INTERNATIONAL STANDARD

ISO 14117

Second edition
2019-09

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

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

Reference number
ISO 14117:2019(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword

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

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 pacemaker*s, *ICD*s 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).

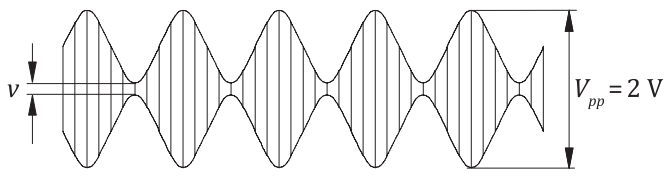
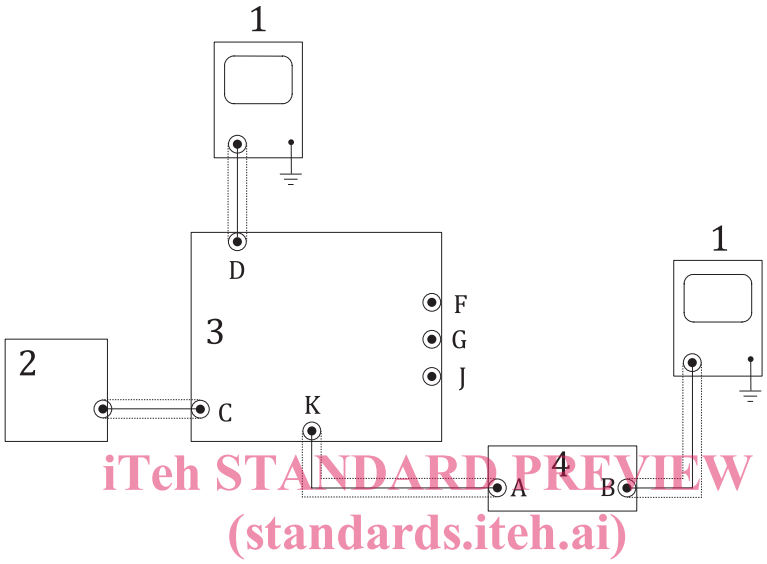


Figure 1 — Test signal 2

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.

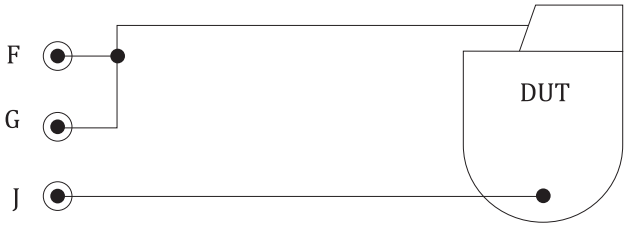


Figure 3 — Connection to a single-channel unipolar device

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.

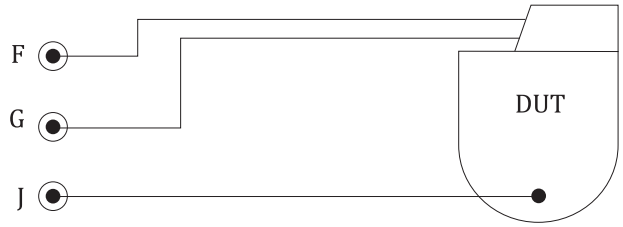


Figure 5 — Common mode connection to single-channel bipolar device

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