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Implants for surgery — Active implantable medical devices —

Part 4: Implantable infusion pumps

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 4: Pompes d'infusion en implant

Reference number
ISO 14708-4:2008(E)

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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 14708-4 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 to deliver a medicinal substance to site-specific locations within the human body, 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.

An implantable infusion pump is a device that delivers either a constant flow rate or a variable flow rate from which a medicinal substance is delivered via an implanted catheter to site-specific locations within the human body. An external programmer might be used to adjust device parameters.

This part of ISO 14708 is relevant to all parts and accessories of implantable infusion pumps, including catheters, refill kits, direct access port kits, programmers and related software. 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 infusion pumps 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 particular part of ISO 14708.

“Addition”: the text of this particular 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 particular part of ISO 14708.

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

Implants for surgery — Active implantable medical devices —

Part 4:
Implantable infusion pumps

1 Scope

This part of ISO 14708 is applicable to active implantable medical devices intended to deliver medicinal substances to site-specific locations within the human body.

This part of ISO 14708 is also applicable to some 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 infusion systems. However, it does apply to devices intended to be used as trial systems because of their close affiliation with implantable infusion pumps.

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 infusion pump
active implantable medical device intended for delivery of a medicinal substance to a specific location within the human body

NOTE For purposes of this part of ISO 14708, an implantable infusion pump 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 and trial systems.

3.102
pump gear
implantable part of an implantable infusion pump containing the fluid reservoir, energy source and, in some cases, control electronics

3.103
fluid path
internal surfaces of the implantable infusion pump which are in direct contact with a medicinal substance

3.104
outlet port
port where fluid enters the delivery catheter

3.105
refill access port
port allowing access to the fluid reservoir

3.106
direct access port
port allowing access to the delivery catheter

3.107
internal volume
fluid volume extending from the reservoir to the outlet port

3.108
reservoir volume
fluid volume of the reservoir that can be discharged while maintaining infusion accuracy within specifications

3.109
residual volume
fluid volume that cannot be removed from the pump gear

3.110
projected service life
period after implantation when the implantable infusion pump remains within stated specifications and characteristics

3.111
stability interval
calculated maximum interval between two subsequent reservoir refills to assure stability of the medicinal substance

3.112
infusion accuracy
how close the true (actual) infusion rate is to the specified rate

3.113
repeatability
value below which the absolute difference between two successive test results obtained with the same implantable infusion pump with the same infusate under the same conditions can be expected to lie, with a probability of 95 %

NOTE 1 A more qualitative way of looking at repeatability is the ability to consistently deliver the same results over time (e.g. infusion rate). Repeatability is a metric independent of accuracy.

NOTE 2 A method for calculating repeatability is given in Annex B of ISO 11631:1998 [9].

3.114
minimum rate
lowest rate selectable by the user

3.115
intermediate rate
rate specified by the manufacturer as typical for the implantable infusion pump

NOTE The rate specified might depend on the application.

3.116
maximum rate
highest rate selectable by the user

3.117
bolus
discrete quantity of liquid that is delivered in a short time

3.118
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 and the following applies.

DUT device under test

5 General requirements for non-implantable parts

This clause of ISO 14708-1 applies.

6 Requirements for particular active implantable medical devices

Additional subclauses:

6.101 Implantable infusion pump characteristics

The specifications and characteristics (e.g. infusion accuracy and repeatability) stated by the manufacturer in the accompanying documentation (see 28.8) shall be maintained over the projected service life and over the range of environmental conditions stated by the manufacturer.

NOTE 1 Minimum environmental conditions for atmospheric pressure are specified in Clause 25.

Infusion accuracy shall be stated for all selectable rates (including bolus rates) over a range of reservoir volumes. Constant flow implantable infusion pump accuracy shall be stated for the specified infusion rate of the pump over a range of reservoir volumes.

The manufacturer shall provide a plot of infusion accuracy versus reservoir volume. For variable rate pumps the plot shall contain curves for minimum rate, maximum rate, and one or more intermediate rates.

The method of computing and determining the infusion accuracy shall be clearly stated in the accompanying documentation. Environmental test conditions used to establish infusion accuracy shall also be stated.

NOTE 2 Accuracy is a commonly used term and might include the effects of systematic and random errors. Although it is convenient to combine all these errors under the heading “accuracy”, it is still a qualitative term.

For all selectable infusion rates, the repeatability of the actual rate shall also be stated. The method of computing and determining the stated repeatability shall be clearly described in the accompanying documentation.

Compliance shall be confirmed by inspection of test procedures and results provided by the manufacturer, supported by the manufacturer’s calculations as appropriate.

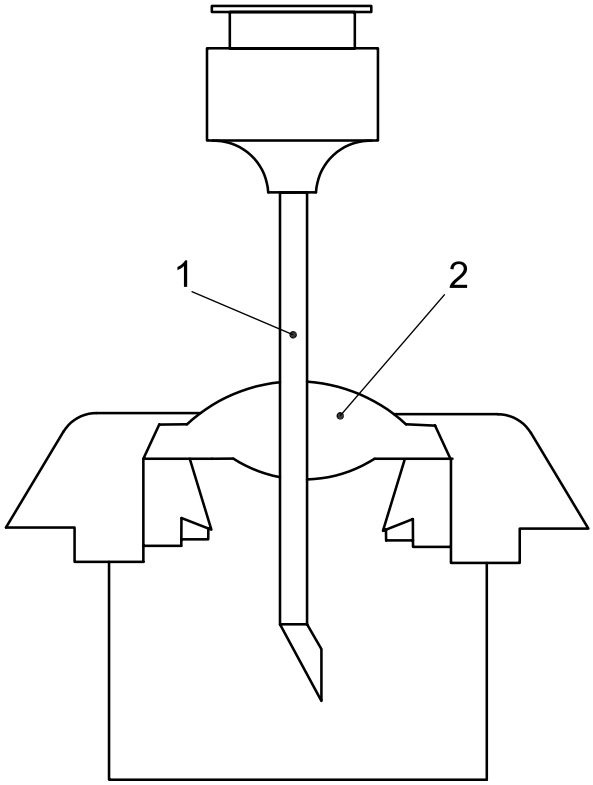
6.102 Septum puncture test

A septum that allows entry to an access port (e.g. refill port or direct access port), shall be able to withstand repeated insertions of a hypodermic needle while maintaining the security of the fluid reservoir throughout the projected service life.

— Test: The DUT shall be conditioned at 37 °C ± 1 °C for not less than 12 h to achieve thermal equilibration. Each implantable pump septum shall be punctured randomly using the needle specified by the manufacturer for septum puncture and in accordance with the manufacturer’s instructions. The needle used for septum puncture shall be replaced if damage to the needle or the needle’s tip is noted by the operator. The needle shall completely penetrate the septum and care should be taken not to damage the needle’s tip during the test. Puncturing shall be done using a straight-line motion parallel to the septum's axial centre-line as shown in Figure 101.

  Septum leakage shall be determined by immersing the test unit in a water bath at 37 °C ± 1 °C and allowing the temperature of the assembly to stabilize for a minimum of 30 min. Leakage shall be determined by air pressure applied slowly to a pressure of twice the pump’s maximum operating pressure or a minimum or 276 kPa. The septum’s exposed surfaces shall be examined for air bubble leakage for 1 min.

Compliance shall be confirmed if the access port life conforms to the manufacturer’s specified limits. The maximum number of punctures recommended by the manufacturer shall be stated (see 28.8).



Key

1 needle
2 septum

Figure 101 — Septum puncture test

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:

Additional subclauses:

8.101 If special handling measures have to be taken during transport, the transport packaging shall be marked accordingly (see for example 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) Pump gear

- reservoir volume;
- infusion flow rate for constant flow pump;
- any additional information and relevant characteristics, as necessary, to identify the device.

b) Catheter

- length (in centimetres);
- any additional information and relevant characteristics, as necessary, to identify the device.

c) Refill kit

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

d) Direct access port kit

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

10 Construction of the sales packaging

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

10.3

Amendment:

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

NOTE Removable stickers (e.g. temporary stickers used in the manufacturing process) that 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) Pump gear

- reservoir volume;
- infusion flow rate for constant flow pumps;
- any additional information and relevant characteristics, as necessary, to identify the device.

b) Catheter

— length (in centimetres);

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

c) Refill kit

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

d) Direct access port kit

— 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 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 infusion pump, 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-reusable 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 $5 \pm 0{,}5 \times$ 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 ± 1 °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 principal [see for example 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:

This requirement also applies to the implantable infusion pump's fluid path materials (indirect contact).

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

Additional subclause:

14.101

For implantable infusion pumps that require the medicinal substance to be periodically replenished, the manufacturer shall establish the maximum interval during which the medicinal substance will maintain a potency of at least 90 % of the initial concentration of the medicinal substance instilled into the pump's reservoir. The manufacturer shall stipulate the stability interval at body temperature for each medicinal substance claimed (see 28.8). In addition, an evaluation for the presence of potentially hazardous degradation products in the medicinal substance, for the stability interval established, shall be conducted.

Compliance shall be confirmed if records provided by the manufacturer establish that the safety and quality of the substance have been verified by analogy with the appropriate methods.

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 60601-1:1988 is replaced by 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 60601-1:1988 is replaced by 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.

17 Protection from harm to the patient caused by heat

Replacement:

No outer surface of an implantable part of the implantable infusion pump 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 Currently, some studies have shown that, depending on the location of specific tissue within the human body, a 2 °C temperature limit might 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 3.110) of the implantable infusion pump 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 infusion pump 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 or 14155-2 [6],[7].

Additional subclause:

19.101 The projected service life for a variable rate implantable infusion pump containing an implanted electrical energy source shall be determined for a range of infusion rates including, but not limited to, various daily infusion volumes when delivered as a continuous infusion. Short-term infusion rates that exceed typical therapeutic infusion rates, but do not appreciably affect device longevity, are excluded from projected service life calculations (see 28.19).

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.

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 and lithotripsy, shall also be considered.

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 an implantable infusion pump shall comply with 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 15.3.4.1 of IEC 60601-1:2005).

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

23.2

Amendment:

The pump gear shall be constructed to withstand the mechanical forces that might 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.

Compliance shall be confirmed if the pump gear conforms to the device specifications after performing the test procedure.

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

Replacement:

Non-implantable parts of an implantable infusion pump shall comply with 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 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 infusion pump 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 infusion pump that is 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 1 For example, essential performance could be related to infusate delivery accuracy and repeatability. A variable rate pump can have several modes of operation (e.g. continuous infusion) and it might be appropriate to test more than one.

NOTE 2 Infusion rates selected for the test could be related to typical use, such as intermediate rates. These are especially appropriate if pump reaction to the immunity tests is unrelated to rate. A higher infusion rate will make it easier to spot changes in infusate delivery. The rate selected has to be appropriate for the test dwell time duration. Catheter length that determines rate for a constant flow pump has no bearing on immunity performance but needs to be long enough to support the test setup

b) Performance criteria

Under the test conditions specified in Clause 27, each function of the implantable infusion pump 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 criteria 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

Prior to each test, fill the pump reservoir with a suitable fluid (coloured fluid is easier to monitor) for delivery into a container during the test. The fluid delivered from the catheter is monitored to evaluate the performance of the DUT.

Fluid volume and, if appropriate, catheter size and length, shall be sufficient to maintain operating mode [see 27.102 a)] for the duration of each test.

The DUT shall consist of the pump gear and any other implantable part necessary for it to achieve its intended function.

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.

It is preferable to verify the operation of a function during the test, and this should be attempted. If this is not possible then verification (of performance during the test) may be performed ex post facto.

e) Implantable infusion pumps 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 infusion pumps without an electrical function

For infusion pumps without an electrical function (e.g. a pressure activated constant flow pump that does not rely on electricity for part of its function) the tests in 27.104, 27.105 and 27.106 do not apply.

27.103 Protection from static magnetic fields

The assessment of the implantable infusion pump 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 an imaginary Y and Z axis. 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 pump'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 catheter will need to be placed in a position that facilitates monitoring of the fluid delivery during the test (see 27.102). Any ancillary equipment that is needed to operate the pump or monitor its output during the test shall, as much as possible, be selected and located to minimize disruption of the uniform field.

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

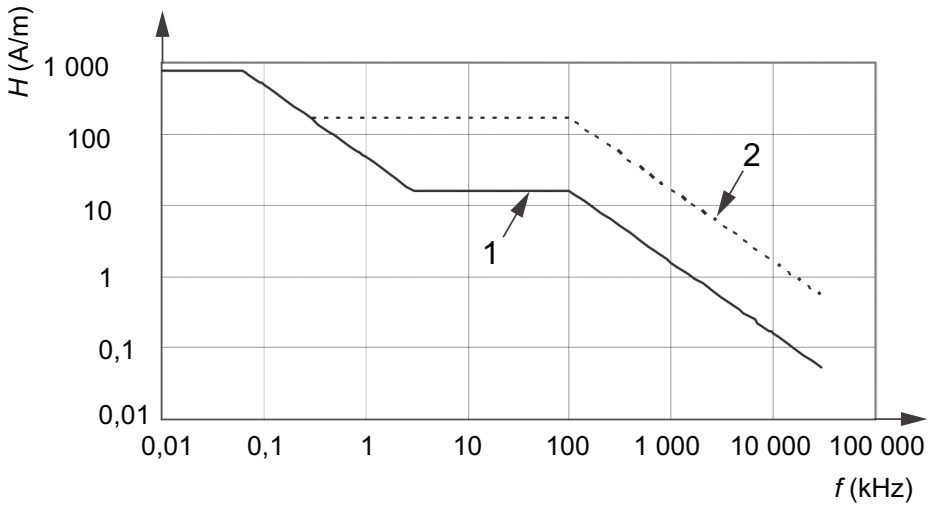
Evaluation of test results: Performance criterion A (1 mT) and performance criterion B (50 mT), as stated in 27.102 b), shall apply.

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

The assessment of the implantable infusion pump 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 102 (values are A/m rms). Test levels vary depending on frequency and performance criteria [see 27.102 b)]. The solid line in the figure 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 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 102 — 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 set-up: 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 an imaginary Y and Z axis. 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 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.

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 pump'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 catheter will need to be placed in a position that facilitates monitoring of the fluid delivery during the test (see 27.102). Any ancillary equipment that is needed to operate the pump or monitor its output during the test shall, as much as possible, be selected and located to minimize disruption of the uniform field.

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 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 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
1,0	2,0	3,0	4,0	5,0	6,0	7,0	8,0	9,0
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 125 Hz, 20 % duty cycle. (The sinusoidal carrier will have an on-time of 1,6 mS and an off-time of 6,4 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 (125 Hz, 20 % 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 set-up.

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 to 450 MHz

The assessment of the implantable infusion pump 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 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). The catheter will need to be placed in a position that facilitates monitoring of the fluid delivery during the test (see 27.102). Any ancillary equipment that is needed to operate the pump or monitor its output during the test shall, as much as possible, be selected and located to minimize disruption of the uniform field.

Test procedures [8]: The test shall be performed with the generating antenna facing the front face of the pump and one edge of the pump. In addition, the polarization of the generated field shall also be accounted for. For example, each side and edge of the DUT chosen to face the antenna shall also be exposed to a vertically and horizontally polarized field. In a typical anechoic chamber with a polarized antenna, this will amount to four scans of the DUT. If a GTEM is used it is sufficient to use three orthogonal orientations of the DUT.

For the test level of 16 V/m RMS, the frequency range of the applied test signals, from 30 MHz to 450 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, step sizes shall be no larger than 5 % of the previous frequency and 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. Test signals shall be 80 % amplitude modulated with a 2 Hz sinewave. Figure 1 of IEC 61000-4-3:2008 provides a definition of the test signal level and waveshapes.

The test level of 140 V/m RMS, is applied at specific frequency steps of 30 MHz, 50 MHz, 75 MHz, 150 MHz, and 450 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. The waveshape of the unmodulated signal is CW sinusoidal as shown in Figure 1a) of IEC 61000-4-3:2002. Test signals shall be pulse modulated at a rate of 2 Hz, 20 % duty cycle. (The sinusoidal carrier will have an on-time of 100 ms and an off-time of 400 ms every modulation cycle.)

Evaluation of test results [9]: Performance criteria A (16 V/m) and performance criteria B (140 V/m), as stated in 27.102 b), shall apply.

27.106 Protection from electromagnetic fields in the range 450 MHz to 3 GHz

The assessment of the implantable infusion pump for the range of frequencies from 450 MHz to 3 GHz is made by exposure to radiated electromagnetic fields using test methods and equipment specified by ANSI/AAMI PC69. ANSI/AAMI PC69 was intended to be written for implantable cardiac devices; parts of the test setup and procedure don't apply and have been modified.

— Test: General test conditions are described in 27.102. The requirements of Clause 6 of ANSI/AAMI PC69:2000 apply except for the changes listed below (numbers in square brackets refer to subclause numbers of ANSI/AAMI PC69). Requirements related to signal injection and parameter programming, as used in ANSI/AAMI PC69, are not applicable.

Sample size [6.2]: sample size is not applicable.

Test setup [6.3]: position the pump so that it is approximately centred at the intersection of the X and Y axes as shown in Figure B.1 of ANSI/AAMI PC69:2000. Keep the pump in the same position for all tests. The catheter may be placed in any orientation that best facilitates the monitoring of the fluid delivery during the test (see 27.102).

Test procedure [6.4]: perform the tests as required for X axis testing [6.4.1.1]. The exposure duration shall be long enough for the DUT to adequately respond to the test signal, but not less than 15 s. Repeat with the antenna elements parallel to the Y axis. Repeat X axis and Y axis testing for all frequencies listed in [6.3.4.2] using the appropriate dipole antenna.

Optional characterization testing [6.4.2]: the optional, higher power levels may be tested at the manufacturer's discretion.

Performance criteria [6.5]: performance criterion A, as stated in 27.102 b), shall apply. Performance criteria for optional characterization testing [6.4.2] shall be determined by the manufacturer.

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.

28.8

Addition:

Specific additional information shall be provided for the following components:

a) Pump gear

- mass (in grams);
- principal dimensions (in millimetres);
- reservoir volume (in millilitres);
- residual volume (in millilitres);
- internal volume (if applicable);
- puncture life of septum;
- available infusion rates;
- maximum and minimum fluid output (in millilitres per applicable unit of time),

b) Catheter

- length (in centimetres);
- volume per unit length.

28.10

Addition:

The instructions for use shall also include the following:

- instructions regarding reservoir refill procedures;
- a list of alarms and their operating conditions;
- a statement that under certain circumstances the specified accuracy and repeatability might not be maintained.

28.12

Addition:

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

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 implantable infusion pump is functioning properly.

Compliance shall be checked by inspection.

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

Compliance shall be checked by inspection.

28.103 The accompanying documentation for implantable parts of an implantable infusion pump 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	Clauses of ISO 14708-1	Clauses of ISO 14708-4 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** Implantable infusion pump characteristics. **6.102** Septum puncture test.
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. **6.102** Septum puncture test. **19.101** The projected service life shall be determined for a range of infusion rates.

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1	Clauses of ISO 14708-4 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, flammability;	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 come 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. **14.101** Requires the manufacturer to stipulate the stability interval for medicinal substances needing periodic replenishment.

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1	Clauses of ISO 14708-4 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. **6.102** Septum puncture test.
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, preservation, 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	—
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	—

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1	Clauses of ISO 14708-4 and aspects covered
4.3 Construction and environmental properties		
4.3.1 If the implant is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performances of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.	9.9 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. **28.103** 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 which 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. **19.101** The projected service life shall be determined for a range of infusion rates.

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1	Clauses of ISO 14708-4 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	Retained.
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	Retained.
4.4.1.1 The measurements, monitoring and display scale should be designed in accordance with ergonomic principles, taking into account the intended purpose of the implant.	5	Retained.
4.4.1.2 If an implant or its accessories 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. Retained.
4.4.2 The measurements made by implants with a measuring function should be expressed in units conforming to the provisions of the ISO 31 series [30].	5	Retained.
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 low 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	—

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1	Clauses of ISO 14708-4 and aspects covered
4.7 Principles for implants connected to or equipped with an energy source		
4.7.1 General		
4.7.1.1 Implants incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to their intended use. In the event of risks (of the system) as determined by a risk analysis for the particular device/system, appropriate means should be adopted to eliminate or reduce as far as possible their risk.	19.3	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. **19.101** The projected service life shall be determined for a range of infusion rates.
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	Amendment. Retained.
4.7.1.4 For implants for which the safety of the patients depends on an external power supply, the external power supply should include an alarm system to signal any power failure.	5	Retained.
4.7.1.5 External devices intended to monitor one or more clinical parameters from an implant should be equipped with appropriate alarm systems to alert the user to situations which could lead to death or severe deterioration of the patient's state of health.	5	Retained.
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	Remained. 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. Retained. 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	Retained.
4.7.3.2 Implants should be designed and manufactured in such a way as to minimize the risks arising from vibration generated by the implants, taking into account technical progress and the means available for limiting vibration, particularly at source, unless the vibrations are part of the specified performance.	5	Retained.

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1	Clauses of ISO 14708-4 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	Retained.
4.7.3.4 Terminals and connectors to electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.	5	Retained.
4.7.4 Protection against the risks posed to the patient by energy supplies or substances		
4.7.4.1 Implants should be designed and constructed in such a way that the proper functioning of the programming and control systems, including software, do not jeopardize the safety of the patient and of the user, taking into account the intended use.	19.3	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	Retained. **6.101** Implantable infusion pump characteristics.
4.7.4.3 Implants designed to administer medicinal products should incorporate suitable means of preventing and/or indicating any inadequacies in the flowrate which could pose a danger.	5	Retained. **19.3** Requires risk assessment.
4.7.4.4 Implants designed to supply energy or administer medicinal substances should be designed and constructed so that suitable means are incorporated to minimize the risk of accidental release of dangerous levels of energy or the medicinal substance.	5	Retained. **19.3** Requires risk assessment.
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	Clauses of ISO 14708-1	Clauses of ISO 14708-4 and aspects covered
4.8.3 The label should bear the following particulars:	5	Retained.
a) the name or trade name and address of the manufacturer;	9.2 11.1	Retained. Retained.
b) the details strictly necessary for the user to identify the implant and the contents of the packaging;	9.3 9.4 9.8 9.10 11.6 11.7	Retained. Addition. Retained. Retained. Retained. Retained. **11.101** Requires additional component information on sterile pack. **28.103** 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. **28.103** 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.
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. **28.102** 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	Retained. Amendment. Retained.

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1	Clauses of ISO 14708-4 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	Addition. **28.101** Requires methods for determining that the device is operating properly.
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	Retained. Retained.
l) precautions to be taken as regards exposure to, in reasonably foreseeable environmental conditions, e.g. magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	28.22	Addition.
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.

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1	Clauses of ISO 14708-4 and aspects covered
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	Addition.
p) degree of accuracy claimed for implants with a measuring function.	5	Retained.
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 14708-4	Fundamental principle of ISO/TR 14283	Clauses of ISO 14708-4	Fundamental principle of ISO/TR 14283
4	4.8.2	11.4	4.8.3 k)
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)	11.5	4.8.3 e)
		11.6	4.8.3 b), 4.8.3 d)
		11.7	4.8.3 b), 4.2.3
6.101	3.3, 4.7.4.2	11.8	4.3.1
6.102	3.3, 3.4, 4.1.5	11.9	4.2.3
7.1	4.2.3	11.10	4.8.3 g)
7.2	3.5, 4.2.3	11.101	4.8.3 b)
8.1	3.1	12.1	4.2.3
8.2	4.8.5	12.2	4.2.3
8.101	3.5	12.3	3.5
8.102	3.5	13.1	4.8.5
9.1	4.5.3	13.2	4.8.5
9.2	4.8.3 a)	13.3	4.7.1.3
9.3	4.8.3 b), 4.8.3 d)	13.4	4.4.1.2
9.4	4.8.3 b)	14.1	4.2.1, 4.2.3, 4.2.4, 4.2.5
9.5	4.8.3 c)	14.2	4.1.2, 4.2.5
9.6	4.8.3 k)	14.3	4.1.1 a), 4.1.1 b), 4.1.2
9.7	4.8.3 e)	14.4	4.1.4
9.8	4.8.3 b)	14.101	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
10.1	3.5, 4.2.3	16.3	4.7.2.2
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)
11.3	4.8.3 c)		

Clauses of ISO 14708-4	Fundamental principle of ISO/TR 14283	Clauses of ISO 14708-4	Fundamental principle of ISO/TR 14283
19.2	3.4, 4.3.2 d), 4.7.1.2	28.2	4.5.3
19.3	3.4, 3.6, 4.1.7, 4.7.1.1, 4.7.4.1, 4.7.4.3, 4.7.4.4	28.3	4.8.6 a) [4.8.3 b)]
		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
19.101	3.4, 4.3.2 d), 4.7.1.2	28.7	4.8.6 m)
20.1	4.3.2 c)	28.8	4.8.6 b), 4.8.6 o)
20.2	4.3.2 c)	28.9	4.8.6 c)
21	4.3.2 c)	28.10	4.8.6 d)
22	4.3.2 c)	28.11	4.8.6 e)
23.1	3.4, 4.3.2 b)	28.12	4.3.2 c), 4.8.6 f)
23.2	3.4, 4.3.2 b)	28.13	4.3.2 c)
23.3	3.4	28.14	4.3.2 c)
23.4	3.4	28.15	4.3.2 c)
23.5	3.4	28.16	4.8.6 a) [4.8.3 c)]
23.6	3.4, 4.3.1	28.17	4.8.6 g), 4.8.6 h)
24	4.3.2 b)	28.18	4.8.6 a) [4.8.3 f)]
25	4.3.2 b)	28.19	4.8.6 k)
26.1	3.4, 4.7.2.2	28.20	4.8.6 k)
26.2	3.5, 4.3.2 b)	28.21	4.8.6 a) [4.8.3 h)]
27.101	4.3.2 b)	28.22	4.8.6 l)
27.102	4.3.2 b)	28.23	3.4
27.103	4.3.2 b)	28.24	4.8.6 n)
27.104	4.3.2 b)	28.101	4.8.6 d)
27.105	4.3.2 b)	28.102	4.8.3 k)
27.106	4.3.2 b)	28.103	4.3.2 b), 4.8.3 b), 4.8.3 d)
28.1	4.8.6 a) [4.8.3 a)]		
NOTE Numbers in brackets indicate indirect relevance to the quoted subclause.			

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 corresponding 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 systems are included in the scope because of the customary practice for a trial period of infusion prior to the decision to implant. It is felt that the trial system needs to have the same requirements for safety as the actual implantable infusion device. External infusion pumps that are used for other purposes and that cannot be considered as accessories to an implantable infusion pump, are excluded from the scope of this part of ISO 14708.

6.101 This subclause clarifies the relationship between the manufacturer's stated specifications and characteristics and the projected service life.

Infusion accuracy is a primary safety factor and it is a well-known characteristic of some implantable pumps that accuracy is somewhat related to reservoir volume. The information required is important for the physician to determine the proper delivery rate and device settings.

Other ISO standards (e.g. ISO 11631 [9]) define accuracy and repeatability which are adopted herein for consistency. Whereas repeatability can be a measurable quantity stated numerically (refers to dataset itself, not to a comparison between the data and true value), actual accuracy, stated against a “true” value, cannot be known. Measurement uncertainty can be stated but is not required in this part of ISO 14708 because the term is not widely known outside of statistical and engineering practice and might lead to confusion. The term "accuracy", on the other hand, is more readily recognised (although perhaps normally misinterpreted) and is useful for the purposes of this part of ISO 14708. However, it is very important for the manufacturer to state exactly how it was computed.

The procedure detail for determining delivery accuracy is predicated on the test set-up being validated for the measurements required. Due to the small delivery volumes required for measurement, errors within the test set-up and pump preparation can be significant if the procedures are not fully validated. It is therefore necessary to examine the manufacturer’s validation procedure of the test set-up and test methods used to establish the delivery accuracy of an implantable infusion pump. Media, such as distilled water, may be used for testing as long as equivalency to actual intended drug use is shown.

It is necessary for the manufacturer to establish appropriate life tests to ensure reliability of the device over the projected service life. These tests may utilize accelerated testing for pump activations and reservoir fills to establish the expected performance over time. These tests may be conducted on samples representative of the final device as long as there is appropriate justification that the parameters being evaluated are not affected by the use of these samples.

6.102 Access port septum, such as those used for refilling the fluid reservoir or allowing direct access to the delivery catheter, are critical components, as failure of the septum would cause the reservoir to empty or fluid to leak into the tissues surrounding the implanted pump. The septum puncture test is intended to provide a standardized method of providing data in order to evaluate septum reliability.

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 60601-1:2005. 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 might be different depending on the intended infusion pump application. The burden of proof is upon the manufacturer to demonstrate via a risk analysis, design analysis, test studies, or other appropriate means.

Since the fluid pathway is in indirect contact with body fluids, via the delivery of a medicinal substance, it too is included in the intent of this subclause.

14.3 Special attention should be given to the selection of materials used in the manufacture of the device. As a prerequisite to biological safety evaluation of the implantable infusion pumps the materials of manufacture should be evaluated for residual monomers, additives, process contaminants, leachables and degradation products.

Fluid path materials might have a chance of indirect contact with body fluids; as a precaution these materials also need to be assessed for biocompatibility.

14.4 It is recognised that medicinal substances typically used with an implantable infusion pump have gone through extensive development and testing prior to being generally available for use.

14.101 Generally recognised procedures to establish the stability of a medicinal substance within the implantable infusion pump should be utilized. It is the responsibility of the manufacturer to develop stability indicating assays or provide the necessary documentation to support the stability interval established in the event that testing was conducted by a third party.

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.

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 may be considered. See reference [10].

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. The original requirement in ISO 14708-1 refers to a pressure reservoir as a source of power; not to be confused with a fluid reservoir as in the case of an implantable infusion pump.

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 14155-1 or ISO 14155-2.

19.5 The implantable pump reservoir and catheter contain materials which could affect the stability and efficacy of the medicinal substance. All device materials in the fluid path of the implantable infusion pump which are exposed to a medicinal substance need to be characterized for their suitability in the design. The characterization should consider the potential for changes in physical characteristics, of the materials and the potential for material degradation from exposure to a medicinal substance over time. Any leachable or degradation product identified should be assessed for their effect on the medicinal substance. And, when present, leachables or degradation products should be quantified and the expected total daily dose that can be infused should be evaluated toxicologically, either through testing or a literature-based justification. It should also be noted if there is a decrease in leachates or degradation products over time.

19.101 It is important for the user to be able to make a determination of projected service life based on more than a typical infusion rate, as rates can have a potentially significant impact.

21 Implantable infusion pumps are anticipated to be unaffected by exposure to high-power electrical fields applied directly to the patient. However, the burden remains on the manufacturer to demonstrate that the requirement of this clause is met. Specific requirements might be specified in future editions of this part of ISO 14708.

22 It is recognized 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 third edition (2005) 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 infusion pump, 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. 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 level. Consequently, there are also two defined sets of performance criterion (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 (also, note that the same criterion is applied to both sets of test levels).

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 infusion pump would work completely as intended, with no loss of function and without any unintentional responses.

The higher test levels represent environments that the general public might be exposed to occasionally, are generally more avoidable, and when exposure does occur, it is 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 pump can be allowed so its clinical benefit can be enjoyed by the patient. This allowance shall depend on the judgment of the manufacturer and regulatory personnel. Extraordinary device behaviour is not expected to occur typically, and the 10x 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.

27.103 The lower level of 1 mT (10 Gs) was chosen because it represents a commonly encountered field strength. Historically, many implantable devices had magnetically activated reed switches internal to the sealed enclosure which 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 Gs), 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 in 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 sufficient time to get a response, provided an appropriate delivery rate has been selected for the test duration.

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 infusion pumps.

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

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

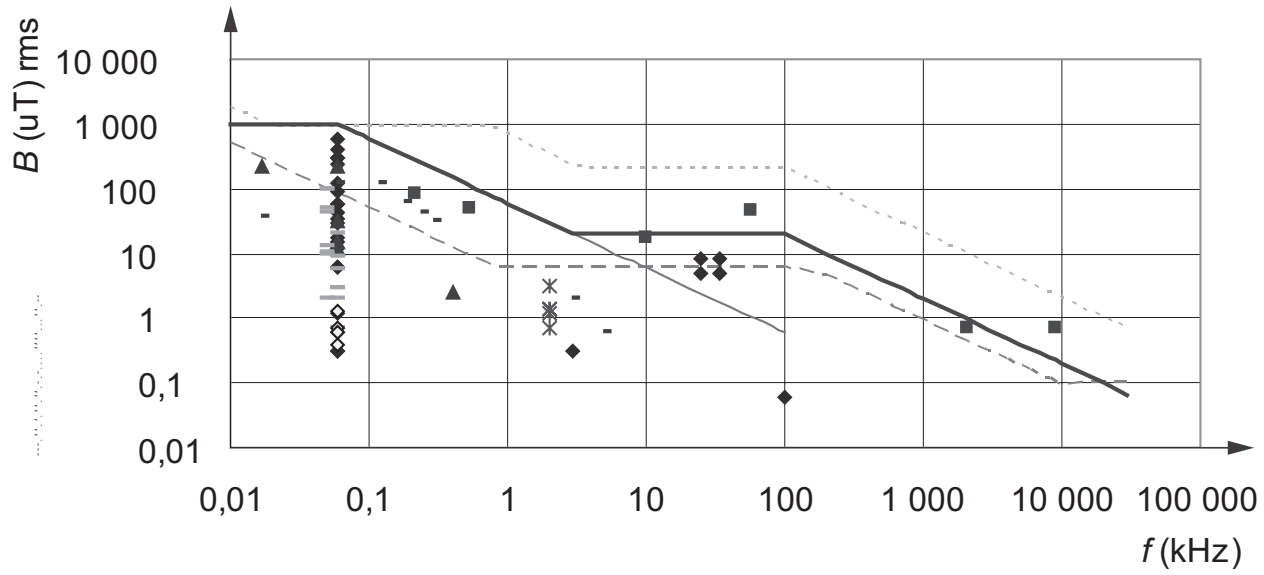
a tissue dielectric of 80, and an average maximum dimension of 6 cm (typical for an implantable infusion pump), frequencies less than about 27 MHz should have insignificant coupling into pump circuitry. Above 27 MHz the electric field attenuation of the titanium enclosure is greater than 35 dB, except 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 infusion pumps.

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 [11] to [19], along with ICNIRP general public reference levels [20], IEEE C95.1 [21] and IEEE C95.6 [22] uncontrolled levels, MIL 461E RS101 levels [23], IEC 61000-2-5:1995 [24] data (Table 6, disturbance degree 4), and A-line test levels (this document).

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) in accordance with IEC 62226-2-1 [25]. 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 does not represent a particular general public environment, *per se*, but corresponds to IEEE C95.1 recommendations for maximum permissible human exposure. The safety margin provided by the B-line is 10× over the A-line ⩾ 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 and 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 implantable infusion pump in normal use. A conductivity of 0,27 S/m is a compromise for various body tissues and for test set-up consistency over the entire test frequency range among all tests.

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 $\geqslant$ 3 kHz to simulate those kinds of signal present in the environment and to place additional stress on the DUT. Below 3 kHz the B-line is sinusoidal because pulsed fields are not prevalent in practice and the modulation rate of 125 Hz is too close to the starting test frequency of 300 Hz. The modulation rate was chosen to not interfere with power frequencies, to be near to the physiological passband, 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.

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 can 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 those 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 in order to protect the general public.

IEEE C95.1 [21], over the frequency range of 30 MHz to 450 MHz, sets electric field exposure limits to 27,5 V/m to 33,6 V/m (uncontrolled) and to 61,4 V/m to 75 V/m (controlled). ICNIRP [20], 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 [26] limits for radiated emissions from ISM equipment (industrial, scientific, and medical) vary by group, class and distance but can be summarised as being approximately 60 dB µV/m (1 000 µV/m), worst case, at 30 m, from 30 MHz to 450 MHz. CISPR 14 [27] limits for household appliances, electric tools and similar apparatus are lower. CISPR 22 [28] limits for ITE (information technology equipment) are not more than 37 dB µV/m (71 µV/m). FCC [29] 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.101 Table 1 of IEC 61000-2-3:1992 [16].

Table CC.101 — Examples of field strengths from authorized transmitters

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

IEC 61000-2-5:1995 [24], 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.102.

Table CC.102 — Electric field strength distances for encountering 10 V/m

AM broadcasting **150 kHz – 30 MHz** **Power = 500 kW**	**Walkie-talkie** **27 – 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).

Amplitude modulation is used to be consistent with the requirements of IEC 60601-1-2 for non-implantable parts. According to rationale in IEC 61000-4-3 amplitude modulation has advantages over other methods. The modulation rate is 2 Hz to be close to the physiological passband.

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 with 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.

A saline bath is used to simulate the *in vivo* environment of the implantable infusion pump 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.

The use of IEC 61000-4-3 as a test procedure is consistent with the requirements for non-implantable parts and is a well recognised 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.

A recently published EMC standard, ANSI/AAMI 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 ANSI/AAMI PC69 due to the equivalencies between implantable pacemakers and implantable infusion pumps 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 ANSI/AAMI PC69 adequately replaces 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. TV and radio).

ANSI/AAMI 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 handheld 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.

28.22 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.

28.103 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.

Bibliography

[1] ISO 780, *Packaging — Pictorial marking for handling of goods*

[2] ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

[3] European Pharmacopoeia, 3rd edition, Council of Europe, 1977

[4] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

[5] ISO 14971, *Medical devices — Application of risk management to medical devices*

[6] ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

[7] ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

[8] ISO/TR 14283:2004, *Implants for surgery — Fundamental principles*

[9] ISO 11631:1998, *Measurement of fluid flow — Methods of specifying flowmeter performance*

[10] WUST et al 1995, Int. J. Hyperthermia 11, 151 – 167

[11] Electric and magnetic fields associated with the use of electric power, NIEHS, June 2002

[12] World Health Organization (WHO) web site (http://www.who.int/peh-emf/en/)

[13] National Grid Company (Warwick, England) EMF web site (http://www.emfs.info/default.asp)

[14] *Children's exposure to magnetic fields produced by U.S. television sets used for viewing programs and playing video games*, Bioelectromagnetics 21:214 – 227 (2000), Tables 3 and 4 combined

[15] IEC/TR 61000-2-7, *Electromagnetic compatibility (EMC) — Part 2: Environment — Section 7: Low frequency magnetic fields in various environments*

[16] IEC/TR 61000-2-3:1992, *Electromagnetic compatibility (EMC) — Part 2: Environment — Section 3: Description of the environment — Radiated and non-network-frequency-related conducted phenomena*

[17] RICKLI H, et al., *Induction ovens and electromagnetic interference: What is the risk for patients with implanted pacemakers?* PACE 2002;26:1494-1497

[18] BINGGELI, et al., *Induction ovens and electromagnetic interference: What is the risk for patients with implanted cardioverter defibrillators?* J of Cardio Electrophysiol 2005;16:399-401

[19] HIROSE, et al., *Electromagnetic interference of implantable unipolar cardiac pacemakers by an induction oven*. PACE 2005;28:540-548

[20] ICNIRP Guidelines:1998, *Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz)*, Health Physics Society

[21] IEEE C95.1:1999, *IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz*

[22] IEEE C95.6:2002, *IEEE Standard for Safety Levels with Respect to Human Exposure to Electromagnetic Fields, 0-3 kHz*

[23] MIL-STD-461E:1999, *Test Specifications — Requirements for the control of electromagnetic interference characteristics of subsystems and equipment*

[24] IEC/TS 61000-2-5:1995, *Electromagnetic compatibility (EMC) — Part 2: Environment — Section 5: Classification of electromagnetic environments*

[25] IEC 62226-2-1, *Exposure to electric or magnetic fields in the low and intermediate frequency range — Methods for calculating the current density and internal electric field induced in the human body — Part 2-1: Exposure to magnetic fields — 2D models*

[26] CISPR 11:2004, *Industrial, scientific and medical (ISM) radio-frequency equipment — Electromagnetic disturbance characteristics — Limits and methods of measurement*

[27] CISPR 14-1:2005, *Electromagnetic compatibility — Requirements for household appliances, electric tools and similar apparatus — Part 1: Emission*

[28] CISPR 22:2006, *Information technology equipment — Radio disturbance characteristics — Limits and methods of measurement*

[29] FCC 47 CFR, Part 15, *Telecommunication — Radio frequency devices*

[30] ISO 31 (all parts), *Quantities and units*

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