SLOVENSKI STANDARD
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Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 5. del: Naprave za podporo cirkulacije (ISO/DIS 14708-5:2019)

Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices (ISO/DIS 14708-5:2019)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 5: Besondere Anforderungen an Kreislaufunterstützungssysteme (ISO/DIS 14708-5:2019)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 5: Appareils annexes circulatoires (ISO/DIS 14708-5:2019)

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Implants for surgery — Active implantable medical devices —

Part 5: Circulatory support devices

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 5: Appareils annexes circulatoires

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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 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 changes compared to the previous edition are 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 (HF) 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 (AHA [24]). 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 (Koelling TM et al,[19]).

The requirements of this document supplement or modify those of ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*.

Figures or tables that are additional to those of Part 1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

In this document, 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.

Information is also provided in Annex AA that explains the relationship between ISO/TR 14283, *Implants for surgery — Essential principles of safety and performance*, ISO 14708-1 and this document.

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 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 within 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.

This clause of ISO 14708-1 applies except as follows:

Additional references

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

IEC 60601-1-2, *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, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

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

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

ISO 5840-1, *Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements*

ISO 5840-2, *Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitute*

ISO 5840-3, *Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques*

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

ISO 14708-1, *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, *Medical devices — Application of risk management 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/

3.101
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 units.

3.102
artificial (VAD) pulse rate
inverse of one period of a repeating sequence of speed changes intended to produce time variance in PUMP OUTPUT, in units of cycles per minute (applicable to ROTARY PUMPS)

3.103
artificial valve
prosthetic valve
component of the circulatory support system that directs the unidirectional flow of the blood into and out of the pump

3.104
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 replacement

3.105
biVAD
biventricular assist device
configuration in which two VADs are used to support both ventricles respectively

3.106
cavitation
sudden formation and collapse of low pressure bubbles in the blood by means of mechanical forces

3.107
circulatory support device
electromechanical device that is used to partially or completely replace the left and/or right ventricular function of a failing heart

3.108
clinical study
evaluation of a device in humans

3.109
conduit
component of the circulatory support system that connects the pump to the patient's circulation

3.110
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

3.111
diastolic pressure
arithmetic average of minimum pressures in a pulsatile pressure waveform over a sufficient number of cycles to filter out cyclic variation

3.112
display
component of the circulatory support system that allows data pertaining to the operation of the system to be observed

3.113
d*p*/d*t*
time derivative of pressure giving the rate of change of pressure with respect to time

Note 1 to entry: d*p*/d*t* is expressed in millimetres of mercury per second, mmHg/s (kiloPascal per second [kPa/s] in SI units).

3.114
d*Q*/d*t*
time derivative of flow giving the rate of change of flow with respect to time

Note 1 to entry: d*Q*/d*t* is expressed in units of litres per minute per second.

3.115
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.

3.116
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.

3.117
DUT
device under test

3.118
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.

3.119
extracorporeal component
component or subsystem of the circulatory support system that is kept external to the patient (outside of the body)

3.120
failure
termination of the ability of an item to perform a required function

Note 1 to entry: After FAILURE, the item has a FAULT.

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.

3.121
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 of the item itself, but might exist without prior FAILURE.

3.122
fully implantable
implanted circulatory support system with no skin penetrations (i.e. PERCUTANEOUS LEAD)

3.123
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

3.124
LVAD
left ventricular assist device
circulatory support device that is intended to be used to support the left ventricle

3.125
peak flow
maximum flow rate during ejection of blood from a pump into the host circulatory system

3.126
peak pressure
maximum pressure generated by the circulatory support system

3.127
percutaneous lead
LEAD (electrical or otherwise) that crosses the patient's skin to connect implantable parts of a circulatory support system to extracorporeal parts of the system

3.128
power source
source of energy (battery, mains)

3.129
pulsatile flow
characteristic of the output of a pump where the flow is time-dependent

3.130
pulse pressure
difference between the systolic and DIASTOLIC PRESSURE readings.

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

3.131
pump fill
filling phase of a VOLUME DISPLACEMENT pump

Note 1 to entry: Diastole is used to describe only the filling phase of the host's native ventricle(s).

3.132
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.

3.133
pump rotor speed
rotational speed of rotor expressed in revolutions per minute (RPM)

Note 1 to entry: This definition is only applicable to ROTARY PUMPS.

3.134
pump stroke volume
performance measure for a circulatory support system indicating the volume pumped into the host circulatory system per beat by a pump with PULSATILE FLOW

Note 1 to entry: The pump stroke volume is expressed in millilitres.

3.135
pump volume
volumetric capacity of the pump

3.136
pump displacement/
volume displacement
pump that imparts its pumping action by changing the volume of the pumping chamber

EXAMPLE By displacement of a diaphragm or pusher plate.

3.137
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[7].

3.138
remote access device
device that will allow information from the system to be accessed from a remote location