

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 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
 - 4.5.2.1 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**
- O.2 Selection of basic design concept and approach to standardization**
- O.3 Selection of basic design concept**
- O.4 Rationale and explanation for requirement elements — Lead connector**
 - O.4.1 General**
 - O.4.2 Functional contact zones (connector cavity)**
 - O.4.3 Functional seal zones (connector cavity)**
 - O.4.4 Pristine contact zones (lead connector)**
 - O.4.5 Pristine seal zones (lead connector)**
 - O.4.6 Areas between pristine contact zones and pristine seal zones (lead connector)**
- O.5 Rationale for requirement elements — Lead connector**
 - O.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**
 - O.5.6 Notch feature obsolescence**
- O.6 Rationale for requirement elements — Connector cavity**
 - O.6.1 Dimensions**
 - O.6.2 Insertion and withdrawal force**
 - O.6.3 Retention force**
 - O.6.4 Contact load**
 - O.6.5 Test pins**
- O.7 Connector types and combinations**
 - O.7.1 High-voltage and low-voltage only versions**
 - O.7.2 Permitted configurations**
 - O.7.3 Integrated bipolar**
 - O.7.4 System compatibility**
- O.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