BS ISO 27186:2010

BSI Standards Publication

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

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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 gérer le rhythme cardiaque — Dimensions et exigences d'essai

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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.

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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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 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 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 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 durometers of nominally 75 Shore D, 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 durometers harder than 75 Shore D nominal, 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 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 Ra 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 mm $-\ M$ maximally, where M is the total axial pin movement in millimetres.

4.2.1.9 Transition zone

The transition from the ∅3,2 mm to the ∅4,1 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 mm ± 0,10 mm dimension.

c) The diameter shall fall within the nominal diameter specified and the tolerance of $^{+0,03}_{-0,10}$ 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.

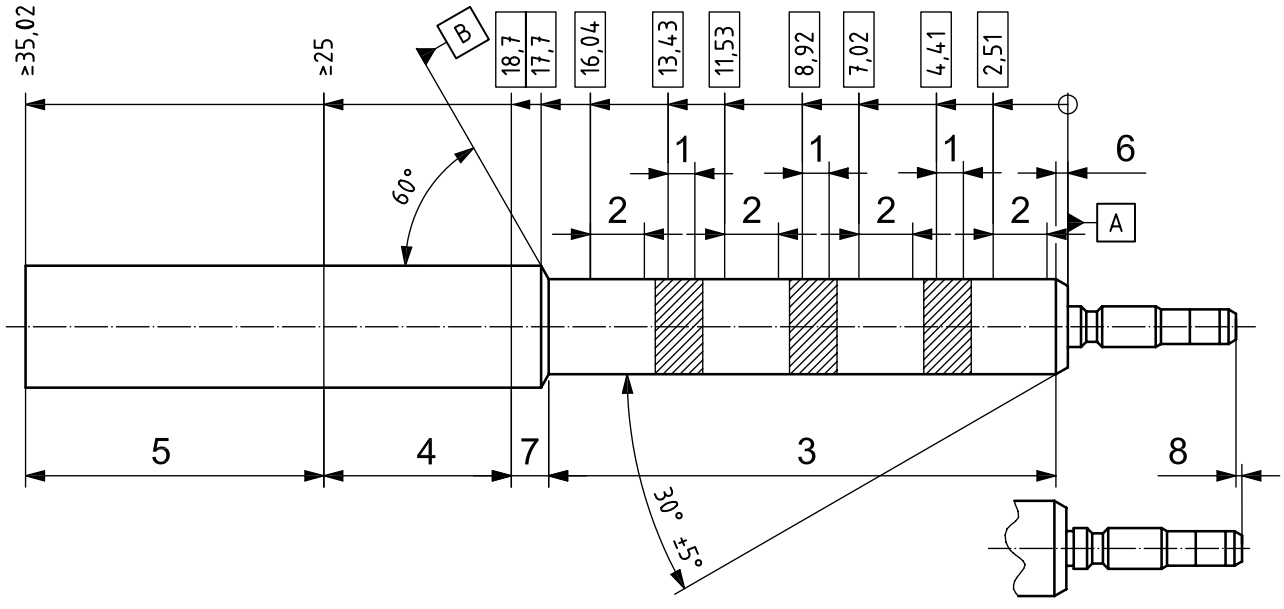
e) Any radial steps shall not exceed 0,05 mm.

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.

Dimensions in millimetres



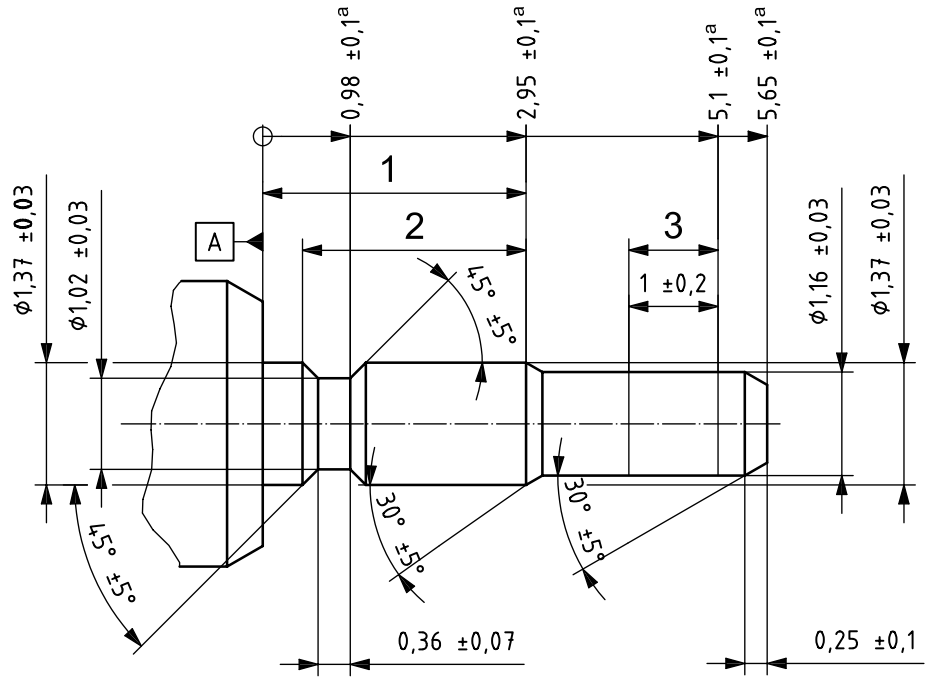
Key

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

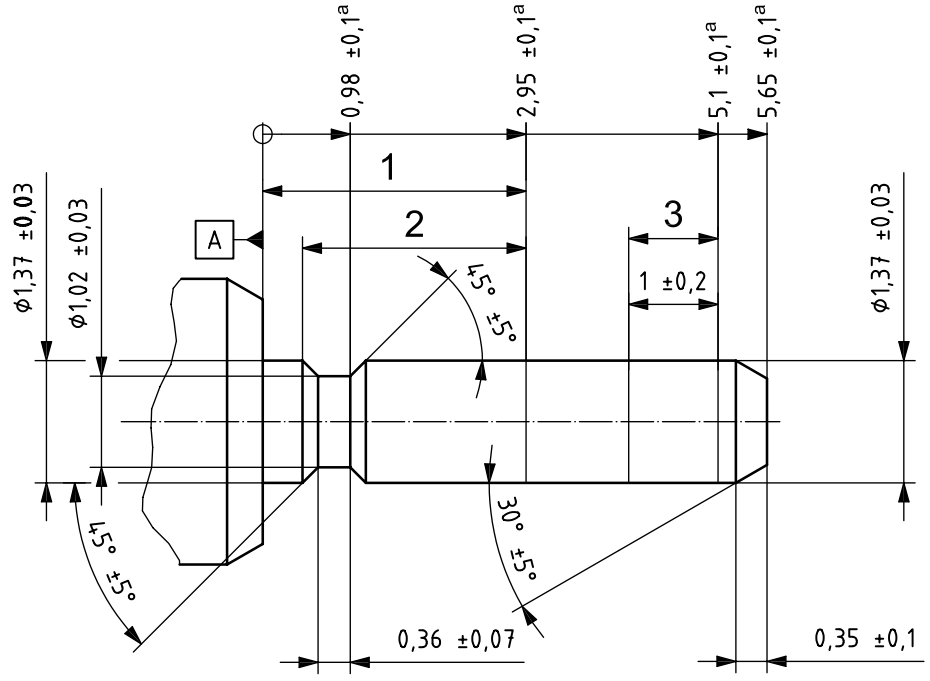
NOTE The diameter dimensions of the soft sections, in zone 4, zone 5 and zone 7, of the lead may be determined as the mean value of three measurements taken at locations oriented approximately 120° apart around the principal axis of the lead connector.

Figure 1 — Four-pole lead connector body

Dimensions in millimetres



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

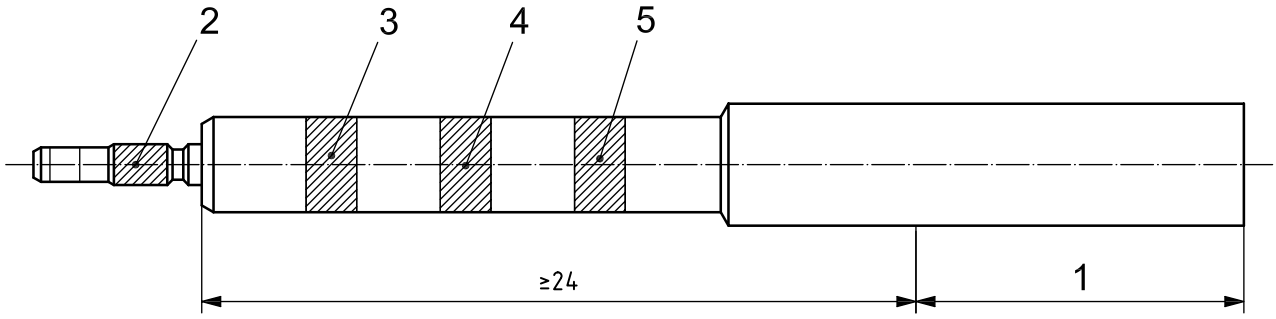
Marking shall be located in the marking zone (see Figure 3).

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.

Dimensions in millimetres



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.

4.2.5 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 International Standard.

NOTE The four-pole lead connectors specified in this International Standard 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 Clause P.3.

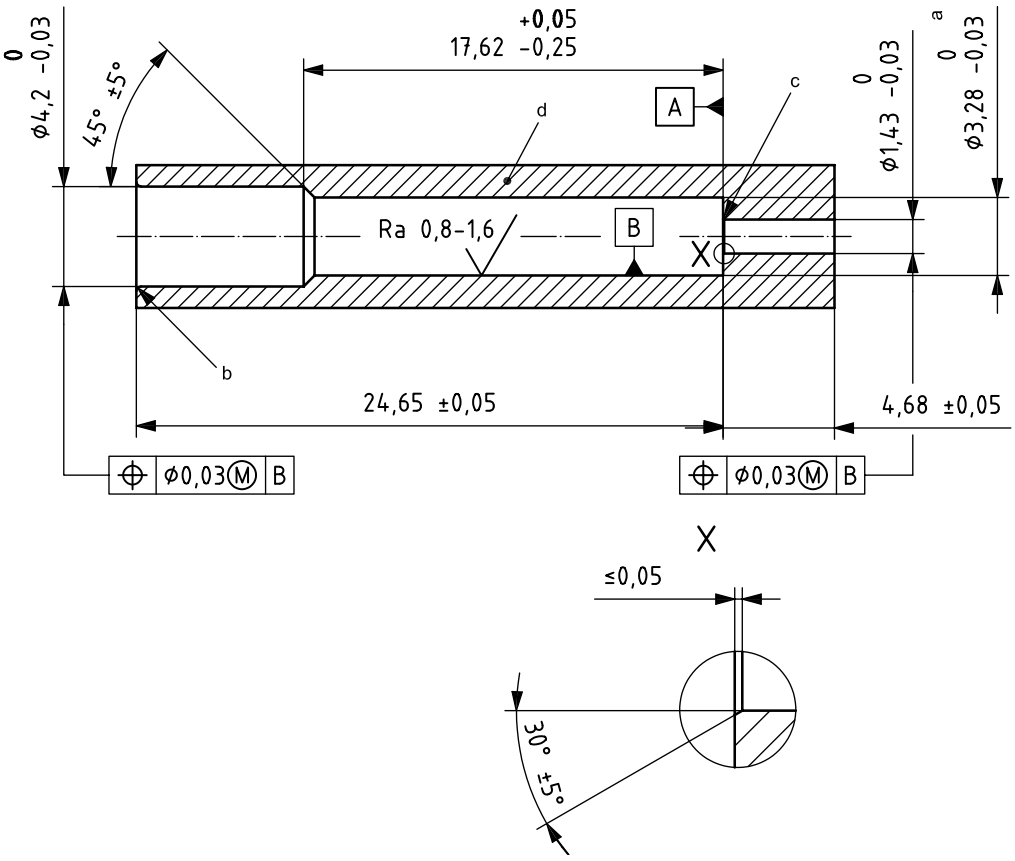
4.3 Lead connector functional requirements

4.3.1 Functional 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 °C ± 5 °C).

Dimensions in millimetres



[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.

[c] Edge break ⩽ 0,1 mm.

[d] Material: metal.

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 °C ± 5 °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 N·m ± 0,01 N·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 recognised 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.

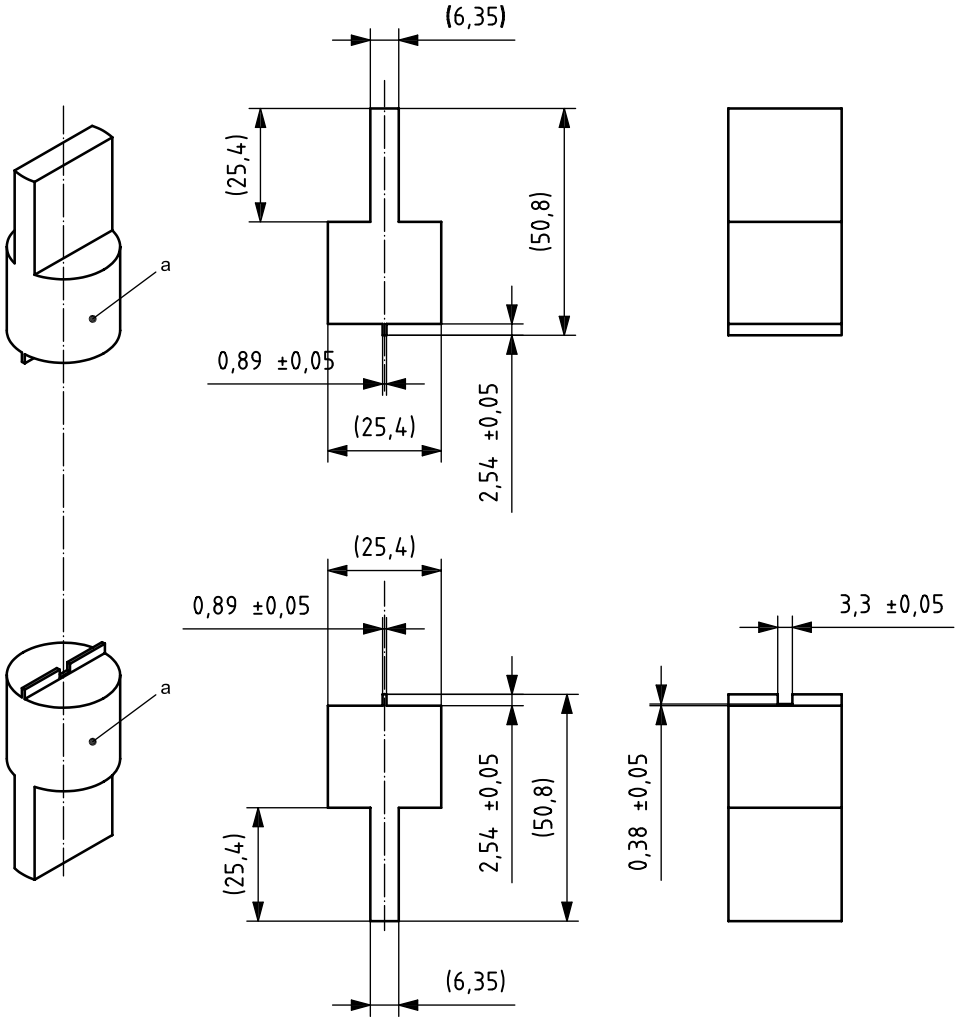
NOTE 3 Lead manufacturers are encouraged to evaluate the durability of their lead connector insertion indicator zone when exposed to the forces associated with handling and implanting conditions, including use with patient cable alligator clips, passive retention systems, set screws and other types of 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 millimetres



[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.

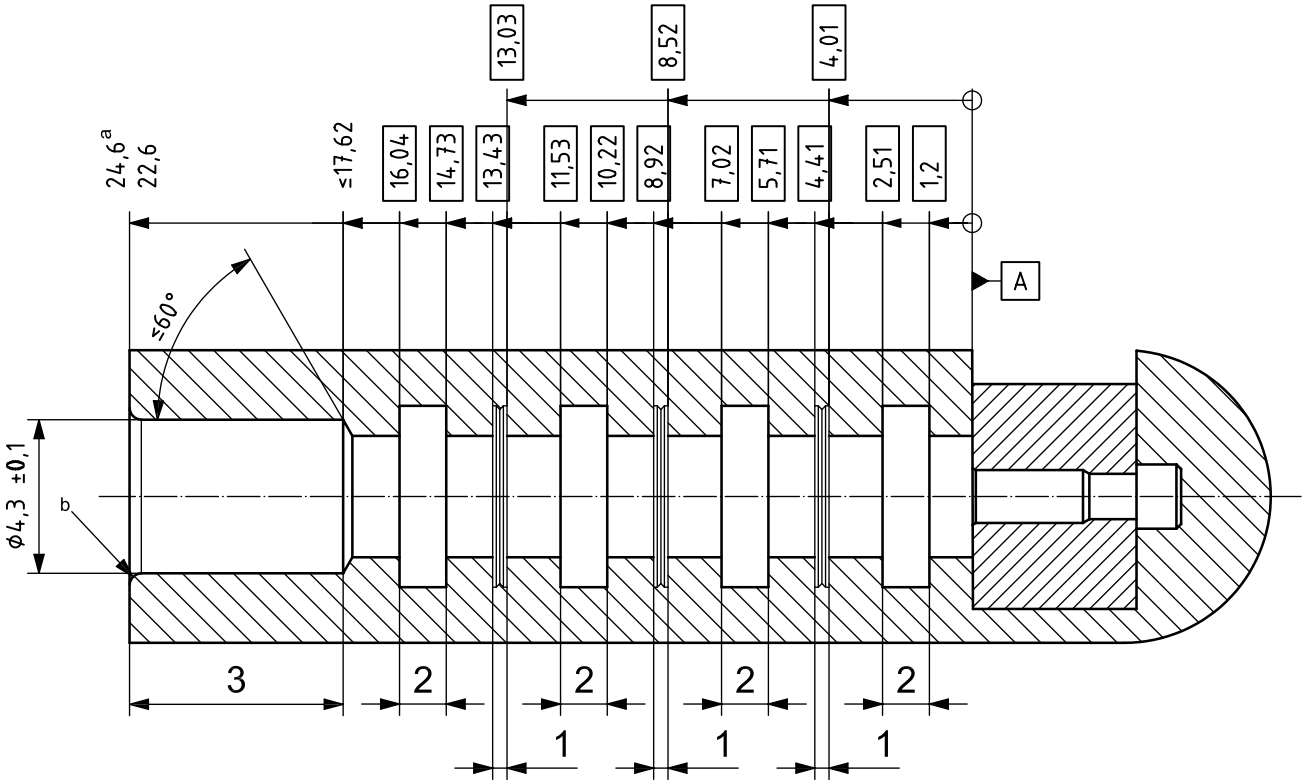
4.4.1.3 Functional seal zones

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.

Dimensions in millimetres



Key

1 functional contact zones

2 functional seal zones

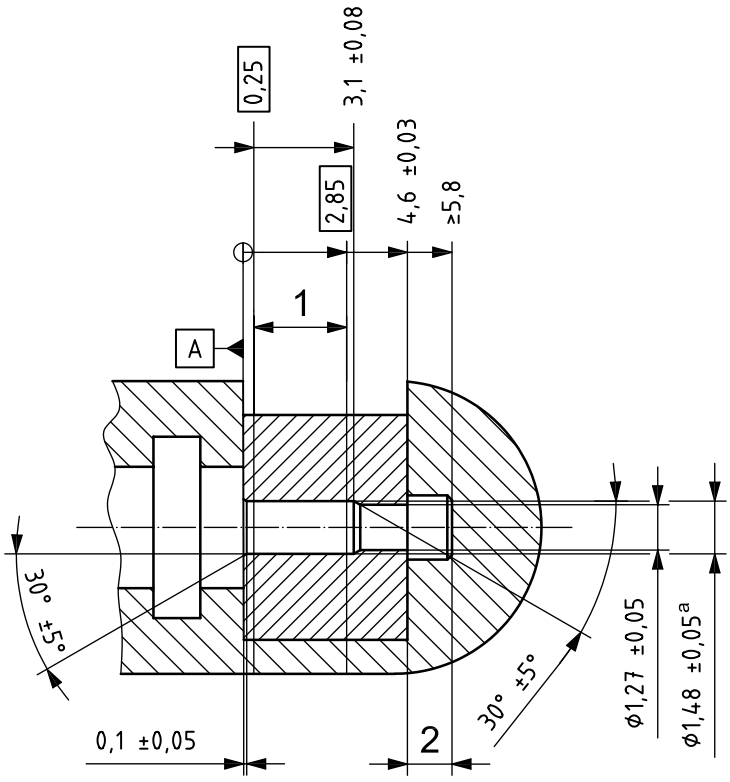
3 stabilization zone

[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.

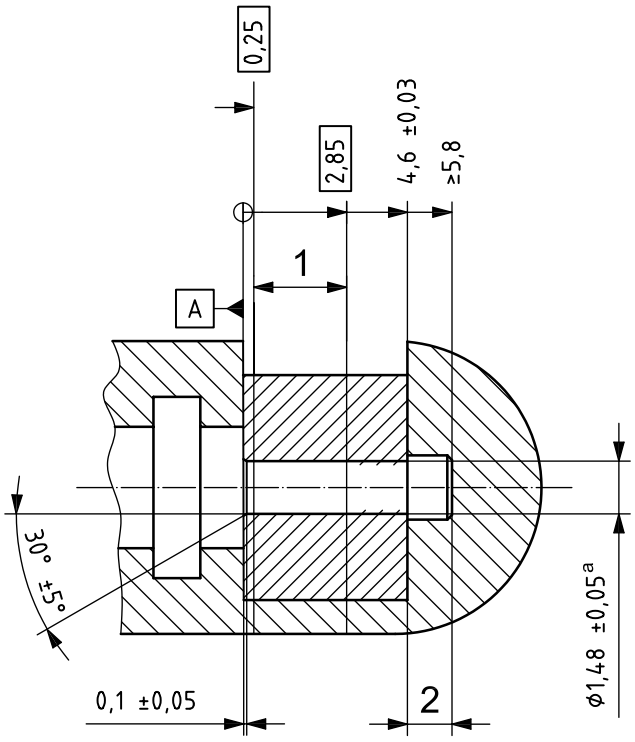
[b] Radius or chamfer, 0,33 mm ± 0,13 mm.

Figure 6 — Four-pole connector cavity

Dimensions in millimetres



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 $\leqslant$ 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).

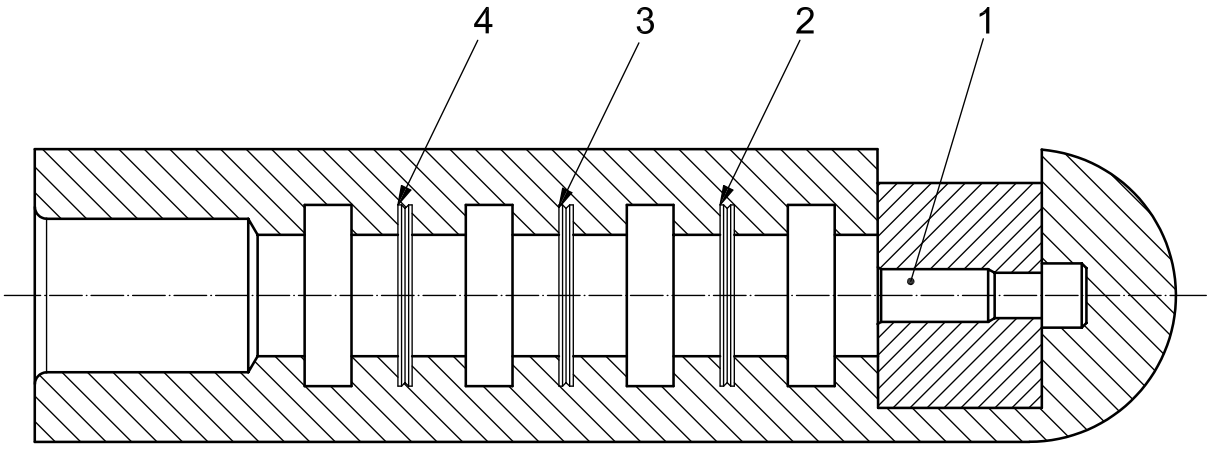
4.4.2.3 High voltage version connector cavities shall conform to Figure 7 a).

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

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 International Standard.

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

4.5.1.1 Test method

Fully insert the metal gauge pin specified in Figure 9 into the device connector cavity while measuring the maximum force required. Remove the insertion force while observing for any displacement of the gauge pin for 15 s minimum.

This test shall be performed in accordance with the manufacturer's recommended implant procedure. This test shall be performed dry.

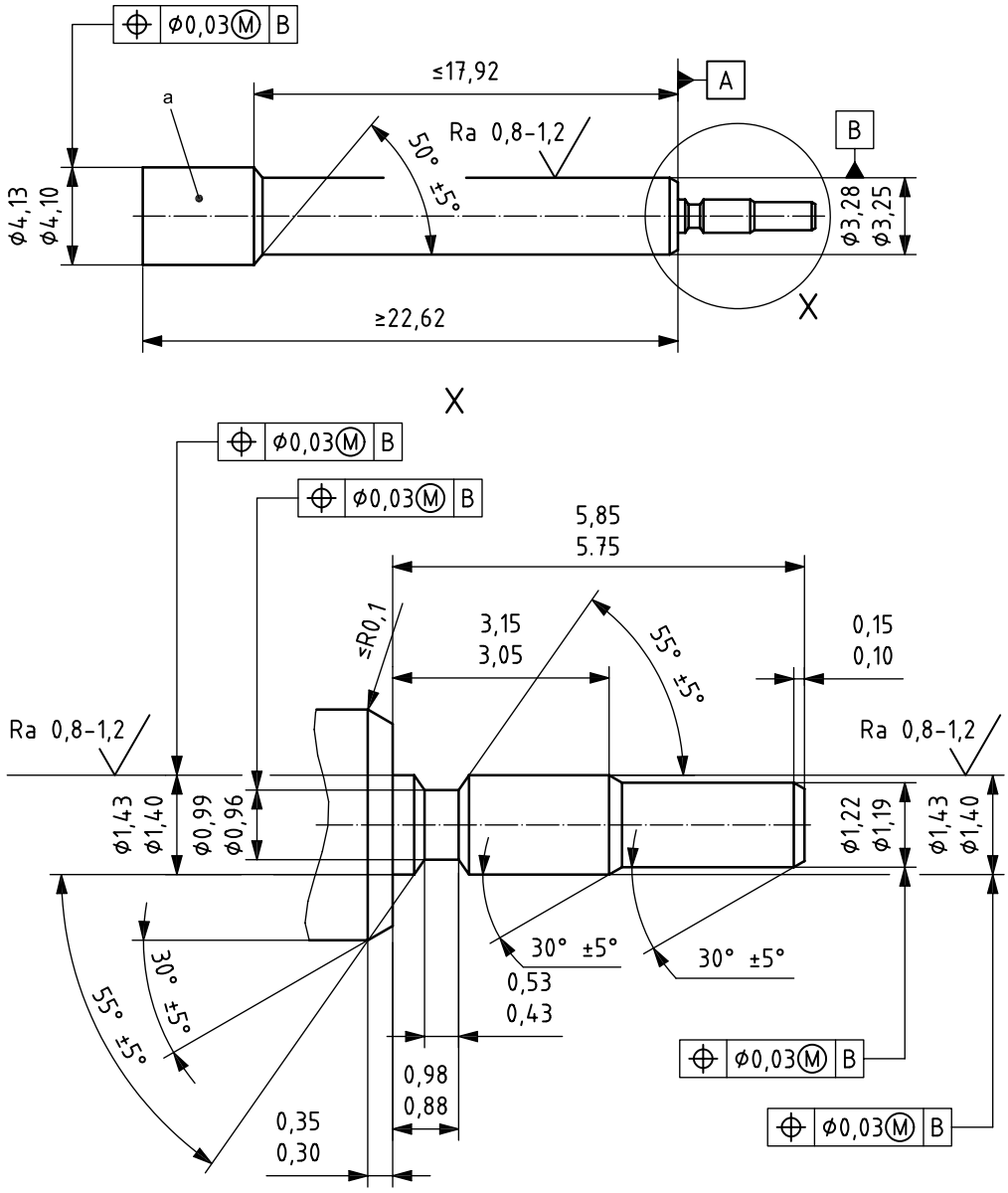
4.5.1.2 Requirement

The maximum force required to fully insert the gauge pin into the device connector cavity shall not exceed 16 N.

The gauge pin shall not become displaced more than 0,5 mm after the insertion force is removed when verified after 15 s minimum.

The connector cavity shall meet the dimensional requirements of Figure 6 and the requirements of 4.5.6, 4.5.7 and 4.5.8.

Dimensions in millimetres



[a] Material: metal (entire pin).

Figure 9 — Maximum connector cavity gauge pin

4.5.2 Retention force

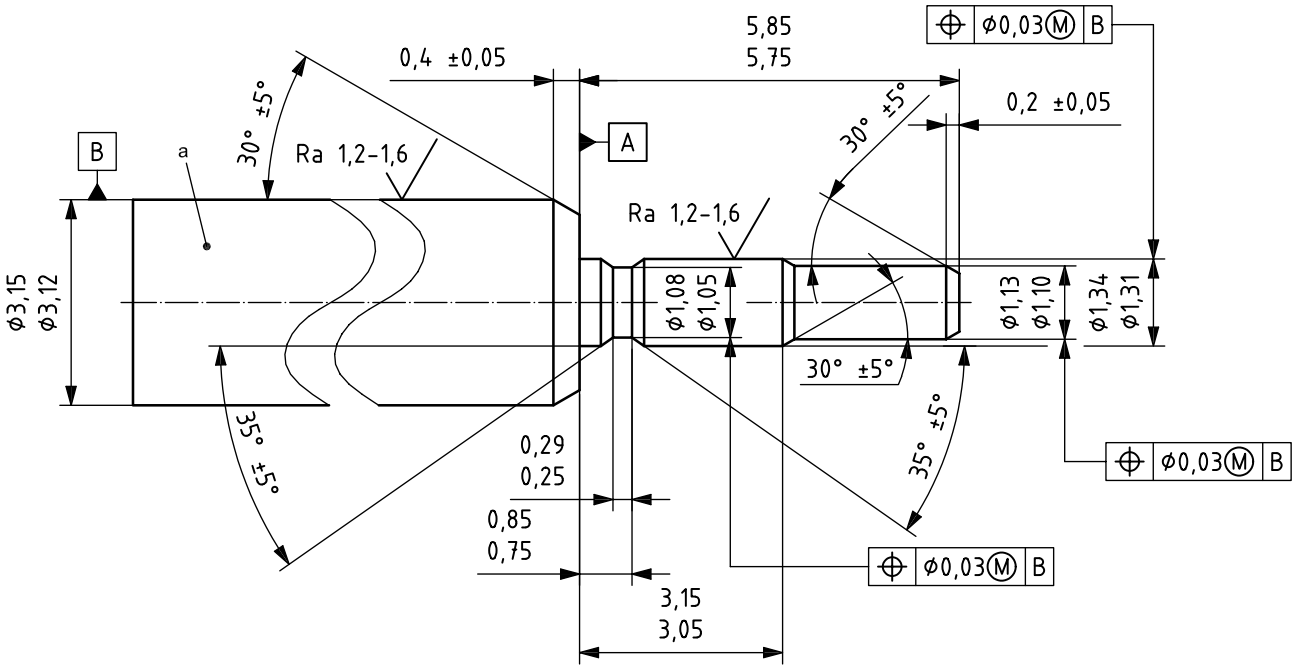
4.5.2.1 Test method

Fully insert the minimum retention gauge pin conforming to Figure 10 into the connector cavity and engage the securing mechanism, as applicable, per manufacturer instructions. Apply an axial tensile load of 10 N for 10 s minimum while observing 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.

Dimensions in millimetres



[a] Material: metal (entire pin).

Figure 10 — Minimum retention gauge pin

4.5.3 Withdrawal force

4.5.3.1 Test method

Insert the gauge pin conforming to Figure 9 fully into the connector cavity. Verify that any active retention mechanisms are disengaged. Fully withdraw the gauge pin whilst measuring the maximum force required.

Perform this test under initial (dry) conditions.

4.5.3.2 Requirement

The maximum force required to fully withdraw the gauge pin shall not exceed 14 N.

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 requirement

There is no functional requirement for 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 It is recommended that each manufacturer evaluate the contact resistance/stability as part of their device reliability and safety testing. See Annex J for a description of one potential test method believed to be practical for measuring 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 °C ± 5 °C for soak and test.

A.1.4 Reference electrode

Use a reference electrode made of titanium which has a surface area of $\geqslant$ 500 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.

NOTE External isolation may 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. All three contact rings and the connector pin should be externally insulated from the test solution and from each other.

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 kΩ. 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

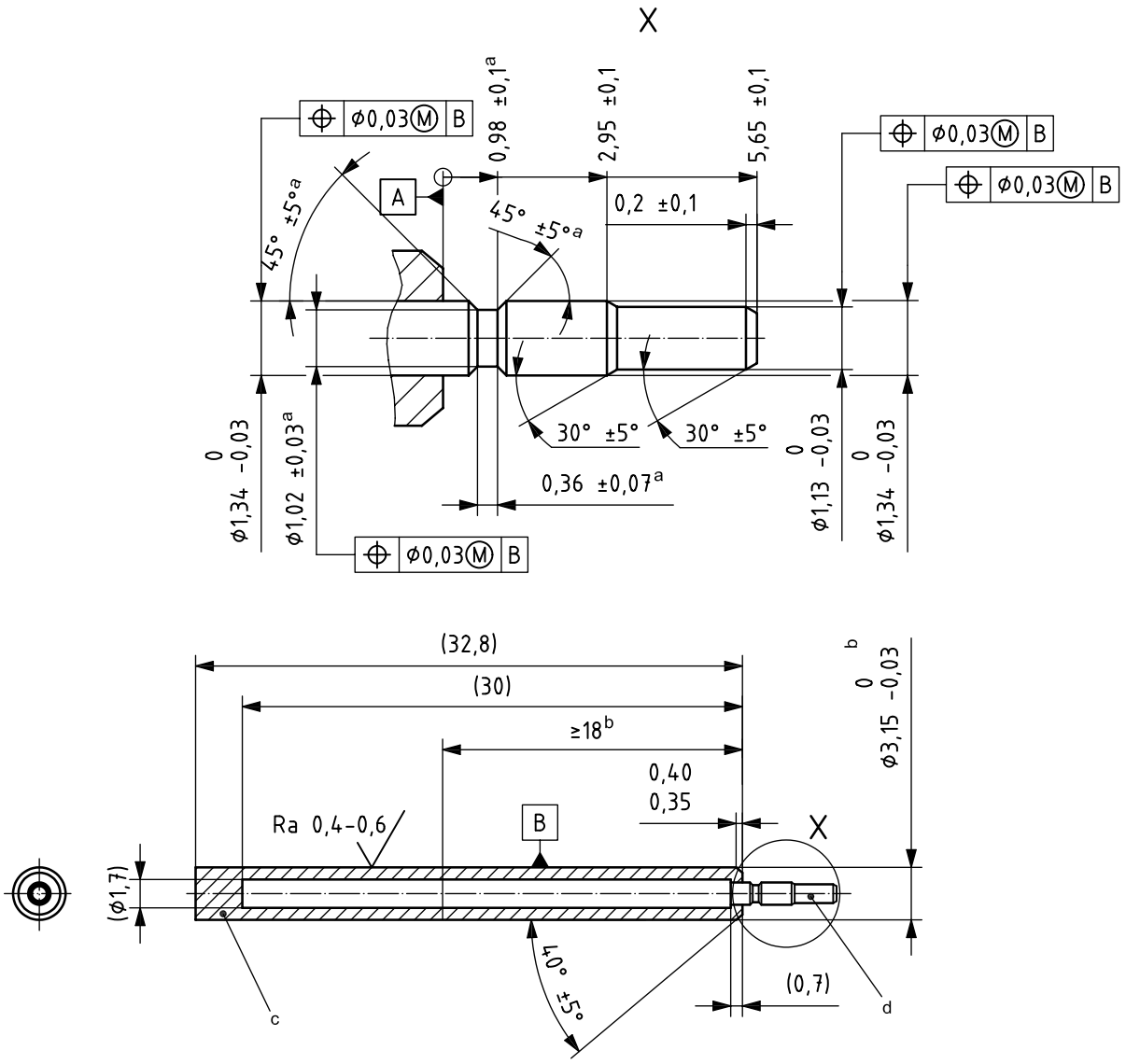
A.3.1 Purpose

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.

Dimensions in millimetres



a For testing connector cavities that do not utilize the retention groove for fixation, these test pin dimensions are for reference only.

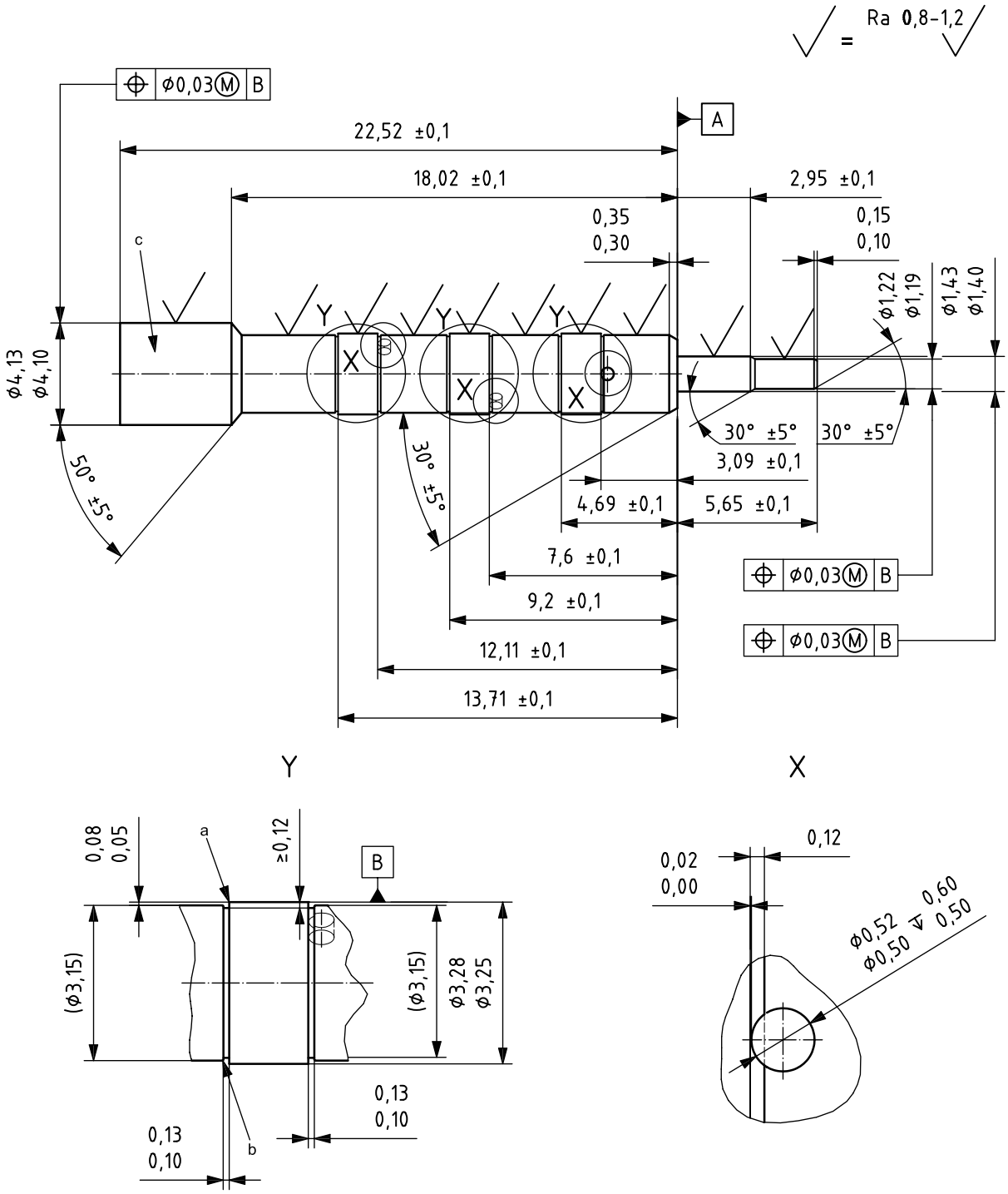
b Diameter and datum B apply to zone indicated.

c Body material: polyetheretherketone.

d Core material: 316L stainless steel.

Figure A.1 — Connector cavity isolation test pin

Dimensions in millimetres



[a] Edge break ⩽ 0,05 mm (6 places).

[b] Edge break ⩽ 0,02 mm (6 places).

[c] Material: metal (entire pin).

Figure A.2 — Maximum offset gauge pin

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.

NOTE 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. Refer to Clause B.3.

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)

Rationale for Annex A

B.1 Isolation impedance

This International Standard 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_s, is the result of the individual contributions of the lead connector, and connector cavity as given by Equation (B.1):

$$\frac{1}{Z_s} = \frac{1}{Z_{Lead}} = \frac{1}{Z_{Cavity}} \tag{B.1}$$

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 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 International Standard 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 International Standard.

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 other components such as septums or feedthroughs. The details of such testing, including test combinations, test conditions, test signal and acceptance criteria should be defined by the manufacturer.

Table B.1 — Recommended test combinations for connector cavities

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

B.4 Connector cavity isolation test pin

The lead seal zone and surface finish requirements described in 4.2.1.4 reflect unique surface finish and surface defect allowances based on the materials used in this area of the lead.

During the development of this International Standard, multiple polyetheretherketone (PEEK™) and 75D polyurethane (Tecothane™ TT1075D) test pins were used for testing connector cavities in order to establish the sensitivity of seal performance to surface defects and material hardness. Such testing indicated that it was more difficult to seal under high voltage when using the harder material test pins (PEEK™) than for the softer material (Tecothane™) given the same diameter and the same created defects. It was believed that this was due to differences in material hardness. Therefore the requirements in this International Standard reflect two different surface finishes and defect allowances depending on the hardness of the material used. It was also found that defect features on test pins were difficult to define and to tolerance, such that they could be consistently reproduced. Therefore the test pins in this International Standard include worst-case material, minimum diameter and worst-case surface finish but do not include other types of conditions that might be allowed on lead connectors as specified in this International Standard.

NOTE Tecothane™ TT1075D is the trade name of a product supplied by The Lubrizol Corporation Wickliffe, OH, USA. PEEK™ is the trade name of a product supplied by Victrex plc, Thornton Cleveleys, Lancashire, UK. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the products named. Equivalent products may be used if they can be shown to lead to the same results.

Annex C
(normative)

Dielectric strength test

C.1 General

C.1.1 Purpose

This annex describes tests to determine compliance with 4.3.7 and 4.5.7. These are type (qualification) tests and are not intended to be used as routine production tests. The manufacturer may use equivalent test methods; however, in a dispute, these test methods shall be used. The tests are applicable to high voltage (DF4) lead connectors and connector cavities.

WARNING — The following test employs high voltages. Failure to use safe laboratory practices could result in severe electrical shock, causing personal injury or death to persons handling the equipment or conducting the test. Damage to electrical equipment is also possible.

C.1.2 Specimen preparation

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

C.1.3 Reagent and materials

Saline solution: nominally 9 g/l NaCl at 37 °C ± 5 °C

Reference electrode: made of titanium (or similar conductive and stable material) with a surface area of $\geqslant$ 500 mm^2.

C.1.4 Dielectric strength test set-up

The electrical diagram and test set-up are shown in Figure C.1

C.1.5 Test signal

The test signal shall have the following elements:

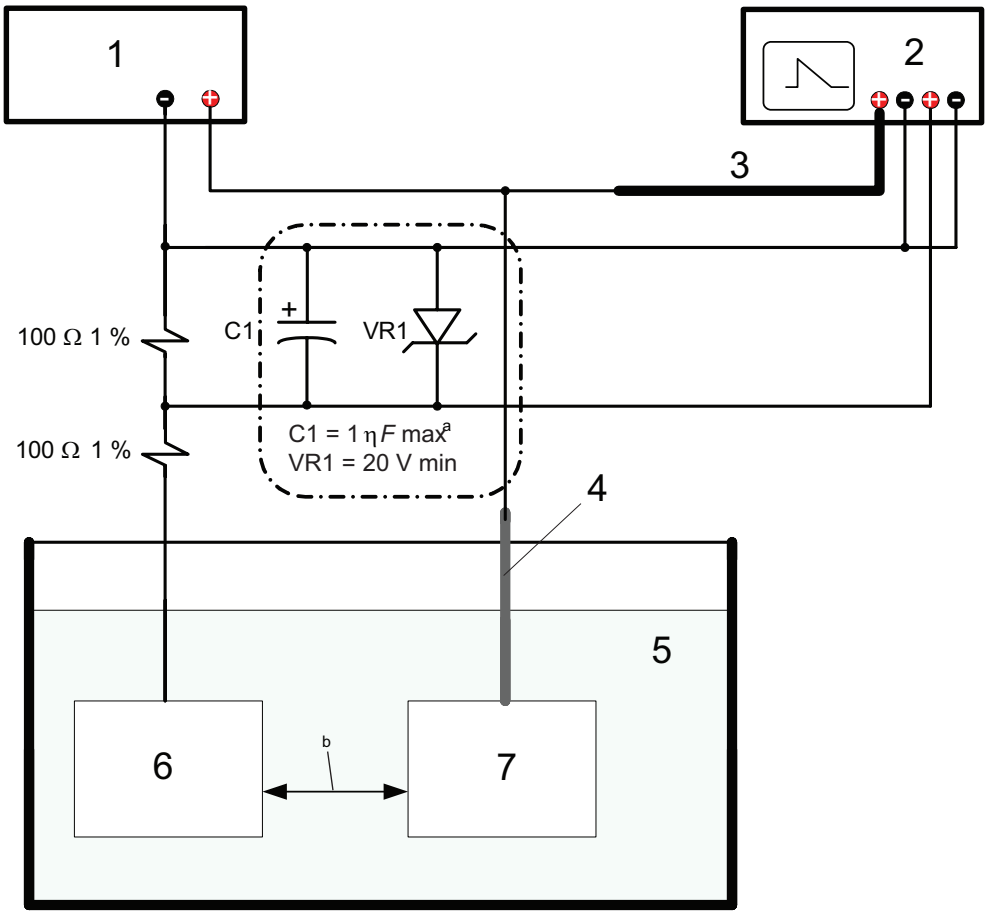
— Form: monophasic truncated exponential specified in Figure C.2 with equipment capable of providing a minimum of 100 mA.

— Rise time: 1,5 µs ± 0,5 µs from 10 % (minimum) to 90 % (maximum) of the peak voltage with a $\mathrm{d}V/\mathrm{d}t$ of 2 kV/µs maximum.

— Pulse duration: 18 ms minimum.

— Amplitude and decay: peak voltage (as specified in Table C.1 to Table C.4) ± 5 % with a minimum of 50 % of peak at 18 ms after the peak amplitude. For example a 1 500 V test pulse would have a minimum amplitude of 750 V at 18 ms.

— Interval: 10 s nominal interval between pulses.



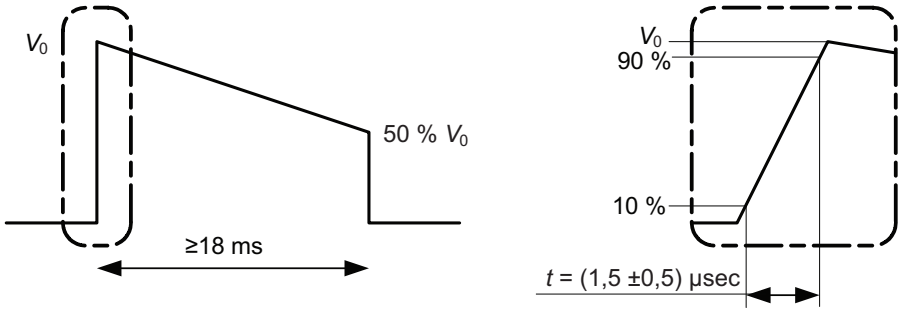
Key

1 test signal generator
2 oscilloscope
3 high voltage probe
4 lead connector body
5 saline solution
6 reference electrode
7 test unit

[a] Optional components.

[b] 50 mm to 200 mm separation.

Figure C.1 — Dielectric strength test set-up



NOTE The capability of the equipment to deliver a minimum of 100 mA can be verified by use of an appropriate load resistor. For example, for a 1 500 V test signal the minimum current should be met with a 14,8 kΩ resistor load.

Figure C.2 — Test signal

C.2 Lead connector test

C.2.1 Preconditioning

Soak the entire lead connector in saline solution for a minimum of 10 d prior to testing. Maintain the lead connector in a soaked state for testing.

C.2.2 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 isolated from the fluid.

NOTE 1 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, the strain relief zone and the grip zone remain submerged in the test solution. All three contact rings and the connector pin should be externally insulated from the test solution and from each other.

NOTE 2 Care should be taken to maintain external isolation from the test solution so that arcing does not occur.

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

Apply a total minimum of 500 test voltage pulses, 250 minimum consecutive in one polarity and 250 minimum consecutive in the reverse polarity, to each contact combination using the test voltage indicated for the combination. For high voltage lead connectors that are not integrated bipolar, apply the pulses to the contact combinations shown in Table C.1. For integrated bipolar high voltage lead connectors (where ring 1 and ring 2 are electrically common) use Table C.2. The peak voltage of the test pulse shall have a peak amplitude as shown in Table C.1 and Table C.2 according to the combination being tested.

Measure the resulting maximum leakage current between 4 µs and 1 ms into the pulse and between 1 ms and 18 ms into the pulse as illustrated in Figure C.3.

Monitor at least the first 10 pulses and last 10 pulses of each polarity for each combination.

Test all contacts, even those that are intended to be electrically inactive (open).

NOTE 3 The test can be performed by tying multiple electrodes together in parallel, as long as the maximum leakage current requirement is satisfied. For example, the reference electrode could be tested against a parallel combination of pin + ring 1 + ring 2 + ring 3.

Table C.1 — Test combinations for high voltage (DF4) lead connectors that are not integrated bipolar

	Pin	Ring 1	Ring 2	Ring 3
Reference	1 500 V	1 500 V	1 500 V	1 500 V
Pin			1 500 V	1 500 V
Ring 1			1 500 V	1 500 V
Ring 2				1 500 V

Table C.2 — Test combinations for integrated bipolar high voltage (DF4) lead connectors

	Pin	Ring 1 + ring 2	Ring 3
Reference	1 500 V	1 500 V	1 500 V
Pin		1 500 V	1 500 V
Ring 1 + ring 2			1 500 V

C.2.3 Acceptance criteria

The measured maximum leakage current shall not exceed the values specified in Table C.3 according to the test signal voltage used. This requirement applies to all contacts including those that are intended to be electrically inactive (open).

Table C.3 — Acceptance criteria

Test signal peak voltage V_0	**Maximum leakage current** mA	
	I_1, 4 µs **to** 1 ms	I_2, 1 ms **to** 18 ms
1 500	100	20

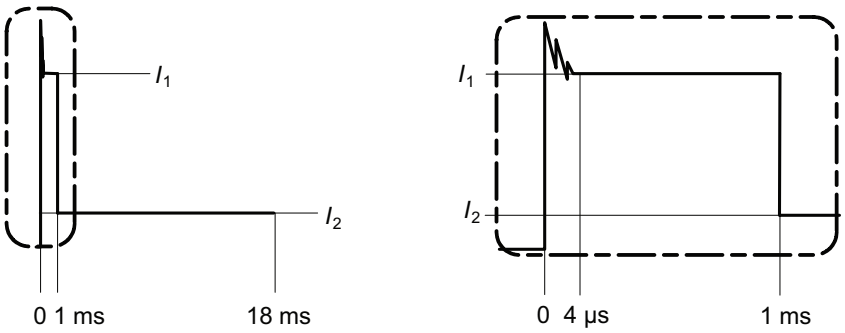


Figure C.3 — Leakage current waveform

C.3 Connector cavity test

C.3.1 Test pin

Use a test pin that conforms to Figure A.1.

C.3.2 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 the saline solution for a minimum of 10 d prior to the test and maintain in the soaked state for testing.

C.3.3 Test method

Carry out the test as follows.

Locate the cavity and pin assembly in the saline test solution so that it is 50 mm to 200 mm from the submerged reference electrode.

Apply a 1 N side load to the test pin at the bore exit perpendicular to the bore axis only during the electrical testing (not during soaking). For devices with a directional pin retention mechanism (such as a set screw), apply the load so it aligns with the direction of the pin retention mechanism.

Apply a minimum total of 200 test voltage pulses, 100 minimum consecutive in one polarity and 100 minimum consecutive in the reverse polarity, to each contact combination. The test voltage shall have a peak amplitude (V_0) that is at least 1,5 $\times$ the peak output voltage of the device and not less than 1 200 V. Test high voltage connector cavities according to the combinations listed in Table C.4.

Measure the resulting leakage current between 4 µs and 1 ms into the pulse and between 1 ms and 18 ms into the pulse illustrated in Figure C.3.

Monitor the first 10 test cycles and the last 10 test cycles of each polarity for each combination of connector contacts and reference electrode.

Test all contacts, even those that are intended to be electrically inactive (open).

NOTE 1 Visible arcing might produce damage to the connector seals, including material loss and contamination. These can affect performance. Any observations of arcing during the test should be further evaluated by the manufacturer.

NOTE 2 Additional testing between electrical conductors or between electrical conductors and the reference electrode can be performed. Refer to Annex D.

Table C.4 — Test combinations for high voltage (DF4) connector cavities

	Pin	Ring 1	Ring 2	Ring 3
Reference				[a]1 200 V to 1 500 V
Pin		[a]1 200 V to 1 500 V		
Ring 1			[a]1 200 V to 1 500 V	
Ring 2				[a]1 200 V to 1 500 V

[a] Test voltage is based on device output. Refer to C.3.3.

C.3.4 Acceptance criteria

The measured maximum leakage current shall not exceed the values specified in Table C.5 according to the test signal voltage used. This requirement applies to all contacts, including those that are intended to be electrically inactive (open).

Table C.5 — Acceptance criteria

Test signal peak voltage V_0	**Maximum leakage current** mA	
	I_1, 4 µs **to** 1 ms	I_2, 1 ms **to** 18 ms
1 200	80	16
1 500	100	20
Other	100 V_0/1 500	20 V_0/1 500

Annex D
(informative)

Rationale for Annex C

D.1 Rationale for performing a high voltage electrical isolation test

The performance of the implantable defibrillator system depends on the ability of keeping electrical conductors insulated from each other and from the outside. This test simulates the effect of high voltage exposure between conductors in order to evaluate the ability of connectors to maintain high voltage electrical isolation.

For the connector cavity, testing adjacent contacts (for example pin - ring 1, ring 1 - ring 2, ring 2 - ring 3, and ring 3 - reference) is specified to evaluate leakage current between seal rings of the connector cavity. Other combinations may be tested to evaluate other components or design features. The need for these other test combinations should be defined by each manufacturer.

D.2 Rationale for test method

D.2.1 Test signal

Rationale for aspects of the test signal is as follows.

Form: a truncated exponential monophasic waveform with a rise time of 1,5 µs ± 0,5 µs was selected because it is similar to the output capabilities of implantable defibrillators that the manufacturers expect to employ for the foreseeable future. The electrical stress of a biphasic waveform is simulated by testing both polarities.

Pulse duration: the minimum duration of 18 ms was selected as being longer than any value considered clinically useful.

Amplitude and decay: the test amplitude was selected as being 1,5 × the maximum service voltage currently envisaged by the manufacturers, 1 kV for the lead connector (see Clause 1) and the maximum output of the pulse generator for the connector cavity. The 1,5 × safety factor between the test and maximum allowed service voltage provides reasonable assurance that electrical isolation will be maintained during normal operation. The 50 % decay at 18 ms reflects output capabilities of implantable defibrillators.

NOTE The major difference between ISO 11318 (DF-1) and this International Standard is that seals reside within the connector cavity instead of on the lead connector. Because of this, the connector cavity need only be tested to what the pulse generator is capable of delivering plus the 1,5 × safety factor. Lead connectors could be used in any pulse generator so still need to be tested to voltages up to the maximum allowed plus the safety factor (same as DF-1).

Interval: the 10 s nominal frequency allows flexibility in testing and is being specified for resolving any potential disputes. Testing with smaller or longer intervals was not thought to be critical to test outcome.

Test system current: the test system's capability of delivering 100 mA at any time during the test pulse allows for verification of the maximum allowable leakage current.

D.2.2 Mechanical load

The 1 N side load is used to simulate transient loads representative of severe daily activities (see Annex B).

D.2.3 Test duration and combinations

Lead connector: 500 test cycles for the lead connector was considered to exceed a worst-case single patient delivery. This includes re-use of the lead.

Connector cavity: 200 test cycles for the connector cavity was considered a worst-case condition based on device output.

D.2.4 Test combinations

Lead connector: the lead connector test combinations include all combinations of high voltage contacts relative to each other in order to test high voltage isolation between these. Also included are all combinations of contacts relative to a reference electrode in order to test high voltage isolation for areas of the lead connector that will be outside the connector cavity.

Connector cavity combinations: the connector cavity combinations are intended to evaluate seal performance in the presence of active potentials. Reference-to-pin, reference-to-ring 1 and reference-to-ring 2 combinations do not apply as this International Standard is intended for the lead/cavity interface only. The test combination reference-to-ring 3 verifies function of the most distal seal assembly.

D.3 Rationale for acceptance criteria

D.3.1 Maximum allowed leakage current

Leakage current limits of 100 mA and 20 mA for a test signal of 1 500 V were adopted from ISO 11318 (DF-1). Other current leakage requirements specified by this International Standard are proportional to the test signal amplitude.

D.3.2 Measurement

Similar to DF-1, maximum leakage current is measured between 4 µs and 1 ms into the pulse and between 1 ms and 18 ms into the pulse. The current is not measured during the first 4 µs in recognition of the extreme difficulty of accurately monitoring a small current in the presence of a large and rapid voltage step. This was considered acceptable since it is unlikely that a unit under test could produce enough current leakage during the first 4 µs to cause tissue damage, and subsequently meet the specified leakage criteria.

D.3.3 Frequency of monitoring

The test requires that, as a minimum, the leakage current be monitored during the first ten cycles and the last ten test cycles. Experience indicates that most failures will occur early in the test procedure. It is possible that an early failure could generate gas inside the connector cavity by electrolysis and drive out the saline. This in turn could increase the isolation impedance and result in passing results for the same connector cavity by cycles 191 to 200. Therefore, it seems prudent to monitor the results at the beginning of the test as well as at the end. It is pointless to require the test of an early failing connector to be run to 200 minimum cycles.

D.4 Informative test combinations for connector cavities and lead connectors

D.4.1 General

The test combinations and voltages specified in Annex C were selected to ensure function and interchangeability of lead connectors and connector cavities. Other test combinations could be used by manufacturers to evaluate isolation of connector contacts in areas other than the seals such as to evaluate performance of specific design features or manufacturing processes. The need for such testing and the details of the test method should be defined by each manufacturer. Some suggested combinations are described in D.4.2 to D.4.4.

Testing of the connector for voltages or currents which could be induced by internal or external defibrillation was considered to be outside the scope of this International Standard. Requirements for induced voltages are dependent on the design of the leads and pulse generators and other system factors. Even though this International Standard does not address this, the test methods of Annex C could be useful for evaluating four-pole connectors under induced voltages as described in D.4.5. The need for such testing and the details of the test method should be defined by each manufacturer.

D.4.2 High voltage (DF4) connector cavities

Combinations additional to those specified in Table C.4 could be used to evaluate high voltage isolation between connector cavity contacts related to wire routings or other design aspects other than sealing. Manufacturers should decide which combinations and test methods (number of pulses, etc.) are appropriate for the specific components or features they want to evaluate. For example, the combination pin-to-reference could be used to evaluate isolation of the septum (grommet) which might be particularly important for devices where the can of the pulse generator could be configured as high voltage relative to the pin connector contact.

D.4.3 Low voltage only (IS4) connector cavities used in high voltage devices

The methods described in C.3 could be used to evaluate low voltage only connector cavities used in devices capable of delivering high voltage output. Manufacturers should decide if such testing is appropriate, and which combinations to test given their particular device design. For example, testing pin to reference or testing ring 3 to reference could be useful to evaluate the isolation and sealing in devices where the can of the pulse generator could be configured as high voltage relative to the low voltage only connector cavity contacts.

D.4.4 Low voltage only lead connectors

The method described in C.2 could be used to evaluate low voltage only lead connectors, particularly those that might be used in pulse generators capable of delivering high voltage output. Manufacturers should decide if such testing is appropriate, and which combinations and voltages to use for test. For example, testing lead connector contacts relative to a reference electrode could be useful to evaluate isolation integrity of the lead connector by simulating a system where the can of the pulse generator could be configured as high voltage relative to the low voltage connector contacts.

D.4.5 Induced voltages on four-pole connectors

Lead connectors and connector cavities, both high voltage and low voltage only, could be subjected to induced voltages from other electromagnetic environments such as internal or external defibrillation. Manufacturers may consider using the dielectric strength test procedures provided in Annex C to evaluate the potential effects of induced voltages on four-pole connector designs. Manufacturers should decide the applicable combinations and number of pulses used for such an evaluation. Possible test combinations and test voltages for each combination are presented in Table D.1.

Table D.1 — Suggested tests for evaluating induced voltages on high voltage and low voltage only lead connectors and connector cavities

	Pin	Ring 1	Ring 2	Ring 3
Reference	1 200 V	1 200 V	1 200 V	1 200 V
Pin		500 V	500 V	500 V
Ring 1			500 V	500 V
Ring 2				500 V

Data collected by the AAMI EMC task force developing ANSI/AAMI PC69 indicate potentials of no more than 1 200 V could be induced on a device during external defibrillation. A conservative estimate for voltage induced on any pair of electrodes during internal defibrillation is half the maximum voltage delivered or 500 V.

Ten (10) test pulses at each combination should be sufficient to reflect the number of shocks typically delivered by an external defibrillator (seven shocks plus a safety factor).

Manufacturers could use high voltage protection circuits that will reduce or prevent the presence of induced potentials in four-pole connectors.

Annex E
(normative)

Current-carrying test high voltage types

E.1 General

This annex describes the test to be employed to determine compliance with 4.3.8 and 4.5.8. This is a type (qualification) test and is not intended to be used as a routine production test. The manufacturer may use equivalent test methods. However, in case of dispute this test method shall be used.

WARNING — The following test employs high voltages and currents. Failure to use safe laboratory practices might result in severe electrical shock, causing personal injury or death to persons handling the equipment or conducting the test. Damage to electrical equipment is also possible.

E.2 Specimen preparation

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

E.3 Test signal

Use a test circuit that conforms to Figure E.2 for lead connector testing and a test circuit that conforms to Figure E.3 for the connector cavity testing. Charge the (200 ± 10 %) µF capacitor to a voltage of 1 000 V minimum.

Discharge the capacitor through the contact being tested and the series power resistor for a minimum of 18 ms.

Allow a 10 s nominal interval between successive capacitor discharges.

E.4 Equipment

The test equipment shall consist of the current-carrying test pin as shown in Figure E.1 and the current-carrying test arrangement as shown in Figure E.2 or Figure E.3.

E.5 Lead connector testing

E.5.1 General

This procedure evaluates ability of the contacts and conductors in the lead connector to withstand the current associated with high voltage therapy.

E.5.2 Lead connector current-carrying capacity test method

Perform the test at 37 °C ± 5 °C while the lead connector is dry. Use a test circuit that conforms to Figure E.2. Connect to the external surface of the ring contact to be tested. Complete the circuit by connecting to the conductor corresponding to the contact at a location distal to the strain relief zone as defined in Figure 1.

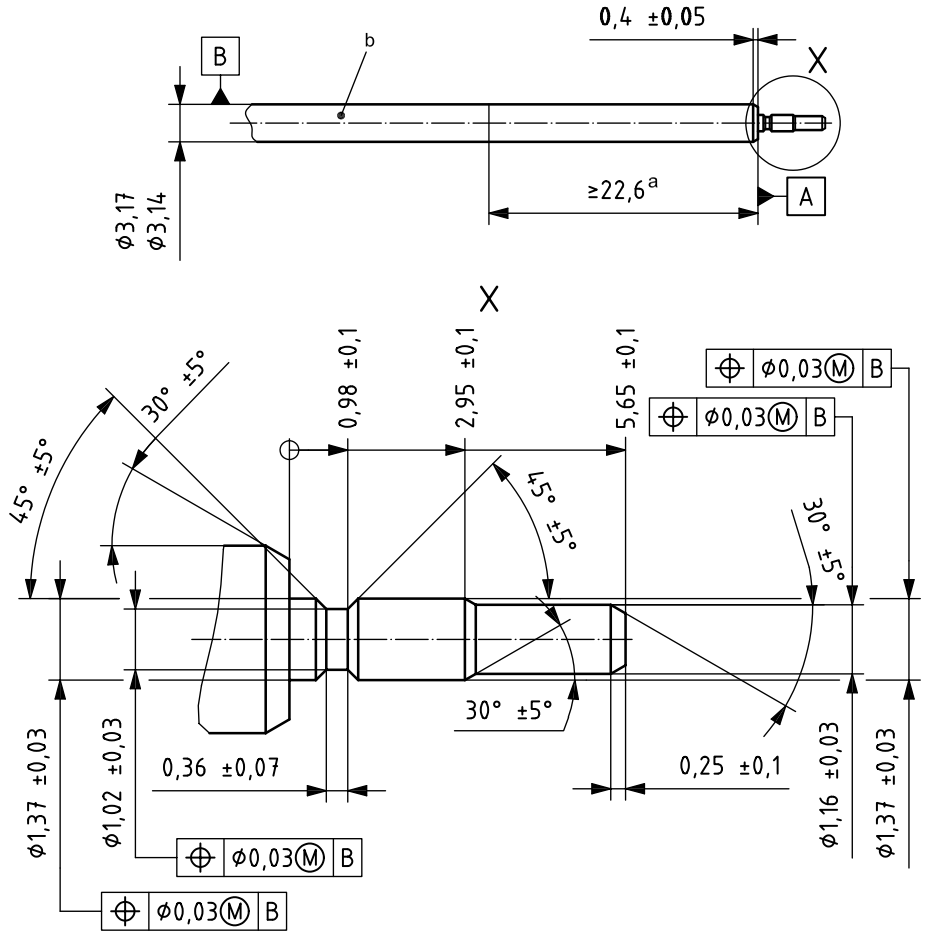
NOTE The connection to the conductors distal to the strain relief zone can include part or all of the lead body resistance.

Use the test signal for lead connectors from E.3. Select a series power resistor (R_1) and peak capacitor voltage as necessary so that the peak circuit current (I_{peak}) is 50 A minimum when measured at 4 µs into the pulse.

Apply a minimum total of 500 test voltage pulses separately to each of the following lead connector contacts: contact ring 2 and contact ring 3.

Do not apply pulses to open or low voltage contact rings.

Dimensions in millimetres



a The diameter and a surface finish of Ra 0,8 minimum applies in this zone. Geometry beyond the minimum length is determined by each manufacturer.

b Material 316L stainless steel (entire pin).

Figure E.1 — Current-carrying test pin

E.5.3 Acceptance criteria

After testing, the following acceptance criteria shall be met:

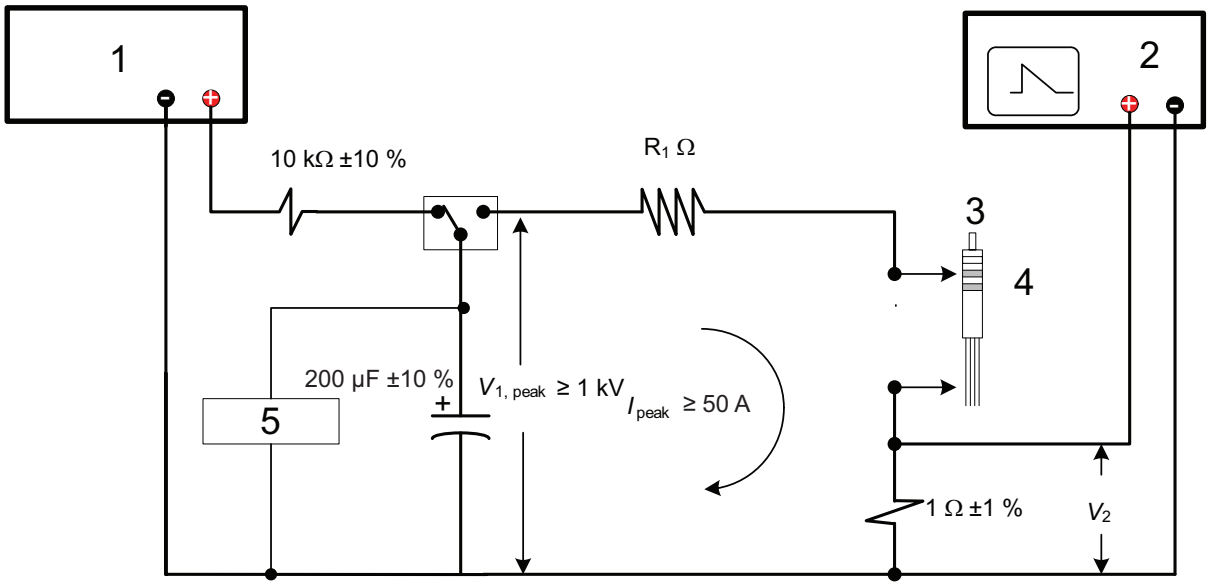
a) the lead connector shall meet the electrical isolation requirements of 4.3.6;

b) the lead connector shall meet the dielectric strength requirement of 4.3.7 as verified for ten pulses at each polarity;

c) the lead connector shall meet the requirements of 4.2.1.5 with the exception of the surface finish requirement;

d) the electrical current after 4 µs into the pulse shall be 50 A minimum;

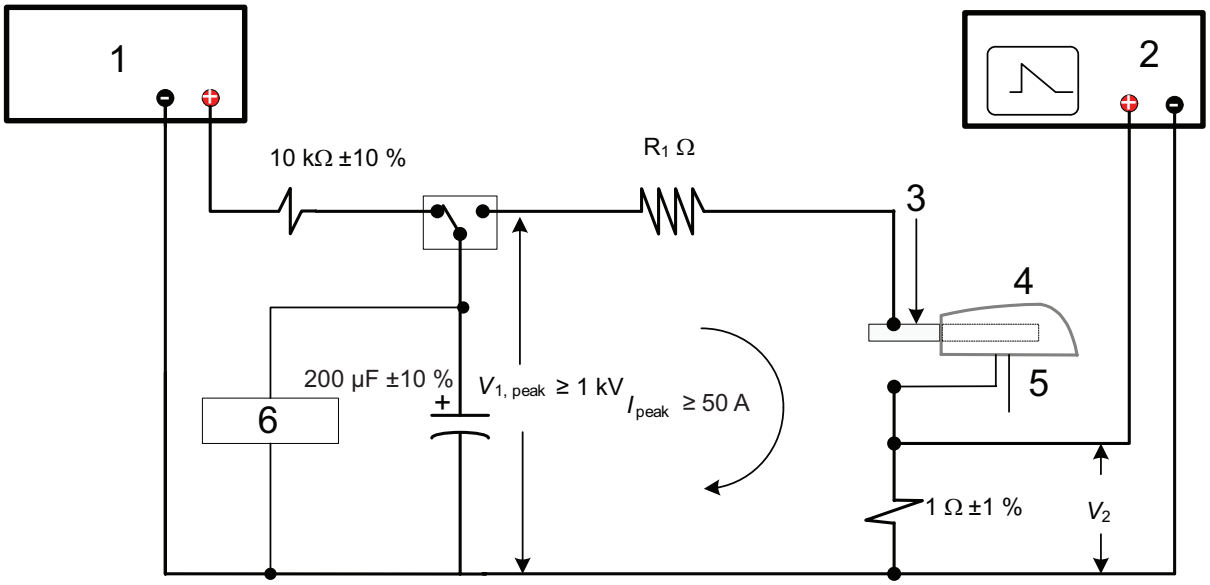
e) the voltage drop across the 1 Ω measurement resistor shall be exponential according to Figure E.4 as verified for the first and last test pulses.



Key

1 1 kV minimum power supply
2 oscilloscope
3 lead connector
4 ring 2 and ring 3 contacts
5 voltmeter

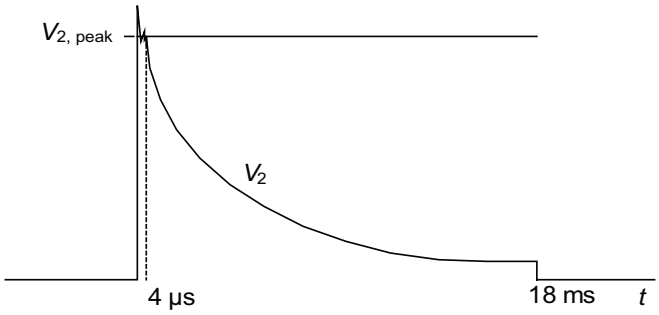
Figure E.2 — Lead connector current-carrying test set-up



Key

1 1 kV minimum power supply
2 oscilloscope
3 current-carrying test pin
4 connector cavity
5 ring 2 and ring 3 contacts
6 voltmeter

Figure E.3 — Connector cavity current-carrying test set-up



$$V_2 = V_{2,\text{peak}}\, e^{-\left(\frac{t}{RC}\right)}$$

where

V_2 is the voltage across the measurement resistor;

$V_{2,\text{peak}}$ is the peak voltage as measured at 4 µs into the pulse;

t is the time;

R is the total circuit resistance;

C is the circuit capacitance.

Figure E.4 — Voltage across the 1 Ω measurement resistor during a pulse

E.6 Connector cavity testing

E.6.1 General

This procedure evaluates the ability of the contacts in the connector cavity to carry currents associated with high voltage therapy.

E.6.2 Connector cavity current-carrying capacity test method

Perform the test at 37 °C ± 5 °C while the connector cavity is dry. Install the current-carrying test pin, which conforms to Figure E.1, into the connector cavity, and fasten with the securing mechanism that the manufacturer has provided for clinical use (e.g. set screw, leaf spring, collet). Complete the electrical contact to the current-carrying test pin as shown in Figure E.3 and to the end of the feedthrough that enters the pulse generator (or the electrical equivalent).

Use the test signal for a device connector cavity according to E.3. Select a series power resistor (R_1) and peak capacitor voltage as necessary so that the peak circuit current, I_{peak}, is 50 A minimum when measured at 4 µs into the pulse.

Apply a minimum total of 200 test voltage pulses to each of the following connector cavity contacts: ring 2 and ring 3. Measure the resulting voltage across the capacitor ($V_{1,peak}$) and use an oscilloscope to measure voltage (V_2) across the 1 Ω measurement resistor (R_2).

Do not apply pulses to low voltage or open contacts.

E.6.3 Acceptance criteria

E.6.3.1 The peak voltage across the 1 Ω measurement resistor shall be as follows as verified for the first and last test pulses:

$$V_{2,peak} \geqslant \frac{\left(V_{1,peak} \times 1\,\Omega\right)}{\left(R_1 + 2\,\Omega\right)} \text{ and } V_{2,peak} \geqslant 50 \text{ V} \qquad \text{(E.1)}$$

where

$V_{1,peak}$ is the peak voltage measured across the capacitor, expressed in volts (V);

$V_{2,peak}$ is the peak voltage across the 1 Ω measurement resistor as measured after 4 µs into the pulse, expressed in volts (V);

R_1 is the set value of the series resistor, expressed in ohms (Ω).

E.6.3.2 The voltage drop, V_2, across the 1 Ω measurement resistor shall be exponential according to Figure E.4 as verified for the first and last test pulses.

E.6.3.3 After application of current, the maximum force required to fully withdraw the test pin shall not exceed 14 N.

Annex F
(informative)

Rationale for Annex E

F.1 Rationale for performing a current-carrying test

An implantable defibrillator system relies on the ability of the connector cavity to make sufficient electrical contact between the pin on the lead connector and the defibrillator generator to carry the defibrillation current to the patient with minimal resistive losses. If the contact is too resistive, or is unable to handle the current required, sufficient power might be dissipated in the connector assembly causing damage to it, or the defibrillation output might be reduced to the point where it is ineffective.

The Connector Task Force agreed that passivated stainless 316L stainless steel, exhibiting higher contact resistance readings of the commonly used materials, would be the appropriate material to use for this current-carrying test vehicle as the “worst-case” test pin. For the connector cavity the current-carrying test indirectly evaluates the high voltage contact resistance.

This test is applicable to ring 2 and ring 3 connections that are used for high voltage therapies only.

F.2 Test parameters

A capacitor discharge test was selected to provide a means of delivering high peak currents in a repeatable, and easy to implement, fashion. It also represents the waveform that the test assembly is expected to experience clinically.

A 200 µF capacitor was selected to provide 100 J of stored energy, which is far in excess of what the manufacturers contemplated using.

The number of test cycles selected for the lead connector was a minimum of 500 because it was considered far in excess of what is expected to be experienced clinically in any one patient.

The number of test cycles selected for connector cavity testing was a minimum of 200, based on a very severe but clinically possible situation.

A peak circuit current of 50 A was selected based on a 20 Ω defibrillation load in order to represent a very severe but clinically possible situation.

A minimum 18 ms capacitor discharge time was selected to ensure that the capacitor would be discharged 99 % on a 20 Ω load under normal conditions; 18 ms is intended to be a longer discharge time than the typical monophasic or biphasic defibrillation.

Peak voltage drop is measured after 4 µs into the pulse to avoid transients. This results in minimal error since the 4 µs represents only 0,1 % of the capacitor discharge, which corresponds to approximately 0,05 V for a 50 V measurement.

The 10 s nominal interval between capacitor discharges allows flexibility in testing and is being specified for resolving potential disputes. The experts participating in the development of this International Standard agreed that testing with smaller or longer time intervals would be adequate.

F.3 Voltage drop across contact for the connector cavity

The resistance between the connector cavity and lead connector pin should not exceed 1 Ω during the delivery of the high voltage defibrillation. For two connectors in series with a typical heart load of 40 Ω, this represents a 5 % loss in output voltage from the device. Any greater voltage loss was considered to be highly undesirable.

Verification that the voltage drop during a pulse is exponential is to confirm acceptable electrical performance over the duration of the pulse.

Measurement of the voltage drop across a fixed 1 Ω measurement resistor, V_2, is used as an indirect measurement of the voltage drop across the connector assembly in order to simplify testing and obtain more stable readings. A requirement that $V_{2,\text{peak}} \geqslant (V_{1,\text{peak}} \times 1\ \Omega)/(R_1 + 2\ \Omega)$ corresponds to a connector system resistance of less than or equal to 1 Ω. Likewise an exponential drop across the measurement resistor reflects an exponential drop across the connector assembly. A 1 Ω measurement resistor was selected to maintain a low voltage reading.

F.4 Post-test requirements for the lead connector

The lead connector should be capable of delivering 50 A minimum peak current during 500 defibrillation shocks without functional or dimensional damage. A post-test verification of the dimensional requirements, electrical isolation and dielectric strength is to confirm that no functional or dimensional damage has occurred as a result of the high current pulses.

F.5 Connector cavity post-test withdrawal force

A withdrawal force requirement at the end of the test is included to check that the connector cavity/test pin assembly have not become welded together.

Annex G
(informative)

Lead connector fatigue strength test

G.1 General

Since lead flex fatigue strength requirements are defined in existing standards (EN 45502-2-1 and EN 45502-2-2), there are no additional test requirements included in this International Standard. The following information, however, is provided to facilitate implementation of the existing requirements and test methods to four-pole lead connectors.

Figure G.1 defines a holding fixture intended for use in conjunction with the procedures in 23.5 of EN 45502-2-1:2003. The holding fixture of Figure G.1 should be made of a rigid material. It should have a bore depth that is maximally set to the minimum allowed for the applicable connector cavity. The entrance edge should be rounded to a radius as shown, and the centre of rotation of flexing should be in the plane where this rounded edge begins (as also described in EN 45502-2-1).

Dimensions in millimetres

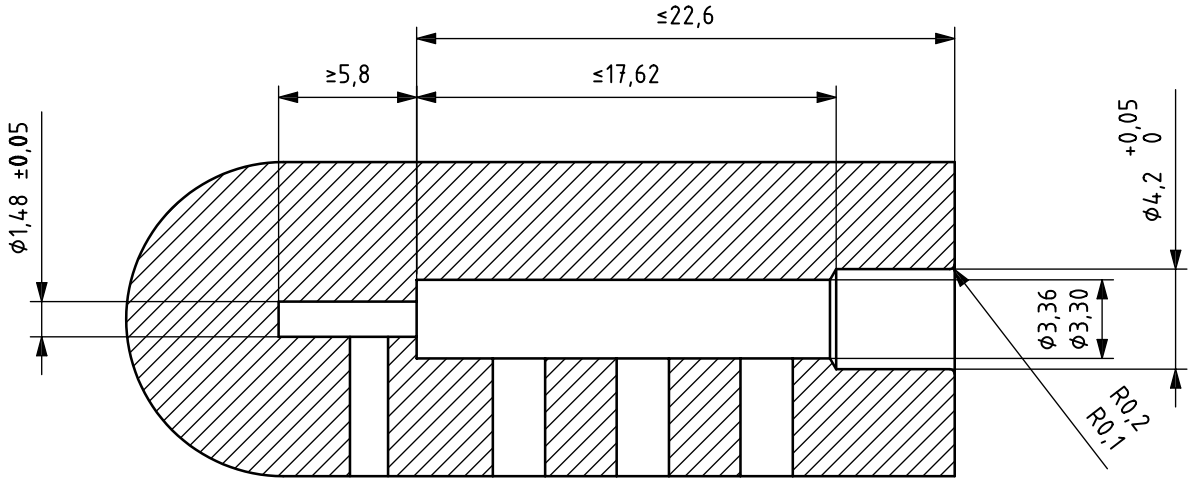


Figure G.1 — Holding fixture

G.2 Rationale for flex fatigue strength testing

Flex fatigue strength testing is performed to ensure that leads can withstand the mechanical stresses that normally occur after implantation. For the flex test described in EN 45502-2-1 and EN 45502-2-2, the leads are evaluated at a critical location which is at the interface between the relatively stiff connector cavity and the relatively flexible lead body.

The four-pole lead connectors defined in this International Standard might be relatively stiffer than similar IS-1 and DF-1 lead connectors. The reason for this is because four-pole lead connectors have a sealing area that is relatively rigid (i.e. made up of metal and hard plastic) since the softer sealing elements are incorporated in the four-pole connector cavity. Additionally, the complexity of the electrical connections necessary for four contacts places a higher demand on the mechanical and electrical integrity of the lead. Therefore, it is important that lead connector designs be evaluated for flex fatigue performance to ensure that they will maintain functional integrity under the flexural stresses that they might encounter *in vivo*.

Annex H
(informative)

Lead connector seal zone materials

H.1 General

In order to allow for design flexibility, this International Standard specifies functional requirements for the lead connector seal zones, but does not include specific material requirements. However three recommendations concerning lead connector seal zone material are provided in H.2, H.3 and H.5.

H.2 Annealing

During the development of this International Standard, measurable seal zone creep exceeding 0,02 mm was observed only when polyurethane test pins or lead connectors were not properly annealed to remove moulding stresses.

NOTE Manufacturers should be aware of the potential for unacceptable creep performance if residual stresses are not properly removed from their lead connectors.

H.3 Hardness

It is recommended that materials for lead connector seal zones have a minimum hardness of 70 Shore D (nominally) for mechanical considerations. For electrical considerations refer to 4.2.1.4 and Clause B.4.

H.4 Rationale for hardness

The recommended minimum hardness for the lead connector seal zone material is based on concerns that a lead connector could potentially become damaged when inserted past the contacts within a connector cavity. Because the details of contact design are not specified in this International Standard, it is not possible to establish a functional requirement for the lead connector. Since materials softer than 75 Shore D (nominal) were not evaluated during the development of this International Standard and might have a greater potential for becoming damaged by contacts, a recommendation is given to use materials that are 70 Shore D or harder for the seal zones of the lead connector. Harder materials can also reduce the potential for damage occurring during handling of the lead connector, such as during attachment of temporary electrical connections made at implant. However, due to its unknown and unbounded nature, inappropriate handling was not addressed by this International Standard and should be addressed separately by each manufacturer by their individual designs, in product literature, written instructions and/or adequate training.

H.5 Use of silicone rubber compounds

It is recommended that the lead connector seal zone surface be of a material other than silicone rubber compounds/composites unless the manufacturer demonstrates that silicone-to-silicone adhesion or bonding will not occur.

H.6 Rationale for recommendation against using silicone rubber compounds/composites

The recommendation for not using silicone rubber compounds/composites for the lead connector seal zone surface is based on the fact it has been industry practice to use silicone rubber compounds to fabricate seal components and it is expected this material will be used for seals in connector cavities. Some silicone rubber compounds have been known to adhere to each other when in contact, especially under loading conditions. If lead connector seal zone surfaces and connector cavity seals were both made from silicone rubber compounds they could adhere to each other, making the lead difficult to remove and potentially damaging the lead and/or pulse generator.

Annex I
(informative)

Seal zone creep

I.1 General

Since leads might remain implanted for more than ten years and might be used with multiple pulse generators during the life of the lead, the lead connector should be designed and manufactured to survive pulse generator change-outs and function with multiple pulse generators. Thus it is important to ensure dimensional and functional stability under expected use conditions. In particular, consideration should be given to the integrity of the lead connector seal zones under seal pressures, since compressive creep or deformation in these areas could prevent proper sealing with a replacement pulse generator.

This International Standard does not include an explicit requirement to control creep performance of the lead connector seal zone. During development of this International Standard, the experts in the Connector Task Force (CTF) evaluated a number of potential requirements intended to control creep performance of the lead connector seal zone. Creep testing would ensure that the lead connector seal zones would not become deformed to an extent that sealing with a replacement pulse generator might be compromised. After considerable experimentation, no practical solution was found; the CTF was unable to develop a satisfactory and reproducible test method.

However, the data generated in these studies confirmed that existing requirements in this International Standard are adequate under specified conditions. Specifically the requirement for maximum insertion force indirectly limits seal pressure by restricting the normal loads that can be applied by the seals to the lead connector. No exact correlation between seal insertion forces and seal pressures can be determined due to the variation allowed in the seal designs. However, based on intercompany testing of actual leads and pulse generators, this condition is adequate as long as sealing mechanisms are passive (i.e. they are not activated or enhanced after the lead connectors are inserted).

NOTE 1 It is recommended that manufacturers do not incorporate active sealing in their connector cavities or pulse generators unless it is demonstrated that the resulting pressure on the lead connector seal zones do not exceed those of passive sealing mechanisms. Active sealing is where seals are activated or enhanced after the lead connector is inserted. Passive sealing does not have such activation or enhancement and therefore seal pressures are limited by insertion force requirements.

NOTE 2 It is also recommended that manufacturers take effective measures to ensure their lead connectors are creep resistant. They should control both design elements and fabrication parameters (including adequate annealing) to ensure the seal zones are robust enough to withstand anticipated seal zone pressures.

I.2 Summary of efforts to develop creep requirements

I.2.1 General

During development of this International Standard, several experiments were performed to identify and quantify sources of variability in creep performance of lead connectors. The results of the two most salient studies are summarised in this annex. For these studies, the specimens were soaked in saline at 37 °C ± 5 °C for 30 d to 32 d. Even though creep can be a long-term phenomenon, experience during the development of this International Standard indicated that when creep was observed on 75 Shore D polyurethane, it presented within 30 d of soaking in 37 °C saline under loading conditions.

I.2.2 Interchangeability testing

In one study, leads and pulse generators manufactured by three different manufacturers were assembled in all possible combinations (nine in total). The specimens were soaked in saline at 37 °C ± 5 °C for 30 d to 32 d. The leads were removed from the pulse generators and the depths of the impressions left by the seal rings were measured using a precision optical measuring system. The depth of the impression was less than 0,02 mm for all specimens.

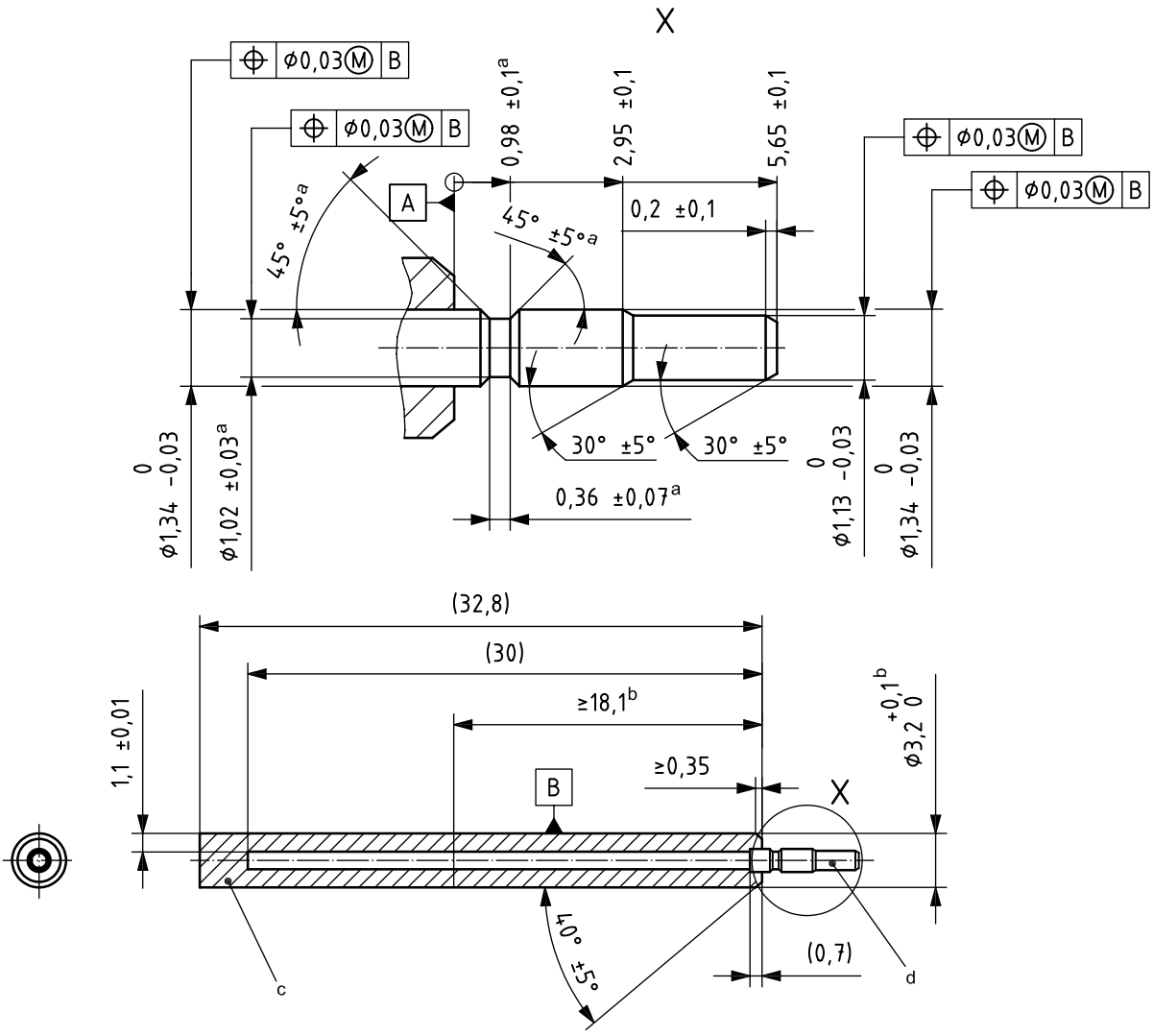
I.2.3 Design limit testing

The second study used standard test pins meant to simulate a typical lead connector and o-rings meant to produce seal pressure considerably greater than would be expected for a practical seal design. These pressures are considered greater than expected since they produced frictional drag that would result in unacceptable insertion forces in a connector system.

The study was performed using creep test pins manufactured in accordance with Figure I.1. Three sets of creep test pins were fabricated by three different suppliers. The same grade of polyurethane material was used for all pins, Tecothane™ TT1075D[1)]. Creep test pins were annealed at 60 °C to 80 °C for 4,0 h minimum. Experience has suggested that this annealing schedule is sufficient to fully anneal the test pins.

1) Tecothane™ TT1075D is the trade name of a product supplied by The Lubrizol Corporation, Wickliffe, OH, USA. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

Dimensions in millimetres



[a] For testing connector cavities that do not utilize the retention groove for fixation, these test pin dimensions are for reference only.

[b] Diameter and datum B apply to the zone indicated.

[c] Body material: Tecothane™ TT1075D moulded polyurethane.

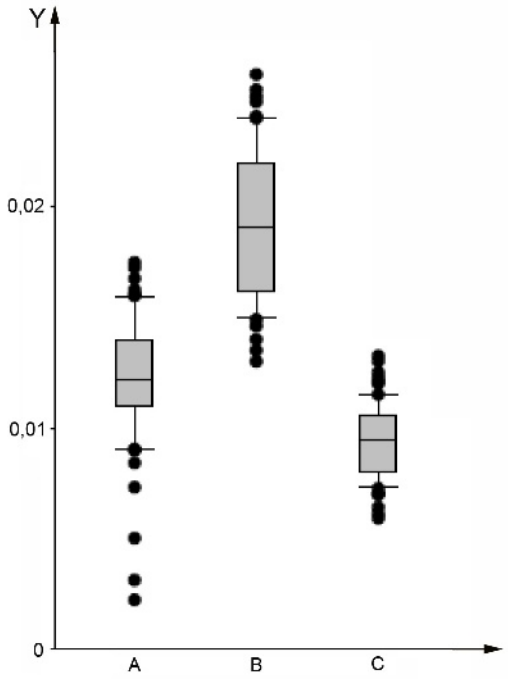
[d] Core material: 316L stainless steel.

Figure I.1 — Creep test pin

Three groups of o-ring were tested. The o-rings met the requirements of AS568-005 (Aerospace Standard 568 published by the Society of Automotive Engineers). Each group of o-rings was moulded with a different compound of EPDM (ethylene-propylene-diene rubber). Two suppliers provided material with a Shore hardness of 70A. One supplier provided material with a Shore hardness of 75A.

Four o-rings were placed on each test pin in the approximate location of seal rings in the pulse generator header. A total of 54 test pins (18 from each supplier) and 216 o-rings (72 from each supplier) were tested in a balanced design. The specimens were soaked in saline at 37 °C ± 5 °C for 30 d to 32 d. The depth of the impression made by each seal ring was measured using a video measuring system.

Results are summarised in Figure I.2.



Key

A, B, C test pin suppliers

Y depth of impression in millimetres

Figure I.2 — Depth of o-ring impressions after specimens were soaked in saline at 37 °C ± 5 °C **for** 30 d **to** 32 d

There was a statistically significant difference between the three creep test pin suppliers and also between the three o-ring suppliers. These results show that differences in test pin fabrication (for example mould gate design, moulding parameters, anneal procedure or other unknown factors) can have a significant effect on creep performance, even when final dimensions, dimensions of the underlying support pin, and specific material grade are specified and held constant. Even though testing was conducted using seal pressures considerably greater than expected for practical seal designs and testing was conducted using test pins, it is supposed that lead connectors could exhibit such variation if not properly processed. Actual lead connectors could have additional variation due to construction details beyond the homogeneous test pins.

I.3 Limits on lead connector creep

During development of this International Standard, the CTF considered and rejected a proposed requirement for lead connector creep performance. The reason for rejection is described in Clause I.5. The proposed requirement had the following elements:

a) acceptance limits: when tested in accordance with the method outlined in I.2.2, creep in the lead connector seal zone shall be less than 0,026 mm;

b) statistical basis for acceptance:

$$\overline{X} + KS < 0{,}026 \text{ mm} \qquad \text{(I.1)}$$

where

$\overline{X}$ is the sample mean;

K is the one-sided 95/99,9 normal tolerance limit factor;

S is the sample standard deviation.

I.4 Limits on connector cavity seal pressure

During development of this International Standard a proposed requirement for limiting the amount of seal pressure that a connector cavity could place on a lead connector was considered and rejected. The reason for rejection is described in Clause I.5. The proposed requirement had the following elements.

— Test pin: use a test pin that conforms to Figure I.1. Test pins shall be fully annealed to relieve residual stresses in the polyurethane prior to being used for the test. Anneal at 60 °C to 80 °C for 4,0 h minimum followed by cooling in air to ambient temperature.

— Test samples: connector cavities for the test shall be in the as-shipped condition.

— Procedure: verify that the test pin dimensions comply with Figure I.1. Immerse the connector cavity in 9 g/l saline solution. Fully insert the test pin into the connector cavity and fasten the securing mechanism that the manufacturer has provided for clinical use (e.g. set screw, leaf spring, collet). After a minimum of 30 d soaking at 37 °C ± 5 °C, remove the test pin and measure the seal contact areas on the test pin for any deformation caused by the seals. Measure the maximum depth of the deformation using appropriate magnification.

— Acceptance limits: the outside diameter of the test pin shall not exhibit surface deformation due to seal contact that exceeds 0,02 mm in depth at any location.

I.5 Rationale for rejecting proposed requirements for lead connector creep performance and connector cavity seal pressure

After extensive testing and review of results, the experts participating in the CTF concluded that the proposed requirements for lead connector creep performance and connector cavity seal pressure would be inadequate for an International Standard because the limits could neither be quantified nor verified by repeatable test methods. Variability in creep performance attributable to test pins, o-rings, apparatus and methods was too great. The test pin manufacturer was the most significant source of variability identified through experimental testing. The o-ring supplier was the second most significant source of variability. The test laboratory was the third most significant source of variability.

It would be possible to refine the method by controlling o-ring material and dimensions more closely. It might be feasible to perform additional, carefully controlled, designed experiments to better quantify the effect of variability in test specimens, apparatus and methods on creep performance, and to establish valid specification limits. However, the available evidence is insufficient to adequately characterize the sensitivity and specificity of the proposed requirements.

Although these studies show that it is not practical to establish functional requirements for creep performance, it is concluded that, for lead connector designs and processes developed by competent medical device engineering organizations, potential hazards associated with lead connector creep are adequately controlled by other provisions of the standard. Existing information in this International Standard is adequate under specified conditions; specifically, the requirement for maximum insertion force indirectly limits seal pressure by restricting the normal loads that can be applied by the seals to the lead connector. The results of tests summarised in this annex, particularly the results in I.2.2, confirm this conclusion.

Annex J
(informative)

Contact resistance stability

J.1 General

This annex describes a test method for measuring the short-term static no-load contact resistance and dynamic contact resistance stability of contacts in connector cavities. This test method defines the minimum applied side load/moment, maximum excitation input (voltage or current), and minimum sampling frequency/resolution recommended for detecting contact resistance intermittencies. Alternative test methods may be used. This is a characterization test and is not intended for use as a routine production test.

J.2 Limits for contact resistance

Pulse generator manufacturers should demonstrate that the electrical contacts within their connector cavity make sufficient electrical contact with lead connectors under static and dynamic loading conditions such that pulse generator function is not compromised. To do this, manufacturers should first establish acceptable limits for (1) static no-load contact resistance, and (2) maximum contact resistance variability and a dynamic threshold time, T, for proper functioning of their specific devices. Then they should perform testing to demonstrate that the contacts in their connector cavities meet those limits.

J.3 Set-up

J.3.1 Specimens

The manufacturer should determine the test sample configuration for this test. Internal jumpers may be used to monitor contact resistance of one or more contacts at a time. All non-set screw contacts should be tested. Samples under test should be representative of product processed in accordance with typical manufacturing operations including test pin insertions and sterilization cycles.

J.3.2 Test pin

The test pin for contact resistance testing should be made of 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562 and should meet the dimensional requirements of the current-carrying test pin specified in Figure E.1. Test pin hardness should be 45 HRC (Rockwell C scale) minimum.

J.3.3 Current-carrying test equipment

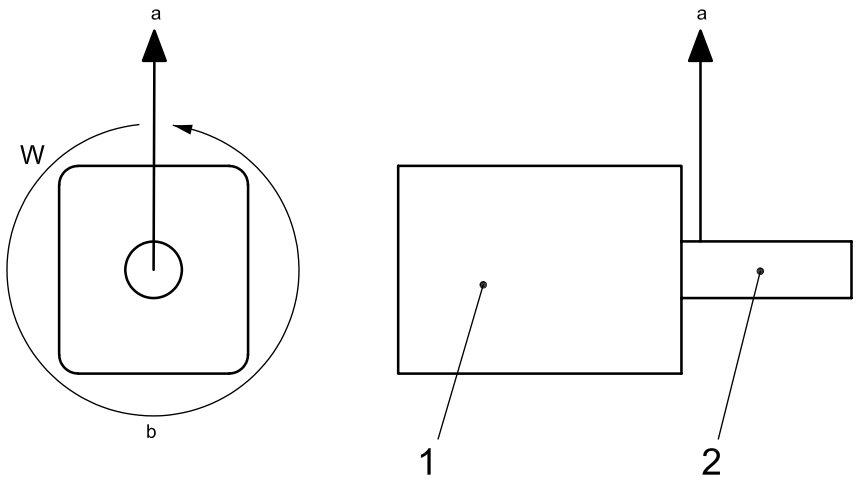
For the current-carrying test used for preconditioning, refer to the equipment and set-up specified in Figure E.2.

J.3.4 Contact resistance test equipment

The test equipment comprises a mechanical fixture and an electrical tester which can do the following.

a) Apply a minimum moment equivalent to the moment supplied by a 1 N side load at the bore entrance. A fixture is required to hold and stabilize the connector cavity while applying a rotating side load to the test pin. One example is a fixture with a rotating handle with spring load applied perpendicular to the test pin as shown in Figure J.1.

b) Measure the manufacturer's specified contact resistance and dynamic contact resistance variability above the manufacturer's specified threshold time. The sampling frequency of the equipment should be $\geqslant$ 1 sample per degree of rotation of the side load or $\geqslant 2/T$, where T is the threshold time requirement defined in J.2. The equipment excitation input should not exceed 100 mV or 100 mA.



Key

1 connector under test

2 test pin

[a] Load.

[b] 360° rotation of side load.

Figure J.1 — 360° **rotation contact resistance fixture**

J.4 Procedure

J.4.1 General

The test procedure consists of three steps in the following sequence:

— preconditioning;

— static no-load contact resistance;

— dynamic contact resistance stability.

J.4.2 Preconditioning

The object of preconditioning is to appropriately precondition the connector cavity under test by simulating multiple lead insertion/withdrawal cycles and other appropriate known stresses that the contacts might encounter during service. To precondition, fully insert and withdraw the maximum connector cavity gauge pin (Figure 9) from the connector cavity one time. Then expose the high voltage contacts of high voltage cavities to the current-carrying test in Annex E for a minimum of 20 pulses.

J.4.3 Static no-load contact resistance

J.4.3.1 Objective

To measure the short-term static no-load contact resistance between each connector non-set screw contact and the test pin.

J.4.3.2 Method

Perform the test dry in air at room temperature as follows.

a) Clean the contact resistance test pin with isopropyl alcohol and allowed to dry before insertion into the connector cavity. Wear clean laboratory gloves when handling the clean test pin to avoid contaminating it.

b) Fully insert the contact resistance test pin into the connector cavity. Do not activate the fixation mechanism (e.g. do not tighten the set screw). Mount the connector cavity in the fixture described.

c) With no load or motion applied to the test pin, use a four-wire (or equivalent) method to measure the contact resistance between the test pin and each intended contact. This measured value is the static no-load contact resistance. It is recommended that the static no-load contact resistance for each spring contact be determined from an average of at least 100 data points.

J.4.3.3 Acceptance criterion

The static no-load contact resistance should not exceed the manufacturer's predetermined requirements for proper function of the device.

J.4.4 Dynamic contact resistance stability

J.4.4.1 Objective

To evaluate the dynamic contact resistance stability of the connector cavity contacts using a fully inserted test pin with a radially applied side load.

J.4.4.2 Method

NOTE It is not necessary to repeat steps a) to c) if already performed as part of the static no-load contact resistance test in J.4.3.

Perform the test dry in air at room temperature as follows.

a) Clean the contact resistance test pin with isopropyl alcohol and allow to dry before inserting into the connector cavity. Wear clean laboratory gloves when handling the clean test pin to avoid contaminating it.

b) Fully insert the contact resistance test pin into the connector cavity. Do no activate the fixation mechanism such as by tightening the set screw. Mount the connector cavity in the fixture described in J.3.4.

c) Apply a side load to the test pin relative to the connector cavity as shown in Figure J.1. The minimum applied moment should be equivalent to a 1 N side load applied at the bore entrance.

d) With the side load applied, monitor the resistance on the contact(s) of interest while completing a minimum of three full clockwise handle rotations then reversing direction and completing a minimum of three full anticlockwise handle rotations. The duration of each full rotation should be between 2 s and 5 s.

J.4.4.3 Acceptance criteria

The maximum dynamic contact resistance and contact resistance fluctuations should not exceed the manufacturer's predetermined requirements of threshold time, T, (in seconds) and contact resistance variability, Ω, for proper function of the device.

Annex K
(informative)

Rationale for Annex J

K.1 General

Annex J describes a test method for evaluating connector cavity contacts used in four-pole connectors. This test method has been used to identify contact design performance differences that were deemed meaningful in selecting an appropriate contact for use in a particular system. This annex lists the rationale for the parameters of the test method described in Annex J.

The common feature that is mandated by this International Standard is the delivery of high voltage defibrillation therapy on the high voltage leads. The contact performance for this therapy is tested as defined in 4.5.8 and Annex E. The testing described in Annex J is intended for low voltage signals of various therapy and measurement features, some of which might reside on high voltage designated contacts, thus testing of all contacts is required.

K.2 Limits for contact resistance

A contact resistance test method is specified in Annex J. The material properties and geometry of lead contact surfaces have been specified elsewhere in this International Standard in terms of the attributes that affect contact resistance, so that a device manufacturer can be sure that leads conforming to this International Standard will have a minimum level of performance in terms of the lead-to-device contact interface. However, during the development of this International Standard, it was recognised that individual spring contact designs of the same material can have different contact resistance and intermittency performances specific to their design, which is not tested elsewhere in this International Standard. Since the device features and spring contact performance both reside in the device, it is recommended that each device manufacturer perform a test to ensure that the contact resistance and stability are acceptable for the performance of their device.

K.3 Rationale for method

K.3.1 Preconditioning

Contact resistance requirements should be met after simulation of typical stress conditions. Multiple lead insertions are expected in normal use. The test pin is being used to simulate a lead.

K.3.2 Static no-load contact resistance

A 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy test pin meeting the dimensional requirements of Figure E.1 is recommended. The test pin material was chosen to represent lead connector materials that meet the other requirements of this International Standard and provide consistent contact resistance results. If individual manufacturers plan to use other lead connector materials, they are advised to perform a similar test with those lead connector materials in addition to the 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy. The minimum hardness of the test pin was chosen to ensure that it is a worst-case representative of the acceptable lead connector material. Test pins greater than 45 HRC have been shown to cause increasing variation in contact resistance after multiple insertion cycles.

K.3.3 Short-term dynamic contact resistance stability

K.3.3.1 General

The set screw (or other active retention mechanism) is not tightened, to allow for movement that can occur with passive retention mechanisms or with lead connectors that have a rotating pin. This test is based on the expectation that some level of motion between the spring contact interface and the lead contact surface can occur. The actual magnitude of this motion is a function of many factors including but not limited to: applied external load, lead design/stiffness in the strain-relief zone, connector cavity seal design, spring contact design, and overall structural integrity of the connector cavity. The impact of this motion on electrical stability might be a critical factor for some features and might be highly dependent on the spring contact design. This test is defined to evaluate the performance of candidate contact designs for sensitivity to relative motion.

K.3.3.2 Minimum applied load

The 1 N minimum side load applied at the bore entrance was chosen based on reported physiologic loading and to be consistent with the electrical isolation testing. See Annex D for rationale.

K.3.3.3 Maximum applied voltage

The maximum applied voltage of 100 mV nominal was chosen to enable detection of contact resistance intermittencies, based on experience gained during the development of this International Standard.

K.3.3.4 Maximum applied current

The maximum input current of 100 mA was chosen to enable detection of contact resistance intermittencies, based on experience gained during the development of this International Standard.

K.3.3.5 Sampling resolution

The sampling resolution of at least one sample per degree of rotation, or at least $2/T$ (where T is the threshold time requirement), was chosen to enable detection of intermittencies.

K.3.3.6 Equipment

The equipment recommendation includes a simple fixture and equipment that is commercially available at a reasonable cost. Experience gained during the development of this International Standard led to the development of a manually rotated fixture to avoid electrical noise that might be introduced by a motor.

Several commercially available digital multi-meter (DMM) units are suitable for this test. Two examples of units used during the development of this International Standard are the following:

a) a DMM used in a dry circuit mode with 20 mV open circuit voltage and 100 mA maximum current with approximately 13 Hz sampling rate;

b) a DMM used in a dry circuit mode with 100 mV open circuit voltage and 10 mA maximum current with approximately 360 Hz sampling rate.

Experience gained during the development of this International Standard indicated that lower voltages enabled detection of contact resistance intermittencies and that the voltage should not be greater than 100 mV nominal. A four-wire measurement method (or equivalent) should be used to measure contact resistance between the test pin and spring contact, subtracting test cable resistances which might be of the same order of magnitude.

The sampling rate and handle rotation rate should be coordinated for a minimum sampling resolution of one sample per degree of rotation, or at least $2/T$ (where T is the threshold time requirement). Examples include rotating the handle at a rate of 1 cycle/min with a sampling rate of 13 Hz, or rotating the handle at a rate of 0,8 cycles/s with a sampling rate of 360 Hz.

Annex L
(informative)

Selection of contact materials

L.1 General

Careful consideration should be made when selecting the conductive materials for the electrical contacts within the connector cavity and for the lead connector, e.g. lead connector rings, lead connector pin and connector cavity contacts. At a minimum, materials for electrical contacts should be selected with consideration for electrical performance and corrosion resistance as described in Annex J, Annex K, Annex M and Annex N. Manufacturers should also consider possible system level interactions of electrical contacts and interfaces including mechanical, electrical and electrochemical variables that could affect the clinical performance of the mated connector system.

L.2 Potential system level considerations

Several factors are believed to affect the electrochemical performance of electrical contacts within the mated connector system, particularly that of metal spring contacts in the connector cavity and their interface with contacts of the lead connector. These factors, at a minimum and in no particular order, are as follows.

— Material selection: including the connector cavity contacts, mating lead connector contacts and, if applicable, the connector blocks within which the connector cavity contacts reside.

— Contamination: either in the material and/or on the surface of the material at the contact site.

— Interface geometry: multiple contact points are preferred, the normal force should be considered and care should be taken to minimize asymmetric loading.

— Interface surface morphology: surface roughness on either side of the interface might generate inappropriate particulates that could potentially become entrapped between the mating surfaces.

— Device connector cavity geometry: lead bore should sufficiently constrain/stabilize the lead connector.

— Fluid ingress: system level testing of the interface should involve some controlled ingress of fluid into the device-to-lead connector cavity area. Neither a zero fluid or open fluid situation is sufficient to adequately characterize the performance.

— Electrical parameters: pacing, shocking, polarity and/or the unique electrical characteristics of each device might affect the electrochemical stability of lead connector-to-device cavity interfaces. For example, reversing the polarity of the shocking pulse might drive corrosion preferentially to one side of the interface, i.e. the lead connector conductor versus the device connector cavity contact.

It is for these reasons that the Connector Task Force recommends that manufacturers perform system level testing relative to mechanical, electrical and electrochemical variables to assess short- and long-term performance of metal contacts and contact interfaces.

L.3 Additional considerations

During the development of this International Standard, several observations were made regarding the performance of lead connector materials. Lead connector contact material selection should consider 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562, which, during the development of this International Standard, was evaluated to have acceptable performance by multiple manufacturers. Regardless of any references here, the materials used should meet all requirements of this International Standard, including the requirements of Annex M.

During the development of this International Standard various grades of titanium specified in ASTM B348 were evaluated to a limited degree without conclusive results.

Grade 316L stainless steel material specified in ASTM A276 was also evaluated as a lead connector contact material. Contact resistance testing specified in Annex M resulted in contact resistance levels significantly above the requirement limits. Crevice corrosion testing specified in M.3.2 resulted in pitting potentials less than 200 mV against a saturated calomel reference electrode, SCE. 316L stainless steel is therefore not recommended based on these test results.

During the development of this International Standard, connector cavity spring contact assemblies composed of 316L stainless steel external housings and 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy canted coil spring contacts also exhibited higher contact resistance variability than similar-design spring contact assemblies which used 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy for both the external housing and spring contact. However, previous industry experience shows that some applications with low voltage lead connectors and connector cavities exhibited acceptable performance.

Annex M
(normative)

Lead connector contact material requirements

M.1 General

This annex describes the requirements and test method for evaluating contact materials used on the lead connector. It covers three separate but related material requirements:

a) surface contact resistance: contact resistance properties of the conditioned surface when contact is made to a reference electrode; this requirement is described in M.2;

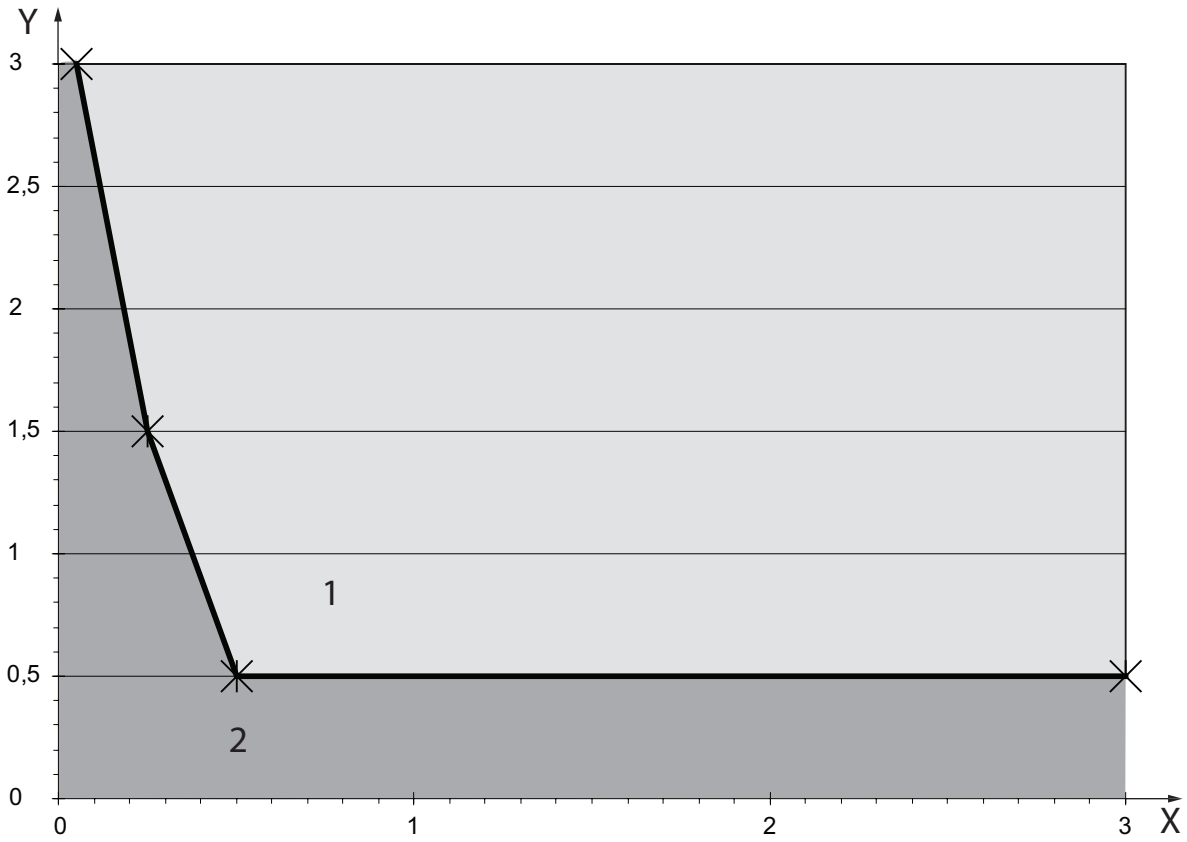
b) corrosion: corrosion resistance of the material surface when tested in multiple tests to ensure acceptable corrosion resistance of the lead connector surface; this series of requirements is described in M.3;

c) hardness: maximum hardness for materials used for the lead connector contacts is defined in M.4.

M.2 Contact resistance

M.2.1 Requirement

The average values of the surface contact resistance shall be below the curve shown in Figure M.1 when tested in accordance with M.2.3 and the associated references.



Key

X force in newtons
Y resistance in ohms
1 unacceptable region
2 acceptable region

Figure M.1 — Cross rod resistance requirement — Force versus resistance

M.2.2 Test samples and preconditioning

Contact resistance requirements shall be met by the lead connector in the condition intended for implant. Preconditioning of test samples shall include simulation of manufacturing processes including sterilization. Preconditioning shall also to include an additional soak in 60 °C aerated de-ionized water for 10 d minimum.

The surface condition of the lead connector test sample shall represent normal manufacturing processing, e.g. machining, chemical cleaning, etc., and shall include sterilization cycles. Actual lead assemblies should be used for this test.

M.2.3 Test method

This test is based on a method in ASTM B896. The reference cross wire shall be wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562 and is considered part of the test fixture. The cross rod shall have a nominal diameter of 1 mm ± 0,1 mm and shall have a surface finish no rougher than 0,4 µm Ra.

Orientate specimens perpendicular to each other in a “cross” with the contact point of the mating electrode in the appropriate contact zone of the lead connector.

Support specimens in a V-groove support block to prevent bending due to applied contact load.

Make electrical connections to the test specimens using flexible leads to ensure no stiffening effects of the lead connections are contributing to the force measured.

Use instrumentation that provides a means for measurement of contact force, contact current, contact voltage and correlation of the resistance measurement to the force measurement. The maximum open circuit voltage should be 10 mV and the maximum current should be 100 mA.

This test may be performed using either of the following methods.

a) Automated force/displacement method: bring the electrical contacts together at a rate of 1 mm/min or less until contact is established. After contact is established, increase the force at a rate of 0,5 N/min until a load of 0,5 N minimum is reached.

b) Discrete loading point method: data should be taken at a minimum of three (3) force values – 0,10 N, 0,25 N, and 0,50 N (maximum at each level). Data should be taken at the lowest force value first and then at increasing load values. Resistance measurements should be taken within 10 s of the application of each load value.

NOTE When using a weight scale for testing, the three force values should be converted prior to testing.

M.3 Corrosion

M.3.1 General

The corrosion requirements herein are for the selection of materials for lead connector contacts. All materials utilized for testing should represent the bulk and surface chemical and metallurgical conditions of the actual components to be used in the final device.

M.3.2 Corrosion resistance to localized or crevice corrosion

M.3.2.1 General

This requirement applies to all metals and alloys considered for use as lead connector contacts conforming to this International Standard. It involves testing based on methods in ASTM F746 for the determination of pitting and crevice corrosion of metallic implant materials.

All materials utilized should represent the bulk and surface chemical and metallurgical conditions of the actual components to be used in the final device.

Test description: all applicable test equipment, sample fabrication, test electrolytes and test procedures should be made in accordance with ASTM F746. The following modifications may be made.

a) The test electrolyte should be nominally 9 g/l saline at 37 °C ± 2 °C.

b) The PTFE collar dimensions and collar material can be changed to represent actual components' chemistry and crevice geometry. The collar crevice should face upwards in order to account for gravity effects.

M.3.2.2 Acceptance criterion 1

Critical potentials for pitting or crevice corrosion shall be equal to or higher than 200 mV against an SCE (saturated calomel electrode).

M.3.2.3 Acceptance criterion 2

Passivation/repassivation behaviour shall follow a decreasing current density versus time curve as illustrated in 4a of ASTM F746-04.

M.3.3 General corrosion

No requirement is specified for general corrosion. However, recommendations for selecting and testing materials are included in N.6.3.

M.4 Material hardness

Materials used for the lead connector pin and lead connector rings shall have a maximum hardness of 45 HRC.

Annex N
(informative)

Rationale for Annex M

N.1 Materials

The intent of the specification on lead connector contact material performance is to allow future innovation in the area of contact resistance performance and corrosion resistance and to ensure that cost-effective and high-performance materials are not excluded from use. The intention is to capture the critical performance attributes of the lead connector contact material to ensure that a minimum level of performance can be assumed by the designers of the mating spring contacts. See also Annex L for conductive material guidance.

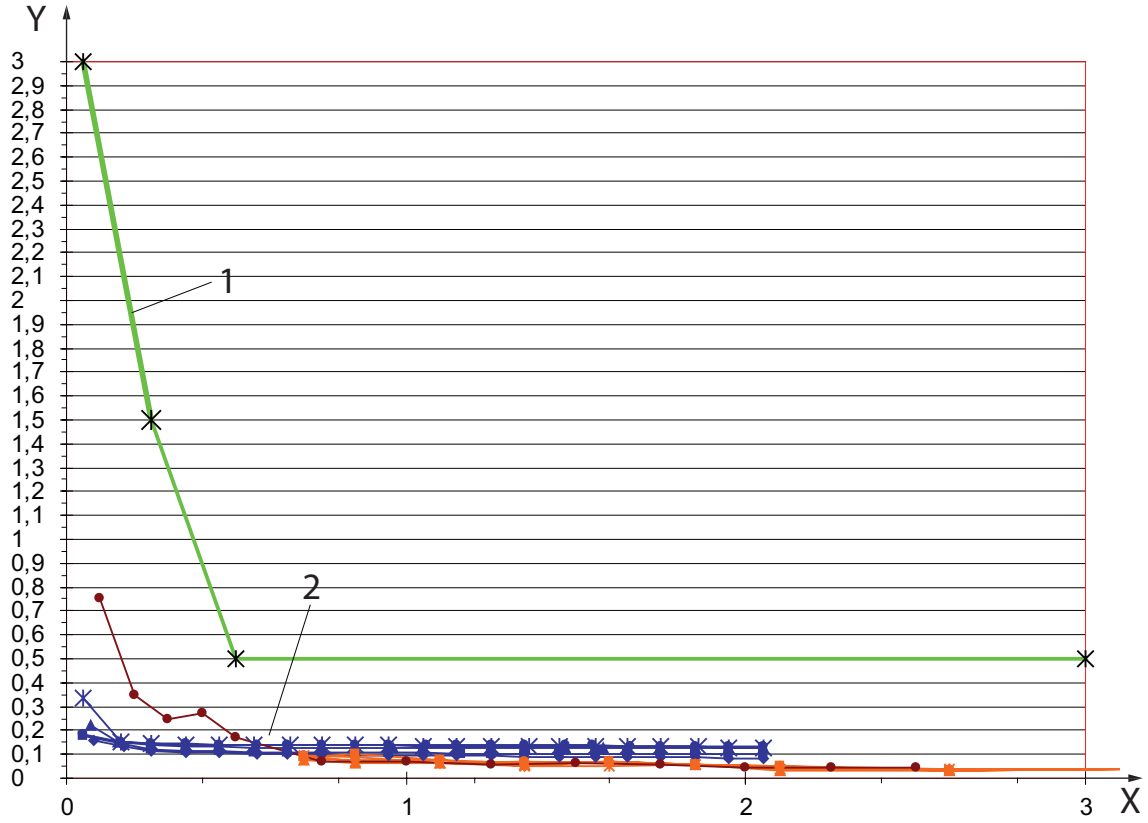
The maximum hardness of the lead connector contact zone material was limited due to test data on harder pins which show increasing variation in contact resistance after multiple insertion cycles. The maximum hardness requirement of the lead was established to give a baseline expectation of lead contact properties to device connector cavity manufacturers.

N.2 Surface contact resistance

The 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562 has been used by the manufacturers participating in the development of the four-pole system. Graphical representation of the performance of 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562 to the requirement detailed in M.2 is shown in Figure N.1. Another material, 316L stainless steel specified in ASTM A276, was also tested and found to have unacceptable electrical performance when tested at the system level specified in Annex J as well as the Annex M testing. The 316L stainless steel evaluated by the manufacturers participating in the development of the four-pole system is considered to be an unacceptable control in this International Standard. The key characteristic of the stainless steel material that is believed to be the root cause of the contact resistance instability was the surface resistance. It is believed that oxides present on the surface of the stainless steel resulted in resistance changes between interfacing contact points of the spring contact and surface of the lead. It is acknowledged that 316L stainless steel has been used successfully in implantable lead contacts in other systems with acceptable field performance but the experts working on this International Standard believed this material to be inferior to the other materials tested in terms of this surface resistance performance. The requirement in Annex M is based on the expectation that the materials above are deemed acceptable and the 316L stainless steel is considered unacceptable for this parameter. The final requirement is based on the test data collected on the reference materials listed. The performance of 316L stainless steel against the requirement of Annex M is shown in Figure N.2.

The increased resistance allowance at lower forces is based on both the practical material characteristics as well as contact theory.

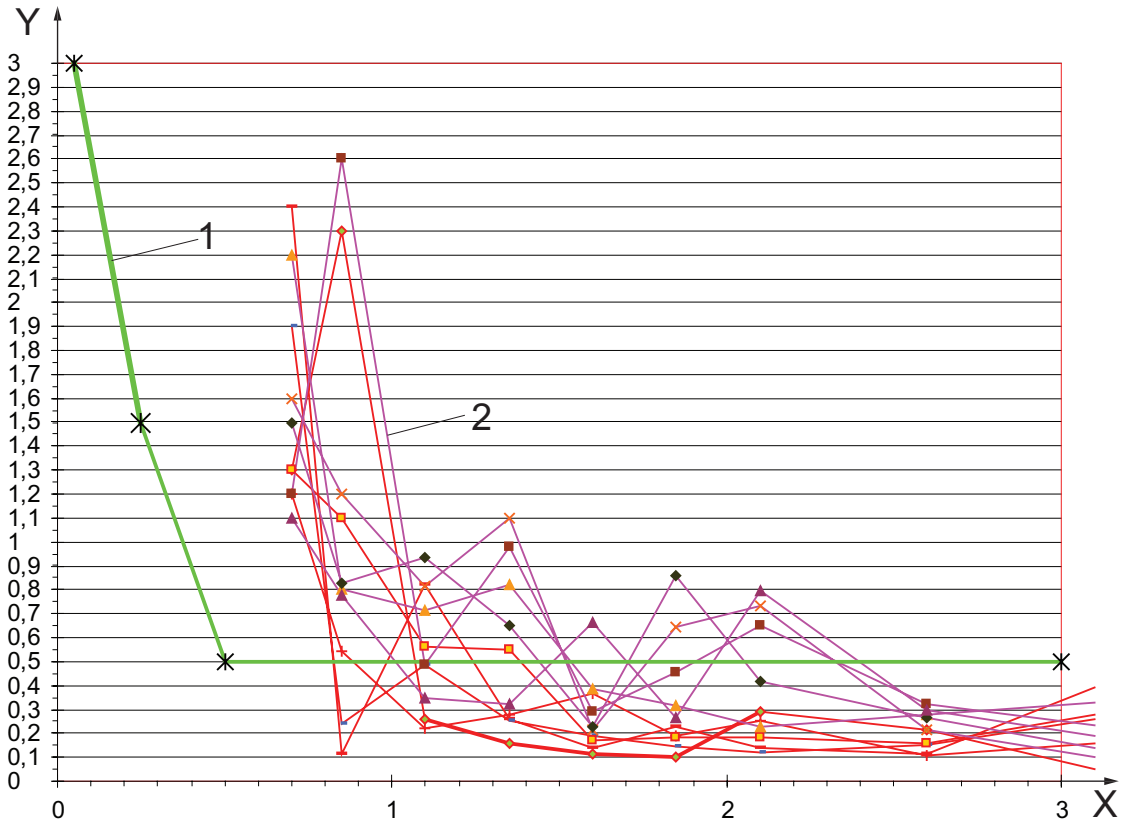
Contact theory suggests that for a fixed insertion force criterion there is a trade-off between the number of redundant contact points and the load at the interface between each contact point which produces frictional resistance to insertion of a lead contact. A reduced number of contact points can apply a larger load per contact and still meet similar insertion force requirements of a high-redundancy, low-force system. Parallel resistance theory indicates that highly redundant systems (with low forces) can have high values for individual contact point resistance values and still produce low system resistance. Therefore low-force systems can have high redundancy and higher per contact resistances are tolerated.



Key

X force in newtons
Y resistance in ohms
1 requirement
2 actual data (acceptable)

Figure N.1 — Force versus average resistance of the alloy specified in ASTM F562



Key

X force in newtons
Y resistance in ohms
1 requirement
2 actual data (unacceptable)

Figure N.2 — Force versus average resistance 316L stainless steel

Assume a maximum allowable sliding force on a given contact is a physical constraint of acceptable system performance.

Equation (N.1) describes the interaction:

$$F_f = F_n \mu N \tag{N.1}$$

where

F_f is the sliding frictional force of a contact on a pin, in newtons;

F_n is the normal force per contact, in newtons;

μ is the coefficient of friction at the contact interface;

N is the number of contacts.

For a low-force contact where F_n = 0,05 N to 0,10 N (use 0,10 for this example) and an estimated number of redundant contact points, use N = 40, the frictional force is calculated by Equation (N.2):

$$F_f = 0{,}10 \times \mu \times 40 \tag{N.2}$$

$$F_f = 4\mu \quad \text{(N.3)}$$

Using Equation (N.1), Table N.1 can be created.

Based on the resistance design value, it can be argued that high redundancy allows higher resistance values for a given individual point of contact. Total resistance of a contact system is determined by Equation (N.4):

$$\frac{1}{R}\,\text{contact system} = \frac{1}{R}\,\text{individual contact} \times N \quad \text{(N.4)}$$

For a target system resistance of 0,5 Ω and a maximum contact load of 4 N based on permissible sliding friction forces (used here for an example only), Equation (N.4) can be used to calculate permissible values for individual point resistances given the number of redundant contact points in the system being considered.

Putting these two concepts together shows that higher resistance values at lower forces will still provide acceptable system resistance if adequate redundant contact points are present. Table N.1 also indicates that as the number of redundant contact points increases, the individual maximum contact loads decrease to maintain the equivalent sliding friction forces.

Table N.1 — Contact resistance

Number of contacts	Maximum resistance per individual contact Ω	Maximum load per individual contact N
40	20	0,1
20	10	0,2
10	5	0,4
4	2	1,0
2	1	2,0

The example here is intended to show the basic relationships only and is not intended to provide requirements for this International Standard. The actual limits in the standard were chosen with this relationship in mind but not the specific values indicated.

N.3 Preconditioning

The lead connector should be tested in the condition intended for implant. Additional preconditioning was included in the requirement to moderately accelerate the formation of oxides on the lead contact surfaces.

N.4 Test method

The test method described in M.2.3 is based on a method described in ASTM B896. It includes some differences such as to the diameter of the reference electrode which was chosen to better reflect the geometry anticipated for spring contacts of a connector cavity.

N.5 Fretting sensitivity numbering

There is no formal requirement for fretting sensitivity within the scope of this International Standard. The following information is included as informative only to provide an awareness of this potential issue. The information here is given for reference and not intended to be complete.

The fretting sensitivity is defined as the potential change in mated surface resistance when a contacting surface is exposed to small repetitive motions between the contact mating surfaces. The system described in this International Standard has the potential to experience small repetitive motions at the mated interface between the spring contact and the lead connector contact due to body forces imparted on the connector system. These body forces could occur during repetitive motions of a physically active patient, for example during an activity such as swimming which involves large and repetitive arm movements. It is believed that the potential for this motion exists even with active set screw fixation due to the potential movement within the lead connector. Lead connector designs that have rotating pins often have clearance designed in to achieve free rotation of the pin. The requirements in this International Standard are based on actual test data for several materials evaluated during development of this International Standard.

The IS-1 and DF-1 International Standards allow the use of set screws for all contact connections, enabling robust contact resistance stability with a wide variety of material combinations. This International Standard limits contact pressure on the three ring contacts to levels well below that of typical set screw technology. Lowered contact forces and the raised potential for motion in this International Standard raise the contact resistance performance requirement for the lead connector and connector cavity contact interface. There is limited industry experience delivering high voltage signals through non-set screw contacts.

N.6 Corrosion

N.6.1 General

The CTF does not believe that it is practically feasible to develop a set of requirements for materials which ensures interchangeability between manufacturers with regard to metal corrosion issues, because the variables are too complex.

During the development of this International Standard, an attempt was made to develop a set of comprehensive requirements for materials which would ensure interchangeability between manufacturers with regard to metal corrosion issues. However, the complex variables involved, including unknown interface materials and geometries, made this practically impossible.

Consideration was given to restricting the materials used for lead connector contacts to a single material, 35Cobalt-35Nickel-20Chromium-10Molybdenum alloy specified in ASTM F562, to reduce the possibility of interchangeability issues by allowing manufacturers to evaluate their connector cavity designs with a known and fixed lead connector interface material. However, such a restriction was felt to overly limit innovation and the possible adoption of alternative materials in the future.

Therefore, a requirement is provided in M.3.2 to ensure that materials utilized for lead connector contacts are resistant to crevice/pitting corrosion and generally suitable for this application. Along with this is a recommendation in N.6.3 that additional material characterization tests be performed to assess general corrosion behaviour. This is especially important for any alternative materials being considered.

It is further recommended that manufacturers perform additional testing at the device, lead and system level to assess other types of corrosion such as uniform, galvanic and fretting, with attention to materials being utilized in the mating connector.

N.6.2 Corrosion resistance to localized or crevice corrosion

The corrosion requirement in M.3.2 is to help ensure materials selected for the lead connector contacts are generally corrosion resistant and suitable for implant use. This test is based on ASTM F746 for the determination of pitting and crevice corrosion of metallic implant materials. The materials utilized for testing should represent the bulk and surface chemical and metallurgical conditions of the actual components to be used in the final device.

Test rationale: localized or crevice corrosion can affect normal function of implantable medical device connectors, and/or might trigger a negative host response to the release of corrosion products. This test method allows the ranking of candidate metallic materials in terms of the potential at which breakdown first

occurs. The higher the potential, the more resistant the alloy is to passive film breakdown and to localized corrosion. The modifications to the recommended test solution are based on the differences between the compositions of the surrounding body fluids and that of the insulated microenvironment developed inside the connector modules. However, if the effects of dissolved oxygen are suspected to be important regarding material repassivation and fatigue then the tests should also be performed in an environment which simulates the lower-percentage oxygen conditions of a biological environment, such as a nitrogen-purged atmosphere.

The 200 mV versus SCE acceptance criterion was based on test data derived from materials used in connector modules for many years. Selecting alloys with performance similar or superior to the recommended parameters will help screen out unsuitable candidate materials.

N.6.3 General corrosion

In addition to meeting the requirement in M.3.2 for crevice/pitting corrosion, it is recommended that manufacturers assess general corrosion behaviour of lead connector contact materials by performing cyclic potentiodynamic polarization measurements that follow the methods outlined in ASTM G5 or ASTM F2129.

The experimental procedures described in ASTM G5 and ASTM F2129, which can also include surface analysis following testing, provide information on the corrosion behaviour of metals (such as breakdown potential and anodic kinetic behaviour), and therefore can be useful in assessing the suitability of the materials for use in this application.

Test articles should be representative of the bulk and surface chemical and metallurgical conditions of the final device.

The following test parameters should be considered:

a) test electrolyte: 9 g/l NaCl solution at 37 °C ± 2 °C;

b) scan rate of 10 mV/min with a final potential of 1,2 V against a saturated calomel electrode (SCE).

The potential limit of 1,2 V against an SCE is one commonly used for such corrosion testing. A test electrolyte of 0,9 wt % NaCl is suggested to reduce test set-up complexity. However, if the effects of dissolved oxygen are suspected of being important regarding material repassivation and fatigue, then the tests should also be performed in an environment that simulates the lower-percentage oxygen conditions of a biological environment, such as a nitrogen-purged atmosphere.

The resulting corrosion behaviour should be compared with that of materials with proven field performance in similar applications (i.e. long-term implantable cardiac lead and device connectors).

Annex O
(informative)

Rationale for requirements in this International Standard

O.1 Need for a connector standard

Implantable cardiac rhythm management (CRM) systems are being developed to address both conventional and novel modalities for treatment of cardiac disease. These systems are tending toward an increase in leads and electrodes and thus an increase in electrical contacts between the lead and the device. Current international connector standards allow for only one or two electrical contacts per connector. Thus there was a need to create a connector assembly having more than two electrical connections. In order to permit leads and pulse generators of various manufacturers to be used interchangeably, it is essential that standards be established to adequately define the criteria for the interface between these devices.

This International Standard for a four-pole connector allows for a reduction in the number of lead connectors and connector cavities and also allows for a reduction or elimination of set screw connections. Use of a four-pole connector on tripolar and four-pole leads will also reduce the pocket bulk associated with lead trifurcations and bifurcations, and it will reduce undesirable interactions of lead bodies within the pocket.

O.2 Selection of basic design concept and approach to standardization

The requirements in this International Standard were structured to accomplish the following.

— Specify a connector system useful for both high voltage (i.e. defibrillation) and low voltage (i.e. pacing/sensing) cardiac rhythm management applications.

— Specify a connector system that allows for a maximum of four electrical connections, a maximum of two of which may be for high voltage. The DF-1 and IS-1 International Standards only allow for a maximum of one or two electrical connections on a single connector.

— Ensure mechanical and functional interchangeability between lead connectors and connector cavities while allowing for maximum flexibility in connector and device design. This International Standard does not address all details of functional compatibility, safety and reliability, which are better addressed by each manufacturer because they can be highly specific to design and therapy requirements.

— Define both the lead connector and the connector cavity of a connector system.

— Specify requirements for lead connectors separately and distinctly from requirements for connector cavities so as not to include requirements that require true system level testing. This allows manufacturers of only one type of device (e.g. a leads only manufacturer) to use and fully comply with this International Standard.

Whenever practical, this International Standard has been structured to include more dimensional requirements for the lead connector and more functional requirements for the connector cavity. This allows for maximum flexibility regarding connector cavity seal and contact designs.

O.3 Selection of basic design concept

The basic design concept was selected to accomplish the following.

— Make use of similar technology currently used on connector systems for cardiac rhythm management devices.

— Allow for an optional passive (non-set screw) retention mechanism, but maintain compatibility with the set screw systems currently used in IS-1 and DF-1.

— Incorporate seal rings inside the device connector cavity, and not on the lead connector, so that seals will be replaced during device change-outs. Previous and existing connector standards for implantable cardiac rhythm management devices locate seals on the lead connector. These standards allow for seals to be located in the connector cavity as well, but this was primarily to accommodate early lead connectors that had no seals. This International Standard for a four-pole connector requires seals to be located in the connector cavity. The seals in this four-pole connector are critical because they are intended to provide electrical isolation between multiple high and/or low voltage terminals in close proximity. Therefore, by requiring the seals to be located in the connector cavity, new seals are introduced to the system with each pulse generator change.

— Physically lock out low voltage type lead connectors from high voltage type connector cavities in order to prevent inadvertent delivery of high voltage device output through low voltage lead electrodes.

O.4 Rationale and explanation for requirement elements — Lead connector

O.4.1 General

Lengths and locations of contacts and seals are specified for both the lead connector and the connector cavity in order to achieve alignment and interchangeability. The length and location of the pristine zones of the lead connector were determined so that a portion of each zone always aligns with the entire corresponding functional zone of the connector cavity when the connector is assembled. The zones of both the lead connector and the connector cavity are dimensioned relative to the hard stop where the 3,2 mm diameter of the lead connector bottoms against the shoulder in the connector cavity. This common datum is referred to as datum A. Subclauses O.4.2 to O.4.6 provide a description of each zone and an explanation of how their lengths were determined.

O.4.2 Functional contact zones (connector cavity)

These zones locate the electrical contacts within the connector cavity. Although the contact hardware may extend beyond these zones, it is intended that the electrical contact within each zone is able to stand alone functionally, since this is the only area that can be assured of having full contact with a conductive contact surface on the lead connector. Functional contact zones are referenced from datum A of the connector cavity.

O.4.3 Functional seal zones (connector cavity)

These zones locate the sealing mechanisms necessary for achieving electrical isolation between contacts within the connector cavity. Although the seals themselves and seal hardware may extend beyond these zones, it is intended that the sealing which occurs within each zone is able to stand alone functionally, since this is the only area that can be assured of making full contact with a non-conductive seal surface on the lead connector. Functional seal zones are referenced from datum A of the connector cavity.

O.4.4 Pristine contact zones (lead connector)

These zones on the lead connector have a “defect-free” conductive contact surface for making electrical connection to the connector cavity. Their locations are referenced from datum A of the lead connector, but their specified lengths are to be calculated using the formula 0,9 mm + M. This formula was created by taking the corresponding lengths of the functional contact zones of the connector cavity (0,4 mm) and then adding on two additional lengths to the proximal side, a fixed length (0,50 mm) and a variable length, M.

The fixed length was added to absorb misalignment between datum A of the lead connector and datum A of the connector cavity as could occur from such things as tolerance stack-ups or misalignment of the securing mechanism or by under-insertion, which is when the lead connector is not fully seated in the connector cavity prior to securing it. This length is a fixed amount and applies to all manufacturers and connector designs.

The additional variable length was added to account for datum misalignment due to axial pin movement, M, as is often present with lead designs utilizing a rotating connector pin. Since axial pin movement, M, depends on the specific lead connector design and fabrication method, this length was made variable, up to a certain maximum value, so that each manufacturer can determine and allow for what is necessary for their particular connector design. For example, if a particular lead connector requires the maximum allowed amount of axial movement (M = 0,25 mm), then that particular lead connector requires at least 0,25 mm of contact length added to the proximal end of each contact ring to ensure alignment at worst-case pull-back. Likewise, if a particular lead connector has no axial pin movement (M = 0), as is the case with some non-rotating pin lead connectors, no additional contact length is required.

NOTE The resultant specified length of pristine contact zone only defines the minimum for a “defect-free” contact surface. It is assumed that the actual length of the contact ring will be longer on both ends of the zone to account for manufacturing variations such as ring length tolerances, ring location tolerances and ring edge breaks.

O.4.5 Pristine seal zones (lead connector)

These zones on the lead connector have a “defect-free” non-conductive seal surface for making contact with the seals of the connector cavity. Their locations are referenced from datum A of the lead connector and their specified lengths are to be calculated using the formula: 1,81 mm + M. This formula was created by taking the corresponding lengths of the functional contact zones of the connector cavity (1,31 mm) and then adding on two additional lengths to the proximal side, a fixed length (0,5 mm) and a variable length, M, both as described in O.4.4.

O.4.6 Areas between pristine contact zones and pristine seal zones (lead connector)

The areas between the pristine contact and pristine seal zones on the lead connector are where the transitions between non-conductive seal surfaces and conductive contact surfaces occur. These transition areas are intended to absorb tolerances as well as certain acceptable tool/fabrication marks that might be present in the lead connector. The lengths of these areas were determined by assuming values for a variety of conceivable tolerances and tool marks. The values were then selectively combined, taking into consideration specific design and fabrication methods since not every tolerance/tool mark was simultaneously applicable. By combining tolerances in this way, rather than simply adding each individual value, the overall length of the connector was kept at a minimum. At the same time, by not specifying the exact location of seal to contact transitions, manufacturers are provided with maximum flexibility for using the area according to their specific tolerance and fabrication needs.

O.5 Rationale for requirement elements — Lead connector

O.5.1 Lead connector pin dimensions

See 4.2.1.1 and Figure 2.

The connector in this International Standard is designed to allow for the use of a set screw to secure the lead connector pin, as is common in existing connector standards. However, this International Standard also

specifies a groove located on the lead connector pin to allow for alternative securing and/or contact mechanisms.

O.5.2 Lead connector functional check

See 4.3.1.

The bore gauge requirement was created to evaluate the fit of a lead connector into a connector cavity, taking into consideration functional factors such as lead connector curvature, diameter and radial offsets. To meet the requirement, those lead connectors that are at the large end of the diameter and/or offset tolerance need to be straighter than those that are at the smaller end of the tolerances. The bore gauge is specified to reflect the connector cavity lead-in diameter (4,2 mm) and connector pin bore length (5 mm) and diameter (1,43 mm).

O.5.3 Tensile loads

See 4.3.2.

This requirement was created to ensure that the lead connector is able to withstand the forces required to disengage it from the connector cavity without sustaining functional damage. The load value of 14 N minimum is based on the maximum withdrawal force of 14 N allowed for the connector cavity (specified in 4.5.3).

O.5.4 Deformation due to pin contact forces

See 4.3.3.

This requirement is to ensure that the lead connector pin is able to withstand loads applied by the securing mechanism. The force of the set screw, as specified in the test, was considered to be significantly higher than forces that would be generated by a passive securing mechanism or by a non-set screw post-insertion activated mechanism.

O.5.5 Deformation due to ring contact forces

See 4.3.4.

This requirement is to ensure that the lead connector rings are able to withstand loads applied by connector cavity contact mechanisms without becoming damaged or permanently deformed. The length of the test fixture blade is based on the length of the lead connector pristine contact zones and the load is based on a reasonable upper limit for post-insertion activated contact mechanisms. It is assumed that connector cavity contact mechanisms that are activated during insertion will have lower contact forces since they will be limited by the insertion force requirements.

O.6 Rationale for requirement elements — Connector cavity

O.6.1 Dimensions

See 4.4.1.

The compliance of a connector cavity to this International Standard is primarily based on functional tests. There are several dimensional requirements and those correspond to the pristine contact and seal zones that are specified on the lead connector, the pin visibility zone that corresponds to the insertion indicator zone of the lead connector pin and the strain relief zone which is intended to provide a minimum length at the opening of the connector cavity that will limit the potential movement of the lead connector as it exits the connector cavity.

O.6.2 Insertion and withdrawal force

See 4.5.1 and 4.5.3.

These requirements ensure that the lead connector can be engaged and disengaged in the clinical setting without undue force that might complicate the procedure and damage the lead. The test method involves insertion of a rigid test pin, set to maximum dimensions, into the connector cavity under test.

Existing international connector standards (IS-1 and DF-1) do not specify use of a rigid test pin since the sealing mechanisms are located on the lead connector, allowing lead connectors to be tested directly in minimum bore test gauges.

The rigid test pin specified in this test was designed to reflect a lead connector having all applicable dimensions set at worst-case tolerance limits. Although it is technically allowed by this International Standard, an actual lead connector is statistically unlikely to include all worst-case dimensions simultaneously. Furthermore, prototype lead connectors having dimensions intentionally set to the same worst-case dimensions as the rigid test pin tended to exhibit lower and more consistent insertion forces when compared to rigid test pins using the same test method. This difference was believed to be due to the flexible nature of the lead connector which reduced the effects of small misalignments in the tester, an unwanted test artifact present with rigid test pins.

Insertion force tends to be related to high voltage electrical isolation performance and to maintaining good electrical contact between the lead connector and cavity contacts. In other words, higher insertion forces generally correlate with better high voltage sealing (stronger seals) and better electrical contact (stronger electrical contacts). Therefore, there is a desire to set insertion force limits low enough so that lead connectors do not become physically damaged during insertion, yet not too low as to increase the potential for compromised electrical function.

The insertion force maximum limit was set to 16 N (increased from the 14 N of current similar international connector standards) to account for the differences inherent with testing with a rigid test pin and to allow for additional design margin for seals and contacts to better ensure acceptable electrical function.

The displacement limit of 0,5 mm is the alignment margin built into this International Standard. It is a new requirement compared with similar connector standards, which was added because alignment of seals and contacts is critical for this four-pole connector system.

O.6.3 Retention force

See 4.5.2.

This requirement ensures that the securing mechanism in the connector cavity is sufficient to retain the lead connector. The minimum retention force of 10 N is intended to exceed any loads that could act on an implanted lead in a direction that could result in unacceptable displacement of the lead connector within the connector cavity. The retention force and 10 s minimum time were generally adopted from EN 45502-2-2, except that the higher retention value of 10 N and more stringent displacement requirements are specified in this International Standard because the alignment of seals and contacts is critical for this connector system.

O.6.4 Contact load

See 4.5.4.

This requirement ensures that device connector cavities do not exceed a maximum load value beyond what lead connectors can withstand. Contact mechanisms that do not require activation after the lead connector is inserted are exempt from this requirement under the assumption that their loads will be limited by insertion/withdrawal force requirements.

O.7 Connector types and combinations

O.7.1 High voltage and low voltage only versions

Two main categories of connectors are specified:

a) high voltage version;

b) low voltage only version.

Low voltage only versions are suitable for applications that require voltages less than or equal to 20 V (e.g. pacing and sensing of intracardiac electrical signals).

High voltage versions are intended for applications that require stimulation voltages between 20 V and 1 000 V peak (e.g. defibrillation).

These two main versions of lead connectors have different connector pin geometries to prevent physical connection between low voltage contacts of the lead connector and high voltage contacts of a connector cavity.

O.7.2 Permitted configurations

Within the two main versions there are several permitted configurations, as shown in Table O.1. Generally (DF4-LLHO excepted), lead connectors of one configuration are not intended to be used with connector cavities of a different configuration even though the two might physically fit together. Table O.1 shows the different configurations and which combinations are intended to be functionally compatible (“INTENDED”) and which combinations are physically locked out (“LOCKED OUT”) from each other. The remaining combinations (“NOT Intended”) are not intended even though they will physically fit together. DF4-LLHO lead connectors were included as “intended” for DF4-LLHH cavities (in addition to DF4-LLHO cavities) because of a perceived practical utility for this combination.

Although the configuration LOLL could potentially be covered by the configuration LLLO, it has been included as a distinct configuration based on a specific clinical application for a VDD lead having a single pacing electrode in the right ventricle and two electrodes in the atrium. There might be other specific designations that are currently not allowed by this International Standard, which might be considered for inclusion in the future to address specific clinical needs. The number of allowed configurations was intentionally limited to reduce potential system incompatibilities.

O.7.3 Integrated bipolar

There are two additional configurations of lead connectors to allow for integrated bipolar applications, where a high voltage lead electrode is also used for low voltage pacing and sensing function. In the integrated bipolar versions, ring 1 contact and ring 2 contact are electrically connected to each other. Although integrated bipolar lead connectors in this International Standard are to be designated with identical marking symbols as non-integrated bipolar lead connectors, a manufacturer might find it useful to distinguish integrated bipolar leads by indication elsewhere on the lead, lead box label or tray label or in other package contents.

O.7.4 System compatibility

This International Standard specifies the type of lead electrodes (i.e. whether high or low voltage), and the order they are to be connected to lead connector contacts. It does not specify other aspects of lead design such as spacing of electrodes or intended implant location or therapy. For the connector cavity, this International Standard specifies the type of voltage output that is to be delivered through each connector cavity contact, but does not address programmability of device outputs.

Because this International Standard does not address all aspects of lead and device design, it does not ensure system compatibility. It is possible that leads and devices that conform to this International Standard, that are mechanically interchangeable and that are used in intended combinations, might not be functionally

compatible. The number of permitted configurations was intentionally limited to reduce the possibility of such occurrences. However, system compatibility regarding therapy delivery was considered to be outside the scope of this International Standard.

Table O.1 — Connector system configurations and combinations

Lead connector	Connector cavity					
	IS4-LLLL	**IS4-LLLO**	**IS4-LOLL**	**DF4-LLHH**	**DF4-LLHO**	**DF4-OOHH**
IS4-LLLL	**INTENDED**	NOT Intended	NOT Intended	**LOCKED OUT**	**LOCKED OUT**	**LOCKED OUT**
IS4-LLLO	NOT Intended	**INTENDED**	NOT Intended	**LOCKED OUT**	**LOCKED OUT**	**LOCKED OUT**
IS4-LOLL	NOT Intended	NOT Intended	**INTENDED**	**LOCKED OUT**	**LOCKED OUT**	**LOCKED OUT**
DF4-LLHH	NOT Intended	NOT Intended	NOT Intended	**INTENDED**	NOT Intended	NOT Intended
DF4-LLHO	NOT Intended	NOT Intended	NOT Intended	**INTENDED**	**INTENDED**	NOT Intended
DF4-OOHH	NOT Intended	NOT Intended	NOT Intended	NOT Intended	NOT Intended	**INTENDED**
DF4-LLHH integrated bipolar	NOT Intended	NOT Intended	NOT Intended	**INTENDED**	NOT Intended	NOT Intended
DF4-LLHO integrated bipolar	NOT Intended	NOT Intended	NOT Intended	**INTENDED**	**INTENDED**	NOT Intended

O.8 Inadvertent use with IS-1 and DF-1

The lead connectors described in this International Standard were designed such that the diameter is larger than an IS-1. Thus a four-pole lead connector (IS4 or DF4) would not fit into an IS-1 connector cavity. If an IS-1 lead connector were inadvertently put into an IS4 or DF4 connector cavity the contacts would not align and thus the lead would not function electrically.

The diameter of the lead connectors described in this International Standard (IS4 and DF4) is smaller than DF-1 connectors. Thus a DF-1 lead connector would not fit into an IS4 or DF4 connector cavity. It is possible to insert an IS4 or DF4 lead connector into a DF-1 connector cavity; however, the connector pin would not extend through the DF-1 connector block.

Annex P
(informative)

Connector products (e.g. adaptors, extenders, patient cables, etc.)

P.1 General

This International Standard applies exclusively to connectors of implantable pulse generators and leads used for cardiac rhythm management. The requirements, test methods and rationale included in this International Standard were developed to apply to these devices only, and might not be directly applicable to other products that could be developed for use with connectors conforming to this International Standard. Such products include implantable adaptors, implantable lead extenders, temporary patient cables and temporary lead connector adaptors which can have a wide range of possible design configurations and intended functionalities. Therefore the establishment of requirements for those types of products was determined to be outside the scope of this International Standard.

Guidelines for the development of connector-related products are addressed in Clauses P.2 and P.3. These guidelines are not intended to be a comprehensive list of requirements, and additional considerations and testing not mentioned in this International Standard might be necessary to ensure functional compatibility. Furthermore, the safety, reliability, biocompatibility and effectiveness of implantable adaptors, extenders and other connector products are the responsibility of the respective manufacturer.

P.2 Special considerations for implantable adaptors and extenders

In general, implantable adaptors and extenders intended for use with connectors complying with this International Standard should meet all applicable requirements of this International Standard, with special consideration given to the following areas specified in Table P.1.

P.3 Special considerations for non-implantable connector products

Non-implantable connector products, such as temporary patient cables and temporary lead connector adaptors, should be designed so that they do not mechanically or electrically damage or otherwise alter lead connectors or connector cavities conforming to this International Standard in such a way they no longer conform to this International Standard.

Table P.1 — Connector system configurations and combinations

Topic	Requirement section (subclause)	Special considerations
Connections	4.2.3 4.4.2	Connections should match up in respective order for contacts in both ends of an adaptor or extender, and should correspond to appropriate connections in the leads and devices with which they are intended to be used. **IMPORTANT — In order to maintain the lockout features of this International Standard and to prevent delivery of high voltage pulses through low voltage lead electrodes, adaptors/extenders should not be designed with a cavity end that is a low voltage type and a corresponding lead end that is a high voltage type.**
Marking	4.2.4 4.4.3	The markings specified in this International Standard are intended exclusively for leads and devices that comply with all the requirements of this International Standard. Adaptors and extenders are not covered by the scope and therefore should not display the marking symbols directly. However, adaptors, extenders and accessories may refer to the marking symbols indirectly when identifying what connector configurations they are intended to be used with (for example “Compatible with DF4-LLHH”, or “Intended for DF4-LLHH”), provided they meet requirements of regulatory agencies and any other applicable standards.
Electrical isolation	4.5.7	For the tests described in Annex C a 1 500 V test voltage should be used since the device output might be unknown.
Contact resistance		Maximum acceptable contact resistance between a connector cavity and a lead connector is governed by pulse generator design. Implantable adaptors/extenders should be evaluated for compatibility to establish that the resistance they add to the system is acceptable.

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