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Implants for surgery — Active implantable medical devices —

Part 3: Implantable neurostimulators

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 3: Neurostimulateurs en implant

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 14708-3:2008), which has been technically revised.

A list of all parts in the ISO 14708 series can be found on the ISO website.

Introduction

This document specifies particular requirements for active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system, to provide basic assurance of safety for both patients and users. It amends and supplements ISO 14708-1:2014, hereinafter referred to as ISO 14708-1.

The requirements of this document take priority over those of ISO 14708-1.

Devices that use electricity to stimulate the nervous system are commonly called "neurostimulators." They produce controlled electrical pulses that are delivered through electrodes in contact with a specific target area. Whether or not a neurostimulator is totally or partially implantable, a lead or extension is usually required to convey stimulation pulses from a form of pulse generator to the electrodes, although newer forms of devices might not utilize leads or extensions. An external programmer might be used to adjust device parameters.

Currently, several types of neurostimulators exist for treating the central or peripheral nervous system. This document is intended to apply to these neurostimulator types regardless of therapy.

This document is relevant to all parts and accessories of implantable neurostimulators, including programmers, software, and technical manuals. Not all parts or accessories might be intended to be totally or partially implanted, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance intended by the manufacturer.

Not included in the scope of this document are non-implantable medical devices, such as external neurostimulators and RF-coupled neurostimulators, even though such devices might have implantable parts, because they are covered under the IEC 60601-1 series of standards.

Within this document, the following terms are used to amend and supplement ISO 14708-1:

"Replacement": the clause of ISO 14708-1 is replaced completely by the text of this document.

"Addition": the text of this document is additional to the requirements of ISO 14708-1.

"Amendment": the clause of ISO 14708-1 is amended as indicated by the text of this document.

"Not used": the clause of ISO 14708-1 is not applied in this document.

Subclauses, figures, or tables that are additional to those of ISO 14708-1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

Implants for surgery — Active implantable medical devices —

Part 3: Implantable neurostimulators

1 Scope

This document is applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES intended for electrical stimulation of the central or peripheral nervous system.

The tests that are specified in this document are type tests and are to be carried out on a sample of a device to assess device behavioural responses, and are not intended to be used for the routine testing of manufactured products.

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 14117:2012, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices*

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 14971, *Medical devices — Application of risk management to medical devices*

ISO/TS 10974:—[1)], *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 61000-4-3:2006+A1:2007+A2:2010, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1 and the following apply.

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

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

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

1) Under preparation.

3.101
implantable neurostimulator
INS
active implantable medical device intended for electrical stimulation of the central or peripheral nervous system

Note 1 to entry: For the purposes of this document, an implantable neurostimulator can be a single article, or a system consisting of a set of components and accessories which interact to achieve the performance intended by the manufacturer. Not all of these components or accessories might be required to be partially or totally implanted, e.g. programmers.

3.102
implantable pulse generator
IPG
part of an *implantable neurostimulator* (3.101), consisting of a power source and electronic circuit, which produces a stimulation voltage or current pulse

3.103
MR Conditional
item with demonstrated safety in the MR environment within defined conditions

Note 1 to entry: Adapted from ASTM F2503, 3.1.11.

3.104
projected service life
period after implantation when the *implantable neurostimulator* (3.101) remains within stated specifications and characteristics

3.105
DUT
device under test
device being tested, including conductive leads

Note 1 to entry: Not all tests require conductive leads.

4 Symbols and abbreviated terms

This clause of ISO 14708-1 applies.

5 General requirements for active implantable medical devices

This clause of ISO 14708-1 applies, except as follows.

Additional subclause:

5.101 Wireless coexistence and wireless quality of service

When communication with the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE is provided through wireless communication channels, the MANUFACTURER shall evaluate wireless coexistence and wireless quality of service through the RISK MANAGEMENT PROCESS and apply the appropriate RISK CONTROL measures to protect the patient from HARM (see 28.105).

Compliance is checked by the inspection of the RISK MANAGEMENT FILE.

6 Requirements for particular ACTIVE IMPLANTABLE MEDICAL DEVICES

No additional requirements are specified in this clause.

7 General arrangement of the packaging

This clause of ISO 14708-1 applies.

8 General markings for ACTIVE IMPLANTABLE MEDICAL DEVICES

This clause of ISO 14708-1 applies.

9 Markings on the sales packaging

This clause of ISO 14708-1 applies.

10 Construction of the sales packaging

This clause of ISO 14708-1 applies.

11 Markings on the sterile pack

This clause of ISO 14708-1 applies.

12 Construction of the non-reusable pack

This clause of ISO 14708-1 applies.

13 Markings on the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

14 Protection from unintentional biological effects being caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

15 Protection from harm to the patient or user caused by external physical features of the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

16 Protection from harm to the patient caused by electricity

This clause of ISO 14708-1 applies.

17 Protection from harm to the patient caused by heat

This clause of ISO 14708-1 applies except as follows.

17.1

Replacement:

In the absence of external influence, an implantable part of the INS, not intended to supply heat to the patient, shall comply with at least one of the following conditions (a, b, or c) when implanted, and when in normal operation, including recharge:

NOTE Examples of external influences include exposure to MRI, electrosurgery, external defibrillation, ultrasound, and electromagnetic fields.

a) no outer surface greater than 39 °C,

b) no tissue receives a thermal dose greater than the CEM43 dose thresholds in Table 101, or

c) manufacturer's evidence that a higher temperature rise, than indicated in Table 101, is justified for a particular application.

Because the values in Table 101 represent tissue dose thresholds, the manufacturer's risk assessment shall include an analysis of any effects to the patient due to the time/temperature relationship.

Table 101 — CEM43 dose thresholds for various tissues

Tissue	CEM43 dose threshold
muscle	40
fat	40
peripheral nerve	40
skin	21
bone	16
brain	2
BBB (blood brain barrier)	15

The CEM43 value is calculated using Formula (1):

$$\mathrm{CEM43} = \sum_{i=1}^{n} t_i \times R^{(43-T_i)} \quad (1)$$

where

t_i is the i-th time interval in minutes;

T_i is the average temperature of the tissue in degrees Centigrade during the interval t_i;

R is 0,25 for T <43 °C and 0,5 for $T \geq 43$ °C;

n is the number of samples taken during the heating duration.

Formula (1) is valid for temperatures between 39 °C and 57 °C.

Compliance is checked by inspection of a design analysis provided by the manufacturer, supported by the manufacturer's calculations and data from test studies as appropriate.

18 Protection from ionizing radiation released or emitted from the active implantable medical device

This clause of ISO 14708-1 applies.

19 Protection from unintended effects caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

20 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by external defibrillators

This clause of ISO 14708-1 applies except as follows.

20.1

Not used.

21 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by electrical fields applied directly to the patient

This clause of ISO 14708-1 applies.

22 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by miscellaneous medical treatments

22.1 Ultrasonic energy

This clause of ISO 14708-1 applies.

22.2 MRI

NOTE 1 This clause does not apply to devices that are not labelled MR CONDITIONAL.

Implantable parts of an INS and any non-implantable components and accessories, which are labelled MR CONDITIONAL, shall be designed and constructed so that no irreversible change to the device or unacceptable risk to the patient results from exposure to MRI.

Assessment: For an implantable part of an INS intended to be used in patients who undergo a magnetic resonance scan in 1,5 T, cylindrical bore, whole body MR scanners, the requirements of ISO/TS 10974 shall apply. For non-implantable components and accessories, or as an alternative for implantable parts, the manufacturer may demonstrate safety using similar or equivalent means.

NOTE 2 Other MR environments will require manufacturer evaluation by similar or other means.

The outcome of each test shall not result in an unacceptable risk to the patient. Additional acceptance criteria are listed in Table 102.

If device samples are used for testing, they shall meet all manufacturer specifications after testing is completed.

Compliance is checked by inspection of test reports and the risk management file.

Table 102 — Acceptance criteria for test requirements of ISO/TS 10974

Test requirement	ISO/TS 10974 Clause #	Acceptance criteria to protect patient from harm
RF field-induced heating of the AIMD	8	RF-induced heating of adjacent tissue(s) shall not cause an unacceptable risk. This heating value shall be below a limit supported by scientific rationale linked to clinical significance for the adjacent tissue(s). The value used for assessment could be CEM43, applied RF power, temperature, or any other measurable and relevant parameter. If temperature rise is ≤2 °C, then no further scientific rationale is needed.
Gradient field-induced device heating	9	Gradient induced heating of adjacent tissue(s) shall not cause an unacceptable risk. This heating value shall be below a limit supported by scientific rationale linked to clinical significance for the adjacent tissue(s). The value used for assessment could be CEM43, applied RF power, temperature, or any other measurable and relevant parameter. If temperature rise is ≤2 °C, then no further scientific rationale is needed.
Gradient field-induced vibration	10	Gradient induced vibration shall not cause an unacceptable risk.
B_0-induced force	11	Magnetically induced force shall be less than the weight of the device or less than a greater specified value that is supported by a scientific-based rationale that the force of this specified value shall not cause an unacceptable risk.
B_0-induced torque	12	Magnetically induced torque shall be less than the worst case gravity-induced torque, which is defined as the product of the weight of the device and the longest linear dimension or less than a greater specified value supported by a scientific-based rationale that the force of this specified value shall not cause an unacceptable risk.
Gradient field-induced lead voltage	13	Induced lead voltages shall not cause an unacceptable risk.
B_0 field-induced device malfunction	14	Device malfunction shall not cause an unacceptable risk.
RF field-induced device malfunction	15	Device malfunction shall not cause an unacceptable risk.
Gradient field-induced device malfunction	16	Device malfunction shall not cause an unacceptable risk.
Combined fields	17	The combined fields test outcome shall not result in an unacceptable risk.

23 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces

This clause of ISO 14708-1 applies except as follows.

23.1

Amendment:

Following the test, the non-implantable part of the active implantable medical device shall operate as specified in IEC 60601-1.

24 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by electrostatic discharge

This clause of ISO 14708-1 applies except as follows.

24.1

Replacement:

The requirements of IEC 60601-1-2 shall apply to the non-implantable parts.

NOTE While the electrostatic discharge is applied only to the non-implantable parts, operation of the ACTIVE IMPLANTABLE MEDICAL DEVICE is evaluated as a system following the test.

Compliance is checked as specified in IEC 60601-1-2.

25 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by atmospheric pressure changes

This clause of ISO 14708-1 applies.

26 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by temperature changes

This clause of ISO 14708-1 applies.

27 Protection of the active implantable medical device from electromagnetic non-ionizing radiation

Replacement:

27.101 General

Implantable parts of the implantable neurostimulator (INS) are expected to maintain their intended use and shall not result in an unacceptable risk because of susceptibility to electrical influences due to external electromagnetic fields.

Assessment: The tests of this clause shall be used to assess device behavioural responses when exposed to electromagnetic (EM) fields representing the general public environment.

NOTE The tests in this clause apply only to the implantable parts. Non-implantable parts are covered by IEC 60601-1-2 (see ISO 14708-1:2014, 5.1).

Compliance is checked by review of the risk management file and test reports.

27.102 Test conditions

27.102.1 Acceptance criteria

During testing of all clauses, the acceptance criteria (pass/fail criteria) shall be based on the manufacturer's intended use of the INS and on a risk assessment, as follows:

— it is expected that the performance intended by the manufacturer will be maintained, and

— no hazardous situations occur that could lead to an unacceptable risk.

Prior to testing, risks shall be identified, taking into account the reasonably foreseeable electromagnetic (EM) environment that is likely to occur during its intended use. Immunity test levels in Clause 27 are based on the reasonably foreseeable maximum levels found in the general public EM environment. Each risk shall be evaluated through a design analysis that takes account of any risk control, according to ISO 14708-1:2014, 5.5.4.

The risk assessment process, performed in accordance with ISO 14971, could result in hazardous situations being identified (see ISO 14971:2007, Figure E.1). Since actual risk cannot be observed

during testing, it will be necessary to observe the performance of the device to see if any hazardous situations occur.

Pass/fail criteria shall be defined prior to testing. Ideally, these criteria can be measurable or observable during testing. If not, the manufacturer shall specify an alternative method for determining that the DUT met the required pass/fail criteria during the test. The use of special hardware or software might be necessary.

If the pass/fail acceptance criteria are not met during and after testing, the manufacturer shall substantiate DUT behavioural responses and explain why the overall risk(s) are acceptable (see Table 103). In no cases are irreversible changes in performance, outside of specification, allowed.

27.102.2 Test configuration and setup

The INS shall be tested in representative configurations, consistent with intended use, that are likely to be the most susceptible to EM disturbances. This shall be determined using risk analysis, experience, engineering analysis, or pretesting.

Unless specified otherwise in a particular test, the test setup shall include

— the IPG,

— attachment of patient leads to all ports as necessary to achieve the intended use,

— for devices that have more than one available electrode configuration for stimulation, such as bipolar or unipolar, they shall be tested with the electrode configuration that is the most susceptible to electromagnetic disturbances, provided that the circuit design and components are equivalent, and

— termination of the implantable parts of the INS as necessary to simulate normal impedance of the patient.

For all tests, provision shall be made to determine the device's behavioural responses, preferably during testing. If the operation of the DUT cannot be observed or verified during the test, the manufacturer shall specify an alternative method for determining that the DUT met the required pass/fail criteria during the test. The use of special hardware or software might be necessary.

27.102.3 Operating functions, modes, and settings

The INS shall be tested using the functions, modes, and settings, consistent with intended use, that are likely to be the most susceptible to EM disturbances. This shall be determined using risk analysis, experience, engineering analysis, or pretesting.

Except for the requirements of 5.101, if the intended use includes a wireless communication channel, the wireless communication function shall be evaluated and tested for EMC in accordance with IEC 60601-1-2.

NOTE A wireless communication function does not have to be tested twice for EMC, as it would be if it were tested according to this document and IEC 60601-1-2.

27.102.4 Patient physiological simulation

If simulation of the patient is required to verify normal operation of the INS, it shall be provided during immunity testing. Physiological simulation shall not provide an intentional conductive or capacitive connection to earth other than that required by 27.102.2.

27.103 Risk management and test report documentation

The information listed in Table 103 shall be provided by the manufacturer.

Table 103 — Minimum risk management and test report contents

No.	Item
1	Description of the intended use, and any unacceptable risks and associated hazardous situations, resulting from the risk assessment.
2	Pass/fail criteria: how it was determined.
3	Pass/fail criteria: how it was monitored during testing.
4	Effects on the DUT that were observed during or after the application of the test disturbances, and the duration for which these effects persisted.
5	If the intended use is not maintained during testing, or if a hazardous situation occurs, the manufacturer shall substantiate DUT behavioural responses and explain why they are not unacceptable.
6	Applicability/tests not performed. The decision and justification not to perform a measurement or test shall be documented. Deviations and modifications to tests shall also be described.
7	DUT configuration during the test, including a block diagram of DUT configuration and all peripherals and auxiliary equipment used.
8	DUT functions, settings, and operating modes listed by test.
9	Name and location of the test facility.
10	Names and functions or equivalent identification of the persons authorizing the test report.
11	Description of the DUT. For example, the device name, model number, manufacturer, and serial numbers, or other means of identification.
12	DUT software/firmware version.
13	Prototype or production version of the DUT. For prototypes, describe the relationship to production versions.
14	Compliance summary statement. Compliance of the DUT with each test.
15	Test data that support the compliance determination for each test performed.
16	Simulators, accessories and auxiliary equipment, including patient physiological and simulation.
17	Documentation of any special hardware or software needed to perform the tests.
18	Test equipment used, including calibration or maintenance dates.
19	Dwell time for each immunity test requiring a dwell time.
20	DUT modifications needed in order to pass any of the tests. A statement that they will all be incorporated into production units.
21	Photographs of each test setup including DUT and all peripherals and auxiliary equipment used.

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

NOTE If the requirements of the B_0 field-induced device malfunction test of 22.2 have been met, then this test is not required. However, this test is not a substitute for any test in 22.2.

For this test, leads are not required and electrode configuration is not applicable.

Test equipment: A field coil capable of generating a magnetic field with a flux density of at least 50 mT in the region to be occupied by the DUT.

Test procedure: The required magnetic field flux density shall be generated before placing the DUT in the field. Then the DUT shall be placed into the centre of the test coil. After at least 15 s of exposure to the magnetic field, the DUT shall be removed from the field. Reorient the DUT so that a second orthogonal axis is aligned with the axis of the field coil, and again subject the DUT to the required field. Repeat with the third orthogonal axis aligned with the axis of the field coil.

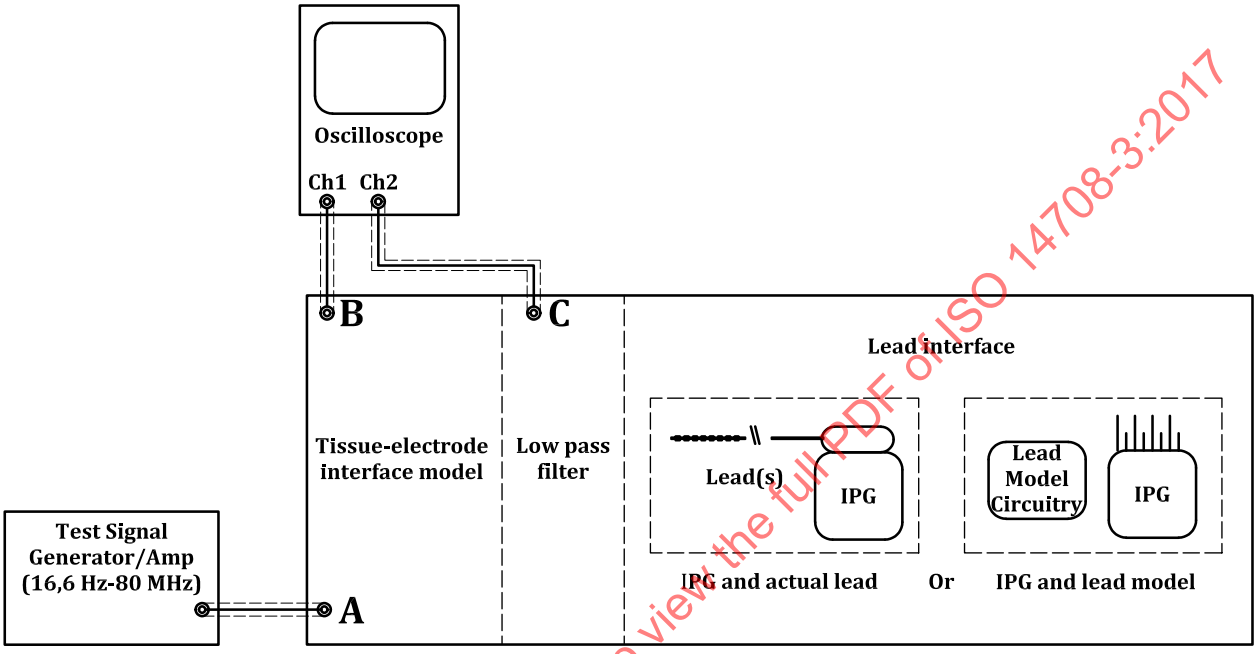
Evaluation of test results: The DUT shall meet the immunity pass/fail criteria determined by the manufacturer.

27.105 Protection from EM disturbances over the frequency range 16,6 Hz to 80 MHz

27.105.1 Voltage injection test for frequencies 16.6 Hz to 80 MHz

For this test, INS termination impedance requirement is accomplished through connection to the injection network.

Test equipment: Injection network setup as illustrated in Figure 101. See Annex CC for a complete description of the network and construction examples including good RF practices.



Key

A test signal input (V_{PP})

B test signal monitor point

C stimulation waveform monitor point

Figure 101 — Injection network diagram for the range of frequencies from 16,6 Hz to 80 MHz

Port A is where the test signal generator, and if needed a suitable amplifier, is connected and is where V_{PP} is injected into the tissue interface board. The test signal generator shall have the ability to modulate a carrier waveform according to the modulation requirements listed later in this subclause.

Port B is where an oscilloscope (≥450 MHz, ≥1 Giga-sample per second) is connected in order to monitor the V_{PP} waveform delivered to the DUT.

Port C is where an oscilloscope (≥450 MHz, ≥1 Giga-sample per second) is connected in order to monitor the DUT output waveform during the immunity test.

In this document, the term “oscilloscope” may also be interpreted as including data acquisition systems capable of performing similar measurements.

The tissue-electrode interface model simulates the impedance created by the tissue-electrode interface and also matches signal generator output to the injection circuit. The injected test voltage (V_{PP}) is based on the theoretical open circuit voltage (V_{OC}) seen across the entire INS system. The interface model would not have to be used but then the entire test voltage would be applied across the IPG and leads. In actual practice, the voltage presented to the IPG is less by a relative amount.

NOTE Annex BB describes the determination of V_{OC} and V_{PP} used in this subclause.

The low pass filter provides points where the monitoring oscilloscope can be connected to observe DUT output stimulation waveforms during the test. Without this filter, it would be more difficult to separate the injected signal from the DUT output waveform.

The lead interface simulates the therapy lead impedance. This may be accomplished by using an actual lead or by circuit model simulation of an actual lead. Both approaches are represented in Figure 101.

Test procedure: A test signal generator, monitoring oscilloscopes, and the DUT are connected to the injection network as indicated in Figure 101. DUT output stimulation will need to be selected so that the output waveform can be reasonably monitored throughout the test. If the design of the DUT is equivalent for all electrodes, then only one configuration needs to be tested (see 27.102.2). In that case, it is not necessary to exercise several combinations of anodes and cathodes.

The frequency range of the applied test signals (V_{PP}) shall be stepped from 16,6 Hz to 80 MHz, pausing to adjust the signal level and to allow enough time for the DUT behavioural response to be observed. Incremental steps are indicated in Table 104.

Test signal levels (V_{PP}) are shown in Table 105 and shall be applied to Port A (see Figure 101) according to the frequency ranges and lead lengths shown in Table 105. The amplitude of the test signal is defined as the peak-peak amplitude, before modulation, as measured on Port B in Figure 101.

At low frequencies and short lead lengths, V_{PP} might be very small. In these cases, the manufacturer may determine the start frequency based on voltages too low to cause a circuit response. For example, at voltages lower than a forward bias diode voltage drop. Rationale shall be provided. The stop frequency is always 80 MHz.

Table 104 — Frequency steps for the voltage injection test

Incremental frequency steps											
Hz	16,6	20	30	40	50	60	70	80	90	—	—
Hz	100	200	300	400	500	600	700	800	900	—	—
kHz	1	2	3	4	5	6	7	8	9	—	—
kHz	10	20	30	40	50	58	60	70	80	90	—
kHz	100	134	150	200	300	400	500	600	700	800	900
MHz	1	2	3	4	5	5,4	6	6,78	7	8	9
MHz	10,1	13,56	14,2	18,1	21	24,9	27,12	29	35	40,68	—
MHz	50	60	70	80	—	—	—	—	—	—	—

Table 105 — Peak-peak injected test levels V_{PP}

Frequency range (f)	**V_{PP} (Volts peak-peak)**	
	Lead length (l) 70 cm to 50 cm	Lead length (l) 49 cm to 2 cm
0,016 6 kHz to 0,400 kHz	0,30 x f x l^2/4 900	
0,4 kHz to 3,0 kHz	0,12 x l^2/4 900	
3,0 kHz to 150,0 kHz	0,04 x f x l^2/4 900	
0,15 MHz to 6,0 MHz	6,0 x l^2/4 900	
6,78 MHz to 24,9 MHz	6,0 x l^2/4 900	3,0 x l/50
27,12 MHz to 35,0 MHz	6,0	6,0 x l/50
40,68 MHz to 80,0 MHz	8,0	8,0 x l/50

NOTE 1 f expressed in kHz or MHz as indicated.

NOTE 2 Test amplitude (V_{PP}) before modulation.

NOTE 3 l (lead length) expressed in cm.

Over the range of frequencies from 16,6 Hz to 80 MHz, the following three types of modulation shall be used.

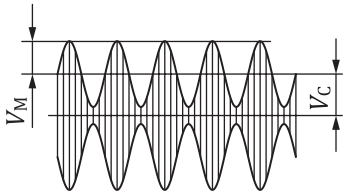
Modulation 1: To be used for the range of frequencies 16,6 Hz to 1 kHz. The test signal, V_{PP}, shall be sinusoidal continuous wave (CW).

Modulation 2: To be used for the range of frequencies 1 kHz to 150 kHz. The test signal, V_{PP}, shall be sinusoidal carrier, amplitude modulated with a 2 Hz sine wave. See Figure 102.

Modulation 3: To be used for the range of frequencies 150 kHz to 80 MHz. The test signal, V_{PP}, shall be sinusoidal carrier, amplitude modulated with a 1 kHz sine wave. See Figure 102.

The modulation index, M, for Figure 102 shall be 0,95, where

$$M = \frac{V_M}{V_C}$$



Key

V_M peak value of modulating signal

V_C peak value of carrier (unmodulated test signal)

Figure 102 — Amplitude modulated test signal for voltage injection test

Evaluation of test results: The DUT shall meet the immunity pass/fail criteria determined by the manufacturer.

27.105.2 Radiated magnetic field test for frequencies 1 kHz to 150 kHz

For this test, leads are not required.

Test equipment: A field coil capable of generating a magnetic field as shown in Table 106 in the region to be occupied by the DUT. The levels shown are minimum values to be maintained across the exposure area. A signal generator/amplifier capable of providing the drive current necessary to produce the required field strength.

Table 106 — Minimum magnetic field test levels *H*

Frequency range (f)	H (A/m rms)
1 kHz to 3 kHz	84/f
3 kHz to 150 kHz	28
NOTE 1 f in kHz. NOTE 2 Test amplitude (H) before modulation.	

Test procedure: Place the DUT, appropriately terminated, within the field coil so that it is centred in the field. Orient the DUT so that the plane of the largest surface area is aligned with the axis of the field coil. This will maximize the exposure of internal DUT coils if they are perpendicular to the primary magnetic flux lines of the field coil. This is the only orientation of the DUT that is required.

The frequency range of the applied radiated magnetic field shall be stepped from 1 kHz to 150 kHz, pausing to adjust the signal level and to allow enough time for the DUT behavioural response to be observed. Incremental steps are indicated in Table 107.

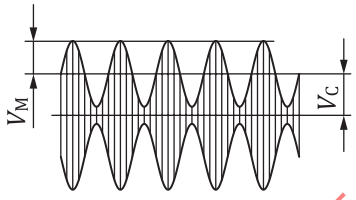
Table 107 — Frequency steps for the radiated magnetic test

Incremental frequency steps										
kHz	1	2	3	4	5	6	7	8	9	
kHz	10	20	30	40	50	58	60	70	80	90
kHz	100	134	150	—	—	—	—	—	—	—

Over the range of frequencies from 1 kHz to 150 kHz, the test signal, *H*, shall be sinusoidal carrier, amplitude modulated with a 2 Hz sine wave. See Figure 103.

The modulation index, *M*, for Figure 103 shall be 0,95, where

$$M = \frac{V_M}{V_C}$$



Key

V_M peak value of modulating signal

V_C peak value of carrier (unmodulated test signal)

Figure 103 — Amplitude modulated test signal for radiated magnetic test

Evaluation of test results: The DUT shall meet the immunity pass/fail criteria determined by the manufacturer.

27.106 Protection from EM disturbances over the frequency range 80 MHz to 2,7 GHz

For this test, the saline bath will accomplish the INS termination impedance requirement.

Test equipment: Use equipment as specified in IEC 61000-4-3 and a saline bath of 0,27 S/m conductivity, large enough to accommodate the DUT within the uniform electric field. A conductivity of 0,27 S/m represents an average value of tissue conductivity. Other values of conductivity may be used if appropriate for a specific location of intended use in the body.

Test procedure: Follow the methods specified in IEC 61000-4-3 unless superseded by a requirement in this document.

The DUT shall be placed within the saline bath as shown in Figure 103. The IPG and lead(s) shall be placed in the same plane and this plane and largest face of the IPG shall face the antenna. Lead routing is not essential but the distance between the distal end and the IPG shall be 50 cm for leads 50 cm and longer. For leads less than 50 cm in length, the lead(s) shall be extended to its full length.

The test shall be performed using two antenna polarizations, vertical and horizontal.

The frequency of the applied test signal shall be from 80 MHz to 2,7 GHz using modulations, step sizes, and dwell times as specified in IEC 61000-4-3. The applied test level shall be 10 V/m rms, before modulation.

Any ancillary equipment that is needed to operate the neurostimulator or monitor its output during the test shall be selected and located to minimize disruption of the uniform field.

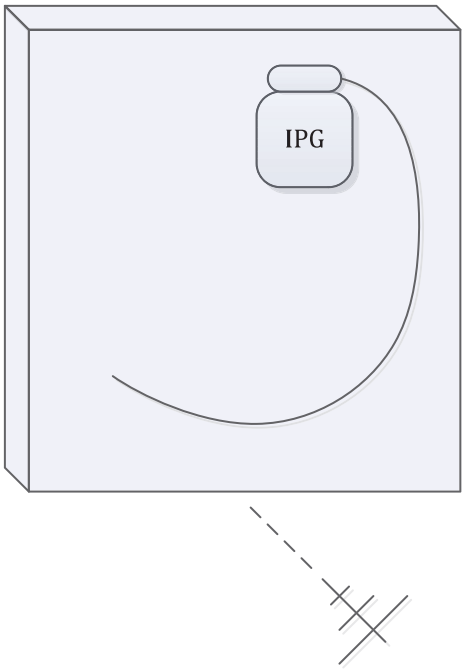


Figure 104 — IPG and lead layout

Evaluation of test results: The DUT shall meet the immunity pass/fail criteria determined by the manufacturer.

27.107 Protection from proximity fields due to RF wireless communications equipment

For this test, the saline bath will accomplish the INS termination impedance requirement.

This test can be performed at two test distances, 15,5 cm and 2,5 cm, as shown in Table 108. Other than distance, all test requirements are the same. If the 15,5 cm distance is used, a statement shall be added to the accompanying documentation (see 28.22). The statement shall be worded to the effect that: Portable RF communications equipment (for example mobile phones) should be kept a minimum distance of 15 cm (6 inches) from the area of the implanted device. No statement is required if the DUT meets acceptance criteria (see 27.102.1) at the 2,5 cm optional distance.

Test equipment: Use equipment as referenced in Table 108.

Test method: In general, this test shall use the dipole method of ISO 14117:2012, 4.9. ISO 14117 has been written for pacemakers and ICD's so some requirements have been modified and some are not applicable. See Table 108 for specific requirements.

Table 108 — Proximity test method requirements

ISO 14117 **sub-clause**	**Test method requirement**
4.9.1	Not applicable
4.9.2.1	Applies with no modification
4.9.2.2	Modification: Dipole element axis centreline to saline surface shall be 15 cm Modification: Dipole element axis centreline to device surface shall be 15,5 cm Other values of saline resistivity may be used if appropriate for a specific location of intended use in the body. Resistivity (ohm-m) as used in ISO 14117 is the reciprocal of conductivity (S/m) as used elsewhere in Clause 27. 375 ohm-cm is the equivalent of 0,27 S/m.
4.9.2.3	Modification: Align the connector bore that is closest to the IPG can with the X-axis

Table 108 *(continued)*

ISO 14117 **sub-clause**	**Test method requirement**
4.9.2.4	a) Modification: VSWR = 1,9:1 b) Modification: Test frequencies and modulation shall be as shown in Table 109
4.9.2.5	Not applicable
4.9.2.6	Applies with no modification
4.9.2.7	Modification: Simulated heart waveform is not applicable. Physiological simulation, if used, is applied to the second pair of plates as described.
4.9.3.1	Modification: Use the *Test procedure* described after this table
4.9.3.2	Modification: optional characterization testing is performed as follows: — dipole element axis centreline to saline surface shall be 2 cm — dipole element axis centreline to device surface shall be 2,5 cm All other requirements of Table 108 apply.
4.9.4	Not applicable

Test procedure: Set up the test equipment in accordance with ISO 14117:2012, Figure G.2. "ECG signal source" in ISO 14117:2012, Figure G.2 is replaced by "physiological simulation".

a) **X-axis testing**

Place a dipole antenna on the grid with the axis of the antenna elements parallel to the X-axis, with the dipole reference point centred over the DUT reference point at the elevation specified in Table 108. Patient physiological simulation shall be on or off, as appropriate.

Set the carrier frequency to match the dipole antenna being used. Set the corresponding dipole net RF power as shown in Table 109. Record the forward and reflected power readings for documentation purposes. The net power calculation is presented in ISO 14117:2012, Annex K.

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

b) **Y-axis testing**

Repeat a) with the antenna elements parallel to the Y-axis.

c) **Testing at remaining frequencies**

Repeat a) and b) for all frequencies listed in Table 109 using the appropriate dipole antenna and power levels.

Table 109 — Test frequencies, modulations, and net RF power

Test frequency MHz	**Pulse modulation**[a]	**Net RF power** W rms
385	18 Hz	1,8
450	18 Hz	2
710	217 Hz	0,2
745	217 Hz	
780	217 Hz	

[a] All test frequencies are pulse modulated using a 50 % duty cycle square wave signal.

Table 109 *(continued)*

Test frequency MHz	Pulse modulation[a]	Net RF power W rms
810	18 Hz	2
870	18 Hz	
930	18 Hz	
1 720	217 Hz	
1 845	217 Hz	
1 950	217 Hz	
2 450	217 Hz	

[a] All test frequencies are pulse modulated using a 50 % duty cycle square wave signal.

Evaluation of test results: The DUT shall meet the immunity pass/fail criteria determined by the manufacturer.

28 Accompanying documentation

This clause of ISO 14708-1 applies except as follows.

28.1

Addition:

The manufacturer's telephone number shall be provided in the accompanying documentation. The manufacturer's email address and web URL may also be provided as an option.

28.12

Addition:

NOTE Additional warning notices are required for MR Conditional devices. See 22.2.

28.13

Addition:

NOTE Additional information is required for MR Conditional devices. See 22.2.

28.22

Replacement:

The accompanying documentation shall provide warnings or precautions to be taken to prevent adverse effects to the patient due to hazards associated with electromagnetic disturbances (e.g. EAS, RFID), and other adverse environmental conditions (e.g. extreme temperature, variations of pressure).

NOTE Additional warning notices are required for MR Conditional devices. See 22.2.

28.23

Addition:

NOTE Additional warning notices are required for MR Conditional devices. See 22.2.

Additional subclauses:

28.104 The accompanying documentation shall include a patient ID card bearing space for at least the following information:

— model designation and name of the device;

— serial number or lot number of the device;

— identity of the patient;

— date of implantation;

— name and telephone number of the treating physician;

— manufacturer's contact telephone number (see 28.1);

— text that says the patient has an implanted medical device.

NOTE Additional information is required for MR Conditional devices. See 22.2.

Compliance is checked by inspection.

28.105 For devices using wireless technologies, the accompanying documentation shall address the following topics if applicable (see of ISO 14708-1:2014, 5.4 and 5.101):

— a brief description of the wireless QoS needed for safe and effective operation;

— a brief description of the recommended wireless security measures such as the WPA2 wireless encryption for IEEE 802.11 technology;

— information about any wireless coexistence issues and mitigations. This can include precautions for proximity to other wireless products, and specific recommendations for separation distances from such products.

Compliance is checked by inspection.

Annex AA
(normative)

Relationship between the fundamental principles in ISO/TR 14283 [1] and the clauses of this document

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
3 General principles		
3.1 The implants should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	8.1	Retained.
3.2 The solutions adopted by the manufacturer for the design and construction of the implants should conform to safety principles, taking into account the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: a) eliminate or reduce risks as far as possible (inherently safe design and construction); b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; c) inform users of the residual risks due to any shortcomings of the protection measures adopted.	Note 1	—
3.3 The implants should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in 3.1 (of ISO/TR 14283:2004), as specified by the manufacturer.	10.4	Retained.
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. NOTE 2 Not applicable to active implantable medical devices. NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile. NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation. NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
3.4 When the implant is subjected to stresses which can occur during normal conditions of use, the characteristics and performances referred to in 3.1, 3.2 and 3.3 (of ISO/TR 14283:2004) should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the implant as indicated by the manufacturer.	19.2 19.3 23.1 23.2 23.3 23.4 23.5 23.6 26.1 28.4 28.23	Retained. Retained. Amendment. Retained. Retained. Retained. Retained. Retained. Retained. Retained. Amendment.
3.5 The implants should be designed, manufactured, and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage, when taking into account the instructions and information provided by the manufacturer.	7.2 10.1 10.2 10.3 12.3 26.2	Retained. Retained. Retained. Retained. Retained. Retained.
3.6 Any undesirable side-effect should constitute an acceptable risk when weighed against the performances intended.	19.3 19.4	Retained. Retained.
4 Specific principles regarding design and construction		
4.1 Chemical, physical, and biological properties		
4.1.1 The implants should be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Clause 3 on general principles. Particular attention should be paid to:		
a) the choice of materials used, particularly as regards toxicity and, where appropriate, inflammability,	14.3	Retained.
b) the compatibility between the materials used and biological tissues, cells, and body fluids, taking into account the intended purpose of the implant.	14.3	Retained.
4.1.2 The implants should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage, and use of the implants and to the patients, taking into account the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.	14.2 14.3	Retained. Retained.
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. NOTE 2 Not applicable to active implantable medical devices. NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile. NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation. NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
4.1.3 The implants should be designed and manufactured in such a way that they can be used safely with the materials, substances, and gases with which they enter into contact during their normal use or during routine procedures. If the implants are intended to administer medicinal products, they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and such that their performance is maintained in accordance with the intended use.	19.5	Retained.
4.1.4 If an implant incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in 2.7 (of ISO/TR 14283:2004) and which is liable to act upon the body with action ancillary to that of the implant, the safety, quality, and usefulness of the substance should be verified, taking into account the intended purpose of the implant.	14.4	Retained.
4.1.5 The implants should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the implant.	25	Retained.
4.1.6 Implants should be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the implant, taking into account the implant and the nature of the environment in which it is intended to be used.	25	Retained.
4.1.7 Implants should be designed and manufactured in such a way as to minimize the risks to the patient or user by the programming and control systems, including software.	19.3	Retained.
4.2 Infection and microbial contamination		
4.2.1 The implants and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user, and third parties. The design should allow easy handling and, where necessary, minimize contamination of the implant by the patient or vice versa during use.	14.1	Retained.
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. NOTE 2 Not applicable to active implantable medical devices. NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile. NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation. NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
4.2.2 Tissues of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Information on the geographical origin of the animals should be retained by the manufacturer. Processing, reservation, testing, and handling of tissues, cells, and substances of animal origin should be carried out so as to provide optimal security. In particular, safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	Note 2	—
4.2.3 Implants delivered in a sterile state should be designed, manufactured, and packed in protective packaging which provides a microbial barrier to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions stipulated by the manufacturer, until the protective packaging is damaged or opened.	7.1 7.2 10.1 10.2 11.7 11.9 12.1 12.2 14.1	Retained. Retained. Retained. Retained. Retained. Retained. Retained. Retained. Retained.
4.2.4 Implants delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	14.1	Retained.
4.2.5 Implants intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	14.1 14.2	Retained. Retained.
4.2.6 Packaging systems for non-sterile implants should keep the product without deterioration at the level of cleanliness stipulated and, if the implants are to be sterilized prior to use, minimize the risk of microbial contamination. The packaging system should be suitable, taking into account the method of sterilization indicated by the manufacturer.	Note 3	—
4.2.7 The packaging and/or label of the implant should distinguish between identical or similar products sold in both sterile and non-sterile conditions.	Note 3	—
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. NOTE 2 Not applicable to active implantable medical devices. NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile. NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation. NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
4.3 Construction and environmental properties		
4.3.1 If the implant is intended for use in combination with other devices or equipment, the whole combination, including the connection system, should be safe and should not impair the specified performances of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.	9.9	Retained.
	11.8	Retained.
	23.6	Retained.
	28.4	Retained.
	28.5	Retained.
4.3.2 Implants should be designed and manufactured in such a way as to remove or minimize as far as possible, the following:		
a) risk of injury, in connection with their physical features, including the volume: pressure ratio, dimensional and where appropriate ergonomic features;	15.1	Retained.
	15.2	Retained.
b) risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature, or variations in pressure and acceleration;	23.1	Amendment.
	23.2	Retained.
	24	Replacement.
	25	Retained.
	26.2	Retained.
	27	Replacement.
c) risks of reciprocal interference with other devices (such as defibrillators or high-frequency surgical equipment) normally used in the investigations or for the treatment given;	20.1	Not used.
	20.2	Retained.
	21	Replacement.
	22	Addition.
	28.12	Addition.
	28.13	Addition.
	28.14	Retained.
	28.15	Retained.
d) risks that may arise where maintenance and calibration are impossible, including (if applicable) excessive increase of leakage currents, ageing of materials used, excess heat generated by the implant, decreased accuracy of any measuring, or control mechanism.	17	Replacement.
	19.1	Retained.
	19.2	Retained.
4.3.3 Implants should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal conditions and fault conditions. By "risks during normal conditions and fault conditions" are meant those risks which have been determined by a risk analysis. Particular attention should be paid to implants whose intended use includes exposure to flammable substances or to substances which could cause combustion.	5	Retained.
4.4 Implants with a measuring function		
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708.		
NOTE 2 Not applicable to active implantable medical devices.		
NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile.		
NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation.		
NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
4.4.1 Implants with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking into account the intended purpose of the implant. The limits of accuracy should be indicated by the manufacturer.	5	Retained.
4.4.1.1 The measurements, monitoring, and display scale should be designed in accordance with ergonomic principles, taking into account the intended purpose of the implant.	5	Retained.
4.4.1.2 If an implant or its accessories bear instructions required for the operation of the implant or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	13.4 5	Retained. Retained.
4.4.2 The measurements made by implants with a measuring function should be expressed in units conforming to the provisions of the ISO 31- series.	5	Retained.
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. NOTE 2 Not applicable to active implantable medical devices. NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile. NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation. NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
4.5 Protection against radiation		
4.5.1 General Implants should be designed and manufactured in such a way that exposure of patients, users, and other persons to radiation is reduced as far as possible, compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	See more particular requirements below.	—
4.5.2 Intended radiation	Note 2	—
4.5.3 Unintended radiation Implants should be designed and manufactured in such a way that exposure of patients, users, and other persons to the emission of unintended, stray, or scattered radiation is reduced as far as possible.	9.1 18.1 18.2 18.3 28.2	Retained. Retained. Retained. Retained. Retained.
4.5.4 Instructions	Note 2	—
4.6 Ionizing radiation	Note 2	—
4.7 Principles for implants connected to or equipped with an energy source		
4.7.1 General		
4.7.1.1 Implants incorporating electronic programmable systems should be designed to ensure the repeatability, reliability, and performance of these systems according to their intended use. In the event of risks (of the system) as determined by a risk analysis for the particular device/system, appropriate means should be adopted to eliminate or reduce as far as possible their risk.	19.3	Retained.
4.7.1.2 Implants for which the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.	19.2	Retained.
4.7.1.3 Implants should bear, if practical and appropriate, a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of implant). It should be possible to read this code, if necessary, without the need for a surgical operation.	13.3 28.6	Retained. Retained.
4.7.1.4 For implants for which the safety of the patients depends on an external power supply, the external power supply should include an alarm system to signal any power failure.	5	Retained.
4.7.1.5 External devices intended to monitor one or more clinical parameters from an implant should be equipped with appropriate alarm systems to alert the user to situations that could lead to death or severe deterioration of the patient's state of health.	5	Retained.

NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708.

NOTE 2 Not applicable to active implantable medical devices.

NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile.

NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation.

NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
4.7.2 Protection against electrical risks		
4.7.2.1 Implants should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal conditions and fault conditions provided the implants are installed correctly. By the "risks during normal conditions and fault conditions" are meant those risks which have been determined by a risk analysis for the particular device(s).	5 16.1	Retained. Retained.
4.7.2.2 Active implants should be designed and manufactured in such a way as to minimize the risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents, and overheating of the devices.	16.2 16.3 17.1 26.1	Retained. Retained. Replacement. Retained.
4.7.3 Protection against mechanical risks		
4.7.3.1 Implants should be designed and manufactured in such a way as to protect the patient and user against mechanical risks, for example, those connected with resistance, stability, and moving parts.	5	Retained.
4.7.3.2 Implants should be designed and manufactured in such a way as to minimize the risks arising from vibration generated by the implants, taking into account technical progress and the means available for limiting vibration, particularly at source, unless the vibrations are part of the specified performance.	5	Retained.
4.7.3.3 Implants should be designed and manufactured in such a way as to minimize the risks arising from the noise emitted, taking into account technical progress and the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	5	Retained.
4.7.3.4 Terminals and connectors to electricity, gas, or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.	5	Retained.
4.7.4 Protection against the risks posed to the patient by energy supplies or substances		
4.7.4.1 Implants should be designed and constructed in such a way that the proper functioning of the programming and control systems, including software, do not jeopardize the safety of the patient and of the user, taking into account the intended use.	19.3	Retained.
4.7.4.2 Implants designed to supply energy or administer medicinal substances should be designed and constructed in such a way that the flow rate can be set and maintained accurately enough to minimize the risk to the patient.	5	Retained.
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. NOTE 2 Not applicable to active implantable medical devices. NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile. NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation. NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
4.7.4.3 Implants designed to administer medicinal products should incorporate suitable means to prevent and/or indicate any inadequacies in the flow rate which could pose a danger.	5	Retained.
4.7.4.4 Implants designed to supply energy or administer medicinal substances should be designed and constructed so that suitable means are incorporated to minimize the risk of accidental release of dangerous levels of energy or the medicinal substance.	5	Retained.
4.8 Information supplied by the manufacturer		
4.8.1 Each implant should be accompanied by the information needed to use it safely and to identify the manufacturer, taking into account the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the implant safely should be set out on the implant itself and/or on the packaging for each unit or, if appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information should be set out in the leaflet supplied with one or more implants. Instructions for use should be included in the packaging for every implant.	10.4 12.3	Retained. Retained.
4.8.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to International Standards. If no standards exist, the symbols and colours should be described in the documentation supplied with the implant.	4	Retained.
4.8.3 The label should bear the following particulars:	5	Retained.
a) the name or trade name and address of the manufacturer;	9.2 11.1	Retained. Retained.
b) the details strictly necessary for the user to identify the implant and the contents of the packaging;	9.3 9.4 9.8 9.10 11.6 11.7	Retained. Retained. Retained. Retained. Retained. Retained.
c) where appropriate, an indication that the contents of the packaging are sterile (e.g. “STERILE”);	9.5 11.2 11.3	Retained. Retained. Retained.
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. NOTE 2 Not applicable to active implantable medical devices. NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile. NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation. NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
d) where appropriate, the batch code or the serial number (SN), preceded by an appropriate identification (e.g. "LOT" or "SN" respectively);	9.3	Retained.
	11.6	Retained.
e) where appropriate, an indication of the date by which the implant should be used;	9.7	Retained.
	11.5	Retained.
f) an indication that the implant is for single use;	28.18	Retained.
g) if appropriate, any indication of special purpose (e.g. "custom-made device" or "exclusively for clinical investigations");	9.12	Retained.
	11.10	Retained.
h) any special storage and/or handling conditions;	9.11	Retained.
i) any special operating instructions;	Note 4	—
j) any warnings and/or precautions to take;	Note 5	—
k) for active implants, month and year of manufacture;	9.6	Retained.
	11.4	Retained.
l) if applicable, method of sterilization.	11.2	Retained.
4.8.4 If the intended purpose of the implant is not obvious to the user, the manufacturer should clearly state it on the label and in the instructions for use.	9.10	Retained.
4.8.5 Wherever reasonable and practicable, the implants and detachable components should be identified, if appropriate in terms of serial numbers or batches, to allow all appropriate actions to be taken following discovery of any potential risk posed by the implants and detachable components.	8.2	Addition.
	13.1	Retained.
	13.2	Retained.
4.8.6 If appropriate, the instructions for use should contain the following particulars:		
a) the details referred to in 4.8.3, with the exception of d), e), and k);	28.1	Addition.
	28.3	Retained.
	28.16	Retained.
	28.18	Retained.
	28.21	Retained.
b) the performances referred to in ISO/TR 14283:2004, 3.3 and any undesirable side-effects;	28.8	Retained.
c) if the implant should be used with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct implants or equipment to use in order to obtain a safe combination;	28.4	Retained.
	28.5	Retained.
	28.9	Retained.
d) all the information needed to verify whether the implant is properly used and can operate correctly and safely, plus, where appropriate, information allowing the lifetime of the energy source to be established;	28.10	Retained.
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708.		
NOTE 2 Not applicable to active implantable medical devices.		
NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile.		
NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation.		
NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
e) where appropriate, information to avoid specified risks in connection with implantation of the implant;	28.11	Retained.
f) information regarding the risks of reciprocal interference posed by the presence of the implant during specific investigations or treatment;	28.12	Addition.
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	28.17	Retained.
h) if implants are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the implant will still comply with the principles in ISO/TR 14283:2004, Clause 3;	28.17	Retained.
i) details of any further treatment or handling needed before the implant can be used (for example, sterilization, final assembly, etc.);	Note 3	—
j) in the case of implants emitting radiation for medical purposes, details of the nature, type intensity, and distribution of this radiation.	Note 2	—
The instructions for use should also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:		
k) precautions to be taken in the event of changes in the performance of the implant;	28.19 28.20	Retained. Retained.
l) precautions to be taken as regards exposure to, in reasonably foreseeable environmental conditions, e.g. magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	28.22	Replacement.
m) adequate information regarding the medicinal product or products which the implant in question is designed to administer, including any limitations in the choice of substances to be delivered;	28.7	Retained.
n) precautions to be taken against any special, unusual risks related to the disposal of the implant;	28.24	Retained.
o) medicinal products incorporated into the implant as an integral part in accordance with ISO/TR 14283:2004, 4.1.4;	28.8	Retained.
p) degree of accuracy claimed for implants with a measuring function.	5	Retained.

NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708.

NOTE 2 Not applicable to active implantable medical devices.

NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile.

NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation.

NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.

Fundamental principles in ISO/TR 14283	**Subclauses of** ISO 14708-1	**Clauses of** ISO 14708-3 **and aspects covered**
4.9 Clinical evaluation If conformity with the fundamental principles for implants should be based on clinical data, such data should be established by either		
a) a compilation of the relevant scientific literature currently available on the purpose intended by the manufacturer, or	19.4	Retained.
b) the results of all the clinical investigations carried out in a way that protects the human subjects and ensures the scientific conduct of the investigation.	19.4	Retained.
NOTE 1 This principle is fundamental to all aspects of an active implantable medical device addressed by ISO 14708. NOTE 2 Not applicable to active implantable medical devices. NOTE 3 Not applicable because 14.1 requires that implantable parts of an active implantable medical device be provided sterile. NOTE 4 For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation. NOTE 5 In the general case, warnings and precautions, except for those dealing with special handling conditions [see 4.8.3.h)], should be described in the accompanying documentation instead of on the label.		

Annex BB
(informative)

Rationale

BB.1 General

The following notes on some of the provisions of this document are provided as an aid to understanding. The notes in this annex carry the numbers of the relevant clauses of this document, therefore, paragraph numbering in this annex is not consecutive.

BB.2 Notes on specific clauses and subclauses

1 Non-implantable neurostimulators, e.g. trial screeners, that cannot be considered as accessories to an implantable neurostimulator are covered by the IEC 60601-1 series of standards (see Clause 5).

5.5.4 When applying the risk management process to a particular neurostimulation product, consideration should be given to the potential hazard of the device's maximum settable level of stimulation energy resulting in nerve damage and overstimulation-related hazards that could occur as a result of susceptibility to electromagnetic non-ionizing radiation, or as a result of any particular device component failure. These types of hazards should be considered within the process of following ISO 14971 such that mitigations can be identified to effectively reduce the potential for these risks to an acceptable level.

17.1 It is generally accepted[2] that a localised temperature of 39 °C does not cause tissue damage. ISO 14708-1 requires <2 °C rise above the normal surrounding body temperature of 37 °C. The committee understands that the actual "normal surrounding body temperature" is influenced by several factors including the location of the implant and the environment and therefore changed to the 39 °C limit. For the purpose of design verification of a device to meet this subclause, the manufacturer can develop a test method and justify the initial starting temperature of the device based on its intended location in the body and other relevant factors.

CEM43 is a generally accepted method to normalise the impact of temperature and time on tissue for temperatures in the range of 39 °C and 57 °C[3]. Reference [4] demonstrates that the CEM43 values that represent the damage thresholds is different depending on the tissue type. Because the research is generally based on the observation of damage, values below these thresholds might be safe but the margin of this safety cannot be determined. Reference [4] therefore concludes that a CEM43 value of <2 is a safe value for any tissue. This is likely to be very conservative and van Rhoon, et al recognises this and recommends higher CEM43 under certain conditions and for various tissue types. The manufacturer is required to provide further analysis for CEM43 values >2 including, for example,

— the margin to the maximum values in Table 101,

— whether the heating events are repeating or a single event,

— medical assessment of the impact of the possible tissue damage and prognosis for the patient, and

— other controls.

The extent of damage to tissue due to heat is dependent on a number of factors including the duration of the exposure and the temperature experienced during the exposure. Reference [5] describes a mathematical model that unifies temperature and the cumulative duration of exposure into a single value equivalent to the Cumulative Equivalent Minutes (CEM) at 43 °C for 1 min. For example, 10CEM43 is equivalent to 10 min of exposure at 43 °C. General consensus is that the units for CEM43 are minutes.

The CEM43 model approximates the non-linear relationship of tissue damage by using two linear relationships with a break point at 43 °C.

The formula for CEM43 for a constant temperature is given by Formula (BB.1):

$$\text{CEM43} = tR^{(43-T)} \quad \text{(BB.1)}$$

where

T is the temperature of the tissue in °C;

R is 0,25 for T <43 °C and 0,5 for $T \geq 43$ °C;

t is the cumulative duration of the heating event in minutes.

Formula (BB.1) is valid for temperatures between 39 °C and 57 °C.

Evaluating the CEM43 formula at different temperatures and a constant duration yields the values shown in Table BB.1.

Table BB.1 — Evaluating CEM43 formula at different temperatures

Temperature °C	Duration (minutes)	CEM43
40	10	0,156 25
41	10	0,625
42	10	2,5
43	10	10
44	10	20
45	10	40
46	10	80
47	10	160
48	10	320
49	10	640
50	10	1 280
51	10	2 560
52	10	5 120
53	10	10 240

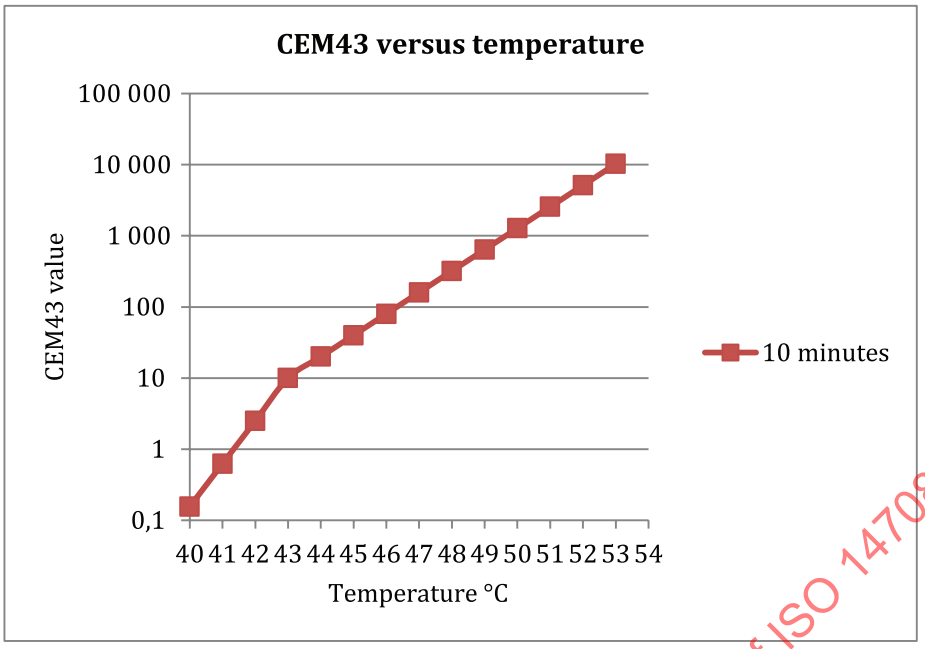


Figure BB.1 — CEM43 versus temperature for constant time

Each data point in Figure BB.1 assumes that the temperature is fixed to a single value for the duration of the exposure. In this case, a plot of the temperature versus time would be a rectangle and its CEM43 value can be calculated using Formula (BB.1).

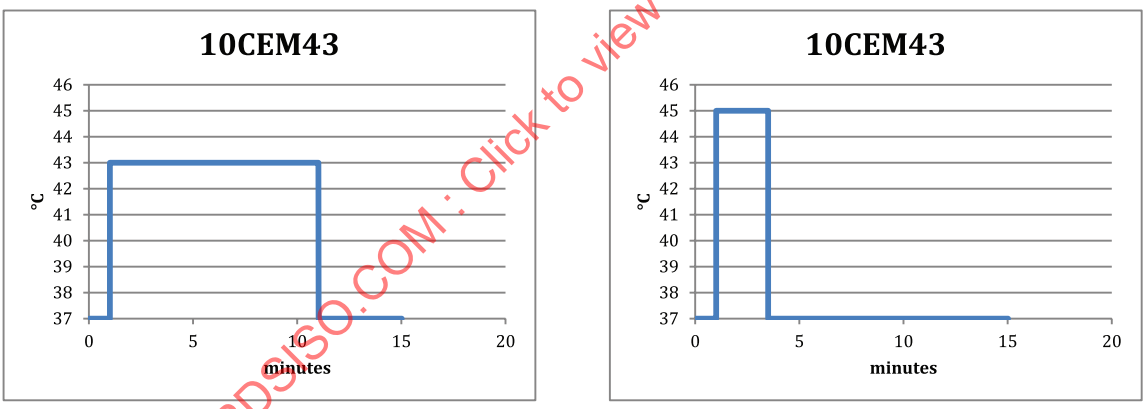


Figure BB.2 — Two examples of the same CEM43 result with different exposure times

The examples in Figure BB.2 both yield a 10CEM43; the first chart shows 10 min exposure at 43 °C while the second is 2,5 min at 45 °C.

In practice, the temperature is likely to vary in value for the duration of exposure. In this case, the CEM43 value can be calculated by the summation of the CEM43 values for a series of rectangles, each with a known duration and temperature. The example in Figure BB.3 shows such a profile which results in a 30CEM43. It consists of an initial temperature exposure of 43 °C for 10 min followed by 2,5 min at 45°C and then another 43 °C for 10 min.

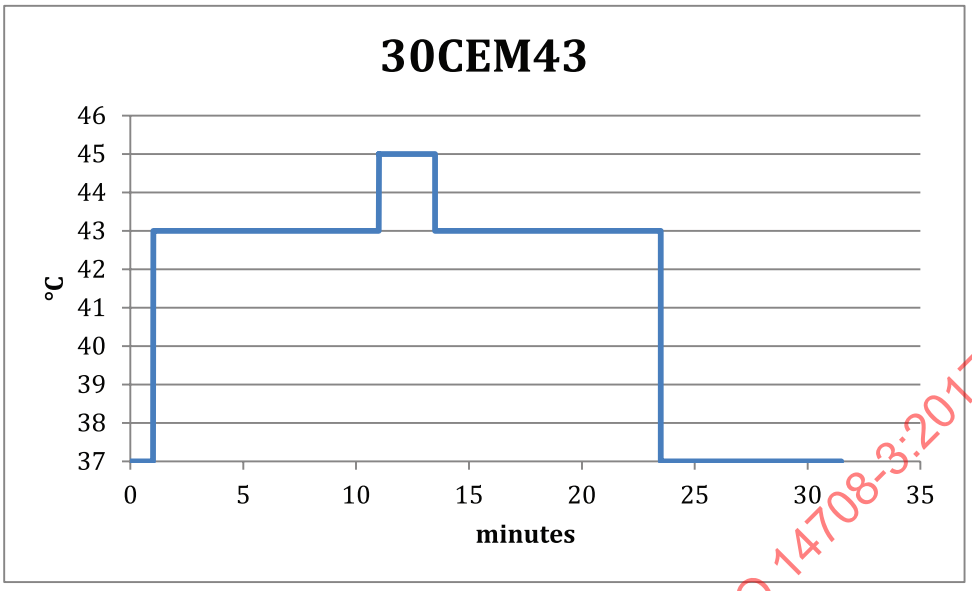


Figure BB.3 — Example showing a time and temperature profile

By sampling the temperature at known time intervals and using the above approach, the CEM43 value for a given temperature profile can be calculated by Formula (BB.2):

$$\mathrm{CEM43} = \sum_{i=1}^{n} t_i \times R^{(43-T_i)} \qquad \text{(BB.2)}$$

where

t_i is the i-th time interval;

n is the total number of time intervals;

T_i is the average temperature of the tissue in °C during the interval t_i;

R = 0,25 for T < 43 °C and 0,5 for T ≥ 43 °C.

Formula (BB.2) is valid for temperatures between 39 °C and 57 °C.

NOTE This method is used in Reference [4].

Single fault conditions were removed from the requirements of 17.1 because single fault conditions are already evaluated as part of 19.3. See rationale for 19.3 for more details on how to address harm related to heat under single fault failure.

19.3 Because 19.3 is responsible for assessing risks from failures, it was decided for this document that all requirements requiring assessment of single fault failures to be moved to 19.3. One such requirement was originally found in 17.1 for protection from harm caused by heat. This rationale is to remind that although 17.1 does not address single fault conditions, harm related to heat under single fault conditions still needs to be evaluated in 19.3. The following explains an example of how this could be executed using the concept of components with high-integrity characteristics, that could also be used for other types of effects from single fault failures.

First, identify components, through the risk management process, that would need to be considered to ensure that patient is protected from harm caused by heat under single fault conditions. Acceptance criteria from 17.1 can be used to determine the acceptability of the risk under single fault conditions. It is possible that certain component failures might not meet the requirement of 17.1 and for which further risk control is not practicable.

Considering ISO 14971:2007, 6.5: "*If the residual risk is not judged acceptable using the criteria established in the risk management plan and further risk control is not practicable, the manufacturer may gather and review data and literature to determine if the medical benefits of the intended use outweigh the residual risk,*" it could be possible for the manufacturer to justify the risk with components that are considered as possessing high-integrity characteristics.

The first step to determine a component with high-integrity characteristics is to conduct a risk analysis to find those characteristics that are required to be maintained. Having done this, the appropriate component can be selected. Reference can be made to IEC or ISO component standards as part of the determination of the characteristics required.

Testing of component with high-integrity characteristics are only part of the required determination of suitability. Since a particular component with high-integrity characteristics has to function as intended or a hazard is likely to occur, additional considerations include as appropriate:

— continuous surveillance as part of the manufacturing process and also after assembly into the end product;

— particular characteristics of the device concerned;

— lot testing;

— calibration;

— control of manufacturing defects;

— maintenance;

— projected service life of the INS;

— use of relevant component standards;

— failure mode characteristics;

— environmental conditions;

— anticipated misuse of the INS;

— interaction with other equipment.

It would not be expected from the manufacturer to test the single component fault condition of a component with high-integrity characteristics (such as required by 17.1), provided that all the aspects identified to ensure the high-integrity characteristics components are met and implemented by the manufacturer.

For example, certain fault from a battery, like an internal short, could result in unacceptable risk and risk controls to prevent this once the device is implanted would not be practicable. In this particular case, the battery selected for this function would require to be a component with high-integrity characteristics, which is defined as a component where one or more characteristics ensure that its function is fault-free in relation to the safety requirements of this document during the projected service life of the implantable neurostimulator in normal use and reasonably foreseeable misuse.

24.1 ISO 14708-1:2014, 24.1 was replaced to reference IEC 60601-1-2 and remove the requirement that the non-implantable part "can be reset and provide all functions as stated by the Manufacturer's specification" following the electrostatic discharge. The original ISO 14708-1:2014, 24.1 requirement was too stringent to apply to all neurostimulator devices because neurostimulators have different levels of risks depending on their application and treatment they provide. This replacement requires the manufacturer to define the appropriate acceptance criteria depending on its application according to IEC 60601-1-2. See IEC 60601-1-2, Annex I for guidance and examples on how the manufacturer can specify acceptance criteria for immunity testing.

The test requirement applies only to non-implantable parts. The implantable part is believed to be sufficiently protected from electrostatic potentials by its packaging and because it is only handled under controlled conditions.

While the electrostatic discharge is applied only to the non-implantable parts, the operation of the active implantable medical device is evaluated as a system following the test. The intent is to demonstrate that the implantable parts continue to operate in a safe mode that does not result in an unacceptable risk to the patient if the electrostatic discharge occurs when the system is most vulnerable, i.e. while the non-implantable part is communicating with the implantable part. For example, the manufacturer can demonstrate that the system has robust error checking so that a message corrupted as a result of the electrostatic discharge is not accepted by the implantable part.

27.101 All test levels in Clause 27 are based on the reasonably foreseeable maximum electromagnetic disturbance levels in the general public environment. This environment is based on the home healthcare environment in IEC 60601-1-2, except for magnetic field test levels.

Tests only simulate the environment and cover the most common sources of electromagnetic disturbances in the general public environment and should be considered the minimum necessary to assess device behavioural responses when exposed to electromagnetic fields.

27.102.1 The acceptance criteria consist of a two-part requirement; that the performance intended by the manufacturer is expected to be maintained and that no hazardous situations will occur that could lead to an unacceptable risk. Although this document is primarily a safety standard, there are performance aspects to it. The general public has an expectation that their implanted device will work as intended, not that it just fails safely.

This document stops just short of stating that intended performance shall be maintained during testing. Due to the wide scope of this document (central and peripheral nervous system), some performance degradation or unintentional responses might occur, during the course of testing, that are not considered to be a part of the intended performance but that are otherwise safe because they will not result in an unacceptable risk. This document requires disclosure, explanation, and justification for any behavioural responses, during the course of testing, which are outside of intended use performance characteristics. These types of responses are expected to be temporary and to end at the cessation of testing. Permanent changes in performance due to these tests, outside of specification, are not allowed.

27.102.3 The tests in this document are intended for the implantable parts of the INS. Since a wireless function necessitates a non-implantable part, which is covered by IEC 60601-1-2, the wireless function is to be evaluated according to that standard.

27.104 Static magnetic field strengths from natural sources in the environment are very low. Man-made sources commonly encountered by the general public are seldom above a few mT, and these are generally caused by permanent magnets such as for refrigerators, speakers, and by magnets supplied by medical device manufacturers to trigger built-in reed or Hall effect switches for control purposes of some devices.

A flux density of 50 mT was chosen because exposure at this level is possible from common sources. Although the exposure rate might be low, devices are still expected to remain safe and to perform their intended use.

27.105 This range of frequencies includes both magnetic field and electric field sources. The test is divided into two parts: one to evaluate the effects of magnetic field and electric field coupling into the patient leads and the other to evaluate the effects of magnetic field coupling directly into device circuitry through the can.

Since the relative permeability of an implanted device is typically close to one, it is essentially transparent to magnetic fields. Therefore, the effects of exposure to low frequency magnetic fields can be caused by both direct coupling and coupling into patient leads. Whereas, the effects of exposure to electric fields in this range are only caused by coupling into patient leads due to device enclosure shielding and to the wavelengths of electric field sources since devices the size of IPGs have very short electrical length.

27.105.1 The test is performed using injected voltage levels that correspond to induced voltage levels (*V*oc) that could occur in patient leads exposed to specific levels of radiated magnetic and electric fields.

Induced voltages from time-varying electric and magnetic fields depend on lead length according to well-known principles. This document uses a maximum lead length of 70 cm upon which to base injected voltage test levels. This length was chosen from anthropometric data[6] for a 95th percentile male which indicates that the longest dimension in the torso from electrode to can would be 50 cm for a lead routed in a general configuration from abdomen to T1 forming two sides of a right-angled triangle, with approximate equal sides of 35 cm length. In this case, the current return path (virtual hypotenuse) is formed by body tissues. The maximum effective electrical length is therefore 50 cm and the maximum effective induction area is 612 cm^2.

NOTE Although a lead might be longer in practice than 70 cm, this is the effective maximum length for the purpose of calculating induced voltage levels. Longer leads will not increase the tip to can distance nor, in practice, the effective induction area.

In order to determine injected voltage test levels, induced voltage calculations were made across the range of frequencies for lead lengths from 2 cm to 70 cm using magnetic and electric field transfer functions. This makes it possible to simulate the effects of radiated fields using injected voltage methods.

For reasons having to do with area versus length and the information provided in FprEN 50527-2-1:2016, Annex E[7], the H-field dominates for frequencies under 6,78 MHz. In the range 6,78 MHz to 24,9 MHz, the H-field dominates for lead lengths of 50 cm to 70 cm and the E-field for lengths under 50 cm. For frequencies above 24,9 MHz to 80 MHz, the E-field dominates. The formulae derived for determining test levels reflect these boundary conditions and, for any given lead length and frequency, are based upon the highest induced voltage caused by either the H-field or E-field.

Since the relative permeability of tissue is one, it is essentially transparent to magnetic fields. Therefore, the open circuit voltage (*V*oc) that is input to an AIMD is described by Faraday's law of induction based on frequency, effective area, and the reasonably foreseeable maximum magnetic field. This document presumes a uniform magnetic field that is perpendicular to the entire bounded area formed by the lead which will yield the most conservative induced voltage and, hence, maximum injected voltage levels. Lead length, frequency, and H-field are factored into injected test level formulas.

The electric field is not so easy to calculate due to the dielectric properties of tissue. The internal field is related to frequency, conductivity, and permittivity. Extensive dosimetric work has been published on SAR computations and measurements and from SAR data the internal E-field can be computed[8][9]. It turns out there is a human body resonance around 80 MHz and this is where the maximum energy absorption, and hence E-field occurs. Calculations show that an internal E-field of just over 5 V/m will result from an ambient E-field of 10 V/m, frequency 70 MHz to 80 MHz, based on whole body average SAR (less for lower frequencies).

NOTE An ambient electric field strength of 10 V/m is presumed to apply which represents the reasonably foreseeable maximum level in the general public environment over this frequency range, except for ISM frequencies. This level is harmonized with the home healthcare environment of IEC 60601-1-2. ISM are also considered as described below.

The open circuit voltage (*V*oc) that is input to an AIMD is on the order of internal E-field times the effective lead length. As already described, the maximum effective length for the purpose of this document is 50 cm. For leads less than 50 cm length, the actual length is also the effective length. Lead length, frequency, and internal E-field are factored into injected test level formulas.

Injected test voltages are meant to simulate *V*oc. The actual voltage that is seen by the IPG in practice can be reduced by device input impedance, lead impedance, and tissue impedance. Considering the wide range of implantable neurostimulators covered by this document, these impedances were not factored into test levels. However, these impedances can be calculated by the manufacturer and incorporated into the injection network.

As previously mentioned, electric field disturbance is harmonized with IEC 60601-1-2 and is considered to be 10 V/m for the home healthcare environment including HAM radio frequencies. ISM frequencies within this range (6,78 MHz, 13,56 MHz, 27,12 MHz, and 40,68 MHz) have no power limits. For the purpose of this document, ISM frequencies are considered limited by human exposure safety levels which range from 28 V/m to 83 V/m depending on frequency and were taken into account in deriving the injected test level formulae.

Exposure to time-varying magnetic fields in this range is primarily from power frequency equipment and appliances and also from EAS/RFID equipment operating at 58 kHz, 134 kHz, and 13,56 MHz. For the purpose of establishing test levels related to magnetic fields, this document is based on the environmental data presented in Figure BB.4 (see References [10] to [24]). This represents the reasonably foreseeable maximum level in the general public environment from 16,6 Hz to 30 MHz. Magnetic fields above 30 MHz are negligible and *V*oc above 30 MHz is dominated by electric fields as previously described.

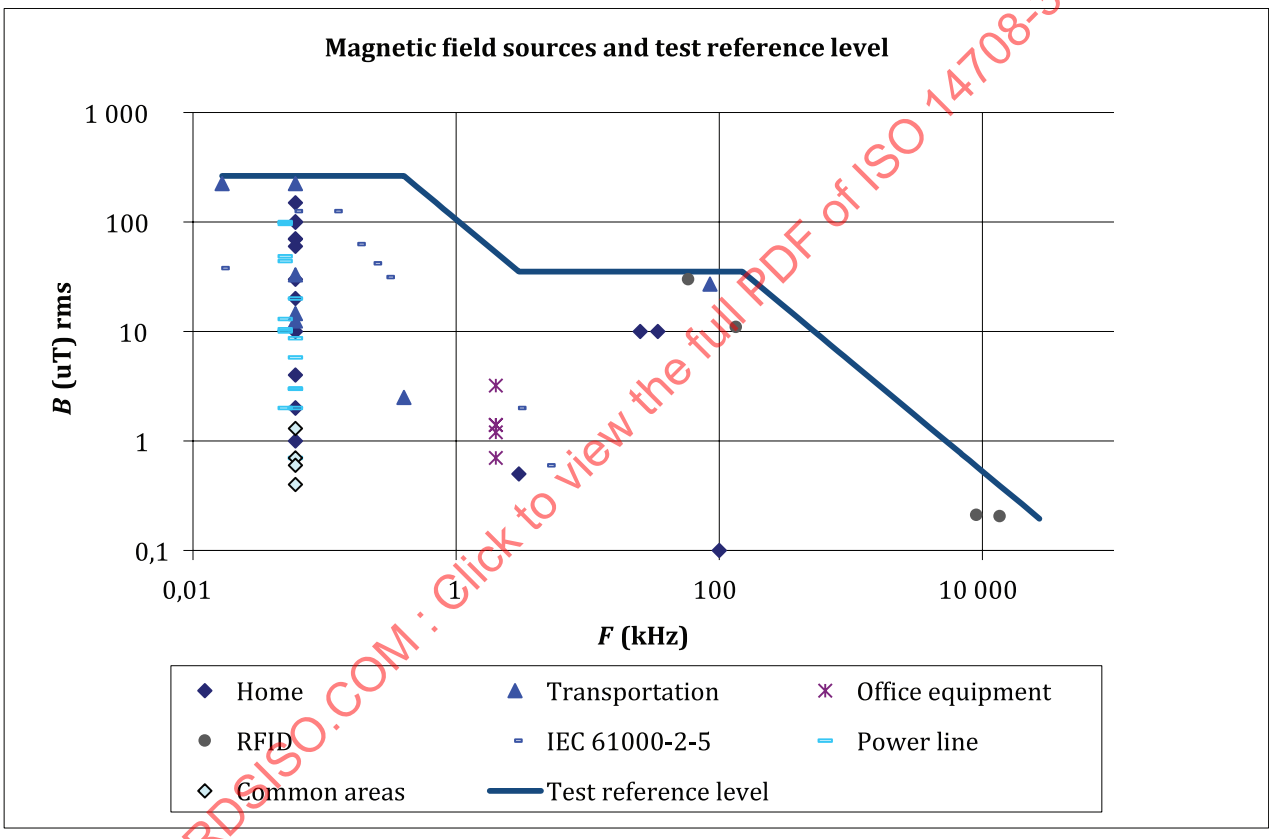


Figure BB.4 — Magnetic field environment test reference level

The numerical equivalent of the test reference level shown in Figure BB.4 is shown in Table BB.2 in units of magnetic field strength (A/m).

NOTE The relationship between flux density (B) and field strength (H) is H = B/μ, where μ is the permeability of the medium. In air $\mu = 4\pi \times 10^{-7}$ N/A^2.

Table BB.2 — Magnetic field test reference levels

Frequency range (f)	H (A/m) rms
16,6 Hz to 400 Hz	210
0,4 kHz to 3 kHz	84/f
3 kHz to 150 kHz	28
0,150 MHz to 30 MHz	4,2/f
NOTE f in kHz or MHz as indicated.	

Consolidating Voc from magnetic and electric field sources over the range of 16,6 Hz to 80 MHz results in the injected voltage test levels shown in Figure BB.5.

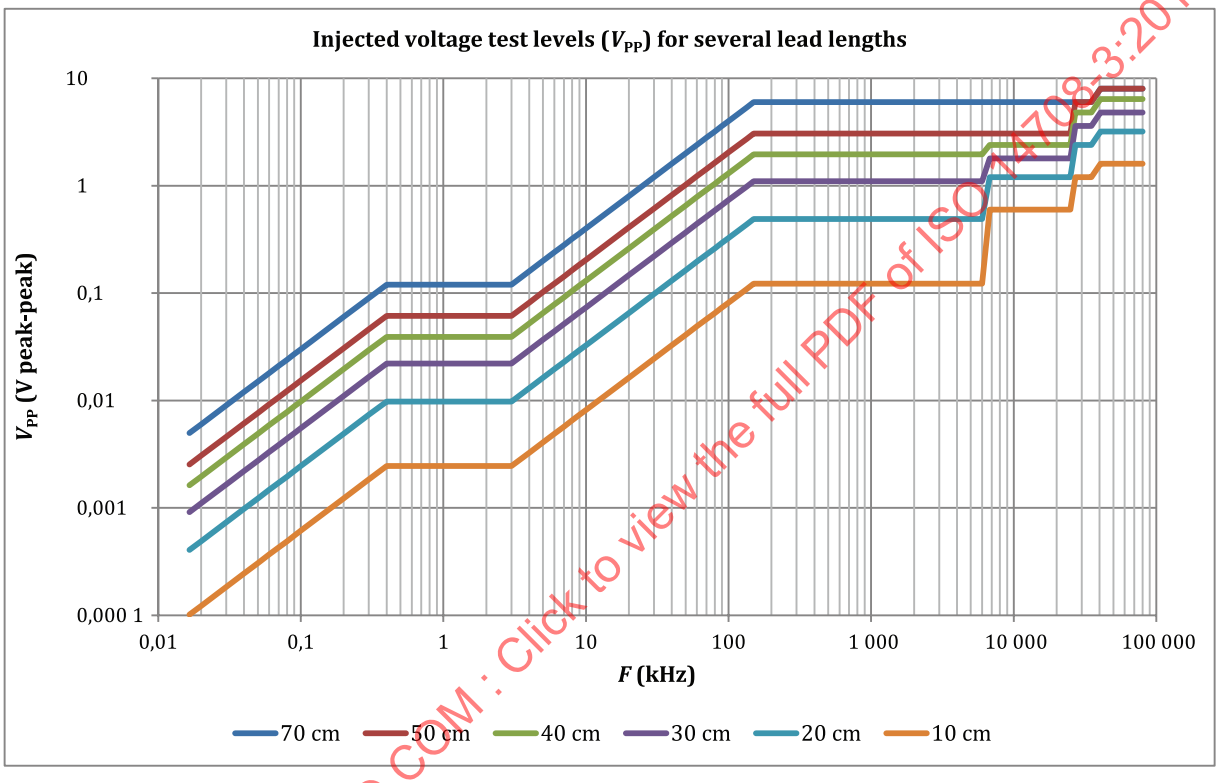


Figure BB.5 — Injected voltage test levels (V_{PP}) 16,6 Hz to 80 MHz

The numerical equivalents of the test levels shown in Figure BB.5 are shown in Table BB.3.

Table BB.3 — Peak-peak injected test levels V_{PP}

Frequency range (f)	V_{PP}	
	Lead length (l) 70 cm to 50 cm	Lead length (l) 49 cm to 2 cm
0,016 6 kHz to 0,400 kHz	0,30 × f × l^2/4 900	
0,4 kHz to 3,0 kHz	0,12 × l^2/4 900	
3,0 kHz to 150,0 kHz	0,04 × f × l^2/4 900	
0,15 MHz to 6,0 MHz	6,0 × l^2/4 900	
6,78 MHz to 24,9 MHz	6,0 × l^2/4 900	3,0 × l/50
27,12 MHz to 35,0 MHz	6,0	6,0 × l/50
40,68 MHz to 80,0 MHz	8,0	8,0 × l/50
NOTE f expressed in kHz or MHz as indicated.		

At low frequencies and short lead lengths, V_{PP} might be very small. In these cases, the manufacturer may determine the start frequency based on voltages too low to cause a circuit response, for example, at voltages lower than a forward bias diode voltage drop. Rationale is required to be provided.

The frequency range of the applied test signals includes an adequate number of incremental steps to assess DUT safety and performance without sacrificing test time. In addition to general coverage of the frequency range, steps include frequencies related to HAM radio, ISM, EAS, and RFID. If desired, the manufacturer may perform a frequency sweep instead.

Due to the multitude of modulation types present in today's environment, it is not possible to test them all, or to even know which types will affect a particular variety of implantable neurostimulator covered by this document. Amplitude modulation of 80 % at 1 kHz has been customarily used for performing immunity testing for frequencies above 150 kHz because it is generally recognized to best simulate the diversity and characteristics of various modulation types in the environment for its ability to create disturbances in the operation of equipment. The same concept is used within this document. For the range of 1 kHz to 150 kHz, 2 Hz modulation is used because it would not make sense to use 1 kHz modulation on a 1 kHz carrier and because 2 Hz represents a reasonable approximation of a physiological passband. No modulation is required under 1 kHz because that is getting close to power line frequencies and harmonics.

27.105.2 This test covers induction of voltages into device circuitry by direct H-field coupling through the can based on the test reference level of Figure BB.4. Since the relative permeability of an implanted device is typically close to one, the can is essentially transparent to magnetic fields. Applying Faraday's Law to internal circuitry, as was done in a similar fashion for patient leads, a range of induced voltages can be calculated based on circuit area, frequency, and magnetic field strength.

Calculations based on frequency and field strength represented by Figure BB.4 reveal that induced voltages for frequencies in this range are insignificant for all circuits except for inductive coils used for communication and for recharging. For all other circuits (collectively herein called "state machine"), their small size averts the induction of voltages that could affect circuit operation. For this reason, a functional test for direct effects on the state machine is not required.

For communication and recharge coils, their potentially larger size and loop areas might contribute to induced voltages that could indirectly affect the state machine. For this reason, a functional test is performed.

NOTE Testing the communication and recharge functions, per se, are outside the scope of this document. Because a programmer or charger is required, these functions are tested according to IEC 60601-1-2.

The start frequency is set to 1 kHz. Below that frequency, none of the circuits mentioned exhibit any significant induced voltage due to the low dB/dt.

The stop frequency is set to 150 kHz. Above that frequency, the magnetic field exhibits a 1/f falloff (see Figure BB.4) and induced voltage has reached a peak and there are no significant magnetic field sources other than 13,56 MHz used for RFID. At that frequency, the inductive coils have very large reactance, resonant frequency being at or below 500 kHz, meaning that induced current is insignificant.

The frequency range of the applied test signals includes an adequate number of incremental steps to assess DUT safety and performance without sacrificing test time. In addition to general coverage of the frequency range, steps include frequencies related to EAS and RFID. If desired, the manufacturer may perform a frequency sweep instead.

The radiated magnetic field test is performed without patient leads. The purpose is to observe device interaction by direct coupling of the magnetic field with internal circuits.

27.106 The test level of 10 V/m has been harmonized with the home healthcare environment of IEC 60601-1-2 (see IEC 60601-1-2:2014, Table 4). This level represents the reasonably foreseeable maximum electromagnetic disturbance level seen in this environment.

27.107 The frequencies and modulations have been harmonized with IEC 60601-1-2:2014, Table 9. The dipole method of ISO 14117 is used because studies have shown that it better simulates cell phone

disturbances for implants. A primary test distance of 15 cm was chosen because it represents the reasonably foreseeable separation distance.

Annex CC
(informative)

Injection network example and board layout guidance

CC.1 General

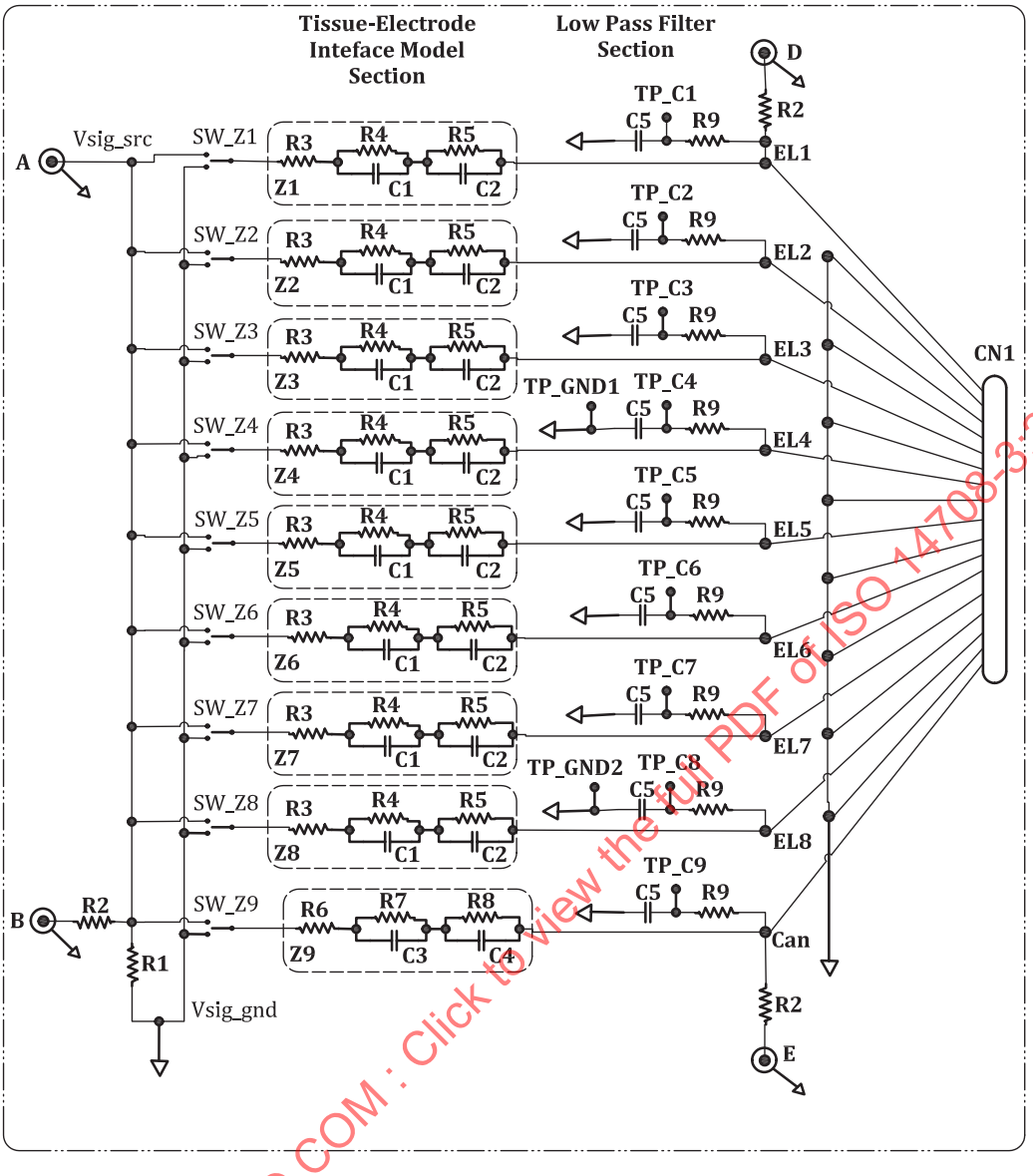
The first intent of this annex is to provide a specific example of an injection network that can be used for the voltage injection test performed in 27.105.1. It will still be up to each manufacturer to identify the specific approach that best matches the needs for their particular product and application, as different INS systems use different types of leads in different parts of the body with different functionality. The specific example in this annex was created for a spinal cord stimulator with output-only (non-sensing) functionality that employs a non-coiled percutaneous lead of known materials and dimensions.

The second intent of this annex is to provide general design guidance for the circuit board layout techniques as well as component types that will result in injection circuit boards with optimum performance over the entire intended injection frequency range of 16,6 Hz to 80 Mhz.

CC.2 Tissue equivalent circuit board example

This subclause describes one particular example of a tissue equivalent circuit board designed for an IPG with eight electrodes that is programmable for either bipolar or monopolar (CAN active) therapy modes.

The network shown in Figure CC.1 was designed for a device with a lead that has eight electrodes where each electrode can be programmed as an anode (+), cathode (-), or off, as well as a case (CAN) that can be programmed as an anode (+) or off. For devices with more than eight electrodes, the network would need to be expanded, although the impedance values for each electrode interface would likely stay the same. This particular example is designed to connect to a separate DUT contactor board for either the IPG and lead or IPG and lead model circuitry. Alternate approaches of embedding the IPG and/or lead interface directly into the tissue equivalent circuit board can also be taken.



Key

A	signal generator input	B	signal generator monitor output
TP_C1–9	stimulation waveform monitor outputs	TP_GND1–2	ground test points
D, E	board checkout monitor points	Z1-Z9	R-C model for tissue-electrode interface
R1	68,1 ohms, ±1 %, ½ watt	R2	953 ohms, ±1 %, 1/8 watt
R3	60,4 ohms, ±1 %, 1/8 watt	R4	90,9 ohms, ±1 %, 1/8 watt
R5	150 ohms, ±1 %, 1/8 watt	R6	20 ohms, ±1 %, 1/8 watt
R7	30 ohms, ±1 %, 1/8 watt	R8	42,2 ohms, ±1 %, 1/8 watt
R9	50 kohms, ±1 %, 1/8 watt	C1	240 pF, ±10 %, 25 V, NPO
C2	56 nF, ±10 %, 25 V, X7R	C3	560 pF, ±10 %, 25 V, NPO
C4	220 nF, ±10 %, 25 V, X7R	C5	180 pF, ±10 %, 25 V, NPO
EL1-8	IPG electrodes	CAN	IPG device enclosure
SW_Z1-9	Z input select switches	CN1	dual row header DUT board connector

Figure CC.1 — Tissue equivalent interface board example

Port A: This BNC connector is where the test signal generator, and if needed, a suitable amplifier, is connected via a 50 ohm cable to a BNC connector. The test signal generator, and/or a suitable amplifier should be configured for a sinusoidal modulated carrier output to a 50 ohm load.

R1: This component value was chosen as 68,1 ohms such that the effective impedance of this resistor in parallel with the interface network would approximate 50 ohms to match the output impedance of the signal generator/amplifier.

Port B: This BNC connector is where the monitoring oscilloscope is connected via a 50 ohm BNC cable to the interface board in order to monitor the V_{PP} waveform delivered to the INS system. The oscilloscope input should be set for 50 ohm input impedance. Resistor R2 between Port A and Port B should be set to provide an attenuation of at least 10 (R2 = 450 ohms) for 10 % loading and preferably 20 (R2 = 950 ohms) for 5 % loading.

SW_Z1-SW_Z9 switches: these are the Z configuration input switches that allow application of the test signal to each IPG tissue-electrode interface point. The particular switch configurations employed for each test depend on the specific therapy mode and program electrode configuration used to represent INS modes. See Table CC.1 for some examples.

Table CC.1 — Tissue interface circuit switch configuration examples

Interference type	Stimulation mode/Parameters	Switch settings/Monitor point	
		Tissue load input	LPF output
Differential	Monopolar (CAN Active) mode, CAN = '+', Electrodes 1-8 = −0000000, (where '+' = Anode, '-' =Cathode, and '0' = Off), Amplitude = 6mA, Frequency = 100Hz, Pulse Width = 200uS	SW_Z1=Vsig_gnd	TP_C1= disconnected
		SW_Z2=Vsig_gnd	TP_C2= disconnected
		SW_Z3=Vsig_gnd	TP_C3= disconnected
		SW_Z4=Vsig_gnd	TP_C4= disconnected
		SW_Z5=Vsig_gnd	TP_C5= disconnected
		SW_Z6=Vsig_gnd	TP_C6= disconnected
		SW_Z7=Vsig_gnd	TP_C7= disconnected
		SW_Z8=Vsig_gnd	TP_C8= disconnected
		SW_Z9=Vsig_src	TP_C9= connected to oscilloscope input, TP_GND2= connected to oscilloscope ground.
Common mode	Bipolar (CAN Inactive) mode, CAN = '0', Electrodes 1-8 = +-000000, (where '+' = Anode, '-' =Cathode, and '0' = Off), Amplitude = 6mA, Frequency = 100Hz, Pulse Width = 200uS	SW_Z1=Vsig_src	TP_C1= connected to oscilloscope input, TP_GND1= connected to oscilloscope ground.
		SW_Z2=Vsig_src	TP_C2= disconnected
		SW_Z3=Vsig_gnd	TP_C3= disconnected
		SW_Z4=Vsig_gnd	TP_C4= disconnected
		SW_Z5=Vsig_gnd	TP_C5= disconnected
		SW_Z6=Vsig_gnd	TP_C6= disconnected
		SW_Z7=Vsig_gnd	TP_C7= disconnected
		SW_Z8=Vsig_gnd	TP_C8= disconnected
		SW_Z9=Vsig_gnd	TP_C9= disconnected

Tissue-electrode interface model section (Electrode 1–8): Figure CC.1 represents the tissue-electrode model for electrodes 1-8 with the components R3, R4, R5, C1, and C2. This network is similar to the one used in the tissue injection circuit for ISO 14117. The values for this particular example were chosen as follows:

— R3 represents the purely resistive aspect of tissue near the electrodes;