INTERNATIONAL STANDARD

ISO 14708-5

First edition
2010-02-01

Implants for surgery — Active implantable medical devices —

Part 5: Circulatory support devices

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 5: Appareils annexes circulatoires

Reference number
ISO 14708-5:2010(E)

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Published in Switzerland

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.

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 14708-5 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

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)*

Introduction

This part of ISO 14708 specifies requirements for safety and performance of active implantable circulatory support devices. It is not intended to be used for extracorporeal perfusion devices, cardiomyoplasty, heart restraint devices, and counter-pulsation devices such as extra- or intra-aortic balloon pumps. It amends and supplements ISO 14708-1:2000, hereinafter referred to as ISO 14708-1. The requirements of this part of ISO 14708 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. The number of newly diagnosed cases is more than 550 000 per year in the USA alone (AHA[13]). In 2001, nearly 53 000 patients in the United States died of HF as a primary cause. Further, heart failure is implicated as a contributing factor in more than 250 000 deaths each year in the USA alone (Yusuf[29]). Particularly at a higher risk for heart failure are the elderly (> 60 years), who account for 70 % of heart failure patients (Haldeman et al[18]), and for whom congestive heart failure is the leading cause of hospitalization. From 1990 to 1999, the annual number of hospitalizations has increased from approximately 810 000 to over 1 million for HF as a primary diagnosis and from 2,4 million to 3,6 million for HF as a primary or secondary diagnosis (Koelling TM et al,[30]). The economic costs are enormous. It has been estimated that in 2005, the total direct and indirect cost of HF in the United States is equal to $27,9 billion (AHA[13]). Worldwide, it is estimated that over $800 billion per year is spent and almost one third of patients are younger than 60. Heart transplantation in recent years has become an effective treatment for end-stage heart failure. Unfortunately the number of donor hearts is limited to just about 3 000 worldwide, available only to a small fraction of patients who need heart transplants. Future drug discoveries and/or biological therapies such as cell regeneration and gene therapy hold promise for the future in the treatment of chronic heart failure. However, as of today, mechanical circulatory devices remain the only alternative to heart transplantation and will continue to be a viable treatment for end-stage heart failure for the foreseeable future.

Within this part of ISO 14708, the following terms are used to amend and supplement ISO 14708-1:

“Replacement”: the clause of ISO 14708-1 is replaced completely by the text of this particular part of ISO 14708.

“Addition”: the text of this particular part is additional to the requirements of ISO 14708-1.

“Amendment”: the clause of ISO 14708-1 is amended as indicated by the text of this particular part of ISO 14708.

“Not used”: the clause of ISO 14708-1 is not applied in this particular part of ISO 14708.

Subclauses, figures, or tables that are additional to those of ISO 14708-1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

Implants for surgery — Active implantable medical devices —

Part 5:
Circulatory support devices

1 Scope

This part of ISO 14708 specifies requirements for safety and performance of active implantable circulatory support devices. It is not applicable to extracorporeal perfusion devices, cardiomyoplasty, heart restraint devices and counter-pulsation devices, such as extra- or intra-aortic balloon pumps.

This part of ISO 14708 specifies 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.

2 Normative references

The following referenced documents are indispensable for the application 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 5198, *Centrifugal, mixed flow and axial pumps — Code for hydraulic performance tests — Precision grade*

ISO 5840, *Cardiovascular implants — Cardiac valve prostheses*

ISO 7198, *Cardiovascular implants —Tubular vascular prostheses*

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

ISO 14155[1)], *Clinical investigation of medical devices for human subjects — Good clinical practice*

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*

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

IEC 60601-1-1, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

1) To be published. (Revision of ISO 14155-1 and ISO 14155-2)

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 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

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

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.

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 Examples are programming units, monitoring units and alternative power supply units.

3.102
artificial valve
prosthetic valve
component of the circulatory support system that directs the unidirectional flow of the blood into and out of the pump

3.103
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

3.104
cavitation
sudden formation and collapse of low pressure bubbles in the blood by means of mechanical forces

3.105
clinical study
evaluation of a device in humans

3.106
conduit
component of the circulatory support system that connects the pump to the patient's circulation

3.107
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

3.108
diastolic pressure
arithmetic average of diastolic blood pressure (when the left ventricle is not contracting), over a sufficient number of cycles to filter out cyclic variation, of the minimum aortic pressures in a pulsatile pressure waveform

3.109
dp/dt
time derivative of pressure giving the rate of change of pressure with respect to time

NOTE dp/dt is expressed in millimetres of mercury per second, mmHg/s (kiloPascal per second [kPa/s] in SI units).

