INTERNATIONAL STANDARD

ISO 27186

First edition
2010-03-15

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

Reference number
ISO 27186:2010(E)

Contents

Page

Foreword ... iv
Introduction ... v
1 Scope ... 1
2 Normative references ... 1
3 Terms and definitions ... 2
4 Requirements ... 5
Annex A (normative) **Electrical isolation test** ... 22
Annex B (informative) **Rationale for Annex A** ... 27
Annex C (normative) **Dielectric strength test** ... 29
Annex D (informative) **Rationale for Annex C** ... 35
Annex E (normative) **Current-carrying test high voltage types** ... 39
Annex F (informative) **Rationale for Annex E** ... 44
Annex G (informative) **Lead connector fatigue strength test** ... 46
Annex H (informative) **Lead connector seal zone materials** ... 47
Annex I (informative) **Seal zone creep** ... 49
Annex J (informative) **Contact resistance stability** ... 54
Annex K (informative) **Rationale for Annex J** ... 58
Annex L (informative) **Selection of contact materials** ... 60
Annex M (normative) **Lead connector contact material requirements** ... 62
Annex N (informative) **Rationale for Annex M** ... 66
Annex O (informative) **Rationale for requirements in this International Standard** ... 72
Annex P (informative) **Connector products (e.g. adaptors, extenders, patient cables, etc.)** ... 79
Bibliography ... 81

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.

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.

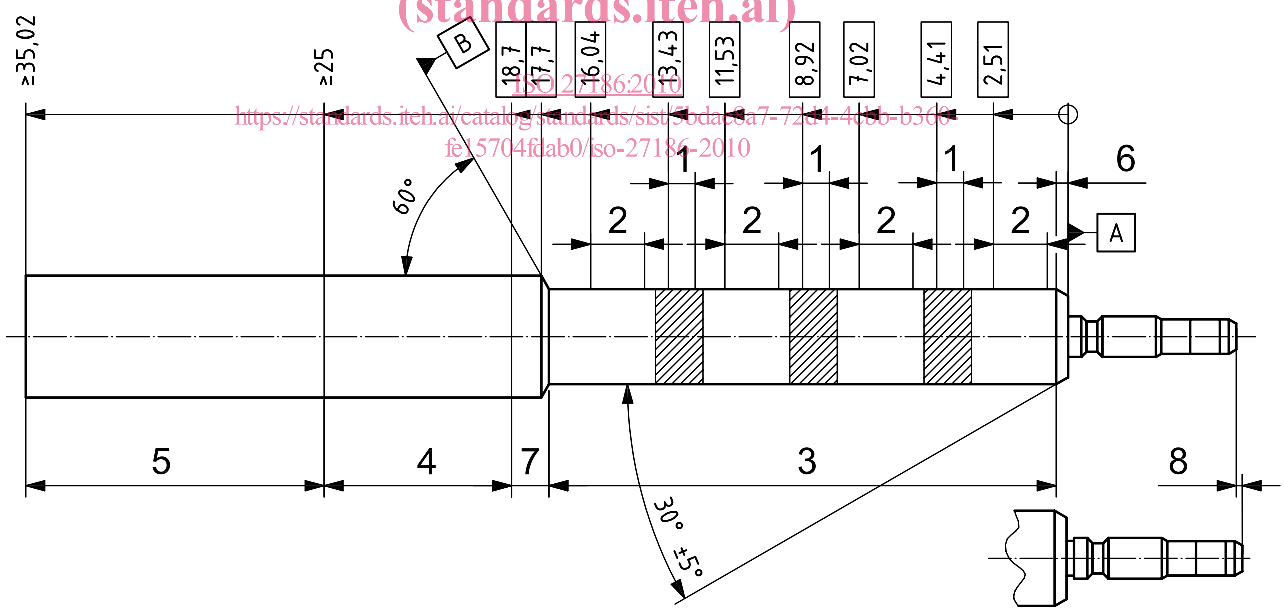
e) Any radial steps shall not exceed 0,05 mm.

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



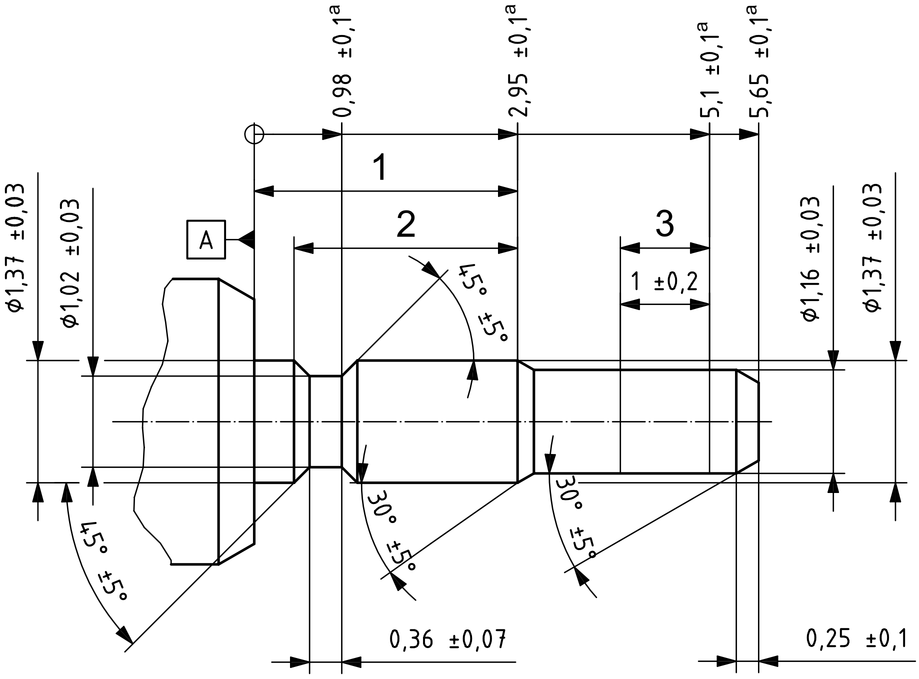
Key

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

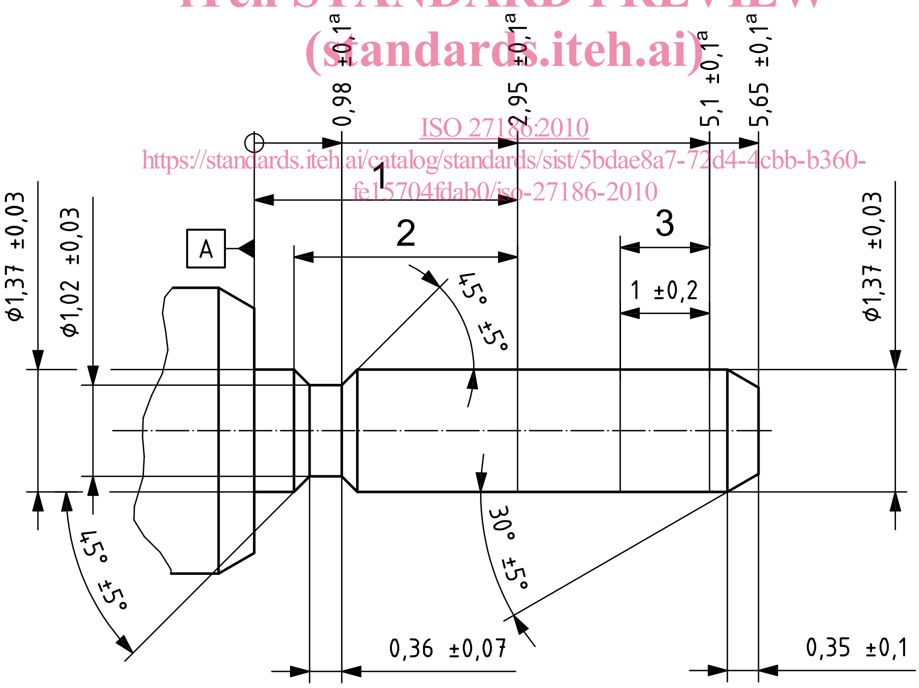
NOTE The diameter dimensions of the soft sections, in zone 4, zone 5 and zone 7, of the lead may be determined as the mean value of three measurements taken at locations oriented approximately 120° apart around the principal axis of the lead connector.

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.