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Introduction

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Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 27186

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*

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ISO/TC 150/SC 6

Secretariat: **ANSI**

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2024-08-29

Voting terminates on:
2024-11-21

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Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	5
4.1 General	5
4.2 Lead connector physical requirements	5
4.2.1 Dimensions	5
4.2.2 Materials	9
4.2.3 Lead connector electrical connections	9
4.2.4 Lead marking	9
4.2.5 Lead package labels and literature	11
4.3 Lead connector functional requirements	11
4.3.1 Functional dimensional check	11
4.3.2 Tensile loads	12
4.3.3 Deformation due to pin contact forces	12
4.3.4 Deformation due to ring contact forces	12
4.3.5 Seal zone requirement	13
4.3.6 Electrical isolation requirement	13
4.3.7 Dielectric strength requirement	14
4.3.8 Current-carrying requirement	14
4.3.9 Corrosion/environmental	14
4.3.10 Lead connector insertion force	14
4.4 Connector cavity physical requirements	14
4.4.1 Dimensions	14
4.4.2 Connector cavity electrical connections	17
4.4.3 Connector cavity/pulse generator marking	17
4.4.4 Pulse generator labels and literature	18
4.5 Connector cavity functional requirements	18
4.5.1 Insertion force	18
4.5.2 Retention force	19
4.5.3 Withdrawal force	20
4.5.4 Ring contact load	20
4.5.5 Seal zone load requirement	20
4.5.6 Electrical isolation requirement	21
4.5.7 Dielectric strength requirement	21
4.5.8 Current-carrying requirement (high-voltage connector cavity)	21
4.5.9 Contact resistance/stability	21
Annex A (normative) Electrical isolation test	22
Annex B (informative) Rational for Annex A	27
Annex C (normative) Dielectric strength test	29
Annex D (informative) Rational for Annex C	34
Annex E (normative) Current-carrying test high-voltage types	38
Annex F (informative) Rational for Annex E	43
Annex G (informative) Lead connector fatigue strength test	45
Annex H (informative) Lead connector seal zone materials	46
Annex I (informative) Seal zone creep	48
Annex J (informative) Contact resistance stability	53

Annex K (informative) Rational for Annex J	56
Annex L (informative) Selection of contact materials	58
Annex M (normative) Lead connector contact material requirements	60
Annex N (informative) Rational for Annex M	63
Annex O (informative) Rationale for requirements in this document	69
Annex P (informative) Connector products	76
Annex Q (normative) Lead connector insertion test	78
Annex R (informative) Rationale for Annex Q	87
Annex S (normative) Connector cavity insertion and withdrawal test	94
Annex T (normative) Rationale for Annex S	100
Bibliography	108

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 jointly by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*, and Technical Committee IEC/SC 62D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This third edition cancels and replaces the second edition (ISO 27186:2020), which has been technically revised.

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

- Updated the requirement and test method for the IPG connector cavity insertion force measurement. [Section 4.5.1](#) was updated to point to [annex S](#). The test method was moved to [Annex S](#) and [Annex T](#) was created to provide background and rationale for the method and limits in [Annex S](#).
- Updated requirement and test method for the Lead insertion force measurement. [Section 4.3.1](#) was clarified to be a dimensional check. [Section 4.3.10](#) Lead connector insertion force was added. The test method is described in [Annex Q](#) and [Annex R](#) was created to provide background and rationale for the method and limits in [Annex Q](#).

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

The intent of this document is to define a four-pole connector assembly that provides interchangeability between implantable leads and pulse generators from different manufacturers.

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.

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

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 (CRM) 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.

NOTE The safety, reliability, biocompatibility, biostability and function of any particular part are the responsibility of the manufacturer.

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.

This document 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 can be safe and reliable and can 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, *Fasteners — Slotted set screws with cup point*

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*

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 <https://www.electropedia.org/>

3.1 axial pin movement

axial movement of a *lead connector pin* (3.18) with reference to the *lead connector* (3.16) 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* (3.16) and a *connector cavity* (3.4) that are electrically and mechanically joined

3.4 connector cavity

cavity within the *pulse generator* (3.27) which is intended to receive a *lead connector* (3.16)

3.5 contact mechanism

conductive hardware within the *connector cavity* (3.4) provided for making electrical connection to corresponding contacts on a *lead connector* (3.16)

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* (3.18). 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

a specified area on the *lead connector pin* (3.18) and within the *connector cavity* (3.4) where the *lead connector* (3.16) 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* (3.21) electrodes and two *high-voltage* (3.12) 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

a specified area within the *connector cavity* (3.4) where electrical contact with a *lead connector* (3.16) occurs

3.10 functional seal zone

a specified area within the *connector cavity* (3.4) where sealing contact with a *lead connector* (3.16) occurs

3.11 grip zone

a specified area of the *lead connector* (3.16) which is provided for grasping during insertion and withdrawal of the lead connector from the *connector cavity* (3.4)

3.12**high-voltage**

electrical potential greater than 20 V and that can go 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 (3.16) or *connector cavity* (3.4) that has *high-voltage* (3.12) contacts

Note 1 to entry: A high-voltage connector may also contain *low-voltage* (3.21) contacts. See also *low-voltage only connector* (3.22).

3.14**insertion indicator zone**

a specified area on the pin of the *lead connector* (3.16) allocated for manufacturers to provide a visual indicator for use in verifying full insertion of a lead connector into a *connector cavity* (3.4)

3.15**integrated bipolar**

two lead poles or *lead electrodes* (3.20) that are electrically common

Note 1 to entry: A typical integrated bipolar ICD lead has a *distal* (3.6) shock electrode that doubles as a *proximal* (3.26) pace/sense ring electrode and is electrically attached to two separate *lead connector contacts* (3.17).

3.16**lead connector**

part of a lead that is intended for insertion into the *connector cavity* (3.4) of a *pulse generator* (3.27)

3.17**lead connector contacts**

conductive elements on the *lead connector* (3.16) which include the *lead connector pin* (3.18) and *lead connector rings* (3.19)

3.18**lead connector pin**

most *proximal* (3.26) conductive element of a *lead connector* (3.16) provided for making electrical contact as well as for securing the lead connector within the *connector cavity* (3.4)

3.19**lead connector ring**

annular conductive element on the *lead connector* (3.16) intended for making electrical contact within the *connector cavity* (3.4)

Note 1 to entry: The *four-pole* (3.8) connector has three lead connector rings and a *lead connector pin* (3.18).

3.20**lead electrode**

distal (3.6) part of a lead through which electrical impulses are transmitted to or from cardiac tissue

Note 1 to entry: *High-voltage* (3.12) electrodes are capable of delivering high-voltage electrical impulses. *Low-voltage* (3.21) 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 (3.16) or *connector cavity* (3.4) that has only *low-voltage* (3.21) contacts

Note 1 to entry: See also *high-voltage connector* (3.13).

3.23**pin visibility zone**

a specified area within the *connector cavity* (3.4) which is allocated for visual verification that the *lead connector* (3.16) is fully inserted

Note 1 to entry: It corresponds to the *insertion indicator zone* (3.14) of the lead connector.

3.24**pristine contact zone**

a specified area on the *lead connector* (3.16) which defines the minimum surface required for making electrical contact with the mating contact in the *connector cavity* (3.4)

Note 1 to entry: The pristine contact zones of the lead connector align with the *functional contact zones* (3.9) of the *connector cavity* (3.4) when the connectors are mated.

3.25**pristine seal zone**

a specified area on the *lead connector* (3.16) which defines the minimum surface required for sealing with the mating seals in the *connector cavity* (3.4)

Note 1 to entry: The pristine seal zones of the lead connector align with the *functional seal zones* (3.10) of the *connector cavity* (3.4) 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* (3.18). 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* (3.4) intended to maintain electrical isolation between electrically insulated parts of an assembled and implanted *connector system* (3.3)

3.29**securing mechanism**

mechanism within the *connector cavity* (3.4) intended for mechanically securing the *lead connector* (3.16), typically a set screw

3.30**strain relief zone**

a specified area on the *lead connector* (3.16) 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**

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 stringent test conditions. However, in the event of dispute, the test methods described in this document shall be used.

The following tests shall 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. See [Annex O](#) for rationale.

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 μ 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 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 μ 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 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 $3,2 \text{ mm} \pm 0,03 \text{ mm}$.

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 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 $\varnothing 3,2$ mm nominal and the $\varnothing 4,1$ mm maximum shall occur within the theoretical envelope between datum B and Datum C. Datum B is defined by the 60° angle and the intersection of the $\varnothing 4,1$ mm at the 17,7 mm dimension. 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.

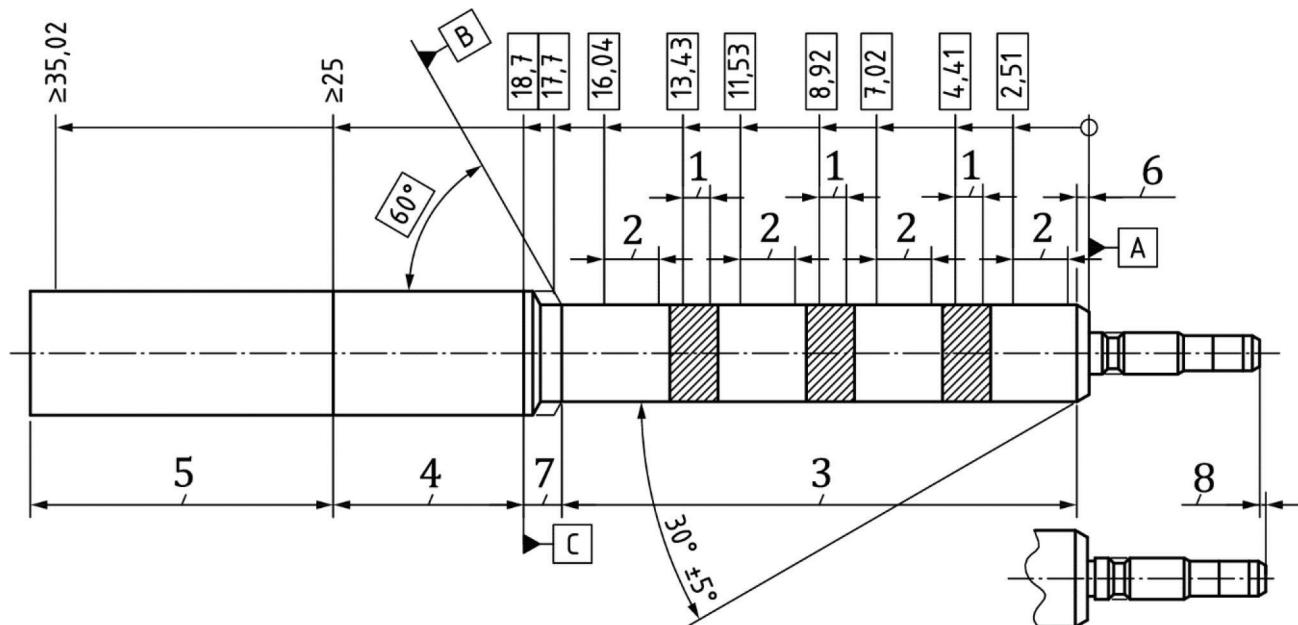
- c) The diameter shall fall within the nominal diameter specified and the tolerance of $\frac{+0,03}{-0,10}$ mm.
- d) Any gaps shall not exceed 0,10 mm in width. For any gap that meets this requirement, the area within the gap need not meet the other requirements of this section, for example diameter 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 μ m maximum.

Dimensions in millimetres

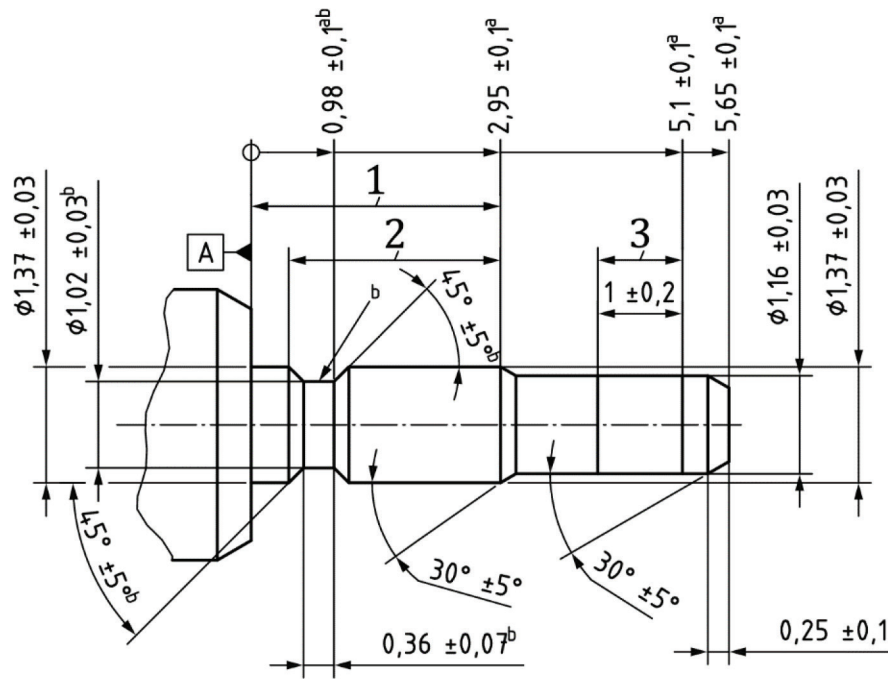


Key

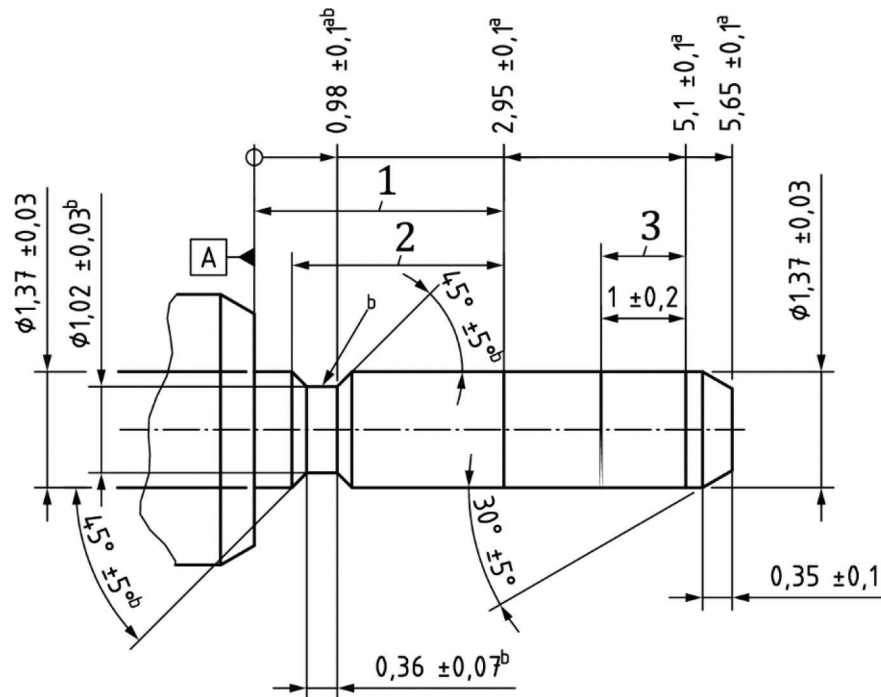
- | | | | |
|---|------------------------|---|-------------------------------|
| 1 | pristine contact zones | 5 | grip zone |
| 2 | pristine seal zones | 6 | chamfer zone |
| 3 | lead connector body | 7 | transition zone |
| 4 | strain relief zone | 8 | total axial pin movement, M |

NOTE The diameter dimensions of the soft sections, in zone 4, zone 5 and zone 7, of the lead can 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



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 only when all axial movement has been biased by seating the connector pin against the connector body.
- ^b Dimension applies to the notch feature. Notch feature is optional and may be omitted.

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 document, 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 document 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.

Ring 2 and ring 3 contacts of high-voltage lead connectors shall not be in direct electrical continuity with lead electrodes that are not intended for high-voltage because they could be exposed to high voltage during use.

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](#)).

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.

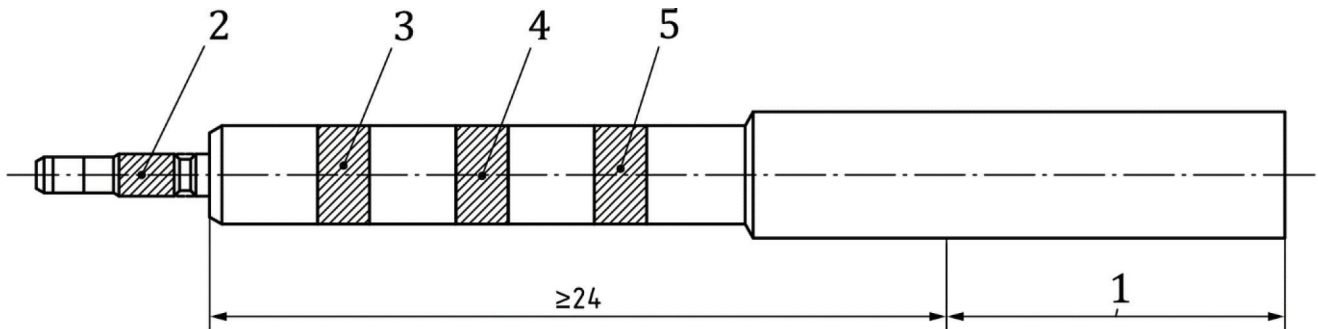
4.2.4.2 Marking location

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 | 4 | lead connector ring 2 |
| 2 | lead connector pin | 5 | lead connector ring 3 |
| 3 | lead connector ring 1 | | |

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	Most distal High-voltage electrode ^a	Most distal High-voltage electrode	Most proximal High-voltage electrode
	DF4-LLHO	Most distal Low-voltage electrode	Most distal High-voltage electrode ^a	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.

4.2.5 Lead package labels and literature

Package labels and product literature are the responsibility of the lead manufacturer; however, the appropriate marking symbols shown in [Table 1](#) should be used at all times when referring to lead connectors conforming to this document.

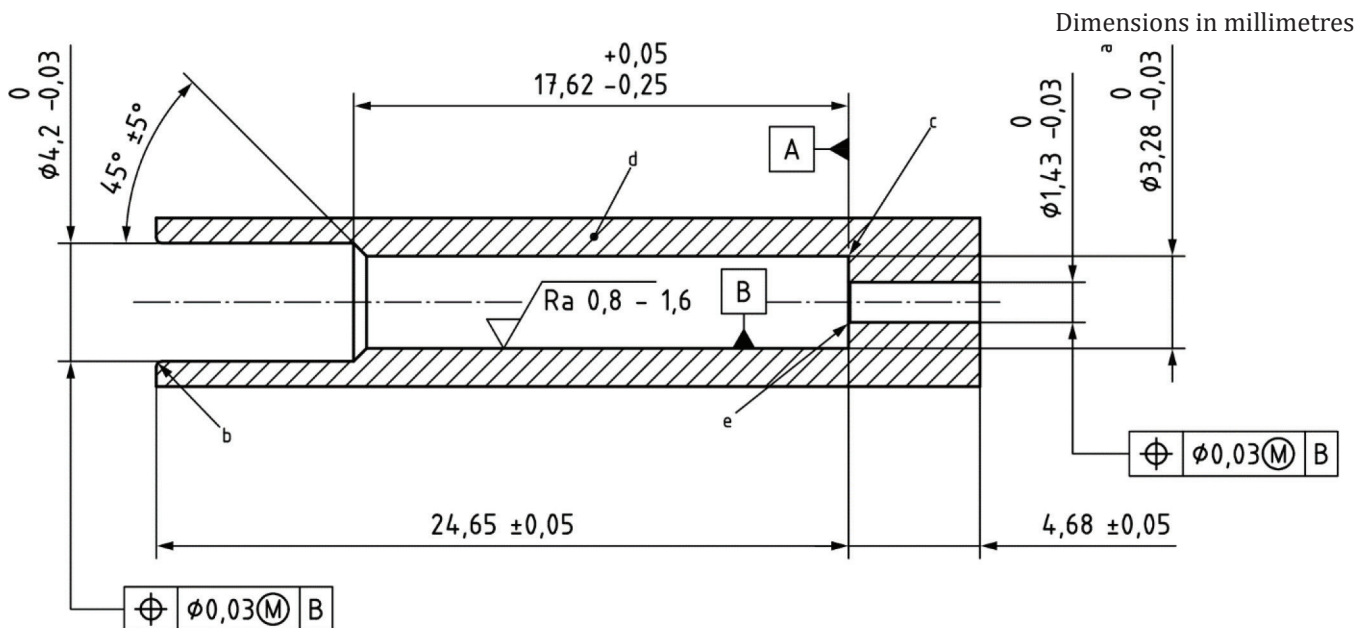
NOTE The four-pole lead connectors specified in this document might not be compatible with the wide variety of existing analyser cables that are currently used with other connectors (such as IS-1 and DF-1). Specifically, the terminals of some analyser cables can result in bridging and shorting of the more closely-spaced lead connector contacts of the four-pole connector. Bridging and shorting during an implant procedure can result in erroneous measurements of performance characteristics (e.g. R waves, P waves, impedances, pacing thresholds) or a temporary inability to provide pacing therapy. Manufacturers are individually responsible for providing appropriate warnings, education or other means of mitigating the risk of bridging and shorting as can occur due to use of analyser cable terminals with their respective lead connectors. See also [P.3](#).

4.3 Lead connector functional requirements

4.3.1 Functional dimensional check

4.3.1.1 Test method

Insert the lead connector into the lead connector go gauge conforming to [Figure 4](#). Perform this test both with the lead connector in an initial state and after a 10 d minimum soak in saline (nominally 9 g/l at $37\text{ °C} \pm 5\text{ °C}$).



- a The 3,28 mm maximum diameter exceeds the largest permissible lead diameter by 0,03 mm to accommodate axis curvature of the lead connector or localized offsets that might be present between lead connector components.
- b Radius or chamfer 0,20 mm maximum.
- c Radius or chamfer 0,1 mm maximum.
- d Material: Steel, Stainless Steel, Titanium, Titanium Alloys or 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562.
- e Edge break 0,05 mm maximum.

Figure 4 — Lead connector go gauge

4.3.1.2 Requirement

Both initially and after soaking, the force to fully insert the lead connector into the lead connector go 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 $37\text{ °C} \pm 5\text{ °C}$) 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 [Figure 1](#) and [Figure 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](#).

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.

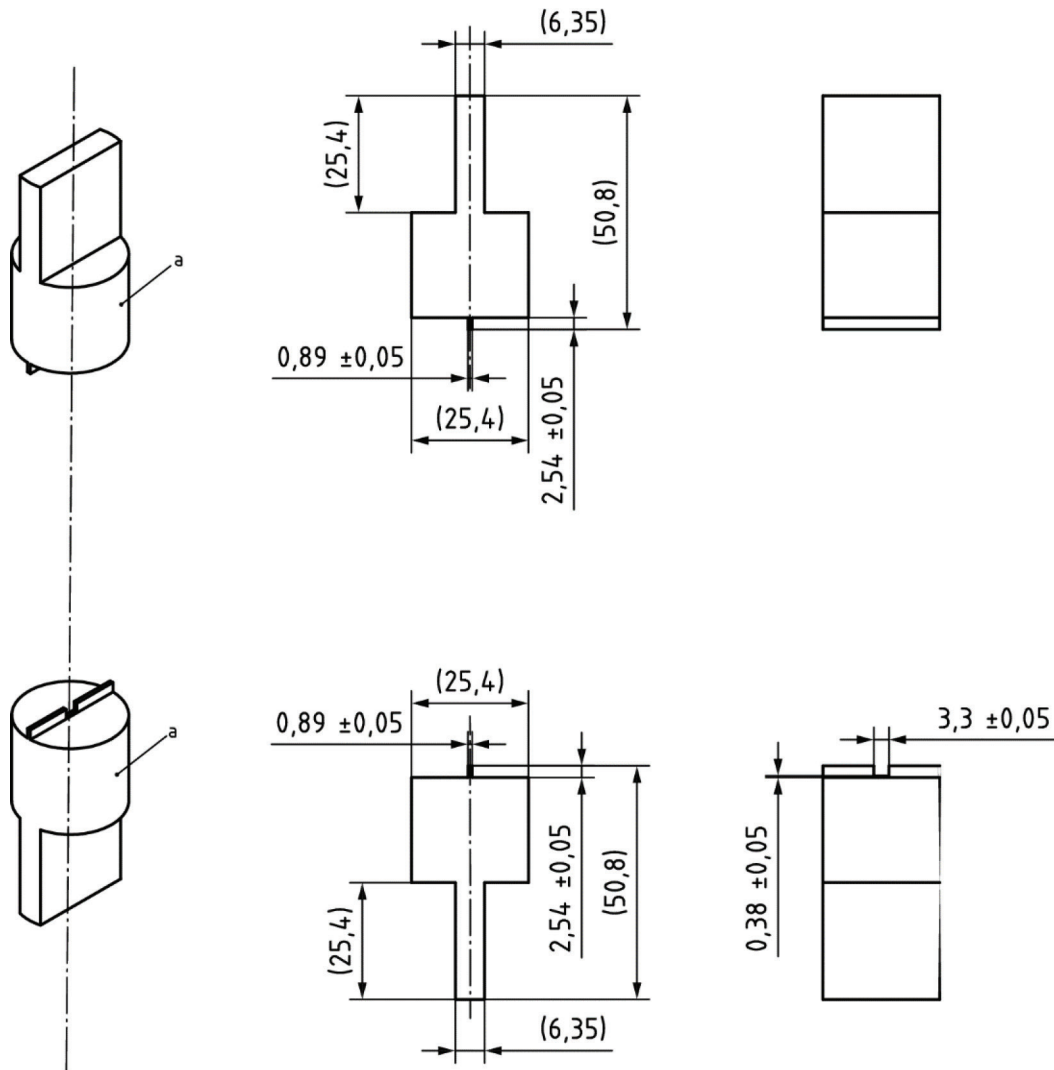
NOTE 1 It is recognized that at the time of publication of this document, most manufactured devices utilize 2–56 hexagon head set screws for lead connector retention. Although they are similar in size, the equivalency between the two types of set screw has not been established. Therefore, an M2 set screw is specified herein for use in a dispute.

NOTE 2 Additional testing can be necessary to confirm that the insertion indicator withstands other handling and implant conditions such as attachment of patient cable alligator clips.

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.



^a Material: steel, stainless steel, titanium, titanium alloys or 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562.

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](#) (see [Annex D](#) for rationale to [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](#).

4.3.10 Lead connector insertion force

The force to fully insert a lead connector shall be less than or equal to 35 N. Compliance shall be determined as described in [Annex Q](#).

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.

The connector cavity shall be designed such that it does not make use of the optional notch feature on the lead connector (see [Figure 2](#) note b).

4.4.1.2 Functional contact zones

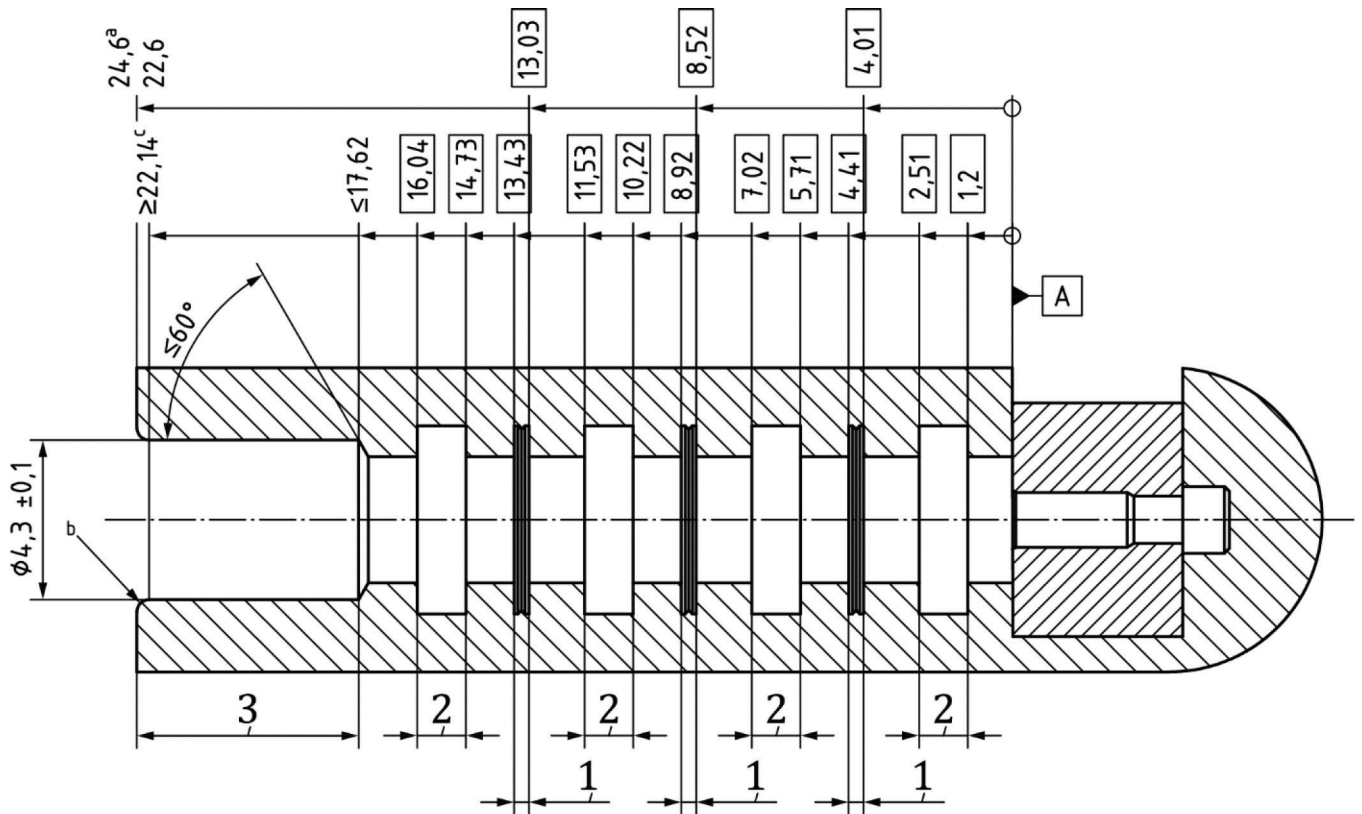
The electrically active contact surfaces for mating with the lead connector shall be located within the functional contact zones (see [Figure 6](#)) and functional pin contact zone (see [Figure 7](#)). Contact hardware may extend beyond these zones. Compliance is determined by dimensional measurement of the contact locations when a 3,2 mm ± 0,05 mm diameter pin is installed to deflect the contacts. This requirement does not apply for contacts that are not electrically 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. Compliance is determined by dimensional measurement of the seal locations when a 3,2 mm ± 0,05 mm diameter pin is installed to deflect the seals.

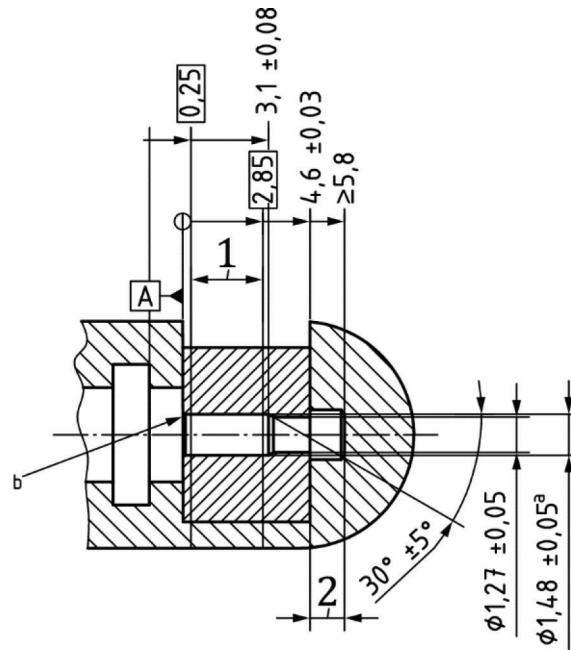
4.4.1.4 Material

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

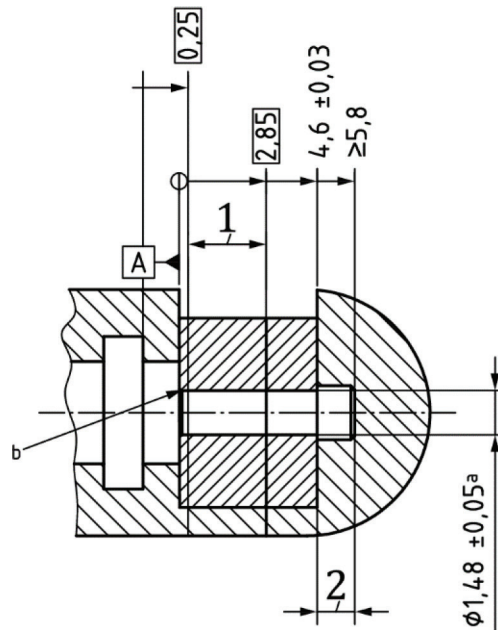
**Key**

- 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, 0,2 mm minimum.
- ^c Radius or chamfer shall not start before the 22,14 mm minimum.

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 may have features that are smaller than the 1,48 mm diameter as necessary to secure the lead connector.
- ^b Break edge 0,40 mm maximum.

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 less than 20 V;
- “HIGH” are device outputs between 20 V and 1 000 V peak and less than 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 document shall be marked with the appropriate symbols in accordance with [Table 2](#) and sized appropriately for the component being marked. See [Figure 8](#) for an illustration of the connector contacts.

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

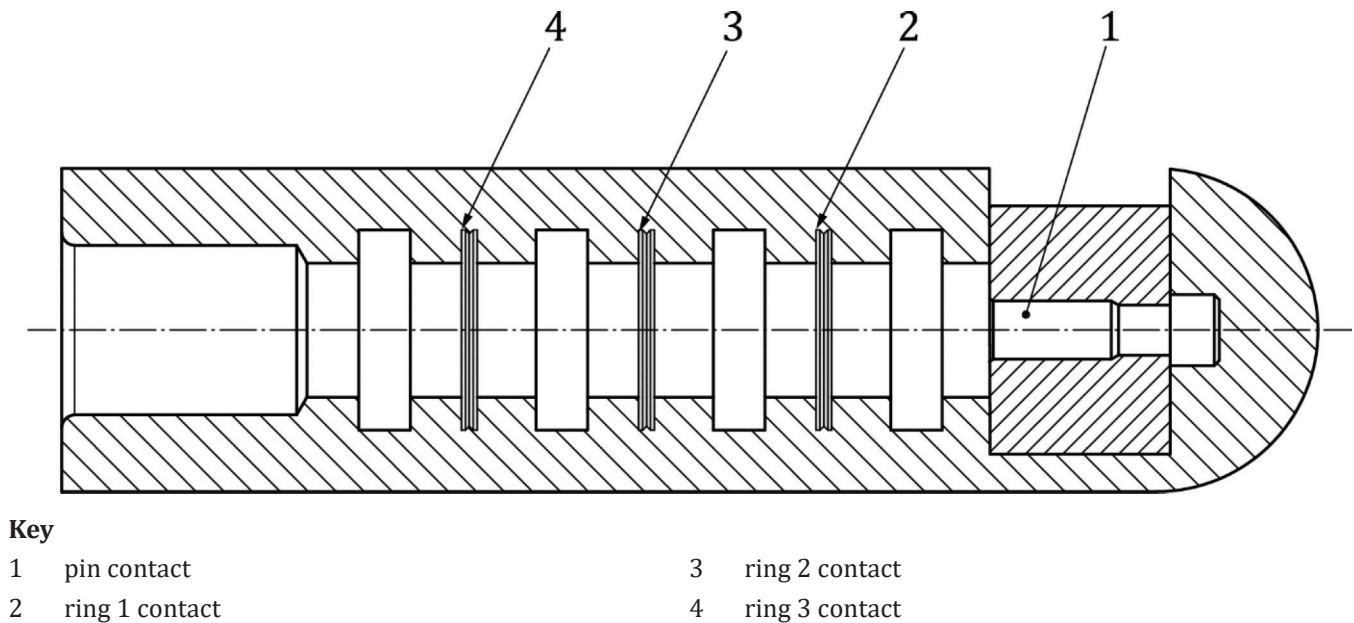


Figure 8 — Identification of contacts in the connector cavity

Table 2 — Pulse generator marking symbols and electrical connections to device outputs — Permitted configurations

	Configuration and marking symbol	Connector cavity contacts			
		Pin contact	Ring 1 contact	Ring 2 contact	Ring 3 contact
Low-voltage only	IS4-LLLL	LOW	LOW	LOW	LOW
	IS4-LLLO	LOW	LOW	LOW	OPEN
	IS4-LOLL	LOW	OPEN	LOW	LOW
High-voltage	DF4-LLHH	LOW	LOW	HIGH	HIGH
	DF4-LLHO	LOW	LOW	HIGH	OPEN
	DF4-OOHH	OPEN	OPEN	HIGH	HIGH

4.4.4 Pulse generator labels and literature

The appropriate marking symbols shown in [Table 2](#) should be used at all times when referring to connectors conforming to this document.

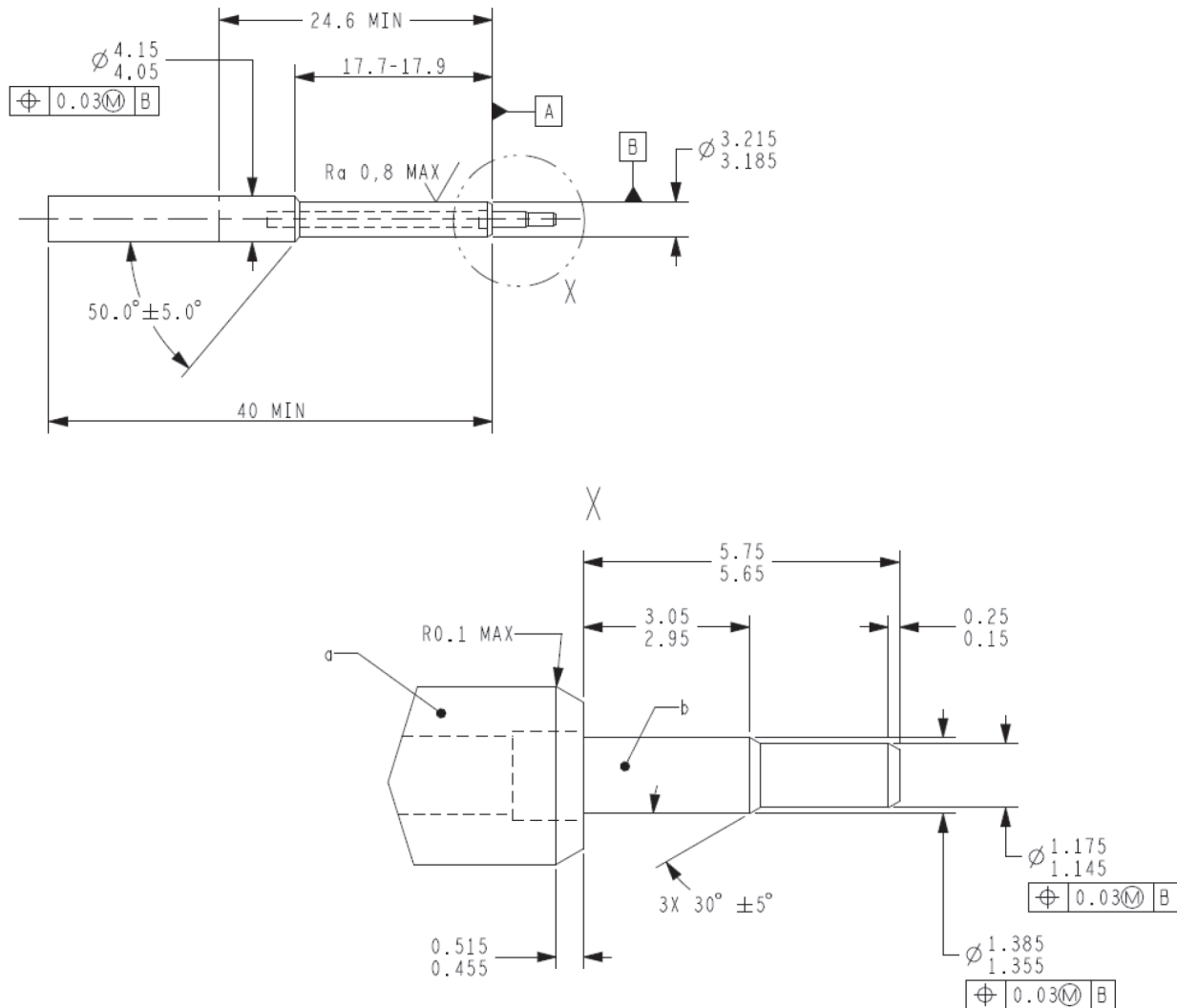
NOTE Package labels and product literature are the responsibility of the pulse generator manufacturer.

4.5 Connector cavity functional requirements

4.5.1 Insertion force

The peak force required to fully insert the gauge pin into the device connector cavity (F_I) shall not exceed 15 N. Compliance shall be determined as described in [Annex S](#).

Full insertion of the gauge shall be achieved and maintained for at least 15 s after removal of the insertion force as described in [Annex S](#).



- a Body material: polyetheretherketone.
- b Tip material: steel, stainless steel, titanium, titanium alloys or 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562.

Figure 9 — Maximum connector cavity gauge pin

4.5.2 Retention force

4.5.2.1 Test method

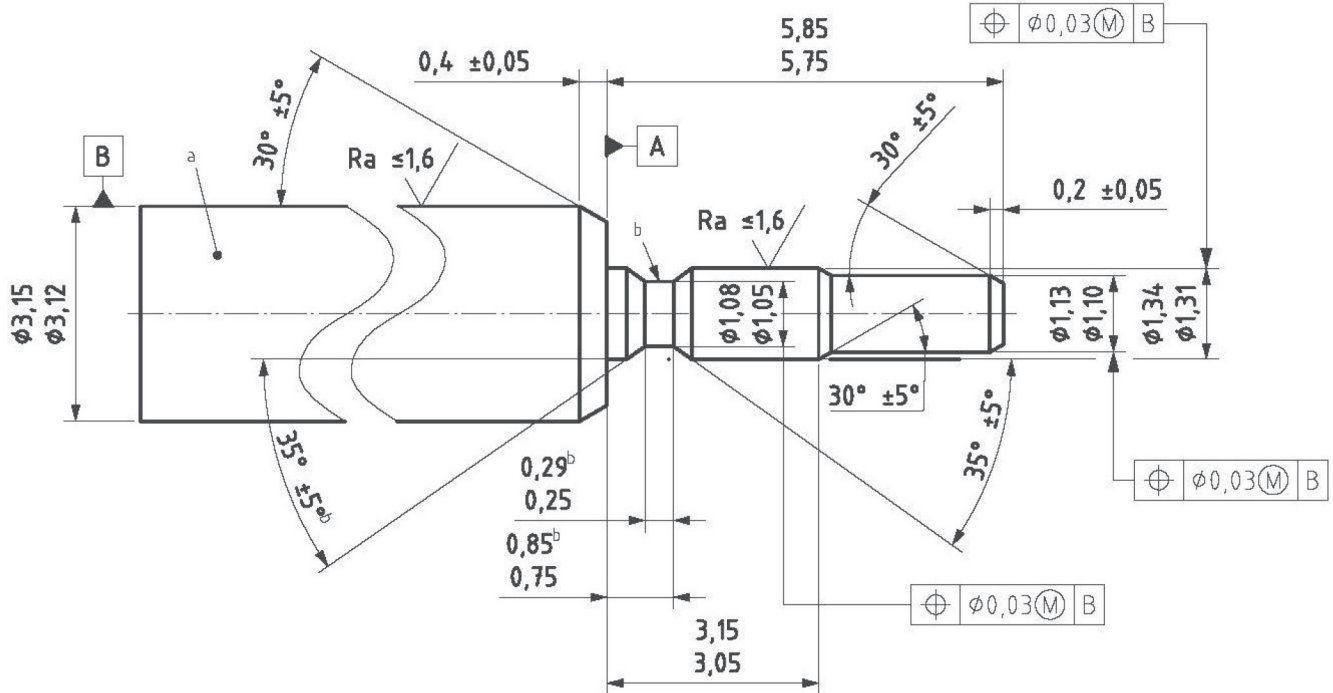
Fully insert the minimum retention gauge pin conforming to [Figure 10](#) into the connector cavity and engage the securing mechanism per manufacturer instructions. Apply an axial tensile load of 10 N for 10 s minimum while monitoring for displacement of the gauge pin.

4.5.2.2 Requirement

The gauge pin shall not become displaced more than 0,5 mm while under the 10 N load.

If using a pin with the optional notch feature the notch shall not become engaged by the securing mechanism.

Dimensions in millimetres



- ^a Material: steel, stainless steel, titanium, titanium alloys or 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562 (entire pin).
- ^b Dimension applies to the notch feature. Notch feature is optional and may be omitted.

Figure 10 — Minimum retention gauge pin

4.5.3 Withdrawal force

The peak force required to fully withdraw the gauge pin after full insertion (F_w) shall not exceed 14 N. Compliance shall be determined as described in [Annex S](#).

4.5.4 Ring contact load

4.5.4.1 Applicability

This requirement applies only to contact mechanisms for lead connector rings that require activation after the lead connector is inserted, such as set screws.

4.5.4.2 Test method

Determine the maximum contact load of the fully activated contact mechanism over a 3,23 mm diameter test pin.

4.5.4.3 Requirement

Contact load shall not exceed the maximum allowed by [4.3.4](#).

4.5.5 Seal zone load requirement

There is no requirement for the forces exerted by the connector cavity seals in the seal zones. See [Annex I](#) for design recommendations.

4.5.6 Electrical isolation requirement

The connector cavity shall provide electrical isolation between each of the connector cavity contacts and between the contacts and the surrounding fluid. Compliance shall be determined as described in [Annex A](#).

4.5.7 Dielectric strength requirement

The connector cavity shall provide high-voltage electrical isolation between each of the connector cavity contacts and between the contacts and the surrounding fluid. This requirement applies to high-voltage connector cavities. Compliance shall be determined as described in [Annex C](#).

4.5.8 Current-carrying requirement (high-voltage connector cavity)

The high-voltage type connector cavity shall be capable of carrying defibrillation current. Compliance shall be determined as described in [Annex E](#).

4.5.9 Contact resistance/stability

There is no requirement for contact resistance/stability since it is dependent on each specific device system's performance.

NOTE [Annex J](#) describes a test method which could be used to evaluate contact resistance/stability as part of device reliability and safety testing or for evaluating the relative performance of various spring contact designs.

Annex A (normative)

Electrical isolation test

A.1 General

A.1.1 Purpose

This annex describes tests to determine compliance with [4.3.6](#) and [4.5.6](#). These are type (qualification) tests and are not intended to be used as routine production tests. The tests are applicable to both high-voltage (DF4) and low-voltage only (IS4) lead connectors and connector cavities.

A.1.2 Specimen preparation

Lead connectors and connector cavities used for test shall be in the as-shipped condition.

A.1.3 Saline solution

Use an aqueous solution that is nominally 9 g/l NaCl.

Maintain the temperature of the saline at $37\text{ °C} \pm 5\text{ °C}$ for soak and test.

A.1.4 Reference electrode

Use a reference electrode made of titanium which has a surface area of $\geq 500\text{ mm}^2$.

A.1.5 Test signal

Frequency: one frequency at or between 50 Hz and 120 Hz.

Voltage: one voltage at or between 0,25 V rms and 1,0 V rms.

A.2 Lead connector test

A.2.1 Purpose

This procedure evaluates isolation of the conductors in the lead connector from datum A to the distal end of the grip zone as defined in [Figure 1](#). The method applies to both high-voltage and low-voltage only lead connectors.

A.2.2 Preconditioning

Soak the entire lead connector in the saline solution for a minimum of 10 d prior to the test. Maintain the lead connector in a soaked state for testing. Return the lead connector to the saline solution between tests or when not testing.

A.2.3 Test method

Carry out the test as follows.

Maintain the entire grip zone, strain relief zone and transition zone of the lead connector (as defined in [Figure 1](#)) in the saline test solution while keeping the exterior of the lead connector rings externally insulated from the fluid.

All three contact rings and the connector pin should be externally electrically isolated from the test solution and from each other. External isolation can be achieved by keeping the rings out of the test solution and drying off the outside, by use of a silicone sleeve or a test fixture with seals, or by another method that provides external isolation while ensuring that the entire transition zone, strain relief zone and grip zone remain submerged in the test solution.

Position the lead connector 50 mm to 200 mm from the submerged reference electrode.

Apply the test voltage between each contact combination under test, for example between the pin and reference electrode. For lead connectors that are not integrated bipolar, test the combinations shown in [Table A.1](#). For integrated bipolar lead connectors, where contact ring 2 and contact ring 1 are intentionally electrically connected, test the contact combinations shown in [Table A.2](#).

Measure the resulting isolation impedances for each test combination.

Table A.1 — Test combinations for lead connectors

	Pin	Ring 1	Ring 2	Ring 3
Reference	test	test	test	test
Pin		test	test	test
Ring 1			test	test
Ring 2				test

Table A.2 — Test combinations for integrated bipolar lead connectors

	Pin	Ring 1 + ring 2	Ring 3
Reference	test	test	test
Pin		test	test
Ring 1 + ring 2			test

A.2.4 Acceptance criteria

The impedance between each contact of the test combinations shown in [Table A.1](#) and [Table A.2](#) shall be greater than 600 k Ω . This requirement applies to both high-voltage and low-voltage only lead connectors. The requirement also applies to all contacts, even those that are not electrically active.

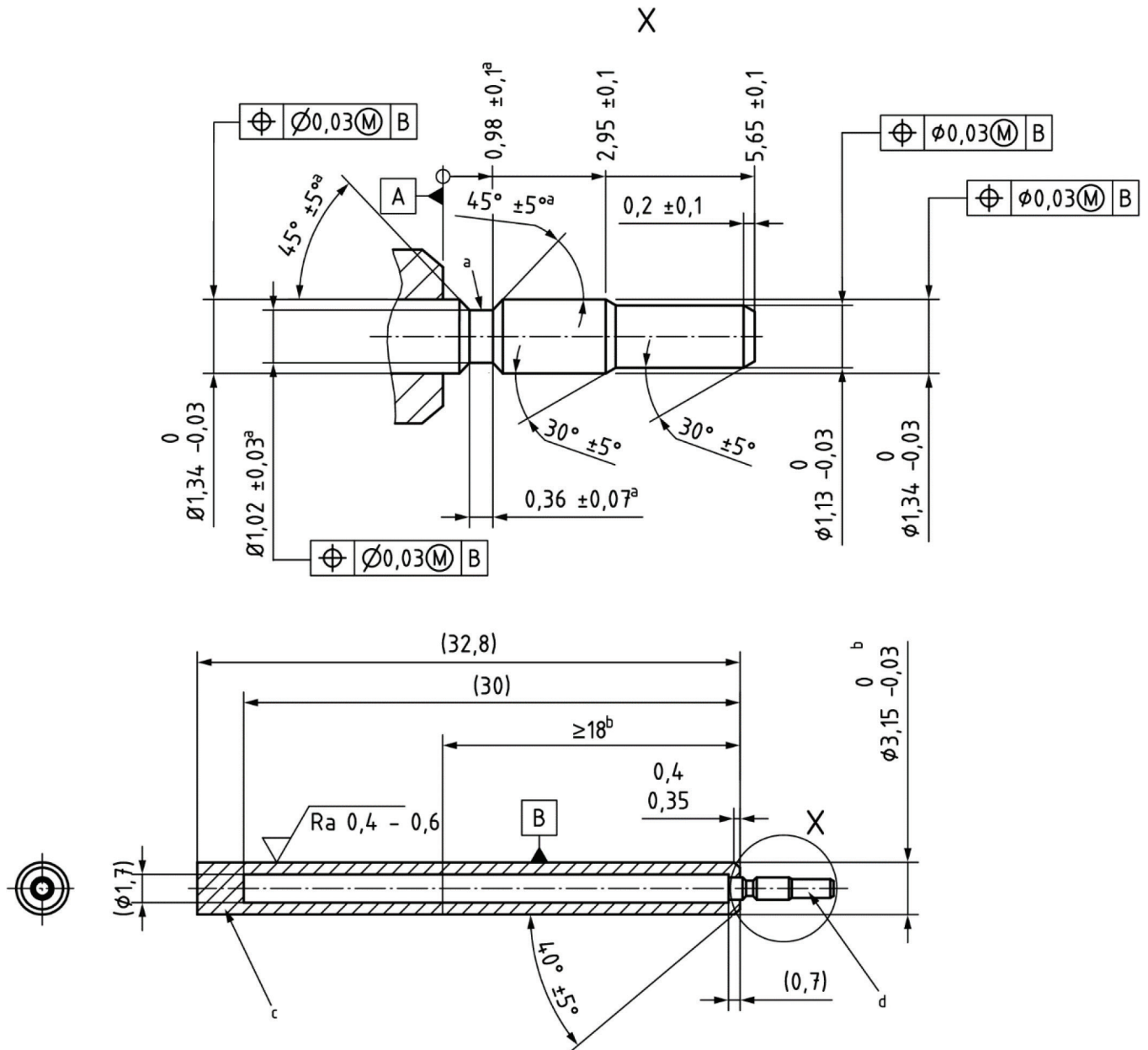
A.3 Connector cavity test

A.3.1 Purpose

This procedure evaluates isolation between the contacts in the connector cavity as well as isolation between the last contact and an external reference electrode when tested with a simulated lead connector as defined in [Figure A.1](#).

A.3.2 Test pin

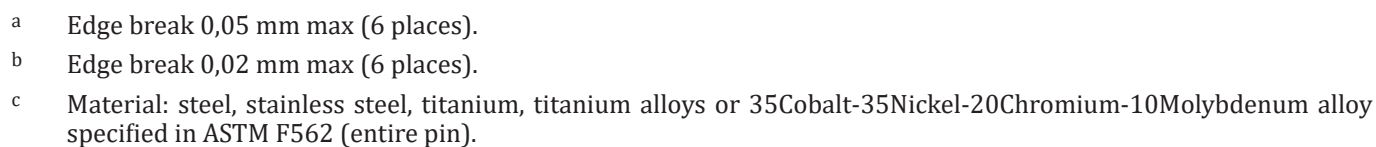
Use a test pin that conforms to [Figure A.1](#).



- a Dimension applies to the notch feature. Notch feature is optional and may be omitted.
- b Diameter and datum B apply to zone indicated.
- c Body material: polyetheretherketone.
- d Core material: 316L stainless steel (entire pin).

Figure A.1 — Connector cavity isolation test pin

✓ = $\nabla \sqrt{\text{Ra } 0,8 - 1,2}$



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A.3.3 Preconditioning

Precondition and prepare the test samples as follows.

Fully insert and completely withdraw a maximum offset gauge pin conforming to [Figure A.2](#) one (1) time.

Perform the preconditioning in a dry state prior to assembling the connector in the saline solution. Full insertion is when the pin tip is visible beyond the tip connector block, and complete withdrawal is when the pin tip is visible outside the connector cavity.

Immerse the connector cavity in the saline solution and then insert the test pin into the cavity, ensuring no air bubbles are trapped. Fasten or deploy any retention mechanisms that are provided with the connector cavity.

Soak the cavity and pin assembly in saline solution for a minimum of 10 d prior to the test and maintain in the soaked state for testing.

A.3.4 Test method

Carry out the test as follows.

Immerse the reference electrode and locate it 50 mm to 200 mm from the connector cavity.

Measure electrical impedance between each contact combination specified as “test” in [Table A.3](#), both at the start of the test (wet) and after 10 d minimum soak.

Apply a side load of 1 N to the test pin at the bore exit during the electrical testing only, not during the soak. Orient the side load perpendicular to the bore axis and, for devices with a pin retention mechanism, the direction of loading shall be in the same plane as the pin retention mechanism force contact point.

The test combinations shown in [Table A.3](#) are for evaluating electrical isolation of seal rings with regard to interchangeability. It is recommended that manufacturers also test other combinations to establish isolation of other components. See [B.3](#) for additional information.

A.3.5 Acceptance criteria

For both high-voltage and low-voltage only connector cavities the impedance between each contact combination (refer to [Table A.3](#)) shall be greater than 120 kΩ. This requirement applies to all contacts including those that are not electrically active.

Table A.3 — Test combinations for connector cavities

	Pin	Ring 1	Ring 2	Ring 3
Reference				test
Pin		test		
Ring 1			test	
Ring 2				test

Annex B (informative)

Rational for [Annex A](#)

B.1 Isolation impedance

This document allows a minimum lead-cavity isolation impedance of 100 kΩ. This lead-cavity impedance has been used to allocate a parallel equivalent of 600 kΩ for the lead connector and 120 kΩ for the connector cavity.

The four-pole connector system isolation impedance (Z_{system}) is the result of the individual contributions of the lead connector impedance (Z_{lead}) and the connector cavity impedance (Z_{cavity}) as given by [Formula \(B.1\)](#):

$$\frac{1}{Z_{\text{system}}} = \frac{1}{Z_{\text{lead}}} + \frac{1}{Z_{\text{cavity}}} \quad (\text{B.1})$$

A 100 kΩ isolation impedance for the four-pole connector system was derived assuming a minimum electrical input impedance of 100 kΩ and a total input impedance of a device of 50 kΩ. Electrical input impedance of modern pacemakers/ICDs is typically greater than 100 kΩ. A 50 kΩ input impedance on a device is close to 10 × the maximum source impedance of intra-cardiac signals; this ensures that signals from the heart are not significantly attenuated.

Furthermore, the 100 kΩ system isolation impedance was used to allocate 120 kΩ isolation impedance for the connector cavity and 600 kΩ isolation impedance for the lead connector. Lower parallel impedance for the connector cavity was assigned based on the characteristics of the isolation testing. The isolation test for the connector cavity includes both internal isolation plus a simulated effect of the lead/cavity interface. The isolation test for the lead connector evaluates internal isolation only.

A 10 d soaking procedure has been adopted from IS-1 (ISO 5841-3) and DF-1 (ISO 11318). This provides the required time for fluid absorption and electrical impedance stabilization between insulated conductors. This requirement is applicable for lead, device or system testing.

B.2 Mechanical load

The application of the side load during testing was intended to simulate transient loads representative of severe daily activities. A reasonable upper bound of the representative side load for these transient conditions was estimated to be 300 g acting on a flexible connector. The 300 g limit was established by the connector task force (CTF) using relevant cadaver test data, biplane fluoroscopic reconstruction of indwelling leads, bench testing of four-pole connector prototypes and input from leading physicians on typical and non-typical implant conditions. The derating of the 300 g *in vivo* load applied to the flexible lead connector was done to ensure the rigid test pin produced the appropriate deflection in the seal zones under test. The side load of 1 N was chosen based on the testing of actual lead prototypes from three manufacturers. The 1 N applied to the test pin defined in this document was shown to produce a displacement of the seal zone that exceeded the actual displacement of an actual lead connector. Flexible lead connectors tested from three independent manufacturers all produced less displacement of the seal zone under a 300 g external load than the test condition specified in this document.

B.3 Test combinations

Testing adjacent contacts as indicated by “test” in [Table B.1](#) is considered the minimum required to evaluate isolation impedance of seal rings in the connector cavity. It is recommended that manufacturers also test the other combinations indicated by “recommended” in [Table B.1](#) in order to evaluate isolation impedance of