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

Second edition
2022-04

AMENDMENT 1
2026-08

Reference number
ISO 80601-2-13:2022/Amd.1:2026(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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).

ISO and IEC draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO and IEC take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO and IEC had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents and https://patents.iec.ch. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

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).

A list of all parts in the ISO 80601 and the IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

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]

201.3.244
Target Security Levels
SL-T
Target Security Levels are the desired level of security for a particular system. This is usually determined by performing a *risk* assessment on a system and determining that it needs a particular level of security to ensure its correct operation

[SOURCE: IEC 62443-3-3:2013, 3.3]

201.3.245
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]

201.3.246
waste volatile anaesthetic agent capture system
system that collects and stores waste volatile anaesthetic agents from the *exhaust port* of a breathing system

201.4

Add the following subclause:

201.4.3.101 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 can 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 can 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 can lead to a *hazardous situation*:

1) the *anaesthetic workstation* shall allow spontaneous *patient* breathing. Manual ventilation shall be available within 15 s in accordance with 201.102.12; and

NOTE 3 During a system recovery, there can 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 alarm generated 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.

201.4

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).

201.5.101.4

Replace the text of the second dash:

— with *Oxygen 90+* if the *anaesthetic workstation* is *rated* compatible or conditionally compatible with *Oxygen 90+*.

Replace the third dash by a NOTE:

NOTE The concentration of oxygen and balance gases can vary over time in a gas supply with *Oxygen 90+*.

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.

Check conformance by application of ISO 20417.

*201.7.2.21**

Replace the existing text by:

This subclause does not apply.

201.7.2.101

Delete this subclause completely.

201.7.2.104

Delete this subclause completely.

201.7.2

Add the following subclause:

201.7.2.107 *Oxygen 90+*

The *anaesthetic workstation* and its components shall be marked whether it is compatible, conditionally compatible or incompatible with *Oxygen 90+*. A workstation that can be used with *Oxygen 90+* with restrictions shall be rated conditionally compatible with *Oxygen 90+,* see 201.7.9.2.101, ii).

An *Oxygen 90+* compatibility marking shall be placed on the *anaesthetic workstation,* next to the gas supply connectors. A single marking may be sufficient to cover all components that are described in the instructions for use of the *anaesthetic workstation*. Additional markings can be required by *risk management*, e.g. to inform the operator.

NOTE Symbols for the marking of compatibility with *Oxygen 90+* have been proposed for inclusion in ISO 7000.

201.7.9.1

Replace the existing text by:

This subclause does not apply.

201.7.9.2.101

Replace the text in list item ii) with the following:

ii)

— the type of oxygen the *anaesthetic workstation* or its individual components are compatible with (oxygen or *Oxygen 90+*) and;
— if the *anaesthetic workstation* or its components is rated conditionally compatible with *Oxygen 90+*, a description of the conditions under which it can be used with *Oxygen 90+* and;
— if the *anaesthetic workstation* or its components is rated conditionally compatible or compatible with *Oxygen 90+*, the gas composition of *Oxygen 90+ as defined in 201.3.242*;

Replace the text in list item jj) with the following:

jj) if the *anaesthetic workstation* or its individual components is rated conditionally compatible or compatible for use with *Oxygen 90+*, the consequences of the use of *Oxygen 90+*, e.g. possible argon accumulation and varying oxygen concentrations;

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.

*201.12.4.101**

Replace the text in list item a) by the following:

a) A means of protection against accidental adjustment of operating controls that can create a *hazardous situation* shall be provided. This includes:

— deactivating *fresh gas* flow to a *patient* permanently (i.e. not reactivating without user interaction);
— deactivating the anaesthetic vapour delivery system permanently (i.e. not reactivating without user interaction);
— activating the standby mode of an *anaesthetic workstation*;
— accidental turning off of the *anaesthetic workstation* or its individual components.

The means for preventing an accidental adjustment shall be single fault safe.

The means preventing the accidental adjustment as listed above shall be analysed and documented in the *risk management file.*

EXAMPLE 1 Requiring a confirmation step can be one method. The same confirmation step as for any other adjustment will possibly not be appropriate.

NOTE 1 Logging of each single *operator* adjustment leading to permanent deactivation of *fresh gas* flow or vapour delivery, activation of the standby mode or turning off the *anaesthetic workstation* or its individual components can help investigating adverse events.

NOTE 2 Detecting *patient* breathing activity during standby or when no *fresh gas* is being delivered to the *patient* and announcing an *alarm signal* (e.g. optical and acoustical with a high volume level) can help to prevent adverse outcomes in such situations.

Add list item d) before the conformance check:

d) If an *anaesthetic workstation* is equipped with a manual configuration for use with *Oxygen 90+*, the configuration shall be protected from unintended use.

NOTE 3 The configuration can be protected e.g. by the use of a password. A configuration that does not match the input oxygen supply can increase inaccuracy or can lead to unexpected behaviour.

*201.12.4.102**

Replace the text in the last 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

*201.12.4.107.3**

Replace the text of the NOTE by the following:

NOTE *Oxygen 90+* can have major influence on the output of a hypoxic mixture delivery selection *protection device*, as the supply oxygen and balance gas concentrations can vary simultaneously.

