SLOVENSKI STANDARD
SIST EN ISO 80601-2-13:2022/A1:2026

01-oktober-2026

Medicinska električna oprema - 2-13. del: Posebne zahteve za osnovno varnost in bistvene lastnosti delovnega mesta za anestezijo - Dopolnilo A1 (ISO 80601-2-13:2022/Amd 1:2026)

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation - Amendment 1 (ISO 80601-2-13:2022/Amd 1:2026)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Anästhesie-Arbeitsplätzen (ISO 80601-2-13:2022/Amd 1:2026)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie - Amendement 1 (ISO 80601-2-13:2022/Amd 1:2026)

Ta slovenski standard je istoveten z: **EN ISO 80601-2-13:2022/A1:2026**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 80601-2-13:2022/A1:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 80601-2-13:2022/A1

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English Version

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This amendment A1 modifies the European Standard EN ISO 80601-2-13:2022; it was approved by CEN on 28 May 2026.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN ISO 80601-2-13:2022/A1:2026 E

Contents

Page

European foreword

This document (EN ISO 80601-2-13:2022/A1:2026) 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 80601-2-13:2022 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2027, and conflicting national standards shall be withdrawn at the latest by February 2027.

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.

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Endorsement notice

The text of ISO 80601-2-13:2022/Amd 1:2026 has been approved by CEN as EN ISO 80601-2-13:2022/A1:2026 without any modification.

International Standard

ISO 80601-2-13

Medical electrical equipment —

Part 2-13:
Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 1

Appareils électromédicaux —

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

AMENDEMENT 1

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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 document 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 or www.iec.ch/members_experts/refdocs).

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This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Medical electrical equipment —

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 1

Foreword

Replace the text of the third dash by the following:

- consideration of *anaesthetic workstations* using *Oxygen 90+;*

201.2

Add the following reference:

ISO 20417:2026, *Medical devices — Information to be supplied by the manufacturer*

201.3

Add the following terms and definitions:

201.3.239
essential function
function or capability that is required to maintain *basic safety*, *essential performance*, a minimum of clinical functionality as specified by the *manufacturer*, and operational availability for the medical device

Note 1 to entry: Essential functions include, but are not limited to, the safety instrumented function (*basic safety* and *essential performance*), the control function and the availability of urgently needed functions and such allowing the *operator* to view and manipulate the medical device safely with the most urgently needed performance (operational availability). The loss of essential function is commonly termed loss of protection, loss of control and loss of view respectively.

Note 2 to entry: The term is derived from IEC 62443-4-2:2019, 3.1.20, and has been refined for the purpose and scope of this document.

[SOURCE: IEC/TR 60601-4-5:2021, 3.10]

201.3.240
firecall
method established to provide emergency access to a secure medical device

Note 1 to entry: In an emergency situation, unprivileged users can gain access to key systems to correct the problem. When a firecall is used, there is usually a review *process* to ensure that the access was used properly to correct a problem. These methods generally either provide a one-time use user identifier (ID) or one-time password or other suitable measures.

Note 2 to entry: Also referred to as “break glass” feature.

[SOURCE: IEC/TR 60601-4-5:2021, 3.11]

***201.3.241**
interchangeable AGSS
anaesthetic gas scavenging system that by design is intended to be used with different models and *manufacturers' anaesthetic workstations*

Note 1 to entry: Connections of *interchangeable AGSSs* can be non-*operator* detachable.

201.3.242
Oxygen 90+ ($O_2$90+)
gas mixture that meets the following criteria for composition:

— Oxygen (O_2): volume fraction of no less than 90%

— Argon (Ar): volume fraction of no more than 5%

— Nitrogen (N_2): volume fraction of no more than 10%

— Carbon dioxide (CO_2): volume fraction of no more than 300 ppm

— Carbon monoxide (CO): volume fraction of no more than 10 ppm

— Nitrogen oxides (NOx): volume fraction of no more than 2 ppm

— Sulfur dioxide (SO_2): volume fraction of no more than 1 ppm

— Water (H_2O): volume fraction of no more than 67 ppm

— Oils: no more than 0.1 mg/m^3

Note 1 to entry: Regional or national regulations can specify the colour coding for *Oxygen 90+*.

Note 2 to entry: It is expected that the definition of Oxygen 90+ is added to ISO 4135.

201.3.243
security level
level corresponding to the required set of countermeasures and inherent cybersecurity properties of devices and systems for a zone or conduit based on assessment of *risk* for the zone or conduit

[SOURCE: IEC/TR 60601-4-5:2021, 3.23]