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

Dispositifs médicaux actifs implantables — Systèmes de branchement à quatre pôles pour dispositifs implantables de gestion du rythme cardiaque — Exigences de dimensions et d'essai

ICS: 11.040.40

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

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

This second edition cancels and replaces the first edition (ISO 27186:2010), which has been technically revised.

The main changes compared to the previous edition are as follows:

— Minor typographical errors were corrected.

— The notch feature on lead connector pins was made optional whereas previously it was required.

— Use of the notch feature for retention is no longer permitted.

— Clarification was made for how to verify the functional sealing and functional contact zone requirements in 4.4.1.2 and 4.4.1.3.

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

Introduction

The purpose of this document 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 document 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 document 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 document 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 document is not to be used on leads intended for low-voltage only therapy.

1 Scope

This document specifies a four-pole connector system for implantable cardiac rhythm management devices which have pacing, electrogram sensing and/or defibrillation functions. This document 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 document 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 document is not applicable to high-voltage systems with intended outputs greater than 1 000 V and/or 50 A. This document 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 document 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 document might be safe and reliable and might have clinical advantages.

2 Normative references

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

ISO 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.

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

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

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

3.1
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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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 1 to entry: 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, typically 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 1 to entry: 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 1 to entry: 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 this document 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 and are not intended to be used as routine production tests. Alternate test methods may be used, including those which result in equivalent or more stringing test conditions. However, in the event of dispute, the test methods described in this document determine compliance.

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 document.

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 mm + M, where M is the total axial pin movement in millimetres.

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 µm 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 mm + *M*, where *M* is the total axial pin movement in millimetres.

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 hardness 75D or less, the surface finish in this zone shall be Ra 0,8 µm 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 hardness above 75D, the surface finish shall be Ra 0,4 µm 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 mm ± 0,03 mm.

The diameter for all non-conductive components and surfaces within this zone shall be 3,2 mm ± 0,05 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 75 Shore D or below.

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

d) Surface finish for zone 3 of Figure 1 shall be Ra 0,8 µm maximum from datum A to 16,04 mm and shall be Ra 1,6 µm maximum from 16,04 mm to the transition zone 7, excluding the chamfer area. Surface finish measurements need not include any surface features that meet the above requirements 4.2.1.5 a to c.

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 4,3 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 mm – *M* maximally, where *M* is the total axial pin movement in millimetres.

4.2.1.9 Transition zone

The transition between the Ø3,2 mm nominal and the Ø4,1 mm maximum shall occur within the theoretical envelope between datum B, which intersects the Ø4,1 mm at the 17,7 mm dimension, and Datum C.

The diameter in this zone shall not exceed 4,1 mm.

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

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 mm ± 0,10 mm dimension.

c) The diameter shall fall within the nominal diameter specified and the tolerance of $\frac{+0,03}{-0,10}$ 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 µm maximum.