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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 14708-1:2000), which has been technically revised.

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

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

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

— *Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

— *Part 7: Particular requirements for cochlear implant systems*

NOTE The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations might need a transitional period following publication of a new, amended, or revised ISO publication in which to make products in accordance with the new requirements and to equip them for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than three years from the date of publication.

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.

For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICE, the general requirements can be supplemented or modified by the requirements of other parts of ISO 14708. A requirement of a particular part of ISO 14708 takes priority over the corresponding requirement of this general part of ISO 14708. Where particular parts of ISO 14708 exist, this general part of ISO 14708 is not intended to be used alone. Special care is required when applying this general part of ISO 14708 alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular International Standard has yet been published.

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 1 For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICES, these general requirements are supplemented or modified by the requirements of particular parts of ISO 14708.

The tests that are specified in ISO 14708 are type tests and are to be carried out on samples of an ACTIVE IMPLANTABLE MEDICAL DEVICE to show compliance.

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 by gas pressure or by springs).

This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the ACTIVE IMPLANTABLE MEDICAL DEVICES.

NOTE 2 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE can be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, 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.

NOTE 3 In this part of ISO 14708, terms printed in small capital letters are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

NOTE 4 The terminology used in this part of ISO 14708 is intended to be consistent with the terminology of ISO/TR 14283:2004.

2 Normative references

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

ISO 8601:2004, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

IEC 60068-2-14:2009, *Environmental testing — Part 2-14: Tests — Test N: Change of temperature*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-47:2005, *Environmental testing — Part 2-47: Tests — Mounting of specimens for vibration, impact and similar dynamic tests*

IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

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

IEC 62304:2006, *Medical device software — Software life cycle processes*

3 Terms and definitions

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

3.1
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

3.2
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 after the procedure

Note 1 to entry: For the purposes of this part of ISO 14708, an ACTIVE IMPLANTABLE MEDICAL DEVICE can be a single ACTIVE MEDICAL DEVICE, or a system consisting of a set of components and accessories, including software, 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.

3.3
authorized representative
any natural or legal person who, explicitly designated by the MANUFACTURER, acts and can be addressed by authorities and bodies instead of the MANUFACTURER with regard to the latter's obligations

3.4
beginning of service
BOS
point at which an individual ACTIVE IMPLANTABLE MEDICAL DEVICE is first released by the MANUFACTURER as fit for placing on the market

3.5
catheter
flexible tube allowing access to a point within the body at its distal end through a lumen, often for delivering a substance

Note 1 to entry: A CATHETER can be combined with a LEAD.

3.6
correct use
NORMAL USE without USE ERROR

[SOURCE: IEC 62366:2007, 3.7]

3.7
end of service
EOS
point at which an individual PROLONGED SERVICE PERIOD has elapsed and performance to design specification cannot be assured

3.8
hand held
part of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to be supported by the hand during NORMAL USE

[SOURCE: IEC 60601-1:2005 + A1:2012, 3.37, modified — "Electrical equipment" replaced by "part of an active implantable medical device".]

3.9
harm
physical injury or damage to health of people, or damage to property or the environment

[SOURCE: ISO 14971:2007, 2.2]

3.10
hazard
potential source of HARM

[SOURCE: ISO 14971:2007, 2.3]

3.11
information security
protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide confidentiality, integrity, and availability

[SOURCE: FIPS PUB 199]

3.12
label
area bearing a MARKING, affixed to an ACTIVE IMPLANTABLE MEDICAL DEVICE or package but not an integral part of the ACTIVE IMPLANTABLE MEDICAL DEVICE or package

3.13
lead
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length

Note 1 to entry: A LEAD can be combined with a CATHETER.

3.14
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, and labelling of an ACTIVE IMPLANTABLE MEDICAL DEVICE before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

Note 1 to entry: This definition also applies to the natural or legal person who assembles, packages, processes, fully refurbishes, and/or labels one or more ready-made products and/or assigns to them their intended purpose as an ACTIVE IMPLANTABLE MEDICAL DEVICE with a view to their being placed on the market under his own name. This definition also applies to the MANUFACTURER of non-implantable parts and accessories of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

3.15
marking
inscription on a device, package, or LABEL

3.16
medical device
instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, together with any accessories, including the software intended by its MANUFACTURER to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the MANUFACTURER to be used for human beings for the purpose of

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

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or handicap,

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

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which can be assisted in its function by such means

3.17
medicinal substance
substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which can be used in or administered to human beings either with a view to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action, or to making a medical diagnosis

Note 1 to entry: Based on Article 1 of European Union Directive 2001/83/EC.

3.18
medicinal substance derived from human blood or human plasma
MEDICINAL SUBSTANCE based on blood constituents which are prepared industrially by public or private establishments, such MEDICINAL SUBSTANCE including, in particular, albumin, coagulating factors, and immunoglobulins of human origin

3.19
non-reusable pack
single-use pack designed to allow the contents to be sterilized and to maintain that sterility

3.20
normal use
operation, including routine inspection and adjustments by any user, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use

Note 1 to entry: USE ERROR can occur in NORMAL USE.

Note 2 to entry: MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

[SOURCE: IEC 60601-1:2005 + A1:2012, 3.71, modified — "Operator" replaced by "user" and "or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use" added to the end of the definition.]

3.21
portable
<part of an ACTIVE IMPLANTABLE MEDICAL DEVICE> intended to be moved from one location to another while being carried by one or more persons

[SOURCE: IEC 60601-1:2005 + A1:2012, 3.85, modified — "Transportable equipment" replaced by "part of an ACTIVE IMPLANTABLE MEDICAL DEVICE".]

3.22
process
set of inter-related or interacting resources and activities which transform inputs into outputs

[SOURCE: ISO 14971:2007, 2.130]

3.23
prolonged service period
PSP
period during which the ACTIVE IMPLANTABLE MEDICAL DEVICE continues to function as defined by the MANUFACTURER beyond the RECOMMENDED REPLACEMENT TIME

3.24
radioactive substance
substance that contains one or more radionuclides, the activity or concentration of which cannot be disregarded as far as radiation protection is concerned

Note 1 to entry: Based on European Council Directive 96/29/Euratom.

3.25
recommended replacement time
RRT
point at which the power source indicator reaches the value set by the MANUFACTURER of the ACTIVE IMPLANTABLE MEDICAL DEVICE for its recommended replacement

Note 1 to entry: This indicates entry into the PROLONGED SERVICE PERIOD.

3.26
residual risk
RISK remaining after RISK CONTROL measures have been taken

[SOURCE: ISO 14971:2007, 2.15]

3.27
risk
combination of the probability of occurrence of HARM and the severity of that HARM

[SOURCE: ISO 14971:2007, 2.16]

3.28
risk analysis
systematic use of available information to identify HAZARDS and to estimate the RISK

Note 1 to entry: RISK ANALYSIS includes examination of different sequences of events that can produce hazardous situations and HARM. See Annex E of ISO 14971:2007.

[SOURCE: ISO 14971:2007, 2.17]

3.29
risk assessment
overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

[SOURCE: ISO 14971:2007, 2.18]

3.30
risk control
PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[SOURCE: ISO 14971:2007, 2.19]

3.31
risk evaluation
PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: ISO 14971:2007, 2.21]

3.32
risk management
systematic application of management policies, procedures, and practices to the tasks of analysing, evaluating, controlling, and monitoring RISK

[SOURCE: ISO 14971:2007, 2.22]

3.33
risk management file
set of records and other documents that are produced by RISK MANAGEMENT

[SOURCE: ISO 14971:2007, 2.23]

3.34
sales packaging
packaging that protects and identifies the ACTIVE IMPLANTABLE MEDICAL DEVICE during storage and handling by the purchaser

Note 1 to entry: The SALES PACKAGING can be enclosed in further packaging, for example, a "shipping package", for delivery.

3.35
sealed source
source containing RADIOACTIVE SUBSTANCES whose structure is such as to prevent, under normal conditions of use, any dispersion of the RADIOACTIVE SUBSTANCES into the environment

Note 1 to entry: Based on European Council Directive 96/29/Euratom.

3.36
sterile pack
NON-REUSABLE PACK in which the contents have been sterilized

3.37
usability
characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning, and user satisfaction

[SOURCE: IEC 62366:2007, 3.17]

3.38
usability engineering
application of knowledge about human behaviour, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

[SOURCE: IEC 62366:2007, 3.18]

3.39
use error
act or omission of an act that results in a different ACTIVE IMPLANTABLE MEDICAL DEVICE response than intended by the MANUFACTURER or expected by the user

Note 1 to entry: USE ERROR includes slips, lapses, and mistakes.

Note 2 to entry: An unexpected physiological response of the patient is not in itself considered USE ERROR.

[SOURCE: IEC 62366:2007, 3.21, modified — "MEDICAL DEVICE" replaced by "ACTIVE IMPLANTABLE MEDICAL DEVICE".]

3.40
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: IEC 62366:2007, 3.26]

4 Symbols and abbreviations (optional)

When appropriate, symbols, abbreviated terms, and identification colour may be used in the MARKINGS and accompanying documentation of an ACTIVE IMPLANTABLE MEDICAL DEVICE. Symbols, abbreviated terms, and identification colour shall conform with harmonized International Standards (e.g. ISO 15223-1). Where no harmonized International Standard exists, the symbols, abbreviated terms, and identification colour shall be described in the accompanying documentation.

Compliance is checked by inspection.

NOTE Symbols for use with particular ACTIVE IMPLANTABLE MEDICAL DEVICES can be specified in subsequent parts of ISO 14708.

5 General requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES

5.1 General requirements for non-implantable parts

The non-implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE which is connected to or equipped with an electrical power source shall comply with the appropriate requirements of IEC 60601-1:2005 + A1:2012, as determined in the RISK ANALYSIS, unless a requirement in that standard is superseded by a requirement in this part or other parts of ISO 14708.

NOTE Other subclauses in this part of ISO 14708 require compliance with some subclauses of IEC 60601–1:2005 + A1:2012 even for non-implantable parts that are not electrically powered.

Compliance is checked by assessment of the test report and the RISK ANALYSIS provided by the MANUFACTURER.

5.2 General requirements for software

Software of an ACTIVE IMPLANTABLE MEDICAL DEVICE or software that falls within the definition of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be designed according to software life cycle process activities compliant with IEC 62304:2006 and shall be validated.

Compliance is checked by assessment of the software life cycle PROCESS in accordance with IEC 62304:2006, 1.4 and assessment of the VALIDATION report provided by the MANUFACTURER.

5.3 USABILITY of non-implantable parts

5.3.1 USABILITY of non-implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE connected to or equipped with an electrical power source

The MANUFACTURER shall address in a USABILITY ENGINEERING PROCESS the RISK of poor USABILITY, including those associated with identification, MARKING, and documents.

Compliance is checked by assessment of the MANUFACTURER's documentation that the acceptance criteria of the USABILITY VALIDATION plan have been met (see IEC 62366:2007, 5.9).

5.3.2 USABILITY of non-implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE not connected to or equipped with an electrical power source

The non-implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall provide adequate USABILITY such that the RISKS resulting from CORRECT USE and USE ERRORS are acceptable.

Compliance is checked by assessment of the MANUFACTURER's documentation that the acceptance criteria of the USABILITY VALIDATION plan have been met (see IEC 62366:2007, 5.9).

5.4 Data security and protection from HARM caused by unauthorized information tampering

When communication with the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE through wireless communication channels is provided, the MANUFACTURER shall evaluate INFORMATION SECURITY through the RISK MANAGEMENT PROCESS and apply the appropriate RISK CONTROL measures to protect the patient from HARM.

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

5.5 General requirements for RISK MANAGEMENT

5.5.1 RISK MANAGEMENT policy

The MANUFACTURER shall define and document a policy for determining acceptable RISK and the acceptability of the RESIDUAL RISK(S) as required in ISO 14971.

Compliance is checked by inspection of the MANUFACTURER's policy for determining criteria for RISK acceptability.

5.5.2 Risk management file

The MANUFACTURER shall establish and maintain a RISK MANAGEMENT FILE complying with those requirements of ISO 14971 necessary to satisfy the requirements of this part of ISO 14708.

Compliance is checked by confirming the existence of an index containing references or pointers to the RISK MANAGEMENT documentation required by this part of ISO 14708.

5.5.3 Risk management plan

The MANUFACTURER shall establish and maintain a RISK MANAGEMENT PLAN complying with the relevant requirements of ISO 14971:2007 except those related to collection and review of production and post-production information. The RISK MANAGEMENT PLAN shall be part of the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the RISK MANAGEMENT PLAN.

5.5.4 Risk management process

For the purposes of this part of ISO 14708, the RISK MANAGEMENT PROCESS shall include the following elements:

a) RISK ANALYSIS;

b) RISK EVALUATION;

c) RISK CONTROL.

These elements of the RISK MANAGEMENT PROCESS shall be performed in accordance with ISO 14971.

Compliance is checked by confirming that the MANUFACTURER has a RISK MANAGEMENT policy conforming to 5.5.1 and has prepared the following for the particular ACTIVE IMPLANTABLE MEDICAL DEVICE under consideration:

— a RISK MANAGEMENT PLAN conforming to 5.5.3;

— a RISK MANAGEMENT FILE containing the RISK MANAGEMENT documentation required by this part of ISO 14708.

5.6 Misconnection of parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE

If misconnection presents an unacceptable RISK, the design and construction of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall prevent misconnection, unless it is not feasible, in which case appropriate MARKINGS, warnings, and instructions shall be provided.

Compliance is checked by inspection of the RISK ASSESSMENT and, if necessary, by inspection of the MARKINGS, warnings, and instructions.

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 can be specified in subsequent parts of ISO 14708.

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).

NOTE The NON-REUSABLE PACK is designed to be sealed yet allow its contents to be sterilized by the MANUFACTURER.

Compliance is checked by inspection.

7.2 The NON-REUSABLE PACK shall be enclosed in the SALES PACKAGING.

Compliance is checked by inspection.

8 General MARKINGS for ACTIVE IMPLANTABLE MEDICAL DEVICES

NOTE Any MARKING required by this part of ISO 14708, in either figures or letters, can be expressed using appropriate symbols specified in relevant International Standards, e.g. ISO 15223-1. (See also Clauses 4, 9, 11, and 13.)

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

Compliance is checked by inspection.

8.2 Implanted parts of ACTIVE IMPLANTABLE MEDICAL 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 an unacceptable RISK in connection with any implanted part.

Compliance is checked by inspection 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

NOTE The SALES PACKAGING can be required to carry other regulatory MARKINGS, such as the CE mark of conformity and identification of the notified body authorizing the mark.

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 is checked by inspection.

9.2 The SALES PACKAGING shall bear the name and full address of the MANUFACTURER.

Compliance is checked by inspection.

9.3 The SALES PACKAGING shall bear a description of the ACTIVE IMPLANTABLE MEDICAL DEVICE (e.g. cardiac pulse generator), the model designation, and, if applicable, the batch number or the serial number of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

Compliance is checked by inspection.

9.4 The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear relevant characteristics for its use.

Compliance is 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 is 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 8601:2004.

Compliance is checked by inspection.

9.7 The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear the "use by" date, expressed as year and month, and, if appropriate, day, in numerals as specified in ISO 8601:2004.

Compliance is 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 is 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 is 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 is checked by inspection.

9.11 The SALES PACKAGING shall bear information about any special 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 is checked by inspection.

9.12 The SALES PACKAGING shall, if applicable, bear an indication that the ACTIVE IMPLANTABLE MEDICAL DEVICE contains a MEDICINAL SUBSTANCE DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA.

Compliance is checked by inspection.

9.13 The SALES PACKAGING of an ACTIVE IMPLANTABLE MEDICAL DEVICE that is intended for a special purpose shall bear an indication of the special purpose (e.g. "custom-made device" or "exclusively for clinical investigations").

NOTE The specific MARKING can be the subject of particular national or regional regulation.

Compliance is checked by inspection.

9.14 In cases where the MANUFACTURER is required to designate an AUTHORIZED REPRESENTATIVE, the SALES PACKAGING shall bear the name and address of the AUTHORIZED REPRESENTATIVE.

This requirement does not apply to products not intended to be placed on the European Market.

Compliance is 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 dropping (shock), stacking (compression), vibration, and temperature that can occur during storage or handling as specified by the MANUFACTURER.

Compliance is checked by assessment 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: Humidity preconditioning treatment is performed in a humidity cabinet containing air with a relative humidity of 93 % ± 3 % where the SALES PACKAGE under test is located. The humidity conditions at other locations in the chamber may vary by ±6 %. The temperature of the air in the cabinet, at all places where the SALES PACKAGE can be located, shall be maintained within 2 °C of any convenient value T in the range of +20 °C to +30 °C. Before being placed in the humidity cabinet, the SALES PACKAGE is brought to a temperature between T and T + 4 °C, and kept at this temperature for at least 4 h before the humidity treatment starts.

Keep THE SALES PACKAGE in the humidity cabinet for 48 h.

After the treatment, the SALES PACKAGE is removed from the humidity cabinet and inspected.

Compliance is checked by inspection of the packaging, MARKINGS, LABELS, or accompanying documentation to determine if there is no visible deterioration.

10.3 The MARKINGS on the SALES PACKAGING of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be indelible.

Test: The package shall be placed so that the MARKINGS under test are uppermost and in a horizontal plane. 10 ml of water shall be dispensed onto the centre of the area. After 1 min, the MARKINGS shall be wiped clear of surface water using a wet, soft cloth.

Compliance is checked by inspection to determine that 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 documentation that defines the purposes and functions of the device and the conditions qualified and specified for its implantation.

Compliance is 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 the MANUFACTURER.

Compliance is checked by inspection.

11.2 The STERILE PACK shall bear a prominent indication that the contents of the package have been sterilized and the method of sterilization.

EXAMPLE 1 The method of sterilization along with the word "STERILE" or the sterile symbol: ISO 7000-2499 (see ISO 15223-1:2012, 5.2.1).

EXAMPLE 2 One of the "sterilized using..." symbols: ISO 7000-2501, ISO 7000-2502, or ISO 7000-2503 (see ISO 15223-1:2012, 5.2.3, 5.2.4, and 5.2.5).

Compliance is checked by inspection.

11.3 The STERILE PACK of an ACTIVE IMPLANTABLE MEDICAL DEVICE that is intended for a special purpose shall bear an indication of the special purpose as required by 9.13.

Compliance is 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 is checked by inspection.

11.5 The STERILE PACK shall bear the "use by" date, as required by 9.7.

Compliance is checked by inspection.

11.6 The STERILE PACK shall bear a description of the device, as required by 9.3.

Compliance is 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 is checked by inspection.

11.8 If the intended use of an ACTIVE IMPLANTABLE MEDICAL 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.

Compliance is checked by inspection.

11.9 The STERILE PACK shall bear instructions for opening the package.

Compliance is checked by inspection.

12 Construction of the NON-REUSABLE PACK

12.1 The NON-REUSABLE PACK shall comply with ISO 11607-1.

Compliance is checked by assessment of records provided by the MANUFACTURER.

12.2 The NON-REUSABLE PACK shall be designed such 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 is checked by inspection.

12.3 The MARKINGS on the NON-REUSABLE PACK shall be indelible.

Compliance is 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 legibly and indelibly bear at least the following particulars, where appropriate, in the form of generally recognized/harmonized symbols:

— the name or trade name of the MANUFACTURER;

— the model or the family name designation of the ACTIVE IMPLANTABLE MEDICAL DEVICE (see rationale for 13.1 in Annex A);

— if applicable, the batch number or serial number of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

Compliance is checked by inspection and, where appropriate, by a wet rub test.

Wet rub test: MARKINGS are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96 % and then for 15 s with a cloth rag soaked with isopropyl alcohol.

The MARKINGS shall 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.

13.2 Implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall contain MARKINGS with sufficient information to allow for positive identification at the time of implantation.

Compliance is checked by inspection.

13.3 The implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear, if feasible, a code by which they and their MANUFACTURER can be unequivocally identified (particularly with regard to the model of device and year of manufacture). It shall be possible to read this code, if necessary, without the need for a surgical operation.

Compliance is checked by inspection and/or by applying the procedure defined by the MANUFACTURER in the instructions for use (see 28.6).

13.4 When an ACTIVE IMPLANTABLE MEDICAL DEVICE or its parts bear instructions required for correct operation or indicate operating or adjustment parameters, by means of a visual system, such information

shall be understandable to the user with reference to the accompanying documentation, taking account of the training and knowledge of the user and, as appropriate, the patient.

Compliance is checked by inspection.

14 Protection from unintentional biological effects being 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 terminally sterilized. The sterilization PROCESS shall achieve the theoretical probability of there being a viable microorganism present on the content of the NON-REUSABLE PACK which shall be equal to or less than 10^{-6}.

Compliance is confirmed if the documentation and records provided by the MANUFACTURER demonstrate that the contents of the NON-REUSABLE PACK have been subjected to a validated sterilization PROCESS fulfilling the above-mentioned requirement.

NOTE Examples for terminal sterilization PROCESSES are described in ISO 11135-1, ISO 11137-1, ISO 11137-2, ISO 17665-1, or ISO 14937.

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 at time of implantation.

Compliance is checked by a suitable test method for collecting and counting surface-born particulate matter.

The following test for counting the number of particles of a particular size utilizes the light obscuration particle count test method. This method shall be used to resolve doubts or dispute.

NOTE 1 This test is intended to evaluate the ability of the part of the ACTIVE IMPLANTABLE MEDICAL DEVICE to be cleaned as well as the particulates that can be transferred to the part from its immediate packaging. It does not evaluate the particulates that might be generated during handling of the packaged part such as during transport and storage.

NOTE 2 The test is carried out under conditions limiting particulate contamination, preferably in a laminar-flow cabinet.

Preparation for the test: Prepare a supply of particle-free water by filtering purified water through a membrane with a pore size of 0,22 µm.

Prepare the necessary containers following good laboratory practice.

Testing of the particle-free water: Determine the particulate contamination in five samples of particle-free water, each of 5 ml, according to the method described below. If the number of particles of size 10 µm or greater exceeds 25 for the combined 25 ml, the precautions taken for the test are not sufficient. The preparatory steps shall be repeated until the environment, used equipment, and water are suitable for this test.

Testing of the container: Fill the container that will be used for extraction (containing the mechanism that is needed for agitation) with 200 ml of particle-free water. Determine the particle counts as described in the measurement section below. Take five samples of each 5 ml. Count the number of 10 µm or greater size particles in each of the five samples.

If the number of particles of 10 µm or greater size exceeds 25 for the combined 25 ml, the precautions taken for the test are not sufficient. The preparatory steps shall be repeated until the environment, glassware, and water are suitable for the test.

The results from this test of the container used, *B* will be subtracted from the results gained with the sample preparation.

The following are the conditions for the testing of extraction of particles from any parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE:

— extraction medium: particle-free water;

— extraction volume, *V*, in millilitres: surface of any parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE [cm^2] × (5 ± 0,5);

— extraction time: 8 h to 24 h at (37 ± 2)°C.

Aseptically remove the part of the ACTIVE IMPLANTABLE MEDICAL DEVICE from the NON-REUSABLE PACK.

Place the part of the ACTIVE IMPLANTABLE MEDICAL DEVICE in an appropriate particle-free container; add the appropriate volume of particle-free water; close the container and agitate the water to extract the particles under the conditions described in the list above.

Remove the part of the ACTIVE IMPLANTABLE MEDICAL DEVICE from the container after the extraction. After equilibration to ambient temperature, the extraction solution can be measured.

Measurement: Remove four portions from the extraction solution, each 5 ml, and count the number of particles with size equal to or greater than 10 µm and 25 µm. Disregard the result obtained for the first portion and calculate the mean number of particles for the extraction portion two to four, expressed as particles/ml, *A*.

Calculation:

$$P = \left(A - \frac{B}{25} \right) \cdot V \tag{1}$$

where

P is the number of particles of a particular size/part of an ACTIVE IMPLANTABLE MEDICAL DEVICE;

A is the average cumulative count [particles/ml];

B is the sum of particles in the container solution [particles/25 ml];

V is the volume of particle-free water, used for extraction [ml].

Where the above test method is used and where the part of the ACTIVE IMPLANTABLE MEDICAL DEVICE is intended for implantation in or access to the vascular system, then the following limits shall apply. Particle counts shall not exceed 6 000 particles equal to or greater than 10 µm and 600 particles equal to or greater than 25 µm.

Where the above situation does not apply, the MANUFACTURER shall conduct a RISK ASSESSMENT to determine appropriate count and size limits for particulates.

Different test methods might be suitable to determine the size and number of particles. The allowable quantity of particulate matter depends on a variety of factors, including chemical composition, potential toxicity, shape, size, and the test method chosen. AAMI TIR42 gives more guidance to determine methods and allowable quantities.

14.3 Parts of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to penetrate the body or intended to come into contact with biological tissues, cells, or body fluids shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

NOTE ISO 10993-9:2009 provides requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES that can generate degradation products as a result of mechanical wear, fatigue loading, or fractures.

Compliance is checked by assessment of the records provided by the MANUFACTURER that establish that the biocompatibility of the parts of ACTIVE IMPLANTABLE MEDICAL DEVICE 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 parts of ACTIVE IMPLANTABLE MEDICAL DEVICES; or

d) by compliance with published procedures for biological evaluation of parts of ACTIVE IMPLANTABLE MEDICAL DEVICES.

14.4 If the ACTIVE IMPLANTABLE MEDICAL DEVICE incorporates a MEDICINAL SUBSTANCE or a MEDICINAL SUBSTANCE DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA, that substance shall be both safe and beneficial to a declared function of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

Compliance is checked by assessment of the records provided by the MANUFACTURER that establish the safety and quality of the MEDICINAL SUBSTANCE or the MEDICINAL SUBSTANCE DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA has been verified by the appropriate methods.

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 9.3 of IEC 60601-1:2005 + A1:2012.

Compliance is 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 is 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 8.7 of IEC 60601-1:2005 + A1:2012.

Compliance is checked as specified in IEC 60601-1:2005 + A1:2012.

16.2 Except for its intended function, implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be electrically neutral when in contact with the body.

The direct current density at the surface of any conductive surface or electrode shall be ≤ 0,75 μA/mm^2.

Compliance is checked by assessment of the design analysis provided by the MANUFACTURER, supported by the MANUFACTURER'S calculations, and data from test studies as appropriate.

16.3 Insulating parts of implanted LEADS or of CATHETERS that incorporate electrical conductors and are subject to electrical potential differences shall withstand a dielectric strength test in which the applied voltage shall be no less than twice the peak voltage experienced by the part.

Test: The insulating parts of the implantable LEADS or CATHETERS that incorporate electrical conductors shall be preconditioned by total immersion in 9 g/l saline solution at 37 °C ± 5 °C for a minimum of 10 d.

After being rinsed with distilled water and being wiped free of surface water, the part shall be tested for its dielectric strength by the method specified by the MANUFACTURER.

Compliance is checked by inspection of the results provided by the MANUFACTURER.

17 Protection from HARM to the patient caused by heat

17.1 Protection from HARM to the patient caused by heat

In the absence of external influence, no outer surface of an implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE not intended to supply heat to the PATIENT 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 component failure (see 19.3).

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

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

17.2 Active implantable medical device intended to supply heat

For ACTIVE IMPLANTABLE MEDICAL DEVICES intended to supply heat to the patient, the clinical effect shall be determined and documented in the RISK MANAGEMENT FILE. The temperature and clinical effect shall be disclosed in the instructions for use.

Compliance is checked by assessment of the documentation in the RISK MANAGEMENT FILE that demonstrates the RESIDUAL RISK is acceptable.

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.

Compliance is checked by assessment 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 is checked by assessment of the documentation in the RISK MANAGEMENT FILE that demonstrates the RESIDUAL RISK is acceptable.

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 is checked by assessment of the 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 ACTIVE IMPLANTABLE MEDICAL DEVICE

NOTE See also 28.20.

19.1 During the lifetime of the implanted parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE as specified by the MANUFACTURER, any gradual, long-term changes in the materials chosen shall not result in an unacceptable RISK.

Compliance is checked by assessment of the records provided by the MANUFACTURER that establish that the RISK(s) resulting from the ageing of the ACTIVE IMPLANTABLE MEDICAL DEVICE are acceptable:

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 ACTIVE IMPLANTABLE MEDICAL DEVICES already on the market together with evidence of traceability to the materials used in those ACTIVE IMPLANTABLE MEDICAL DEVICES, or

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

19.2 If the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE contains within it a non-rechargeable source of power, such as a primary battery or pressure reservoir, the ACTIVE IMPLANTABLE MEDICAL DEVICE shall include an "elective replacement indicator" that gives an appropriate advance warning of energy source depletion causing the EOS of the ACTIVE IMPLANTABLE MEDICAL DEVICE. The MANUFACTURER shall define the interval (PSP) between the activation of this elective replacement indicator, which indicates the RRT, and the EOS of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

If the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE contains within it a rechargeable source of power, the MANUFACTURER shall provide information about recharging and replacement of the rechargeable source of power.

Compliance is checked by assessment of the 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, software of the ACTIVE IMPLANTABLE MEDICAL DEVICE, or software that falls within the definition of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall not result in an unacceptable RISK.

The RISK ANALYSIS of the failure of any single component or part, the RISK EVALUATION and any subsequent RISK CONTROL shall be carried out according to 5.5.4 and shall be documented in the RISK MANAGEMENT FILE.

The software of the ACTIVE IMPLANTABLE MEDICAL DEVICE or software that falls within the definition of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall comply with 5.2.

NOTE IEC 62304:2006, 4.2 requires application of a RISK MANAGEMENT PROCESS consistent with 5.5.4.

Compliance is checked by assessment of the documentation in the RISK MANAGEMENT FILE that demonstrates the RESIDUAL RISK is acceptable.

19.4 Possible side effects arising from the intended use of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall not result in an unacceptable RISK.

Side effects and benefits from the intended use of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall be identified either by reference to current medical practice and demonstrated by analogy, or by reference to clinical investigations concluded according to ISO 14155.

Compliance is checked by assessment of the MANUFACTURER'S documentation.

19.5 If the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE is intended to administer a MEDICINAL SUBSTANCE, then the parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE intended to come

in contact with the MEDICINAL SUBSTANCE shall be designed and manufactured in such a way as to be compatible with the MEDICINAL SUBSTANCE concerned.

Compliance is checked by assessment of the design analysis provided by the MANUFACTURER, supported by the MANUFACTURER'S calculations and data from test studies, as appropriate.

19.6 If an ACTIVE IMPLANTABLE MEDICAL DEVICE is intended to use a transcutaneous energy transfer system such a system shall not result in an unacceptable RISK.

Compliance is checked by assessment of the documentation in the RISK MANAGEMENT FILE that demonstrates the RESIDUAL RISK is acceptable.

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

NOTE See also 28.12.

20.1 The function of non-implantable parts of ACTIVE IMPLANTABLE MEDICAL DEVICES connected to electrodes shall be designed so that defibrillation of the patient will not permanently affect the ACTIVE IMPLANTABLE MEDICAL DEVICE, provided that the defibrillator electrodes do not come into direct contact with the electrodes.

Compliance is checked by inspection and by the testing as specified in 8.5.5 of IEC 60601-1:2005 + A1:2012.

20.2 Parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE with LEADS and electrodes and intended to be implanted in the torso shall be designed so that defibrillation of the patient will not permanently affect the implanted part, provided that the defibrillator electrode does not come into direct contact with the implanted part.

Test 1 and Test 2, as described below, shall be performed.

Test 1

Test equipment: Use a defibrillation test voltage generator providing a damped sinus waveform with the following characteristics:

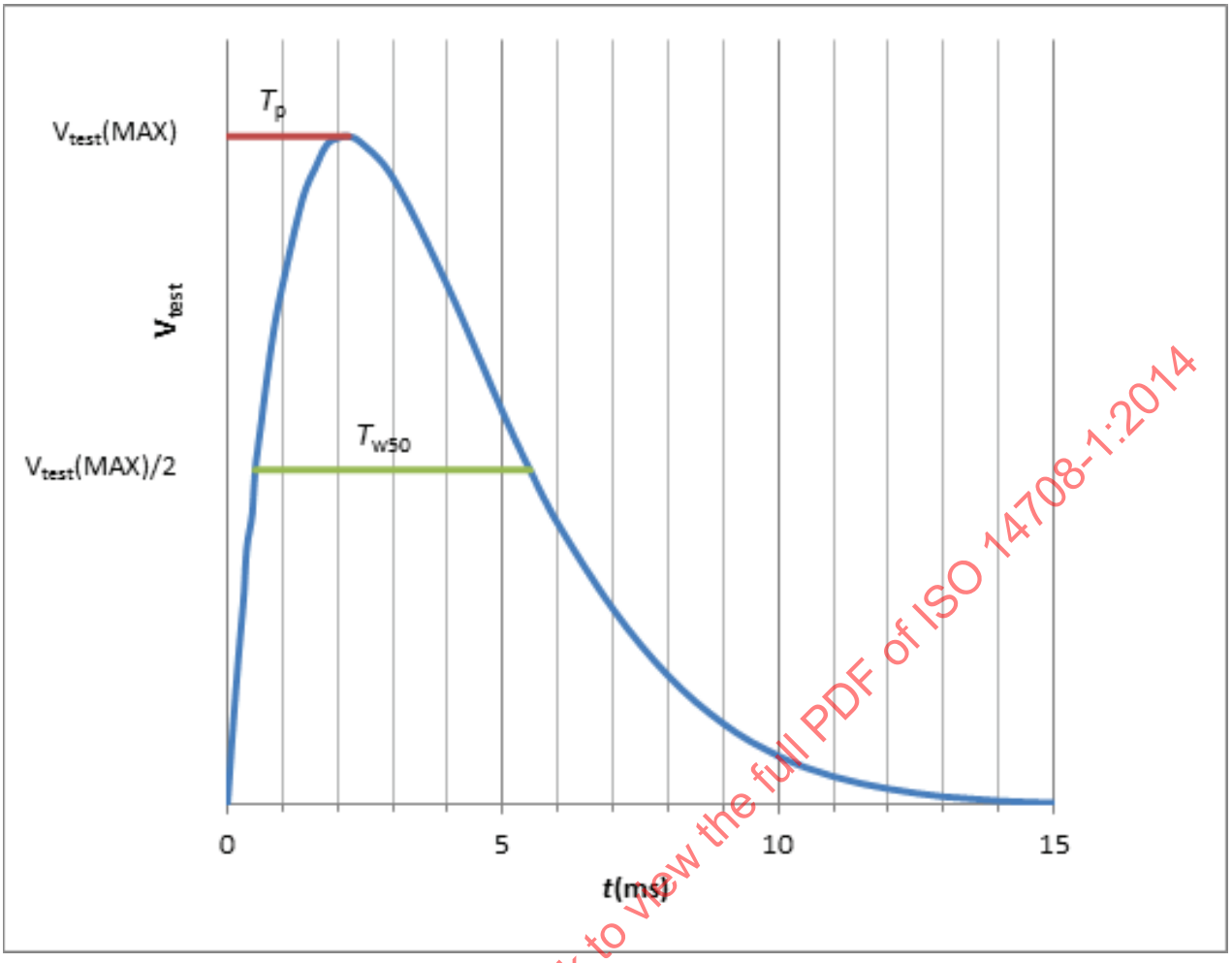
$$1{,}5\ \text{ms} < T_p < 2{,}5;\ 3\ \text{ms} < T_{w50} < 5{,}5\ \text{ms} \tag{2}$$

where

T_p designates the time interval from start of the damped sinus defibrillation waveform to the maximum value of Vtest (see Figure 1);

T_{w50} designates the time interval during which the test voltage is above the 50 % level of the maximum value of Vtest (see Figure 1);

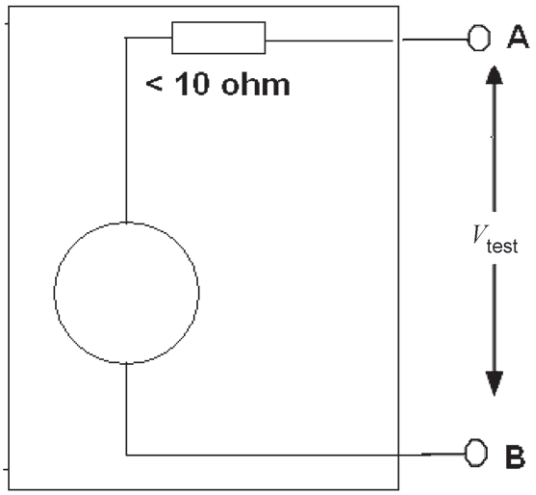
V_{test} is the damped sinus defibrillation waveform (see Figure 1).



NOTE A typical damped sinus defibrillation waveform is shown, which can be generated using a function generator or an RLC circuit as shown in Figure A.1.

Figure 1 — Damped sinus defibrillation waveform

Test procedure (Test 1): Adjust the maximum value of V_{test} to 140^{+7}_{0} V (see Figure 2). Identify each conducting part, other than a metallic case, that can come into contact with body tissue. Connect output A of the defibrillation test voltage generator through a (300 ± 15) Ω resistor to each of the conducting parts in turn, and connect output B of the defibrillation test voltage generator to the metallic case. If the case of the device is covered with an insulating material or is constructed of insulating material, immerse that case of the device in a metallic container filled with 9 g/l saline solution and connect the metallic container to output B.



NOTE The source impedance of the circuit shall be less than 10 Ω.

Figure 2 — Defibrillation test voltage generator

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 3).

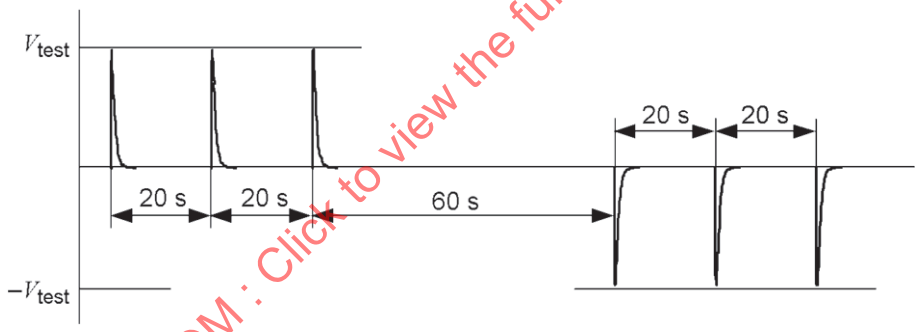


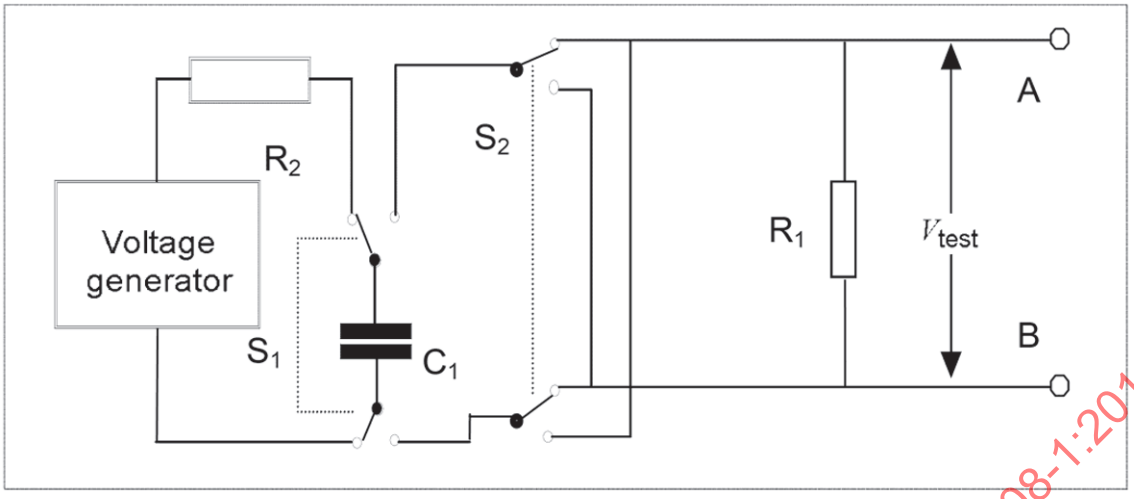
Figure 3 — Timing sequence used for Test 1 and Test 2

Test 2

Test equipment: A defibrillation pulse generator that produces a truncated exponential waveform with a pulse duration of (10 ± 0,5) ms. Figure 4 illustrates an example schematic of a defibrillation pulse generator for truncated exponential waveform with C_1 = (150 ± 50)μF, R_1 = 65 Ω, and two coupled switches S_1 and S_2.

A monophasic, truncated exponential waveform with duration of T_d = (10 ± 0,5) ms will be generated between output A and B by activating the coupled switches S_1 from left to right position during a time period of T_d.

A biphasic, truncated exponential waveform is accomplished by changing position of the coupled switches S_2 during the ongoing pulse after a time of $T_d/2$ [S_2 position altered after (5 ± 0,5) ms]. The initial position of the coupled switches S_2 determines the initial polarity of the output pulse.



NOTE R_2 is a protection resistor.

Figure 4 — Test setup for truncated exponential DEFIBRILLATION waveform

The timing parameters of the test voltage for the truncated exponential waveform shall be within the values shown in Table 1 (see also Figure 5).

Table 1 — Timing parameters of test signal for Test 2

Waveform	Pulse duration T_d	Rise time t_r	Fall time t_f	Commutation time t_c
Monophasic	9,5 ms < T_d < 10,5 ms	1 µs < t_r < 5 µs	1 µs < t_f < 5 µs	Not applicable
Biphasic	9,5 ms < T_d < 10,5 ms	1 µs < t_r < 5 µs	1 µs < t_f < 5 µs	$t_c \leq 2$ ms

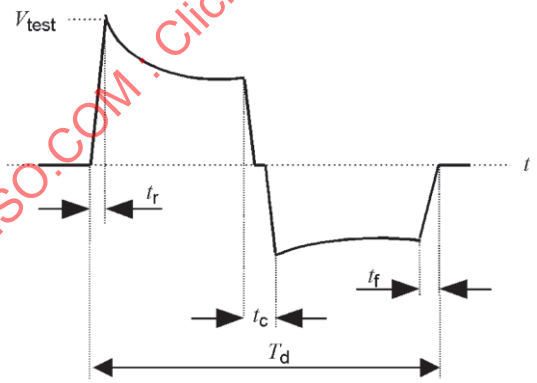


Figure 5 — Biphasic DEFIBRILLATION waveform for Test 2

Test procedure (Test 2): Adjust the maximum pulse amplitude of the defibrillation pulse (V_{test}) at the output of the defibrillation pulse generator to 140^{+7}_{0} V. Identify each conducting part, other than a metallic case, that can come into contact with body tissue. Connect output A of the defibrillation pulse generator through a (300 ± 15) Ω resistor to each of the conducting parts in turn and connect output B of the defibrillation pulse generator to the metallic case. If the case of the device is covered with an insulating material or is constructed of insulating material, immerse that case of the device in a metallic container filled with 9 g/l saline solution and connect the metallic container to output B.

Test each conducting part by applying a sequence of three monophasic 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 (for timing sequence, see Figure 3).

Repeat the test using biphasic voltage pulses.

Compliance is checked by assessment that the ACTIVE IMPLANTABLE MEDICAL DEVICE is not permanently affected and the settings are recoverable through reprogramming after performing the complete procedure (Test 1 and Test 2 above).

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

NOTE See also 28.12 and 28.13.

21.1 Implanted electrically conductive parts (of an ACTIVE IMPLANTABLE MEDICAL DEVICE) in contact with the body shall be constructed so that effects caused by known electrical treatment applied directly to the patient will not damage the ACTIVE IMPLANTABLE MEDICAL 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 is checked by assessment of the design analysis provided by the MANUFACTURER, supported by the MANUFACTURER'S calculations and data from test studies as appropriate.

The MANUFACTURER shall declare and provide information if a patient wearing an ACTIVE IMPLANTABLE MEDICAL DEVICE is contraindicated for known electrical treatments identified as having the potential to damage the ACTIVE IMPLANTABLE MEDICAL DEVICE (for example, application of diathermy).

Compliance is checked by inspection of the accompanying document (see 28.26).

21.2 Requirements for protection of particular ACTIVE IMPLANTABLE MEDICAL DEVICES susceptible to electrical fields applied directly to the patient are not detailed in this part of ISO 14708, but they can be specified in subsequent parts of ISO 14708.

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

NOTE See also 28.12, 28.14, and 28.15.

22.1 The implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE, other than LEADS and CATHETERS, shall be designed and constructed so that no irreversible change will be caused by exposure to diagnostic levels of ultrasonic energy.

Compliance is checked by the following test.

The implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall be immersed in a water bath at room temperature and subject to an acoustic field with the following properties at the surface of the implantable part:

— centre frequency: 3,5 MHz ± 0,175 MHz;

— duty cycle: 20 % ± 1 %;

— intensity (I_{SPTA}) ≥ A x 1 500 mW/cm^2.

NOTE 1 Specifications of the acoustic field refer to free-field measurements in water. Measurement of the acoustic field is made at the same position at which the implantable part will be placed for exposure. Terminology and acoustic measurement procedures are explained in IEC 62127–1.

The attenuation factor, A, is used to adjust the beam intensity in recognition of the fact that the implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE can reside in different locations of the body and at various implant depths. The MANUFACTURER shall establish and document in the RISK MANAGEMENT FILE the minimum implant depth d (expressed in cm) according to the intended use of the device(s) under test. The attenuation factor is then calculated using Formula (3):

$$A = 10^{-(d x 0{,}189)} \tag{3}$$

NOTE 2 This factor uses the attenuation value of 0,54 dB/(cm-MHz) for average soft tissue at a frequency of 3,5 MHz according to Reference [19].

The MANUFACTURER may optionally choose to set A = 1, in which case a minimum implant depth, d, does not need to be established.

The implantable part shall be positioned so that the beam axis of the acoustic field is perpendicular to the largest surface area of the implantable part. This surface shall be positioned at the plane of maximum intensity within the beam.

The beam cross-sectional area shall expose the surface to be tested for duration of at least 3 min at any position on the surface. The beam cross-sectional area is to be determined as the area on the surface of a plane perpendicular to the beam axis consisting of all points where the beam intensity is reduced by ≤ 12 dB from the beam spatial peak within the plane of measurement.

NOTE 3 In most situations, the –12 dB beam cross-sectional area will be smaller than the largest surface area of the device to be tested. In this case, either the beam or the implantable part under test can be scanned transverse to one another to expose the entire device surface. In such cases, total test time for the selected surface can be significantly longer than 3 min.

Repeat the test for all other major surfaces of the implantable part.

NOTE 4 Many ACTIVE IMPLANTABLE MEDICAL DEVICES are contained in flattened metal cases ("cans") with two primary faces. Such an implanted part would be simply flipped over and the testing repeated. Implanted parts with multiple major facets would require testing of each facet.

After completion of the test, there shall be no irreversible damage to the implantable part.

22.2 The manufacturer shall declare and provide information if and under which conditions a patient wearing an active implantable medical device can undergo an MRI procedure without exposing the patient to unacceptable risk (see 28.12 and 28.13).

NOTE A Technical Specification (ISO/TS 10974) in the field of ACTIVE IMPLANTABLE MEDICAL DEVICE and magnetic resonance (MR) compatibility has been developed.

23 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces

23.1 Non-implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE that are either HAND-HELD in NORMAL USE or PORTABLE shall be constructed so that shocks caused by mishandling or dropping while in use do not damage the ACTIVE IMPLANTABLE MEDICAL DEVICE.

Test: HAND-HELD or PORTABLE parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall withstand the free-fall test in accordance with 15.3.4.1 and 15.3.4.2 of IEC 60601-1:2005 + A1:2012.

Following the test, the non-implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall operate as stated in the MANUFACTURER'S specification.

Compliance is checked by functional test.

23.2 Implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE or patient-carried parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE, other than LEADS or CATHETERS, shall be constructed to withstand the mechanical forces which might occur during normal conditions of use, including the time prior to implant.

Test: The implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE or patient-carried part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, mounted in accordance with the requirements and guidance given in IEC 60068-2-47:2005, shall withstand a random vibration test in accordance with IEC 60068-2-64:2008, Test Fh, under the following conditions:

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

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

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

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

Following the test, the implantable part or patient-carried part of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall operate as stated in the MANUFACTURER'S specification.

Compliance is checked by functional test.

23.3 Implantable LEADS or CATHETERS shall withstand the tensile forces that might occur during or after implantation or replacement of the device to which they are connected, without fracture of any conductor or cracking of either any functional electrical insulation or of the body of the LEAD or CATHETER.

Compliance is checked by assessment of the 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 is checked by assessment of the design analysis provided by the MANUFACTURER, 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 is checked by assessment of the 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 connect implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE, shall be identified. The MANUFACTURER shall declare (see 28.4) the intended performance as implanted. The quality of connection shall not degrade during use. Re-connection shall be possible without a degradation in the performance of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

Compliance is checked by assessment of the design analysis provided by the MANUFACTURER, supported by the MANUFACTURER'S calculations and data from test studies, as appropriate.

23.7 The implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE, other than LEADS or CATHETERS, shall be constructed so that minor mechanical shocks caused by mishandling during the implant procedure do not damage the implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

Test: The implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, other than a LEAD or CATHETER, shall withstand the mechanical shock test in accordance with IEC 60068-2-27:2008, test Ea, under the following conditions:

a) shock shape: half sine or haversine;

b) severity: peak acceleration: 5 000 m/s^2 (500 g);

c) duration of shock: 1 ms;

d) direction and number of shocks: one shock in each direction along three mutually perpendicular axes (total of six shocks).

Following the test the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall operate as stated in the MANUFACTURER'S specification.

Compliance is checked by functional test.

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

24.1 The ACTIVE IMPLANTABLE MEDICAL DEVICE shall be designed and constructed so that no irreversible change will be caused by an electrostatic discharge applied to the electrically powered non-implantable parts.

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

Test: The ACTIVE IMPLANTABLE MEDICAL DEVICE shall be set to function according to the MANUFACTURER'S instructions.

The non-implantable part shall be exposed to the electrostatic charge test as referenced in Clause 17 of IEC 60601-1:2005 + A1:2012.

Following the test, the ACTIVE IMPLANTABLE MEDICAL DEVICE shall operate in a safe mode which does not result in an unacceptable RISK, and it can be reset to provide all functions as stated in the MANUFACTURER'S specification.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and functional test.

24.2 Requirements for protection of particular ACTIVE IMPLANTABLE MEDICAL DEVICES susceptible to damage caused by electrostatic discharge are not detailed in this part of ISO 14708, but they can be specified in subsequent parts of ISO 14708.

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

25.1 Implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be constructed to withstand the changes of pressure which can occur during transit or normal conditions of use.

Compliance is checked by assessment of the data provided by the MANUFACTURER investigating the effects of deformation due to absolute pressures at 70 kP ± 3,5 kP and 150 kP ± 7,5 kP applied for not less than 1 h.

25.2 Requirements for protection of particular ACTIVE IMPLANTABLE MEDICAL DEVICES susceptible to damage caused by atmospheric pressure changes are not detailed in this part of ISO 14708, but they can be specified in subsequent parts of ISO 14708.

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

26.1 For electrically powered non-implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE, see 5.1.

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 can 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 60068-2-14:2009, test Nb, under the following conditions:

a) where the MANUFACTURER specifies a specific low or high temperature value, use this value;

b) in the absence of a MANUFACTURER's specification, the low temperature value is –10 °C ± 3 °C and the high temperature value is 55 °C ± 2 °C;

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

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. See 28.22.

Following the test, the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall operate as stated in the MANUFACTURER'S specification.

Compliance is checked by functional test.

27 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from electromagnetic non-ionizing radiation

27.1 Implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall not result in an unacceptable RISK because of susceptibility to electrical influences due to external electromagnetic fields, whether through

— malfunction,

— damage,

— heating, or

— by causing local increase of induced electrical current density within the patient.

Assessment: RISKS shall be identified, taking into account the electromagnetic environment in which implantable and patient-carried parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE are intended to be used. Each RISK shall be evaluated through a design analysis that takes account of any RISK CONTROL according to 5.5.4. The design analysis shall be supported by test studies, as appropriate. Due to the wide variety of functional configurations and electrical interfaces that are present among ACTIVE IMPLANTABLE MEDICAL DEVICES, specific methods to carry out test studies are not provided in this part of ISO 14708. These methods can be found in other parts of ISO 14708 covering particular devices.

When implantable and patient-carried parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE are intended to be used outside the clinical environment, the foreseeable electromagnetic environment can be derived from the European Council Recommendation 1999/519/EC, which was based on the recommendation for General Public of the ICNIRP Guidelines 1998.

The EU Recommendation provides exposure values for continuous whole body exposures called General Public Reference Levels, which are defined as field strength. The operation of implantable and patient-carried parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE should not be influenced by field levels up to these General Public Reference Levels. Exceptions shall be declared (see 28.22).

The EU Recommendation also provides Basic Restrictions, which are defined in ICNIRP Guidelines 1998 as induced current density in the body tissue and correspond to local field strength above the General Public Reference Levels. Short-term exposure to fields associated with the Basic Restrictions shall not damage the implantable and patient-carried parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE

and the implantable and patient-carried parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE shall maintain the functionality as specified by the MANUFACTURER. The RESIDUAL RISKS shall be declared (see 28.22).

NOTE If the ACTIVE IMPLANTABLE MEDICAL DEVICE includes a LEAD, the strength of some fields above the general public reference levels might cause unforeseen adverse biological effects, such as thermal damage to the tissue, induced fibrillation, or nerve stimulation due to the currents induced in the LEAD, which are not covered in this Clause.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

27.2 Requirements for protection of particular ACTIVE IMPLANTABLE MEDICAL DEVICES from electromagnetic non-ionizing radiation are not detailed in this part of ISO 14708, but they can be specified in subsequent parts of ISO 14708.

28 Accompanying documentation

NOTE 1 The accompanying documentation can be required to carry other regulatory MARKINGS, such as the CE mark of conformity, year of fixation of the CE mark, and identification of the notified body authorizing the mark.

NOTE 2 The accompanying documentation can include items such as instructions for use, physicians manual, patient handbook, and patient ID card.

28.1 The accompanying documentation shall include the name and full address of the MANUFACTURER.

Compliance is 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 is checked by inspection.

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

Compliance is 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 accessory, the accompanying documentation shall provide information on the connector specifications, assembly instructions and connector performance determined according to 23.6.

Compliance is checked by inspection.

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

Compliance is 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 is checked by inspection.

28.7 If applicable, the accompanying documentation shall include information regarding the MEDICINAL SUBSTANCES which the ACTIVE IMPLANTABLE MEDICAL DEVICE is designed to administer.

NOTE This subclause does not apply to any MEDICINAL SUBSTANCE which forms an integral part of the ACTIVE IMPLANTABLE MEDICAL DEVICE (see also 14.4).

Compliance is checked by inspection.

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

Compliance is checked by inspection.

28.9 The accompanying documentation shall provide information allowing the physician to select a suitable ACTIVE IMPLANTABLE MEDICAL DEVICE, related devices and accessories (e.g. a programmer).

Compliance is 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 ACTIVE IMPLANTABLE MEDICAL DEVICE correctly.

Compliance is checked by inspection.

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

Compliance is checked by inspection.

28.12 The accompanying documentation shall contain warnings regarding the known HAZARDS caused by reciprocal interference between the ACTIVE IMPLANTABLE MEDICAL DEVICE and other medical equipment likely to be used in the course of other clinical procedures or medical treatments.

Examples of such medical treatments are referred to in Clause 22.

Compliance is checked by inspection.

28.13 The accompanying documentation shall contain warnings of known medical treatments where an electrical current conducted or induced into the body from an external source that are contraindicated for patients with an ACTIVE IMPLANTABLE MEDICAL DEVICE.

For medical treatments where an electrical current conducted or induced into the body from an external source that are not contraindicated, the accompanying documentation shall include either

— actions or programmed settings necessary for the ACTIVE IMPLANTABLE MEDICAL DEVICE, or

— instructions to monitor the functioning of the ACTIVE IMPLANTABLE MEDICAL DEVICE during the initial stages of medical treatment.

Examples of such medical treatments are referred to in 20.2, 21.1, and 22.2.

Compliance is checked by inspection.

28.14 The accompanying documentation shall contain a warning that implanted parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE should not be exposed to therapeutic levels of ultrasound energy, as the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE can inadvertently concentrate the ultrasound field and cause HARM.

Compliance is checked by inspection.

28.15 If appropriate, the accompanying documentation shall contain a warning that electronic components in an ACTIVE IMPLANTABLE MEDICAL DEVICE can be damaged by therapeutic ionizing radiation,

and warn that any damage to the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE might not be immediately detectable.

Compliance is 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 and method of sterilization.

Compliance is checked by inspection. (See also Clause 11).

28.17 If appropriate, instructions shall be included 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 is checked by inspection.

28.18 If appropriate, the accompanying documentation shall contain 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 implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE can be reused only if it is reconditioned under the responsibility of a MANUFACTURER.

Compliance is checked by inspection.

28.19 If the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE contains an energy source, the accompanying documentation shall include

— the characteristics of the energy source, and

— information about the lifetime of the energy source when adjusted to the nominal and worst case settings specified by the MANUFACTURER.

Compliance is 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 is checked by inspection.

28.21 The accompanying documentation shall include information about any special 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 9.11).

Compliance is checked by inspection.

28.22 The accompanying documentation shall declare exceptions from the requirements of 27.1 and 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 is checked by inspection.

28.23 The accompanying documentation shall include advice that the patient bearing an ACTIVE IMPLANTABLE MEDICAL DEVICE 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 preventing entry by patients.

Compliance is checked by inspection.

28.24 If appropriate, the instructions for use shall provide warnings and instructions how to prevent misconnections.

Compliance is checked by inspection.

28.25 The instructions for use shall contain the date of issue or an indication of the latest revision.

Compliance is checked by inspection.

28.26 The MANUFACTURER shall declare and provide information if a PATIENT wearing an ACTIVE IMPLANTABLE MEDICAL DEVICE is contraindicated for a medical procedure using effects caused by electrical fields (for example, application of diathermy).

Compliance is checked by inspection.

28.27 The accompanying documentation of an ACTIVE IMPLANTABLE MEDICAL DEVICE that is intended for a special purpose shall include an indication of the special purpose (e.g. "custom-made device" or "exclusively for clinical investigations").

Compliance is checked by inspection.

28.28 If applicable, the accompanying documentation of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall include an indication that the device contains a MEDICINAL SUBSTANCE DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA.

Compliance is checked by inspection.

28.29 If applicable, the accompanying documentation shall include instructions for the proper removal and disposal for the ACTIVE IMPLANTABLE MEDICAL DEVICE.

Compliance is checked by inspection.

28.30 In cases where the MANUFACTURER is required to designate an AUTHORIZED REPRESENTATIVE, the accompanying documentation shall include the name and address of the AUTHORIZED REPRESENTATIVE.

Compliance is checked by inspection.

Annex A
(informative)

General guidance and rationale

A.1 General

This part of ISO 14708 attempts to quantify the fundamental principles of ISO/TR 14283:2004. In many clauses, this part of ISO 14708 does this by detailing a particular aspect of the fundamental principles and specifying an assessment procedure or test.

For some HAZARDS, this part of ISO 14708 prescribes specific requirements along with compliance measures (e.g. leakage current levels) which, if met, would satisfy an aspect of the fundamental principles of ISO/TR 14283:2004. Compliance is then determined by assessment 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 ensure the performance of the device after several years' implantation. This part of ISO 14708 then requires the MANUFACTURER to prepare documented studies suitable for expert assessment.

A.2 Rationale for specific subclauses

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 and subclauses 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 MARKINGS on the outside of the SALES PACK, then the construction of the SALES PACK, and so on, to tests on the device, and finally to checks of the accompanying documentation.

5.2 Software of an ACTIVE IMPLANTABLE MEDICAL DEVICE should be developed according to the principles of the software lifecycle PROCESS. Thereby, software can be validated as integral part of the ACTIVE IMPLANTABLE MEDICAL DEVICE-system or as standalone software. Software which is not an integral part of an ACTIVE IMPLANTABLE MEDICAL DEVICE, but which is needed for programming, diagnosing, or therapy planning in close connection with the use of an ACTIVE IMPLANTABLE MEDICAL DEVICE, can be considered as an ACTIVE IMPLANTABLE MEDICAL DEVICE standalone software. In these cases, the standalone software would be considered as a kind of an accessory to the ACTIVE IMPLANTABLE MEDICAL DEVICE. The level of VALIDATION for software can vary according to its complexity. The software of the ACTIVE IMPLANTABLE MEDICAL DEVICE can be validated using the clauses of IEC 62304 as an integral component of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

5.3 When investigating the USABILITY of an ACTIVE IMPLANTABLE MEDICAL DEVICE system, different users (e.g. patients, physicians, nurses, etc.) and environments should be considered.

5.4 New wireless communication technologies used in connection with the ACTIVE IMPLANTABLE MEDICAL DEVICE create the RISK of unauthorized access to the ACTIVE IMPLANTABLE MEDICAL DEVICE

system. It is necessary to protect the ACTIVE IMPLANTABLE MEDICAL DEVICE and the data stored in the ACTIVE IMPLANTABLE MEDICAL DEVICE against accidental corruption or intentional attacks.

This subclause considers HARM to the patient through direct or indirect means, including irreversible damage to the ACTIVE IMPLANTABLE MEDICAL DEVICE which indirectly causes HARM to the patient. An example of this would be irreversible damage to the ACTIVE IMPLANTABLE MEDICAL DEVICE that would likely result in the replacement of the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

5.5 This subclause specifies the elements of the RISK MANAGEMENT PROCESS that are required for compliance with this part of ISO 14708. Although the elements of the RISK MANAGEMENT PROCESS specified in this part of ISO 14708 are required to comply with the relevant requirements of ISO 14971, the RISK MANAGEMENT PROCESS specified in this part of ISO 14708 is not as extensive as, and does not include all of the elements required for compliance with, ISO 14971. For example, the RISK MANAGEMENT PROCESS required for compliance with this part of ISO 14708 does not include the production and post-production monitoring required in ISO 14971. Furthermore, verification of compliance with the RISK MANAGEMENT requirements of this part of ISO 14708 can be carried out by examining the documentation required by this part of ISO 14708 and does not require auditing of the RISK MANAGEMENT PROCESS.

5.6 In particular, in the case where the connection between different components of an ACTIVE IMPLANTABLE MEDICAL DEVICE system has to be made during the implantation of an ACTIVE IMPLANTABLE MEDICAL DEVICE, it is necessary to find constructive solutions (such as coding of colours or dimensions) to minimize the RISK of misconnections or incorrect (e.g. too weak) connections.

7.1 According to 4.2.3 of ISO/TR 14283:2004, 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.

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

8.2 If failures occur in some samples of the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE, it might become apparent that action has to be taken to prevent HARM to patients with similar devices. The patients involved have to be precisely identified if unnecessary medical procedures are to be avoided. This requires precise identification of both the implantable parts and their component parts, without the need to explant devices. Correct identification of components can depend on the MANUFACTURER maintaining systematic records. Guidance on one approach to record-keeping is provided by ISO 13485.

9 In general, MARKINGS on the SALES PACKAGING should be restricted to avoid nonessential information reducing the clarity of the essential data required by this part of ISO 14708.

9.1 Packages containing a RADIOACTIVE SUBSTANCE can be subject to additional specific regulatory controls.

9.2 If the MANUFACTURER is not located in the European Union or in a country where relevant mutual recognition agreements with the European Union already exist, the requirement of 9.14 also has to be fulfilled.

9.4 It might be that the information specifically required on the SALES PACKAGING by other subclauses is insufficient to identify and characterize the device.

9.6 The year-month-date format has been widely accepted for ACTIVE IMPLANTABLE MEDICAL DEVICES. ISO 8601 established a date format that is internationally accepted.

9.7 For some parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE, such as implantable parts that contain a power source, a use-before date consisting of a year and month might not provide sufficient granularity. In such cases, a day of the month might be appropriate.

9.8 It should not be necessary to open the SALES PACKAGING 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 SALES PACKAGING, 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.

9.13 The SALES PACKAGING needs to indicate clearly if the ACTIVE IMPLANTABLE MEDICAL DEVICE is intended for a special purpose, such as a clinical investigation, and might not be suitable for use with the general patient population.

9.14 This requirement is applicable for devices intended to be distributed in the European Union market if the MANUFACTURER is not located in the European Union or in a country where a relevant agreement with the European Union exists. Several regions in the world require the conformity of MEDICAL DEVICES with the European regulation as a tool for entry into their markets. Since the address of the European AUTHORIZED REPRESENTATIVE is only relevant for the European market, it should be possible that devices on these non-European Union markets not bear the name of the AUTHORIZED REPRESENTATIVE. However, there is a certain RESIDUAL RISK that devices from these markets could reach the European market without knowledge of the MANUFACTURER. This could create problems for the MANUFACTURER.

10.1 The SALES 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 5.7 of IEC 60601-1:2005 + A1:2012.

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 7.1.3 of IEC 60601-1:2005 + A1:2012.

10.4 It is a fundamental principle that the ACTIVE IMPLANTABLE MEDICAL 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 reducing the clarity of the essential data required by this part of ISO 14708.

11.2 It is necessary for the user to be able to recognize that the contents of the STERILE PACK were terminally sterilized and satisfied the requirement of 14.1 when placed on the market. The user also needs to understand the method that the MANUFACTURER used to sterilize the contents. Symbols have been developed for the most common terminal sterilization PROCESSES listed in the Note in 14.1. The MANUFACTURER can use these harmonized symbols to satisfy this MARKING requirement and avoid the need to translate the description of the method of sterilization into local language.

11.3 The STERILE PACK needs to clearly indicate if the ACTIVE IMPLANTABLE MEDICAL DEVICE is intended for a special purpose, such as a clinical investigation, and might not be suitable for use with the general patient population.

11.4 The year-month-date format has been widely accepted for ACTIVE IMPLANTABLE MEDICAL DEVICES. ISO 8601 established a date format that is internationally accepted.

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 STERILE PACK is left open for an undue period before implantation, the device might be subject to contamination or damage.

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

ISO 11607-1 is the generic standard for packaging sterile products.

13.1 This MARKING provides identification of the ACTIVE IMPLANTABLE MEDICAL DEVICE on explant. Some implantable parts might be too small to carry all this information. Some accessories (for example, associated tools) might not need the model or family name designation or a batch or serial number.

There are many market-released ACTIVE IMPLANTABLE MEDICAL DEVICE models. Typically, the feature set of the ACTIVE IMPLANTABLE MEDICAL DEVICE has more value to a physician than the model number. For some ACTIVE IMPLANTABLE MEDICAL DEVICES, family name might be a better descriptor of the feature set than the model number. In addition, ACTIVE IMPLANTABLE MEDICAL DEVICES can be upgradable after implant. The behaviour of these ACTIVE IMPLANTABLE MEDICAL DEVICES can be modified by downloadable firmware. In this case also, the family name on the ACTIVE IMPLANTABLE MEDICAL DEVICE can be a more accurate description of the implanted device than a model number.

The MARKINGS on an ACTIVE IMPLANTABLE MEDICAL DEVICE are frequently etched or moulded into the device. The wet rub test is inappropriate for such MARKINGS. However, in some instances (e.g. for some accessories) the MARKINGS might be printed on the device or affixed with an adhesive label. In such instances, the web-rub test is appropriate to demonstrate that the MARKINGS will remain clearly legible and any adhesive LABELS do not loosen or curl at the edges. The wet rub test is adapted from the test in 7.1.3 of IEC 60601-1:2005 + A1:2012.

13.2 The MARKINGS on the implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE are used by a physician just prior to implant to check that the implantable part is, in fact, the correct and desired part.

13.3 This subclause addresses the concern expressed by 4.7.3 of ISO/TR 14283:2004 that the implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE should be identifiable without performing a surgical operation. The present state of the art is to identify the MANUFACTURER and model with radio-opaque symbols. This can be easily done for parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE of sufficient size. In practice, it might not be feasible to suitably mark small implantable parts because the radio-opaque symbol itself would be so small as to make reading it on an X-ray image highly problematic.

Implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE that have telemetry should enable the implant to transmit the appropriate information such as the serial number or date of manufacture. Reading the radio-opaque symbols should enable the user to select a suitable telemetry device.

13.4 If each ACTIVE IMPLANTABLE MEDICAL DEVICE is to be used safely, giving appropriate credit to the training and knowledge of the potential user, then it has to be accompanied by key information. As far as practicable and appropriate, the information needed to use the ACTIVE IMPLANTABLE MEDICAL DEVICE safely should be set out on the ACTIVE IMPLANTABLE MEDICAL DEVICE itself. Where appropriate, this information should take the form of symbols, but any symbols and identification colours should conform with harmonized International Standards. If no standards exist, the symbols and colours should be described in the documentation supplied with the ACTIVE IMPLANTABLE MEDICAL 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 specified requirement that an implanted part of an ACTIVE IMPLANTABLE MEDICAL DEVICE does not introduce infective agents into the body, there should be no unnecessary introduction of loose particulate matter ("sterile dirt").

For equipment not intended to be implanted in contact with flowing blood, RISK ANALYSIS, design analysis, test studies, or other appropriate means can be used to evaluate the HAZARD caused by particulate matter based on the location of implant and define the requirements for particulate matter.

A method is to be chosen so that meaningful quantitative limits can be set for assessing the results of the test.

AAMI TIR42:2010 is intended to assist vascular medical device MANUFACTURERS in determining the source of particulates, establishing product particulate limits, defining appropriate test methods, and assessing the clinical relevance of particulate contamination and may be a good source for these test methods.

Although the AAMI TIR42:2010 does not set acceptance criteria for the different methods, it refers to the US Pharmacopoeia (USP) < 788 > as one possible source for count limits for small volumes.

The test method and the acceptance criteria in 14.2 of this part of ISO 14708 are derived from the US Pharmacopoeia (USP) < 788 >. That general chapter is harmonized with the European and Japanese Pharmacopoeia.

14.3 The ISO 10993 series describes methods, materials and procedures to investigate the biocompatibility of MEDICAL DEVICES. Biological tests covering the implant lifetime of the device are impracticable. Experience with similar devices is likely to be restricted by the small available target population and the relatively low incidence of the target pathology. Documented evidence exists for materials in common use, but experience has proved that changes in surface treatments or changes in handling the device during manufacture can sometimes be significant.

14.4 In cases of a combination product (ACTIVE IMPLANTABLE MEDICAL DEVICE with an ancillary MEDICINAL SUBSTANCE) the European Directive 90/385/EEC requires a consultation process between the Notified Body performing the conformity assessment and the European Medicine Agency (EMEA) or a national competent authority (NCA) on the quality and safety of the medicinal product. The NCA or the EMEA should provide their opinion within 210 days. The Notified Body has to take the opinion/recommendation of the NCA or EMEA into consideration. The Notified Body has to inform the EMEA or NCA about their final decision.

In cases of a combination product (ACTIVE IMPLANTABLE MEDICAL DEVICE with an ancillary MEDICINAL SUBSTANCE DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA) the European Directive 90/385/EEC requires a consultation process between the Notified Body performing the conformity assessment and the EMEA on the quality and safety of the medicinal product. The EMEA should provide their opinion within 210 days. The Notified Body has to take the opinion/recommendation of the EMEA into consideration. The Notified Body has to inform the EMEA about their final decision.

16.2 Unbalanced or monopolar currents flowing through implanted electrodes can result in several HAZARDS. These include corrosion, release of degradation products, and long-term destruction of tissue. The corrosion of the electrode surface is in the form of oxidation and dissolution (especially when non-noble metal is used as the electrode material). MANUFACTURERS should evaluate the risk of material degradation.

Steady-state DC current can cause destruction of tissue. A study conducted by Hurlbert et al.[26] demonstrated that mammalian central nervous system can tolerate chronic steady-state DC currents in the order of 75 μA/cm^2. Work by Mortimer[27] and Scheiner[28] indicates muscle tissue can safely tolerate DC leakage of up to 1 000 μA/cm^2.

Hurlbert et al.[26] conducted their experiments using platinum/iridium electrodes with a surface area of 2 mm^2 implanted in rat spinal cords. They concluded that maximum current density tolerated by the rodent spinal cord is in the order of 75 μA/cm^2, and this did not result in any pathological changes.

16.3 Electrical insulation has to be adequate even though the insulator can 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 can specify other compliance tests.

17.1 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 part of an ACTIVE IMPLANTABLE MEDICAL DEVICE requires significant power dissipation from common implantable energy sources. More complex test methodologies and protection mechanisms might be required if the implanted energy 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 implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE under specific operating or fault conditions will depend on the patient's own body temperature, which is the ambient temperature for the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE. The temperature limit set by this part of ISO 14708 is lower than the relevant limit in IEC 60601-1:2005+A1:2012 because of the increased difficulty of taking corrective action when the source of heat is implanted.

This subclause addresses the temperature rise of the outer surface of the implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE when in normal operation and single-fault condition. It does not address the temperature rise of any part of the ACTIVE IMPLANTABLE MEDICAL DEVICE during exposure to a medical procedure, such as MRI, or charging of rechargeable implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

18.1 to **18.3** In Europe, ACTIVE IMPLANTABLE MEDICAL DEVICES that contain RADIOACTIVE SUBSTANCES are required to comply with 96/29/Euratom and 97/43/Euratom. The requirements of this part of ISO 14708 are intended to be consistent with those European Directives.

19.1 Most ACTIVE IMPLANTABLE MEDICAL DEVICES are designed to be implanted for 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 might be 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

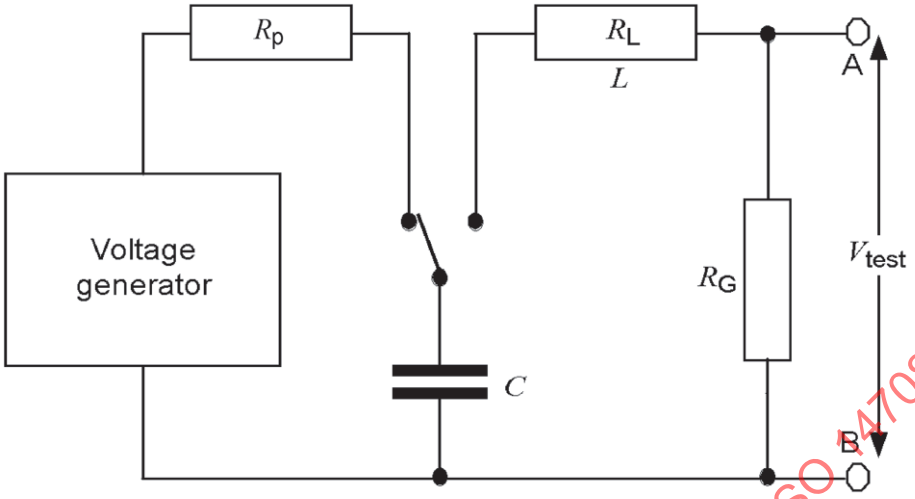
b) it is possible with a reasonable degree of assurance to extrapolate from the accelerated environment to the conditions of use.

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 should 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 source of power of an ACTIVE IMPLANTABLE MEDICAL DEVICE does not cause it to cease functioning without previous warning. The MANUFACTURER needs to define the PSP with regard to the use case of the ACTIVE IMPLANTABLE MEDICAL DEVICE.

19.4 Safety testing of an ACTIVE IMPLANTABLE MEDICAL DEVICE frequently involves bench testing. However, the evaluation of possible side effects generally involves collecting and evaluating clinical data. This data can come from relevant scientific literature currently available relating to the safety, performance, design characteristics, and intended use of the device or from clinical investigations involving human subjects. Some traditional pharmaceutical clinical investigation criteria might 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 Figure A.1 illustrates an example schematic of an RLC implementation of a defibrillation test voltage generator, where R_L is the resistance of the inductance (L) and R_G is the defibrillation test voltage generator output resistance. Ensure that the inductor is not magnetically saturated during the pulse.



C = 330 µF, L = 13,3 mH, R_G = 12 Ω, and R_p is any value to protect the circuit.

NOTE Component values are recommendations to achieve the specified waveform and output impedance.

Figure A.1 — RLC implementation for generating a damped sinus defibrillation waveform

Testing is conducted using various types of external defibrillation waveforms that the patient might be subjected to. Test 1 is designed to explore the ability of the implanted part of the ACTIVE IMPLANTABLE MEDICAL DEVICE to withstand external defibrillation applied from units that provide a typical monophasic "damped sinus defibrillation waveform" as shown in Figure 1 (similar to Edmark, Lown, Pantridge waveform). This test is intended to stress the implanted part of the ACTIVE IMPLANTABLE MEDICAL DEVICE with a high voltage. Test 2 was designed to explore the ability of the implanted part of the ACTIVE IMPLANTABLE MEDICAL DEVICE to withstand external defibrillation applied from units with monophasic and/or biphasic "truncated exponential defibrillation waveform" as shown in Figure 5 employing very fast rise and fall time. Test 2 stresses the implanted device with a high voltage along with a high dV/dt. The circuit details of Figure 2 and Figure 4 are specified so that the energy delivered to the implanted part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, when it is directly connected to the test equipment through a 300 Ω resistor, is similar to the energy delivered to the implanted device through the LEADS or electrodes when the subject is defibrillated using external defibrillation paddles. The specified tests avoid the use of the high voltages delivered directly by defibrillator paddles.

Defibrillation attempts often have to be repeated and the polarity of the signal introduced cannot be restricted, which is reflected in the timing sequence as shown in Figure 3. 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 IMPLANTABLE MEDICAL DEVICES containing semiconductors. Damage that is not apparent can cause reduced lifetime of semiconductor components. See also the requirement for appropriate 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 27.1.) In general, it is not possible to provide absolute immunity for ACTIVE IMPLANTABLE MEDICAL DEVICES containing semiconductors. Damage that is not apparent can cause reduced lifetime of semiconductor components, hence, the requirement for warnings in 28.13.

22.1 This requirement addresses exposure to expected acoustic output levels of diagnostic ultrasound. Exposure of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE to typical acoustic output levels of therapeutic and other medical ultrasound devices is covered by a requirement for a warning (see 28.14).

LEADS and CATHETERS are excluded from this requirement because it is presumed that as non-active components of the ACTIVE IMPLANTABLE MEDICAL DEVICE, they will not be affected by diagnostic levels of ultrasound. However, the MANUFACTURER should consider in their RISK ANALYSIS the possibility that these parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE could be damaged by exposure to diagnostic ultrasound.

The acoustic output from an ultrasound transducer is typically measured in the laboratory in water using a hydrophone. The intensity of an acoustic field (I) is the acoustic energy transmitted per unit time in the direction of acoustic wave propagation per unit area normal to this direction at a particular point in an acoustic field. Intensity is measured in Watts per square metre, W/m^2.

However, because the output is pulsed, a measurement of interest is the temporal-average of the intensity (I_{TA}) measured in mW/m^2. This is the time average of intensity at a point in space taken over a full number of pulse cycles. The value of the temporal-average intensity at the point in the acoustic field where the temporal-average intensity is a maximum is referred to as the spatial-peak temporal-average intensity (I_{SPTA}) measured in W/m^2. In most cases, the values are given in mW/cm^2.

The free-space field measurement of I_{SPTA} is made in water in the laboratory. However, acoustic energy is attenuated by body tissue. The output of a diagnostic ultrasound device can be described using an acoustic attenuation coefficient to account for ultrasonic attenuation of tissue between the source and a particular location in the tissue. This coefficient varies with the type of tissue, and total attenuation is both frequency and path length dependent. Attenuated parameters are often denoted with a subscript "α". The derated I_{SPTA} is denoted as $I_{SPTA.\alpha}$.

Although there is no universally accepted maximum intensity for diagnostic ultrasound, a value commonly found is an $I_{SPTA.\alpha}$ of ≤720 mW/cm^2 for imaging peripheral vessels.

For purposes of this test, a free-field value for I_{SPTA} of 1 500 mW/cm^2 was chosen to represent a reasonable worst-case exposure to a diagnostic ultrasound generator capable of generating an $I_{SPTA.\alpha}$ of 720 mW/cm^2. This corresponds to an average tissue attenuation of approximately 3 db. The testing performed here allows the MANUFACTURER to adjust the exposure to their particular implant situation based upon a RISK ASSESSMENT with an option to test to the unattenuated maximum free-field value.

In most scanning modes, the ultrasound pulses are typically of very short duration compared to the pulse repetition period, giving rise to a low duty cycle. However, in Doppler mode, the duty cycle can approach 20 %. A duty cycle of 20 % was selected for this test to represent a reasonable worst-case situation.

Diagnostic ultrasound transducers typically operate at frequencies above 1 MHz. Due to the fact that the attenuation coefficient for tissue can range from as low as 0,3 dB/(cm-MHz) to as much as 8 dB/(cm-MHz) to 9 dB/(cm-MHz), it was decided to standardize the exposure frequency and, hence, the exposure level, based on implant depth to be used in the testing specified here.

A centre frequency of 3,5 MHz has been chosen for two reasons. First, this frequency closely matches that which has been used to obtain attenuation characteristics for a variety of tissue types. Secondly, a review of available immersion type ultrasonic transducers shows that devices with this centre frequency are readily available.

The positioning of the device within the acoustic beam is depicted in Figure A.2. A typical commercial immersion-type ultrasound transducer can have a beam cross-sectional area of approximately 75 mm^2 while ACTIVE IMPLANTABLE MEDICAL DEVICE can have single surface areas of about 1 000 mm^2 or more. This means that to expose the entire device will require translational scanning of either the transducer or the device relative to each other within the water bath.

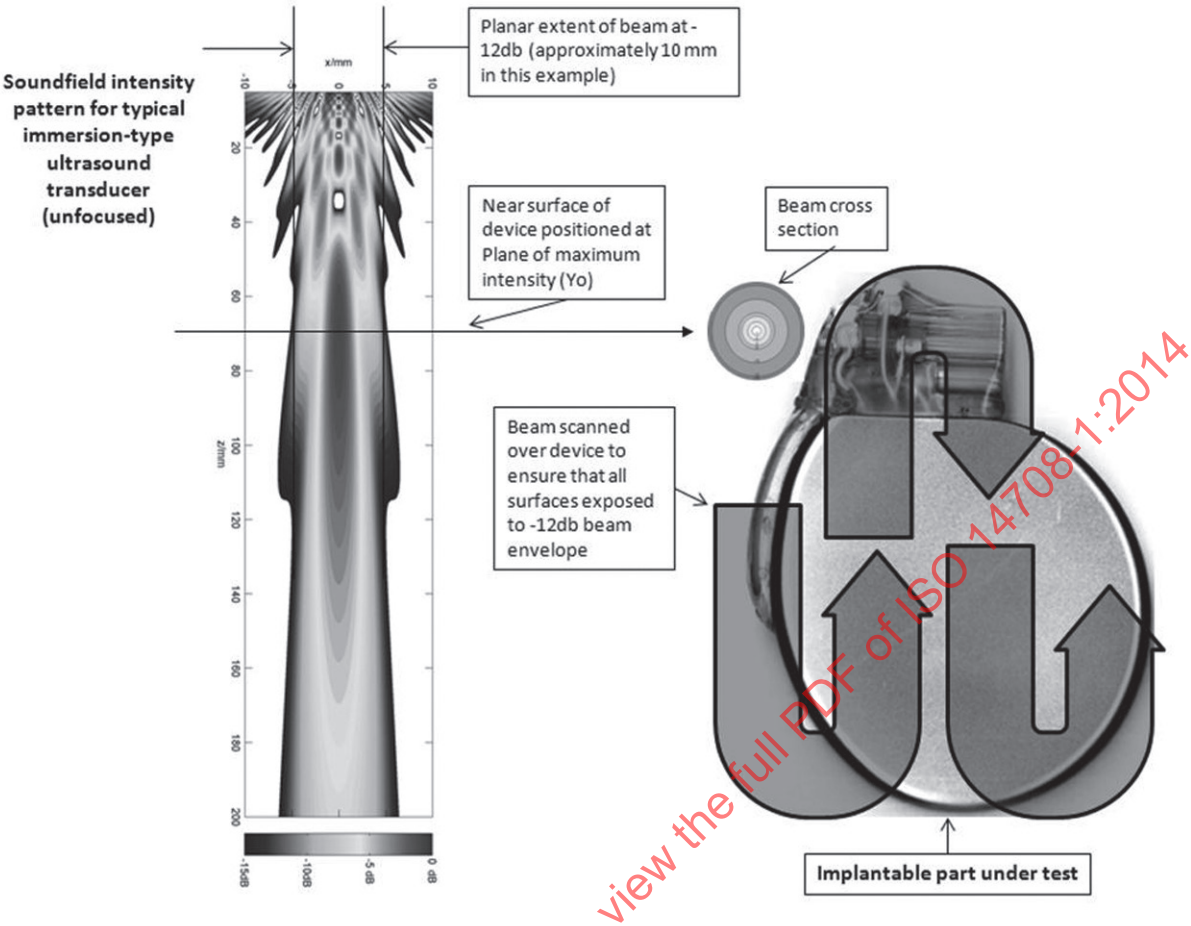


Figure A.2 — Positioning and scanning the ultrasound field exposure upon the implantable part

22.2 The object of the Technical Specification ISO/TS 10974 is to define the requirements and conditions for ACTIVE IMPLANTABLE MEDICAL DEVICE/MRI compatibility. ISO/TS 10974 reflects today's expert knowledge in the field of ACTIVE IMPLANTABLE MEDICAL DEVICE/MRI compatibility. At present, the scope of ISO/TS 10974 is limited to 1,5 Tesla closed-bore MRI scanners.

23.1 The test conditions are the same as in IEC 60601-1:2005 + A1:2012 because HAND-HELD programmers and PORTABLE device analysers can be subject to severe mechanical shocks during handling. If such impacts cause damage not immediately apparent to the user, the damaged device can mis-set the implanted part of an ACTIVE IMPLANTABLE MEDICAL DEVICE or give an erroneous analysis of an implanted part of an ACTIVE IMPLANTABLE MEDICAL DEVICE, which could subsequently result in an unnecessary explantation. Therefore, the dropped part is required to operate according to its original specifications following the test. This is a more stringent pass/fail criterion than specified in IEC 60601-1:2005 + A1:2012 that requires that any damage cannot result in an unacceptable RISK.

23.2 This test is intended to establish minimum requirements for the durability of the implanted part of an ACTIVE IMPLANTABLE MEDICAL DEVICE with respect to mechanical robustness. The text is based on a part of IEC 60068-2-64:2008. The test severity is determined by the test conditions a) to d). The range of test frequencies is based on experience with the sinusoidal sweep method in common use for a number of years within the pacemaker industry. The value for the acceleration spectral density was also derived from the sinusoidal sweep method in 8.1.1 of EN 50061:1988. That test specifies a peak acceleration of 25 m/s^2. This translates into a root mean square (r.m.s.) value of 1,77 g. An acceleration spectral density of $0{,}7(m/s^2)^2/Hz$ translates into an r.m.s. value of 1,86 g. This last calculation is an approximation that might vary slightly depending on the equipment used to generate the random vibration. However, the level of stress on the implanted part of an ACTIVE IMPLANTABLE MEDICAL DEVICE is comparable to the

level in the method in EN 50061. In general, a short duration test will produce low confidence level results. The duration value for this test is the midpoint of the recommended values in 5.5 of IEC 60068-2-64:1994. It should provide reasonable confidence in the reproducibility of the results while producing a test method whose overall time to complete is also reasonable. Protection of the implanted part of an ACTIVE IMPLANTABLE MEDICAL DEVICE during delivery and storage is provided by appropriate design of the packaging, which is evaluated with respect to vibration in 10.1.

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.

23.4and **23.5** These requirements are intended to ensure adequate studies are carried out to ensure the prevention of fatigue failures of implanted LEADS and CATHETERS. The compliance criteria specify design analysis which can simply be a summary of test studies performed by the MANUFACTURER.

23.6 This part of 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, ensuring that implanted connector pairs are reliable when subject to tensile force.

23.7 An implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE can be subject to minor mechanical shocks during the implant procedure. The user can drop the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE onto the operating table or other rigid surface and yet have it remain within the sterile operating field. The implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE should not be damaged by this type of drop and should still be implantable, assuming that it remains sterile. The shock test simulates the dropping of the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE while it is being removed from its STERILE PACK.

24.1 The test requirement applies only to non-implantable parts that can 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.

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

25.1 The lower range limit corresponds to an altitude of approximately 3 000 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 part of ISO 14708. Any device that cannot be subjected to the full temperature range specified by this subclause will require additional warnings on the packaging (see 9.11). If damage caused by freezing is not immediately apparent, then special temperature indicators might be required in the packaging.

The requirements for testing in the STERILE PACK only recognize the fact that STERILE PACK can be shipped prior to being placed into the SALES PACKAGING.

27.1 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 DEVICES in the other parts of ISO 14708.

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

28.7 The documentation should provide information about the MEDICINAL SUBSTANCES which are intended to be administered with the ACTIVE IMPLANTABLE MEDICAL DEVICE. That means that the MEDICINAL SUBSTANCES should be approved by the appropriate authority with jurisdiction. Also, the administration by means of an ACTIVE IMPLANTABLE MEDICAL DEVICE should be in the scope of the approved indication of the MEDICINAL SUBSTANCES. If the intended use of the ACTIVE IMPLANTABLE MEDICAL DEVICE includes the administration of non-approved MEDICINAL SUBSTANCES, it would be necessary to make an application for approval of these substances to the relevant institution.

28.14 Direct exposure to therapeutic levels of ultrasound can damage the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE. It can also result in focusing the ultrasound-energy-producing effects such as heating of tissue around the implant.

28.15 Direct exposure to therapeutic ionizing radiation, such as that used to treat certain types of tumours, can damage the sensitive electronics in the implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE. The damage might not always be immediately detectable. It can results in shortened battery life or premature failure of components.

28.17 Re-sterilization always requires appropriate VALIDATION. In practice, some devices might not be suited to re-sterilization and some other devices might be suited to re-sterilization only by the original MANUFACTURER.

28.18 If an implanted device is reused, the "person" responsible for reuse becomes the MANUFACTURER and should demonstrate that all requirements of this part of ISO 14708 have been met.

28.19 Energy source characteristics could include type of source (primary, rechargeable, chemical, mechanical, etc.), nominal energy capacity, etc.

Information concerning nominal and worst-case settings is provided to enable the user to more accurately establish the energy source lifetime.

28.23 Organizations operating possible sources of electromagnetic interference might rely on warnings addressed only to "pacemaker patients". This warning can be relevant to other ACTIVE IMPLANTABLE MEDICAL DEVICES although, without specific advice, a patient with an ACTIVE IMPLANTABLE MEDICAL DEVICE other than a pacemaker might decide to ignore the warning. Hence, the subclause is not intended to encourage patients to disregard warnings; rather, it is intended to ensure that a patient with an ACTIVE IMPLANTABLE MEDICAL DEVICE other than a pacemaker recognizes that a warning addressed to pacemaker patients might be important to them.

Annex B
(informative)

Relationship between the fundamental principles in ISO/TR 14283:2004 and the clauses of this part of ISO 14708

Fundamental principles	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 might 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.	(This principle is fundamental to all aspects of an ACTIVE IMPLANTABLE MEDICAL DEVICE addressed by this part of ISO 14708.) 5.3 Requires USABILITY ENGINEERING PROCESS be applied to non-implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE 5.5 Requires parts of an ISO 14971-compliant RISK MANAGEMENT PROCESS to be applied
3.2 The solutions adopted by the manufacturer for the design and construction of the implants should conform with 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.) 5.4 Requires the MANUFACTURER to provide INFORMATION SECURITY when communication with the implantable part is through wireless communication channels 5.5 Requires parts of an ISO 14971-compliant RISK MANAGEMENT PROCESS to be applied
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 14283:2004, as specified by the manufacturer.	(This principle is fundamental to all aspects of an ACTIVE IMPLANTABLE MEDICAL DEVICE addressed by this part of ISO 14708.)

Fundamental principles	Clauses of ISO 14708-1 and aspects covered
3.4 The characteristics and performances referred to in 3.1, 3.2 and 3.3 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 PACKAGING to be indelible 10.4 Requires accompanying documentation to be physically associated with the device 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 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**	(See more particular requirements below.)
4.1 **Chemical, physical, and biological properties**	(See more particular requirements below.)
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 the following:	(See more particular requirements below.)
4.1.1 a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;	14.3 Requires investigation of biocompatibility
4.1.1 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

Fundamental principles	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, might be considered to be medicinal product as defined in 2.4 of ISO/TR 14283 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.	25.1 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.	25.1 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**	(See more particular requirements below.)