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Implants for surgery — Active implantable medical devices —

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

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 1: Exigences générales pour la sécurité, le marquage et pour les informations à fournir par le fabricant

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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 3.

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 part of ISO 14708 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14708-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

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*

Additional parts are under discussion in TC 150.

Annexes A, B and C of this part of ISO 14708 are for information only.

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Introduction

This part of ISO 14708 specifies general requirements for active implantable medical devices, to provide basic assurance of safety for both patients and users.

To minimize the likelihood of a device being misused, this part of ISO 14708 also details comprehensive requirements for markings and for other information to be supplied as part of the documentation with any active implantable medical device.

This part of ISO 14708 is based on the fundamental principles in ISO/TR 14283, which closely parallel the essential requirements of the European Directives applicable to medical devices.

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Implants for surgery — Active implantable medical devices —

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

1 Scope

This part of ISO 14708 specifies requirements that are generally applicable to active implantable medical devices.

NOTE For particular types of active implantable medical devices, these general requirements are supplemented or modified by the requirements of particular standards which form additional parts of ISO 14708. Special care is required in applying this part of ISO 14708 to active implantable medical devices where no particular standard exists.

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

This part of ISO 14708 is applicable not only to active implantable medical devices that are electrically powered, but also to those powered by other energy sources (for example gas pressure or springs).

This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the devices (see 3.3).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14708. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14708 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times*.

ISO 11607:1997, *Packaging for terminally sterilized medical devices.*

ISO 14155:1996, *Clinical investigation of medical devices*.

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*.

IEC 60068-2-14:1986, *Environmental testing — Part 2: Tests. Test N: Change of temperature*.

IEC 60068-2-32:1990, *Environmental testing — Part 2: Tests. Test Ed: Free fall (Procedure 1)*.

IEC 60068-2-47:1999, *Environmental testing — Part 2-47: Test methods — Mounting of components, equipment and other articles for vibration, impact and similar dynamic tests.*

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IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety. Amendment 1:1991 and Amendment 2:1995.*

IEC 60601-1-1:1992, *Medical electrical equipment — Part 1: General requirements for safety — 1. Collateral standard: Safety requirements for medical electrical systems.*

IEC 60601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety — 2. Collateral standard: Electromagnetic compatibility – Requirements and tests.*

IEC 60601-1-4:1996, *Medical electrical equipment — Part 1: General requirements for safety — 4. Collateral standard: Programmable electrical medical systems.*

IEC 60601-2-27:1994, *Medical electrical equipment — Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment*.

IEC 61000-4-2:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 2: Electrostatic discharge immunity test. Basic EMC Publication.*

3 Terms and definitions

For the purposes of this part of ISO 14708, the following terms and definitions apply.

3.1
medical device
article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the

— diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means but which may be assisted in its function by such means

3.2
active medical device
medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.3
active implantable medical device
active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain in place after the procedure

NOTE For purposes of this part of ISO 14708, an active implantable medical device may be a single active medical device, 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 may be required to be partially or totally implanted, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

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3.4
catheter
flexible tube allowing access to a point within the body at its distal end through a lumen, often for delivering a substance

NOTE A catheter may be combined with a lead.

3.5
lead
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length

NOTE A lead may be combined with a catheter.

3.6
non-reusable pack
single-use pack designed to allow the contents to be sterilized and to maintain that sterility

3.7
sterile pack
non-reusable pack in which the contents have been sterilized

3.8
sales packaging
packaging that protects and identifies the active implantable medical device during storage and handling by the purchaser

NOTE The sales packaging may be enclosed in further packaging, for example a “shipping package”, for delivery.

3.9
marking
inscription on a device, package or label

3.10
label
area bearing a marking, affixed to a device or package but not an integral part of the device or package

3.11
radioactive substance
any substance that contains one or more nuclides whose activity or concentration cannot be disregarded as far as radiation protection is concerned

3.12
sealed source
source containing radioactive substances which is firmly incorporated in solid and effectively inactive materials or is sealed in an inactive container of sufficient strength to prevent, under normal conditions of use, any dispersion of radioactive substances

3.13
medicinal substance
substance which, when used separately, is intended for the treatment or prevention of disease in human beings, or which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings

3.14
harm
physical injury or damage to health or property

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3.15
hazard
potential source of harm

3.16
unacceptable hazard
hazard whose probability of causing harm is greater than a stated value determined by considering the severity of the harm

3.17
hazard control
design feature of an active implantable medical device intended to ensure that it does not cause an unacceptable hazard

3.18
portable equipment
equipment intended to be moved from one location to another while being used or between periods of use while being carried by one or more persons

3.19
hand-held equipment
equipment intended to be supported by the hand during normal use

4 Symbols and abbreviated terms

When appropriate, symbols, abbreviated terms and identification colour may be used in the markings and accompanying documents of an active implantable medical device. Symbols, abbreviated terms and identification colour shall conform to published International Standards and conventions (e.g. ISO 15223). Where no standard exists, the symbols, abbreviated terms and identification colour shall be described in the accompanying documentation.

Compliance shall be checked by inspection.

NOTE Symbols for use with particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

5 General requirements for non-implantable parts

The non-implantable part of an active implantable medical device which is connected to or equipped with a power source shall comply with the requirements of IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2 and IEC 60601-1-4, unless a requirement in these standards is superseded by a requirement in this part of ISO 14708.

NOTE 1 IEC 60601-1 is applied here as it would be for an electromedical device for which there is no particular standard. Specific sections of IEC 60601-1 are cited in the requirements of this part of ISO 14708 where they address a fundamental principle in ISO/TR 14283.

NOTE 2 Requirements for non-implantable parts of particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

6 Requirements for particular active implantable medical devices

Requirements for particular active implantable medical devices are not detailed in this part of ISO 14708, but they may be specified in subsequent parts of ISO 14708.

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7 General arrangement of the packaging

7.1 Implantable parts of active implantable medical devices shall be supplied in a non-reusable pack (see 14.1).

The non-reusable pack should be designed to be sealed yet allow its contents to be sterilized by the manufacturer.

Compliance shall be checked by inspection.

7.2 The non-reusable pack shall be enclosed in the sales packaging.

Compliance shall be checked by inspection.

8 General markings for active implantable medical devices

NOTE See also 4.

8.1 Any warning notices required by this part of ISO 14708 shall be prominently displayed.

Compliance shall be checked by inspection.

8.2 Implanted parts of devices and components of those parts shall be identified in such a way as to allow any necessary measure to be taken following the discovery of a possible hazard in connection with any implanted part.

Compliance shall be checked by review of the manufacturer’s explanation of the relationship between the identity of the active implantable medical device and the identities of its component parts.

9 Markings on the sales packaging

9.1 If the sales packaging contains any radioactive substance**,** it shall have markings that state the type and activity of the radioactive substance**.**

Compliance shall be checked by inspection.

9.2 The sales packaging shall bear the manufacturer's name and address, including at least the city and the country.

Compliance shall be checked by inspection.

9.3 The sales packaging shall bear a description of the device (e.g. cardiac pulse generator), the model designation of the device and, if applicable, the batch number or the serial number of the device.

Compliance shall be checked by inspection.

9.4 The sales packaging of implantable parts of an active implantable medical device shall bear any additional information and relevant characteristics, as necessary, to identify the device.

Compliance shall be checked by inspection.

9.5 The sales packaging of implantable parts of an active implantable medical device shall bear a statement that the contents of the package have been sterilized.

Compliance shall be checked by inspection.

9.6 The sales packaging of implantable parts of an active implantable medical device shall bear the year and month of manufacture, expressed in numerals as specified by ISO 8601.

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Compliance shall be checked by inspection.

9.7 The sales packaging of implantable parts of an active implantable medical device shall bear the “use before” date, expressed as year and month.

Compliance shall be checked by inspection.

9.8 The markings on the sales packaging of implantable parts of an active implantable medical device shall identify the accessories within the packaging or, if there is insufficient space on the sales packaging, the contents shall be identified within the sales packaging.

Compliance shall be checked by inspection.

9.9 If the intended use of an implantable part of an active implantable medical device enclosed within the sales packaging requires that it be connected to another device or accessory not included in the pack, the sales packaging shall identify the connector types or configurations required.

Compliance shall be checked by inspection.

9.10 The sales packaging of implantable parts of an active implantable medical device shall carry a clear description of the intended use of the device, if this is not obvious from the device description as required by 9.3 and 9.4.

Compliance shall be checked by inspection.

9.11 The sales packaging shall bear information about any exceptional environmental or handling constraints (for example, protection from impact, vibration, temperature, pressure or humidity) necessary to allow the devices to be correctly handled and stored (see clause 10).

Compliance shall be checked by inspection.

9.12 If the device is intended for a special purpose, the sales package shall bear an indication of the special purpose (e.g., “custom-made device” or “exclusively for clinical investigations”).

Compliance shall be checked by inspection.

10 Construction of the sales packaging

10.1 The sales packaging of an active implantable medical device shall be constructed to protect the device and to withstand the hazards of dropping (shock), stacking (compression), vibration and temperature that occur during storage or handling as specified by the manufacturer.

Compliance shall be confirmed by inspection and review of records provided by the manufacturer.

10.2 The sales packaging of an active implantable medical device shall be sufficiently protected against the effects of humidity during storage or handling to prevent visible deterioration of the packaging, markings, labels or accompanying documentation.

— Test: Place the sales packaging in a test chamber for two days. The temperature of the test chamber shall be stabilized at 30 °C ± 2 °C. The relative humidity in the test chamber shall be 93 % ± 3 %.

Compliance shall be confirmed by examination of the manufacturer’s records.

10.3 The markings on the sales packaging of an active implantable medical device shall be indelible.

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— Test: Place the package so that the markings under test are uppermost and in a horizontal plane. Dispense 10 ml of water onto the centre of the area. After 1 min, wipe the markings clear of surface water using a wet, soft cloth.

Compliance shall be confirmed if, after performing the procedure above, all markings remain clearly legible. If the markings are on a label, the adhesive fixing the label shall not have loosened and the label shall not have become curled at any edge.

10.4 The sales packaging shall ensure association between the active implantable medical device and the accompanying documentary information that defines the purposes and functions of the device and the conditions qualified and specified for its implantation.

Compliance shall be checked by inspection.

11 Markings on the sterile pack

11.1 The sterile pack shall bear the name or trade name of the manufacturer, and the address (city and country) of manufacture.

Compliance shall be checked by inspection.

11.2 The sterile pack shall bear a statement that the package and its contents have been sterilized and indicate the method of sterilization used (see ISO 15223 for recommended symbols).

Compliance shall be checked by inspection.

11.3 The symbol

in accordance with ISO 15223 shall be prominently displayed on the sterile pack.

Compliance shall be checked by inspection.

11.4 The sterile pack shall bear the year and month when the packaged device was manufactured, as required by 9.6.

Compliance shall be checked by inspection.

11.5 The sterile pack shall bear the “use before” date, as required by 9.7.

Compliance shall be checked by inspection.

11.6 The sterile pack shall bear a description of the device, as required by 9.3.

Compliance shall be checked by inspection.

11.7 The markings on the sterile pack shall identify the contents, unless the sterile pack is transparent and the contents are visible.

Compliance shall be checked by inspection.

11.8 If the intended use of a device enclosed in a sterile pack requires that it be connected to other devices or accessories not included in the sterile pack, the sterile pack shall identify the connector types or configurations, as required by 9.9.

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Compliance shall be checked by inspection.

11.9 The sterile pack shall bear instructions for opening the package.

Compliance shall be checked by inspection.

11.10 If the device is intended for a special purpose, the sterile pack shall bear an indication of the special purpose (e.g. “custom-made device” or “exclusively for clinical investigations”).

Compliance shall be checked by inspection.

12 Construction of the non-reusable pack

12.1 The non-reusable pack shall comply with ISO 11607.

Compliance shall be checked by inspection and by review of records provided by the manufacturer.

12.2 The non-reusable pack shall be so designed that once it has been opened, this is readily apparent and, if it has been opened and resealed, it shall remain thereafter apparent that it has been previously opened.

Compliance shall be checked by inspection.

12.3 The markings on the non-reusable pack shall be indelible.

Compliance shall be checked as described in 10.3.

13 Markings on the active implantable medical device

13.1 As far as practicable and appropriate, the active implantable medical device shall bear the name or trademark of the manufacturer, the model designation of the device and, if applicable, the batch number or serial number of the device.

Compliance shall be checked by inspection, and by a wet rub test.

— Wet rub test: Rub the markings by hand, without undue pressure, first for 15^{+5}_{0} s with a cloth rag soaked in methylated spirit at ambient temperature and then for 15^{+5}_{0} s with a cloth rag soaked in water at ambient temperature, after which the markings shall remain clearly legible.

13.2 If the individual implantable units of a particular model of active implantable medical device incorporate different models of power source, it shall be possible to group the devices by power source, for example by reference to the accompanying documents or by use of a designating suffix.

Compliance shall be checked by inspection.

13.3 Implantable parts of an active implantable medical device with an internal power source shall incorporate a code by which the device and the manufacturer can be unequivocally identified (particularly with regard to the model of device). It shall be possible to read this code, when necessary, without knowledge of the make or model of device and without the need for a surgical operation.

Compliance shall be checked by a procedure defined by the manufacturer in the instructions for use (see 28.6).

13.4 Any visual indicators carried on an active implantable medical device shall be understandable with reference to the accompanying documentation, taking account of the training and knowledge of the likely user.

Compliance shall be checked by inspection.

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

14.1 Any implantable part of an active implantable medical device or other parts enclosed in the non-reusable pack (see 7.1) and not contained within an implantable, hermetically-sealed, impermeable container shall be sterile.

Compliance shall be confirmed if the process validation records provided by the manufacturer establish that the non-reusable pack has been sterilized by a validated process (for example, according to ISO 11134 or ISO 11135).

14.2 Any part of the active implantable medical device, intended in normal use to be in contact with body fluids, shall cause no unacceptable release of particulate matter when the device is used as intended by the manufacturer.

— Test: Remove the active implantable medical device aseptically from the non-reusable pack. Immerse the implantable part in a bath of 9 g/l saline solution, suitable for injection, in a neutral glass container. The volume of saline shall be approximately 10 to 20 times the volume of the specimen under test. Cover the container with a glass lid and maintain aseptically at 37 °C ± 2 °C for between 8 h and 18 h, agitating the bath throughout the period. Prepare a reference bath of similar volume from the same batch of saline, maintain and agitate in a similar way to the specimen. Compare a sample of liquid from the specimen bath with one from the reference bath using a suitable apparatus for automatic measurement of particle size that operates on the electrical zone-sensing principle (e.g. the Coulter principle), using a sampling procedure recommended by the manufacturer.

Compliance shall be confirmed if the excess average count of particles from the specimen compared to the reference sample does not exceed 1 000 per ml for particles greater than 2,0 μm and does not exceed 100 per ml for particles greater than 5,0 μm.

14.3 Parts of the device intended to penetrate the surface of the body shall be biocompatible.

Compliance shall be confirmed if records provided by the manufacturer establish that the biocompatibility of the materials selected has been demonstrated

a) by analogy with published data;

or

b) by the selection of materials already shown to be biocompatible by proven clinical use in a similar application;

or

c) by experience with similar devices already on the market, together with evidence of traceability to the materials used in those devices;

or

d) by compliance with published procedures for biological evaluation of medical devices.

14.4 If the active implantable medical device incorporates a medicinal substance and either the substance or a derivative of the substance is intended to be released into the patient (although the substance is bound as an integral part of the active implantable medical device), that substance shall be both safe and beneficial to a declared function of the active implantable medical device.

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.

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15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device

15.1 External surfaces of non-implantable parts of an active implantable medical device shall comply with clause 23 of IEC 60601–1:1988.

Compliance shall be checked by inspection.

15.2 Implantable parts of an active implantable medical device shall have no surface features, such as sharp corners or edges, that could cause excessive reaction or inflammation beyond that caused by the implanting procedure, or rough surfaces which are not required for the correct functioning of the device.

Compliance shall be checked by inspection.

16 Protection from harm to the patient caused by electricity

16.1 External parts of an active implantable medical device shall comply with clause 19 of IEC 60601–1:1988.

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

16.2 Except for its intended function, implantable parts of an active implantable medical device containing a power source shall be electrically neutral when in contact with the body. No leakage current (direct current) of more than 1 µA shall be sustained in any of the current pathways when the device is in use.

Compliance shall be confirmed by inspection of test procedures and results provided by the manufacturer.

16.3 Insulating parts of implanted leads or of catheters that incorporate electrical conductors and are subject to electrical potential differences of greater than 10 V shall withstand a dielectric strength test in which the applied voltage shall be not less than twice the peak voltage experienced by the part.

— Test: Precondition the insulating parts of the implantable leads or catheters that incorporate electrical conductors by total immersion in 9 g/l saline solution at 37 °C ± 5 °C for a minimum of 10 days. After rinsing the part with distilled water and wiping free of surface water, test the part for its dielectric strength by the method specified by the manufacturer.

Compliance shall be confirmed by inspection of test procedures and results provided by the manufacturer.

17 Protection from harm to the patient caused by heat

No outer surface of an implantable part of the active implantable medical device shall be greater than 2 °C above the normal surrounding body temperature of 37 °C when implanted, and when the active implantable medical device is in normal operation or in any single-fault condition (see 19.3).

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 Requirements for protection from harm to the patient caused by heat for particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

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

18.1 If an active implantable medical device contains any radioactive substance, it shall be in the form of a sealed source.

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

18.2 If an active implantable medical device contains any radioactive substances, consequent exposure to ionizing radiation shall be justified by the advantages which the radioactive substances provide.

Compliance shall be confirmed by inspection of the manufacturer's calculations and data from test studies as appropriate.

18.3 If an active implantable medical device contains any radioactive substances, consequent exposure to ionizing radiation shall be kept as low as reasonably achievable.

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.

19 Protection from unintended effects caused by the device

NOTE See also 28.20.

19.1 Implantable parts of an active implantable medical device shall be designed so that gradual, long-term change in materials that might occur within the lifetime of the device shall not cause an unacceptable hazard.

— Assessment: The gradual, long-term changes in materials shall be demonstrated

a) by analogy with published data;

or

b) by the selection of materials already shown to be stable by proven clinical use in a similar application;

or

c) by experience with similar devices already on the market together with evidence of traceability to the materials used in those devices;

or

d) by compliance with published procedures for evaluation of materials for implantation.

A documented analysis of the experience with the material and its role in the device shall identify any hazards and show that unacceptable hazards have been eliminated.

Compliance shall be confirmed by review of the appropriate documentation prepared by the manufacturer.

19.2 If the implantable part of an active implantable medical device contains within it a source of power, such as a battery or a pressure reservoir, the active implantable medical device shall include an "elective replacement indicator" that gives advance warning of energy source depletion causing the "end-of-life" of the device. The manufacturer shall define the interval between the activation of this elective replacement indicator and the end-of-life of the device.

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.

19.3 An active implantable medical device 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.

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— Assessment: Identify the hazards caused by possible single-fault conditions and associated with each function of the device. For each hazard**,** assess the probability of harm by a design analysis that takes account of any hazard control and allows the probability of harm being caused by each fault condition to be evaluated. The design analysis shall be supported by test studies as appropriate.

For each hazard, the hazard controls incorporated in the device and the assessment of probability of harm shall be documented, together with the design analysis and appropriate test results.

Compliance shall be confirmed by review of the appropriate documentation prepared by the manufacturer.

19.4 Possible side effects arising from the intended use of an active implantable medical device shall not cause undue harm.

— Assessment: Identify side effects and benefits from the intended use of the device, either by reference to current medical practice and demonstrated by analogy, or by reference to clinical investigations conducted in accordance with ISO 14155.

Compliance shall be confirmed by an assessment of the manufacturer's documentation.

19.5 If the implantable part of an active implantable medical device is intended to administer medicinal products, then the device shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned.

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

NOTE See also 28.12.

20.1 The electrical function of non-implantable parts of active implantable medical devices connected to electrocardiograph electrodes shall be designed so that defibrillation of the patient will not permanently affect the device, provided that the defibrillator electrodes do not come into direct contact with the electrocardiograph electrodes.

Compliance shall be checked by inspection and by the testing as specified in 51.101 of IEC 60601-2-27:1994.

20.2 Parts of an active implantable medical device intended to be implanted in the torso shall be designed so that defibrillation of the patient will not permanently affect the device, provided that the defibrillator electrode does not come into direct contact with the implanted part.

— Test: Use a defibrillation pulse generator consisting of an RCL circuit as shown in Figure 1 with:

C = 330 µF ± 16,5 µF L = 13,3 mH ± 0,13 mH $R_L + R_G$ = 10 Ω ± 0,2Ω

where

R_L is the resistance of the inductance, in ohms;
R_G is the resistance of the defibrillation pulse generator, in ohms;
V_{test} is the output voltage, in volts.

The maximum pulse amplitude of the output voltage (V_{test}) at the output of the defibrillation pulse generator, across R_G, shall be 140 V ± 7 V.

Ensure that the inductor is not magnetically saturated during the pulse.

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Identify each conducting part, other than a metallic case, that may come into contact with body tissue. Connect the defibrillation pulse generator through a $300\,\Omega \pm 6\,\Omega$ resistor (see Figure 1) between each of the conducting parts in turn and the metallic case. If the body of the device is enclosed in a metallic case covered with an insulating material or is constructed of insulating material, immerse the body of the device in a metallic jar filled with physiological 9 g/l saline solution and make the case connection to the jar.

Test each conducting part by applying a sequence of three voltage pulses of positive polarity at 20^{+2}_{0} s intervals. Then after an interval of 60^{+2}_{0} s repeat the test with pulses of negative polarity (see Figure 2).

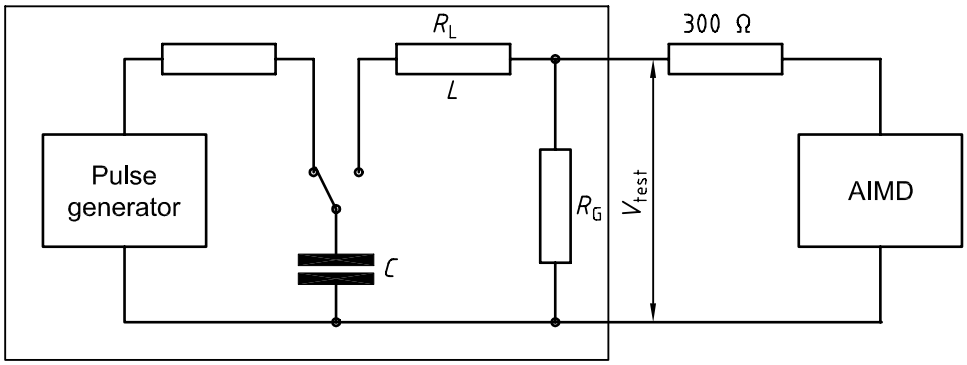

Figure 1 — *RCL* circuit for defibrillation test

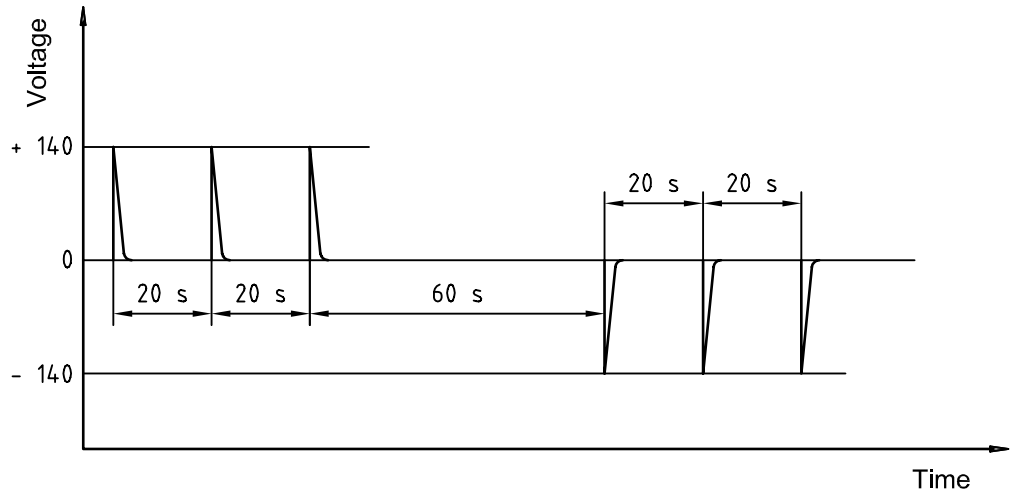

Figure 2 — Form of pulses used in defibrillation

Compliance shall be confirmed if the active implantable medical device conforms to the device specifications after performing the complete procedure above.

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21 Protection of the device from changes caused by high-power electrical fields applied directly to the patient

Implanted electrically-conductive parts (of an active implantable medical device) in contact with the body shall be constructed so that effects caused by high-power electrical treatment applied directly to the patient (for example, application of diathermy) will not damage the device, provided that the implanted parts neither lie directly in the applied current path nor lie within the part of the body being treated.

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

NOTE 1 See also 28.12 and 28.13.

NOTE 2 Requirements for protection from changes caused by high-power electrical fields for particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments

The implantable parts of an active implantable medical device shall be designed and constructed so that no irreversible change will be caused by exposure to diagnostic levels of ultrasonic energy.

— Test: Immerse the implantable parts of the active implantable medical device (other than leads or catheters) in a water bath at room temperature and subject for 1 h to ultrasonic energy of 500 $W/m^2 \pm 25$ W/m^2 when using a spatial peak, temporal average mode. The signal used shall be pulsed with a duty cycle of 50 % ± 10 %. The frequency selected shall be between 2 MHz and 5 MHz.

NOTE 1 This test is not applied to leads and catheters, as it presumed these devices will not be affected by diagnostic ultrasound.

Compliance shall be confirmed by checking that no irreversible damage is caused by the test by inspection of documentation provided by the manufacturer, supported by data from test studies as appropriate.

NOTE 2 See also 28.12, 28.14 and 28.15.

NOTE 3 Requirements for protection from changes caused by miscellaneous medical treatments for particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

23 Protection of the active implantable medical device from mechanical forces

23.1 Parts of an active implantable medical device that are either hand-held in normal use or portable and weigh not more than 10 kg, shall be constructed so that shocks caused by mishandling or dropping while in use do not damage the device.

— Test: Subject hand-held or portable parts of an active implantable medical device weighing up to 10 kg to the free-fall test in accordance with IEC 60068-2-32, under the following conditions:

a) test surface: hard wood of density not less than 630 kg/m^3 and thickness between 50 mm and 55 mm;

b) height of fall:
   i) hand-held devices: 1 m;
   ii) portable devices: 50 mm;

c) attitude in which specimen is dropped: attitude as in normal use.

Compliance shall be confirmed if the dropped part operates as stated in the manufacturer's original specification for that part when it is checked after performing the complete procedure above.

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23.2 Implantable parts or patient-carried parts of an active implantable medical device**,** other than leads or catheters, shall be constructed to withstand the mechanical forces which may occur during normal conditions of use.

— Test: Mount each implanted part or patient-carried part of an active implantable medical device in accordance with the guidance given in appendix A to IEC 60068-2-47:1999 on test equipment capable of subjecting the device to a random vibration test in accordance with IEC 60068-2-64 under the following conditions:

a) frequency range: 5 Hz to 150 Hz;

b) ASD spectrum level: 0,1 g^2/Hz;

c) duration of conditioning: 90 min equally divided between three mutually perpendicular directions;

d) reproducibility: medium.

Compliance shall be confirmed if the active implantable medical device conforms to the device specifications after performing the complete procedure above.

23.3 Implantable leads or catheters shall withstand the tensile forces that might occur during or after implantation, without fracture of any conductor or cracking of either any functional electrical insulation or of the body of the lead or catheter.

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

23.4 Implantable leads having a junction of two or more conductive components shall be designed such that the junctions are relieved from strain caused by the flexural stresses that might occur during or after implantation.

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

23.5 Implantable leads or catheters shall withstand the flexural stresses that might occur during or after implantation without fracture of any conductor or cracking either of any functional electrical insulation or of the body of the lead or catheter.

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

23.6 Implantable connectors, intended for use by physicians to join implantable devices or their accessories shall be identified (see 8.2 and 9.9). The manufacturer shall declare (see 28.4) the intended performance as implanted, determined according to the following test.

— Test: Precondition the mated connector pair by immersion in saline solution of approximately 9 g/l at room temperature for not less than 8 h. After removal from the saline bath, subject the pair to straight separating pulls of 5 $\pm$ 0,5 N, 7,5 N $\pm$ 0,5 N and 10 N $\pm$ 0,5 N, each for not less than 10 s, while experiencing a relative torque of 0,02 N·m $\pm$ 0,005 N·m. If the mated connector pair is designed to allow free relative rotation between the mated parts, then do not apply torque in the test. Record the maximum force that did not result in disconnection as the test result.

Compliance shall be confirmed by examination of the manufacturer's records.

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

Non-implantable parts of an active implantable medical device shall be designed and constructed so that no irreversible change will be caused by an electrostatic discharge, such as might be experienced during handling.

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— Test: The device shall be set to function according to the manufacturer's instructions. The non-implantable part shall withstand the electrostatic charge test as described in IEC 61000-4-2 (with the climatic conditions as explicitly defined by 8.1.1) with a test voltage of 2 kV in the case of contact discharge to conductive surfaces and 8 kV in the case of air discharge to insulating surfaces. At least ten discharges at the 2 kV test voltage and five discharges at the 8 kV test voltage shall be applied to each test point.

Compliance shall be confirmed if the active implantable medical device operates in a safe mode and can be reset to provide all functions as stated in the manufacturer's specification for the device when it is checked after performing the test above.

NOTE Requirements for protection from damage caused by electrostatic discharge for particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes

Implantable parts of an active implantable medical device shall be constructed to withstand the changes of pressure which may occur during transit or normal conditions of use.

Compliance shall be confirmed by inspection of a design analysis and assessment of manufacturer's data from test studies investigating the effects of deformation due to absolute pressures at 70 kPa ± 3,5 kPa and 150 kPa ± 7,5 kPa applied for not less than 1 h.

NOTE Requirements for protection from damage caused by atmospheric pressure changes for particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

26 Protection of the active implantable medical device from damage caused by temperature changes

26.1 Electrically powered non-implantable parts of an active implantable medical device shall be designed and constructed to comply with clause 42 of IEC 60601-1:1988.

Compliance shall be confirmed as specified by IEC 60601-1.

26.2 Implantable parts of an active implantable medical device shall be designed and constructed so that no irreversible change will be caused by the changes in temperature to which they may be subjected during transportation or storage.

— Test: The implantable parts of the active implantable medical device in only the sterile pack shall be subjected to a test in accordance with IEC 60068-2-14 :1986, test Nb, under the following conditions:

a) low temperature: the lowest storage value stated by the manufacturer, or −10 °C ± 3 °C (whichever is the higher);

b) high temperature: the highest storage value stated by the manufacturer, or 55 °C ± 2 °C (whichever is the lower);

c) rate of change of temperature: (1 ± 0,2) °C/min.

Compliance shall be confirmed if the active implantable medical device conforms to the device specification after performing the test. If temperatures other than – 10 °C ± 3 °C and 55 °C ± 2 °C are used, these shall be recorded with the record of the test result.

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

Implantable parts of an active implantable medical device 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.

— Assessment: Identify possible hazards, taking into account the electromagnetic environment in which the active implantable medical device is intended to be used. For each hazard**,** evaluate the probability of harm through a design analysis that takes account of any hazard controls. Support the design analysis by test studies as appropriate.

NOTE 1 As a first guide, consider a magnetic intensity of 150 A/m falling inversely with frequency above 100 kHz to a maximum test frequency of 30 MHz. The electric field need not be investigated.

Compliance shall be confirmed by review of the appropriate documentation prepared by the manufacturer.

NOTE 2 Requirements for protection of particular active implantable medical devices from electromagnetic non-ionizing radiation may be specified in subsequent parts of ISO 14708.

28 Accompanying documentation

28.1 The accompanying documentation shall include the manufacturer's name and address, including at least the city and the country.

Compliance shall be checked by inspection.

28.2 If the package contains any radioactive substance, the accompanying documentation shall include information about the type and activity of the radioactive substance. (See also clause 18.)

Compliance shall be checked by inspection.

28.3 The accompanying documentation shall include a description of the device (e.g. cardiac pulse generator) and the model designation.

Compliance shall be checked by inspection.

28.4 If the package contains an implantable part of an active implantable medical device intended to be connected to another implantable device or implantable accessory, the accompanying documentation shall provide information on the maximum proven connector retention strength, determined according to 23.6.

Compliance shall be checked by inspection.

28.5 The accompanying documentation shall include information listing the accessories that might be required with the device and their essential functions.

Compliance shall be checked by inspection.

28.6 The accompanying documentation shall include an explanation of the method of interpreting the identification code required by 13.3.

Compliance shall be checked by inspection.

28.7 If applicable, the accompanying documentation shall include information regarding the medicinal products which the active implantable medical device is designed to administer. (See also 14.4 and 19.5.)

NOTE This subclause does not apply to any medicinal substance which forms an integral part of the active implantable medical device.

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Compliance shall be checked by inspection.

28.8 The accompanying documentation shall describe the intended use of the device, give the device specifications and characteristics, and provide any information about significant side effects (see 19.4).

Compliance shall be checked by inspection.

28.9 The accompanying documentation shall provide information allowing the physician to select a suitable device, its accessories and related devices (for example, a programmer).

Compliance shall be checked by inspection.

28.10 The accompanying documentation shall include instructions for using the active implantable medical device, so that physicians and, where appropriate, the patient are able to use the device correctly.

Compliance shall be checked by inspection.

28.11 The accompanying documentation shall include information on avoidable hazards at implantation.

Compliance shall be checked by inspection.

28.12 The accompanying documentation shall contain warning notices regarding the medical use of the device, including information about the hazards caused by interference between the implantable device and other equipment likely to be used in the course of other clinical procedures or medical treatments, such as the treatments referred to in 20.2, 21, 22 and 27.

Compliance shall be checked by inspection.

28.13 The accompanying documentation shall warn that, if the patient with the active implantable medical device is subsequently given any medical treatment in which an electrical current is passed through his/her body from an external source, either the device should first be deactivated, or care should be taken to monitor the functioning of the active implantable medical device during the initial stages of treatment.

Compliance shall be checked by inspection.

28.14 The accompanying documentation shall warn that implanted parts of an active implantable medical device should not be exposed to therapeutic levels of ultrasound energy, as the device may inadvertently concentrate the ultrasound field and cause harm.

Compliance shall be checked by inspection.

28.15 The accompanying documentation shall warn, if appropriate, that electronic components in an active implantable medical device may be damaged by therapeutic ionizing radiation, and warn that any damage to the device may not be immediately detectable.

Compliance shall be checked by inspection.

28.16 The accompanying documentation shall include a declaration that the implantable parts of the active implantable medical device have been sterilized.

Compliance shall be checked by inspection. (See also clause 11.)

28.17 If appropriate, the accompanying documentation shall include instructions on the method of sterilization for accessories that are delivered non-sterile and on dealing with the contents of the sterile pack in the event that it has been damaged or has been previously opened.

Compliance shall be checked by inspection.

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28.18 If appropriate, the accompanying documentation shall include a warning that implantable parts are not to be reused if they have previously been implanted in another patient. Otherwise the accompanying documentation provided with implantable parts shall include a warning that the device can be reused only if it is reconditioned under the responsibility of the manufacturer.

Compliance shall be checked by inspection.

28.19 If the device has an implanted energy source, the accompanying documentation shall include information allowing the lifetime of the energy source to be estimated both when the device is adjusted to the nominal settings specified by the manufacturer and when adjusted to the combination of parameters that result in the highest current drain consistent with practical clinical application.

Compliance shall be checked by inspection.

28.20 The accompanying documentation shall warn of recommended precautions to prevent adverse effects due to performance changes in the active implantable medical device.

Compliance shall be checked by inspection.

28.21 The accompanying documentation shall include information about any exceptional environmental or handling constraints (for example, protection from impact, vibration, temperature, pressure, or humidity) necessary to allow the active implantable medical device to be correctly handled and stored (see clause 10).

Compliance shall be checked by inspection.

28.22 The accompanying documentation shall warn of precautions to be taken to prevent adverse effects to the patient due to specific adverse environmental conditions (for example electromagnetic interference, extreme temperature, variations of pressure).

Compliance shall be checked by inspection.

28.23 The accompanying documentation shall include advice that the patient should be warned to seek medical guidance before entering environments which could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice preventing entry by patients fitted with a pacemaker.

Compliance shall be checked by inspection.

28.24 If appropriate, the accompanying documentation shall include instructions for the proper removal and disposal for the active implantable medical device.

Compliance shall be checked by inspection.

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Annex A
(informative)

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

Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 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** Requires warnings to be prominent.
3.2 The solutions adopted by the manufacturer for the design and construction of the implants should conform to safety principles, taking account of 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.	(This principle is fundamental to all aspects of an active implantable medical device addressed by this part of ISO 14708. This approach is particularly applicable to the requirements in clauses 14, 19 and 21.)
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 2.1 (of ISO/TR 14283:1995), as specified by the manufacturer.	**10.4** Requires accompanying documentation to be physically associated with the device.

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 and aspects covered
3.4 The characteristics and performances referred to in 3.1, 3.2 and 3.3 (of ISO/TR 14283:1995) 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, when the implant is subjected to the stresses which can occur during normal conditions of use.	**19.2** Requires power source depletion indicator. **19.3** Defines methodology to ensure single fault conditions are not a hazard. **23.1** Defines drop test for non-implantable parts. **23.2** Defines vibration test for patient-carried parts. **23.3** Sets test of tensile strength (leads, etc.). **23.4** Requires strain relief (leads, etc.). **23.5** Requires fatigue resistance (leads, etc.). **23.6** Requires connections to be reliable. **26.1** Requires protection from heat from powered non-implantable parts. **28.4** Requires disclosure of maximum proven connector retention strength. **28.23** Requires warning against patient entry into hazardous environments.
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, taking account of the instructions and information provided by the manufacturer.	**7.2** Requires sterile pack to be protected by sales packaging. **10.1** Requires packaging to be durable. **10.2** Requires packaging to be protected against the effects of humidity. **10.3** Requires markings on the sales package to be indelible. **12.3** Requires markings on the sterile pack to be indelible. **26.2** Requires device to be protected against the effect of temperature changes.
3.6 Any undesirable side-effect should constitute an acceptable risk when weighed against the performances intended.	**19.3** Defines methodology to ensure that single fault conditions are not a hazard. **19.4** Requires investigation of unintended effects caused by the device.
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 of the "General principles". Particular attention should be paid to:	
a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;	**14.3** Requires investigation of biocompatibility.
b) the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the implant.	**14.3** Requires investigation of biocompatibility.

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 and aspects covered
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 account of 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** Defines test for particulate contamination. **14.3** Requires investigation of biocompatibility.
4.1.3 The implants should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the implants are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	**19.5** Demonstrate compatibility with medicinal substances.
4.1.4 Where an implant incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in 2.4 (of ISO/TR 14283:1995) 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 account of the intended purpose of the implant.	**14.4** Requirement for quality and safety of incorporated medicinal substances.
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** Requires implanted parts to withstand pressure changes.
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** Requires implanted parts to withstand pressure changes.
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 systems, including software.	**19.3** Requires a design analysis and defines the methodology for the analysis.
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** Requires device to be supplied sterile.

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 and aspects covered
4.2.2 Tissues of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Information on the geographical origin of the animals should be retained by the manufacturer. Processing, reservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	(Not applicable to active implantable medical devices)
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** Requires device to be supplied in non-reusable pack. **7.2** Requires sterile pack to be protected by sales packaging. **10.1** Requires packaging to be durable. **10.2** Requires packaging to be proof against the effects of humidity. **11.7** Requires contents of sterile pack to be declared or visible. **11.9** Requires the sterile pack to be marked with the instructions for opening it. **12.1** Applies ISO 11607 to the non-reusable pack. **12.2** Shall be apparent if sterile pack has been opened. **14.1** Requires device to be supplied sterile.
4.2.4 Implants delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	**14.1** Confirmed if device sterilized by a validated process.
4.2.5 Implants intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	**14.1** Requires device to be supplied sterile. **14.2** Defines test for particulate contamination
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 account of the method of sterilization indicated by the manufacturer.	(Not applicable because subclause 14.1 requires that implantable parts of an active implantable medical device be provided sterile.)
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.	(Not applicable because subclause 14.1 requires that implantable parts of an active implantable medical device be provided sterile.)

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 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** Requires implantable connectors to be identified on sales pack. **11.8** Requires implantable connectors to be identified on sterile pack. **23.6** Requires connector retention force to be specified. **28.4** Requires disclosure of maximum proven connector retention strength. **28.5** Requires provision of information on accessories that might be required to facilitate the intended use of the device.
4.3.2 Implants should be designed and manufactured in such a way as to remove or minimize as far as is possible:	
a) the risk of injury, in connection with their physical features, including the volume/ pressure ratio, dimensional and where appropriate ergonomic features;	**15.1** Sets requirement for surfaces of non-implantable parts. **15.2** Requires implantable parts to have appropriate physical form.
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** Defines drop test for non-implantable parts. **23.2** Defines vibration test for patient-carried parts. **24** Defines electrostatic discharge test for non-implantable parts. **25** Requires implanted parts to be proof against pressure changes. **26.2** Requires implantable devices to be undamaged by extremes of temperature in transit. **27** Defines requirement for electromagnetic immunity.
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** Requires defibrillation protection of external ECG leads. **20.2** Defines test to prove defibrillation protection of implanted device. **21** Requires protection against diathermy, etc. **22** Requires protection against diagnostic ultrasound. **28.12** Requirement for warning notices. **28.13** Requires warning about monitoring device in case of diathermy etc. **28.14** Requires warning not to expose device to therapeutic levels of ultrasound. **28.15** Requires warning about the effect of therapeutic irradiation on implanted devices.
d) risks which may arise where maintenance and calibration are impossible, including (if applicable): excessive increase of leakage currents, ageing of the materials used, excess heat generated by the implant, decreased accuracy of any measuring or control mechanism.	**17** Requires investigation of local heating caused by faulty implanted device. **19.1** Requires a design analysis. **19.2** Requires power-source depletion indicator.

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 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. With the 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** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
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 account of the intended purpose of the implant. The limits of accuracy should be indicated by the manufacturer.	**5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.4.1.1 The measurements; monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the implant.	**5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.4.1.2 When an implant or its accessories bear instructions required for the operation of the implant or indicate operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and, as appropriate, the patient.	**13.4** Requirement about visual indicators. **5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.4.2 The measurements made by implants with a measuring function should be expressed in units conforming to the provisions of the ISO 31 series.	**5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
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 be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	(See more particular requirements below)
4.5.2 Intended radiation	(Not presently applicable to active implantable medical devices)

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 and aspects covered
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** Requires markings warning of any radioactive substances. **18.1** Requirement for sealed sources. **18.2** Requires justification of radiation dose on patient. **18.3** Requires radiation dose as low as is possible. **28.2** Requires information to be provided about radioactive substances.
4.5.4 Instructions	(Not presently applicable to active implantable medical devices)
4.6 Ionizing radiation	(Not presently applicable to active implantable medical devices)
4.7 Principles for implants connected to or equipped with an energy source	
4.7.1 Implants incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to the 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** Requires a design analysis and defines the methodology for the analysis.
4.7.2 Implants where 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** Requires power source depletion indicator.
4.7.3 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** Requirement stated and expanded. **28.6** Requires an explanation of code to be provided with the device.
4.7.4 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** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 and aspects covered
4.7.5 External devices intended to monitor one or more clinical parameters from an implant should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	**5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.7.6 Protection against electrical risks	
4.7.6.1 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. With 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** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device. **16.1** Sets safety limits for leakage currents from non-implantable parts.
4.7.6.2 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** Sets safety limits for leakage currents from implantable parts. **16.3** Requires testing of electrical insulation (leads, etc.). **17** Requires investigation of local heating caused by implanted device. **26.1** Requires protection from heat from powered non-implantable parts.
4.7.7 Protection against mechanical risks	
4.7.7.1 Implants should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	**5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.7.7.2 Implants should be designed and manufactured in such a way as to minimize the risks arising from vibration generated by the implants, taking account of technical progress and of the means available for limiting vibration, particularly at source, unless the vibrations are part of the specified performance.	**5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.7.7.3 Implants should be designed and manufactured in such a way as to minimize the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	**5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.7.7.4 Terminals and connectors to the 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** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.7.8 Protection against the risks posed to the patient by energy supplies or substances	
4.7.8.1 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 account of the intended use.	**19.3** Requires a design analysis and defines the methodology for the analysis.

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 and aspects covered
4.7.8.2 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** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.7.8.3 Implants designed to administer medicinal products should incorporate suitable means to prevent and/or indicate any inadequacies in the flowrate that could pose a danger.	**5** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
4.7.8.4 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** Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.
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 account of the training and knowledge of the potential users.	**10.4** Requires accompanying documentation to be physically associated with the device. **12.3** Requirement that any markings shall be indelible.
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, where 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 e every implant.	
4.8.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to international standards. Where no standards exist, the symbols should be described in the documentation supplied with the implant.	**4** Allows use of symbols, abbreviated terms and identification colours.
4.8.3 The label should bear the following particulars:	**5** Invokes the labelling requirements of IEC 60601-1 for non-implantable parts.
a) the name or trade name and address of the manufacturer;	**9.2** Requires name and address of manufacturer on the sales pack. **11.1** Requires identification of manufacturer on sterile pack.
b) the details strictly necessary for the user to identify the implant and the contents of the packaging;	**9.3** Requires description of device and model designation on the sales pack. **9.4** Requires marking with characteristics sufficient to identify device. **9.8** Requires sales pack to bear information about accessories provided. **9.10** Requires supplementary description, if 9.3 and 9.4 are inadequate to declare purpose. **11.6** Requires description of device and mode designation on the sterile pack. **11.7** Requires identification of contents of sterile pack.

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 and aspects covered
c) where appropriate, an indication that the contents of the packaging are sterile (e.g. “STERILE”);	**9.5** Requires statement that the package has been sterilized. **11.2** Requires declaration that the package and its contents have been sterilized. **11.3** Requires display of the “sterile” symbol.
d) where appropriate, the batch code or the serial number, preceded by an appropriate identification (e.g. “LOT” or “SN” respectively);	**9.3** Requires batch code or serial number on the sales pack. **11.6** Requires batch code or serial number on the sterile pack.
e) where appropriate, an indication of the date by which the implant should be used;	**9.7** Requires marking of a “use-before date”. **11.5** Requires marking of a “use-before date”.
f) an indication that the implant is for single use;	**28.18** Requires and defines warning notice about reuse of the device.
g) where appropriate, any indication of special purpose (e.g. “custom-made device” or “exclusively for clinical investigations”);	**9.12** Requires marking of special purpose. **11.10** Requires marking of special purpose.
h) any special storage and/or handling conditions;	**9.11** Requires marking with information on any exceptional environmental or handling constraints.
i) any special operating instructions;	(For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation.)
j) any warnings or precautions to take;	(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.)
k) for active implants, month and year of manufacture;	**9.6** Requires marking and defines format. **11.4** Requires marking and defines format.
l) if applicable, method of sterilization.	**11.2** Requires method of sterilization to be marked.
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** Requires supplementary description, if 9.3 and 9.4 are inadequate to declare purpose.
4.8.5 Wherever reasonable and practicable, the implants and detachable components should be identified, where 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** Requires implanted parts to be traceable. **13.1** Requires identification of manufacturer, model etc. on device. **13.2** Requires that if different power sources might have been used, the actual source used shall be identified.
4.8.6 Where 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** Requires name and address of manufacturer. **28.3** Requires description of the device. **28.16** Requires statement that implantable parts of a device have been sterilized. **28.18** Requires and defines warning notice about reuse of the device. **28.21** Requires marking with information on any exceptional handling constraints.

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b) the performances referred to in 3.3 (of ISO/TR 14283:1995) and any undesirable side-effects;	**28.8** Requires information to be provided about the intended use and characteristics, and about possible side effects.
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** Requires disclosure of maximum proven connector retention strength. **28.5** Requires provision of information on accessories that might be required to facilitate the intended use of the device. **28.9** Requires information to allow selection of device, accessories and related devices.
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** Requires definitive instructions for use to be provided.
e) where appropriate, information to avoid specified risks in connection with implantation of the implant;	**28.11** Requires information on avoiding hazards during implantation are provided.
f) information regarding the risks of reciprocal interference posed by the presence of the implant during specific investigations or treatment;	**28.12** Requires warning notices on hazards arising from interaction.
g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	**28.17** Requires precautions for dealing with opened or damaged sterile pack.
h) where 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 14283:1995);	**28.17** Requires instructions for sterilizing accessories that are provided non-sterile.
i) details of any further treatment or handling needed before the implant can be used (for example, sterilization, final assembly, etc.);	(Not applicable because subclause 14.1 requires that active implantable medical device be provided sterile.)
j) in the case of implants emitting radiation for medical purposes, details of the nature, type intensity and distribution of this radiation.	(Not applicable to active implantable medical devices.)
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** Requires information allowing the lifetime of the energy source to be estimated. **28.20** Requires information on precautions to be taken to prevent adverse effects from changes in device performance.
l) precautions to be taken as regards exposure to, in reasonably foreseeable environmental conditions, e.g. to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	**28.22** Requires warnings on precautions to avoid adverse environments.
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** Requires information about medicinal products which the device is designed to administer.

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Fundamental principles in ISO/TR 14283	Clauses of ISO 14708-1 and aspects covered
n) precautions to be taken against any special, unusual risks related to the disposal of the implant;	**28.25** Requires information on proper disposal of the device.
o) medicinal products incorporated into the implant as an integral part in accordance with 4.1.4 (of ISO/TR 14283:1995);	**28.8** Requires information to be provided about the intended use and characteristics, and about possible side effects.
p) degree of accuracy claimed for implants with a measuring function.	**5** Applies 6.8 of IEC 60601-1:1988 to the non-implantable parts of the active implantable medical device.
4.9 Clinical evaluation Where conformity with the fundamental principles for implants should be based on clinical data, as in 3.6 (of ISO/TR 14283:1995) 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** Requires investigation of unintended effects caused by the device.
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** Requires investigation of unintended effects caused by the device.

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

Subclause	Relevant fundamental principle		Subclause	Relevant fundamental principle
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, 4.7.4, 4.7.5, 4.7.7.1, 4.7.7.2, 4.7.7.3, 4.7.7.4, 4.7.8.2, 4.7.8.3, 4.7.8.4, 4.8.3 and 4.8.6 p)		11.5	4.8.3 e)
			11.6	4.8.3 b) and 4.8.3 d)
			11.7	4.8.3 b) and 4.2.3
7.1	4.2.3		11.8	4.3.1
7.2	3.5 and 4.2.3		11.9	4.2.3
8.1	3.1		11.10	4.8.3 g)
8.2	4.8.5		12.1	4.2.3
9.1	4.5.3		12.2	4.2.3
9.2	4.8.3 a)		12.3	3.5
9.3	4.8.3 b) and 4.8.3 d)		13.1	4.8.5
9.4	4.8.3 b)		13.2	4.8.5
9.5	4.8.3 c)		13.3	4.7.3
9.6	4.8.3 k)		13.4	4.4.1.2
9.7	4.8.3 e)		14.1	4.2.1, 4.2.3, 4.2.4 and 4.2.5
9.8	4.8.3 b)		14.2	4.1.2 and 4.2.5
9.9	4.3.1		14.3	4.1.1 a), 4.1.1 b) and 4.1.2
9.10	4.8.3 b) and 4.8.4		14.4	4.1.4
9.11	4.8.3 h)		15.1	4.3.2 a)
9.12	4.8.3 g)		15.2	4.3.2 a)
10.1	3.5 and 4.2.3		16.1	4.7.6.1
10.2	3.5 and 4.2.3		16.2	4.7.6.2
10.3	3.5		16.3	4.7.6.2
10.4	3.3 and 4.8.1		17	4.7.6.2 and 4.3.2 d)
11.1	4.8.3 a)		18.1	4.5.3
11.2	4.8.3 c) and 4.8.3 l)		18.2	4.5.3
11.3	4.8.3 c)		18.3	4.5.3

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Subclause	Relevant fundamental principle		Subclause	Relevant fundamental principle
19.1	4.3.2 d)		28.3	4.8.6 a) [4.8.3 b)]
19.2	3.4, 4.3.2 d) and 4.7.2		28.4	3.4, 4.3.1 and 4.8.6 c)
19.3	3.4, 3.6, 4.1.7, 4.7.1 and 4.7.8.1		28.5	4.3.1 and 4.8.6 c)
19.4	3.6, 4.9 a) and 4.9 b)		28.6	4.7.3
19.5	4.1.3		28.7	4.8.6 m)
20.1	4.3.2 c)		28.8	4.8.6 b) and 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)
			28.11	4.8.6 e)
23.1	3.4 and 4.3.2 b)		28.12	4.3.2 c) and 4.8.6 f)
23.2	3.4 and 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) [3.8.3 c)]
23.6	3.4 and 4.3.1		28.17	4.8.6 g) and 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 and 4.7.6.2		28.20	4.8.6 k)
26.2	3.5 and 4.3.2 b)		28.21	4.8.6 a) [4.8.3 h)]
27	4.3.2 b)		28.22	4.8.6 l)
28.1	4.8.6 a) [4.8.3 a)]		28.23	3.4
28.2	4.5.3		28.25	4.8.6 n)

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Annex C
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Rationale

C.1 Introduction

ISO/TR 14283 presents a compilation of fundamental principles applicable to the design and manufacture of implants for surgery. This part of ISO 14708 interprets these fundamental principles for active implants in general. In many clauses, this part of ISO 14708 does this by detailing a particular aspect of a fundamental principle and specifying an assessment procedure or test.

These fundamental principles are the basic rationale for this part of ISO 14708 and for subsequent parts (particular standards). They should be read in conjunction with the following information. For convenience, the fundamental principles are listed in association with the specific clauses of this part of ISO 14708 in annex A.

C.2 General

The following notes on some of the provisions of this part of ISO 14708 are provided as an aid to understanding. This annex is directed towards those who are familiar with the construction or use of active implantable medical devices but have not themselves participated in drafting this part of ISO 14708. The notes in this annex carry the numbers of the relevant clauses of this part of ISO 14708; therefore, paragraph numbering in the annex is not consecutive.

Apart from clauses 5, 7 and 8, the clauses of this part of ISO 14708 are arranged so they can be addressed in sequence, proceeding from checking of markings on the outside of the sales pack, then the construction of the sales pack, and so on through to tests on the device, and finally to checks of the accompanying documentation.

For some hazards, ISO 14708 gives specific requirements along with compliance measures (e.g. leakage current levels) which, if met, would address one or more fundamental principles. For other risks, this part of ISO 14708 requires potential hazards to be identified and addressed using risk management procedures following the precepts laid down in fundamental principle 3.2 of ISO/TR 14283:1995. Compliance is then determined by review of documentation provided by the manufacturer.

In some cases, no laboratory test of limited duration can provide adequate assurance of the characteristics of a particular design, or assure the performance of the device after several years' implantation. ISO 14708 then requires the device manufacturer to prepare documented studies suitable for expert review.

By its very nature, a general standard cannot be applied equally to all products within its scope. For example, risk management may show that a particular device will require more stringent limits on particular parameters (e.g., leakage current limits where very small electrodes are used). In another case, the temperature limits could be relaxed where the available technology generates more heat but the application allows that heat to be dissipated safely.

For a particular active implantable medical device, special care is required when applying this part of ISO 14708 alone. When a particular standard exists, this part of ISO 14708 should never be used alone.

C.3 Notes on specific clauses and subclauses

5 IEC 60601-1 is a widely accepted standard which covers the majority of the safety issues associated with the non-implantable parts of an active implantable medical device.

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7.1 The non-reusable pack becomes the sterile pack when the pack and its contents have been sterilized. The requirement for sterility is addressed by 14.1.

7.2 The sales package provides protection for non-reusable pack against the rigours of transport and storage as well as insuring that the accompanying documentation is available at the point of use. See also 10.4.

8 In general, the information provided in the marking of an active implantable medical device is to be useful for the clinician in applying the device in a course of medical treatment. Adding information that is irrelevant to this purpose may obscure information that is essential to the proper use of the device.

8.1 Required warnings should be immediately apparent, neither too small nor obscured by other warning notices, in order to prevent undue risk to patients.

8.2 If failures occur in some samples of an implanted device, it may become apparent that action must be taken to prevent harm to patients with similar devices. The patients involved must be precisely identified if unnecessary medical procedures are to be avoided. This requires precise identification of both the devices and their component parts, without the need to explant devices. Correct identification of components may depend on the manufacturer maintaining systematic records. Guidance on one approach to record-keeping is provided by the ISO 9000 family of standards, together with ISO 13485 and ISO 13488.

9 In general, markings on the sales packaging should be restricted to avoid non-essential information which reduces the clarity of the essential data required by this part of ISO 14708.

9.1 Packages containing radioactive sources may be subject to additional specific regulatory controls.

9.3 The intention is to provide only that information necessary for the user to identify the device in the process of selecting it for a medical procedure.

9.4 It may be that the information specifically required on the sales packaging by other subclauses is insufficient to identify and characterize the device.

9.5 This requirement is intended to help assure prudent handling of the device.

9.6 and 11.4 ISO 5841-1 for implantable cardiac pacemakers, which has been widely accepted, has already established the requirement for the date format. ISO 8601 establishes a date format which is internationally accepted.

9.8 It should not be necessary to open the pack to discover the precise contents. The user should not discover after the pack has been opened that some specific accessory is required but has not been included. This will prevent the unpacked but unused device being insufficiently protected from damage.

9.9 After opening the pack, the user should not discover that the enclosed device will not interface with an accessory, supplied separately, which the physician intends to use in the course of the implantation. Also, this will prevent the unpacked but unused device being left unprotected while a suitable accessory is found.

9.11 See clause 25 and subclause 26.2 for a discussion of exceptional transport and storage conditions.

9.12 and 11.10 An indication of special purpose helps avoid having a device applied to the wrong patient.

10.1 The packaging should ensure that the device is not subjected to unsafe conditions during delivery and storage. Acceptable limits depend on the design specification of the device in question.

10.2 Atmospheric humidity during shipment should not cause the information provided for the user to deteriorate. The requirement is based on 4.10 of IEC 60601-1:1988 and on test Cb of IEC 60068-2-56:1988.

10.3 The wet wipe test defines the requirement that the markings on the package are permanent and indelible. The requirement is based on the compliance requirement of 6.1 of IEC 60601-1:1988.

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10.4 It is a fundamental principle that the device be suitable for the function stated by the manufacturer and declared to the user in the markings and accompanying documentation. This requirement would be subverted if the information could not always be correctly associated with the particular device.

11 In general, markings on the sterile pack should be restricted to avoid non-essential information which reduces the clarity of the essential data required by this part of ISO 14708.

11.7 It is necessary for users to be able to check that they have everything they require just before implantation without first having to open the sterile pack. If the pack is left open for an undue period before implantation, the device may be subject to contamination or damage.

11.8 This allows final confirmation of connector types before opening the pack. (For example, the sterile pack may have become separated from the accompanying documentation.) If the pack is left open for an undue period before implantation, the device may be subject to contamination or damage.

12.1 ISO 11607 is the generic standard that specifies requirements for single-use materials and reusable containers for packaging terminally sterilized medical devices.

13.1 This marking provides identification of the device on explant. Some implantable parts may be too small to carry all this information. Some accessories (for example, associated tools) may not need batch or serial numbering. The requirement is based on the compliance requirement of 6.1 of IEC 60601–1:1988.

13.2 This requirement enables the user to group units when analyzing longevity experience. Characteristics of batteries that, initially, are nominally equivalent have frequently proved to be significantly different towards the end of the lifetime of the implant.

13.3 This subclause addresses the fundamental principle that any device in use can be identified without performing a surgical operation and without requiring special equipment specific to a manufacturer or model of a device. In practice it may not be possible to suitably mark small passive devices. The present state-of-the-art is to identify the manufacturer and model with radio-opaque symbols if the device contains a power source. Reading the radio-opaque symbol should allow a suitable telemetry device to be selected. The telemetry device may be able to identify the serial number of the implanted device.

13.4 If each device is to be used safely, giving appropriate credit to the training and knowledge of the potential user, then it must be accompanied by key information. As far as practicable and appropriate, the information needed to use the device safely should be set out on the device itself. Where appropriate, this information should take the form of symbols, but any symbols and identification colours should conform to International Standards. If no standards exist, the symbols and colours should be described in the documentation supplied with the device.

14.1 To avoid further handling and processing in the hospital, implantable parts of active implantable medical devices are to be supplied sterile in a non-reusable pack. If for convenience other parts are included in the non-reusable pack, they too have to be sterile to avoid contamination of the implantable parts. Material that is contained within a hermetically sealed container throughout the lifetime of the device is not required to be sterile.

14.2 As well as the specific requirement that an implant does not introduce infective agents into the body, there should be no unnecessary introduction of loose particulate matter (“sterile dirt”). The method is specified so that meaningful quantitative limits can be set for assessing the results of the test. Any measuring equipment using the technique will be suitable. The test is based on a standard test for particulates given in the British Pharmacopoeia.

14.3 In this context, the term “biocompatible” means that there is a high confidence that the implanted material will function as intended without causing harm to the body or being harmed by the body. Biological tests covering the implant lifetime of the device are impracticable. Accordingly, demonstration of biocompatibility can only be made by inference from existing experience and/or recognized procedures for biological evaluation (e.g. one of the parts of ISO 10993).

16.2 Sustained small direct currents (d.c.) from implanted electrodes may cause tissue damage or electrode corrosion. The safe limit may need to be reduced to 0,1 μA for small electrodes. The test method should be applicable to a device even while in use and controlling a physiological process.

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16.3 Electrical insulation must be adequate even though the insulator may be permeated by body fluids. There is some functional relationship between the rise time of the applied test voltage, the voltage, and the number of times the test is repeated, but this relationship cannot be defined across the variety of products covered by this part of ISO 14708. The values selected are intended to set a practicable test giving a significant result. Other parts of ISO 14708 may specify other compliance tests.

17 Because of the good thermal contact between an active implantable medical device and the patient's tissue, a 2 °C rise on the external surface of the implantable device requires significant power dissipation from common implantable energy sources. More complex test methodologies and protection mechanisms may be required if the implanted power source can deliver energy at high rates, such as in the case of an implantable defibrillator. The actual temperature attained on the surface of the device under specific operating or fault conditions will depend on the patient's own body temperature, which is the ambient temperature for the implant. The temperature limit set by this part of ISO 14708 is lower than the relevant limit in IEC 60601-1 because of the increased difficulty of taking corrective action when the source of heat is implanted.

18.1 to 18.3 Few active implantable medical devices are believed now to contain radioactive substances. No active implantable medical devices that intentionally emit radiation are known at the time of writing this part of ISO 14708. The only requirements considered in this clause are those applicable to a radioactive power source.

19.1 Most active implantable medical devices are designed to have an implanted life of several years. Therefore, tests aimed at obtaining accurate time-to-failure or lifetime information are often impractical. An accepted practice is to reduce the time required to obtain the desired information by changing the environment in which the test is performed (accelerated testing). From the results of such a test, it is possible to draw conclusions about lifetime properties in a more benign environment provided that:

a) the failure modes observed in the accelerated environment are the same as those observed under conditions of use; and

b) it is possible with a reasonable degree of assurance to extrapolate from the accelerated environment to the conditions of use.

Experience with active implantable medical devices put into service in recent years indicates that devices achieve, and users expect, a very low incidence of premature device failure. Therefore, the accelerated tests which are used to draw conclusions about the reliability of an active implantable medical device are not only required to meet the conditions listed above but have to be designed to achieve statistical significance with typical failure rates of less than 0,5 % per year.

19.2 It is important that exhaustion of the power supply of an active implantable medical device does not cause it to cease functioning without previous warning. The warning mechanism provided should not be invalidated by different therapies that deplete the power source at differing rates.

19.3 An active implantable medical device should be "fail-safe". Because of the design constraints on practicable devices, it is believed first-fault analysis can be made only by the device designer. The methodology for the analysis is set by this part of ISO 14708. The requirement for reliable software with programmable systems is handled by the same methodology.

19.4 Some traditional pharmaceutical clinical investigation criteria may not be applicable to active implantable medical devices: for example, age distributions and double blind controls. The scope of any clinical investigation will be restricted by the small available target population and the relatively low incidence of the target pathology.

20.2 The circuit details in Figure 1 are specified so that the energy delivered to the device, when it is directly connected to the test equipment through the 300 Ω resistor, is similar to the energy delivered to the device through the pacing lead when the subject is defibrillated using external defibrillation paddles. The specified test avoids the use of the high voltages delivered directly by defibrillator paddles. The requirement is based on clause 6 and Figures 1 and 2 of ISO 5841-1:1989.

Defibrillation attempts often have to be repeated and the polarity of the signal introduced cannot be restricted. The subclause is intended to set a practical level of protection so that, in most cases, defibrillation will not damage an active implantable medical device. In general, it is not possible to provide absolute immunity for active implants

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containing semiconductors. Damage that is not apparent may cause reduced lifetime of semiconductor components. Hence the requirement for warnings in 28.13.

21 This clause is intended to ensure a reasonable degree of protection from identifiable hazards such as surgical treatment or a course of physiotherapy using diathermy. (The requirement is supplemented by the lower-level immunity analysis given in clause 27.) In general, it is not possible to provide absolute immunity for active implants containing semiconductors. Damage that is not apparent may cause reduced lifetime of semiconductor components. Hence the requirement for warnings in 28.13.

22 Note this requirement addresses only exposure to diagnostic ultrasound. In this part of ISO 14708, exposure of an active implantable medical device to therapeutic levels of ultrasound is covered by a requirement for a warning notice (see 28.14).

23.1 This requirement is known to be more severe than the similar requirement in IEC 60601-1. Hand-held programmers and portable device analysers may be subject to severe mechanical shocks during handling by other than the expert user. If such impacts cause damage not immediately apparent to the user, the damaged device may miss-set the implant or give an erroneous analysis of an implanted device, which could subsequently result in an unnecessary explantation.

23.2 This subclause sets a minimum standard of robustness for an active implantable medical device. The guidance provided by IEC 60068 suggests that this random vibration test is more appropriate than the sinusoidal vibration test described in another part of that standard and which was previously specified for the assessment of implanted cardiac pulse generators.

The frequency range is defined from a consideration of device usage. The low frequency limit extends to 5 Hz because implanted devices may be subjected to low frequency vibration which might excite relative movement of internal subassemblies. The high frequency limit is restricted to 150 Hz because the patient's body will tend to protect the device from high frequency vibrations which would otherwise be significant to small electronic devices.

Protection of the device during delivery and storage is provided by appropriate design of packaging.

23.3 Implanted leads and catheters are known sometimes to be subject to tensile forces after implantation. These forces are possibly caused by bodily movements, during sporting activity, or by physical force directly applied to the body, for example during an accident.

23.4 and 23.5 These requirements are intended to ensure that adequate studies are carried out to ensure the prevention of fatigue failures of implanted leads and catheters.

23.6 ISO 14708 leaves the method of providing a secure connection to the manufacturer's specification. Thus the manufacturer is required to specify compatible connector parts (see 9.9 and 28.9) so that specified parts can be selected for test so ensuring that implanted connector pairs are reliable when subject to tensile force.

In the compliance requirement of ISO 14708, in addition to a tensile force, a torque is applied because implanted connectors may be subjected to rotational forces because of slow movement of an implanted device over its lifetime.

The subclause specifies an agreed torque and test forces to prove the integrity of the connector pair, but design of the test equipment applying and monitoring the test is left to the device manufacturer or individual test house.

24 The test requirement applies only to non-implantable parts which may be exposed to the general hospital environment. The implantable part is believed to be sufficiently protected from electrostatic potentials by its packaging and because it is only handled under controlled conditions.

25 The lower range limit corresponds to an altitude of approximately 3000 m (i.e. 30 kPa below normal atmospheric pressure). The upper limit corresponds approximately to a depth of 5 m in water (i.e. 50 kPa above normal atmospheric pressure).

26.2 It is known that some implants cannot withstand freezing. This should be addressed in the relevant particular standard (part of ISO 14708). Any device that cannot be subjected to the full temperature range specified by this

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subclause will require additional warning notices on the packaging (see 9.11). If damage caused by freezing is not immediately apparent, then special temperature indicators may be required in the packaging.

27 This general procedure is intended to ensure general immunity from electromagnetic interference. The requirement is likely to be supplemented by detailed tests applicable to specific types of active implantable medical device in the other parts of ISO 14708.

28.6 The code required by 13.3 has to be explained to the user.

28.18 If an implanted device is reused, then the “re-manufacturer” has to meet all the requirements of this standard. The requirement is considered to address the fundamental principle regarding information on the package labels as well as in the accompanying documents.

28.19 Neither user adjustments to the implant within practical clinical application, nor patient physiology nor physical behaviour should invalidate the lifetime determination.

28.23 Some sources that might cause a hazard for different types of electronic implants are commonly indicated by warning notices addressed only to “pacemaker patients”. The warning may therefore be relevant to other active implantable medical devices although, without specific advice, a patient might decide to ignore the warning if not fitted with a pacemaker.

Hence the subclause is not intended to encourage patients to disregard warning notices; rather, it is intended to ensure that a patient with an active implantable medical device other than a pacemaker recognises that a warning addressed to pacemaker patients may be important to themselves.

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