
Medicinska električna oprema - 2-13: del: Posebne zahteve za osnovno varnost in bistvene lastnosti delovnega mesta za anestezijo - Dopolnilo A2 (ISO 80601-2-13:2011/DAM 2:2017)

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation - Amendment 2 (ISO 80601-2-13:2011/DAM 2:2017)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Anästhesie-Arbeitsplätzen - Änderung 2 (ISO 80601-2-13:2011/DAM 2:2017)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie - Amendement 2 (ISO 80601-2-13:2011/DAM 2:2017)

Ta slovenski standard je istoveten z: EN ISO 80601-2-13:2012/prA2

ICS:

11.040.10	Anestzijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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SIST EN ISO 80601-2-13:2013/oprA2:2017

en,fr,de

DRAFT AMENDMENT

ISO 80601-2-13:2011/DAM 2

ISO/TC 121/SC 1

Secretariat: DIN

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2017-04-10Voting terminates on:
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Medical electrical equipment —

Part 2-13:

Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 2

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie

AMENDEMENT 2

ICS: 11.040.10

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

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ISO/CEN PARALLEL PROCESSING



Reference number
ISO 80601-2-13:2011/DAM 2:2017(E)

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Foreword

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Amendment 2 to ISO/IEC 80601-2-13:2011 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62 D, *Electromedical equipment*.

ISO 80601-2-13:2011/DAM 2:2017(E)**Introduction**

The first edition of IEC 80601-2-13 was published in 2011. This amendment is intended

- to indicate that the collateral standard IEC 60601-1-9, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design* does not apply to the products covered by the scope of this document;
- to amend the gender of the screw-threaded (NIST) inlet connector for pipeline supplies to be in line with the specification given in the previous edition of this standard (IEC 60601-2-13:2003) and with the specifications given in ISO 18082, *Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*;
- to amend the speed for the frame-door-shock for an ANAESTHETIC WORKSTATION with a weight exceeding 125 kg in its NOMINAL configuration and only movable manually.

Medical electrical equipment —

Part 2-13:

Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 2

201.1.3 Collateral standards

Add IEC 60601-1-9:2007+AMD1:2013 (*Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*) to the sentence that states those collateral standards of the IEC 60601 series that do not apply, so that this sentence then reads:

IEC 60601-1-3:2008, IEC 60601-1-9:2007+AMD1:2013 and IEC 60601-1-11:2010 do not apply.

201.2 Normative references

Delete IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

201.15 Construction of ME EQUIPMENT

Add the following subclause:

201.15.3.5 Rough handling test

Addition:

For an ANAESTHETIC WORKSTATION with a weight exceeding 125 kg in its NOMINAL configuration and only movable manually, the speed in c) frame-door-shock shall be reduced from 0,8 m/s to 0,4 m/s.

201.101.4.2.1 Inlet connector

Replacement:

Replace list item a) by the following text:

- a) female non-interchangeable screw-threaded (NIST) connector, or

209 Requirements for environmentally conscious design

Replace the existing text by:

IEC 60601-1-9 does not apply.

ISO 80601-2-13:2011/DAM 2:2017(E)

Bibliography

Add

IEC 60601-1-9, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*