

American National Standard



ANSI/AAMI/ ISO 14708-5: 2010/(R)2015

Implants for surgery —
Active implantable medical
devices — Part 5: Circulatory
support devices

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

Implants for surgery—Active implantable medical devices— Part 5: Circulatory support devices

Approved 8 March 2010 by
Association for the Advancement of Medical Instrumentation

Approved 1 April 2010 and reaffirmed 20 November 2015 by
American National Standards Institute, Inc.

Abstract: Specifies requirements for safety and performance of active implantable circulatory support devices. Excluded from this scope are intra-aortic balloon pumps, external corporeal perfusion devices and cardiomyoplasty. This standard specifies type tests, animal studies and clinical evaluation requirements that are to be carried out to show compliance with this standard.

Keywords: artificial heart, ventricular assist devices, active implants, LVADs, TAHs, 14708-5

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI, or by visiting the AAMI website at www.aami.org.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795
www.aami.org

© 2010 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO, ANSI, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, complete the reprint request form at www.aami.org or contact AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1–57020–378-4

Contents

Page

Glossary of equivalent standards	v
Committee representation	vii
Background of ANSI/AAMI adoption of ISO 14708-5:2010	viii
Foreword	ix
Introduction	x
1 Scope.....	1
2 Normative references	1
3 Terms and definitions.....	2
4 Symbols and abbreviated terms.....	6
5 General requirements for non-implantable parts	6
6 Requirements for particular active implantable medical devices.....	6
7 General arrangement of the packaging	21
8 General markings for active implantable medical devices.....	21
9 Markings on the sales packaging.....	21
10 Construction of the sales packaging	22
11 Markings on the sterile packaging.....	22
12 Construction of the non-reusable packaging	22
13 Markings on the active implantable medical device	23
14 Protection from unintentional biological effects caused by the active implantable medical device.....	23
15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device.....	23
16 Protection from harm to the patient caused by electricity	23
17 Protection from harm to the patient caused by heat.....	23
18 Protection from ionizing radiation released or emitted from the active implantable medical device.....	23
19 Protection from unintended effects caused by the device.....	23
20 Protection of the device from damage caused by external defibrillators	25
21 Protection of the device from changes caused by high-power electrical fields applied directly to the patient.....	25
22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments	25
23 Protection of the active implantable medical device from mechanical forces.....	25

24	Protection of the active implantable medical device from damage caused by electrostatic discharge	25
25	Protection of the active implantable medical device from damage caused by atmospheric pressure changes.....	25
26	Protection of the active implantable medical device from damage caused by temperature changes.....	25
27	Protection of the active implantable medical device from electromagnetic non-ionizing radiation	26
28	Accompanying documentation	26
Annex AA	(informative) Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this part of ISO 14708.....	28
Annex BB	(informative) Relationship between the clauses of this part of ISO 14708 and the fundamental principles listed in Annex AA.....	38
Annex CC	(informative) Rationale.....	40
Annex DD	(informative) <i>In vitro</i> test	45
Bibliography		49

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation Mechanical Circulatory Support Systems Committee

The adoption of ISO 14708-5:2010 as an American National Standard was initiated by the AAMI Mechanical Circulatory Support Systems Committee. The AAMI Mechanical Circulatory Support Systems Committee also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Mechanical Circulatory Support Systems Committee (U.S. Sub-TAG for ISO/TC 150/SC 6/WG 6) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Mechanical Circulatory Support Systems Committee** had the following members:

Cochairs	James C. Conti, PhD, Dynatek Dalta Scientific Instruments John T. Watson, PhD, University of California at San Diego
Members	Tim Baldwin, PhD, NHLBI NIH (Independent Expert) Michael R. Berman, FDA/CDRH David Borzelleca, Evaheart Medical USA Inc. Kevin Bourque, Thoratec Corporation Richard Chan, CCP, Northshore University Hospital (Independent Expert) Arthur A. Ciarkowski, (Independent Expert) James C. Conti, PhD, Dynatek Dalta Scientific Instruments Tirone E. David, American Association for Thoracic Surgery Leonard A R Golding, MD, Cleveland Clinic Foundation (Independent Expert) Mark Kurusz, CCP, (Independent Expert) Jeff A. Larose, HeartWare Inc. James Lee, WorldHeart Inc. Chisato Nojiri, MD PhD, Terumo Medical Corporation Yukihiko Nose, MD PhD, Baylor College of Medicine (Independent Expert) Mark S. Slaughter, MD, Cardiac Surgery Clinical Research Center Inc (Independent Expert) John T. Watson, PhD, University of California at San Diego (Independent Expert)
Alternates	Alan S. Berson, PhD, US National Institutes of Health Patrick Biggins, Evaheart Medical USA Inc. Michael Geringer, Thoratec Corporation Jean E. Rinaldi, FDA/CDRH

NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of ISO 14708-5:2010

As indicated in the foreword to the main body of this document (page ix), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150, *Implants for surgery*, Subcommittee (SC) 6, *Active implants*, to fill a need for safety and performance requirements for active implantable circulatory support devices.

The AAMI *Mechanical Circulatory Support Systems Committee* serves as the U.S. sub-TAG for the relevant ISO working group and supports the adoption of ISO 14708-5:2010.

This 1st edition of ANSI/AAMI/ISO 14708-5 is a revision and replacement of AAMI TIR26:2000. ANSI/AAMI/ISO 14708-5:2010 updates the terms and definitions, provides additional requirements for *in vitro* and *in vivo* evaluation, and also provides additional information on packaging and protection against unintended effects. A new informative annex on *in vitro* tests is also included.

The U.S. adoption of ANSI/AAMI/ISO 14708-5:2010 was approved by the American National Standards Institute (ANSI) on 1 April 2010.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of international standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with each.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the standard. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 Fairfax Drive, Suite 301, Arlington, VA 22203.

NOTE—Beginning with the foreword on page “ix”, this American National Standard is identical to ISO 14708-5:2010.

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 \$900 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 14155¹⁾, *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).

3.110

dQ/dt

time derivative of flow giving the rate of change of flow with respect to time

NOTE dQ/dt is expressed in units of litres per minute per second.

3.111

drive line

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.

3.112

durability

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

NOTE 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.

3.113

ejection/fill

E/F

ratio between the ejection time period and the filling time period of the blood pump cycle

NOTE E/F is identical to S/D (systolic/diastolic) when related to the natural heart.

3.114

extracorporeal component

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

3.115

failure

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

NOTE 1 After failure, the item has a fault.

NOTE 2 "Failure" is an event, as distinguished from "fault", which is a state.

NOTE 3 This concept as defined does not apply to items consisting of software only.

3.116

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 A fault is often the result of a failure of the item itself, but might exist without prior failure.

3.117**fully implantable**

implanted circulatory support system with no skin penetrations (i.e. percutaneous lead)

3.118**hazard analysis**

identification of hazards and their initiating causes

3.119**labelling
marking**

any written, printed, 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

3.120**monitor**

component of the circulatory support system that allows data pertaining to the operation of the system to be displayed

3.121**peak flow**

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

3.122**peak pressure**

maximum pressure generated by the circulatory support system

3.123**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

3.124**power supply**

source of energy

3.125**pulsatile flow**

characteristic of the output of a pump where the flow is time-dependent (flow varies with time during one beat)

3.126**pump fill**

filling phase of a volume displacement pump

NOTE Diastole is used to describe only the filling phase of the host's native ventricle(s).

3.127**pump output**

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

NOTE The pump output is expressed in litres per minute or its equivalent in other units.

3.128

pump/pulse rate

performance measure for a circulatory support system indicating the number of complete pump cycles per minute

NOTE The pump rate is expressed in beats per minute.

3.129

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 The pump stroke volume is expressed in millilitres.

3.130

pump volume

volumetric capacity of the pump

3.131

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.

3.132

reliability

probability that an item can perform a required function under given conditions for a given time interval (t_1 , t_2)

NOTE 1 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 The term “reliability” is also used to denote the reliability performance quantified by this probability [see 191-02-06 of IEC 60050-191 definition of reliability (performance)].

3.133

remote access device

component of the circulatory support system that allows modification and/or monitoring of the controller and the operation of the system

3.134

rotary pump

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

3.135

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

3.136

safety

freedom from unacceptable risk

[ISO/IEC Guide 51:1999, definition 3.1]

3.137**safety hazard**

potentially detrimental effect on the patient, other persons, animals, or the surroundings, arising directly from the circulatory support system

3.138**sales packaging**

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

NOTE The sales packaging should be enclosed in further packaging, for example a "shipping package", for delivery.

3.139**stroke volume**

amount of blood pumped by the ventricle of the heart in one contraction

3.140**systolic pressure**

arithmetic average, over a sufficient number of cycles to filter out cyclic variation, of the peak aortic pressures in a pulsatile pressure waveform

3.141**transcutaneous energy transmission system****TETS**

system used to send electrical energy wirelessly into a device implanted inside the body

3.142**total artificial heart****TAH**

circulatory support system that replaces the pumping function of a patient's native heart

3.143**ventricular assist system****ventricular assist device****VAS/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 abbreviated terms

This clause of ISO 14708-1 applies.

5 General requirements for non-implantable parts

This clause of ISO 14708-1 applies.

6 Requirements for particular active implantable medical devices

Addition

6.101 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) and where it may be used safely (e.g. hospital, home, ground and/or air transport vehicles). 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.

6.102 System description

6.102.1 General

A comprehensive description of the system should be documented, including discussions on the principle(s) of operation, design consideration(s), system configuration(s), system component(s), and system performance and operating limits.

Design specifications for the complete system include the full range of system operating limits for each parameter (e.g. beat rates, E/F ratio, rotation speeds, power), system operational modes (e.g. manual, automatic), system component configurations (e.g. hospital, home, power sources, optional display, optional subsystems, optional console), alarm thresholds, and all associated tolerances on each of these parameters.

6.102.2 Principle of operation

A discussion of the operating principle of the system should include the blood pumping mechanism, connections to the cardiovascular system, power system, and control mechanisms.

6.102.3 Design consideration

The rationale for key design choices should be given. This should include, but is not limited to, approaches taken to minimize blood component damage, methods for thermal management, choice of drive mechanisms, a power management scheme, reliability considerations, adequacy of anatomic fit, and patient interaction.

6.102.4 System configuration

A detailed physical description of the system shall be given including implantation sites of various implantable components, external wearable units, and external consoles. Size, shape, weight, and volume of the components should be given, as well as the different configurations of system components that can be used to provide support.

6.102.5 System performance and operating limits

The entire performance range of the system shall be given, even if some operation conditions are not expected to be used clinically or might cause the system to malfunction.

6.103 Design analysis

A comprehensive analysis should be performed for the integrated system, the various component configurations, as well as for each system component for all safety and effectiveness issues, including human factors. The *in vitro*, *in vivo*, and clinical testing performed to address each issue should be identified.