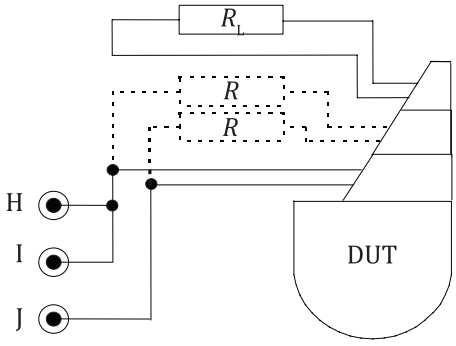
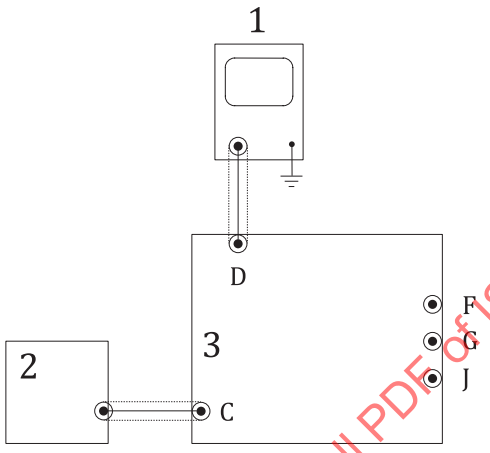


Figure 25 — Differential mode connection for multichannel bipolar devices

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 specified 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.



Key

1 oscilloscope
2 test signal generator
3 tissue equivalent interface

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 connected to one of the terminals under test through a resistor $R \geq 10$ kΩ as specified by the manufacturer.

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.

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

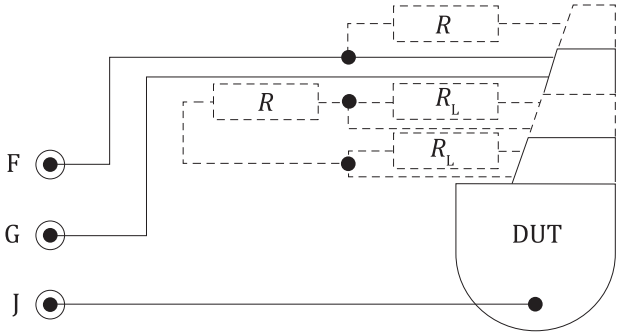


Figure 27 — Common mode connection for cardioversion/defibrillation terminals

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).

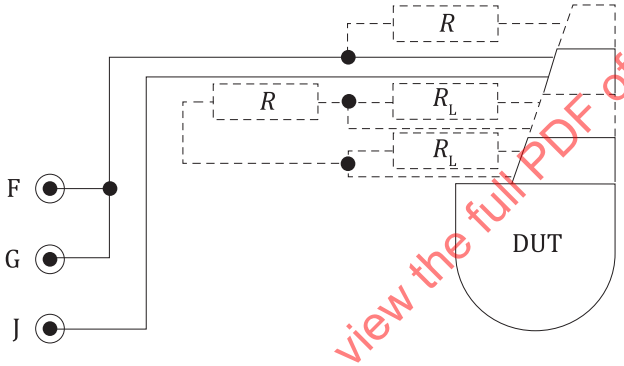


Figure 28 — Differential mode connection for cardioversion/defibrillation terminals

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 385 MHz

4.3.3.2.1 Test equipment and signal

Test equipment: Use the test setup as shown in Figure 30, using the injection network specified by Figure D.5; an oscilloscope (#1), input impedance 50 Ω, accuracy of ±10 % within a bandwidth of at least 385 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 edge to leading edge (see Figure 29). The burst-to-burst interval, *T*, of the modulated signal shall be set to 700 ms ± 50 ms.

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.

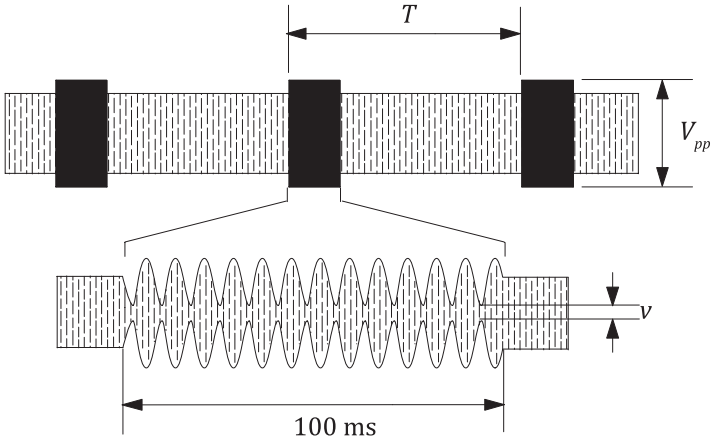


Figure 29 — Test signal for frequencies between 10 MHz and 385 MHz

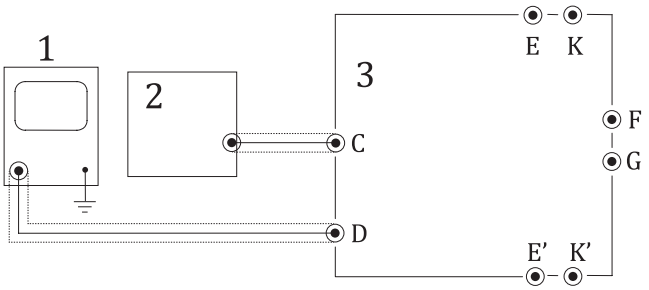
The modulation bursts shall start and terminate at zero crossings of the modulation signal, thus the envelope starts and terminates continuously. The burst count is 13 complete modulation cycles. The modulation index, M, shall be 95 %, where:

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

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 385 MHz (i.e. 10, 20, 40, 60, 80, 100, 200, 385) with an evenly distributed dwell time of at least 60 s per decade.



Key

1 oscilloscope
2 test signal generator
3 injection network

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

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 50 Ω, 25 W resistors, R'_L as required by the HV therapy configuration.

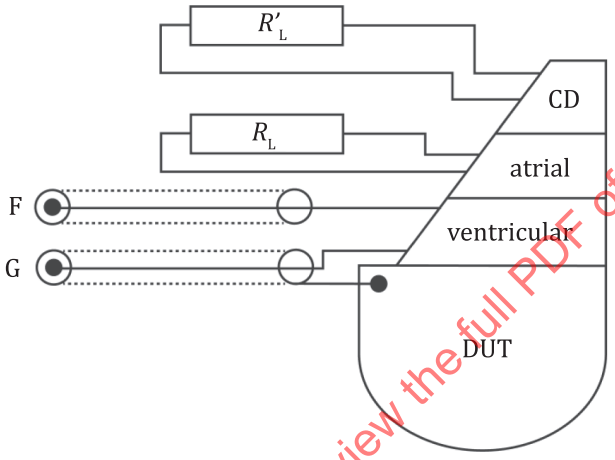


Figure 31 — Connection of the DUT

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 interference in the frequency range of 385 MHz to 3 000 MHz

Test: the DUT shall be subjected to the test procedure of 4.9.3.2 “optional characterization” of this document (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 Protection from malfunction caused by temporary exposure to CW sources

4.4.1 *Pacemaker* and *CRT-P* device response to temporary continuous wave sources in the frequency range 16,6 Hz to 167 kHz

*Pacemaker*s 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.

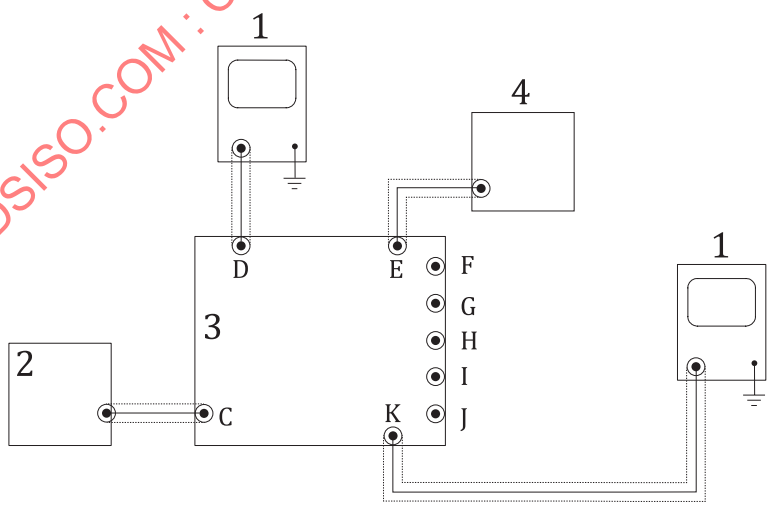
Test equipment: Use the tissue-equivalent interface circuit specified by Figure D.2 and two oscilloscopes, input impedance nominal 1 MΩ, <30 pF, The oscilloscope connected to test point D in Figure 32 shall have an accuracy of ±10 % within a bandwidth of at least 20 MHz; an inhibition signal generator, output impedance not greater than 1 kΩ that provides a simulated heart signal in the form specified 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. The total time during which the test signal amplitude is increased from zero to its maximum shall not be less than four preset intervals. At the conclusion of testing at each frequency, the test signal amplitude shall be returned to zero.

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

The test frequencies of 16,6 Hz, 50 Hz, 60 Hz and 100 Hz shall 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.



Key

1 oscilloscope
2 test signal generator
3 tissue equivalent interface
4 inhibition generator

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

Devices might 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.

When it is possible to distinguish between the uninfluenced and *interference mode* of operation the test shall be performed with the DUT in the pacing mode. If testing is performed in pacing mode, the test point E of the interface shall be connected to the signal ground (as shown in Figure 13).

When it is not possible to distinguish between the uninfluenced and *interference mode* of operation the test shall be performed with the DUT in synchronized mode. 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.

If tests are performed in DDD mode, then only tests of ventricular pacing need to be performed.

Testing in both AAI and VVI mode in lieu of DDD mode is allowed.

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 $R \geq 10\ k\Omega$, as shown or specified by the manufacturer.

Compliance shall be confirmed when:

a) either 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 DUT transitions from its set mode to its *interference mode* when the test signal amplitude is increased by no more than 6 dB, or;

   if while increasing the test signal amplitude the DUT transitions from its set mode to its *interference mode*, the time between either

   — delivery of a pacing pulse, or

   — inhibition of pacing due to sensing of the simulated heart signal,

   is no more than two preset intervals.

If the test signal amplitude required to enter *interference mode* exceeds the maximum required test amplitude (1 Volt for bipolar common mode/unipolar mode; 0,1 Volt for bipolar differential mode), then the transition to *interference mode* does not need to be verified; and

when the test signal amplitude is returned to zero, the device shall return to its set mode, and during this transition, the time interval between either delivery of a pacing pulse, or inhibition of pacing due to sensing of the simulated heart signal, is no more than two pre-set intervals.

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 *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.

4.4.2 *ICD*s and *CRT-D* devices

The manufacturer shall characterize the performance of *ICD*s 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.

NOTE *Interference mode* is intended for short-term operation for periods of seconds and is not intended for routine long-term operation. Such short-term operation is recognized as being clinically acceptable, with the risk of adverse events increasing with time of exposure.

Test equipment: Use the tissue-equivalent interface circuit specified 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 specified 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).

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

The test frequencies of 16,6 Hz, 50 Hz, 60 Hz and 100 Hz shall 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.

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 specified in this subclause shall be prepared.

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

4.5 Protection from sensing EMI as cardiac signals

4.5.1 General requirements

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 might allow for a number of fixed sensitivity settings. Where both unipolar and bipolar sensing are available, both modes should be tested. 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 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 specified by Figure D.2; two oscilloscopes, input impedance nominal 1 MΩ, <30 pF. 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 specified 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.

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

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

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-equivalent 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 specified by Table 6.

Table 6 — 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)

Bipolar differential mode performance shall be tested using test signal reduced to one-tenth amplitude of the common mode test.

Test signal 2 modulation: 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 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.

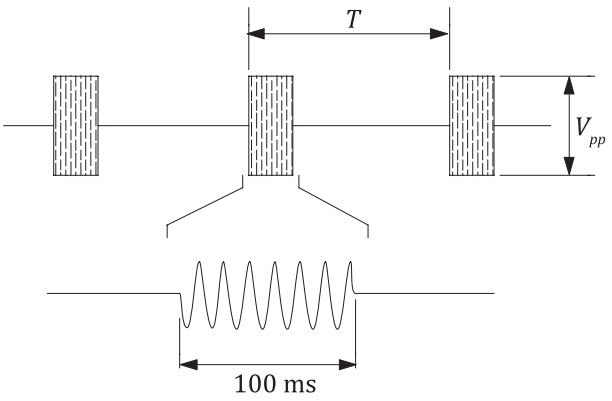


Figure 33 — Test signal 2: Used in the range of 1 kHz to 150 kHz

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-equivalent interface.)

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

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

If the DUT is a multichannel device, it should 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 a 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 specified by Figure D.2; two oscilloscopes, input impedance nominal 1 MΩ, <30 pF. 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 specified 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 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.

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

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

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-equivalent interface. The amplitude of the test signal, V_{pp}, shall be a function of the carrier frequency, *f*, as specified 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.

Test signal 2 modulation: 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 34). The burst shall start and terminate at zero crossings of the carrier, and only complete carrier cycles shall be used (true gated signal).

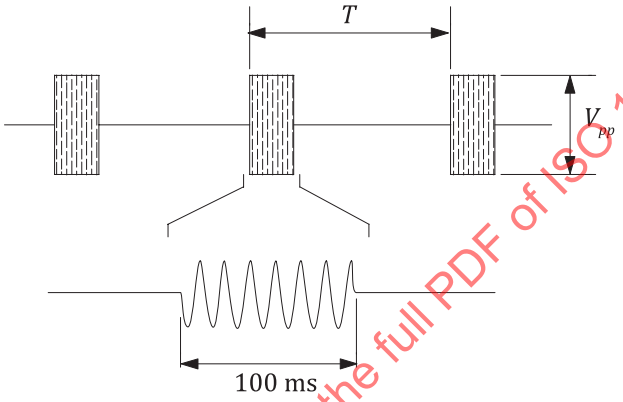


Figure 34 — Test signal 2: Used in the range of 1 kHz to 150 kHz

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-equivalent 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 ± 25 ms.

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

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

NOTE 2 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.

Since the DUT might require that it detect several consecutive input signals before therapy is initiated, sufficient time should 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 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).

   If the DUT is a multichannel device, it should be programmed to minimize the occurrence of possible cross-talk between 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 DUT 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 DUT 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 specified in 4.5.2.1 of this document.

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 35).

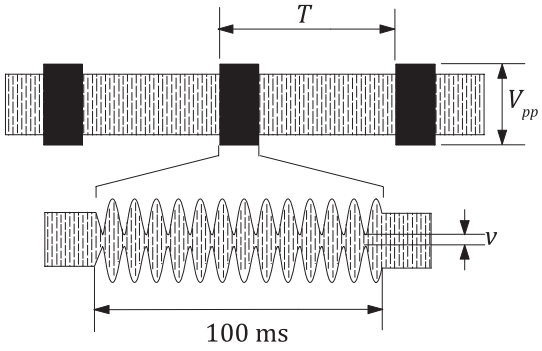


Figure 35 — Test signal for frequencies 150 kHz to 10 MHz

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:

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

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-equivalent 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 specified 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 one-tenth 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-equivalent 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 specified 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 one-tenth 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 36).

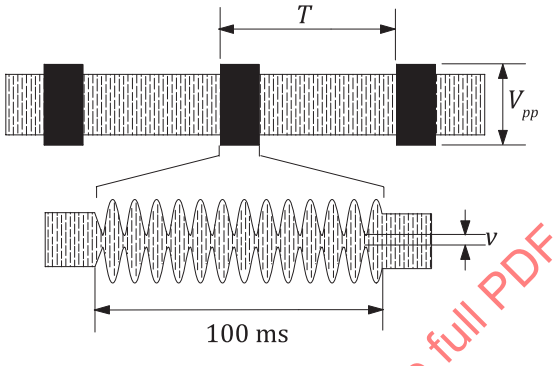


Figure 36 — Test signal for frequencies 150 kHz to 10 MHz

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:

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

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 might 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 *DUT* 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 *DUT* 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 385 MHz

4.5.4.1 *Pacemakers* and *CRT-P* devices

Test equipment: use the injection network specified by Figure D.5; an oscilloscope (#1), input impedance 50 Ω, accuracy of ±10 % within a bandwidth of at least 385 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 specified by J1; and a test signal generator, output impedance 50 Ω.

Test signal: the test signal shall be a modulated signal of the form specified by 4.5.3.1 (see Figure 36). The modulated test signal shall be applied at a minimum of six distinct, well-spaced frequencies per

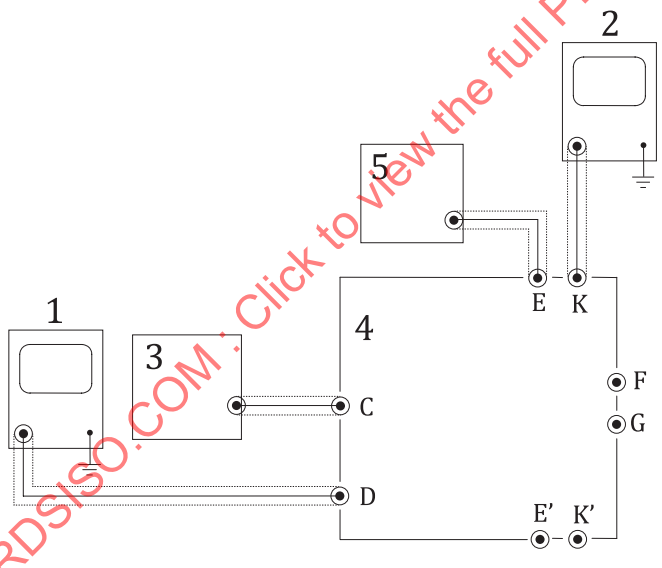
decade, beginning at 10 MHz and ending at 385 MHz (e.g. 10, 20, 40, 60, 80, 100, 200, 385), with an evenly distributed dwell time of at least 60 s per decade. The amplitude of the test signal (V_{pp}) is defined as the peak-to-peak amplitude of the open-circuit voltage driving the outputs (F, G) of the injection network. The amplitude of the test signal, V_{pp}, shall be 10 V.

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 37 . 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.



Key

1 oscilloscope #1
2 oscilloscope #2
3 test signal generator
4 injection network
5 inhibition generator

Figure 37 — 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 38), 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).

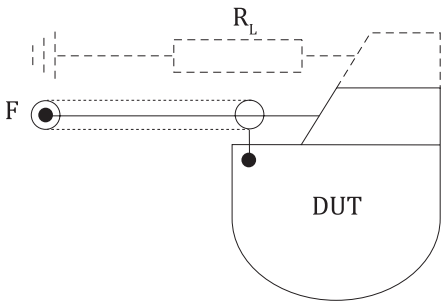


Figure 38 — Connection to a unipolar device

Bipolar devices shall be connected to outputs F and G of the injection network (as shown in Figure 39), 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).

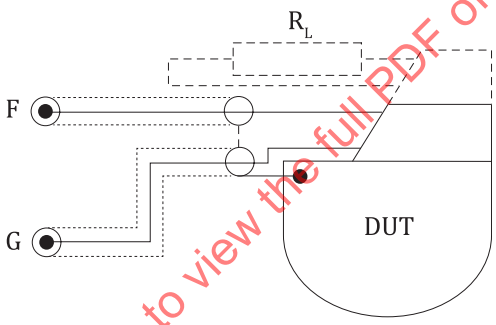


Figure 39 — Connection to a bipolar device

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

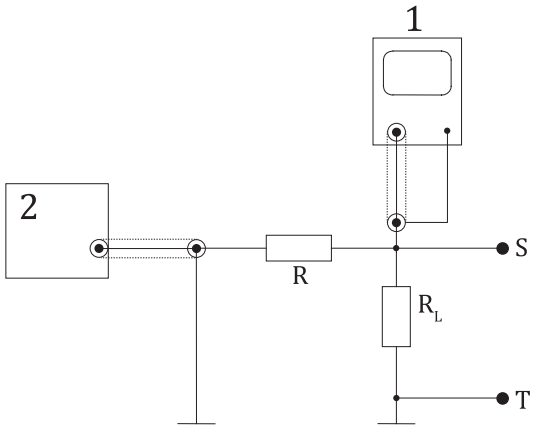
4.6.1 General requirements

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 specified 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 40), 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).



Key

1 oscilloscope

2 test signal generator

Figure 40 — 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.

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 requirements

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 requirements

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

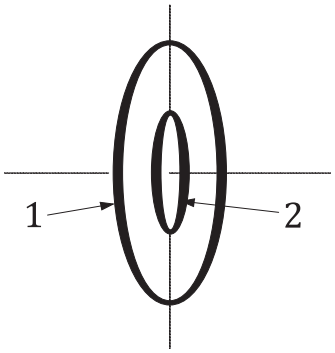
Test equipment: use a radiating coil (for example a Helmholtz coil), diameter ≥12 cm and exceeding the largest linear dimension of the DUT by 50 %, and a calibration coil, diameter ≤4 cm. The radiating coil shall be energized by a signal generator.

Test field: the test magnetic field, H, shall be modulated at a frequency, *f*, as specified 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 41). Remove the calibration coil.



Key

1 radiating loop

2 field monitoring loop

Figure 41 — 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 385 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 lead and bipolar lead systems when appropriate;

— *ICD*s 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 document 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 can affect the repeatability of this test.

4.9.2.2 Torso simulator in Annex G

The torso simulator shall be constructed as specified 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 equivalent to 0,266 7 S/m 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 specified in Annex H.

b) Test frequencies and modulation: the carrier signal shall be a sinusoidal waveform at each of the following frequencies: 385 MHz, 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 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 specified 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. 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.

NOTE In this document, 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 Protection from proximity fields at 15 cm separation distance

NOTE The requirements of this subclause may be met by meeting the requirements of 4.9.3.2.

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 385 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 385 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 in Annex K shall be used.

   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* 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 might 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 385 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 385 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 (*pacemaker*s and *CRT-P* devices) — minimum of 5 s;

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

Exposure duration might 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 385 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 385 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.

If the manufacturer chooses to perform this test and the DUT meets the conformity criteria given in 4.9.4, testing in accordance with 4.9.3.1 is not required.

If the manufacturer chooses not to perform the optional characterization testing or the DUT fails to meet any of the applicable performance criteria of 4.9.4, then the *manufacturer* shall provide a warning in accordance with 7.4.

For optional DUT characterization, net dipole power is set to 8 W rms for the frequency range 385 MHz ≤ f < 1 000 MHz and to 2 W rms (CW) for the frequency range 1 000 MHz ≤ f ≤ 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.

4.10 Transient exposure to stationary low-frequency electromagnetic field sources in the frequency range 16,6 Hz to 167 kHz

The manufacturer shall evaluate *transient exposure* to stationary low-frequency electromagnetic field sources through the risk management process. Risks shall be identified and evaluated, taking into account the electromagnetic environment in which the active implantable cardiovascular device is intended to be used. Each risk shall be evaluated through an analysis that takes into account applicable risk controls and potential effects on therapeutic function. The manufacturer shall determine the necessity for test studies based upon their risk management process. At the discretion of the manufacturer, Annex O can be used to guide test studies. Compliance is checked by inspection of the risk management file.

NOTE Annex O is considered to be an example test method, and is not required for compliance with this clause.

5 Testing above frequency of 3 000 MHz

This document 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 document, 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 might 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 document.

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

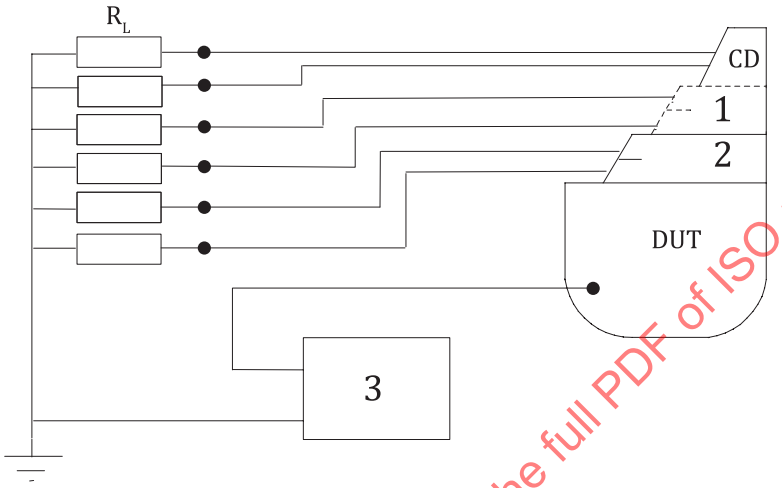
6.1.1 General requirements

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.

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 42). The case of the DUT shall be connected directly to the signal generator output, unless the case is covered with an insulating material.



Key

1 atrial
2 ventricular
3 test signal generator

Figure 42 — 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 Ω. 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 requirements

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.

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 47 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 43, 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}).

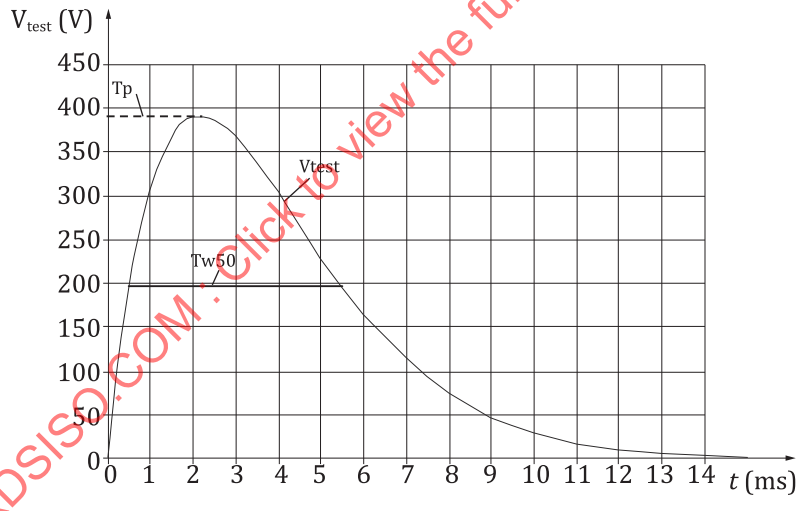
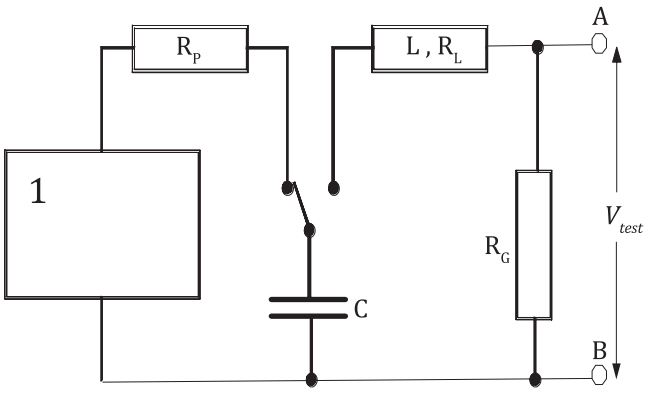


Figure 43 — Damped sinus waveform

Figure 44 illustrates an example schematic with C = 330 µF ± 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 inductor (in ohms) and R_G is the output resistance (in ohms) of the defibrillation test voltage generator.



Key

1 voltage generator

Figure 44 — 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 47 (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 47).

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 45).

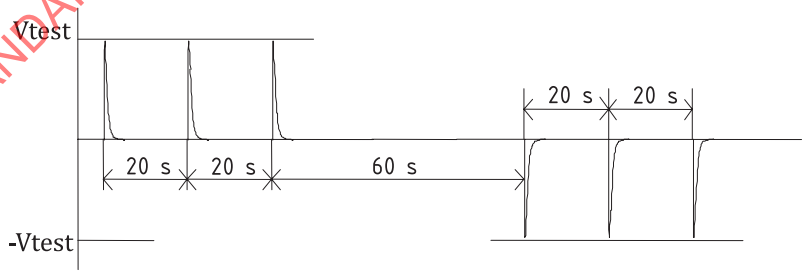


Figure 45 — Timing sequence used in Tests 1 and 2

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 46 with C = (150 ± 50) µF and two sets of coupled switches, S1 and S2, and the resistive network in Figure 47 using the parameters specified in Table 13, Test 2.

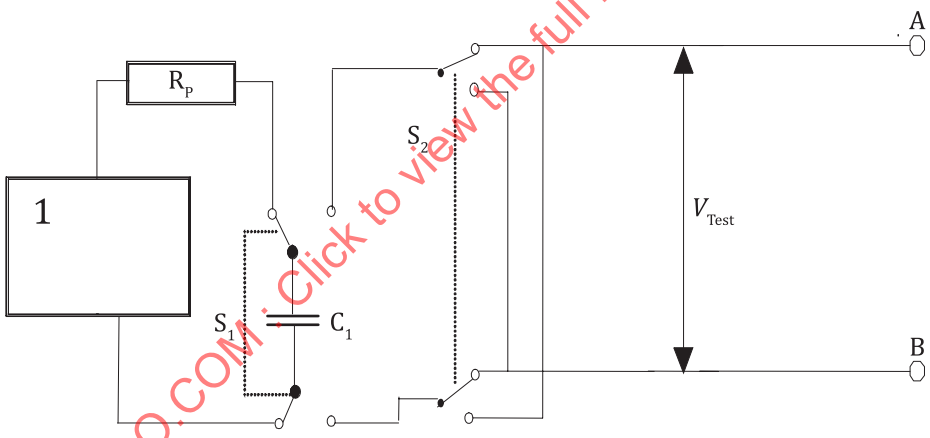
Test signals: A monophasic, truncated exponential waveform with duration of *Td* = (10 ± 0,5) ms will be generated between outputs A and B, activating coupled switches S1 for a time period *Td*; the waveform will have an exponential decay with a nominal time constant of 9,75 ms [based on the above capacitance 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 48 with the following parameters: 1 µs < t_r < 5 µs; t_c ≤ 2 ms; 1 µs < t_f < 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 48.



Key

1 voltage generator

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

Figure 46 — Test setup for Test 2 (using a truncated exponential defibrillation waveform)

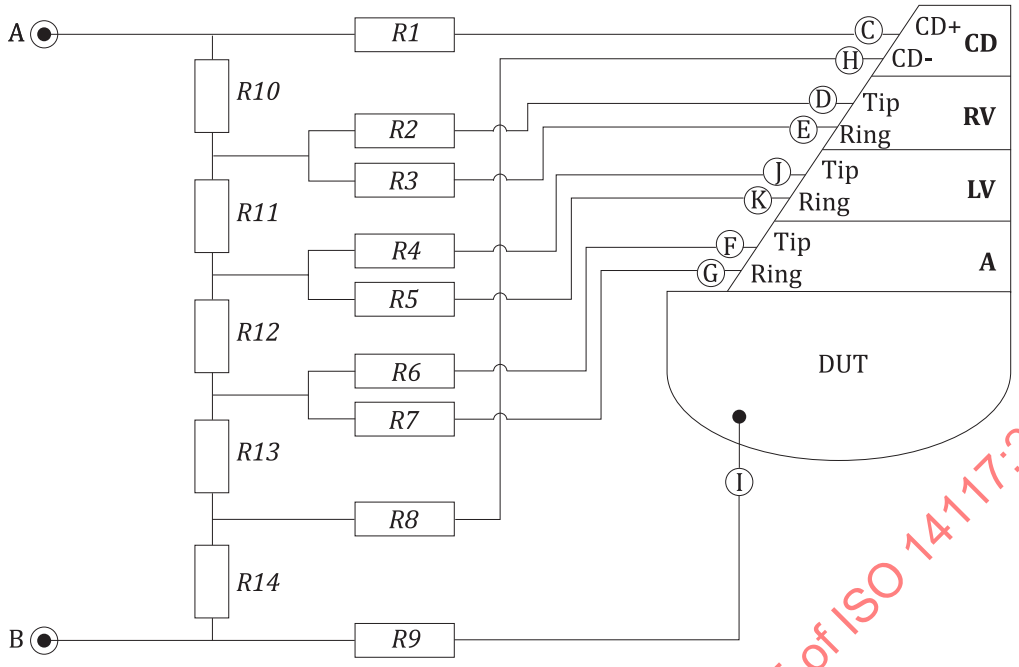


Figure 47 — Resistor network for Tests 1 and 2

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 R14 will be 25 W.														

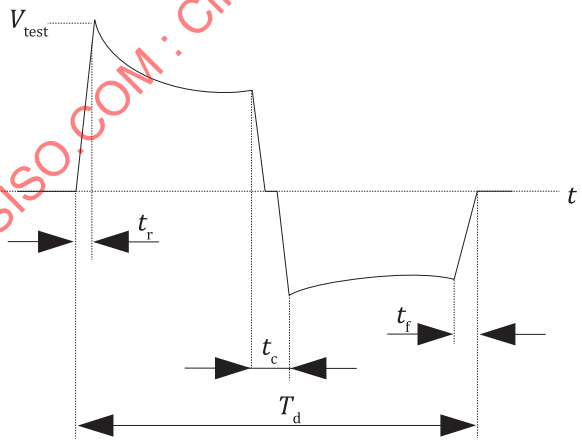


Figure 48 — Biphasic defibrillation waveform for Test 2

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 47, 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 warning indicating that their use might 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.

7.4 Minimum separation distance from hand-held transmitters

The accompanying documentation for the DUT shall include a warning to maintain a minimum separation distance of 15 cm (6 in) between the hand-held transmitter and the implanted device as a result of not demonstrating conformance to the optional characterization test of 4.9.3.2.

Compliance shall be confirmed by inspection.

Annex A
(informative)

Rationale

A.1 Rationale for test requirements for the frequency band 0 Hz ≤ f < 385 MHz (see 4.1 to 4.8)

Exposure of the DUT to an electromagnetic field can

— 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 can be activated by magnetic fields. The magnetic control component or other circuit components of the DUT can 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.

This document does not address the following exposure scenarios:

— Exposure to therapeutic and diagnostic treatments (with the exception of external defibrillation and electrosurgery) Hence, the device manufacturer might need to be consulted in case of uncertainty relating to specific treatments.

— EM fields that occur in some occupational environments. Within the European Union, occupational exposure to EM fields is governed by the EMF Directive[29] 2013/35/EU. Under this directive, CENELEC TC106x/WG15 developed a standard[30] for the assessment of risk to workers bearing an AIMD in general, as well as one for those implanted with *pacemaker* / *CRT-P* devices[31]. A similar standard covering patients implanted with *ICDs* or *CRT-D* devices is under development[32]. These standards specifically address exposure scenarios in occupational environments where EM field levels might exceed those expected within the general public environment.

— At frequencies below 385 MHz, voltages applied to or currents induced in any embedded telemetry antenna external to the EM shield of the DUT, unless such an antenna is an integral part of a lead. This includes the susceptibility of a medical implant's telemetry link to a physician's programmer, or other patient monitoring equipment, in the presence of external RF noise and interference. Note that medical implants typically communicate with external medical equipment using very low power radio frequency signals, or inductive coil telemetry methods, and there is the risk that the implant telemetry link can fail in the presence of external electrical noise. There are, however, other standards that include a requirement to demonstrate the implant can adequately perform this function, in the presence of external electrical noise, at levels typically encountered in hospitals, clinics, and patient's homes. Possible sources of interference include, but are not limited to, electrical motors, cell phones, wireless networks, hand-held portable radios used by police, fire, and medical personnel, etc. Electromagnetic compatibility (EMC) for medical implants are addressed in ETSI standards EN 301 489 -1/-27/-29/-31/-35[41]–[45]. These standards test radio frequency, and inductive coil, telemetry link susceptibility to external interference in the frequency range of 80 MHz to 6 000 MHz, at a level of 3 V/m. Since manufacturers typically test to these European Norms in order to demonstrate compliance to the applicable radio regulations, repeating such tests in ISO 14117 is unnecessary.

— 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. During preparation of this edition of the standard, consideration was given to the inclusion of specific tests for operation with physiologic sensors turned on. Due to the wide variety of sensors in use, and without standardized tests for these sensors, a decision was made to not include any testing requirements. Rather, such testing, if necessary, is left to each manufacturer as part of the risk assessment process required by the general standard.

— Exposure to the fields generated by Electronic Article Surveillance (EAS) systems operating at frequencies below 100 kHz. These systems are typically mounted on pedestals, or within floors or walls. Such systems are generally known to interfere with the devices covered by this document. As a result, a consensus-based test for continuous exposure to these emitters is not included in this edition of the standard. Such tests might be considered for subsequent editions of this document as emitter technology or device immunity evolves. Until this happens, patients with devices within the scope of this document are still advised to observe the "don't lean, don't linger" recommendations established by the US FDA[38].

— Exposure to the fields generated by RFID systems operating at frequencies up to 13,56 MHz[39][40][46].

— Wireless charging systems for vehicles and personal electronic devices. The working group is currently evaluating these technologies, and tests or exclusions for them will be considered in subsequent editions of this document.

— Human Body Communications systems, such as those based upon IEEE Std 802.15.6[33]. The working group has considered such systems currently under development but has not found sufficient information to enable determination of whether they represent an EMC threat. In July 2011, a related presentation titled "Active Implantable Medical Device Industry Concerns about Human Body Communication (HBC)"[34] was delivered to Task Group 6, IEEE 802.15.

— EM fields in current generation vehicle related to keyless entry systems, passenger occupancy, or electric drivetrain components used in hybrid or all electric systems.

Consideration for nominal test levels

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.

Considerations for warnings

In this document, 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 0,3 mV in a bipolar sense configuration setting, and more sensitive than 2,0 mV in a unipolar sense configuration setting. More sensitive settings than 0,3 mV (bipolar) and 2,0 mV (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 might 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.

Test Frequency spacing

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

Injected testing

EM fields can 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 385 MHz and by a near-field test of the DUT connected to its leads at frequencies above 385 MHz. The injected voltage tests use tissue-equivalent interfaces (between 16,6 Hz and 10 MHz) or an injection network (between 10 MHz and 385 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 can 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 (1999/519/EC), 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 can 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 *pacemaker*s and 232 cm^2 (typical) for *ICD*s, and the largest will not normally exceed 319 cm^2 (worst case); see Annex L for details.

The leads of multichannel unipolar *pacemaker*s can act as multiple antennae. Thus, each channel should be tested as if it were a single-channel device. This is considered sufficient since:

— There is sufficient margin in the test levels to accommodate the small amount of cross-talk expected in modern devices.

— Different ports are sensitive to interfering signals at different time points in the cardiac cycle, precluding the need for simultaneous injection.

— Injecting a signal into one port can lead to blanking of another port, masking any measured results; the interference signal is masked most of the time during the exposure if the signal would have been sent into all ports simultaneously.

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 (≤20 mm) of tip and ring electrodes, the applicable test signal is reduced to 10 % of the common mode test signal amplitude.

Selection of C_x During the development of this second edition of ISO 14117, investigations were undertaken to determine quantifiable criteria for the selection of capacitor C_x as described in Annex E and used in many of the tests. Manufacturers examined the range of C_x values required to sufficiently attenuate signal generation artefacts, as well as the specific artefact levels provided by their test signal generation equipment. It was found that the artefact levels are heavily affected by the age of the technology used and the state of the calibration of the equipment. The specific approach to producing

burst modulation was found to include gating by using one or more discrete generators, or by using direct waveform synthesis. The study also looked at the impact of C_x on the intended quality of the generated signal, especially with regards to possible corruption of the square pulse modulation envelope. Results indicated that over the entire range of practical C_x values (a few nF to several uF) there was no degradation of the modulation. For this reason, Annex E now only provides guidance on the choice of C_x, as it was the consensus of the working group that no specific procedure is necessary. In short, manufacturers can use any value of C_x that achieves the desired test voltage amplitudes for the carrier frequencies being tested.

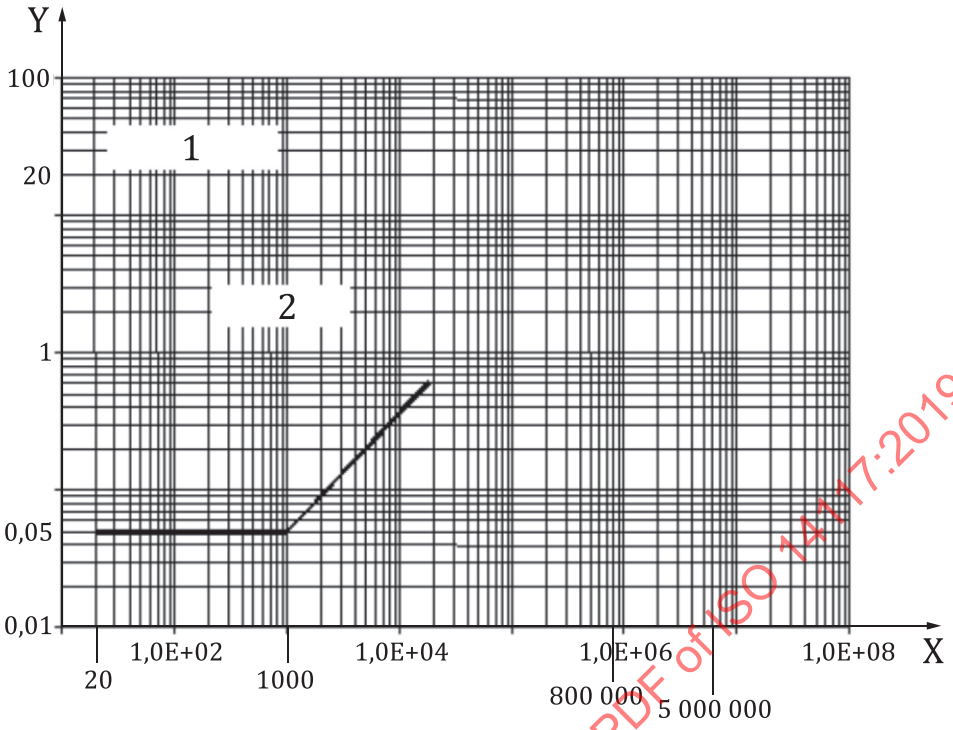
4.1: Because the tests of 4.2 to 4.8 might permanently change some electrical characteristics of the DUT, a final test against the manufacturer's electrical specifications is required.

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 can cause currents sufficient to cause fibrillation. In addition, direct therapeutic treatment also can induce currents that produce local tissue burns. If the therapeutic signals are modulated, demodulation in the circuitry of the DUT can 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.1 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.



Key

X frequency (Hz)

Y current (mA, Rms)

1 EMI - current

2 Fibrillation

Figure A.1 — Maximum allowed current when injected to the heart

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-equivalent interface provides two outlets for each channel.

If the channel under test is unipolar, both outlets of the tissue-equivalent 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-equivalent 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.

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 can 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 can be galvanically (conductively) coupled into the DUT by a patient touching some household device.

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 might start to sense the interference. As the signal amplitude is further increased, one or more changes in the therapeutic behaviour can 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 document, 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.

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 might be sensitive to some of these frequency components for good and useful reasons. DUTs usually have an *interference mode* to ensure that they provide pacing at a fixed rate 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 specified, 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 over-modulation 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 might 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 385 MHz, 4.5.4, replaces the tissue-equivalent interfaces used at lower frequencies by a 50 Ω injection network.

Above 385 MHz injected voltage tests are less appropriate, and a radiated near field test method is required. The objective of the near field test above 385 MHz is to approximate the exposure of portable transmitters in proximity to the DUT. These methods were developed prior to the publication of AAMI PC69:2000 to best approximate the exposure of portable transmitters, most notably, cellular telephones. Studies are ongoing (in 2016) at the US FDA to determine if the near field test above 385 MHz approximates the exposure of modern cellular telephones. Preliminary findings have revealed that the field strength delivered to the DUT from the near field test are greater (i.e. conservative) than the field strengths measured from modern cellular telephones.

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 provides a reasonable assurance of 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 provides a reasonable assurance of uninfluenced function of the DUT 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 will not be confused with heart beats.

The test also provides a reasonable assurance of 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*.

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 might be exposed to. An example is the magnetic strip used to seal refrigerator doors. Traditionally, this field limit has been set at 1 mT (10 gauss).

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.

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

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 might 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 14708-1:2014. 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 385 MHz ≤ f ≤ 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 document 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 multi-connector DUT is defined as the common reference point because this definition should encompass most devices. If a multi-connector 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 document 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 document.

A.2.3 Rationale for the optional characterization testing

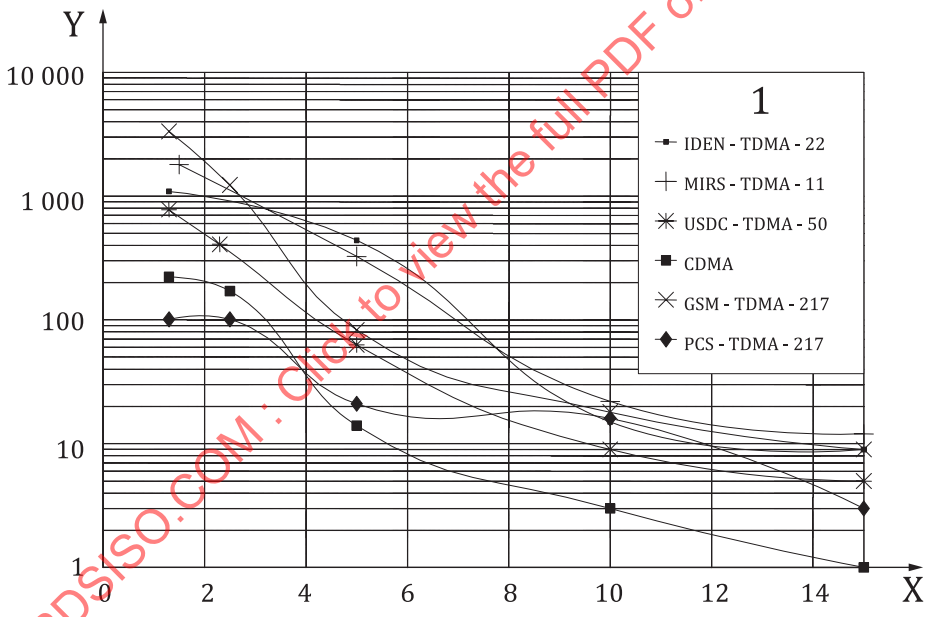
The 120 mW power level described in this document allows a high level of confidence that an implantable DUT will not be affected by EMI from a hand-held emitter at a distance of 15 cm. A manufacturer can perform the optional characterization tests to demonstrate immunity without regard to the separation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

A.2.4 Rationale for test power levels

The first edition of this document was based partly upon 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 as part of ANSI/AAMI PC69:2000, and is retained for the purpose of informing users of this document's evolution.

The dipole antenna power levels specified in ANSI/AAMI PC69:2000 were derived from measurements of RF signals coupled to an instrumented DUT can with leads installed. The chart in Figure A.2 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 cm, 10 cm, 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. 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*.



Key

X phone antenna-to-device spacing (cm)

Y dipole net power (milliwatts)

Figure A.2 — Dipole net power measurements (dipole spacing = 2,5 cm) conducted for ANSI/AAMI PC69:2000

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.

In the early 1990's GSM replaced analog and older digital technologies in the cellular (850 MHz) band and could transmit peak pulse powers in this lower band of 2 W. Although overall time-averaged transmit power levels might 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 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 this second edition of ISO 14117, consideration has been given to the rapid changes in RF technology and product diversity associated with handheld phones, RFID, and current generation network infrastructure. In collaboration with the IEC TC62/SC62A/MT23 (authors of the EMC standard for external medical electrical equipment, IEC 60601-1-2), the exposure values and exposure frequencies related to transmitting devices that might be in close proximity to a patient implanted with the devices within the scope of this document have been reassessed. The result of this assessment was to retain the exposure levels described below, but to extend the lower frequency limit for radiated electromagnetic compatibility testing to 385 MHz. This was done in recognition of the deployment of handheld radios now commonly used by first responder personnel in multiple geographies (e.g. the TETRA radio service). Test levels have not been changed, as there are no services currently known that would result in an exposure level greater than those anticipated at the time the radiated tests level in 4.9 were originally established.

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 385 MHz ≤ f < 1 000 MHz and 2 W in the frequency range 1 000 MHz ≤ f ≤ 3 000 MHz. These power levels were selected on the basis of the maximum power levels likely to be encountered from the portable and handheld radios and cellular telephones on the market at the time when AAMI PC69:2000 was written. 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 document 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 document. 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

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 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 specified in this document.

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 can 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 might 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 might 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 47 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]).

During the development of this second edition of ISO 14117, consideration was given to the energy reduction effects that could occur due to the presence of an implanted cardiac device. This effect could lead to the inability to achieve defibrillation using an external defibrillator. This effect is considered for external medical electrical equipment within the scope of IEC 60601-1. This issue was presented to clinicians (members of AAMI CRMD committee) and there was agreement that energy reduction was not an issue. Therefore, this topic is not considered within ISO 14117. Additionally, consideration was given as to the potential need to adjust the defibrillation test voltages of 6.2. The working group examined the current draft of IEC 60601-4-2, and found that there are no plans to increase available energy. Therefore, the test levels in ISO 14117 remain unchanged.

A.4.3 Test signal modulation format

The first edition of this document included two possible forms of pulse burst modulation for the tests up to 150 kHz. One of these consisted of a “square” burst of pulses which is representative of on-off keying for data communication, or that may originate from pulsed magnetic fields. The second modulation consisted of a modified pulse burst whose envelope was shaped. As the two modulations were similar, in this edition the second modulation was deleted as an option, and the first was retained as it was considered to be the more challenging to device behaviour of the two options.

Annex B
(informative)

Rationale for test frequency ranges

The table of emitters and associated frequencies of operation has been removed from this edition of the standard. The rapid pace at which new emitter technologies are being introduced onto the marketplace renders such a table obsolete by the time of its publication.

The tests in this document are performed in one of two ways:

— directly injecting into the device ports a simulated interfering signal, or

— exposing a device and its leads to a radiated EM field that simulates known or suspected emitters

Generally, the radiated tests are performed beginning at a frequency corresponding to the lowest known operational frequency for telecommunication devices operating above several hundred MHz. The demarcation frequency between injected testing and radiated testing in the first edition of this document was previously set to be 450 MHz, corresponding to earlier analogue phone services. In this second edition of the standard, the demarcation frequency was reduced to 385 MHz in recognition of a new class of mobile radio/phone services (e.g. TETRA) now in use worldwide. The field strengths anticipated during exposure of a device and its leads to these handheld emitters are sufficiently above those of the current injected testing strategy so as to warrant their inclusion in the radiated testing of 4.9.

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.

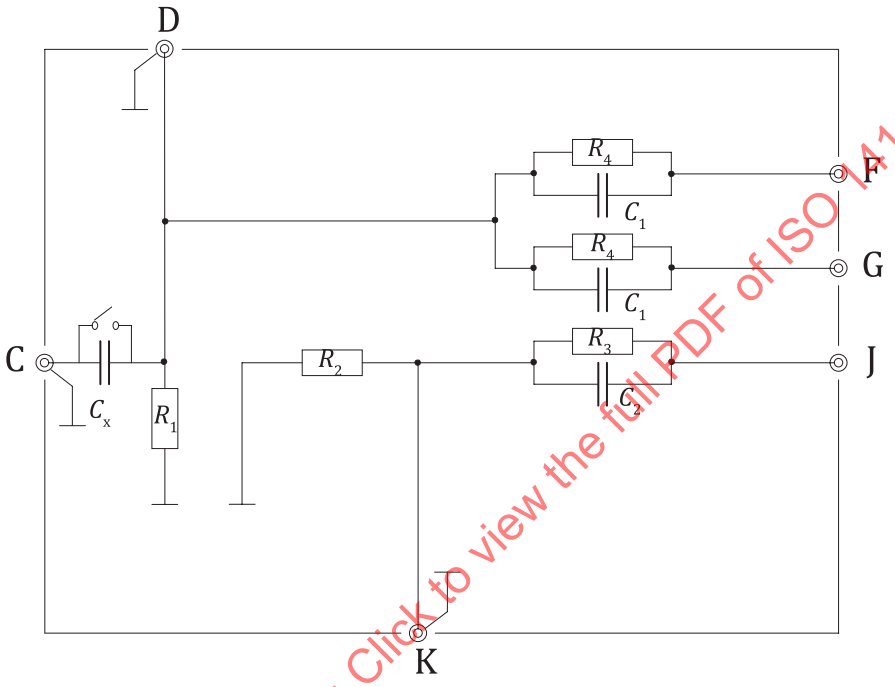
— Position III: Tachycardia detection — This position distinguishes devices that detect tachycardia by means of electrogram signal processing ("E") alone from those that sense one or more haemodynamic-related variables ("H") as well, such as blood pressure or transthoracic impedance. Position III is 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-equivalent interface in order to prevent electrical cross-talk within the circuit.



Key

C input (test signal)
D test point (test signal)
F output to DUT
G output to DUT
J output to DUT
K monitoring point

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

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

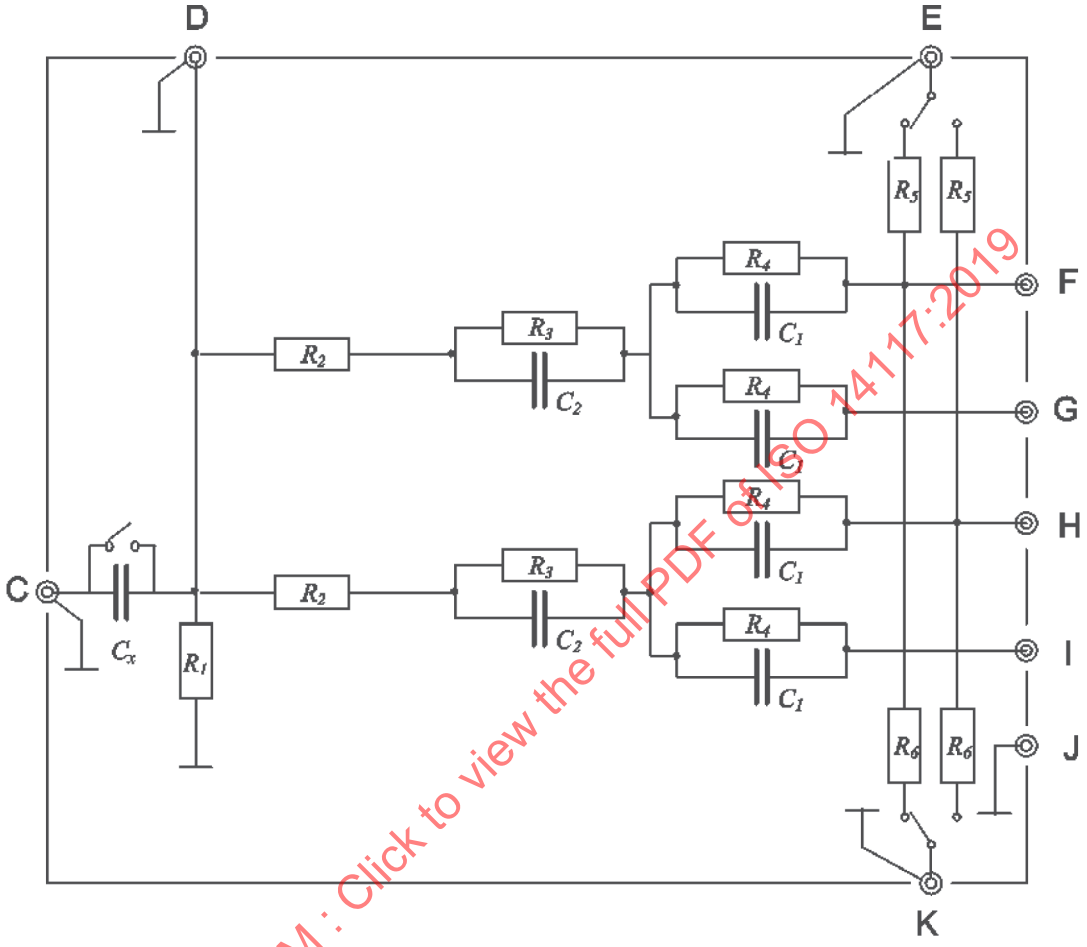
R_1 68 Ω (2 W)	C_1 15 nF
R_2 82 Ω (1 W)	C_2 180 pF
R_3 120 Ω	C_x Refer to Annex E
R_4 560 Ω	

Table D.1 b) — 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

Table D.1 *(continued)*

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*)
F output to DUT
G output to DUT
H output to DUT
I output to DUT
J signal ground
K monitoring point

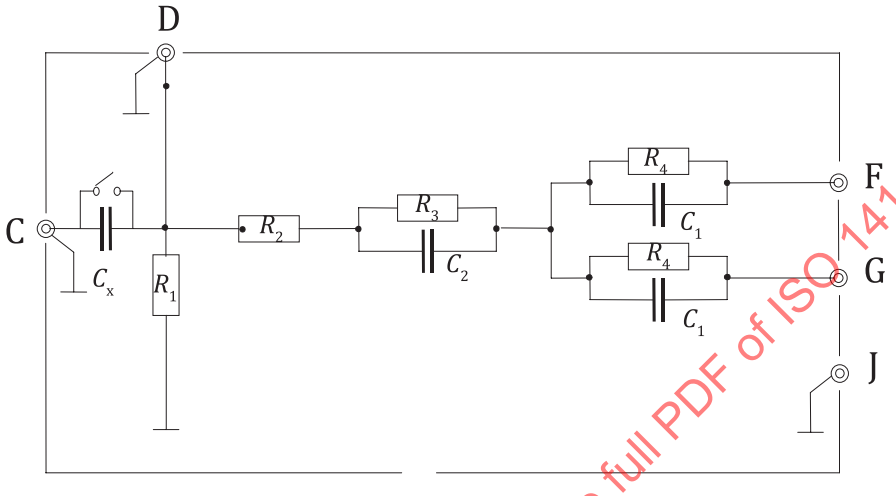
Figure D.2 — Tissue-equivalent interface circuit to check for malfunction

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 Figure D.2 to provide equivalent voltages and impedances for additional channels, as needed. See Table D.2.

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

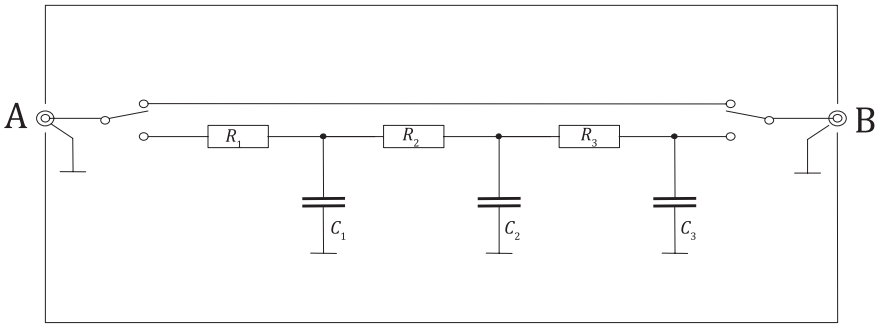
C input (test signal)
D test point (test signal)
F output to DUT
G output to DUT
J signal ground

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 (see 4.2.2, 4.2.3, and Annex E)

The low-pass filter shown in Figure D.4 is an example implementation using discrete elements (see also Table D.4). The manufacturer may implement this filter using alternative approaches as long as the following constraints are met:

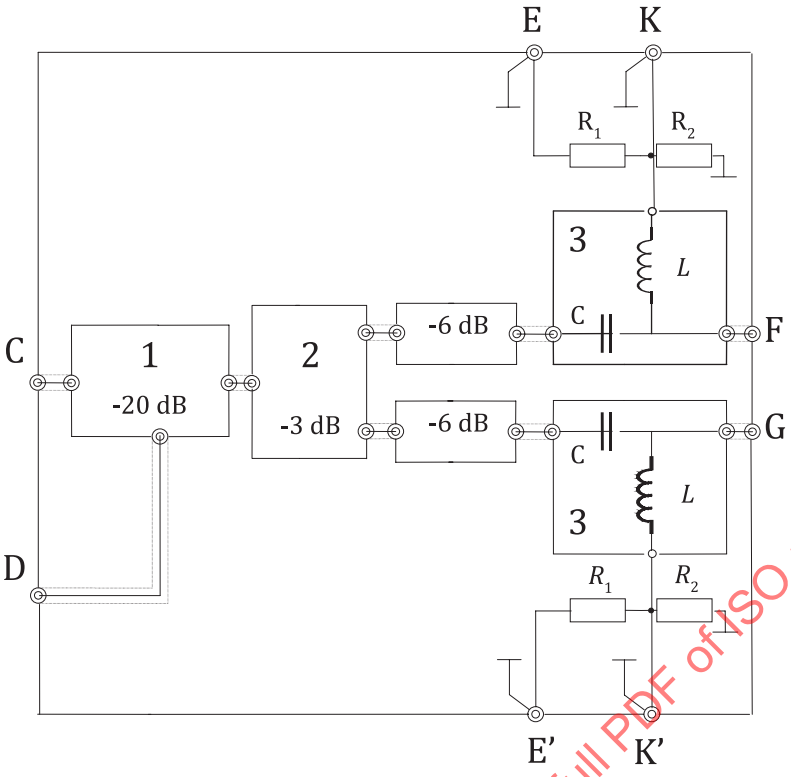
— The input impedance of the filter is ≥67 kΩ; and

— The output impedance of the filter is ≤67 kΩ; and

— The response is that of a maximally flat, third order filter with a –3 dB rolloff at 565 Hz ± 6 %.

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

1 directional coupler
2 power splitter
3 bias tee
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 (see also Table D.5).

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 provides guidance and a suggested procedure for selecting capacitor C_x that is used in the tissue-equivalent interface circuits described in Annex D.

The tests in this document requiring burst modulated interference signals can result in an erroneous failed compliance result due to the introduction of low frequency artefacts created due to imperfect signal generation. Specifically, when a gated carrier is produced where the gating is not performed precisely at carrier zero crossings, such artefacts are likely to exist whose amplitudes typically scale with the desired signal peak-to-peak value. This spurious noise might incorrectly identify a DUT as sensitive to some or all of the test signals.

To attenuate these spurious signals, the capacitor C_x, in combination with a 68 Ω resistor, forms a high-pass filter to reduce spuriously injected low-frequency signals from the interference signal generator.

At low frequencies, the effect of C_x can be opposite to that desired. As an example, if the user 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. See Figure E.1 for an illustration of this effect. This increase in signal can increase the amount of spurious low-frequency noise. Thus, the attenuation of the low-frequency spurious noise by C_x can be more than offset by the increased amplitude injected. In this case, the use of C_x can cause an otherwise unaffected device to be affected by the test signal (corrupted by the spurious noise) and might indicate false failure of the device. The use of C_x should be limited to cases where failure to comply might 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.

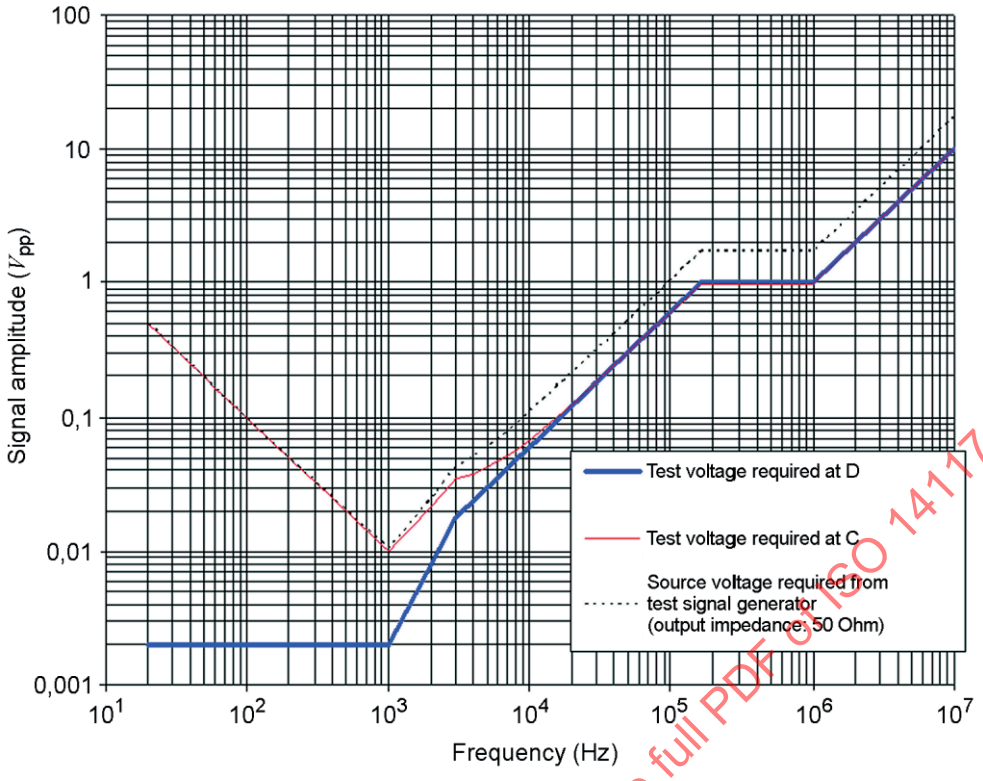


Figure E.1 — Example amplitude at point D and C of the tissue-equivalent interface (C_X selected for 5 000 Hz corner frequency)

The shunt resistor R_1 of the tissue-equivalent 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-equivalent 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 optimal value of C_x is one that preserves the highest possible peak-to-peak amplitude at port D of the tissue-equivalent interface, while simultaneously limiting the residual low frequency signal amplitude to a value below that of the sensitivity of the device under test.

Unfortunately, a single value of C_x might not achieve these constraints for certain types of signal generation or carrier frequencies.

In one specific case, a manufacturer demonstrated that it would be practical to use three different capacitors in the range 1 kHz to 10 MHz:

1 kHz 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 have been found to be practical:

1 kHz 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.

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

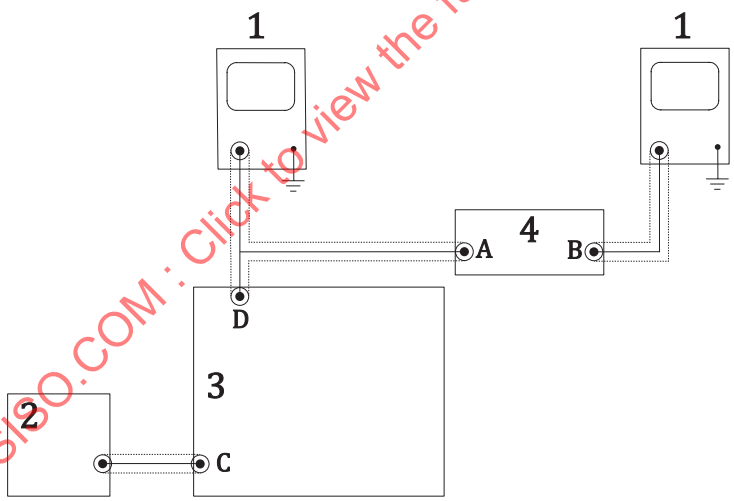
For frequencies above 9 kHz, the low-pass filter should have the characteristics described by Figure D.4. For frequencies below 9 kHz, the low-pass filter may require proper scaling.

The test signal generator and tissue-equivalent interface circuit to be used in the test procedure are connected to the oscilloscopes and low-pass filter as shown in Figure E.2. 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 can be difficult to achieve in practice with standard test equipment.



Key

1 oscilloscope
2 test signal generator
3 tissue equivalent interface
4 filter

Figure E.2 — 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:

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

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 385 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}) 4.3.2.2 and 4.3.3.2	Output F (V_{pp}) 4.5.4
10	3,61	2,58
20	5,39	3,85
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.		

Table F.1 *(continued)*

Frequency (MHz)	Output F (V_{pp}) 4.3.2.2 and 4.3.3.2	Output F (V_{pp}) 4.5.4
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
385	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 Torso simulator

The torso simulator consists of a non-conductive tank, minimum capacity of 26,5 litres (28 quarts), measuring a minimum of 51 cm in length, 36 cm in width, 14 cm in height (20,1 in × 14,17 in × 5,51 in) ±10 %, and filled with saline solution according to Table 11. The dipole antenna rests on the top grid and the DUT rests on the bottom grid.

G.2 Top grid

The purpose of the top grid is to support the dipole antenna a specific distance above the saline solution as defined in 4.9 of this document and allows the saline to flow freely throughout the grid while not perturbing the radiated field from the dipole. The top grid is made of a non-conductive material which fits inside the torso simulator so that the top grid's top surface is no lower than the top of the torso simulator. An example grid is constructed of a material that is 0,16 cm (0,06 in) ±10 % wide and 0,87 cm (0,34 in) ±10 % thick and spaced 1,35 cm (0,53 in) apart in two directions forming an array of square holes that are 1,27 cm (0,5 in) ±10 % on each side.

NOTE It is possible to source the grid using the non-conductive "eggcrate" diffuser of a fluorescent light fixture.

G.3 Cutout

A central area with dimensions of 11,43 cm by 12,7 cm (4,5 in by 5 in) ±10 % of the top grid is removed so that the DUT can be positioned in the upper grid and the dipole antenna can be consistently placed in close proximity to the DUT as defined in 4.9 of this document. The dipole antenna is supported over this large central hole using non-conductive support fixturing.

NOTE Examples of support fixturing for the dipole antenna includes monofilament fishing line, rubber bands, or nylon cable ties.

This support fixturing should be strong enough to support the dipole antenna and not absorb water, resulting in a dry, stable surface on which to place the dipole antenna.

G.4 Bottom grid

A bottom grid made of the same material as the top grid is used to support the DUT inside the torso simulator. The bottom grid has non-conductive support fixturing which allows changes to the bottom grid's vertical position in the torso simulator. This, in turn, varies the device's depth of immersion in the torso simulator.

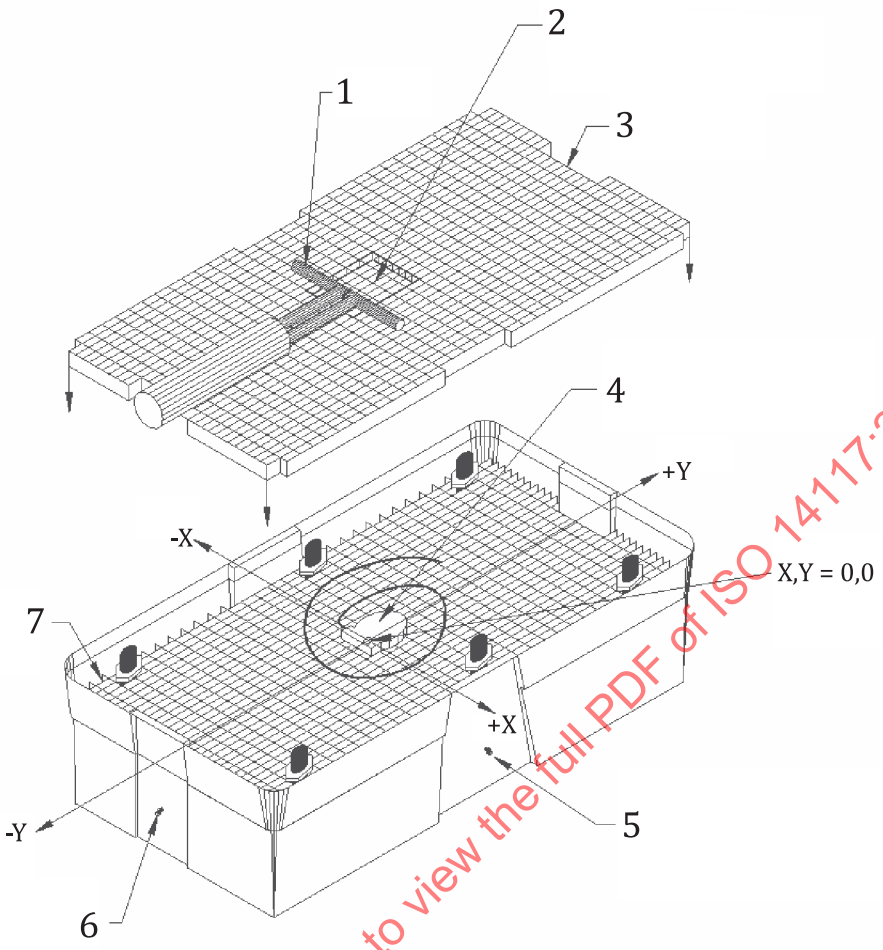
G.5 Torso simulator electrodes

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 × 0,08 in) ±10 %. Each plate is positioned at the middle of one of the inner walls of

the torso simulator. One pair of plates is placed on opposite walls of the torso simulator and allows monitoring of the DUT. The second pair of plates are placed on opposite walls and adjacent to the DUT monitoring plates. The second pair of plates 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 torso simulator and is secured with a nut to form a watertight seal. The screw extends outside the torso simulator 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

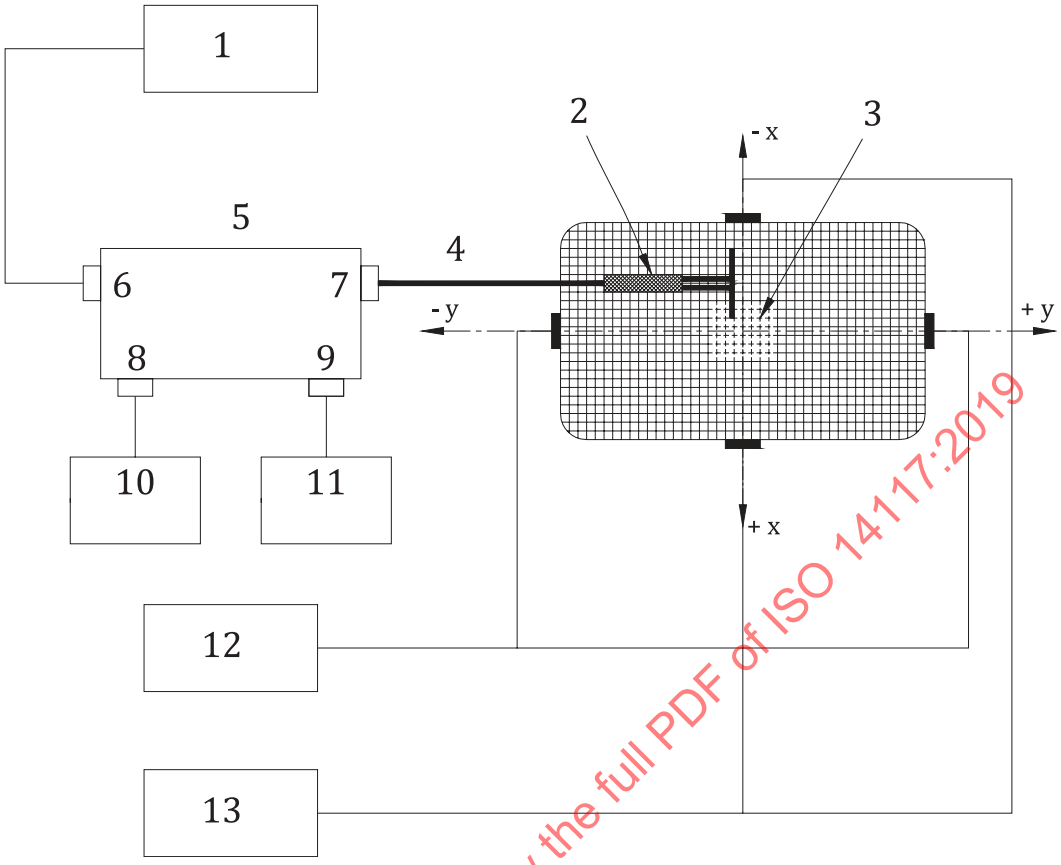
Figure G.1 and Figure G.2 illustrate all the features discussed above.



Key

1 antenna
2 cutout area
3 antenna support grid
4 DUT and lead immersed in saline bath
5 typical DUT output monitoring electrodes (on opposite internal sides)
6 typical ECG input electrodes (on opposite internal sides)
7 DUT support grid

Figure G.1 — Torso simulator



Key

1 RF signal generator
2 dipole antena
3 cutout area
4 antenna cable
5 dual directional coupler
6 input
7 output
8 forward power
9 reflected power
10 power meter A
11 power meter B
12 ECG signal source
13 monitoring equipment

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 C63.5-2006, Annex E, 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.

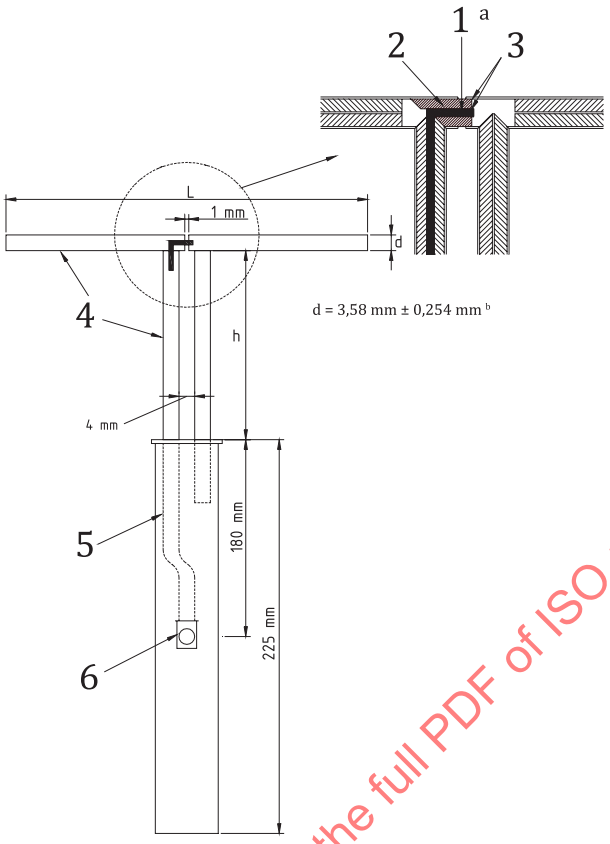
Table H.1 — Dipole description

Test frequencies	Specified in 4.9.2.4 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 K.1.1) and reflected dipole power (see K.1.3).

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



Key

1 antenna reference point [a]
2 Teflon ® or equivalent
3 soldered
4 standard semi-rigid coaxial cable
5 coaxial lead
6 SMA connector

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

NOTE 1 This drawing was developed by Schmid and Partner Engineering AG, Zurich, Switzerland, for IEEE C34 SC 2.

NOTE 2 Teflon ® is a registered trademark of E.I. du Pont de Nemours and Company This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Figure H.1 — Example of a dipole antenna

Annex I
(normative)

Pacemaker/*ICD* programming settings

I.1 General

This annex describes the programmable settings for the DUT.

I.2 *Pacemaker*

I.2.1 Parameters

Table I.1 — *Pacemaker* parameters

Parameter (where appropriate/available)	Single-chamber device	Dual-chamber or *CRT-P* device	Single-pass lead
Bradycardia mode (most comprehensive)[a,b]	VVI (AAI), VVIR (AAIR)	DDD, DDDR[c]	VDD[c]
Sensing polarity	Unipolar and bipolar	Unipolar and bipolar	Unipolar and bipolar
Pacing polarity	Unipolar and bipolar	Unipolar and bipolar	Unipolar and bipolar
Pacing rate	Nominal	Nominal	Nominal
A/V blanking	Minimum	Minimum	Minimum
Cross-ventricular blanking	—	Minimum, if present	—
A/V refractory	Minimum	Minimum	Minimum
PVARP	—	Minimum	Minimum
A/V sensitivity	As specified in the test being conducted	As specified in the test being conducted	As specified in the test being conducted
V-V interval[d]	—	Minimum	—
Rate response	As specified in the test being conducted	As specified in the test being conducted	—
Hysteresis	Off (VVI/AAI)	Off (VVI)	—
Other parameters	As appropriate (nominal preferred)	As appropriate (nominal preferred)	As appropriate (nominal preferred)

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

[b] Applies to 4.9.

[c] During testing with the ECG signal on or during testing requiring injected signal, dual-chamber devices may be tested in both AAI(R) and VVI(R) modes in lieu of DDD(R), as listed above. *CRT-P* devices may also be tested one chamber at a time, e.g. AAI, VVI on right ventricle, VVI on left ventricle.

[d] Only applies to *CRT-P* devices.

If certain parameters specified in this tabel are automatically set by the device and cannot be programmed to the required value, the test shall be performed regardless.

I.2.2 Diagnostic settings

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

I.3 *ICD*

I.3.1 Parameters

Table I.2 — Tachycardia device parameters

Parameter	Single-chamber device	Dual-chamber or *CRT-D* device
Mode (most comprehensive)[a]	VVI (AAI), VVIR	DDD, DDDR[b]
Bradycardia parameters	Nominal	Nominal
A/V blanking	Minimum	Minimum
Cross-ventricular blanking	—	Minimum, if present
A/V refractory	Minimum, if applicable	Minimum, if applicable
PVARP	—	Minimum
A/V sensitivity	As specified in the test being conducted	As specified in the test being conducted
V-V interval[d)]	—	Minimum
Detection enable	On	On
Detection criteria	As specified in the test being conducted	As specified in the test being conducted
ICD ATP therapy[c]	Off	Off
VT/VF therapy #1	Lowest energy setting or appropriate monitoring means	Lowest energy setting or appropriate monitoring means
VT/VF therapy #2, …, etc.	Off, if possible	Off, if possible
Rate response	As specified in the test being conducted	As specified in the test being conducted
Hysteresis	Off (VVI/AAI)	Off (VVI)
Other parameters	As appropriate (nominal preferred)	As appropriate (nominal preferred)

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

[b] During testing with the ECG signal on or during testing requiring injected signal [4.9.3.1 b) and 4.9.4.2 b)], dual-chamber devices may be tested in both AAI(R) and VVI(R) modes in lieu of DDD(R), as listed above. CRT-D devices may also be tested one chamber at a time, e.g. AAI, VVi on right ventricle, VVI on left ventricle.

[c] For ATP-only devices, the feature shall be programmed with the signal on, with other parameters set to nominal settings.

[d] Only applies to CRT-D devices.

If certain parameters specified in this table are automatically set by the device and cannot be programmed to the required value, the test shall be performed regardless.

I.3.2 Diagnostic settings

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

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

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

Annex J
(normative)

Simulated cardiac signal

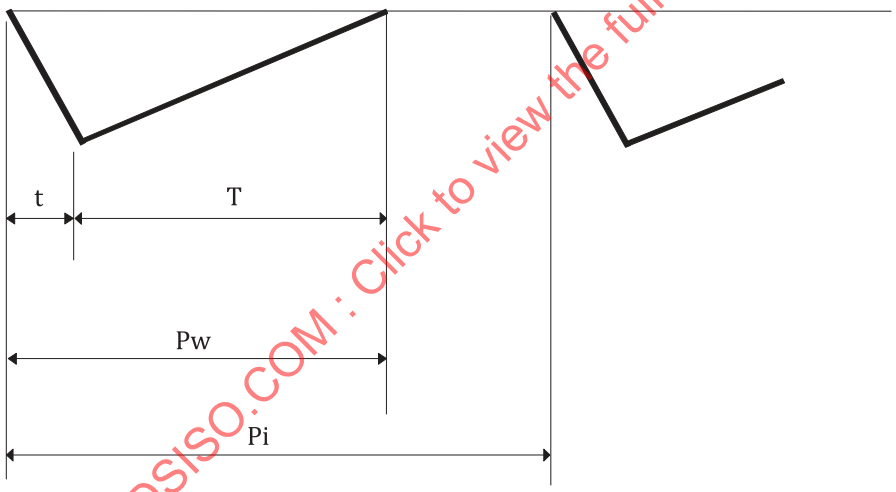
J.1 Heart simulated signal

The simulated waveform (see Figure J.1) shall have the following characteristics:

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

— total pulse width is 15 ms (see Figure J.1).

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



Key

P_w pulse width

P_i pulse interval

Figure J.1 — Simulated cardiac signal

Annex K
(normative)

Calculation of net power into dipole antenna

K.1 Calculation of net dipole power

The test setup shown in Figure K.1 is used to measure net power into a dipole antenna for the test protocol specified in this document. Net power into the dipole antenna is defined to be the forward power minus the reflected power at the cable terminal of the dipole antenna. Dipole net power is calculated from power measurements made at a dual-directional coupler by using the calculations defined hereafter. Factors DCF, DCR, and ACA used in these expressions shall be derived for each test frequency by using the measurement methodology described herein or an equivalent method, with justification provided.

K.1.1 Calculation of forward dipole power (dBm)

$$FPdBm = AdBm + DCF - ACA$$

where

FPdBm is the forward dipole power (dBm);

AdBm is the power meter "A" reading (dBm);

DCF is the directional coupler forward port coupling factor (+dB);

ACA is the antenna cable attenuation (+dB).

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

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

where

FP is the forward dipole power (mW);

FPdBm is the forward dipole power (dBm).

K.1.3 Calculation of reflected dipole power (dBm)

$$RPdBm = BdBm + DCR + ACA$$

where

RPdBm is the reflected dipole power (dBm);

BdBm is the power meter "B" reading (dBm);

DCR is the directional coupler reflected port coupling factor (+dB);

ACA is the antenna cable attenuation (+dB).

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

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

where

RP is the reflected dipole power (mW);

RPdBm is the reflected dipole power (dBm).

K.1.5 Calculation of net dipole power (mW)

$$NP = FP - RP$$

where

NP is the net dipole power (mW);

FP is the forward dipole power (mW);

RP is the reflected dipole power (mW).

K.2 Measurement of factors for net power calculations

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

K.2.1 DCF — Directional coupler forward port coupling factor

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

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

$$DCF = BdBm - AdBm$$

where

DCF is the directional coupler forward port coupling factor (dB);

BdBm is the power meter B reading (dBm);

AdBm is the power meter A reading (dBm).

K.2.2 DCR — Directional coupler reflected port coupling factor

Configure the test equipment as shown in Figure K.3 with power meter B connected directly to the input port of the directional coupler. If an attenuator will be installed at the reflected power port of the directional coupler during tests with the setup shown in Figure K.1, install the same attenuator at the reflected power port for this measurement. The attenuator loss is embedded within the directional coupler coupling factor. At each test frequency, apply an unmodulated sine signal to the output port of

the directional coupler, using sufficient amplitude to provide >20 dB signal-to-noise ratio at both power meters and to record the power levels (dBm) at power meters A and B.

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

$$DCR = BdBm - AdBm$$

where

BdBm is the power meter B reading (dBm);

AdBm is the power meter A reading (dBm).

K.2.3 ACA antenna cable attenuation

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

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

$$ACA = AdBm + DCF - BdBm$$

where

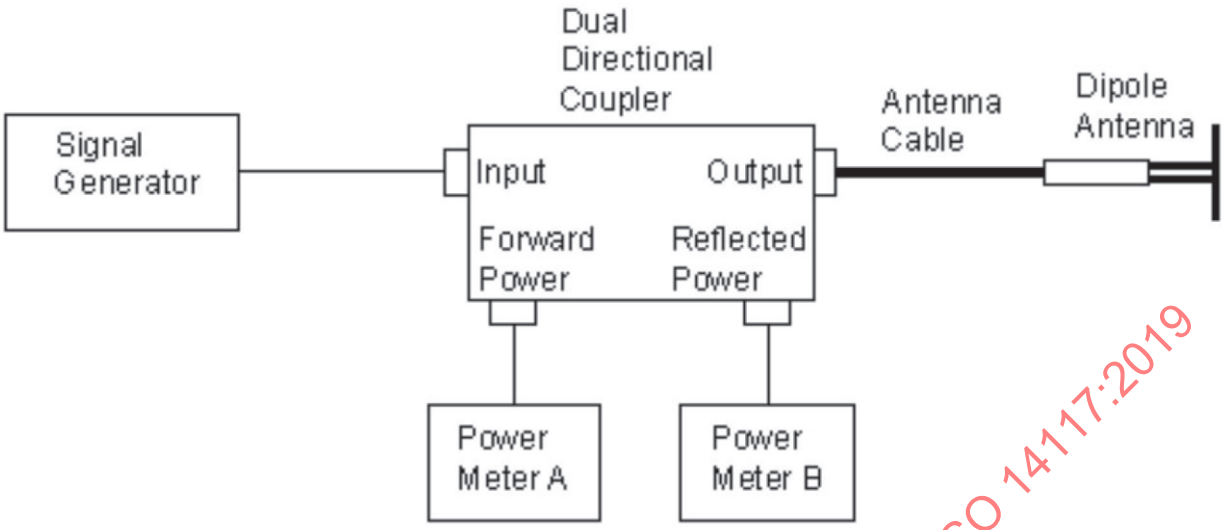
ACA is the antenna cable attenuation (dB);

AdBm is the power meter A reading (dBm);

DCF is the directional coupler forward port coupling factor (+dB);

BdBm is the power meter B reading (dBm).

Excess internal antenna losses (see Table H.1) shall be added to ACA.

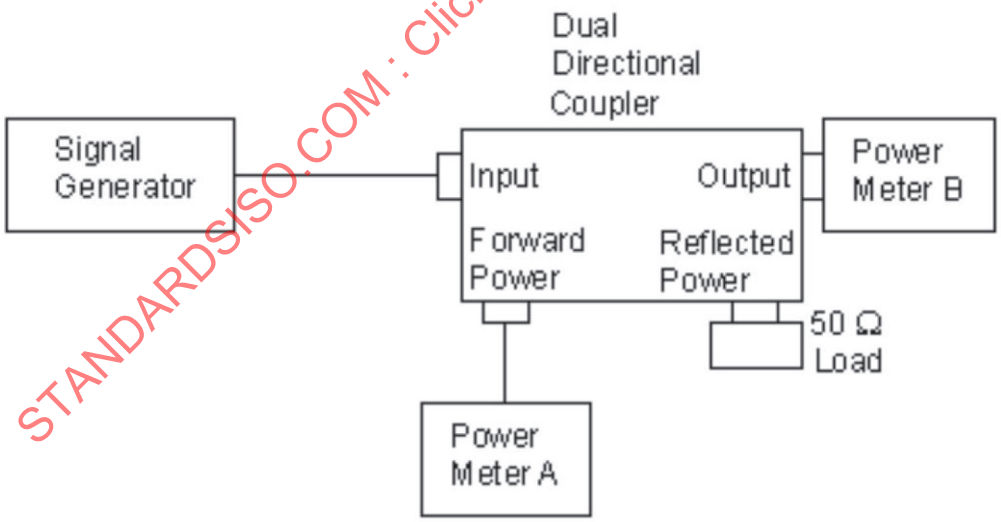


NOTE 1 All RF interfaces are 50 Ω characteristic impedance.

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

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

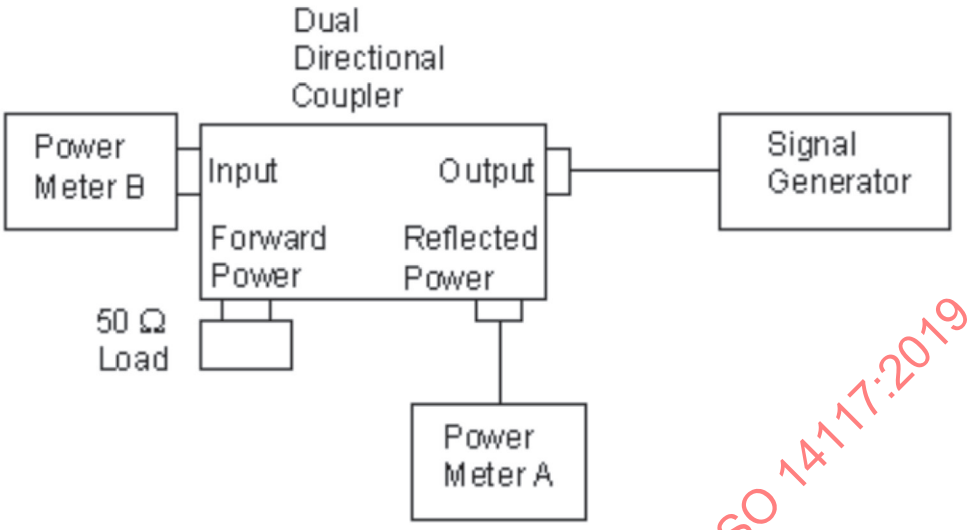
Figure K.1 — Test setup



NOTE 1 All RF interfaces are 50 Ω characteristic impedance.

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

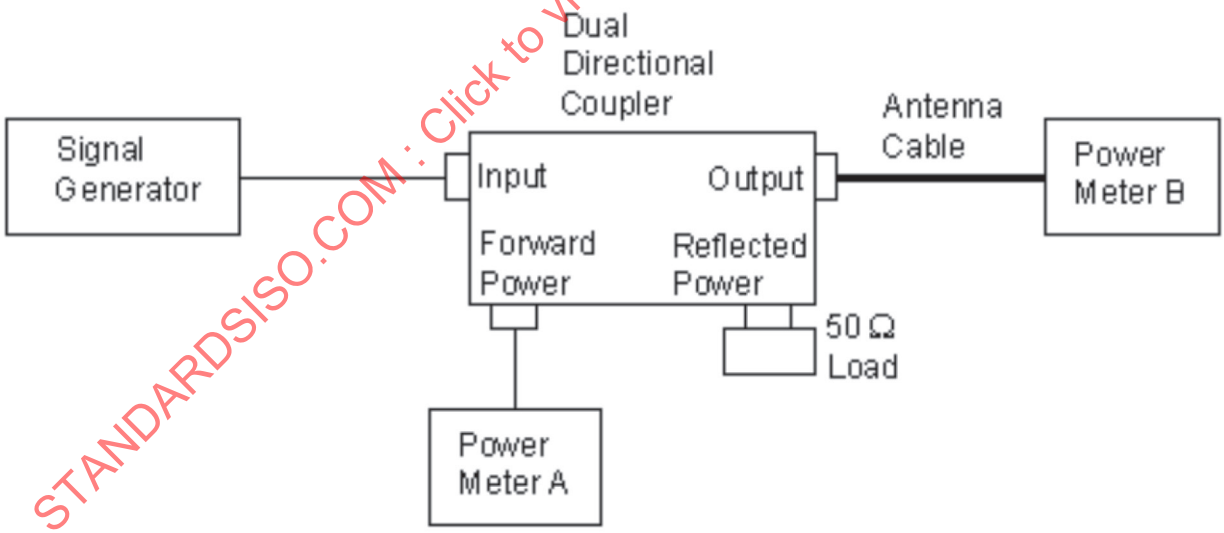
Figure K.2 — Directional coupler forward port coupling factor



NOTE 1 All RF interfaces are 50 Ω characteristic impedance.

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

Figure K.3 — Directional coupler reverse port coupling factor



NOTE 1 All RF interfaces are 50 Ω characteristic impedance.

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

Figure K.4 — Antenna cable attenuation

Annex L
(informative)

Loop area calculations

L.1 Purpose

Initial evaluation of implanted leads was done in the mid-1980s. Information was published (Irnich and Barold, 1985[4]) that indicated that unipolar *pacemaker*s with a semicircle lead configuration can form a 570 cm^2 loop area.

Articles published in the 1990s indicated lower effective coupling areas (Scholten and Silny, 2001[9]; Irnich, 2002[3]).

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

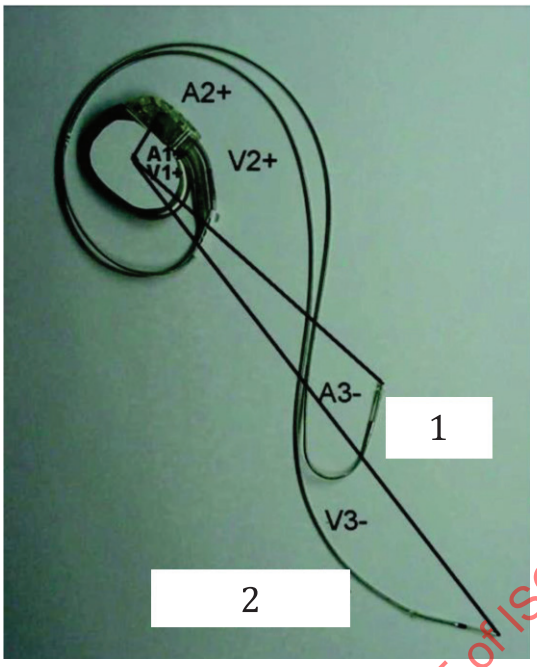
As a result, a study was conducted to evaluate the effective loop areas in relation to EMI susceptibility, of the *pacemaker*s and *ICD* lead systems, and 1) to determine whether a difference exists in the effective lead loop area for *pacemaker*s and *ICD*s and 2) to correlate actual implanted systems with modelling done in various studies in Europe.

The **geometrical lead loop area** in this annex is defined as the area enclosed by leads and an imaginary straight line between the electrode tip (ring) and the metallic case of the implanted DUT.

L.2 Procedure

X-rays from *pacemaker* and *ICD* patients were obtained and analysed using a LASICO Model L-30[1)] planimeter to determine the two-dimensional lead area. Planimeter measurements were made on each LEAD from the device to the lead tip in the implanted ventricular or atrial transvenous lead systems. Additionally, planimeter measurements of the lead segment within a circle with a diameter of 141 cm^2 (approximately 22 in^2), a typical size for partial exposure, were made by placing the circle over the implanted system and keeping the centre of the device within the circle.

1) LASICO L-30 is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.



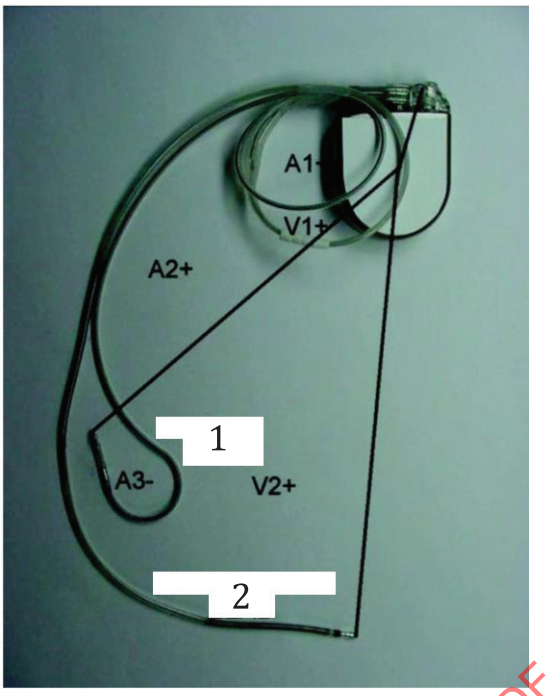
Effective atrial area = A1 + A2 − A3

Effective ventricular area = V1 + V2 − V3

1 atrial lead

2 ventricular lead

Figure L.1 — Simulated right pectoral dual-chamber *pacemaker* X-ray



Effective atrial area = A1 + A2 − A3

Effective ventricular area = V1 + V2

1 atrial lead

2 ventricular lead

Figure L.2 — Simulated left pectoral dual-chamber *ICD* X-ray

L.3 Results

The mean effective coupling areas for a large loop (a person walking into an EM field) and for a small loop (a person with only a part of the body exposed to an EM field) are shown in Table L.1 (*pacemaker*s, *n* = 100 patients) and Table L.2 (*ICD*s, *n* = 59 patients).

Each table is broken down by device and implant location: right pectoral or left pectoral. Lead length and effective coupling areas are provided for the available frontal view of the atrial and ventricular leads, as well as the available lateral view. Also provided are large lead loop measurements and small [12,7 cm (5 in) diameter] lead loop measurements.

Table L.1 — *Pacemaker* systems

IPG location and quantity	Statistics	V lead length cm	A lead length cm	Coupling area							
				Small loop				Large loop			
				V frontal	V lateral	A frontal	A lateral	V frontal	V lateral	A frontal	A lateral
47 Left pectoral	Average	57	52	46	48	45	48	191	117	120	88
	Maximum	65	57	88	70	83	80	314	187	166	154
	Minimum	52	45	12	20	13	19	57	72	59	45
	Standard deviation	5	5	22	18	22	19	62	35	26	30
NOTE A = atrial; V = ventricular.											

Table L.1 *(continued)*

IPG location and quantity	Statistics	V lead length cm	A lead length cm	Coupling area							
				Small loop				Large loop			
				V frontal	V lateral	A frontal	A lateral	V frontal	V lateral	A frontal	A lateral
49 Right pectoral	Average	55	46	70	57	73	58	68	117	95	91
	Maximum	76	55	100	101	100	99	169	189	159	137
	Minimum	48	37	8	42	43	40	6	62	45	63
	Standard deviation	5	4	19	16	15	16	31	31	25	19
4 Abdominal	Average	54	53	28	33	—	34	91	109	58	83
	Maximum	58	53	81	33	—	34	143	135	105	103
	Minimum	52	53	8	33	—	34	42	80	11	62
	Standard deviation	3	—	35	—	—	—	45	39	67	29
NOTE A = atrial; V = ventricular.											

Table L.2 — *ICD* systems

ICD location and quantity	Statistics	V lead length cm	A lead length cm	Coupling area							
				Small loop				Large loop			
				V frontal	V lateral	A frontal	A lateral	V frontal	V lateral	A frontal	A lateral
54 Left pectoral	Average	65	52	57	40	57	35	232	108	137	66
	Maximum	78	62	97	76	107	69	389	190	201	105
	Minimum	55	42	13	23	20	20	91	23	79	20
	Standard deviation	5	5	19	14	20	13	51	38	28	25
3 Right pectoral	Average	68	52	59	—	41	—	167	93	145	57
	Maximum	75	53	80	—	56	—	233	93	147	57
	Minimum	58	50	31	—	26	—	101	93	144	57
	Standard deviation	9	2	25	—	21	—	93	—	2	—
2 Abdominal	Average	105	—	33	—	—	—	140	—	—	—
	Maximum	105	—	42	—	—	—	167	—	—	—
	Minimum	105	—	24	—	—	—	112	—	—	—
	Standard deviation	—	—	—	—	—	—	—	—	—	—

In summary, for the large loop areas (full lead system):

a) For *pacemaker*s, 47 left pectoral implants and 49 right pectoral implants were analysed (see Table L.1).

b) For *ICD*s, 54 left pectoral implants and 3 right pectoral implants were analysed (see Table L.2).

c) As seen when comparing Figure L.1 with Figure L.2, the left pectoral lead system results in larger geometrical lead loop areas as compared with the "lazy S" orientation of the right pectoral leads. The right pectoral lead tends to have the more effective geometrical lead loop area subtracted, as shown in Figure L.1.

d) Left pectoral, frontal orientation of ventricular leads provided the largest effective geometrical lead loop areas; the averages were 191 cm^2 for *pacemaker*s and 232 cm^2 for *ICD*s (see Tables L.1 and L.2).

e) The maximum effective geometrical lead loop areas measured were 314 cm^2 for *pacemaker*s and 389 cm^2 for *ICD*s (see Table L.1 and Table L.2).

f) The difference in effective geometrical lead loop area can be attributed to the use of longer leads with *ICD*s. The average left pectoral ventricular lead length was 65 cm for *ICD*s and 57 cm for *pacemaker*s (see Table L.1 and Table L.2).

In summary, for the small loop areas (partial lead system):

— For *pacemaker*s, 47 left pectoral implants and 49 right pectoral implants were analysed (see Table L.1).

— For *ICD*s, 54 left pectoral implants and 3 right pectoral implants were analysed (see Table L.2).

— The left pectoral lead systems resulted in approximately the same effective geometrical lead loop area, since the subtractive parts of the "lazy S" orientation seen in right pectoral leads typically fell outside the 12,7 cm (5 in) diameter area measured. Left pectoral, frontal orientation of ventricular leads resulted in average geometrical lead loop areas of 46 cm^2 for *pacemaker*s and 57 cm^2 for *ICD*s, whereas the right pectoral, frontal orientation of ventricular lead averaged 57 cm^2 for *pacemaker*s and 59 cm^2 for *ICD*s (see Table L.1 and Table L.2).

— The maximum effective geometrical lead loop areas measured were 88 cm^2 for the right pectoral ventricular lead of a *pacemaker* and 107 cm^2 for an atrial left pectoral lead for an *ICD* (see Table L.1 and Table L.2).

L.4 Summary — Geometrical lead loop area

The study described above found the average left pectoral geometrical lead loop area for *pacemaker*s to be 191 cm^2, which confirms the previous use of 200 cm^2 in estimations of effective loop area. The study further found a maximum geometrical lead loop area of 314 cm^2 for left pectoral *pacemaker* implants.

Measurement of *ICD* systems found an average left pectoral geometrical lead loop area of 232 cm^2. The difference between loop areas of 200 cm^2 and 232 cm^2 is essentially insignificant; therefore, the same loop area was applied to *ICD*s and *pacemaker*s.

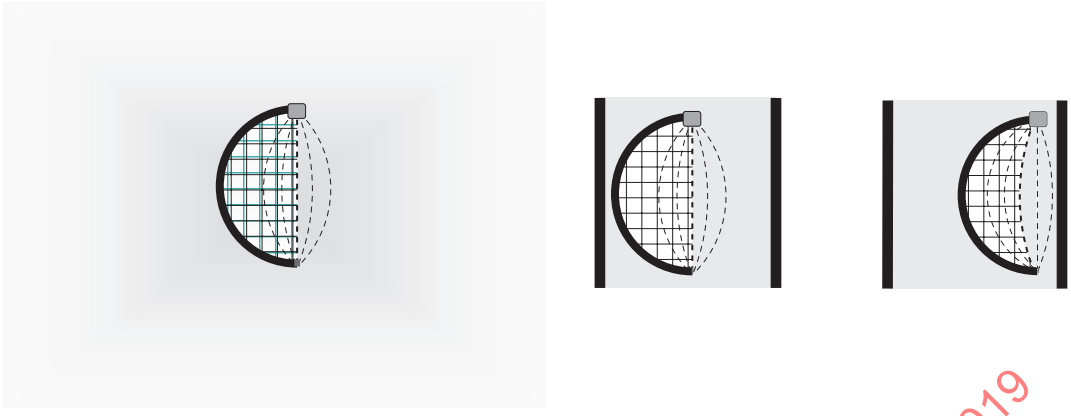
The geometric lead loop area was defined as the area enclosed by leads and an imaginary straight line between the electrode tip (ring) and the metallic case of the implanted DUT (see also Figure L.1, Figure L.2, and Figure L.3).

L.5 Effective induction area

In the case where a lead is placed in an infinitely extended conductive medium, the loop can be thought of as being closed by a straight wire from the tip connector of the lead to the non-insulated case of the DUT. The induction area A for a lead of given length L will be maximal with a semicircle layout:
$A = L2 / 2\pi$.

This is still true within a finite space (as in the thorax) in case the imaginary straight line is centred within the body. Real implantations however are shifted towards the wall of the thorax, reducing the effective induction area. Theoretical field calculations and measurements both confirm this reduction effect [Scholten A, Silny J (2001)[9]; Gustrau F.et al. (2002)[10]; Irnich (1999)[11]].

Figure L.3 illustrates a unipolar lead in a semicircle layout schematically.



Key

conductive medium/body tissue

effective induction area

Figure L.3 — Effective induction area of an open wire loop inside a conductive medium

As shown above, along with the evaluation of the X-rays, the maximum geometrical lead loop area is achieved with left pectoral implantation of the DUT. The maximum achievable visible area was about 315 cm^2 but taking the above mentioned reduction effects into account the maximum achievable effective induction area $A_{ind}{}^{max}$ is about 225 cm^2 only. This means that the maximum sensitive implanted unipolar cardiac lead delivers the same induced interference voltage as an equivalent closed wire loop with 225 cm^2 loop area.

L.6 Consideration of Lead Loop Area based on *CRT-P*/*CRT-D* devices and Left Ventricular lead placement

In the first edition of ISO 14117, this annex identified maximum geometrical lead loop areas on the order of 200 cm^2. That analysis, however, did not consider left ventricular leads.

For this second edition of ISO 14117, additional analyses were performed using SEMCAD, an FDTD modelling tool. Simulations of Duke (the largest human body model in the Virtual Family from the IT'IS Foundation in Zurich, Switzerland) were used with a 100 cm LV LEAD with three trajectories each from left and right pectoral implants. The front (anterior-posterior) and side (lateral) areas for the six trajectories were determined. The largest loop area was 205 cm^2. This is not appreciably more than that determined previously, likely due to the fact that the additional lead length is arbitrarily coiled.

Thus there is no need to increase the lead loop area based on adding LV leads to the scope of this document.

Annex M
(informative)

Correlation between levels of test voltages used in this document and strengths of radiated fields

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

An intentional or inadvertent emitter that produces field levels that are at or substantially below human safety exposure standards or national telecommunication regulations (such as EC 519/99, IEEE C95.1 and C95.6, and those of the FCC) could still interfere with the proper operation of an *implantable pacemaker* or *ICD*. These standards and regulations are intended to avoid biological effects from electromagnetic fields (EMF). They are not intended to ensure EMC between emitting equipment and *pacemaker*s or implantable defibrillators. *Implantable pacemaker*s and *ICD*s are particularly sensitive to peak signals.

Modern devices within the scope of this document are life-sustaining and are designed to sense low-level physiological signals (as low as 0,1 mV) that have frequency content of interest up to 500 Hz. Modern devices utilize analogue pre-filtering in conjunction with A/D conversion, and therefore have initial sampling rates that approach 1 kHz. 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 available to implement analogue pre-filters. Therefore, designing for high rejection of unwanted signals between 500 Hz and 1 000 Hz is difficult, and emitted fields, whether intentional or not, with frequency components up to 1 kHz can be particularly problematic. For these reasons, the boundary between zones 1 and 2 as was set at 1 kHz.

These emitted frequency components can be either from the carrier signal or from modulation of the carrier signal. While there are very few intentional emitters (other than AC power distribution systems) that create EMF fields (carriers) below 1 kHz, there are many intentional emitters utilizing modulation frequencies below 1 kHz. Here it is important to note that the type of modulation employed (amplitude versus phase/frequency) drastically affects the likelihood of EMI effects. Carriers that are only frequency or phase modulated have a lesser effect on *pacemaker* / *ICD* sensing circuits. Carriers that are amplitude modulated with signals whose baseband content falls in the 0 Hz to 500 Hz range represent the largest potential EMI threat. This threat is realized when the peak-to-peak amplitude interfering EMF results in an induced voltage at the input to the device that exceeds the attenuation capability of the device's filters to keep the input to the sensing circuity within its linear dynamic range. When this happens, demodulation of the carrier can occur, and the baseband content of the emitter is then presented to the sensing circuits as interference.

In summary, the potential for interference with *implantable pacemaker*s and *ICD*s is a complex topic; interference depends on a number of factors:

— frequency of the emitted carrier signal (modern filters are most effective above 10 MHz);

— modulation format (amplitude modulation is single largest threat);

— proximity to the patient;

— coupling factors (orientation between the patient's lead system and the incident EMF);

— duration of exposure;

— power of the signal.

When a *pacemaker* is subjected to EMI, it can exhibit one or more of the following adverse responses:

— missed pacing beats or stop pacing (*pacemaker* inhibition);

— stopped sensing (noise reversion to asynchronous pacing);

— fast pacing (tracking of the EMI by dual-chamber devices);

— current induced into the lead system that can trigger an arrhythmia;

— activation of the magnetic switch.

When an *ICD* is subjected to EMI it can exhibit one or more of the following adverse responses:

— high-voltage shock (inappropriate delivery of therapy);

— inability to identify the need for therapy (inability to properly detect cardiac tachyarrhythmia owing to noise);

— missed pacing beats or stopped pacing (oversensing that manifests itself as inhibition);

— stopped sensing (noise reversion to asynchronous pacing);

— fast pacing (tracking of the EMI by dual-chamber devices);

— current induced into the lead system that can trigger an arrhythmia;

— activation of the magnetic switch, which suspends therapies or causes other changes, depending on the device model.

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

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

However, it is possible to estimate the induced input voltages that result from exposure to time-varying magnetic fields. Additional information on this topic can be found in EN 50527-2-1[31]. Emitter manufacturers typically measure the radiated output levels of their equipment in EM field strength units.

The following is a correlation between the voltage test levels in Clause 4 and EM field strength levels (amps/meter, peak). This correlation uses Faraday's law and reflects an effective induction loop area of 225 cm^2, considered worst case for left pectoral implants. It should be noted, as discussed in Annex L, that the largest geometrical implantation loop areas can exceed 300 cm^2 for special cases (e.g. large patients or abdominally implanted systems).

In most circumstances it is possible to identify exposures which are totally or almost totally magnetic in nature. In such circumstances, the magnetic field levels which can generate the *pacemaker* lead voltages corresponding to the device test limits can be derived using Faraday's law and applying an effective induction area of 225 cm^2 for frequencies below about 5 MHz. However, some exposures involve both magnetic and electric fields and the effects of these would need to be combined.

Device immunity closely follows, and generally exceeds, the 1998 ICNIRP General Public Reference Levels. Figure M.1 shows a comparison between the voltage test levels applied to the device input terminals from this document and the voltage that would be induced by an external magnetic field with a strength at the specified General Public Reference Level. Figure M.2 provides a similar comparison, examining the actual ICNIRP field strengths and those field levels required to achieve the voltage test levels of this document. It assumes the above-mentioned worst case effective induction loop area of 225 cm^2, and a unipolar lead. This assumption can lead to an underestimation of the induced voltages in patients who have greater lead loop areas. Figure M.3 and Figure M.4 designate operations that can occur at levels above those shown in Figure M.1 and Figure M.2. Requirements specified in this document provide reasonable protection from interference due to external sources of EMI.

Considerations for adjustment of immunity test levels:

The immunity test levels specified in this document are based upon numerous considerations:

— EMF levels that might be encountered by the general public in the absence of particular sources of emissions. Such levels might be specified either as part of regulatory law or guidance.

— EMF levels associated with known emitters that might be commonly encountered by patients with an implanted device but not necessarily in occupational settings

— Consensus agreement among manufacturers of devices within the scope of this document that the specified immunity is achievable

In 2010, ICNIRP published updated Reference Levels, which at the time of publication of this second edition have not yet been adopted by the European Commission. Furthermore, while the IEEE has published similar standards for public and occupational exposure, these have not been adopted within legislation or guidance issued by known regulatory bodies. If and when changes are made to the recommended or required public exposure reference levels, they will be considered as a basis for the revision of immunity test levels in a subsequent revision of this document.

As part of the development of this second edition, a re-assessment of the maximum achievable immunity of current generation devices to EMI for frequencies below 10 MHz was initiated in 2015. Initial results indicate that the industry as a whole does not yet achieve immunity that would be consistent with the ICNIRP 2010 or IEEE C95.1/C95.6 guidelines for general public reference levels over the entire range of frequencies it specifies.

Additionally, ongoing *in vitro* tests by manufacturers of current generation devices in conjunction with EAS systems continues to show the potential to interfere with intended operation. This is not unexpected, as some of these systems have emissions at or near the ICNIRP 2010 reference levels.

Based upon all of the considerations above, the working group has not changed the immunity requirements for frequencies up to 10 MHz, based upon either regulatory considerations or consensus concerning specific known emitters.

Sensing regions for implantable pacemakers and ICDs (Zone 1): This region is particularly sensitive for *implantable pacemaker*s and *ICD*s. Fundamental frequencies or modulation formats in this region have a significantly greater likelihood to interfere with *pacemaker*s and *ICD*s.

EMF levels below filter response (Zone 2): In this region, continuous exposure to an EMI source is unlikely to have an effect on *implantable pacemaker* or *ICD* operation and is of nominal concern for emitter manufacturers.

EMF level above filter response (Zone 3a): In this region, the EMI source can cause an *ICD* to deliver inappropriate high-voltage therapy or reversion to asynchronous pacing in *implantable pacemaker*s or implantable defibrillators. Asynchronous pacing at a fixed rate can result in competitive rhythms with intrinsic cardiac activity, and long-term use of this modality is not always clinically appropriate. In general, the interfering signal should be unmodulated, or the modulation frequency should not be in the range of 1 Hz to 1 000 Hz (1 kHz). Exposures to those levels should be infrequent and transient, lasting a matter of seconds. Although longer exposures of *pacemaker*s are not necessarily unsafe, they can deny the patient the optimal therapy, and such exposures should, therefore, be minimized. In the case

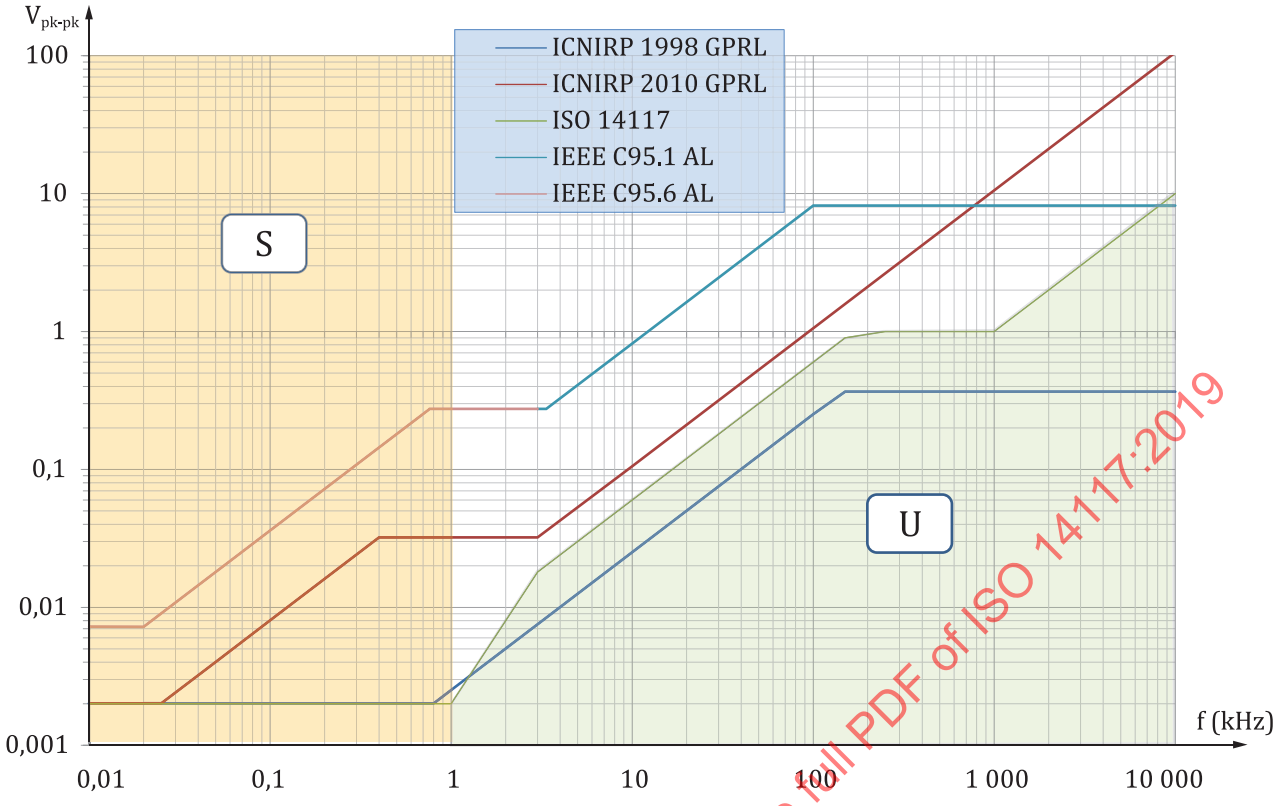
of rate-responsive *pacemaker* or implantable defibrillators, such exposures can cause the device to shift to the upper tracking rate. Furthermore, in the case of *ICD*s, an unwanted therapy might be delivered or a needed therapy might be withheld. The generally accepted advice for Zone 3a is for the patient (in the absence of other advice from their physician) to limit exposure duration to a period on the order of 10 seconds or less. Manufacturers of Zone 3a emitter equipment that is not readily recognizable by the public are encouraged to provide informational signage to inform *pacemaker* and *ICD* patients of the existence of an EM field to allow them to minimize their exposure time.

EMF level above filter response (Zone 3b): In this region, the operation of the device is unknown, but no permanent malfunction will affect the *implantable pacemaker*s or *ICD*s. In this region, exposure should be infrequent and short-term (lasting a matter of seconds). It should be noted that when the field is removed, the device functions as it did before exposure without further adjustment.

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

It is important to understand that *pacemaker* and *ICD* devices function by detecting peak voltages, which could result from a magnetic field coupling with the implanted lead system. The previously mentioned human safety EMF exposure guidelines can allow for duty cycle and rms time-averaging of the emitted signal. In order to assess the likelihood of interference resulting from field strengths specified with rms or duty cycle averaging, these values need to be corrected either by application of a factor of $\sqrt{2}$, 1/Duty Cycle, or both as appropriate. To ensure the safety of *pacemaker* and *ICD* patients, it is recommended that their exposure be limited to the frequencies (either as a carrier or modulation) and power levels shown in Figure M.1 and Figure M.2.

If it is not possible for an emitter manufacturer to avoid the frequencies and levels shown in Figure M.1 and Figure M.2, then emitter manufacturers are strongly advised to consult with *pacemaker* and *ICD* manufacturers to determine the appropriate EMI mitigation steps that the emitter manufacturers can take to avoid the potential for interference with *implantable pacemaker*s and *ICD*s.



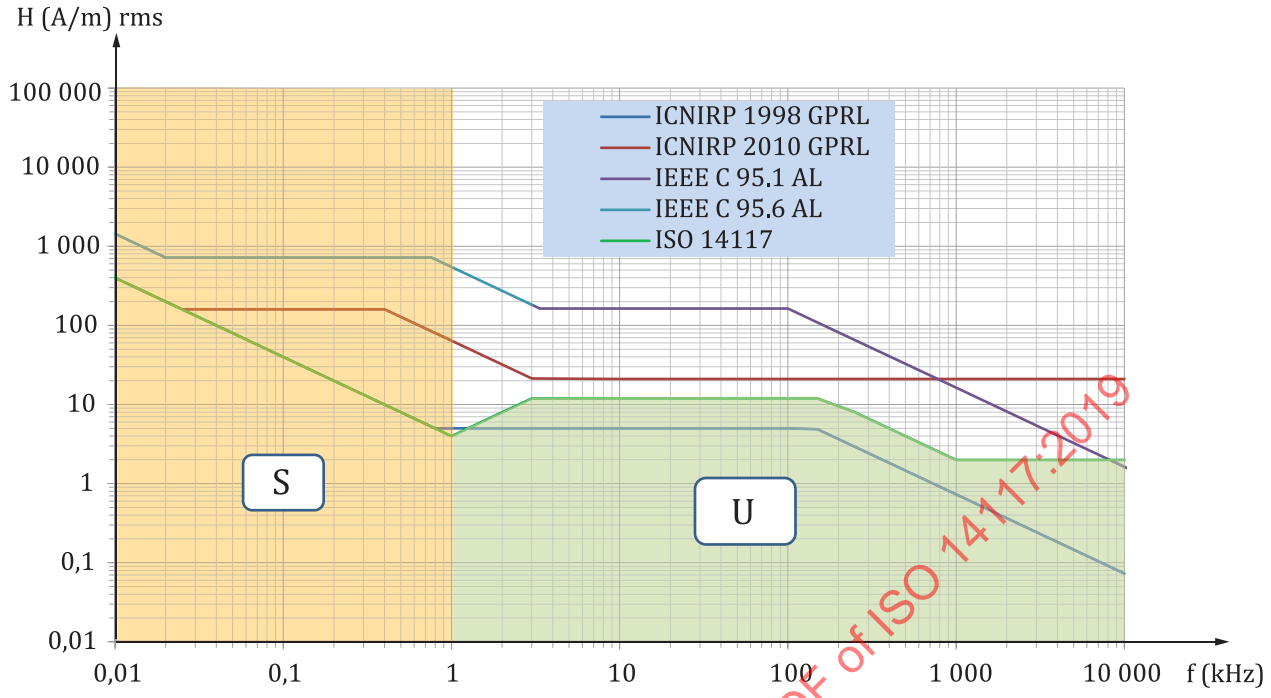
Key

S sensing and operation region for DUTs

U DUTs operate uninfluenced in this region

NOTE Emitters are encouraged to avoid region S.

Figure M.1 — Comparison of induced voltages resulting from ICNIRP and IEEE H-field general public reference levels and the test limits of this document



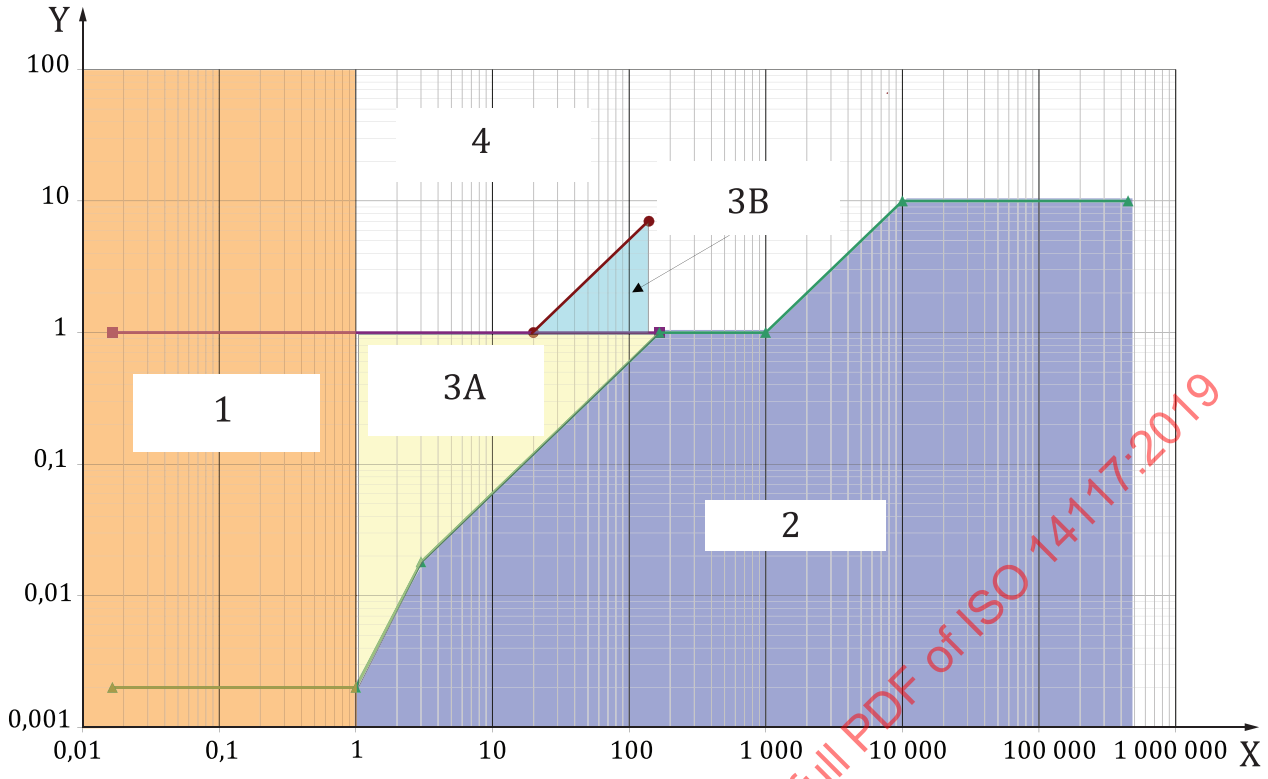
Key

S sensing and operation region for DUTs

U DUTs operate uninfluenced in this region

NOTE Emitters are encouraged to avoid region S.

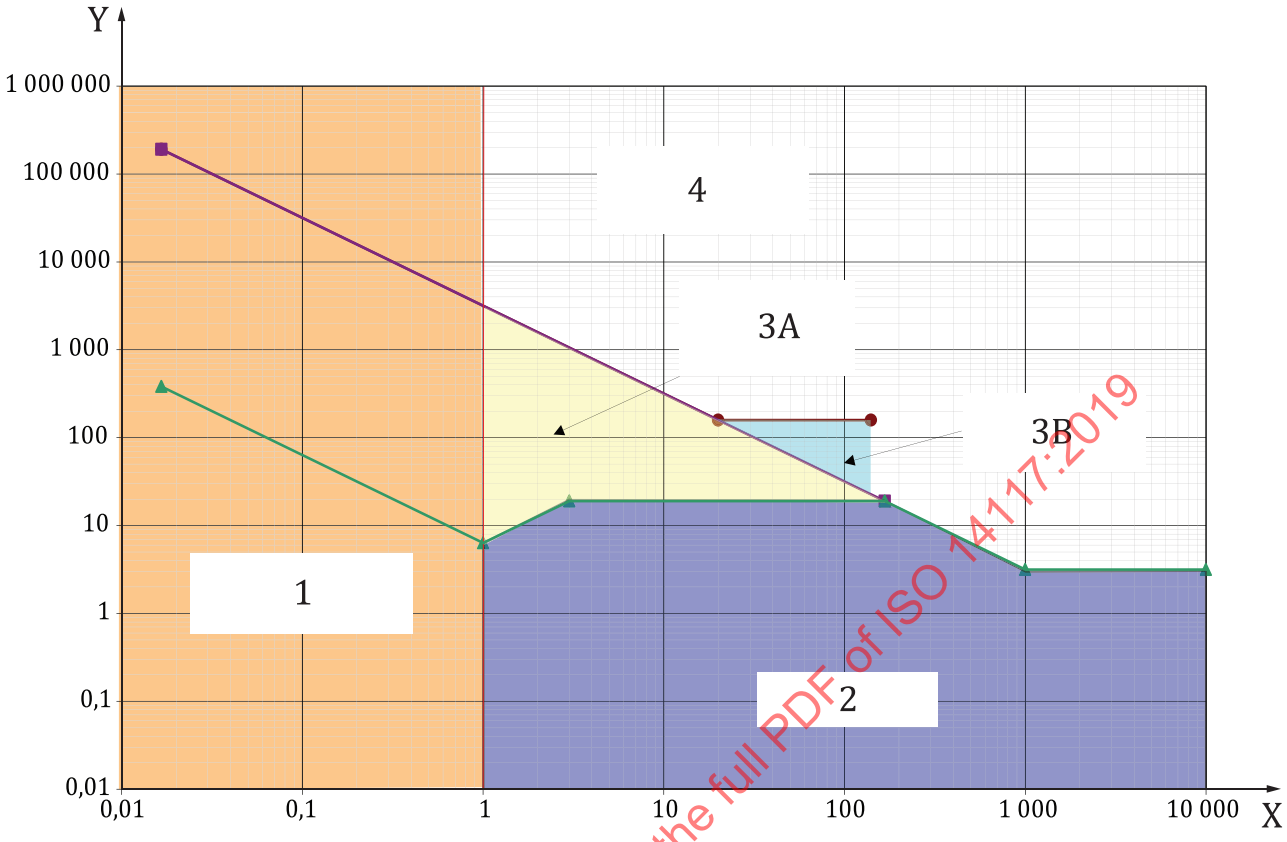
Figure M.2 — Comparison of magnetic field general public reference exposure values from ICNIRP and IEEE with equivalent magnetic field immunity from ISO 14117



Key

x	frequency (kHz)
y	amplitude (V_{p-p})
1	Zone 1 Sensing and operation region for pacemakers and ICDs
2	Zone 2 Operation unaffected
3A	Zone 3a No permanent damage, Pacemakers - reversion, ICDs - characterization
3B	Zone 3b Operation unknown, No permanent malfunction
4	Zone 4 Operation unknown, Permanent damage possible
—●—	Clause 4.3 - Unmodulated
—■—	Clause 4.4 - Unmodulated
—▲—	Clause 4.5 - Modulated

Figure M.3 — Induced voltage zones



Key

x	frequency (kHz)
y	amplitude (A/m peak)
1	Zone 1 Sensing and operation region for pacemakers and ICDs
2	Zone 2 Operation unaffected
3A	Zone 3a No permanent damage, Pacemakers - reversion, ICDs - characterization
3B	Zone 3b Operation unknown, No permanent malfunction
4	Zone 4 Operation unknown, Permanent damage possible
—●—	Clause 4.3 - Unmodulated
—■—	Clause 4.4 - Unmodulated
—▲—	Clause 4.5 - Modulated

Figure M.4 — Magnetic field zones

Annex N
(informative)

Connections to DUTs having ports with more than two electrode connections

N.1 Introduction

In 2010, the standard ISO 27186[37] was published. That standard specifies connectors for leads with multiple electrodes in both low and high-voltage applications (IS-4 and DF-4). Since that time, a new generation of leads and devices have emerged that incorporate the requirements of ISO 27186.

NOTE 1 For the purposes of this annex, the term *port* is equivalent to a connector cavity as specified in related connector standards[35][36].

The purpose of this annex is to give guidance to manufacturers for extending the required testing described in this document to devices incorporating IS-4 or DF-4 connectors, or, more generally, to a connector cavity having any number of possible electrode connections.

In the next subclause, a new nomenclature is introduced to address multi-polar ports. Next, a series of examples is provided showing application of the nomenclature. In the last two subclauses, the test setups described in this document are generalized in order to be applicable to multi-polar ports; a series of examples is also provided.

NOTE 2 By increasing the number of electrodes of one port the number of test combinations can increase dramatically. However, in some cases the effective EMI impact on a device does not vary significantly when switching the injection points of a multi-polar port (for example, by permuting the bipolar pair across an IS-4 electrode array). The specific combinations of electrode connections and tests for multi-polar connectors should be considered as part of the risk assessment required by 27.1 of ISO 14708-1:2014..

N.2 New nomenclature of ports and electrodes

The tip/ring nomenclature originally developed for this document does not work properly when considering the case of multi-polar leads/devices. For this reason, a new electrode nomenclature has been developed and is described in this annex.

A generic electrode is identified by the following elements:

— The type of electrode: 'L' for low-voltage, 'H' for high-voltage

— The device port to which the electrode is connected

— The actual electrode position within the port, where 1 is the most distal electrode, and the proximal electrodes are numbered such the most proximal has the highest number

Figure N.1 below shows an example device, containing all the standardized ports (IS-1, IS-4, DF-1, DF-4).

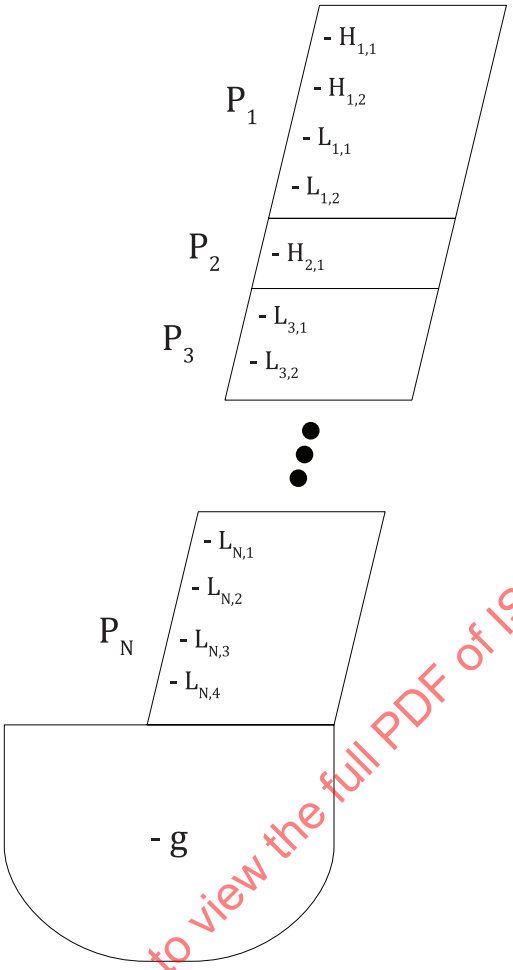
— $\mathbf{L_{p,e}}$ refers to a generic low voltage electrode

— $\mathbf{H_{p,e}}$: refers to a generic high-voltage electrode (cardioverter defibrillation)

where:

— Suffix **p** refers to the port

— Suffix **e** refers to the electrode position on the lead (1 = most distal, cf. Figure N.1)



Key

P_1 port 1; RV DF-4 in the example figure

P_2 port 2; RV DF-1, SVC DF-1 in the example figure

P_3 port 3; RV IS-1, RA IS-1, LV IS-1 in the example figure

P_N port N; LV IS-4 in the example figure

g CIED case

NOTE 1 In the figure above, the port numbering is for illustration purposes only.

NOTE 2 The new nomenclature can be reduced to the simpler case of a bipolar IS-1 port, where the tip corresponds to electrode number 1 and the ring to the electrode number 2.

NOTE 3 The figure does not depict an actual CIED and is shown for illustration purpose only.

Figure N.1 — Schematic representation of ports and electrodes for a generic multi-port multi-polar device; the order of the ports, and electrodes in each port shown in the picture is arbitrary

N.3 Examples of application of the nomenclature to typical DUTs

Figure N.2 depicts a dual-port CIED where:

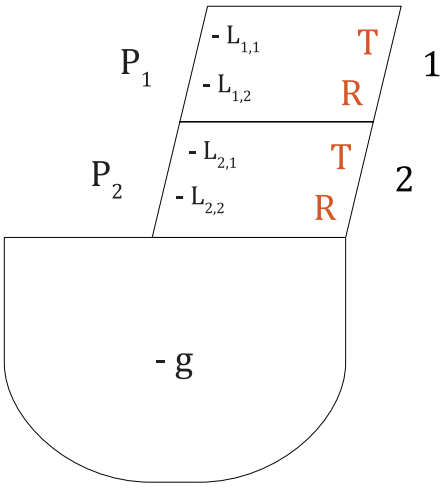
— port 1: IS-1 connected to RV chamber

  — $L_{1,1}$ = tip

- $L_{1,2}$ = ring

— port 2: IS-1 connected to RA chamber

- $L_{2,1}$ = tip
- $L_{2,2}$ = ring



Key

P_1	port 1: IS-1 connector
P_2	port 2: IS-1 connector
g	CIED case
T	tip electrode (distal)
R	ring electrode (proximal)
1	RV cavity
2	RA cavity

NOTE The order of stacking ports is arbitrary and does not reflect the actual position of the cavities in the device header.

Figure N.2 — Example of DR *pacemaker* device according to the new nomenclature

Figure N.3 depicts a multi-port CIED where:

— Port 1: DF-1 connected to RV coil

- $H_{1,1}$ = RV

— Port 2: DF-1 connected to SVC coil

- $H_{2,1}$ = SVC

— Port 3: IS-1 connected to RV chamber

- $L_{3,1}$ = tip
- $L_{3,2}$ = ring

— Port 4: IS-1 connected to RA chamber

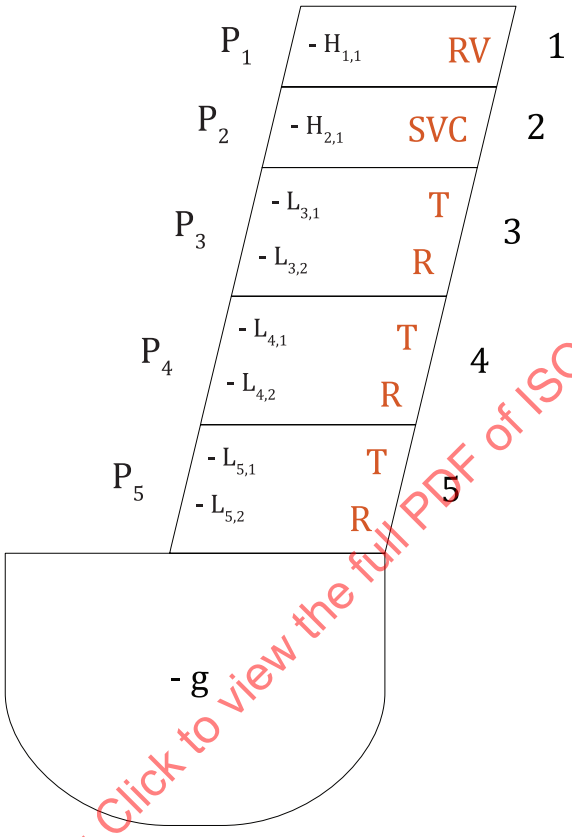
- $L_{4,1}$ = tip

— $L_{4,2}$ = ring

— Port 5: IS-1 connected to LV chamber

— $L_{5,1}$ = tip

— $L_{5,2}$ = ring



Key

P_1	port 1: DF-1 connector
P_2	port 2: DF-1 connector
P_3	port 3: IS-1 connector
P_4	port 4: IS-1 connector
P_5	port 5: IS-1 connector
g	CIED case
RV	RV defibrillation coil
SVC	SVC defibrillation coil
T	tip electrode (distal)
R	ring electrode (proximal)
1	RV defibrillation cavity
2	SVC defibrillation cavity
3	RV cavity
4	RA cavity
5	LV cavity

NOTE The order of stacking ports in the picture is arbitrary and does not reflect the actual position of the cavities in the device header.

Figure N.3 — Example of DF-1 *CRT-D* device according to the new nomenclature