ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Marec 2020

STN	**Zdravotnícke elektrické prístroje Časť 2-13: Osobitné požiadavky na základnú bezpečnosť a na nevyhnutné prevádzkové vlastnosti anestéziologických systémov (ISO 80601-2-13: 2011/Amd 2: 2018) Zmena A2**	**STN EN ISO 80601-2-13/A2** 85 2105

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/20

Obsahuje: EN ISO 80601-2-13:2012/A2:2019, ISO 80601-2-13:2011/Amd 2:2018

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-13:2012/A2

November 2019

ICS 11.040.10

English Version

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/Amd 2:2018)

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/Amd 2:2018)

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/Amd 2:2018)

This amendment A2 modifies the European Standard EN ISO 80601-2-13:2012; it was approved by CEN on 4 November 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 80601-2-13:2012/A2:2019 E

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European foreword

This document (EN ISO 80601-2-13:2012/A2:2019) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 80601-2-13:2012 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-13:2011/Amd 2:2018 has been approved by CEN as EN ISO 80601-2-13:2012/A2:2019 without any modification.

INTERNATIONAL STANDARD

ISO 80601-2-13

First edition
2011-08-01

AMENDMENT 2
2018-07

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

Reference number
ISO 80601-2-13:2011/Amd.2:2018(E)

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by 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/Amd.2:2018(E)

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

Replace the second paragraph with the following:

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.*