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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.

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

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

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

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

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

Introduction

The number and the types of electromagnetic (EM) emitters to which patients with active implantable cardiovascular devices are exposed in their day-to-day activities have proliferated over the past two decades. This trend is expected to continue. The interaction between these emitters and active implantable cardiovascular devices (pacemakers and implantable cardioverter defibrillators, or ICDs) is an ongoing concern of patients, industry and regulators, given the potential life-sustaining nature of these devices. The risks associated with such interactions include device inhibition or delivery of inappropriate therapy that, in the worst case, could result in serious injury or patient death.

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

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

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

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

It is important to understand that these interactions may occur despite the conformance of the device to this International Standard and the conformance of emitters to the relevant human exposure safety standards and pertinent regulatory emission requirements, e.g. those of the U.S. Federal Communications Commission (FCC).

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

The potential for emitter equipment to interfere with active implantable cardiovascular devices is complex and depends on the following factors:

— frequency content of the emitter,

— modulation format,

— power of the signal,

— proximity to the patient,

— coupling factors, and

— duration of exposure.

Devices within the scope of this International Standard are life-sustaining and are designed to sense low-level physiological signals (as low as 0,1 mV) that have frequency content up to several hundred Hertz. For patient safety and comfort, these devices are small, offer many therapeutic features, and have a long battery life. These highly desired features, combined with the intrinsic functionality, limit the size and number of components and thus place practical constraints on the capability to control electromagnetic interference (EMI).

An emitter with a fundamental carrier frequency up to several hundred Hertz has the potential to be sensed directly by the pacemaker or ICD. Also, higher-frequency carriers that are modulated up to several hundred Hertz and that have sufficient proximity and power may be sensed by the pacemaker or ICD.

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

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

a) 0 Hz ≤ f < 450 MHz

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

— electronic article surveillance (EAS) systems;

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

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

— magnetic levitation rail systems;

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

— metal detectors;

— magnetic resonance imaging; and

— experimental use of transponders for traffic control.

b) 450 MHz ≤ f < 3 000 MHz

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

Two decades ago, relatively few pacemaker patients used hand-held transmitters or were exposed to EM fields from portable transmitters. Hand-held, frequency-modulated transceivers for business, public safety, and amateur radio communications represented the predominant applications. However, the environment has changed rapidly during the past 15 years, with wireless phone systems becoming increasingly common as this technology matured and received widespread public acceptance. Thus, it is becoming increasingly likely that a large portion of the pacemaker and ICD patient population will be exposed to EM fields from portable wireless phone transmitters operated either by themselves or by others. Also, it should be expected that the wireless technology revolution will continue to evolve new applications using increasingly higher microwave frequencies.

Most electronic equipment, including external medical devices, has been designed for compatibility with relatively low-amplitude EM conditions. Recognizing the wide range of EM environments that patients could encounter, implantable devices have been designed to tolerate much higher-amplitude EM conditions than most other electronic products. However, in some instances, even this enhanced immunity is not sufficient to achieve compatibility with the complex electric and magnetic fields generated by low-power emitters located within a few centimetres of the implantable device. Studies in the mid-1990s demonstrated that some models of pacemakers and ICDs had insufficient immunity to allow unrestricted use when in close proximity to some hand-held emitters (e.g. wireless telephones and two-way radios). Although operating restrictions can help prevent EM interaction with implantable devices, this approach is not viewed as an optimum long-term solution. Rather, improved EM compatibility is the preferred method for meeting patient expectations for using wireless services with minimal operating restrictions.

Some technological factors are contributing to the expanding variety of emitters to which patients may now be exposed:

— smaller wireless phones,

— the introduction of digital technology, and

— peak transmitter power.

Wireless phone size has now been reduced sufficiently so that it is possible for patients to carry a phone that is communicating or in standby mode in a breast pocket immediately adjacent to a pectorally implanted device.

Since 1994, reported studies have indicated that interference effects in pacemakers are more severe from digital phones than from analog phones. As of September 2010, there were more than 5 billion digital subscriptions worldwide.

The various wireless phone standards allow for a range of power levels and modulation schemes. Most digital wireless phones are capable of producing greater peak transmitted power than analog phones are capable of producing. Those factors contribute to greater potential interactions with pacemakers and ICDs.

For frequencies of 450 MHz $\leq f \leq$ 3 000 MHz, this International Standard specifies testing at 120 mW net power into a dipole antenna to simulate a hand-held wireless transmitter 15 cm from the implant. An optional characterization test is described that uses higher power levels to simulate a hand-held wireless transmitter placed much closer to the implant. Claims that the manufacturer may wish to make on the basis of the results of the optional characterization are to be negotiated between the manufacturer and the appropriate regulatory authorities.

c) $f \geq$ 3,000 MHz

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

1) the types of radiators of frequencies above 3 GHz,

2) the increased device protection afforded by the attenuation of the enclosure and body tissue at microwave frequencies,

3) the expected performance of EMI control features that typically are implemented to meet the lower-frequency requirements of this International Standard, and

4) the reduced sensitivity of circuits at microwave frequencies.

Additional details can be found in Clause 5.

In conclusion, it is reasonable to expect that patients with pacemakers and ICDs will be exposed to increasingly complex EM environments. Also, the rapid evolution of new technologies and their acceptance by patients will lead to growing expectations for unrestricted use. In view of the changing EM environment and customer expectations, manufacturers will need to evaluate their product designs to assess compatibility with the complex fields, broad range of frequencies, and variety of modulation schemes associated with existing and future applications.

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

1 Scope

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

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

0 Hz $\leq f <$ 450 MHz;

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

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

2 Normative references

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

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

3 Terms and definitions, symbols and abbreviations

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

3.1
implantable pacemaker
active implantable medical device intended to treat bradyarrhythmias, comprising an implantable DUT and leads

3.2
implantable cardioverter defibrillator
ICD
active implantable medical device intended to detect and correct tachycardias and fibrillation by application of cardioversion/defibrillation pulses to the heart, comprising an implantable DUT and leads

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

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

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

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

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

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

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

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

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

Table 1 shows acronyms and abbreviations used in this International Standard.

Table 1 — List of acronyms and abbreviations

Acronym or abbreviation	Description
A	atrial
AAMI	Association for the Advancement of Medical Instrumentation
ACA	antenna cable attenuation (+dB)
AdBm	power meter “A” reading (dBm)
ASIC	Application Specific Integration Circuit
ATP	antitachycardia pacing
BdBm	power meter “B” reading (dBm)
BPEG	British Pacing and Electrophysiology Group
bpm	beats per minute
CENELEC	European Committee for Electrotechnical Standardization
CW	continuous wave
dB	decibel
dBm	decibels above a milliwatt
DCF	directional coupler forward port coupling factor (+dB)
DCR	directional coupler reflected port coupling factor (+dB)
DUT	device under test
EAS	electronic article surveillance
ECG	electrocardiogram
EGM	electrogram

Table 1 *(continued)*

Acronym or abbreviation	Description
EM	electromagnetic
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EN	European Norm
ESMR	enhanced specialized mobile radio
f	frequency
FCC	Federal Communications Commission
FP	forward dipole power (mW)
FPdBm	forward dipole power (dBm)
ICD	implantable cardioverter defibrillator
ICNIRP	International Commission on Non-Ionizing Radiation Protection
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
λ	wavelength
NASPE	North American Society of Pacing and Electrophysiology
NP	net dipole power (mW)
o.d.	outside diameter
Ωcm	measure of resistivity (Ohm-cm)
PCS	personal communication services
PVARP	post ventricular atrial refractory period
RF	radio frequency
RFID	radio frequency identification
rms	root mean square
RP	reflected dipole power (mW)
RPdBm	reflected dipole power (dBm)
SMA	subminiature “A”
T_{shs}	simulated heart signal interval
V	ventricular
VF	ventricular fibrillation
VSWR	voltage standing wave ratio
VT	ventricular tachycardia

NOTE Throughout this International Standard, DUT has been used to designate all devices within the scope of this International Standard. When a certain test or requirement applies only to a specific type of device, that designation is used.

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

4.1 General

Implantable pacemakers, ICDs and CRT devices shall not cause any *harm* because of susceptibility to electrical influences due to external EM fields, whether through malfunction of the device, damage to the device, heating of the device, or by causing local increase of induced electrical current density within the patient.

Compliance shall be confirmed if, after performance of the appropriate procedures described in 4.2 to 4.9, the values of the characteristics when measured are as stated by the manufacturer specification of the DUT. All requirements shall be met for all settings of the DUT, except as follows.

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

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

NOTE 1 This does not mean that all combinations of settings are tested, but at least the setting to which the device is preset by the manufacturer should be tested completely.

NOTE 2 If the case of the DUT is covered with an insulating material, the DUT (or part of it) should be immersed in a 9 g/l saline bath held in a metal container; the metal container should be connected directly to the test circuit as applicable in each test set up.

NOTE 3 Manufacturers that use an automatic gain control function (or similar feature) for sensing purposes should include a detailed test method.

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

NOTE 5 The following tests are generally intended to address the compatibility of the intracardiac signal sensing. Any additional physiological sensors may be turned off during testing unless otherwise specified. Tests for these additional sensors are under consideration.

4.2 Induced lead current

4.2.1 General considerations

The DUT shall be constructed so that ambient EM fields are unlikely to cause hazardous local increases of induced electrical current density within the patient.

4.2.2 Pacemakers and CRT-P devices

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

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

Test signal 1 shall be a sinusoidal signal of 1 V peak-to-peak amplitude. The frequency shall be either swept over the range 16,6 Hz to 20 kHz at a rate of 1 decade per minute or applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz and 20 kHz, with an evenly distributed dwell time of at least 60 s per decade.

Test signal 2 shall be a sinusoidal carrier signal, frequency 500 kHz, with continuous amplitude modulation at 130 Hz (double sideband with carrier) (see Figure 1).

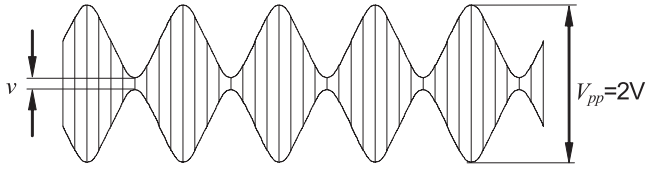

Figure 1 — Test signal 2

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

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

Test procedure: The test signal generator shall be connected through input C of the interface circuit as shown in Figure 2. The test signal shall be measured on the oscilloscope connected to monitoring point D.

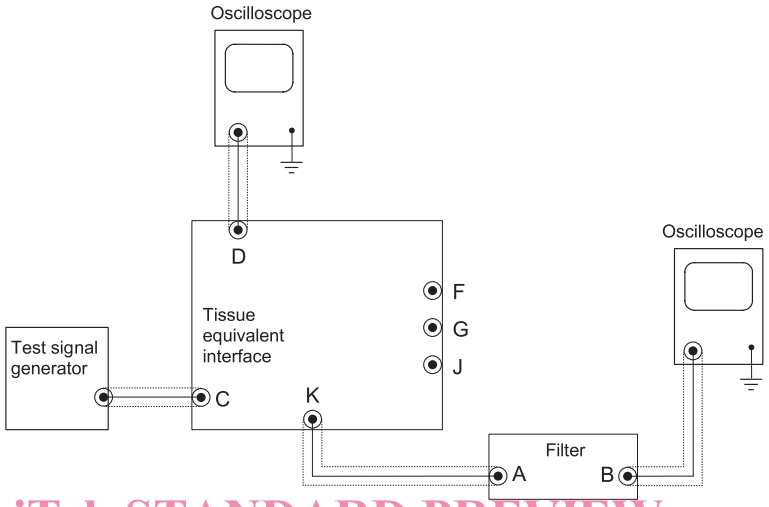

Figure 2 — Test setup for measurement of induced current

The induced electrical current is measured by the oscilloscope connected to test point K through the low-pass filter (as defined in Figure D.4), as shown in Figure 2. When test signal 1 is being used, the low-pass filter shall be switched to bypass mode.

The capacitor C_X of the interface circuit (see Figure D.1) shall be bypassed unless required to eliminate spurious low-frequency signals produced by the interference signal generator (see Annex E).

NOTE 1 It is not mandatory that a current measurement be made in the period from 10 milliseconds (ms) preceding a stimulation pulse to 150 ms after the stimulation pulse.

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

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

— multichannel unipolar devices shall be Group b);

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

— multichannel bipolar devices shall be Group d).

NOTE 2 The bipolar channel should be tested in unipolar or bipolar mode, or both, according to the programmability of the device and should be changed where applicable.

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

Group a): the DUT shall be connected to the coupled outputs F and G of the tissue-equivalent interface (as shown in Figure 3), with output J connected to the case.

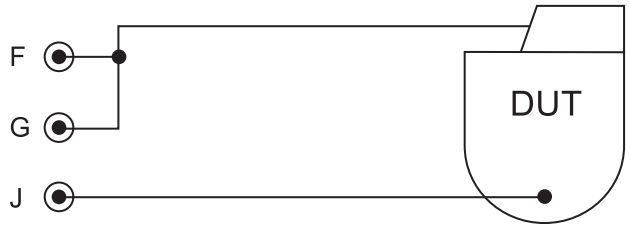

Figure 3 — Connection to a single-channel unipolar device

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

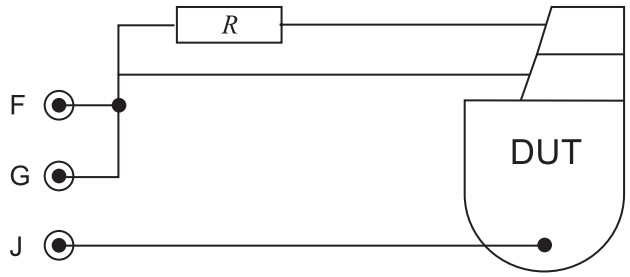

Figure 4 — Connection to a multichannel unipolar device

Group c): common mode performance shall be tested with the DUT connected to the outputs F and G of the tissue-equivalent interface (as shown in Figure 5), with output J connected to the case.

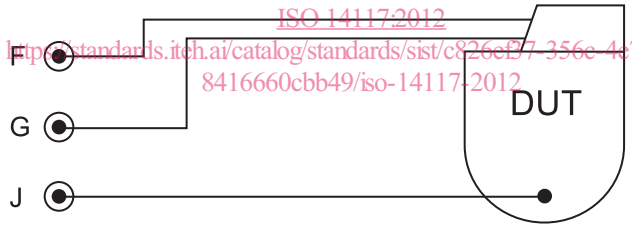

Figure 5 — Common mode connection to single-channel bipolar device

Differential mode performance shall be tested using the test signals reduced to one-tenth amplitude. The pacemaker shall be connected between the coupled outputs F and G and the output J of the tissue-equivalent interface (as shown in Figure 6).

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

Group d): common mode performance shall be tested by every input and output of the pacemaker being connected, in turn, to outputs F and G of the tissue-equivalent interface (as shown in Figure 7), with output J connected to the case.

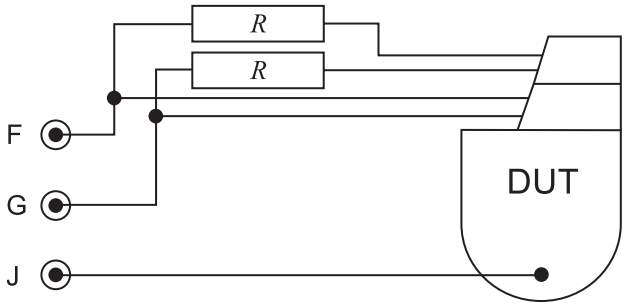

Figure 7 — Common mode connection to multichannel bipolar device

Differential mode performance shall be tested using the test signals reduced to one-tenth amplitude. Every input and output of the pacemaker shall be connected, in turn, between the coupled outputs F and G and the output J of the tissue-equivalent interface (as shown in Figure 8).

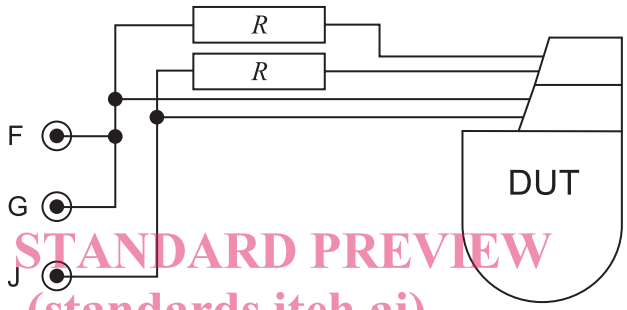

Figure 8 — Differential mode connection to multichannel bipolar device

The current (root mean square, or rms) shall be determined by dividing the peak-to-peak voltage reading on the oscilloscope, connected to test point K by 232 Ω for test signal 1. For test signal 2, the measurement will be taken with a true rms voltmeter connected to test point B (at the filter output) and divided by 82 Ω.

Compliance shall be confirmed if:

— for test signal 1, the measured current is not greater than that specified in Table 2; and

— for test signal 2, the current at modulating frequency of 130 Hz is not greater than 50 μA rms.

Table 2 — Spurious injection current limits

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

4.2.3 ICDs and CRT-D devices

4.2.3.1 Test requirements

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

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

NOTE 1 Care needs to be taken that the test signal generator does not itself produce low-frequency components (see Annex E).