

Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements

ICS 11.040.40

National foreword

This British Standard reproduces verbatim ISO 11318:2002 and implements it as the UK national standard. It supersedes BS 7778:1994 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/150, Implants for surgery, to Subcommittee CH/150/6, Active implants, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

Cross-references

The British Standards which implement international publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 29 November 2002

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*Défibrillateurs cardiaques — Ensemble connecteur DF-1 pour défibrillateurs
implantables — 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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11318 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 11318:1993), which has been technically revised.

Annexes A and B form a normative part of this International Standard. Annexes C, D and E are for information only.

Introduction

The purpose of this International Standard is to specify a standard connector assembly, DF-1, 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.

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

Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements

1 Scope

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

This International Standard does not specify other connector features such as fastening means and material. This International Standard is applicable to the form and fit of the connector assembly, and does not address all aspects of functional compatibility, system performance, or reliability of different implantable defibrillator leads and implantable defibrillator generator assemblies.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, this publication do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 7436:1983, *Slotted set screws with cup point*

3 Terms and definitions

For the purposes of this International Standard, the following terms and 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 that is inserted into the connector cavity

3.3

connector cavity

that part of the connector assembly that 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