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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.