ISO 27186:2020 (E)

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

Contents

Foreword

Introduction

- 1 Scope
- 2 Normative references
- 3 Terms and definitions

4 Requirements

- 4.1 General
- 4.2 Lead connector physical requirements
- 4.2.1 Dimensions
- 4.2.1.1 General
- 4.2.1.2 Total axial pin movement, M
- 4.2.1.3 Pristine contact zones
- 4.2.1.4 Pristine seal zones
- 4.2.1.5 Lead connector body
- 4.2.1.6 Strain relief zone
- 4.2.1.7 Grip zone 4.2.1.8 Chamfer zo
- 4.2.1.8 Chamfer zone
- 4.2.1.9 Transition zone
- 4.2.1.10 Insertion indicator zone 4.2.1.11 Pin pristine contact zone
- 4.2.2 Materials
- 4.2.2.1 Contact materials
- 4.2.2.2 Seal surface material
- 4.2.3 Lead connector electrical connections
- 4.2.4 Lead marking
- 4.2.4.1 Marking symbol
- 4.2.4.2 Marking location
- 4.2.4.3 Marking orientation
- 4.2.5 Lead package labels and literature
- 4.3 Lead connector functional requirements
- 4.3.1 Functional dimensional check
- 4.3.1.1 Test method
- 4.3.1.2 Requirement
- 4.3.2 Tensile loads
- 4.3.2.1 Test method
- 4.3.2.2 Requirement
- 4.3.3 Deformation due to pin contact forces
- 4.3.3.1 Test method
- 4.3.3.2 Requirement
- 4.3.4 Deformation due to ring contact forces
- 4.3.4.1 Test method
- 4.3.4.2 Requirement
- 4.3.5 Seal zone requirement
- 4.3.6 Electrical isolation requirement
- 4.3.7 Dielectric strength requirement
- 4.3.8 Current-carrying requirement
- 4.3.9 Corrosion/environmental

- 4.4 Connector cavity physical requirements
- 4.4.1 Dimensions
- 4.4.1.1 General
- 4.4.1.2 Functional contact zones
- 4.4.1.3 Functional seal zones
- 4.4.1.4 Material
- 4.4.2 Connector cavity electrical connections
- 4.4.3 Connector cavity/pulse generator marking
- 4.4.4 Pulse generator labels and literature
- 4.5 Connector cavity functional requirements
- 4.5.1 Insertion force
- 4.5.1.1 Test method
- 4.5.1.2 Requirement 4.5.2 Retention force
- 4.5.2 Retention force 4.5.2.1 Test method
- 4.5.2.2 Requirement
- 4.5.3 Withdrawal force
- 4.5.3.1 Test method
- 4.5.3.2 Requirement
- 4.5.4 Ring contact load
- 4.5.4.1 Applicability
- 4.5.4.2 Test method
- 4.5.4.3 Requirement
- 4.5.5 Seal zone load requirement
- 4.5.6 Electrical isolation requirement
- 4.5.7 Dielectric strength requirement
- 4.5.8 Current-carrying requirement (high-voltage connector cavity)
- 4.5.9 Contact resistance/stability

Annex A (normative) Electrical isolation test

- A.1 General
- A.1.1 Purpose
- A.1.2 Specimen preparation
- A.1.3 Saline solution
- A.1.4 Reference electrode
- A.1.5 Test signal
- A.2 Lead connector test
- A.2.1 Purpose
- A.2.2 Preconditioning
- A.2.3 Test method
- A.2.4 Acceptance criteria
- A.3 Connector cavity test
- A.3.1 Purpose
- A.3.2 Test pin
- A.3.3 Preconditioning
- A.3.4 Test method
- A.3.5 Acceptance criteria

Annex B (informative) Rational for Annex A

- B.1 Isolation impedance
- B.2 Mechanical load
- B.3 Test combinations
- B.4 Connector cavity isolation test pin

Annex C (normative) Dielectric strength test

- C.1 General
- C.1.1 Purpose
- C.1.2 Specimen preparation
- C.1.3 Reagent and materials
- C.1.4 Dielectric strength test set-up
- C.1.5 Test signal
- C.2 Lead connector test
- C.2.1 Preconditioning
- C.2.2 Test method

- C.2.3 Acceptance criteria
- C.3 Connector cavity test
- C.3.1 Test pin
- C.3.2 Preconditioning
- C.3.3 Test method
- C.3.4 Acceptance criteria

Annex D (informative) Rational for Annex C

- D.1 Rationale for performing a high-voltage electrical isolation test
- D.2 Rationale for test method
- D.2.1 Test signal
- D.2.2 Mechanical load
- D.2.3 Test duration and combinations
- D.2.4 Test combinations
- D.3 Rationale for acceptance criteria
- D.3.1 Maximum allowed leakage current
- D.3.2 Measurement
- D.3.3 Frequency of monitoring
- D.4 Informative test combinations for connector cavities and lead connectors
- D.4.1 General
- D.4.2 High-voltage (DF4) connector cavities
- D.4.3 Low-voltage only (IS4) connector cavities used in high-voltage devices
- D.4.4 Low-voltage only lead connectors
- D.4.5 Induced voltages on four-pole connectors

Annex E (normative) Current-carrying test high-voltage types

- E.1 General
- E.2 Specimen preparation
- E.3 Test signal
- E.4 Equipment
- E.5 Lead connector testing
- E.5.1 General
- E.5.2 Lead connector current-carrying capacity test method
- E.5.3 Acceptance criteria
- E.6 Connector cavity testing
- E.6.1 General
- E.6.2 Connector cavity current-carrying capacity test method
- E.6.3 Acceptance criteria
- Annex F (informative) Rational for Annex E
 - F.1 Rationale for performing a current-carrying test
 - F.2 Test parameters
 - F.3 Voltage drop across contact for the connector cavity
 - F.4 Post-test requirements for the lead connector
 - F.5 Connector cavity post-test withdrawal force
- Annex G (informative) Lead connector fatigue strength test
 - G.1 General
 - G.2 Rationale for flex fatigue strength testing
- Annex H (informative) Lead connector seal zone materials
 - H.1 General
 - H.2 Annealing
 - H.3 Hardness
 - H.4 Rationale for hardness
 - H.5 Use of silicone rubber compounds
 - H.6 Rationale for recommendation against using silicone rubber compounds/composites
- Annex I (informative) Seal zone creep
 - I.1 General
 - I.2 Summary of efforts to develop creep requirements
 - I.2.1 General
 - I.2.2 Interchangeability testing
 - I.2.3 Design limit testing

- I.3 Limits on lead connector creep
- I.4 Limits on connector cavity seal pressure
- I.5 Rationale for rejecting proposed requirements for lead connector creep performance and connector cavity seal pressure

Annex J (informative) Contact resistance stability

- J.1 General
- J.2 Limits for contact resistance
- J.3 Set-up
- J.3.1 Specimens
- J.3.2 Test pin
- J.3.3 Current-carrying test equipment
- J.3.4 Contact resistance test equipment
- J.4 Procedure
- J.4.1 General
- J.4.2 Preconditioning
- J.4.3 Static no-load contact resistance
- J.4.3.1 Objective
- J.4.3.2 Method
- J.4.3.3 Acceptance criterion
- J.4.4 Dynamic contact resistance stability
- J.4.4.1 Objective
- J.4.4.2 Method
- J.4.4.3 Acceptance criteria

Annex K (informative) Rational for Annex J

- K.1 General
- K.2 Limits for contact resistance
- K.3 Rationale for method
- K.3.1 Preconditioning
- K.3.2 Static no-load contact resistance
- K.3.3 Short-term dynamic contact resistance stability
- K.3.3.1 General
- K.3.3.2 Minimum applied load
- K.3.3.3 Maximum applied voltage
- K.3.3.4 Maximum applied current
- K.3.3.5 Sampling resolution
- K.3.3.6 Equipment

Annex L (informative) Selection of contact materials

- L.1 General
- L.2 Potential system level considerations
- L.3 Additional considerations

Annex M (normative) Lead connector contact material requirements

- M.1 General
- M.2 Contact resistance
- M.2.1 Requirement
- M.2.2 Test samples and preconditioning
- M.2.3 Test method
- M.3 Corrosion
- M.3.1 General
- M.3.2 Corrosion resistance to localized or crevice corrosion
- M.3.2.1 General
- M.3.2.2 Acceptance
- M.3.3 General corrosion
- M.4 Material hardness

Annex N (informative) Rational for Annex M

- N.1 Materials
- N.2 Surface contact resistance
- N.3 Preconditioning
- N.4 Test method
- N.5 Fretting sensitivity numbering

- N.6 Corrosion
- N.6.1 General
- N.6.2 Corrosion resistance to localized or crevice corrosion
- N.6.3 General corrosion

Annex O (informative) Rationale for requirements in this document

- O.1 Need for a connector standard
- 0.2 Selection of basic design concept and approach to standardization
- 0.3 Selection of basic design concept
- 0.4 Rationale and explanation for requirement elements Lead connector
- O.4.1 General
- 0.4.2 Functional contact zones (connector cavity)
- 0.4.3 Functional seal zones (connector cavity)
- O.4.4 Pristine contact zones (lead connector)
- 0.4.5 Pristine seal zones (lead connector)
- 0.4.6 Areas between pristine contact zones and pristine seal zones (lead connector)
- 0.5 Rationale for requirement elements Lead connector
- 0.5.1 Lead connector pin dimensions
- O.5.2 Lead connector functional check
- O.5.3 Tensile loads
- O.5.4 Deformation due to pin contact forces
- O.5.5 Deformation due to ring contact forces
- 0.5.6 Notch feature obsolescence
- 0.6 Rationale for requirement elements Connector cavity
- O.6.1 Dimensions
- 0.6.2 Insertion and withdrawal force
- O.6.3 Retention force
- O.6.4 Contact load
- O.6.5 Test pins
- 0.7 Connector types and combinations
- 0.7.1 High-voltage and low-voltage only versions
- 0.7.2 Permitted configurations
- 0.7.3 Integrated bipolar
- O.7.4 System compatibility
- 0.8 Inadvertent use with IS-1 and DF-1
- Annex P (informative) Connector products
 - P.1 General
 - P.2 Special considerations for implantable adaptors and extenders
 - P.3 Special considerations for non-implantable connector products

Page count: 81