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Implants for surgery — Active implantable medical devices —

Part 5: Circulatory support devices

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 5: Dispositifs d'assistance circulatoire

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Contents

Page

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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 14708-5:2010), which has been technically revised. The main change compared to the previous edition is as follows:

— alignment to the revised ISO 14708-1:2014.

A list of all parts in the ISO 14708 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document specifies requirements for safety and performance of active implantable circulatory support devices. It amends and supplements ISO 14708-1:2014, hereinafter referred to as ISO 14708-1. The requirements of this document take priority over those of ISO 14708-1.

Heart failure is a major public health problem. It is estimated that worldwide more than 5 million people die per year due to heart failure. In addition, it accounts for a large portion of health care expenditure and rehospitalisation (see Reference [35]). Circulatory support devices are needed for promoting myocardial recovery following acute heart failure as well as long-term support until eventual transplantation or permanent therapy. Circulatory support devices may be fully implanted, partially implanted, or delivered by percutaneous approach. The growth of heart failure is expected to increase with the aging population (see Reference [30]).

The requirements of this document supplement or modify those of ISO 14708-1.

In this document, terms printed in italics are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in italics unless the concept thus qualified is also defined.

Information is also provided in Annex A that explains the relationship between ISO/TR 14283, ISO 14708-1 and this document.

Notes on this document are provided in Annex B for information.

Annex C provides guidance on pre-clinical in vitro and in silico evaluation. Annex D provides information device hazards, associated failure modes, and evaluation methods. All annexes are informative.

Implants for surgery — Active implantable medical devices —

Part 5: Circulatory support devices

1 Scope

This document specifies requirements for safety and performance of active implantable circulatory support devices, including type tests, animal studies and clinical evaluation requirements.

NOTE The device that is commonly referred to as an active implantable medical device can in fact 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 main requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

The tests that are specified in this document are type tests and are to be carried out on a sample of a device to assess device behavioural responses and are not intended to be used for the routine testing of manufactured products.

Included in the scope of this document are:

— ventricular assist devices (VAD), left or right heart support;

— total artificial hearts (TAH);

— biventricular assist devices (biVAD);

— percutaneous assist devices;

— paediatric assist devices.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

IEC 60068-1:2013, *Environmental testing — Part 1: General and guidance*

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

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: rough handling shocks, primarily for equipment-type specimens*

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

IEC 60601-1:2018, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

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

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1 and ISO 14971 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
accessory device
separate part of a circulatory support system that is not essential to the primary function of the circulatory support system

Note 1 to entry: Examples are programming units, monitoring units and alternative *power source* (3.18) units.

3.2
artificial valve
prosthetic valve
component of the circulatory support system that directs the unidirectional flow of the blood into and out of the pump

3.3
atrial cuff
connector between the right or left atrial ring after resection of the natural ventricle and the inlet of the right or left blood pump in *total artificial heart* (3.31) replacement

3.4
biVAD
biventricular assist device
configuration in which two VADs are used to support both ventricles respectively

3.5
cavitation
sudden formation and collapse of low-pressure bubbles in the blood by means of mechanical forces

3.6
circulatory support device
electromechanical device that is used to partially or completely replace the left and/or right ventricular function of a failing heart

3.7
conduit
component of the circulatory support system that connects the pump to the patient's circulation

3.8
controller
component of the circulatory support system that contains the logic, circuitry and/or software to control the driving mechanism that enables the system to perform its primary function

3.9
diastolic pressure
arithmetic average of minimum pressures in a pulsatile pressure waveform over a sufficient number of cycles to filter out cyclic variation

3.10
display
component of the circulatory support system that allows data pertaining to the operation of the system to be observed

3.11
driveline
tube and/or cable that connects a driver or energy source to the pump

EXAMPLE The tube that connects a pneumatic console to a pneumatically driven pump.

3.12
durability
ability of an item to perform a required function under given conditions of use and maintenance, until a limiting state is reached

Note 1 to entry: A limiting state of an item should be characterized by the end of the useful life, unsuitability for any economic or technological reasons, or other relevant factors.

3.13
DUT
device under test

3.14
ejection/fill
E/F
ratio between the ejection time period and the filling time period of the blood pump cycle

Note 1 to entry: E/F is identical to S/D (systolic/diastolic) when related to the natural heart.

3.15
failure
termination of the ability of an item to perform a required function

Note 1 to entry: After failure, the item has a *fault* (3.16).

Note 2 to entry: "Failure" is an event, as distinguished from "fault", which is a state.

Note 3 to entry: This concept as defined does not apply to items consisting of software only.

3.16
fault
state of an item characterized by inability to perform a required function, excluding the inability during preventive maintenance or other planned actions, or due to lack of external resources

Note 1 to entry: A fault is often the result of a *failure* (3.15) of the item itself but might exist without prior *failure*.

3.17
labelling
marking
any written, printed, electronic information, or graphical matter affixed to a medical device or any of its containers or wrappers, or accompanying the medical device related to identification, technical description and use, but excluding shipping documents

3.18
power source
source of energy (battery, mains)

3.19
pulsatile flow
characteristic of the output of a pump where the flow is time dependent

3.20
pulse pressure
difference between the systolic and *diastolic pressure* (3.9) readings

Note 1 to entry: It represents the force that the heart generates each time it contracts.

3.21
pump output
performance measure for a circulatory support system indicating the volume of blood pumped into the host circulatory system per minute

Note 1 to entry: The pump output is expressed in litres per minute or its equivalent in other units.

3.22
volume displacement
pump displacement
pump that imparts its pumping action by changing the volume of the pumping chamber

EXAMPLE By displacement of a diaphragm or pusher plate.

3.23
reliability
probability that an item can perform a required function under given conditions for a given time interval (t1, t2) for a specified confidence level

Note 1 to entry: It is generally assumed that the item is in a state to perform this required function at the beginning of the time interval.

Note 2 to entry: The term “reliability” is also used to denote the reliability performance quantified by this probability[11].

3.24
rotary pump
pump that imparts its pumping action directly on the blood by a rotating mechanism

3.25
safe and effective
reasonable assurance that a device will not induce harm to the recipient and that it will provide clinical benefit for the recipient for its conditions of use

3.26
safety
freedom from unacceptable risk

Note 1 to entry: See ISO/IEC Guide 51.

3.27
sales packaging
packaging that protects and identifies the device during storage and handling by the purchaser

Note 1 to entry: The sales packaging should be enclosed in further packaging, for example a “shipping package”, for delivery.

3.28
service life
period after implantation when the circulatory support system remains within stated specifications and characteristics

Note 1 to entry: The service life of the components of the system can vary (implanted components might have longer lifetimes versus the peripheral components which are replaceable).

3.29
stroke volume
amount of blood pumped by the ventricle of the heart in one contraction

3.30
transcutaneous energy transmission system
TETS
system used to send electrical energy wirelessly into a device implanted inside the body

3.31
total artificial heart
TAH
circulatory support system that replaces the pumping function of a patient’s native heart

3.32
ventricular assist device
VAD
circulatory support system that augments the function of either one or both ventricles of the patient's native heart by capturing blood from the atrium(a) or ventricle(s) and providing work to pump blood into the pulmonary and/or systemic circulation

4 Symbols and abbreviations

The text in ISO 14708-1:2014, Clause 4 applies.

5 General requirements for active implantable medical devices

5.1 General requirements for non-implantable parts

The text in ISO 14708-1:2014, 5.1 applies.

5.2 General requirements for software

The text in ISO 14708-1:2014, 5.2 applies.

5.3 Usability of non-implantable parts

The text in ISO 14708-1:2014, 5.3 applies.

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

The text in ISO 14708-1:2014, 5.4 applies.

5.5 General requirements for risk management

The text in ISO 14708-1:2014, 5.5 applies.

5.6 Misconnection of parts of the active implantable medical device

The text in ISO 14708-1:2014, 5.6 applies.

5.7 Wireless coexistence and wireless quality of service

When communication with any part of an active implantable medical device is provided through wireless communication channels, the manufacturer shall evaluate wireless coexistence and wireless quality of service through the risk management process and apply the appropriate risk control measures to protect the patient from harm (see 27.6).

Testing of wireless communication channels, for EMC, is performed in accordance with IEC 60601-1-2:2014.

Compliance is checked by the inspection of the risk management file.

6 Requirements for particular active implantable medical devices

6.1 Intended clinical use/indications

The intended use and indications for the device system shall be described. The intended use describes what the device system does (e.g. provides circulatory support), where it may be used safely (e.g. hospital, home, ground and/or air transport vehicles), and the intended duration of use. The indications are the disease(s) or condition(s) the device will diagnose, treat, prevent, cure, or mitigate and a description of the target population for which the device is intended without causing unreasonable risk of illness or injury associated with use of the device.

Compliance is checked by the inspection of the manufacturer's documentation.

6.2 System description

6.2.1 General

A comprehensive description of the system shall be documented, including discussions on the principles of operation, rationale for key design choices, system configurations, system components, and system performance and operating limits.

Compliance is checked by the inspection of the manufacturer's documentation.

The rationale for key design choices, for example:

— approaches taken to minimize blood component damage;

— methods for thermal management;

— choice of drive mechanisms;

— power management scheme;

— choice of connectors to prevent misuse;

— reliability considerations;

— adequacy of anatomic fit;

— electromagnetic compatibility (EMC)/ interference;

— driveline damage resistance;

— exposure to environmental conditions;

— human factors.

Design specifications for the complete system include the full range of system operating limits for each parameter, for example:

— beat rates;

— E/F ratio;

— rotation speeds;

— power consumption;

— flow rate as a function of pressure head (with varying pump rotational speed or beat rate).

Required system components, for example:

— hydrodynamic bearings;

— magnetic bearings.

System operational modes, for example:

— manual;

— automatic.

System component configurations, for example:

— hospital;

— home;

— power sources;

— optional display;

— optional subsystems;

— optional console.

Alarm thresholds, and all associated tolerances on each of these parameters.

Principle(s) of operation, for example:

— blood pumping mechanism;

— connections to the cardiovascular system;

— power system;

— control mechanisms.