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AMENDMENT 1
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Cardiac defibrillators — Connector assembly for implantable defibrillators — Dimensional and test requirements

AMENDMENT 1

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

AMENDEMENT 1



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

Foreword

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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 $\left(5,75^{+0,25}_{-1,0}\right)$ mm from $(5 \pm 0,25)$ mm.

Page 5, figure 4

- 1) Change the diameter of the lead connector pin contact zone to $\varnothing\left(1,31^{+0,1}_{0}\right)$ mm from $\varnothing\left(1,31^{+0,05}_{0}\right)$ 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."