

Specification for

Connector assembly DF-1 for implantable cardiac defibrillators

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Committees responsible for this British Standard

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- Association of British Health-care Industries
- Biological Engineering Society
- British Cardiac Society
- British Pacing and Electrophysiology Group
- British Surgical Trades Association
- Department of Health
- Electricity Association
- Institute of Physical Sciences in Medicine (IPSM)
- Institution of Electrical Engineers
- Medical Research Council
- Ministry of Defence
- National Heart and Lung Institute
- National Radiological Protection Board
- Royal College of Physicians of London
- Society of Cardiothoracic Surgeons of Great Britain and Ireland

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Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
1 Scope	1
2 Normative reference	1
3 Definitions	1
4 Requirements	2
Annex A (normative) Lead connector electrical isolation test	7
Annex B (normative) Connector cavity current-carrying test	11
Annex C (informative) Rationale for lead connector electrical isolation test	13
Annex D (informative) Rationale for connector cavity current-carrying test	14
Annex E (informative) Rationale for requirements of Standard	14
Figure 1 — DF-1 lead connector	3
Figure 2 — DF-1 lead connector GO gauge	4
Figure 3 — Marking	4
Figure 4 — DF-1 connector cavity	5
Figure 5 — DF-1 connector cavity GO gauge	6
Figure A.1 — Electrical isolation test arrangement	8
Figure A.2 — Test signal	9
Figure A.3 — Test cavity	10
Figure A.4 — Impedance test pin	10
Figure A.5 — Current leakage waveform	11
Figure B.1 — Current-carrying test pin	12
Figure B.2 — Current-carrying test arrangement	12
Figure B.3 — Current-carrying test waveform	13
List of references	Inside back cover

National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 11318:1993 *Cardiac defibrillators — Connector assembly for implantable defibrillators — Dimensional and test requirements*, published by the International Organization for Standardization (ISO).

The connector assembly, DF-1, has been specified in order to provide interchangeability between implantable defibrillator leads and defibrillator pulse generators from different manufacturers. The safety, reliability and function of a particular connector part are the responsibility of the manufacturer.

Cross-references

International Standard	Corresponding British Standard
ISO 7436:1983	BS EN 27436:1992 <i>Slotted set screws with cup point</i> (Identical)

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 16, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This International Standard specifies a unipolar connector assembly, DF-1, intended for use in connecting implantable defibrillator leads to implantable defibrillator generators which do not produce more than 1 kV/50 A peak output. Essential dimensions and performance requirements are specified along with test methods.

This International Standard does not specify other connector features such as fastening means and material. Nor does it address all aspects of functional compatibility or reliability of different implantable defibrillator leads and implantable defibrillator generators assembled into an implantable defibrillator system.

NOTE 1 Defibrillator connector systems not conforming to this International Standard may be safe and reliable, and may have clinical advantages.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards. ISO 7436:1983, *Slotted set screws with cup point*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1

connector assembly

assembly, consisting of a lead connector and a connector cavity, for the electrical and mechanical connection to a defibrillator generator

3.2

lead connector

that part of the connector assembly which is inserted into the connector cavity

3.3

connector cavity

that part of the connector assembly which is part of the defibrillator generator

3.4

sealing mechanism

circumferential barrier intended to maintain the electrical insulation between electrically isolated parts of the connector assembly

3.5

seal zone

surface in the connector cavity and on the lead connector on which one or more seals are intended to bear

3.6

sealing mechanism zone

portion of the lead connector (and optionally the connector cavity) in which the sealing mechanism is permitted

3.7

connector cavity GO gauge

tool for assessing the ability of a connector cavity to accept a lead connector of maximum size

3.8

lead connector GO gauge

tool for assessing the ability of a lead connector to be inserted into a connector cavity of minimum size

3.9

lead connector pin

conductive element of the lead connector intended to contact the connector cavity conductive element

3.10

defibrillator system

assembly consisting of defibrillator generator and a defibrillator lead(s)

3.11

defibrillator lead

means of electrically connecting a defibrillator generator to the patient

3.12

defibrillator generator

portion of the defibrillator system which includes the power supply and electronic circuits

3.13

grip zone

area of lead connector which is provided for grasping the lead connector during insertion and withdrawal

3.14

connector contact

current-carrying interface between the connector cavity and the lead connector

4 Requirements

The test methods provided for the requirements that follow are type (qualification) tests. Equivalent test methods may be used. However, in the event of a dispute, the test methods described in this International Standard shall be used.

The tests shall be conducted at room temperature unless otherwise specified.

4.1 Defibrillator lead connector

4.1.1 Design requirements

4.1.1.1 Sealing mechanism

At least one seal shall be provided on the lead connector and be located as specified in Figure 1.

4.1.1.2 Dimensions

The lead connector shall have the dimensions specified in Figure 1.

4.1.2 Other requirements

4.1.2.1 Insertion and withdrawal forces

As shipped, the lead connector shall fit completely into the lead connector GO gauge specified in Figure 2. Neither the insertion force nor the withdrawal force shall exceed 14 N. After insertion and withdrawal the lead connector shall comply with Figure 1.

4.1.2.2 Deformation due to setscrew and grip zone forces

When tested as described below, the forces imposed by the securing mechanism shall not cause the lead connector to be deformed to the extent that it does not comply with 4.1.2.1.

Compliance shall be determined as follows.

Insert the lead connector into a lead connector GO gauge complying with Figure 2. Fasten the lead connector in the centre of zone 1 (see Figure 2) with an M2 setscrew with cup point complying with ISO 7436, applying a torque of $(0,15 \pm 0,01)$ N m. Apply an axial withdrawal force of (15 ± 1) N for (60 ± 10) s to the grip zone and then retract the setscrew. Check that the lead connector still complies with 4.1.2.1.

4.1.2.3 Electrical isolation requirement

The lead connector shall provide electrical isolation between the lead connector pin and the surrounding fluid. Compliance shall be determined as described in Annex A.

4.1.3 Marking

Marking shall be permanent and legible.

The lead connector shall be marked with the symbol “DF-1” as depicted in Figure 3.

4.2 Defibrillator connector cavity

4.2.1 Design requirements

4.2.1.1 Optional seal mechanism

4.2.1.1.1 Location

If provided, seal(s) shall be located at the zone specified in Figure 4.

4.2.1.1.2 Electrical isolation requirement

If provided, seal(s) shall provide electrical isolation. Compliance shall be determined as described in Annex A.

4.2.1.2 Dimensions

The connector cavity dimensions shall be as specified in Figure 4.

4.2.2 Other requirements

4.2.2.1 Insertion and withdrawal forces

As shipped, the connector cavity shall accept the GO gauge specified in Figure 5. Neither the insertion force nor the withdrawal force shall exceed 9 N. After insertion and withdrawal, the connector cavity shall comply with Figure 4.

4.2.2.2 Current-carrying requirement

The connector contact shall be capable of carrying current. Compliance shall be determined as described in Annex B.

4.2.3 Marking

The defibrillator generator shall be marked with the symbol “DF-1” as depicted in Figure 3.

