DRAFT INTERNATIONAL STANDARD ISO/DIS 14708-1

ISO/TC **150**/SC **6** Secretariat: **ANSI**

Voting begins on **2013-04-22** Voting terminates on **2013-07-22**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

[Revision of first edition (ISO 14708-1:2000)]

ICS 11.040.40

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Foreword

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

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

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

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

ISO 14708-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants* in collaboration with the CEN/CENELEC Joint Working Group on active implantable medical devices.

This second edition cancels and replaces the first edition, 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*

Introduction

This International Standard 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 standard 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 particular standards as separate parts of ISO 14708. A requirement of such a particular standard takes priority over the corresponding requirement of this general standard. Where particular standards exist, this general standard should not be used alone. Special care is required when applying this general standard alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular 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 1 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 standards which form additional parts of this International Standard.

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 1 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 1 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 International Standard, 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 International Standard 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.

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, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1 (2012)

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

IEC 62127-1:2007, *Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

IEC 62304:2006, *Medical devices software – Software life-cycle processes*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

ISO 10993-1:2009, *Biological testing of medical devices – Part 1: Evaluation and testing within a risk management process*

ISO 11607-1:2006, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155:2011, *Clinical investigation of medical devices for human subjects -- Good clinical practice*

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

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

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 purposes of this Part 1 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
means any natural or legal person established in the European Community who, explicitly designated by the MANUFACTURER, acts and may be addressed by authorities and bodies in the Community instead of the MANUFACTURER with regard to the latter's obligations

3.4
BEGINNING OF SERVICE
BOS
when 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 may 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
when the PROLONGED SERVICE PERIOD has elapsed and performance to design specification cannot be assured

3.8
HAND HELD
term referring to part of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to be supported by the hand during NORMAL USE

[SOURCE: IEC 60601-1:2006 + 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
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

3.12
LEAD
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length

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

3.13
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.

3.14
MARKING
inscription on a device, package, or LABEL

3.15
MEDICAL DEVICE
any 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,
- 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 may be assisted in its function by such means

3.16
MEDICINAL SUBSTANCE
any 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 may 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 Directive 2001/83/EC.

3.17
MEDICINAL SUBSTANCE DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA
MEDICINAL SUBSTANCES based on blood constituents which are prepared industrially by public or private establishments, such MEDICINAL SUBSTANCES including, in particular, albumin, coagulating factors and immunoglobulins of human origin

3.18
NON-REUSABLE PACK
single use pack designed to allow the contents to be sterilized and to maintain that sterility

3.19
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 60601-1:2006, 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.]

3.20
PORTABLE
term referring to 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 60601-1:2006 + A1:2012, 3.85, modified — 'Transportable equipment' replaced by 'part of an ACTIVE IMPLANTABLE MEDICAL DEVICE'.]

3.21
PROCESS
set of inter-related or interacting resources and activities which transform inputs into outputs

[SOURCE: ISO 14971:2007, 2.130]

3.22
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

3.23
RADIOACTIVE SUBSTANCE
any 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 96/29/Euratom.

3.24
RECOMMENDED REPLACEMENT TIME
RRT
when 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.

3.25
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

[SOURCE: ISO 14971:2007, 2.15]

3.26
RISK
combination of the probability of occurrence of HARM and the severity of that HARM

[SOURCE: ISO 14971:2007, 2.16]

3.27
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]