

American National Standard

ANSI/AAMI/ISO 27186:2010



Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements

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.

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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.

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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.

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Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements

Approved 10 August 2011 by
Association for the Advancement of Medical Instrumentation

Approved 24 August 2011 by
American National Standards Institute, Inc.

Abstract: This includes all essential design and performance requirements for two types of four-pole electrical connectors, low voltage and high/low voltage, intended for use on implantable cardiac pacemakers and implantable defibrillators.

Keywords: pacemakers, implantable defibrillators, active implants

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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. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

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 and ANSI/AAMI ES60601-1:2005/A2:2010 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 60601-2-4:2010	ANSI/AAMI/IEC 60601-2-4:2010	Identical
IEC 60601-2-16:2008	ANSI/AAMI/IEC 60601-2-16:2008	Identical
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 60601-2-27:2011	ANSI/AAMI/IEC 60601-2-27:2011	Identical
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 80001-1:2010	ANSI/AAMI/IEC 80001-1:2010	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 62366:2007	ANSI/AAMI/IEC 62366:2007	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010	ANSI/AAMI/ISO 8638:2010	Identical
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006/(R)2010	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/(R)2010	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006/(R)2010	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:2010	ANSI/AAMI/ISO 10993-13:2010	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 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	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
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical

International designation	U.S. designation	Equivalency
ISO 11137-2:2006 (2006-08-01 corrected)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1:2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2:2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3:2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4:2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5:2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	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/(R)2010	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006/(R)2010	Identical
ISO 11663:2009	ANSI/AAMI/ISO 11663:2009	Identical
ISO 11737-1:2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO/TS 12417:2011	ANSI/AAMI/ISO TIR12417:2011	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 13958:2009	ANSI/AAMI/ISO 13958:2009	Identical
ISO 13959:2009	ANSI/AAMI/ISO 13959:2009	Identical
ISO 14155:2011	ANSI/AAMI/ISO 14155:2011	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/(R)2010	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	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/(R)2010	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 20857:2010	ANSI/AAMI/ISO 20857:2010	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 23500:2011	ANSI/AAMI/ISO 23500:2011	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 26722:2009	ANSI/AAMI/ISO 26722:2009	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 80369-1:2010	ANSI/AAMI/ISO 80369-1:2010	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

Cardiac Rhythm Management Device Committee

The adoption of ISO 27186 as an American National Standard was initiated by the AAMI Cardiac Rhythm Management Device Committee. The AAMI Cardiac Rhythm Management Device 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 Cardiac Rhythm Management Device Committee (U.S. Sub-TAG for ISO/TC 150/SC 6/JWG 1) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Cardiac Rhythm Management Device Committee** had the following members:

Cochairs	Roger G. Carrillo, MD, University of Miami Hospital (Independent Expert) Robert A Stevenson, Greatbatch Inc.
Members	Roger G. Carrillo, MD, University of Miami Hospital (Independent Expert) Luis Arabia Cortes, Instituto Oulton (Independent Expert) Tushar Dharampal, St Jude Medical Inc. Veronica Ivans, IMD Standards LLC (Independent Expert) Nimrod Kadim, BioControl Medical Patricia Krantz, Medtronic Inc. WHQ Campus Dongping Lin, PhD, (Independent Expert) Hans Moore, Washington DC VA Medical Center (Independent Expert) Ronald Reitan, Boston Scientific Corporation Mitchell J. Shein, FDA/CDRH Robert A Stevenson, Greatbatch Inc. Lawrence J. Stotts, PhD, Micro Systems Engineering Inc. William D. Toff, University of Leicester (Independent Expert) Frank Tyers, MD FRCSC FACS FACC, University of British Columbia (Independent Expert)
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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 27186:2010

As indicated in the foreword to the main body of this document (page viii), 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 guidance regarding design and performance requirements for two types of four-pole electrical connectors intended for use on implantable cardiac pacemakers and implantable defibrillators.

The AAMI Cardiac Rhythm Management Devices Committee serves as the U.S. sub-TAG for the relevant ISO working group and supports the adoption of ISO 27186:2010. Experts from the United States made a considerable contribution to this standard.

ANSI/AAMI/ISO 27186:2010 was approved by the American National Standards Institute (ANSI) on 24 August 2011.

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 ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

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 recommended practice. “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 N. Fairfax Drive, Suite 301, Arlington, VA 22203.

NOTE—Beginning with the foreword on page “viii”, this American National Standard is identical to ISO 27186:2010.

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 27186 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

Introduction

The purpose of this International Standard is to specify a four-pole connector assembly to provide interchangeability between implantable leads and pulse generators for cardiac rhythm management from different manufacturers. The safety, reliability, biocompatibility, biostability and function of any particular part are the responsibility of the manufacturer.

The four-pole connector was created to allow for a reduction in the number of individual lead connectors, reduce pocket bulk associated with existing bifurcated or trifurcated leads, reduce interaction of the lead bodies in the pocket and reduce set screw connections.

This International Standard establishes two types of connector assembly: a “high voltage connector” and a “low voltage only connector”, each of which has several configurations. The high voltage connectors either have two low voltage contacts combined with one or two high voltage contacts, or they have only two high voltage contacts. The low voltage only connectors have either three or four low voltage contacts.

The high voltage and low voltage only connectors and their voltage configurations are not intended to be interchangeable. This International Standard specifies a dimensional lockout feature that prevents the low voltage contacts of the lead connectors from contacting the high voltage contacts of high voltage connector cavities.

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WARNING — The low voltage only connector cavity specified in this International Standard is not to be used if the implantable pulse generator is capable of introducing dangerous non-pacing stimuli (e.g. defibrillation shocks) through the contacts of that connector cavity. Likewise, the high voltage lead connector specified in this International Standard is not to be used on leads intended for low voltage only therapy.

1 Scope

This International Standard specifies a four-pole connector system for implantable cardiac rhythm management devices which have pacing, electrogram sensing and/or defibrillation functions. This International Standard includes requirements for the connector portion of an implantable lead as well as for the mating connector cavity attached to an implantable pulse generator. Essential dimensions and performance requirements are specified together with appropriate test methods.

This International Standard is not intended to replace or provide alternatives for unipolar or bipolar connector standards that currently exist (such as ISO 11318 and ISO 5841-3). This International Standard is not applicable to high voltage systems with intended outputs greater than 1,000 V and/or 50 A. This International Standard is not applicable to systems which include sensors or unique electrodes that are not capable of conventional pacing, electrogram sensing and/or defibrillation functions.

This International Standard does not specify all connector features. It does not address all aspects of functional compatibility, safety or reliability of leads and pulse generators assembled into a system.

NOTE — Lead and pulse generator connector systems not conforming to this International Standard might be safe and reliable, and might have clinical advantages.

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 7436, *Slotted set screws with cup point*

ASTM A276, *Standard Specification for Stainless Steel Bars and Shapes*

ASTM B348, *Standard Specification for Titanium and Titanium Alloy Bars and Billets*

ASTM F562, *Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications*

ASTM F746-04, *Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials*

ASTM B896, *Standard Test Methods for Evaluating Connectability Characteristics of Electrical Conductor Materials*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

axial pin movement

axial movement of a lead connector pin with reference to the lead connector body as present in some designs, particularly those with a rotating connector pin

3.2

bipolar

having two poles or electrodes

NOTE See also tripolar (3.31), integrated bipolar (3.15), and four-pole (3.8).

3.3

connector system

assembly consisting of a lead connector and a connector cavity that are electrically and mechanically joined

3.4

connector cavity

cavity within the pulse generator which is intended to receive a lead connector

3.5

contact mechanism

conductive hardware within the connector cavity provided for making electrical connection to corresponding contacts on a lead connector

3.6

distal

farthest from a point of reference

NOTE The point of reference for a lead is the lead connector pin. Therefore, the most distal electrode of a lead is the electrode that is farthest from the lead connector pin. See also proximal (3.26).

3.7

fixation zone

zone located on the lead connector pin and within the connector cavity where the lead connector is mechanically secured within the connector cavity

3.8

four-pole

having four poles or electrodes

NOTE Generally a four-pole ICD lead has two low voltage electrodes and two high voltage electrodes. A four-pole low voltage only lead has four low voltage electrodes. See also bipolar (3.2) and tripolar (3.31).

3.9

functional contact zone

zone in the connector cavity which defines a site where electrical contact with a lead connector is to occur

3.10

functional seal zone

zone within the connector cavity which defines a site where sealing contact with a lead connector is to occur

3.11

grip zone

area of the lead connector which is provided for grasping during insertion and withdrawal of the lead connector from the connector cavity

3.12

high voltage

electrical potentials greater than 20 V up to 1,000 V

NOTE High voltages are generally used for defibrillating the heart.

3.13

high voltage connector

lead connector or connector cavity that has high voltage contacts

NOTE A high voltage connector may also contain low voltage contacts. See also low voltage only connector (3.22).

3.14

insertion indicator zone

zone on the pin of the lead connector allocated for manufacturers to provide a visual indicator for use in verifying full insertion of a lead connector into a connector cavity

3.15

integrated bipolar

having two lead poles or lead electrodes that are electrically common

NOTE A typical integrated bipolar ICD lead has a distal shock electrode that doubles as a proximal pace/sense ring electrode and is electrically attached to two separate lead connector contacts.

3.16

lead connector

part of a lead that is intended for insertion into the connector cavity of a pulse generator

3.17

lead connector contacts

conductive elements on the lead connector which include the lead connector pin and lead connector rings

3.18

lead connector pin

most proximal conductive element of a lead connector provided for making electrical contact as well as for securing the lead connector within the connector cavity

3.19

lead connector ring

annular conductive elements on the lead connector intended for making electrical contact within the connector cavity

NOTE The four-pole connector has three lead connector rings and a lead connector pin.

3.20

lead electrode

distal part of a lead through which electrical impulses are transmitted to or from cardiac tissue

NOTE High voltage electrodes are capable of delivering high voltage electrical impulses. Low voltage electrodes are used for transmitting and sensing low voltage impulses and are generally not suitable for delivering high voltage.

3.21

low voltage

electrical potential less than or equal to 20 volts

NOTE Low voltage is generally used for pacing and sensing the heart. See also high voltage (3.12).

3.22

low voltage only connector

lead connector or connector cavity that has only low voltage contacts

NOTE See also high voltage connector (3.13).

3.23

pin visibility zone

zone within the connector cavity which is allocated for visual verification that the lead connector is fully inserted

NOTE It corresponds to the insertion indicator zone of the lead connector.

3.24

pristine contact zone

zone on the lead connector which defines the minimum surface required for making electrical contact with the mating contact in the connector cavity

NOTE The pristine contact zones of the lead connector align with the functional contact zones of the connector cavity when the connectors are mated.

3.25

pristine seal zone

zone on the lead connector which defines the minimum surface required for sealing with the mating seals in the connector cavity

NOTE The pristine seal zones of the lead connector align with the functional seal zones of the connector cavity when the connectors are mated.

3.26

proximal

nearest to a point of reference

NOTE The point of reference for a lead is the lead connector pin. Therefore, the most proximal electrode of a lead is the electrode closest to the lead connector pin. See also distal (3.6).

3.27

pulse generator

device that delivers electrical energy to affect cardiac rhythms

3.28

sealing mechanism

circumferential barriers within the connector cavity intended to maintain electrical isolation between electrically insulated parts of an assembled and implanted connector system

3.29

securing mechanism

mechanism within the connector cavity intended for mechanically securing the lead connector

NOTE A securing mechanism can be an active mechanism such as a set screw or it can be a passive mechanism such as a self-engaging latch. It can also serve a second function of providing electrical contact with the lead connector, as is the case with a set screw.

3.30

strain relief zone

zone on the lead connector provided for making a gradual transition from a more rigid section to a more flexible section

NOTE The gradual transition results in an area over which strain is distributed so that concentrated mechanical forces do not occur when the lead is flexed.

3.31

tripolar

having three poles or electrodes

NOTE See also bipolar (3.2) and four-pole (3.8).

4 Requirements

4.1 General

Not all connector features or pulse generator features are specified nor do the requirements in 4.2 to 4.5 address all aspects of functional compatibility, safety or reliability of leads and pulse generators assembled into a system. Each manufacturer is responsible for any requirements and tests necessary to address these as well as the biocompatibility and biostability of their material choices.

The test methods provided for the requirements are type (qualification) tests. Equivalent test methods may be used. However, in the event of a dispute, the test methods described in 4.2 to 4.5 shall be used.

The following tests should be conducted under ambient conditions unless otherwise specified. Each manufacturer is responsible for any preconditioning required to represent “as-shipped” configurations, as well as for selection of appropriate sample sizes.

Leads and pulse generators marked according to Table 1 and Table 2 shall comply with all requirements in this International Standard.

4.2 Lead connector physical requirements

4.2.1 Dimensions

4.2.1.1 General

Lead connectors shall have the dimensions specified in Figure 1 and Figure 2 and shall meet the requirements outlined in 4.2.1.2 to 4.2.1.11 according to each zone.

4.2.1.2 Total axial pin movement, M

Total axial pin movement is the difference in lead connector pin length from when the connector pin is fully seated against datum A to when the connector pin is fully extended from datum A. Total axial pin movement shall not be greater than 0.25 mm.

4.2.1.3 Pristine contact zones

The minimum length of each of the pristine contact zones shall be $0.90 \text{ mm} + M$, where M is the total axial pin movement.

Lead connectors shall have an electrically conductive contact surface over the entire length of each of the pristine contact zones. Contact surfaces may extend beyond the pristine contact zones.

The surface finish in these zones shall be $Ra 0.8 \mu\text{m}$ maximum. The entire surface area shall be considered when measuring surface finish. No indentations, protrusions, gaps or steps exceeding surface finish allowance are allowed in these zones.

4.2.1.4 Pristine seal zones

The minimum length of each pristine seal zone shall be $1.81 \text{ mm} + M$, where M is the total axial pin movement in millimeters.

Lead connectors shall have a seal surface over the entire length of each of the pristine seal zones. Seal surfaces may extend beyond the pristine seal zones. No indentation, protrusions, gaps or steps exceeding surface finish allowance are allowed in these zones.

For surfaces of materials with durometers of nominally 75 Shore D, the surface finish in this zone shall be $Ra 0.8 \mu\text{m}$ maximum. The entire surface shall be considered when measuring surface finish except that uniform linear protrusions, such as caused by mould parting lines, may be excluded from the measurement if they do not exceed 0.025 mm in height as measured radially or 0.12 mm in width.

For surfaces in this zone made from materials with durometers harder than 75 Shore D nominal, the surface finish shall be $Ra 0.4 \mu\text{m}$ maximum when the entire surface is considered, including any uniform linear protrusions.

4.2.1.5 Lead connector body

The diameter for all conductive components and surfaces within this zone shall be $3.2 \text{ mm} \pm 0.03 \text{ mm}$.

The diameter for all non-conductive components and surfaces within this zone shall be $3.2 \text{ mm} \pm 0.05 \text{ mm}$.

For all areas in this zone except pristine seal zones and pristine contact zones, the following requirements apply.

- a) Any radial steps or protrusions, such as can occur between two adjacent components or by welds, shall not exceed 0.05 mm (in height) and shall not cause the diameter to go outside the tolerance specified with the following exception. Uniform linear protrusions that do not exceed 0.025 mm in height as measured radially or 0.12 mm in width are allowed only for surfaces of materials that are at nominally 75 Shore D.
- b) Any gap shall not exceed 0.1 mm in width when measured to include all edge breaks at the gap edge. There shall not be more than one gap between each pristine zone. For any gap that meets these requirements, the area within the gap need not meet the other requirements of this subclause, for example diameter and radial step requirements.
- c) Any indentations, such as holes or weld depressions, shall not exceed 0.5 mm in diameter and/or 0.5 mm in depth.
- d) Surface finish shall be R_a 1.6 μm maximum. Surface finish measurements need not include any surface features that meet the above requirements.

4.2.1.6 Strain relief zone

The diameter in this zone shall be 4.1 mm maximum and 3.8 mm minimum.

4.2.1.7 Grip zone

The diameter in this zone shall be 4.1 mm maximum.

4.2.1.8 Chamfer zone

The length of the chamfer in this zone shall be 0.35 mm minimally and $0.7 \text{ mm} - M$ maximally, where M is the total axial pin movement in millimeters.

4.2.1.9 Transition zone

The transition from the $\varnothing 3.2 \text{ mm}$ to the $\varnothing 4.1 \text{ mm}$ diameter shall occur within the envelope between datum B intersecting the 17.7 mm diameter and the 4.1 mm diameter and a line parallel to datum B intersecting the 18.70 mm maximum dimension.

NOTE The 60° dimension defines datum B, and transition geometry need not match this angle.

The diameter in this zone shall not exceed 4.1 mm.

4.2.1.10 Insertion indicator zone

This zone is provided for an optional insertion indicator. If an insertion indicator is present it shall meet the following requirements.

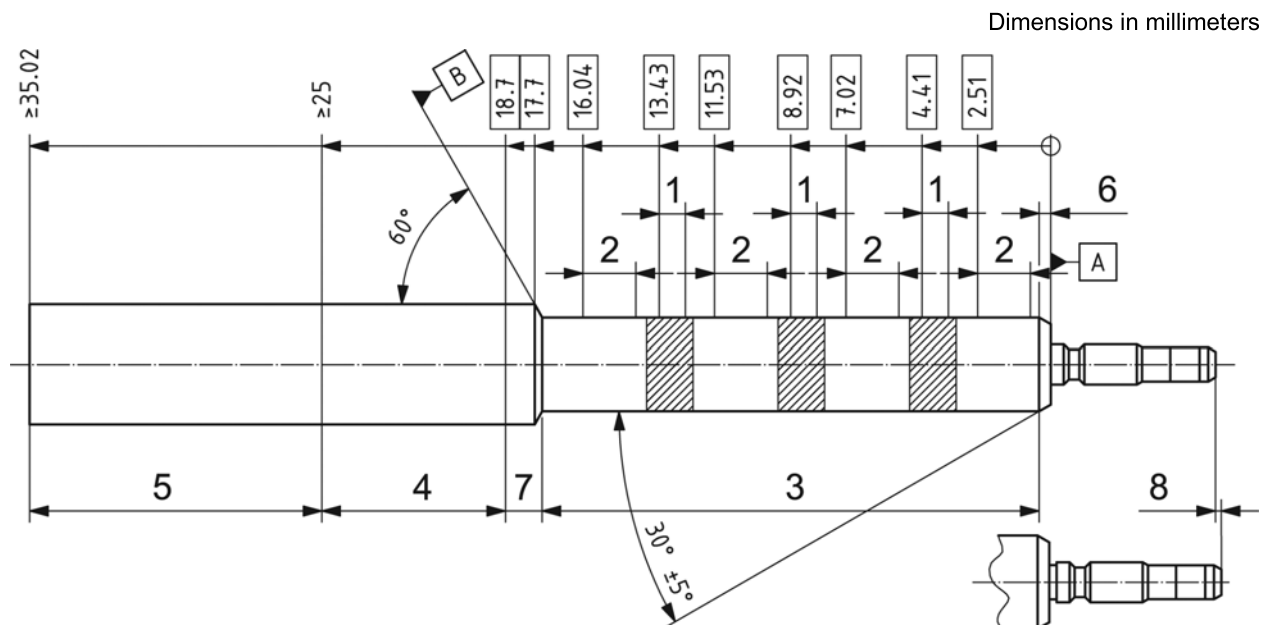
- a) The indicator shall not extend beyond the zone.
- b) The proximal edge shall meet the $5.10 \text{ mm} \pm 0.10 \text{ mm}$ dimension.
- c) The diameter shall fall within the nominal diameter specified and the tolerance of $^{+0.03}_{-0.10} \text{ mm}$.

- d) Any gaps shall not exceed 0.10 mm in width. For any gap that meets this requirement, the area within the gap need not meet the other requirements of this section, for example diameter and radial step requirements.
- e) Any radial steps shall not exceed 0.05 mm.

4.2.1.11 Pin pristine contact zone

Lead connectors shall have an electrical contact surface over the entire length of this zone.

The surface finish in this zone shall be Ra 0.8 μ m maximum.



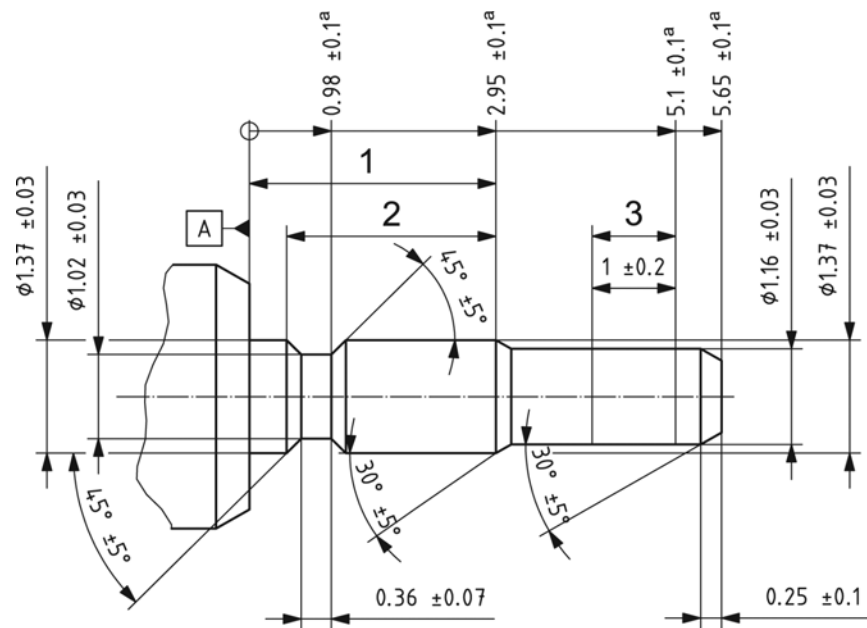
Key

- | | |
|--------------------------|--------------------------------------|
| 1 pristine contact zones | 5 grip zone |
| 2 pristine seal zones | 6 chamfer zone |
| 3 lead connector body | 7 transition zone |
| 4 strain relief zone | 8 total axial pin movement, <i>M</i> |

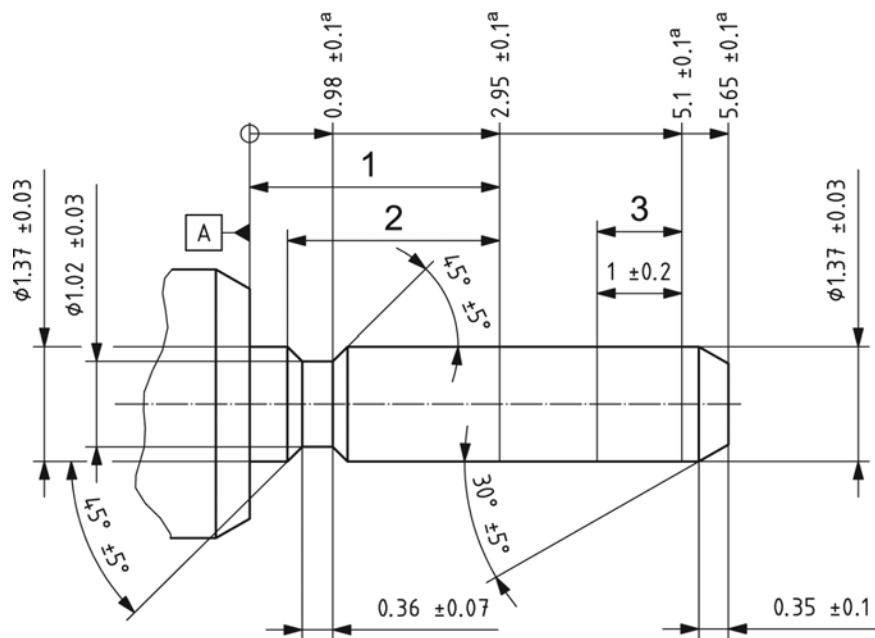
NOTE The diameter dimensions of the soft sections, in zone 4, zone 5 and zone 7, of the lead may be determined as the mean value of three measurements taken at locations oriented approximately 120° apart around the principal axis of the lead connector.

Figure 1 — Four-pole lead connector body

Dimensions in millimeters



a) High voltage lead connector pin



b) Low voltage only lead connector pin

Key

- 1 pin fixation zone
- 2 pin pristine contact zone
- 3 insertion indicator zone

^a Dimension applies when amount of pin axial movement has been minimized such as by axially seating the connector pin against datum A.

Figure 2 — Four-pole lead connector high voltage and low voltage only pin details

4.2.2 Materials

4.2.2.1 Contact materials

Lead connector contact materials shall meet the requirements of Annex M.

Based on observations made during the development of this International Standard, it is recommended that manufacturers consider selecting 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562 as a material for lead connector contacts. This material performed acceptably when evaluated by multiple manufacturers and was more consistent than several other materials tried. Contact material was identified as critical to connector performance and therefore verification to the requirements in this International Standard should be made when using this or any other material.

4.2.2.2 Seal surface material

Lead connector seal zone materials are not specified; however, recommendations are provided in Annex H.

4.2.3 Lead connector electrical connections

4.2.3.1 According to the appropriate configuration, each lead connector contact shall be in electrical continuity with the specific and distinct lead electrode described in Table 1 when the following applies:

- “LOW voltage” refers to stimulating electrodes having pacing and electrogram sensing function;
- “HIGH voltage” refers to stimulating electrodes having high voltage defibrillation capability;
- “OPEN” refers to lead connector contacts that are not in electrical continuity with any lead electrode.

4.2.3.2 The lead connector pin of low voltage only lead connectors shall conform to Figure 2 b).

4.2.3.3 The lead connector pin of high voltage lead connectors including integrated bipolar connectors shall conform to Figure 2 a).

NOTE Ring 2 and ring 3 contacts of high voltage lead connectors should not be in direct electrical continuity with lead electrodes that are not intended for high voltage.

4.2.4 Lead marking

4.2.4.1 Marking symbol

Lead connectors shall be marked with the appropriate symbol according to Table 1 and sized appropriately for the component being marked.

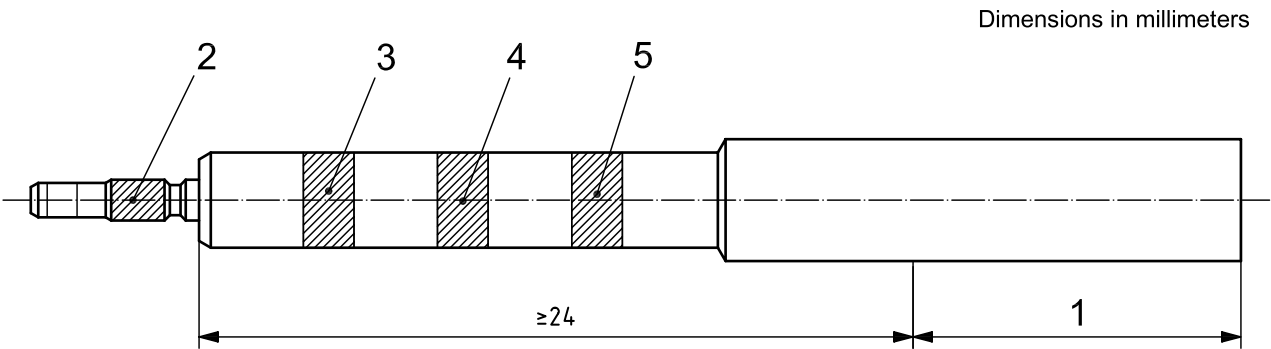
4.2.4.2 Marking location

Marking shall be located in the marking zone (see Figure 3).

4.2.4.3 Marking orientation

Marking shall read left to right when the lead connector is oriented with the connector pin to the left.

NOTE It is the responsibility of the manufacturer to ensure marking on lead connectors is permanent and legible under intended use conditions.



Key

- 1 marking zone
- 2 lead connector pin
- 3 lead connector ring 1
- 4 lead connector ring 2
- 5 lead connector ring 3

Figure 3 — Identification of lead connector contacts

Table 1 — Lead marking symbols and electrical connections within the lead — Permitted configurations

	Configuration and marking symbol	Connector pin	Ring 1	Ring 2	Ring 3
Low voltage only	IS4-LLLL	Most distal LOW voltage electrode	2nd most distal LOW voltage electrode	3rd most distal LOW voltage electrode	Most proximal LOW voltage electrode
	IS4-LLLO	Most distal LOW voltage electrode	2nd most distal LOW voltage electrode	3rd most distal LOW voltage electrode	OPEN
	IS4-LOLL	Most distal LOW voltage electrode	OPEN	2nd most distal LOW voltage electrode	Most proximal LOW voltage electrode
High voltage	DF4-LLHH	Most distal LOW voltage electrode	2nd most distal LOW voltage electrode	Most distal HIGH voltage electrode	Most proximal HIGH voltage electrode
	DF4-LLHO	Most distal LOW voltage electrode	2nd most distal LOW voltage electrode	Most distal HIGH voltage electrode	OPEN
	DF4-OOHH	OPEN	OPEN	Most distal HIGH voltage electrode	Most proximal HIGH voltage electrode
Integrated bipolar	DF4-LLHH	Most distal LOW voltage electrode	^a Most distal HIGH voltage electrode	Most distal HIGH voltage electrode	Most proximal HIGH voltage electrode
	DF4-LLHO	Most distal LOW voltage electrode	^a Most distal HIGH voltage electrode	Most distal HIGH voltage electrode	OPEN

^a For integrated bipolar leads the most distal HIGH voltage electrode may also be used for low voltage pacing and sensing function.

4.3.1.2 Requirement

Both initially and after soaking, the force to fully insert the lead connector into the lead connector gauge shall be less than 4.5 N. The lead connector is considered fully inserted into the gauge when the connector pin is visible outside the 1.43 mm diameter. The lead connector need not be bottomed out in the gauge in order to be considered fully inserted.

4.3.2 Tensile loads

4.3.2.1 Test method

Soak the lead connector in saline (nominally 9 g/l at $37\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$) for 10 d minimum prior to testing. After soaking and while in a wetted state, fasten the lead connector at the lead connector pin and apply a tensile load of 14 N minimum at the grip zone. Maintain the load for at least 10 s. Repeat tensile loading a minimum of five cycles.

4.3.2.2 Requirement

After tensile loading the lead shall meet the linear dimensions in Figures 1 and 2 measured from datum A and the requirements of 4.2.1.2, 4.3.6, 4.3.7 and 4.3.8.

4.3.3 Deformation due to pin contact forces

4.3.3.1 Test method

Insert the lead connector into a test cavity that conforms to the bore dimensions of Figure 7 a) for high voltage and Figure 7 b) for low voltage only and which has M2 screw threads located within the functional pin contact zone. Use an M2 titanium grade 5 as described in ASTM B348, 860 MPa minimum tensile strength, set screw with cup point that complies with ISO 7436.

Tighten the screw to a torque of $0.15\text{ N}\cdot\text{m} \pm 0.01\text{ N}\cdot\text{m}$. Maintain the load for 10 s minimum and then release the set screw.

4.3.3.2 Requirement

The force to withdraw the lead connector from and re-insert it into the test cavity shall not exceed 4.5 N.

After removal, the lead connector shall meet the contact zone diameter requirements in Figure 2.

NOTE 1 For lead connector designs utilizing a through-hole for stylets, it is recommended that the manufacturer verify that the through-hole is still functional following application of the set screw load.

NOTE 2 It is recognized that at the time of this International Standard most manufactured devices utilize 2-56 hexagon head set screws for lead connector retention. Although they are similar in size, the equivalency between the two types of set screw has not been established. Therefore an M2 set screw is specified herein for use in a dispute.

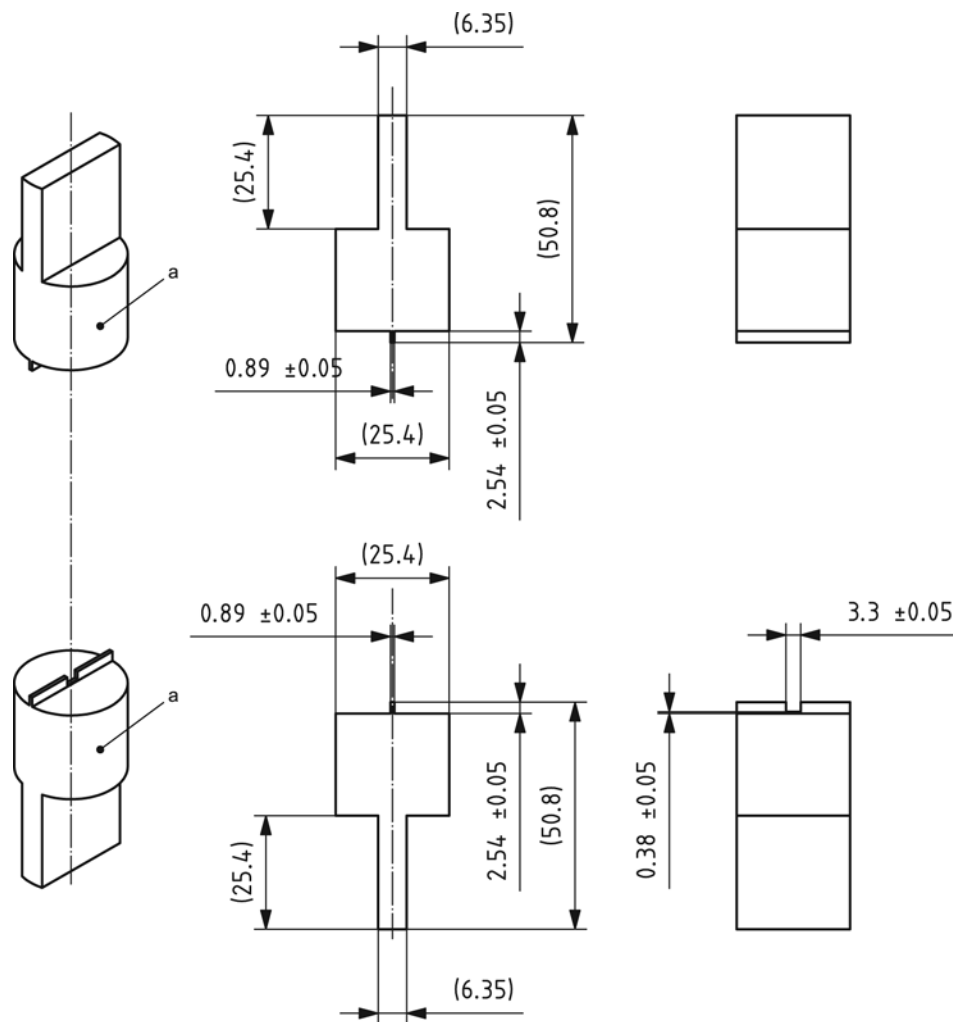
NOTE 3 Lead manufacturers are encouraged to evaluate the durability of their lead connector insertion indicator zone when exposed to the forces associated with handling and implanting conditions, including use with patient cable alligator clips, passive retention systems, set screws and other types of tool that might be used during an implant procedure. Manufacturers should confirm that the insertion indicator does not become functionally degraded or dislodged from the lead connector pin after exposure to handling and implant conditions.

4.3.4 Deformation due to ring contact forces

4.3.4.1 Test method

Use two aligned metal blade indenters that conform to Figure 5 to apply a compressive load to the outer diameter of each ring in the pristine contact zone (see Figure 1). Apply a minimum load of 9 N and maintain the load for a minimum of 10 s.

Dimensions in millimeters



a Material: metal.

Figure 5 — Ring contact force test fixture

4.3.4.2 Requirement

After application and release of the load, the lead connector shall meet the requirements of 4.2.1.5 with the exception of the surface finish requirement, the functional check of 4.3.1 and the electrical requirements of 4.3.6, 4.3.7 and 4.3.8.

4.3.5 Seal zone requirement

There is no functional requirement for seal zones. See Annex H and Annex I for design recommendations.

4.3.6 Electrical isolation requirement

The lead connector shall provide electrical isolation between each of the lead connector contacts and between the contacts and the surrounding fluid. Compliance shall be determined as described in Annex A.

4.3.7 Dielectric strength requirement

The lead connector shall provide high voltage electrical isolation between each of the lead connector contacts and between the contacts and the surrounding fluid. This requirement applies only to high voltage lead connectors. Compliance shall be determined as described in Annex C.

4.3.8 Current-carrying requirement

The high voltage lead connectors shall be capable of carrying defibrillation current. Compliance shall be determined as described in Annex E.

4.3.9 Corrosion/environmental

Compliance shall be determined as described in Annex M.

4.4 Connector cavity physical requirements

4.4.1 Dimensions

4.4.1.1 General

The connector cavity shall have the dimensions specified in Figure 6 and Figure 7 and shall meet the following requirements according to each zone.

4.4.1.2 Functional contact zones

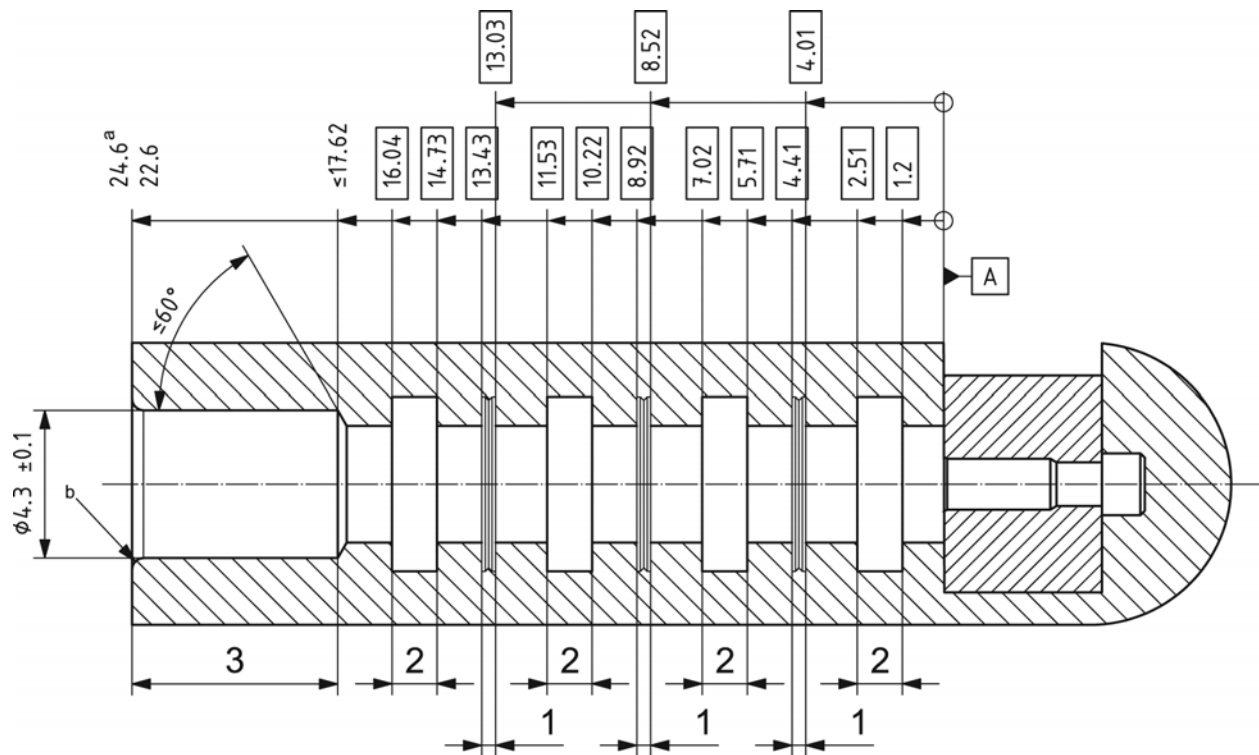
The electrically active contact surfaces for mating with the lead connector shall be located within the functional contact zones (see Figure 6) and functional pin contact zone (see Figure 7). Contact hardware may extend beyond these zones. This requirement does not apply for contacts that are not active.

4.4.1.3 Functional seal zones

Connector cavities shall provide for functional sealing within the functional seal zones (see Figure 6). Seal hardware may extend beyond these zones.

4.4.1.4 Material

The structural support of the connector cavity shall be constructed of a material with a minimum hardness of 70 Shore D.



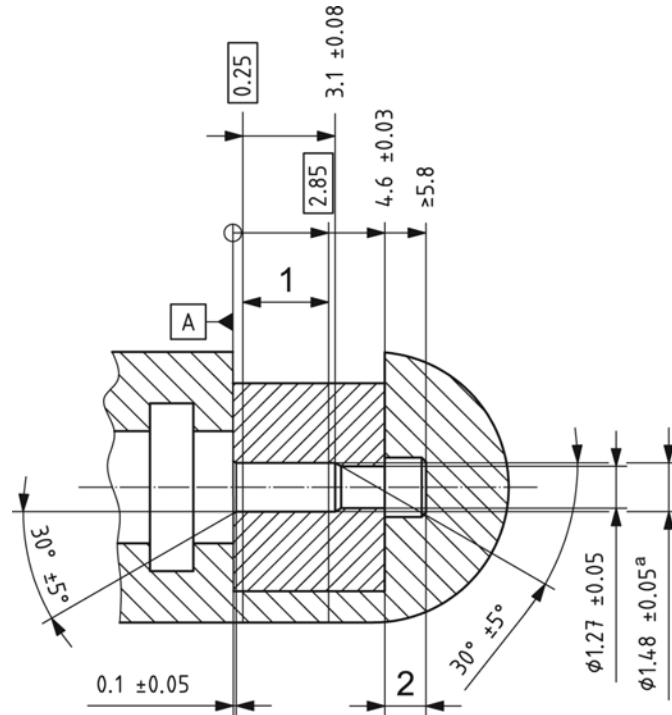
Key

- 1 functional contact zones
- 2 functional seal zones
- 3 stabilization zone

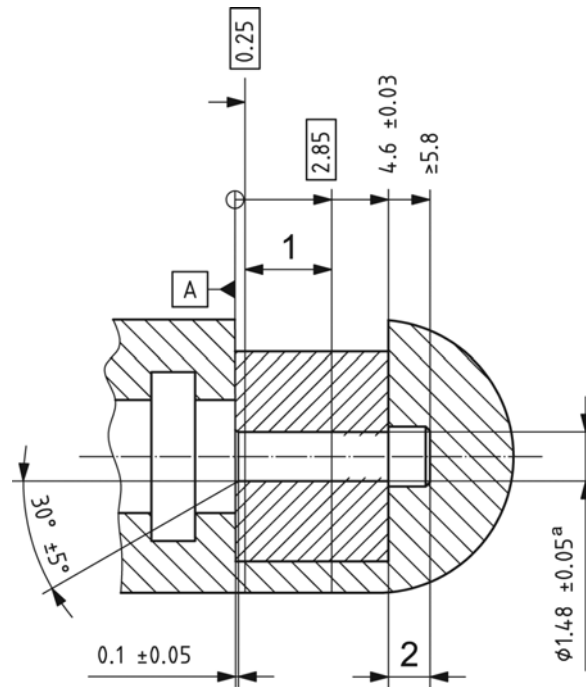
^a The surface of the bore entrance need not be perpendicular to the bore axis as long as the entire circumference of the bore entrance is located within the 22.6 mm minimum and 24.6 mm maximum specified.

^b Radius or chamfer, 0.33 mm ± 0.13 mm.

Figure 6 — Four-pole connector cavity



a) High voltage pin cavity



b) Low voltage only pin cavity

Key

1 functional contact zone 2 pin visibility zone

^a Securing mechanisms can have features that are smaller than the 1.48 mm diameter as necessary to secure the lead connector.

Figure 7 — Four-pole connector cavity tip detail

4.4.2 Connector cavity electrical connections

4.4.2.1 According to the appropriate configuration, each connector cavity contact shall be in electrical continuity with the specific device outputs described in Table 2 when the following applies:

- “LOW” are device outputs ≤ 20 V;
- “HIGH” are device outputs between 20 V and 1,000 V peak and < 50 A;
- “OPEN” refers to connector cavity contacts that are not in electrical continuity with any device output.

4.4.2.2 Low voltage only version connector cavities shall conform to Figure 7 b).

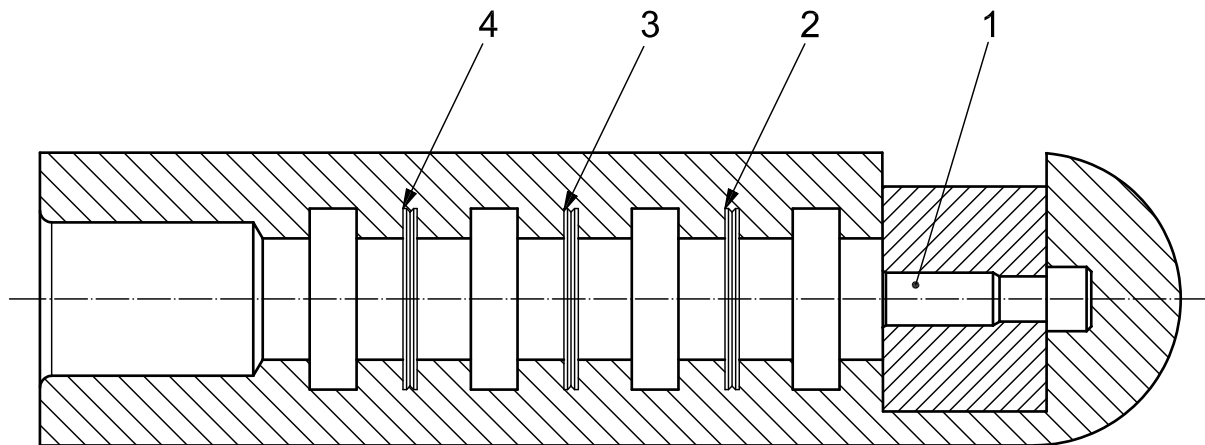
4.4.2.3 High voltage version connector cavities shall conform to Figure 7 a).

NOTE Connector cavity contacts designated as low voltage are not designed to deliver high voltage output.

4.4.3 Connector cavity/pulse generator marking

Pulse generators with connector cavities conforming to this International Standard shall be marked with the appropriate symbols in accordance with Table 2 and sized appropriately for the component being marked.

NOTE It is the responsibility of the manufacturer to ensure marking on pulse generators is permanent and legible under intended use conditions.



Key

- 1 pin contact
- 2 ring 1 contact
- 3 ring 2 contact
- 4 ring 3 contact

Figure 8 — Identification of contacts in the connector cavity