INTERNATIONAL STANDARD

ISO 14708-3

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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

Reference number
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Foreword

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

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

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

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

ISO 14708-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

ISO 14708 consists of the following parts, under the general title *Implants for surgery — Active implantable medical devices*:

— *Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

Introduction

This part of ISO 14708 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 14708-1:2000, hereinafter referred to as ISO 14708-1.

The requirements of this part of ISO 14708 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 device 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 part of ISO 14708 is intended to apply to these neurostimulator types regardless of therapy. (See Clause 3 for device type definitions used throughout this part of ISO 14708.)

This part of ISO 14708 is relevant to all parts and accessories of implantable neurostimulators, including programmers, trial screeners, 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.

Requirements for physiologic sensing functions of implantable neurostimulators are not included in this edition of this part of ISO 14708 but might be considered in future editions.

Within this part of ISO 14708 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 part of ISO 14708.

"Addition": the text of this part of ISO 14708 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 part ISO 14708.

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

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.

INTERNATIONAL STANDARD ISO 14708-3:2008(E)

Implants for surgery — Active implantable medical devices —

Part 3: Implantable neurostimulators

1 Scope

This part of ISO 14708 is applicable to active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system.

This part of ISO 14708 is also applicable to all non-implantable parts and accessories of the devices as defined in Clause 3.

The tests that are specified in this part of ISO 14708 are type tests intended to be carried out on a sample of a device to show compliance, and are not intended to be used for the routine testing of manufactured products.

NOTE This part of ISO 14708 is not intended to apply to non-implantable neurostimulation devices. However, it does apply to devices intended to be used as trial screeners because of their close affiliation with implantable neurostimulators.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 61000-4-3:2002, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

ANSI/AAMI PC69:2000, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*

3 Terms and definitions

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

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

NOTE For purposes of this part of ISO 14708, 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, screeners and RF transmitters.

3.102
implantable pulse generator
IPG
implantable part of a particular type of implantable neurostimulator, typically consisting of a power source and electronic circuit, which produces a stimulation voltage or current pulse

NOTE The complete neurostimulator includes a means for conveying the output pulse to the stimulation site.

3.103
RF transmitter
non-implantable part of a particular type of implantable neurostimulator, typically consisting of a power source and electronic circuit, which produces an electrical output pulse transmitted through an antenna to an implanted RF receiver

3.104
RF receiver
implantable part of a particular type of implantable neurostimulator which converts an electrical pulse received from an external RF transmitter into a stimulation voltage or current pulse

3.105
trial screener
non-implantable neurostimulator, used during a trial period of stimulation, typically consisting of a power source and electronic circuit, which produces a stimulation voltage or current pulse conveyed to the stimulation site through a lead or leads

NOTE Although a medical device in its own right, a screener is considered by this part of ISO 14708 as an accessory to an implantable neurostimulator.

3.106
projected service life
period after implantation when the implantable neurostimulator remains within stated specifications and characteristics

3.107
DUT
device under test, including conductive leads

3.108
essential performance
performance necessary to achieve freedom from unacceptable risk

NOTE For guidance on essential performance concepts, see IEC 60601-1.

4 Symbols and abbreviated terms

This clause of ISO 14708-1 applies.

5 General requirements for non-implantable parts

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

Addition:

NOTE 3 This clause applies to RF transmitters, trial screeners, and programmers, for example. A percutaneous lead, such as might be used with screeners, is considered to be an implantable part.

6 Requirements for particular active implantable medical devices

Additional subclauses:

6.101 Measurement of stimulation pulse characteristics

This subclause describes a uniform method of measurement for certain stimulation pulse characteristics (amplitude, pulse width, pulse rate and pulse shape). The related specifications and characteristics stated by the manufacturer in the accompanying documentation (see 28.8) shall correspond with the results obtained in accordance with this method.

If the neurostimulator has multiple channels or output modes (e.g. bipolar or unipolar), the characteristics of each channel or mode shall be determined. Consideration shall be given to all states of operation, i.e. channels or modes operating individually or simultaneously.

Test conditions and device settings applicable to the stimulation pulse characteristics stated in the accompanying documentation shall also be stated (see 28.8).

NOTE 1 Test conditions refer, for example, to ambient temperature and any special circumstances that existed during the measurements. Device settings refer, for example, to the rate and pulse width values that were set during the amplitude measurement.

The test sample shall be representative of production units, be in normal working condition, and shall not have reached the elective replacement indication (see 19.2).

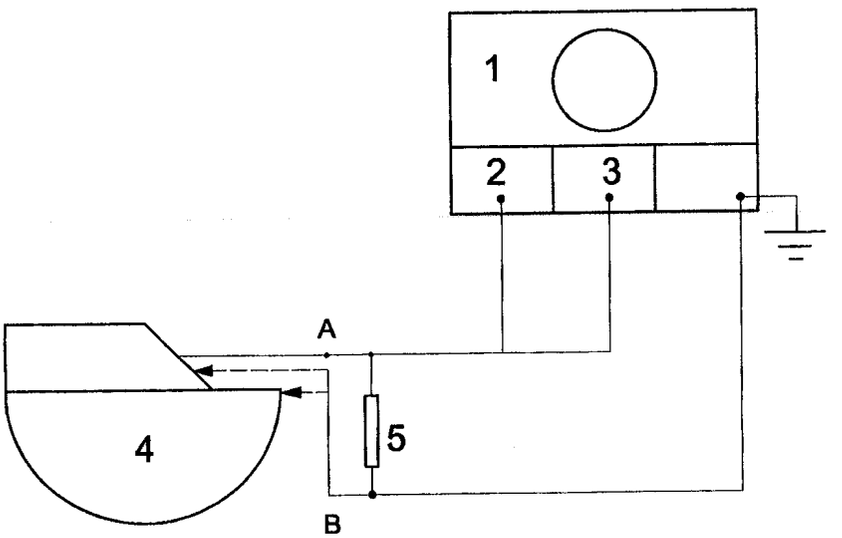
— Method: The pulse generator (i.e. IPG, RF receiver, trial screener) shall be connected to a load resistor, R_L, and test equipment as shown in Figure 101. Resister values for R_L shall be determined by the manufacturer based on appropriate tissue impedances for use of the product. Measurements shall be replicated to characterize operation at minimum, typical and maximum load impedances. More complex impedances may be used if they better represent actual use. In addition, the measurements shall be performed using a nominal impedance, R_L, of 499 $\Omega \pm 1$ %. The load impedances used to obtain the stimulation pulse characteristics stated in the accompanying documentation (see 28.8) shall also be stated.

  Points A and B, as shown in Figure 101, represent either the direct electrical output of the pulse generator or the electrodes at the distal end of a lead (or lead-extension combination), if applicable. The manufacturer shall unequivocally state the configuration(s) that are applicable to the stimulation pulse characteristics stated in the accompanying documentation (see 28.8).

NOTE 2 Configuration refers to the point of measurement and to the model mix of pulse generator, and leads and extensions, (if applicable).

While performing these measurements, the pulse shapes associated with each channel shall be characterized and described in the accompanying documentation (see 28.8). Any variations in pulse shapes, between channels, output modes, states of operation or load conditions, shall also be described.

The measurement accuracy of the test set-up shall be within ± 5 %. Test equipment and test sample shall be at room temperature.

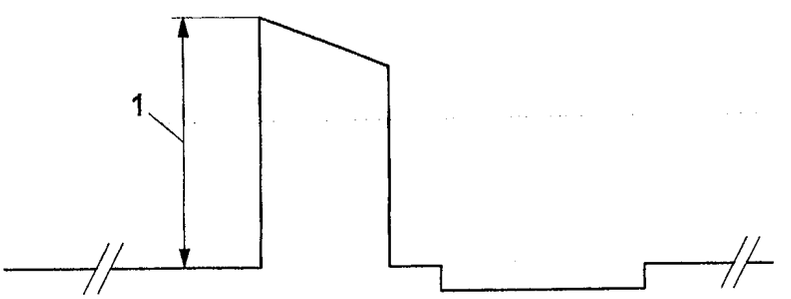


Key

1 oscilloscope
2 channel 1
3 trigger
4 pulse generator
5 load (as specified)

Figure 101 — Test set-up for measuring stimulation pulse characteristics

The pulse amplitude shall be measured from the base (just prior to the pulse transition) to the peak of the pulse as shown in Figure 102. The result shall be expressed in volts or milliamperes, as appropriate. In addition, other units may be used at the manufacturer's discretion.

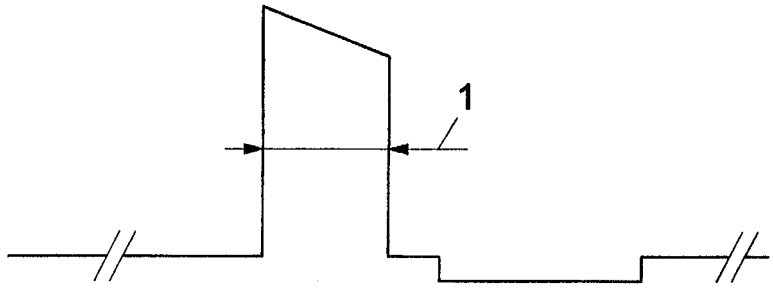


Key

1 amplitude

Figure 102 — Measurement of pulse amplitude

The pulse width shall be measured between the points on the pulse equal to one-half of the peak pulse amplitude as shown in Figure 103. The result shall be expressed in microseconds. In addition, other units may be used at the manufacturer's discretion.

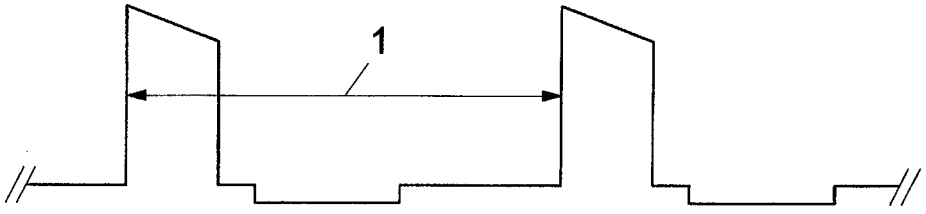


Key

1 pulse width (at ½ amplitude point)

Figure 103 — Measurement of pulse width

The pulse rate shall be determined by measuring the interval from the leading edge of one pulse to the leading edge of the next pulse from the same point on the pulse used to measure pulse width (see Figure 104). The actual rate is calculated from the reciprocal of the interval measurement. The result shall be expressed in Hertz (Hz). In addition, other units may be used at the manufacturer's discretion.



Key

1 pulse interval (at ½ amplitude point)

Figure 104 — Measurement of pulse interval to determine rate

6.102 Measurement of lead or extension d.c. resistance

This subclause describes a uniform method of measurement for lead or extension d.c. resistance. The related specifications and characteristics stated by the manufacturer in the accompanying documentation (see 28.8) shall correspond with the results obtained in accordance with this method.

If the lead or extension has multiple conductors, the d.c. resistance of each conductor shall be determined.

Test conditions applicable to the lead or extension d.c. resistance stated in the accompanying documentation shall also be stated (see 28.8).

NOTE Test conditions refer, for example, to ambient temperature and any special circumstances that existed during the measurements.

The test sample shall be representative of production units and be in normal working condition.

— Method: The d.c. resistance of lead and extension conductors shall be measured by applying a four terminal ohmmeter (offset compensated) between the proximal and distal end of each conductive element. The results shall be expressed in ohms. In addition, other units may be used at the manufacturer's discretion.

  The measurement accuracy of the test setup shall be within ± 5 %. Test equipment and test sample shall be at room temperature.

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 except as follows.

8.2

Addition:

NOTE For leads that are not intended to be implanted and are used only temporarily, this requirement does not apply.

Additional subclauses:

8.101 If special handling measures have to be taken during transport, the transport packaging shall be marked accordingly (see ISO 780 [1] or ISO 15223 [2]).

Compliance shall be checked by inspection.

8.102 The permissible environmental conditions for transport shall be marked on the outside of the transport packaging.

Compliance shall be checked by inspection.

9 Markings on the sales packaging

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

9.4

Addition:

Specific additional information shall be provided for the following components:

a) Implantable pulse generator (IPG) and trial screener

— number of electrodes and channels,

— if the output is constant voltage or constant current,

— any additional information and relevant characteristics, as necessary, to identify the device.

b) Lead

— type of lead (e.g. surgical, percutaneous, cuff, CNS, peripheral),

— number of electrodes per lead,

— lead length (in centimetres),

— any additional information and relevant characteristics, as necessary, to identify the device.

c) Extension

— type of extension (e.g. low profile, bifurcated),

— number of electrodes per extension,

— extension length (in centimetres),

— any additional information and relevant characteristics, as necessary, to identify the device.

d) RF receiver

— number of electrodes and channels,

— if the output is constant voltage or constant current

— maximum recommended implant depth,

— a means of identifying the corresponding RF transmitter,

— a means of identifying the corresponding lead, if not permanently attached,

— any additional information and relevant characteristics, as necessary, to identify the device.

e) RF transmitter

— number of channels,

— maximum recommended transmission distance,

— a means of identifying the corresponding RF receiver,

— any additional information and relevant characteristics, as necessary, to identify the device.

Additional subclause:

9.101 The sales packaging shall, when appropriate, bear an indication that the contents are intended for single use only.

Compliance shall be checked by inspection.

10 Construction of the sales packaging

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

10.3

Amendment:

The test is replaced by subclause 7.1.3 b) of IEC 60601-1:2005.

NOTE Removable stickers (e.g. temporary stickers used in the manufacturing process), which provide supplementary information exceeding the information specified in Clause 9, need not be subjected to this test.

11 Markings on the sterile pack

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

Additional subclause:

11.101 The sterile pack shall bear specific additional information for the following components:

a) Implantable pulse generator (IPG)

— number of electrodes and/or channels,

— if the output is constant voltage or constant current,

— maximum recommended implant depth, if applicable,

— any additional information and relevant characteristics, as necessary, to identify the device.

b) Lead

— type of lead (e.g. surgical, percutaneous, cuff, CNS, peripheral),

— number of electrodes per lead,

— lead length (in centimetres),

— any additional information and relevant characteristics, as necessary, to identify the device.

c) Extension

— type of extension (e.g. low profile, bifurcated),

— number of electrodes per extension,

— extension length (in centimetres),

— any additional information and relevant characteristics, as necessary, to identify the device.

d) RF receiver

— maximum recommended implant depth

— a means of identifying the corresponding RF transmitter

— a means of identifying the corresponding lead, if not permanently attached

— any additional information and relevant characteristics, as necessary, to identify the device.

Compliance shall be checked by inspection.

12 Construction of the non-reusable pack

This clause of ISO 14708-1 applies.

c) Extension

— type of extension (e.g. low profile, bifurcated),

— number of electrodes per extension,

— extension length (in centimetres),

— any additional information and relevant characteristics, as necessary, to identify the device.

d) RF receiver

— number of electrodes and channels,

— if the output is constant voltage or constant current

— maximum recommended implant depth,

— a means of identifying the corresponding RF transmitter,

— a means of identifying the corresponding lead, if not permanently attached,

— any additional information and relevant characteristics, as necessary, to identify the device.

e) RF transmitter

— number of channels,

— maximum recommended transmission distance,

— a means of identifying the corresponding RF receiver,

— any additional information and relevant characteristics, as necessary, to identify the device.

Additional subclause:

9.101 The sales packaging shall, when appropriate, bear an indication that the contents are intended for single use only.

Compliance shall be checked by inspection.

10 Construction of the sales packaging

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

10.3

Amendment:

The test is replaced by subclause 7.1.3 b) of IEC 60601-1:2005.

NOTE Removable stickers (e.g. temporary stickers used in the manufacturing process), which provide supplementary information exceeding the information specified in Clause 9, need not be subjected to this test.

11 Markings on the sterile pack

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

Additional subclause:

11.101 The sterile pack shall bear specific additional information for the following components:

a) Implantable pulse generator (IPG)

— number of electrodes and/or channels,

— if the output is constant voltage or constant current,

— maximum recommended implant depth, if applicable,

— any additional information and relevant characteristics, as necessary, to identify the device.

b) Lead

— type of lead (e.g. surgical, percutaneous, cuff, CNS, peripheral),

— number of electrodes per lead,

— lead length (in centimetres),

— any additional information and relevant characteristics, as necessary, to identify the device.

c) Extension

— type of extension (e.g. low profile, bifurcated),

— number of electrodes per extension,

— extension length (in centimetres),

— any additional information and relevant characteristics, as necessary, to identify the device.

d) RF receiver

— maximum recommended implant depth

— a means of identifying the corresponding RF transmitter

— a means of identifying the corresponding lead, if not permanently attached

— any additional information and relevant characteristics, as necessary, to identify the device.

Compliance shall be checked by inspection.

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 except as follows.

13.1

Amendment:

The wet rub test is replaced by subclause 7.1.3 b) of IEC 60601-1:2005, after which the markings shall remain clearly legible.

14 Protection from unintentional biological effects caused by the active implantable medical device

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

14.2

Replacement:

Any part of the implantable neurostimulator, intended in normal use to be in contact with body fluids, shall be evaluated to determine if the release of particulate matter is hazardous.

— Test: Remove the implantable part aseptically from the non-re-usable pack. Immerse the implantable part in a bath of approximately 9 g/l saline solution, suitable for injection, or filtered saline or ultra-pure water, in a neutral glass container. The volume of the saline in millilitres shall be (5 ± 0,5) times the numerical value of the surface area of the implantable part expressed in cm^2. The container shall be covered with a glass lid and maintained at 37 °C ± 2 °C for between 8 h and 18 h, the bath being agitated throughout the period. A reference sample of similar volume shall be prepared from the same batch of saline, maintained and agitated in a similar way to the specimen. A sample of liquid from the specimen bath and from the reference bath shall be compared using apparatus suitable for measurement of particle size, such as apparatus operating on the light blockage principle [see method 2.9.19 of the European Pharmacopoeia, 3rd edition, 1977, (Council of Europe)[3]].

The excess average count of particles from the specimen compared to the reference sample shall not exceed the amount determined, by the manufacturer, to be hazardous. If the manufacturer does not make this determination then the excess average count shall not exceed 100 per ml greater than 5,0 µm and shall not exceed 5 per ml greater than 25 µm.

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

14.3

Addition:

Biocompatibility may be assessed in accordance with one or more parts of ISO 10993, such as ISO 10993-1[4].

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 except as follows.

15.1

Amendment:

Clause 23 of IEC 60601-1:1998 is replaced by subclause 9.3 of IEC 60601-1:2005. (See Clause 5.)

Compliance shall be checked as specified in IEC 60601-1.

16 Protection from harm to the patient caused by electricity

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

16.1

Amendment:

Clause 19 of IEC 60601-1:1998 is replaced by subclause 8.7 of IEC 60601-1:2005. (See Clause 5.)

16.2

Addition:

If the results of a risk assessment or other means (e.g. published data, test studies, calculations) indicate that the current limit should be less than 1 µA for a particular application, then the allowable limit shall be changed so that the risk is mitigated.

NOTE This subclause is intended to include implantable parts that depend on a source of electrical energy, such as RF receivers.

16.3

Replacement:

Insulating parts of implantable leads or extensions that incorporate electrical conductors shall be designed to withstand the electrical stresses placed on the insulation in normal working conditions over the planned lifetime of the product.

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

Additional subclause:

16.101 The design of the neurostimulator shall include protection of the electrical output pulse characteristics from unintended changes.

NOTE 1 Examples of unintended changes are excess charge density, excess voltage, sudden changes in stimulation amplitude and rate runaway.

Compliance shall be confirmed by inspection of a design or risk analysis provided by the manufacturer, supported by the manufacturer's calculations and data from test studies as appropriate.

NOTE 2 The analysis can be included in results from the risk analysis performed in accordance with 19.3

17 Protection from harm to the patient caused by heat

Replacement:

No outer surface of an implantable part of the implantable neurostimulator shall be greater than 2 °C above the normal surrounding body temperature, in normal operation or single-fault condition, unless the manufacturer demonstrates that a higher temperature rise is justified for a particular application.

Compliance shall be confirmed by a review of the manufacturer's documentation, including results from modelling, a design or risk assessment, test studies, or other appropriate means.

NOTE At the present time some studies have shown that, depending on the location of specific tissue within the human body, a 2 °C temperature limit can be unnecessarily restrictive. Under this circumstance, the manufacturer is allowed the burden of substantiation.

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 device

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

19.2

Replacement:

If the service life (see 3.106) of the implantable neurostimulator is dependent upon an implanted source of electrical energy, such as a battery, an indication shall be provided that gives an advanced notice of energy source depletion. The manufacturer shall define the expected duration of the remaining service life following this notice.

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

NOTE This subclause is also applicable to rechargeable energy sources.

19.3

Replacement:

An implantable neurostimulator shall be designed so that the failure of any single component, part or (if the device incorporates a programmable electronic system) software program shall not cause an unacceptable hazard.

— Assessment: Risk assessment and risk control shall be conducted in accordance with published standards, such as ISO 14971 [5].

Compliance shall be confirmed by a review of the risk management report or equivalent manufacturer's documents.

19.4

Amendment:

The Assessment is amended to allow clinical investigations conducted in accordance with published standards, such as ISO 14155-1 [6] and ISO 14155-2 [7].

20 Protection of the device from damage caused by external defibrillators

This clause of ISO 14708-1 applies.

21 Protection of the device from changes caused by high-power 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

Addition:

Other treatments and procedures, such as (but not limited to) MRI, PET scans, therapeutic ultrasound and lithotripsy, shall also be considered. Compliance shall be confirmed by a review of the manufacturer's documentation, including results from modelling, a design or risk assessment, test studies, or other appropriate means.

23 Protection of the active implantable medical device from mechanical forces

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

23.1

Replacement:

Non-implantable parts of neurostimulators shall comply with subclause 15.3 of IEC 60601-1:2005. (See Clause 5). The number of drops for patient-carried parts that are hand-held shall be three from each of three different starting orientations encountered during normal use (see subclause 15.3.4.1 of IEC 60601-1:2005).

Compliance shall be checked as specified in IEC 60601-1.

23.2

Amendment:

The implantable parts of the neurostimulator shall be constructed to withstand the mechanical forces that can occur during normal conditions of use.

a) test frequency range: 5 Hz to 500 Hz;

b) acceleration spectral density: 0,7 $(m/s^2)^2/Hz$;

c) shape of acceleration spectral density curve: flat horizontal, 5 Hz to 500 Hz;

d) duration of testing: 30 min in each of three mutually perpendicular axes.

24 Protection of the active implantable medical device from damage caused by electrostatic discharge

Replacement:

Non-implantable parts of a neurostimulator shall comply with subclause 6.2.2 of IEC 60601-1-2:2007. (See Clause 5.)

Compliance shall be 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 except as follows.

26.1

Amendment:

Clause 42 of IEC 60601-1:1998 is replaced by subclause 11.1 of IEC 60601-1:2005. (See clause 5.)

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

Replacement:

27.101 Immunity

Implantable parts of the implantable neurostimulator shall not cause any harm because of susceptibility to electrical influences due to external electromagnetic fields, whether through malfunction of the device, damage to the device, heating of the device or by causing local increase of induced electrical current density within the patient.

Compliance shall be confirmed by review of test results and documentation, prepared by the manufacturer, for the tests in 27.103 to 27.106.

27.102 General test conditions

a) Operating mode

During immunity testing, each function of the implantable neurostimulator associated with essential performance shall be tested in a mode that is most critical from a patient outcome perspective, based on a risk analysis. The test documentation shall state the function and mode used.

NOTE For example, essential performance could very well be related to pulse amplitude or to other output characteristics where a sudden change could be hazardous.

b) Performance criteria

Under the test conditions specified in Clause 27, each function of the implantable neurostimulator that is tested [see 27.102 a)] shall be evaluated for general performance using the appropriate criteria stated in Table 101. If DUT performance satisfies the criteria stated, then compliance with the requirements of the test(s) is, consequentially, achieved. For criterion B, performance degradation, loss of function or unintentional responses are allowed if no unacceptable risk is created.

NOTE A risk assessment can demonstrate that a hazard, created as a result of performance degradation, loss of function, or an unintentional response, does not result in an unacceptable risk.

The following degradations are not allowed:

— component failures;

— changes in programmable parameter settings;

— reset to factory defaults;

— change of operating mode;

— false alarms;

— initiation of any unintended operation.

Table 101 — General performance criteria of the DUT for the immunity tests in clause 27

Criterion	During test	After test	Test summary
A	Operate as intended No loss of function No unintentional responses	Operate as intended No loss of function No degradation of performance Conforms to device specs	27.103 – 1 mT level 27,104 – A-line 27.105 – 16 V/m 27.106 – 40 mW
B	Allowed if no unacceptable risk: Performance degradation Loss of function Unintentional responses	Operate as intended No loss of function No degradation of performance Conforms to device specs Lost functions shall be self-recoverable	27.103 – 50 mT level 27.104 – B-line 27.105 – 140 V/m
C	Manufacturer defined	Manufacturer defined	27.106 – optional levels

Test documentation shall include the details of the performance criteria used, a description of the methods used to verify performance, justification for any allowances of this subclause used, and a report of the test results indicating DUT performance as it pertains to criterion A, B or C.

Electromagnetic interference that the patient should avoid or be aware of, as a result of DUT performance during these immunity tests, shall be described in the accompanying documentation (see 28.22).

c) DUT configuration

The DUT shall consist of the IPG, lead and any other implantable part necessary for it to achieve its intended function. Lead length and layout are described in the test setup for each test.

Neurostimulators that have more than one available electrode configuration for stimulation, such as bipolar or unipolar, shall be tested with the electrode configuration that is the most susceptible to electromagnetic interference.

NOTE For magnetic field tests the electrode configuration that is normally the most susceptible is unipolar. For electric fields, susceptibility is usually dependant upon neurostimulator design implementation.

Test documentation shall describe the DUT configuration and environmental conditions affecting the test (e.g. temperature and pressure).

d) Testing of normally non-observable functions

If the operation of a function to be tested [see 27.102 a)] cannot normally be observed or verified during the test, a method shall be provided for determining performance. The use of special hardware or software might be necessary.

e) Implantable neurostimulators that use wireless telemetry

For a wireless telemetry function tested to satisfy the requirements of 27.102 a), criterion B shall apply in an exclusion band. All other functions shall comply with the requirements as stated.

The exclusion band shall not be larger than normally required for the telemetry function to operate as intended.

f) Implantable RF receiver type neurostimulator

For a neurostimulator that has a design based on a non-implantable RF transmitter and implantable RF receiver the appropriate tests in IEC 60601-1-2 shall apply. The test setup for the implantable part shall be based on the setup described in 27.105.

NOTE The tests in Clause 27 of this part of ISO 14708 do not apply. An implantable RF receiver works in tandem with a non-implantable transmitter that is subject to IEC 60601-1-2. The RF receiver needs only to be subjected to radiated immunity in accordance with IEC 60601-1-2.

27.103 Protection from static magnetic fields

The assessment of the implantable neurostimulator for static magnetic fields is made by exposure of the DUT to two levels of static (non time varying) fields.

— Test: General test conditions are described in 27.102.

  Test levels: two test field strengths are used, applying different performance criteria to each. A lower level of 1 mT shall be subjected to the DUT, applying performance criterion A, as stated in 27.102 b). A second level of 50 mT shall be used, applying performance criterion B.

Test setup: the apparatus for generating the magnetic field shall be capable of producing a field with uniformity of $^{0}_{+3}$ dB over an area of radius 7,5 cm (minimum) that lies on a plane parallel to the apparatus.

This plane shall be called the central plane. The uniformity of the magnetic field is only prescribed over the central plane, which contains imaginary Y and Z axes. Uniformity is not prescribed in the X+ or X– direction, which represents the imaginary, perpendicular, axis running through the centre of the plane of the apparatus and the central plane.

For most test configurations [see 27.102 c)] a uniform area of radius 7,5 cm will be large enough to cover the DUT. If not, the uniform area shall be increased until it meets the requirements of this subclause.

Place the DUT at the centre of the central plane where the magnetic field is the most uniform. The plane of the largest surface area of the DUT is placed parallel to the central plane (this exposes the neurostimulator's largest surface to the primary magnetic flux lines which are perpendicular to the central plane). This is the only orientation of the DUT that is required.

The layout of the conductive lead is not critical. It only needs to be placed in a position that facilitates monitoring of the neurostimulator during the test. Any ancillary equipment that is needed to operate the neurostimulator or monitor its output during the test shall, as much as possible, be selected and located to minimize disruption of the uniform field. Neurostimulator output can be monitored by using an oscilloscope connected to a sense resistor in series with the lead.

Test procedure: monitor the performance of the DUT for a minimum of 10 min at each test level.

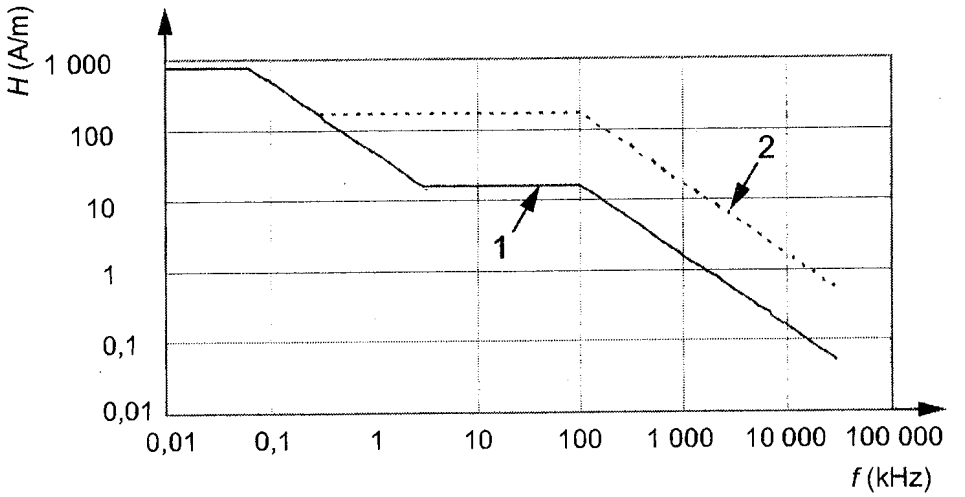
Evaluation of test results: performance criterion A (1 mT) and performance criterion B (50 mT), as stated in 27.102 b), shall apply.

27.104 Protection from magnetic fields in the range 10 Hz to 30 MHz

The assessment of the implantable neurostimulator for the range of frequencies from 10 Hz to 30 MHz is made by exposure of the DUT to continuous wave and pulsed magnetic fields.

— Test: General test conditions are described in 27.102.

Test levels: magnetic field test levels are shown graphically in Figure 105 (values are A/m rms). Test levels vary depending on frequency and performance criteria [see 27.102 b)]. The solid line in Figure 105 represents test levels that are subjected to the DUT, applying performance criterion A, as stated in 27.102 b). The dashed line represents test levels applying performance criterion B. These shall be referred to as the A-line and the B-line, respectively, throughout this subclause. Both sets of test levels shall be applied to the DUT.



Key

1 A-line (test levels, performance criterion A)
2 B-line (test levels, performance criterion B)

Figure 105 — Magnetic field test levels (RMS)

Test levels as a function of frequency are indicated numerically in Table 102.

Table 102 — Magnetic field test levels (RMS)

Frequency range kHz	Field strengths for A-line		Field strengths for B-line	
	H-field A/m	B-field μT	H-field A/m	B-field μT
0,01 – 0,06	795	1 000	—	—
0,06 – 0,3	47,7/*f*	60/*f*	—	—
0,3 – 3,0	47,7/*f*	60/*f*	159	200
3,0 – 100	15,9	20	159	200
100 – 30 000	1 590/*f*	2 000/*f*	15 900/*f*	20 000/*f*
NOTE *f* is the frequency in kHz. All field levels are root-mean square (RMS).				

Test setup: the test coil(s) for generating the magnetic field shall be capable of producing a field with uniformity as specified in Table 103. The uniform field shall exist over an area of radius 7,5 cm (minimum) that lies on a plane parallel to the coil(s). This plane shall be called the central plane. The uniformity of the magnetic field is only prescribed over the central plane, which contains imaginary Y and Z axes. Uniformity is not prescribed in the X+ or X– direction, which represents the imaginary, perpendicular, axis running through the centre of the plane of the coils and the central plane.

For most test setups a uniform area of radius 7,5 cm will be large enough to cover the DUT. If not, the uniform area shall be increased until it meets the requirements of this subclause.

Table 103 — Magnetic field uniformity

A-line	B-line
$f \leqslant$ 100 kHz, $^{0}_{+1}$ dB $f >$ 100 kHz, $^{0}_{+3}$ dB	300 Hz $\leqslant f \leqslant$ 30 MHz, $^{0}_{+3}$ dB
NOTE f is the test frequency.	

Place the DUT into a saline bath of 0,27 S/m conductivity (equivalent to 370 Ω·cm volume resistivity) at the centre of the central plane where the magnetic field is the most uniform. The plane of the largest surface area of the DUT is placed parallel to the central plane (this exposes the neurostimulator's largest surface to the primary magnetic flux lines which are perpendicular to the central plane). This is the only orientation of the DUT that is required.

The conductive lead is wrapped in a spiral around the IPG (see Figure 106) so that the entire DUT fits inside the uniform area. The total area enclosed by a lead of length L (in centimetres) shall equal:

$$0{,}09\,L^2 \tag{101}$$

For example, if a lead is 85 cm long, the total area enclosed by the lead would need to equal 650 cm^2 to satisfy the requirement. This might require adding an extension onto the test lead.

It will be necessary to estimate the total area enclosed by the test lead. A formula that can be used for this approximation is given in formula 102:

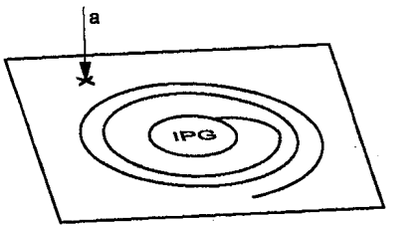
$$(R_m^2/2)\,[L/R_m - \sin\,(L/R_m)] \tag{102}$$

where

L is the test lead length;

R_m is the median radius formed by the spiral wrapped test lead.

This formula is valid for a semi-circle and will have to be applied accordingly. Although the manufacturer is not required to use this method, it can be used to confirm the manufacturer's measurement or calculation and should agree within a reasonable amount.



Key

a B-field.

Figure 106 — IPG and lead layout on central plane

Any ancillary equipment that is needed to operate the neurostimulator or monitor its output during the test shall, as much as possible, be selected and located to minimize disruption of the uniform field. Neurostimulator output can be monitored by using an oscilloscope connected to a sense resistor in series with the lead or by using another lead placed into the saline as a pickup lead.

Test procedure: the frequency range of the applied test signals, from 10 Hz to 30 MHz, may be either swept or stepped. If a continuous frequency sweep is used the rate of sweep shall not be greater than 0,000 3 decades/second. If stepped, the step size within each decade shall be no larger than F_d, where F_d is the starting frequency of each decade. The starting frequency of each decade is, respectively: 10 Hz, 100 Hz, 1 kHz, 10 kHz, 100 kHz, 1 MHz, 10 MHz. The dwell time at each step shall be long enough for the DUT to adequately respond to the test signal, but not less than 15 s.

Using the frequency step method and meeting the minimum step size requirements will result in the frequencies being tested that are listed in Table 104.

Table 104 — Frequencies tested using minimum step size requirements (kHz)

0,01	0,02	0,03	0,04	0,05	0,06	0,07	0,08	0,09
0,1	0,2	0,3	0,4	0,5	0,6	0,7	0,8	0,9
1	2	3	4	5	6	7	8	9
10	20	30	40	50	60	70	80	90
100	200	300	400	500	600	700	800	900
1 000	2 000	3 000	4 000	5 000	6 000	7 000	8 000	9 000
10 000	20 000	30 000						

NOTE Frequencies are in kHz. This illustration is based on the frequency step method using minimum required step sizes. Using the frequency sweep method or smaller step sizes will result in more frequencies being tested. The frequencies listed adhere to the relation $n\,10^x$, where n assumes a value of 1 – 9, representing the nine steps per decade, and x assumes a value of 1 – 7, representing the seven frequency decades.

The test signals corresponding to A-line (see test levels) shall be applied as sinusoidal continuous wave (CW) signals over the entire frequency range. The test signals corresponding to B-line shall be applied as sinusoidal CW signals at frequencies < 3 kHz and as pulse modulated signals at frequencies $\geqslant 3$ kHz. The pulse modulation rate shall be 200 Hz, 32 % duty cycle. (The sinusoidal carrier shall have an on-time of 1,6 ms and an off-time of 3,4 ms every modulation cycle.)

If performance degradation or unintentional responses occur during B-line testing at frequencies $\geqslant 3$ kHz (those that employ pulse modulated test signals) that do not occur during initial A-line testing (employing CW test signals), repeat A-line testing using pulse modulated test signals (200 Hz, 32 % duty cycle) at those same frequencies that exhibited said degradation or responses during B-line testing.

The test is performed on one orientation of the DUT as described in Test setup.

Evaluation of test results: performance criterion A (A-line) and performance criterion B (B-line), as stated in 27.102 b), shall apply.

27.105 Protection from electromagnetic fields in the range 30 MHz – 450 MHz

The assessment of the implantable neurostimulator for the range of frequencies from 30 MHz to 450 MHz is made by exposure to radiated electromagnetic fields using test methods and equipment specified by IEC 61000-4-3. For the purposes of this part of ISO 14708 some parts of IEC 61000-4-3 have been modified.

— Test: General test conditions are described in 27.102. The requirements of IEC 61000-4-3 apply except for the changes listed below (numbers in square brackets refer to clause numbers of IEC 61000-4-3).

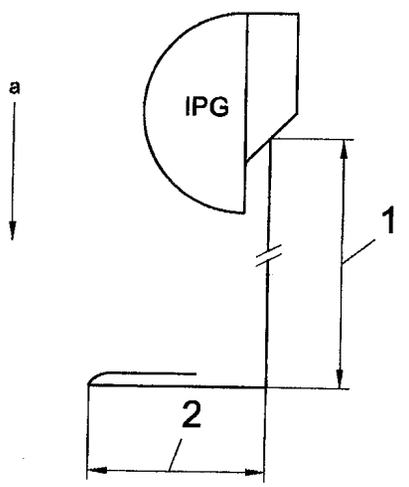
Test levels [5]: Two test field strengths are used, applying different performance criteria to each. A lower level of 16 V/m RMS shall be subjected to the DUT, over the test frequency range, applying performance criterion A, as stated in 27.102 b). A second level of 140 V/m RMS shall be used at the specific frequencies of 30 MHz, 50 MHz, 75 MHz, 150 MHz and 450 MHz, applying performance criterion B. Both field strengths stated are the levels of the unmodulated test signal. Modulation requirements are specified in test procedures [8] below.

Test setup [7]: place the DUT into a saline bath of conductivity 0,27 S/m (equivalent to 370 Ω·cm volume resistivity).

Conductive lead placement is as follows (see Figure 107). Bend the lead into a right angle of sides a and b. The length of side a is equal to 0,62 × the total lead length (rounded to the nearest whole number), but not more than 53 cm. For example, if a lead is 85 cm in length, the length of side a would be 53 cm. The remainder of the lead is placed along side b. Long leads might need to be folded back, always keeping the excess length parallel to side b. Side a will be oriented in the direction of the electric field.

Placing the IPG in the orientation shown in Figure 107 will facilitate testing, as only one orientation of the test setup will need to be exposed to the electric field.

Any ancillary equipment that is needed to operate the neurostimulator or monitor its output during the test shall, as much as possible, be selected and located to minimize disruption of the uniform field. Neurostimulator output can be monitored by using an oscilloscope connected to a sense resistor in series with the lead or by using another lead placed into the saline as a pickup lead.



Key

1 side a
2 side b

[a] E-field.

Figure 107 — IPG and lead layout

28 Accompanying documentation

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

28.1

Addition:

Additional contact information shall be provided, e.g. telephone number or e-mail address, in the event the user or their device needs immediate service or supplementary instructions for proper use.

28.12

Addition:

— a warning statement on the possible safety hazards associated with Magnetic Resonance Imaging (MRI), if applicable.

28.19

Amendment:

This requirement applies to any part with an energy source that can become depleted, not just to implanted parts.

28.22

Addition:

— a warning statement on the possible safety hazards associated with hyperbaric chambers, if applicable;

— a warning statement on the possible safety hazards associated with electronic article surveillance (EAS) systems, metal detectors, and other security systems, if applicable;

— information regarding possible safety hazards from electromagnetic interference (see clause 27).

Additional subclauses:

28.101 The accompanying documentation shall include recommended methods for determining that the neurostimulator is functioning properly.

Compliance shall be checked by inspection.

28.102 The accompanying documentation shall include a description of combinations of device setting and parameters that will influence neurostimulator safety.

Compliance shall be checked by inspection.

28.103 Each separate piece of accompanying documentation shall include the year of issue.

Compliance shall be checked by inspection.

28.104 The accompanying documentation for an IPG or RF receiver shall include a patient ID card bearing at least the following:

a) instruction that the card be retained by the patient;

b) space for the following:

— model designation and name of the device;

— serial number or lot number of the device;

— identity of the patient;

— date of implantation;

— name and address of the implanting centre;

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

NOTE The card can be shown to security or medical personnel who will be aware of procedures to avoid electromagnetic interference and high power electromagnetic fields, if they have been informed the patient has an implanted medical device.

Compliance shall be checked by inspection.

Annex AA
(informative)

Relationship between the fundamental principles in ISO/TR 14283 [8] and the clauses of this part of ISO 14708

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. **6.101** Measurement of stimulation pulse characteristics. **6.102** Measurement of lead or extension d.c. resistance.
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	Replacement. Replacement. Replacement. Replacement. Retained. Retained. Retained. Retained. Amendment. Retained. Retained.

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
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. Amendment. Retained. Retained. **8.101** Marking of packaging for special handling during transport. **8.102** Marking of packaging for permissible environmental conditions during transport.
3.6 Any undesirable side-effect should constitute an acceptable risk when weighed against the performances intended.	19.3 19.4	Replacement. Amendment.
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	Addition.
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	Addition.
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	Replacement. Addition.
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.

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
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	Replacement.
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.
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. Replacement.
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	—

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
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	—
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 11.8 23.6 28.4 28.5	Retained. Retained. Retained. Retained. 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 15.2	Amendment. 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 23.2 24 25 26.2 27	Replacement. Replacement. Replacement. Retained. Retained. Replacement. **27.101** Requirement for immunity from electromagnetic fields. **27.102** General test conditions. **27.103** Protection from static magnetic fields. **27.104** Protection from magnetic fields in the range 10 Hz to 30 MHz. **27.105** Protection from electromagnetic fields in the range 30 MHz to 450 MHz. **27.106** Protection from electromagnetic fields in the range 450 MHz to 3 GHz. **28.104** Requires an ID card signifying the patient has an implant.
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 20.2 21 22 28.12 28.13 28.14 28.15	Retained. Retained. Retained. Addition. Addition. Retained. Retained. 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 19.1 19.2	Replacement. Retained. Replacement.

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
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	Addition.
4.4 Implants with a measuring function		
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	Addition.
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	Addition.
4.4.1.2 If an implant or its accessories bears 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. Addition.
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	Addition.
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		

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
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	Replacement.
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	Replacement.
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	Addition.
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	Addition.
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	Addition. Amendment.
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 26.1	Addition. Replacement. Replacement. Amendment.
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	Addition.
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	Addition.

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
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	Addition.
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	Addition.
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	Replacement.
4.7.4.2 Implants designed to supply energy or administer medicinal substances should be designed and constructed in such a way that the flowrate can be set and maintained accurately enough to minimize the risk to the patient.	5	Addition. **6.101** Measurement of stimulation pulse characteristics.
4.7.4.3 Implants designed to administer medicinal products should incorporate suitable means to prevent and/or indicate any inadequacies in the flowrate which could pose a danger.	5	Addition.
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	Addition. **16.101** Protection from unintended changes of output pulse characteristics.
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.

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
4.8.3 The label should bear the following particulars:	5	Addition.
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. Addition. Retained. Retained. Retained. Retained.
		11.101 Requires additional component information on sterile pack.
		28.104 Requires a patient ID card with model designation and implant centre information.
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.
d) where appropriate, the batch code or the serial number (SN), preceded by an appropriate identification (e.g. "LOT" or "SN" respectively);	9.3 11.6	Retained. Retained.
		28.104 Requires a patient ID card with device serial or lot number.
e) where appropriate, an indication of the date by which the implant should be used;	9.7 11.5	Retained. Retained.
f) an indication that the implant is for single use;	28.18	Retained.
		9.101 Requires single use labelling on the sales packaging.
g) if appropriate, any indication of special purpose (e.g. "custom-made device" or "exclusively for clinical investigations");	9.12 11.10	Retained. 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 11.4	Retained. Retained.
		28.103 Requires each piece of documentation to bear the year of issue.
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 13.1 13.2	Addition. Amendment. Retained.

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
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 28.3 28.16 28.18 28.21	Addition. Retained. Retained. Retained. Retained.
b) the performances referred to in 3.3 of ISO/TR 14283:2004 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 28.5 28.9	Retained. Retained. 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. **28.101** Requires methods for determining that the device is operating properly. **28.102** Requires information on device settings and parameters for safe operation.
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 Clause 3 of ISO/TR 14283:2004;	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	Amendment. 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	Addition.

Fundamental principles in ISO/TR 14283	Subclauses of ISO 14708-1	Clauses of ISO 14708-3 and aspects covered
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 4.1.4 of ISO/TR 14283:2004;	28.8	Retained.
p) degree of accuracy claimed for implants with a measuring function.	5	Addition.
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	Amendment.
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	Amendment.
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)

Relationship between the clauses of this part of ISO 14708 and the fundamental principles listed in Annex AA

Clauses of ISO 14708-3	Fundamental principle of ISO/TR 14283	Clauses of ISO 14708-3	Fundamental principle of ISO/TR 14283
4	4.8.2	11.3	4.8.3 c)
5	4.4.1, 4.4.1.1, 4.4.1.2, 4.4.2, 4.7.1.4, 4.7.1.5, 4.7.3.1, 4.7.3.2, 4.7.3.3, 4.7.3.4, 4.7.4.2, 4.7.4.3, 4.7.4.4, 4.8.3, 4.8.6 p)	11.4	4.8.3 k)
		11.5	4.8.3 e)
		11.6	4.8.3 b), 4.8.3 d)
6.101	3.3, 4.7.4.2	11.7	4.8.3 b), 4.2.3
6.102	3.3	11.8	4.3.1
7.1	4.2.3	11.9	4.2.3
7.2	3.5, 4.2.3	11.10	4.8.3 g)
8.1	3.1	11.101	4.8.3 b)
8.2	4.8.5	12.1	4.2.3
8.101	3.5	12.2	4.2.3
8.102	3.5	12.3	3.5
9.1	4.5.3	13.1	4.8.5
9.2	4.8.3 a)	13.2	4.8.5
9.3	4.8.3 b), 4.8.3 d)	13.3	4.7.1.3
9.4	4.8.3 b)	13.4	4.4.1.2
9.5	4.8.3 c)	14.1	4.2.1, 4.2.3, 4.2.4, 4.2.5
9.6	4.8.3 k)	14.2	4.1.2, 4.2.5
9.7	4.8.3 e)	14.3	4.1.1 a), 4.1.1 b), 4.1.2
9.8	4.8.3 b)	14.4	4.1.4
9.9	4.3.1	15.1	4.3.2 a)
9.10	4.8.3 b), 4.8.4	15.2	4.3.2 a)
9.11	4.8.3 h)	16.1	4.7.2.1
9.12	4.8.3 g)	16.2	4.7.2.2
9.101	4.8.3 f)	16.3	4.7.2.2
10.1	3.5, 4.2.3	16.101	4.7.4.4
10.2	3.5, 4.2.3	17	4.7.2.2, 4.3.2 d)
10.3	3.5	18.1	4.5.3
10.4	3.3, 4.8.1	18.2	4.5.3
11.1	4.8.3 a)	18.3	4.5.3
11.2	4.8.3 c), 4.8.3 l)	19.1	4.3.2 d)

Clauses of ISO 14708-3	Fundamental principle of ISO/TR 14283	Clauses of ISO 14708-3	Fundamental principle of ISO/TR 14283
19.2	3.4, 4.3.2 d), 4.7.1.2	28.3	4.8.6 a) [4.8.3 b)]
19.3	3.4, 3.6, 4.1.7, 4.7.1.1, 4.7.4.1	28.4	3.4, 4.3.1, 4.8.6 c)
19.4	3.6, 4.9 a), 4.9 b)	28.5	4.3.1, 4.8.6 c)
19.5	4.1.3	28.6	4.7.1.3
20.1	4.3.2 c)	28.7	4.8.6 m)
20.2	4.3.2 c)	28.8	4.8.6 b), 4.8.6 o)
21	4.3.2 c)	28.9	4.8.6 c)
22	4.3.2 c)	28.10	4.8.6 d)
23.1	3.4, 4.3.2 b)	28.11	4.8.6 e)
23.2	3.4, 4.3.2 b)	28.12	4.3.2 c), 4.8.6 f)
23.3	3.4	28.13	4.3.2 c)
23.4	3.4	28.14	4.3.2 c)
23.5	3.4	28.15	4.3.2 c)
23.6	3.4, 4.3.1	28.16	4.8.6 a) [4.8.3 c)]
24	4.3.2 b)	28.17	4.8.6 g), 4.8.6 h)
25	4.3.2 b)	28.18	4.8.6 a) [4.8.3 f)]
26.1	3.4, 4.7.2.2	28.19	4.8.6 k)
26.2	3.5, 4.3.2 b)	28.20	4.8.6 k)
27.101	4.3.2 b)	28.21	4.8.6 a) [4.8.3 h)]
27.102	4.3.2 b)	28.22	4.8.6 l)
27.103	4.3.2 b)	28.23	3.4
27.104	4.3.2 b)	28.24	4.8.6 n)
27.105	4.3.2 b)	28.101	4.8.6 d)
27.106	4.3.2 b)	28.102	4.8.6 d)
28.1	4.8.6 a) [4.8.3 a)]	28.103	4.8.3 k)
28.2	4.5.3	28.104	4.8.3 b), 4.8.3 d)

Annex BB
(informative)

Relationship between the clauses of this part of ISO 14708 and the fundamental principles listed in Annex AA

Clauses of ISO 14708-3	Fundamental principle of ISO/TR 14283	Clauses of ISO 14708-3	Fundamental principle of ISO/TR 14283
4	4.8.2	11.3	4.8.3 c)
5	4.4.1, 4.4.1.1, 4.4.1.2, 4.4.2, 4.7.1.4, 4.7.1.5, 4.7.3.1, 4.7.3.2, 4.7.3.3, 4.7.3.4, 4.7.4.2, 4.7.4.3, 4.7.4.4, 4.8.3, 4.8.6 p)	11.4	4.8.3 k)
		11.5	4.8.3 e)
		11.6	4.8.3 b), 4.8.3 d)
6.101	3.3, 4.7.4.2	11.7	4.8.3 b), 4.2.3
6.102	3.3	11.8	4.3.1
7.1	4.2.3	11.9	4.2.3
7.2	3.5, 4.2.3	11.10	4.8.3 g)
8.1	3.1	11.101	4.8.3 b)
8.2	4.8.5	12.1	4.2.3
8.101	3.5	12.2	4.2.3
8.102	3.5	12.3	3.5
9.1	4.5.3	13.1	4.8.5
9.2	4.8.3 a)	13.2	4.8.5
9.3	4.8.3 b), 4.8.3 d)	13.3	4.7.1.3
9.4	4.8.3 b)	13.4	4.4.1.2
9.5	4.8.3 c)	14.1	4.2.1, 4.2.3, 4.2.4, 4.2.5
9.6	4.8.3 k)	14.2	4.1.2, 4.2.5
9.7	4.8.3 e)	14.3	4.1.1 a), 4.1.1 b), 4.1.2
9.8	4.8.3 b)	14.4	4.1.4
9.9	4.3.1	15.1	4.3.2 a)
9.10	4.8.3 b), 4.8.4	15.2	4.3.2 a)
9.11	4.8.3 h)	16.1	4.7.2.1
9.12	4.8.3 g)	16.2	4.7.2.2
9.101	4.8.3 f)	16.3	4.7.2.2
10.1	3.5, 4.2.3	16.101	4.7.4.4
10.2	3.5, 4.2.3	17	4.7.2.2, 4.3.2 d)
10.3	3.5	18.1	4.5.3
10.4	3.3, 4.8.1	18.2	4.5.3
11.1	4.8.3 a)	18.3	4.5.3
11.2	4.8.3 c), 4.8.3 l)	19.1	4.3.2 d)

Clauses of ISO 14708-3	Fundamental principle of ISO/TR 14283	Clauses of ISO 14708-3	Fundamental principle of ISO/TR 14283
19.2	3.4, 4.3.2 d), 4.7.1.2	28.3	4.8.6 a) [4.8.3 b)]
19.3	3.4, 3.6, 4.1.7, 4.7.1.1, 4.7.4.1	28.4	3.4, 4.3.1, 4.8.6 c)
19.4	3.6, 4.9 a), 4.9 b)	28.5	4.3.1, 4.8.6 c)
19.5	4.1.3	28.6	4.7.1.3
20.1	4.3.2 c)	28.7	4.8.6 m)
20.2	4.3.2 c)	28.8	4.8.6 b), 4.8.6 o)
21	4.3.2 c)	28.9	4.8.6 c)
22	4.3.2 c)	28.10	4.8.6 d)
23.1	3.4, 4.3.2 b)	28.11	4.8.6 e)
23.2	3.4, 4.3.2 b)	28.12	4.3.2 c), 4.8.6 f)
23.3	3.4	28.13	4.3.2 c)
23.4	3.4	28.14	4.3.2 c)
23.5	3.4	28.15	4.3.2 c)
23.6	3.4, 4.3.1	28.16	4.8.6 a) [4.8.3 c)]
24	4.3.2 b)	28.17	4.8.6 g), 4.8.6 h)
25	4.3.2 b)	28.18	4.8.6 a) [4.8.3 f)]
26.1	3.4, 4.7.2.2	28.19	4.8.6 k)
26.2	3.5, 4.3.2 b)	28.20	4.8.6 k)
27.101	4.3.2 b)	28.21	4.8.6 a) [4.8.3 h)]
27.102	4.3.2 b)	28.22	4.8.6 l)
27.103	4.3.2 b)	28.23	3.4
27.104	4.3.2 b)	28.24	4.8.6 n)
27.105	4.3.2 b)	28.101	4.8.6 d)
27.106	4.3.2 b)	28.102	4.8.6 d)
28.1	4.8.6 a) [4.8.3 a)]	28.103	4.8.3 k)
28.2	4.5.3	28.104	4.8.3 b), 4.8.3 d)

Annex CC
(informative)

Rationale

CC.1 General

The following notes on some of the provisions of this part of ISO 14708 are provided as an aid to understanding. The notes in this annex carry the numbers of the relevant clauses of this part of ISO 14708, therefore, paragraph numbering in this annex is not consecutive.

CC.2 Notes on specific clauses and subclauses

1 Trial screeners are included in the scope because of the customary practice for a trial period of stimulation prior to the decision to implant. It is felt that the trial screening device needs to have the same performance and characteristics as the actual neurostimulator. Non-implantable neurostimulators that are used for other purposes and that cannot be considered as accessories to an implantable neurostimulator, are excluded from the scope of this part of ISO 14708.

6.101 This subclause provides a uniform method for measuring stimulation pulse characteristics so the specifications and characteristics provided by the manufacturer in the accompanying documentation are acquired in a consistent manner.

It is important for the user to understand the stimulation pulse shapes and measurement parameters, such as load. In particular, if pulse shapes or other characteristics are different depending on output mode, state or configuration these elements of device operation need to be brought to the attention of the user.

Measurement units, such as volts or milliamperes, are specified for uniformity. In addition, other units can be used if the manufacturer chooses.

Load impedance, R_L, is specified by the manufacturer to allow for variations in tissue impedances depending on application. In addition, a uniform load impedance is specified for comparative purposes.

Room temperature is specified for the test equipment and test sample for convenience. It is not expected, with the use of modern technology, to have significant changes in measured values between room temperature and 37 °C.

In particular, when stimulating sensory nerves, it is important that the stimulation pulse be stable to prevent unintentional changes in stimulation intensity that might be perceived by the patient as shocking, intermittent stimulation or loss of therapy.

8.2 The intent of ISO 14708-1 was to cover implanted parts because of the risk and inconvenience of replacement. Therefore, this part of ISO 14708 excludes temporary leads, such as might be used for trial screeners, from the requirement.

8.101 This requirement extends labelling for handling during transport to all parts, including implantable parts. Electrically powered non-implantable parts are covered by the requirements of Clause 5.

8.102 This requirement extends labelling for environmental conditions during transport to all parts, including implantable parts. Electrically powered non-implantable parts are covered by the requirements of Clause 5.

10.3 The test in this part of ISO 14708 is harmonized with the test in IEC 60601-1. The note explains that removable stickers are excluded if they contain information beyond the requirements in this part of ISO 14708.

13.1 The wet rub test was changed to be consistent with 10.3.

14.2 The requirements of ISO 14708-1 were originally written for blood borne particulates. This part of ISO 14708 allows the manufacturer to define the requirements for particulate matter that can be different depending on the intended neurostimulator application. The burden of proof is upon the manufacturer to demonstrate via a risk analysis, design analysis, test studies or other appropriate means.

15.1 Applies the current edition of the referenced standard.

16.1 Applies the current edition of the referenced standard.

16.2 Requires the manufacturer to determine if leakage current limits are adequate based on actual device application.

16.3 The requirement recognises that various applications can use different stimulation thresholds and energy and that 10 V, *per se*, is not a particularly unique stress level.

16.101 For neurostimulation applications the prevention of sudden changes in output stimulation characteristics, even if within normal programmable ranges, is an important patient safety consideration. Excessive current density and the perception of shocking or jolting are examples of potential hazards that might result from unexpected output stimulation changes.

17 Limiting temperature increases to 2 °C might be overly restrictive, which is based on whole body temperature distribution. When perfusion is considered, larger local temperatures increases can be considered. See reference [9].

19.2 Modified to use terms defined within this part of ISO 14708 (i.e. service life) and to clarify what is meant by a source of power.

19.3 Modified to reflect the current usage of risk assessment according to ISO 14971. Replaces the former, and less comprehensive, requirement of using a single technique, such as FMEA.

19.4 Simply modifies the former requirement to allow for clinical investigations conducted in accordance with published standards other than ISO 14155.

21 Implantable neurostimulators can be affected by exposure to high-power electrical fields applied directly to the patient. Specific requirements might be specified in future editions of this part of ISO 14708.

22 It is recognised that newer treatments and procedures might also need to be evaluated. Specific requirements might be specified in future editions of this part of ISO 14708.

23.1 Harmonized with the 2005 edition of IEC 60601-1, but increased the number of drops for hand-held to account for the prevalence of patient-carried devices.

23.2 Modified from ISO 14708-1 to reflect the environment seen by implantable parts only. Non-implantable parts are tested for shock in 23.1 and Clause 10 requires consideration of vibration during storage and handling.

24 The ESD test levels cited in ISO 14708-1 are obsolete. The new requirement, referring to IEC 60601-1-2, will insure that devices are tested to levels that are currently considered appropriate. Clause 24 is also harmonized with Clause 5.

26.1 Applies the current edition of the referenced standard.

27.102 The most important functions of the implantable neurostimulator, from a safety standpoint, are subjected to the immunity tests. Functions not associated with essential performance do not need to be tested. Usually, a function can be thought of as a clinically significant feature that the device is intended to provide. The current edition of this part of ISO 14708 does not define "function" in Clause 3 however, because it is conceivable that a function that is not clinically significant could somehow be associated with essential performance and, would therefore, be subject to the immunity tests.

Most of the immunity tests incorporate two sets of test levels. Consequently, there are also two defined sets of performance criteria (a third criterion level is defined by the manufacturer).

The test levels that have been chosen for all the tests are based on general public exposure conditions and, in some cases, are related to biological exposure guidelines. None of the test levels is expected to cause any permanent damage or lasting effects. Therefore, performance criteria, post-test, are set accordingly.

Performance criteria, during test, are set according to test level. The lower test levels are based on common, everyday exposure conditions. These are levels typical of a home environment, including power lines, transportation, common areas (school, retail, office and hospital), and office equipment; and where exposure is more likely to occur with longer duration. Therefore, in this environment, it is reasonable to expect that an implantable neurostimulator would work completely as intended, with no loss of function and without any unintentional responses.

The higher test levels represent environments to which the general public might occasionally be exposed, are generally more avoidable, and when exposure does occur, it's generally for a shorter duration. Sources in this category include the higher powered electronic article surveillance (EAS) gates and higher powered mobile communications equipment. For magnetic fields, the higher immunity test levels have a 10× margin above the lower, common levels and for electric fields there is a 5× margin. There is a 3× margin above the highest known EAS gate and a 5× margin above typical worst case mobile transceivers. In this environment the device is expected to be free from damage and unacceptable risk. Since every conceivable situation cannot be foreseen, an allowance is made for temporary degradation of performance and unintentional responses as long as patient safety is maintained. In this way, use of the neurostimulator can be allowed so its clinical benefit can be enjoyed by the patient. This allowance has to become the judgment of the manufacturer and regulatory personnel.

Some examples of unintentional responses are a change in pulse width or amplitude outside of normal operating specifications, or a pulse or spike where none was intended. Extraordinary device behaviour is not expected to occur typically, and the 10× test levels should verify this experimentally.

Some degradations are not allowed because of safety concerns and because they are not justified by the severity of the test levels.

Induced voltage from time-varying magnetic fields is related to a conductive lead loop area which is greatest for devices operating with a unipolar electrode configuration as compared to a bipolar electrode configuration. For electric fields the voltage developed across a lead will typically depend upon lead orientation to the electric field, rather than electrode configuration. Unless the manufacturer knows from prior testing, it might be necessary to test all electrode configurations to discover worst case susceptibility.

27.103 The lower level of 1 mT (10 Gauss) was chosen because it represents a commonly encountered field strength. Historically, many implantable devices had magnetically activated reed switches internal to the sealed enclosure that were used for control purposes. These reed switches were usually activated with a magnetic field of around 1 mT. Therefore, it is expected that all devices will function normally when in the presence of a 1 mT field.

The higher level of 50 mT (500 Gauss), although seldom encountered, is a possibility for the general public. Static magnetic field strengths, right on the surface of common household magnets (e.g. refrigerator magnets) and from magnets supplied from medical device manufacturers to trigger built-in reed switches, are typically on the order of 50 mT (magnetic fields fall off rapidly, so field strengths just a few centimetres away are usually insignificant). Therefore, devices are not expected to suffer any permanent damage or change of state after exposure to these field levels. Because some implantable medical devices still depend on reed switch activation for some control features, a change of operational mode would be expected to occur when in the presence of a static magnetic field of greater than 1 mT.

The requirement of a + 3 dB uniform field is justified for quality of test data and its generation is within available technological capability.

The one required orientation of the DUT, with its largest surface exposed to the primary magnetic field vector, is sufficient to test for interactions. Other orientations present such a small device profile it is unlikely to see interactions not seen with the required orientation.

Ten minutes should be a sufficient time to get a response.

27.104 General public exposure to electromagnetic energy in the frequency range of 10 Hz to 30 MHz consists of both electric and magnetic fields. Only the magnetic fields are considered to have a potential for causing disturbances in implantable neurostimulators.

Electric fields in this frequency range have an insignificant amount of coupling into devices the size of neurostimulators, which have very short electrical length based on a conservative figure of 1/20 wavelength. Using the following relationship,

$$\lambda_{saline} = \frac{\lambda_{freespace}}{\sqrt{\text{tissue dielectric constant}}} \qquad \text{(CC.101)}$$

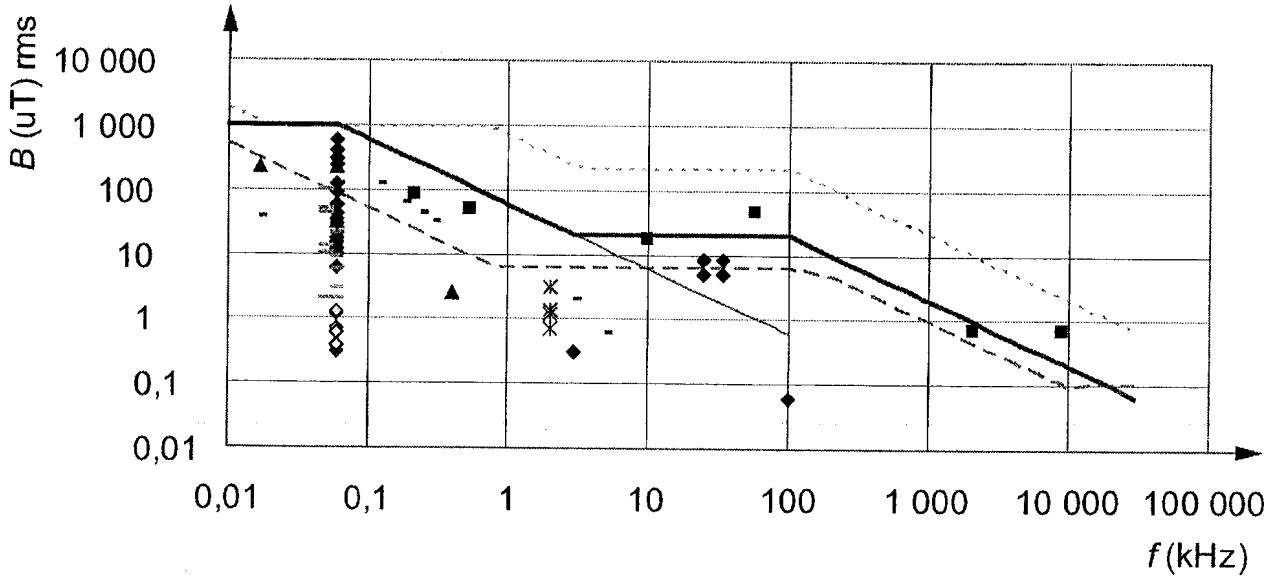
a tissue dielectric of 80, and an average maximum dimension of 6 cm (typical for a neurostimulator), frequencies less than about 27 MHz should have insignificant coupling into neurostimulator circuitry. Above 27 MHz the electric field attenuation of the titanium enclosure is greater than 35 dB, except for the connector block area. Emitters in this frequency range, which include amateur radio, AM radio, time and frequency broadcasts, ISM, personal and private radio services, and maritime radio-navigation, have not been known to cause interference with implantable neurostimulators.

Exposure to magnetic fields, with the potential to cause disturbances, is primarily from power frequency equipment and appliances. Most everyday exposure occurs in the home, but it also occurs near power lines, transportation vehicles, office equipment, and in common areas such as school, retail, office and hospital.

Figure CC.101 illustrates the derivation of the A-line and B-line from environmental source data (see references [10] to [18]), along with ICNIRP general public reference levels[19], IEEE C95.1[20] and IEEE C95.6[21] uncontrolled levels, MIL 461E [22] RS101 levels, IEC 61000-2-5[23] data (Table 6, disturbance degree 4) , and ISO 14708-3 A-line test levels.

The A-line is intended to represent common, everyday exposure of the general public, to magnetic fields. It follows the MIL 461 level from 30 Hz to 3 kHz. Above 3 kHz it closely tracks the ICNIRP general public reference level, except it is a factor of 3,2 higher to 100 kHz and about 2,2 higher to 30 MHz. These factors can be used to account for pulsation margins. The data in the figure already account for localization effects based on homogeneity of source field (including size and proximity) according to IEC 62226-2-1[24]. General public exposure to magnetic fields represented by the A-line is considered to be probable, frequent and unavoidable. Operation of the implantable device, under these exposure conditions, is expected to be normal.

The B-line is used for additional assurance of protection from exposure above the A-line. It doesn't represent a particular general public environment, *per se*, but corresponds to IEEE C95.1[20] recommendations for maximum permissible human exposure. The safety margin provided by the B-line is 10× over the A-line $\geqslant$ 3 kHz. Potential sources at this level appear to be relatively few and proximity to the source is necessary to reach these levels. Therefore, general public exposure to magnetic fields represented by the B-line is considered to be possible, relatively infrequent and for short duration when occurring, and generally avoidable when sources are known. Operation of the implantable device, under these exposure conditions, is expected to be free from damage and unacceptable risk.



Key

ICNIRP GP REF LVL		Home		IEEE C95.1/C95.6	
Transportation		Office equipment		EAS	
MIL 461E		IEC 61000-2-5		Power line	
Common areas		ISO 14708-3 A-line			

Figure CC.101 — Magnetic source data and ICNIRP general public reference levels, IEEE C95.1/C95.6 uncontrolled levels, MIL 461E RS101 levels, IEC 61000-2-5 data (Table 6, disturbance degree 4), and ISO 14708-3 A-line test levels

The uniform field is required to be tightest for the frequencies up to 100 kHz which cover the majority of the common environment. At these low frequencies it is easier to generate a uniform field over a given area. The uniformity is relaxed at higher frequencies and test levels due to test fixture limitations.

A saline bath is used to simulate the *in vivo* environment of the neurostimulator in normal use. A conductivity of 0,27 S/m is a compromise for various body tissues and for test setup consistency over the entire test frequency range among all tests.

Induced voltages from time-varying magnetic fields are, according to Faraday's Law, dependent upon enclosed loop area formed by the conductive lead. Formula 101 is based on a maximum practical lead length of 85 cm and an effective electrical loop area of 650 cm^2. The lead length was chosen from anthropometric data for a 95th percentile man (see references [25] and [26]) which indicates that the longest dimensioned lead in a torso would be placed abdominally and routed up the spine to C1 forming two sides of a right angled triangle with abdominal length of 32 cm and spinal length of 53 cm. The geometric area enclosed by the lead, using body tissue as the hypotenuse, would be 850 cm^2 (32 × 53/2). However, based on reference [27] the effective electrical loop area is smaller than the geometric loop area. They found a factor of approximately 1,5 to be reasonable to relate the electrical and geometric areas, but this part of ISO 14708 is based on a more conservative factor of 1,3. The result is an effective loop area of approximately 650 cm^2. The maximum effective area of 650 cm^2 is still based on a lead length of 85 cm which results in formula 101 ($0,09 \times 85^2 = 650$ cm^2).

Step sizes as specified give reasonable coverage of the frequency range without creating a burdensome number of test measurements.

The A-line uses sinusoidal continuous wave test signals to emulate the common environment. The B-line is pulse modulated ⩾ 3 kHz to simulate those kinds of signals present in the environment and to place additional stress on the DUT. Below 3 kHz the B-line is sinusoidal because pulsed fields aren't prevalent in practice and the modulation rate of 200 Hz is too close to the starting test frequency of 300 Hz. The modulation rate was

chosen to not interfere with power frequencies or typical stimulation rates which are usually less than 200 Hz, and to simulate known magnetic field sources.

Retesting the A-line at frequencies exhibiting a pulse modulation effect provides an additional assurance of safety.

One orientation of the DUT in the test fixture, with its largest surface exposed to the primary magnetic field vector, is sufficient to test for interactions. Other orientations present such a small device profile it is unlikely to see interactions not seen with the required orientation. The maximum induced voltage comes from a lead loop perpendicular to a magnetic field.

27.105 General public exposure to electromagnetic energy in the frequency range of 30 MHz to 450 MHz is primarily an electric field phenomenon from sources distal to the patient. Primary transmitters in this frequency range consist of radiated oscillatory sources which typically are broadcasting transmitters, portable and mobile transmitters and ISM equipment.

Normally, at locations inhabited or visited by the general public, field strengths from these sources are less than 10 V/m. A comparative immunity test standard, IEC 60601-1-2 used for non-implantable medical devices, specifies test field strengths of 3 V/m for non-life support equipment and 10 V/m for life support equipment. Depending on proximity and source, field strengths might be higher.

NOTE All electric field strength values given in this rationale are RMS, unless stated otherwise.

Biological safety standards can be used, for comparative purposes, to assess the potential threat to human safety. The limits presented in these standards can be used as a guideline for setting immunity test levels based on the presumption that public exposure to electromagnetic fields should be limited. Recently, certain countries have taken steps to pass legislation controlling source emissions to protect the general public.

IEEE C95.1[20], over the frequency range of 30 MHz to 450 MHz, sets electric field exposure limits at 27,5 V/m to 33,6 V/m (uncontrolled) and to 61,4 V/m to 75 V/m (controlled). ICNIRP[19], over the same frequency range, limits electric field exposure to 28 V/m to 29 V/m (general public) and to 61 V/m to 63,6 V/m (occupational).

CISPR 11[28] limits for radiated emissions from ISM equipment (industrial, scientific and medical) vary by group, class and distance but can be summarized as being approximately 60 dB μV/m (1 000 μV/m), worst case, at 30 m, from 30 MHz to 450 MHz. CISPR 14[29] limits for household appliances, electric tools and similar apparatus are lower. CISPR 22[30] limits for ITE (information technology equipment) are not more than 37 dB μV/m (71 μV/m). FCC[31] limits for class A digital devices are not more than 46,5 dB μV/m (210 μV/m),

Examples of field strengths from authorized transmitters, at typical separation distances, are shown in Table CC.102 [15 – Table 1].

Table CC.102 — Examples of field strengths from authorized transmitters

Service	Frequency range MHz	Typical range of separation distance m	Calculated field strength range corresponding to separation distance V/m
LF broadcast and maritime	0,014 – 0,5	2 000 – 20 000	5,5 – 0,55
AM broadcast	0,2 – 1,6	500 – 2 000	12,5 – 0,78
HF amateur	1,8 – 30	10 – 100	22,1 – 2,21
HF communications including SW broadcasting	1,6 – 30	1 000 – 20 000	0,7 – 0,04
Citizens' band	27 – 28	10 – 100	2,4 – 0,24
Amateur VHF/UHF	50 – 52 144 – 146 434 – 438 1 290 – 1 300	10 – 500 39	63 – 0,44 16
Fixed and mobile communications	29 – 40 68 – 87 146 – 174 422 – 432 438 – 470 860 – 990	2 – 200 5	40 – 0,25 16
Portable telephones including cordless phones	1 880 – 1 990	1 – 100 0,5 – 10	15,6 – 1,56 14 – 0,7
VHF TV	48 – 68 174 – 230	500 – 2 000	8 – 1,11
FM broadcast	88 – 108	250 – 1 000	8,9 – 2,2
UHF TV	470 – 853	500 – 3 000	10 – 1,6

IEC 61000-2-5:1995[23], Table B.1 contains probabilities that electric field strengths will not be exceeded at certain distances from common transmitters. According to that table, the probability is virtually insignificant (0,000 1 %) that a field strength of 10 V/m will be exceeded from the emitter classes and distances shown in Table CC.103.

Table CC.103 — Electric field strength distances for encountering 10 V/m

AM broadcasting 150 kHz – 30 MHz Power = 500 kW	Walkie-talkie 27 MHz – 1 000 MHz Power = 5 W	CB 27 MHz Power = 12 W	TV – VHF 48 – 223 MHz Power = 200 kW
495 m	1,6 m	2,4 m	313 m

Considerations for setting immunity test levels in this part of ISO 14708 took into account that an implant cannot easily be removed from its environment, and that it is inseparable from its host without surgery. It seems reasonable to require an immunity test level above that required for non-implantable medical devices, at the same time keeping it in line with real-world sources commonly encountered by the general public.

A level of 16 V/m RMS, when amplitude modulated at 80 %, is in line with the information provided above (≈ 28 V/m maximum RMS) and provides an increase of 5× above the non-life support requirement of IEC 60601-1-2 (1,6× above the life support requirement).

A saline bath is used to simulate the *in vivo* environment of the neurostimulator in normal use. A conductivity of 0,27 S/m is a compromise for various body tissues and for test setup consistency over the entire test frequency range among all tests.

Lead placement exposes the longest practical dimension of a lead placed in the torso, to a parallel electric field polarization. Anthropometric data for a 95th percentile man (see references [25] and [26]) indicates that the longest dimensioned lead in a torso would be placed abdominally and routed up the spine to C1 forming two sides of a right triangle with abdominal length of 32 cm and spinal length of 53 cm, for a total lead length of 85 cm. Using a factor of 0,62 for side a in Figure 107 keeps the side exposed to the parallel electric field proportional to the overall lead length. The remainder of the lead (side b) is kept orthogonal to the electric field in order to minimize an opposite polarity voltage developing across that side.

Test lead lengths are based on the torso where the majority of implants occur. Longer lead lengths, such as those for a leg implant, are simulated by using a higher test voltage of 140 V/m. (A consideration for performing the test in saline is the size of the saline tank. Keeping the required lead length to the practical minimum helps keep size and weight manageable.)

The connector block area of a typical neurostimulator, with titanium enclosure, is the most susceptible to short wavelength electric fields. The test requires this area of the enclosure to be presented parallel to the electric field polarization in order to maximize coupling.

Amplitude modulation is used to be consistent with the requirements of IEC 60601-1-2 for non-implantable parts. According to the rationale in IEC 61000-4-3, amplitude modulation has advantages over other methods. The modulation rate is 200 Hz which is close to the physiological passband and avoids power line frequencies and typical stimulation rates.

Step sizes of 5 % give reasonable coverage of the frequency range without creating a burdensome number of test measurements.

Pulsation and localization effects of electromagnetic fields are taken into account in biological safety standards. There is no localization factor for the electric field. In theory, the pulsation factor for the electric field could be as high as 32 in persons without implants. In practice, there are no known sources with public access that utilize such levels. A pulsation factor of 5 was chosen as a reasonable limit, which results in an upper test level of 140 V/m RMS (28 V/m × 5).

The upper level is pulse modulated (rather than AM) primarily due to test facility limitations producing large amplitude fields. Frequency steps were chosen to cover a representative sample of sources occupying the frequency range.

The use of IEC 61000-4-3 as a test procedure is consistent with the requirements for non-implantable parts and is a well recognized standard. It is appropriate to use the IEC standard methodology due to the similarity of the electromagnetic environmental exposure encountered by external and implantable medical devices.

27.106 General public exposure to electromagnetic energy in the frequency range of 450 MHz to 3 GHz is primarily an electric field phenomenon. Sources with field strengths high enough to cause potential interference with implanted medical devices consist primarily of hand-held wireless transmitters (e.g. cellular phones), at close range.

An ANSI/AAMI EMC standard, PC69, written by the EMC Task Force of the AAMI Pacemaker Committee, was written primarily to cover this type of equipment. This part of ISO 14708 incorporates the requirements and test methods of PC69 due to the equivalencies between implantable pacemakers and implantable neurostimulators regarding the patient environment, appropriate mechanical and electrical design elements, and the application of the products *in vivo*.

Although intended, primarily, to simulate wireless devices at close range, power levels of PC69 adequately replace more traditional forms of radiated immunity testing that was done under far field conditions at field levels of 3 V/m or 10 V/m. The threat from hand-held wireless devices is higher than from other (far field) broadcast media (e.g. television and radio).

PC69 provides rationale for the selection of test frequencies within this range and for test levels. The standard level of 40 mW is to simulate a hand held wireless transmitter 15 cm from an implant, which is a generally accepted reasonable distance. The optional, higher levels of 8 W < 1 000 MHz and 2 W ⩾ 1 000 MHz simulate closer distances and allow the manufacturer to make claims of additional performance or immunity. Since this testing is optional, the manufacturer is allowed the discretion to set the performance criteria on which to base these claims.

28.1 Additional manufacturer information is required to provide the user with alternative ways of making contact, especially for immediate needs.

28.12 MRI is becoming a very important and widely prescribed diagnostic procedure. It is very important that the patient and physician understand the risks involved with implantable devices. Unless the manufacturer can provide sufficient evidence of compatibility a warning statement will be necessary, until such time as standardized test procedures and requirements can be developed for the assessment of device performance and patient safety.

28.19 An implantable neurostimulator can have non-implantable parts that contain an energy source. The requirement does not apply to energy sources that cannot be depleted, such as line-powered devices.

28.22 EAS and similar surveillance systems are everywhere in the general public environment, and they cannot always be easily avoided or detected. Likewise, other potential sources of electromagnetic interference exist that can be unseen by patients in their normal environment. Based on performance results from the tests in Clause 27, it might be necessary to include warning notices in the user documentation.

28.104 By placing text on the patient ID card that states the holder of the card has an implanted medical device will serve as a reminder to the patient and inform security personnel that precautions might need to be taken to avoid potentially hazardous electromagnetic interference or high-power electromagnetic fields.

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