SLOVENSKI STANDARD
SIST EN ISO 80601-2-13:2022/oprA1:2025

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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/DAmd1:2025)

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/DAmd1:2025)

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/DAmd1:2025)

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

SIST EN ISO 80601-2-13:2022/oprA1:2025 **en,fr,de**

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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

ICS: 11.040.10

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Amendment 1 to ISO/IEC 80601-2-13:2022 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 *Electrical equipment in medical practice*, Subcommittee SC 62D *Electromedical equipment*, 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

201.2

Add the following reference:

ISO 20417, *Information to be supplied by the manufacturer*

201.3

Add the following terms and definitions:

201.3.239
waste volatile anaesthetic agent capture system
system that collects and stores waste volatile anaesthetic agents from the exhaust port of a breathing system

***201.3.240**
interchangeable AGSS
anaesthetic gas scavenging system that by design is intended to be used with different *anaesthetic workstations*

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

201.3.241
system recovery
method for fault handling via an automatic restart of programmable electronic subsystem (PESS) for parts of the *ME equipment* or for the complete *ME equipment*

NOTE 1 to entry: There is guidance or rationale for this definition contained in Clause AA.

[SOURCE: ISO 80601-2-12:2023, 201.3.298]

201.4

Add the following subclause:

201.4.5 Alternative risk control measures or test methods for *ME equipment* or *ME system*

Amendment (add prior to the compliance check):

aa) Subsequent revisions of dated references (new editions or amendments) may be used in substitution of a referenced document provided the manufacturer can demonstrate the hazard or hazardous situation addressed in the dated normative reference is adequately resolved in the subsequent revision.

*201.4.10.101**

Add the following new NOTE below NOTE 2:

NOTE 3 *Anaesthetic workstations* can provide the supply gas to drive other devices such as high flow therapy, oxygen flow meters or suction equipment. See also 201.7.9.2.101 qq).

201.4

Add the following subclause:

201.4.11* System recovery

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.

a) Following a malfunction, the *anaesthetic workstation* should perform a *system recovery* to attempt to restore *essential performance* of the *anaesthetic workstation*.

NOTE 2 An *anaesthetic workstation* or a subassembly function can become disturbed by a malfunction that could jeopardize the *essential performance* of the *anaesthetic workstation*. Without *system recovery*, the patient would have to be disconnected and connected to an alternative means of ventilation or gas delivery. Ventilation or gas delivery would thus be interrupted until an alternative means of ventilation or gas delivery is connected. *System recovery*, as specified in this subclause, attempts to automatically re-establish ventilation or gas delivery in a shorter period. If necessary, the *anaesthetic workstation* can be replaced later when it has fewer consequences for the patient´s therapy.

b) System recovery may result in the temporary:

1) cessation in the ventilation or gas delivery leading to risk of harm; or
2) reduction in the function of *anaesthetic workstation* subassemblies without cessation of ventilation or gas delivery.

EXAMPLE The temporary blanking of the display.

c) During a *system recovery* with a cessation of ventilation or gas delivery that could lead to a hazardous situation:

1) the *anaesthetic workstation* shall allow spontaneous patient breathing and should allow manual ventilation in accordance with 201.102.12; and

NOTE During a system recovery, there may be a short period where manual ventilation is not possible because the pneumatic system may have to be restarted by the *anaesthetic workstation*.

2) the *anaesthetic workstation* shall be equipped with an alarm system to indicate *system recovery* with a cessation of ventilation or gas delivery.

i) The alarm condition for a *system recovery* with a cessation of ventilation or gas delivery shall be high priority or may be an alternative alarm signal. The type of alternative alarm signal or alarm condition delay and alarm signal generation delay for the alarm signal shall be documented in the risk management file.

d) During a *system recovery* without a cessation of ventilation or gas delivery, the *anaesthetic workstation* shall be equipped with an alarm system to indicate *system recovery* without a cessation of ventilation or gas delivery.

1) The alarm condition for system recovery without a cessation of ventilation or gas delivery shall be at least low priority with an auditory alarm signal or may be an alternative alarm signal. The type of alternative alarm signal or alarm condition delay and alarm signal generation delay for the alarm signal shall be documented in the risk management file.

e) Following a *system recovery* without *operator* intervention, the *anaesthetic workstation* shall attempt to operate with the same system configuration settings, ventilation or gas delivery settings and alarm settings as before the *system recovery*.

1) If ventilation settings, gas delivery settings or alarm settings are different after the system recovery, the *anaesthetic workstation* alarm system shall indicate any change in settings.

2) The change in settings alarm conditions shall be at least medium priority.

f) The duration of a system recovery with a cessation of ventilation or gas delivery should be as short as practicable to avoid an unacceptable risk to the patient and shall be documented in the risk management file.

g) The maximum duration of a *system recovery* of ventilation or gas delivery shall be disclosed in the instructions for use.

Check conformance by inspection of the instructions for use, inspection of the risk management file and functional testing.

201.7

Add the following subclause:

201.7.1.101 Information to be supplied by the manufacturer

The information supplied by the manufacturer including marking, labelling and instructions for use shall conform with ISO 20417:2021.

Check conformance by application of ISO 20417:2021.

*201.7.2.21**

Replace the existing text by:

This subclause does not apply.

201.7.2.101

Replace the existing text by:

This subclause does not apply.

201.7.2.104

Replace the existing text by:

This subclause does not apply.

201.7.9.1

Replace the existing text by:

This subclause does not apply.

201.7.9.2.101

Add the following list items and NOTE below oo)*:

pp) list of any component or function that is pneumatically powered, the type of gas needed and its consumption of gas in l/min.

qq) a description of those components that are pneumatically powered that cannot be used in parallel.

NOTE If too many devices are used in parallel the pressure supply to the anaesthetic workstation can be overloaded.

*201.9.2.103**

Delete this subclause completely.

*201.9.2.104**

Delete this subclause completely.

*201.12.4.102**

Replace the text in row for subclause 201.12.4.108 of Table 201.104 by the following:

protection device for the workplace environment (*AGSS)* if the *anaesthetic workstation* is equipped with means to deliver nitrous oxide or is designed to be equipped with an *anaesthetic vapour delivery system*

201.12.4.104

Add the following text:

Anaesthetic workstations equipped with an anaesthetic ventilator shall have a means to monitor the exhaled volume.

*201.12.4.104.1**

Replace Table footnote a in Table 201.105 by the following:

a V_T is measured by means of a pressure sensor at the test lung, where

$V_T = C \times (P_{insp} - P_{exp})$ and

V_T is the volume delivered to the test lung

C is the Compliance of the test lung

P_{insp} is the inspiratory pressure measured in the test lung

P_{exp} is the expiratory pressure measured in the test lung

*201.12.4.108**

Replace the first paragraph by the following text:

If the *anaesthetic workstation* is equipped with means to deliver nitrous oxide or is designed to be equipped with an *anaesthetic vapour delivery system*, the *anaesthetic workstation* shall either