

INTERNATIONAL
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11318

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AMENDMENT 1
1996-10-15

**Cardiac defibrillators — Connector
assembly for implantable defibrillators —
Dimensional and test requirements**

AMENDMENT 1

iTeh **STANDARD PREVIEW**

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*Défibrillateurs cardiaques — Ensemble connecteur pour défibrillateurs
implantables — Prescriptions dimensionnelles et d'essai*

ISO 11318:1993/Amd 1:1996

<https://standards.iso.org/standards/sist/08f9ce77-199c-4288-9525-077bb5918f7a/iso-11318-1993-amd-1-1996>



Reference number
ISO 11318:1993/Amd.1:1996(E)

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.

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.

Amendment 1 to International Standard ISO 11318 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

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Cardiac defibrillators — Connector assembly for implantable defibrillators — Dimensional and test requirements

AMENDMENT 1

Cover page

At the next revision, amend the title to read:

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

Page 3, figure 1

Change the dimension of the lead connector pin length to $(5,75^{+0,25}_{-1,0})$ mm from $(5 \pm 0,25)$ mm.

Page 5, figure 4

- 1) Change the diameter of the lead connector pin contact zone to $\varnothing(1,31^{+0,1}_0)$ mm from $\varnothing(1,31^{+0,05}_0)$ mm.
- 2) Delete the extraneous dimension 10,37.
- 3) In the Key, delete “**3** When lead is locked in place, lead axis shall not be displaced from the connector cavity by more than 0,07 mm.” and remove reference **3** from the illustration.

Page 16, annex C

Add a second paragraph to clause C.1 as follows.

“It is recognized that a lead pin offset of 0,095 mm would be the worst possible theoretical offset. However, in practice with the soft materials used in lead constructions, a 0,095 mm lead offset will not occur in the seal zone.”

Page 18, annex E

Insert as the second paragraph of clause E.3.1, the following.

“A maximum lead pin length is recommended for optimum visibility of the lead pin.”

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ICS 11.040.40

Descriptors: medical equipment, electromedical apparatus, surgical implants, defibrillators, connectors, single-pole connectors, specifications, dimensions, tests, marking.

Price based on 1 page
