



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-13:2022. It is identical to ISO 80601-2-13:2022. It supersedes BS EN ISO 80601-2-13:2012+A2:2019, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/1, Breathing attachments and anaesthetic machines.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 02351 0

ICS 11.040.10

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 June 2022.

Amendments/corrigenda issued since publication

Date	Text affected
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English Version

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

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

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

This European Standard was approved by CEN on 25 May 2022.

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European foreword

This document (EN ISO 80601-2-13:2022) 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by June 2025.

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.

This document supersedes EN ISO 80601-2-13:2012.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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 80601-2-13:2022 has been approved by CEN as EN ISO 80601-2-13:2022 without any modification.

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents) or the IEC list of patent declarations received (see patents.iec.ch).

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 *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).

This second edition cancels and replaces the first edition (ISO 80601-2-13:2011), which has been technically revised. It also incorporates the Amendments ISO 80601-2-13:2011/Amd 1:2015 and ISO 80601-2-13:2011/Amd 2:2018.

The main changes are as follows:

- update of normative references;
- update of terms and definitions;
- consideration of *anaesthetic workstations* using Oxygen 93;
- addition of requirements for *expected service life*;
- amendment of the requirements on test equipment;
- amendment of the requirements on warning and safety notices, on the instructions for use and on the technical description as well as design documentation;

- addition of marking requirements regarding the suitability of *anaesthetic workstations* and its components for use in a magnetic resonance environment;
- amendment of the requirements on compatibility with substances used with the *anaesthetic workstation* and its components;
- amendment of the requirements on *internal electrical power source*;
- amendment of the requirements on the exhaled volume *monitoring equipment*;
- amendment of the requirements on detachable, flow-direction-sensitive parts and accessories;
- amendment of the requirements on *multiple socket-outlets*;
- amendment of the requirements and recommendations for signal input/signal output part;
- amendment of the requirements on the flow-rate adjustment control;
- amendment of the requirements on the *maximum limited pressure protection device*;
- amendment of the requirements on the reservoir bag port connection port connector;
- amendment of the requirements on the inspiratory and expiratory pressure/flow rate characteristics
- amendment of the requirements on *breathing tubes* and *breathing tube sets*;
- amendment of the requirements on circle absorber assemblies;
- addition of requirements on ventilation modes;
- amendment of the requirements on *anaesthetic gas scavenging systems* by differentiation between active and non-active systems;
- amendment of the requirements on *anaesthetic ventilators* in case of interruption of the electrical or pneumatic *power supply*.

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.

Introduction

In this document, the following print types are used:

- Requirements and definitions: roman type.
- Terms defined in Clause 3 of the general standard, in this particular standard and test specifications: italic type.
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term

- “clause” means one of the eight numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.12 are all subclauses of Clause 201.7).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

- “shall” means that conformance with a requirement or a test is mandatory for conformity with this document;
- “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- “may” is used to describe permission (e. g. a permissible way to achieve conformance with a requirement or test);
- “can” is used to describe a possibility or capability; and
- “must” is used to express an external constraint.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This document considers both an *anaesthetic workstation* supplied complete and its individual components in combination with its *accessories*. It has been structured to allow *responsible organizations* to configure an *anaesthetic workstation* from individual components in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, this document identifies particular requirements pertinent to specific *anaesthetic workstation* components, including associated *monitoring equipment*, *alarm system(s)* and *protection device(s)*, and defines the interfaces.

Thus this document also defines requirements for individual components that can be used to form an *anaesthetic workstation*.

The following table identifies the individual components of an *anaesthetic workstation* and provides an overview of the structure of this document.

Table 201.101 — Configuration of an *anaesthetic workstation* and corresponding organization of this document

<i>anaesthetic workstation</i>		
General requirements Clauses 201.1 – 201.17, 201.106, 201.107, 202-212	including associated <i>monitoring equipment,</i> <i>alarm systems</i> and <i>protection devices</i>	These are mandatory components; see also Table AA.1
<i>anaesthetic gas delivery system</i> Clause 201.101		
<i>anaesthetic breathing system</i> Clause 201.102		
<i>anaesthetic gas scavenging system</i> (AGSS) Clause 201.103	including associated <i>monitoring equipment,</i> <i>alarm systems</i> and <i>protection devices</i>	These are optional components; see also Table AA.1
<i>anaesthetic vapour delivery system</i> Clause 201.104		
<i>anaesthetic ventilator</i> Clause 201.105		

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

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 * Scope

Replacement:

This document is applicable to the *basic safety* and *essential performance* of an *anaesthetic workstation* for administering inhalational anaesthesia whilst continuously attended by a professional *operator*.

This document specifies particular requirements for a complete *anaesthetic workstation* and the following *anaesthetic workstation* components which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant *anaesthetic workstation* components, to form an *anaesthetic workstation* to a given specification:

- *anaesthetic gas delivery system;*
- *anaesthetic breathing system;*
- *anaesthetic gas scavenging system (AGSS);*
- *anaesthetic vapour delivery system;*
- *anaesthetic ventilator;*
- *monitoring equipment;*
- *alarm system;*
- *protection device.*

NOTE 1 *Monitoring equipment, alarm systems and protection devices* are summarized in Table AA.1.

An *anaesthetic workstation* supplied complete and its individual components are considered as *ME equipment* or *ME systems* with regard to the general standard.

NOTE 2 The applicability of this document is indicated in Table AA.2.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to an *anaesthetic workstation* where the characteristics of those *accessories* can affect the *basic safety* and *essential performance* of the *anaesthetic workstation*.

If a clause or subclause is specifically intended to be applicable to *anaesthetic workstation* components or its *accessories* only, the title and content of that clause or subclause will say so. If that is not the case,

the clause or subclause applies both to an *anaesthetic workstation* and its individual components including *accessories*, as relevant.

Hazards inherent in the intended physiological function of an *anaesthetic workstation* and its individual components including *accessories* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 3 See also IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

This document is not applicable to any *anaesthetic workstation* intended for use with flammable anaesthetic agents, as determined by Annex BB.

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for an *anaesthetic workstation* and its individual components designed for use in the *anaesthetic workstation* (as defined in 201.3.210) and its *accessories*.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

IEC 60601-1-3:2008+AMD1:2013+AMD2:2021, IEC 60601-1-9:2007+AMD1:2013+AMD2:2020,
IEC 60601-1-11:2015+A1:2020 do not apply.

201.1.4 *Particular standards

Addition:

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1 (the general standard) with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 206.4 in this document addresses the content of Clause 4 of the IEC 60601-1-6 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

“Addition” means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 to 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 206 for IEC 60601-1-6, etc.

The term “this document” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

If an *anaesthetic workstation* is supplied with physiological monitoring, having more than one *applied part* on the *patient*, then IEC 80601-2-49:2018 applies. Measured parameters related to the inherent function of an *anaesthetic workstation* (i.e. *airway pressure*, ventilation volume, oxygen concentration, volatile anaesthetic agent concentration, CO₂/N₂O), including derived and related parameters such as spontaneous ventilation volume or CO₂ production, are not considered to be a *physiological monitoring unit* as per IEC 80601-2-49.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Clause 2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Addition:

ISO 407:2021, *Small medical gas cylinders — Pin-index yoke-type valve connections*

ISO 5145:2017, *Gas cylinders — Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2:2012+AMD1:2019, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359:2014 +AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5360:2016, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

ISO 9170-1:2017, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 9170-2:2008, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems*

ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 18082:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-7:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

ISO/IEC 80079-20-1:2017, *Explosive atmospheres — Part 20-1: Material characteristics for gas and vapour classification — Test methods and data*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-10:2007+AMD1:2013+AMD2:2020, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-12:2014+AMD1:2020, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in, IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

NOTE An index of defined terms is found in Annex CC.

201.3.201

active anaesthetic gas scavenging system

active AGSS

AGSS in which gas flow in the *disposal system* results from a power device

[SOURCE: ISO 4135:2022, 3.9.1.2]

201.3.202

AGSS disposal system

part of an *AGSS* which conveys gas from a *receiving system* to a point of discharge

Note 1 to entry: The point of discharge can be, for example, the exterior of a building or a non-recirculating extract ventilation system.

[SOURCE: ISO 4135:2022, 3.9.1.3, modified by adding Note 1 to entry.]

201.3.203

airway pressure

pressure at the *patient connection port*, relative to ambient pressure unless otherwise specified

[SOURCE: ISO 19223:2019, 3.6.1, modified by deleting the notes 1 to 7.]

201.3.204

anaesthetic breathing system

breathing system intended for use with volatile or gaseous anaesthetic agents

[SOURCE: ISO 4135:2022, 3.6.1.8]

201.3.205

anaesthetic gas

gases and, if present, vapour of a volatile anaesthetic agent, used in anaesthesia

Note 1 to entry: In parts of an *anaesthetic breathing system*, *anaesthetic gas* includes gases exhaled by the *patient*.

[SOURCE: ISO 4135:2022, 3.1.1.5]

201.3.206

anaesthetic gas delivery system

anaesthetic workstation component that receives separate supplies of medical gases and delivers mixed gases in concentrations or individual flow rates adjustable by the *operator*

Note 1 to entry: An *anaesthetic gas delivery system* can include a means of flow rate adjustment control, *flowmeters* or a gas mixer and *anaesthetic gas delivery system* piping but does not include vaporizers.

[SOURCE: ISO 4135:2022, 3.3.2.1]

201.3.207

anaesthetic gas scavenging system

AGSS

system which is connected to the *exhaust ports* of a breathing system or of other equipment for the purpose of conveying excess gases to an appropriate point of discharge

Note 1 to entry: Functionally, an *AGSS* comprises three parts: a *transfer system*, a *receiving system* and an *AGSS disposal system*. These three functionally discrete parts may be either separate or sequentially combined in part or in total. One or more parts of an *AGSS* may be combined with an *anaesthetic breathing system* component or other equipment.

Note 2 to entry: The excess gases can contain *anaesthetic gases* and vapours.

[SOURCE: ISO 4135:2022, 3.9.1.1, modified by replacing "excess *anaesthetic gases* and vapours" by "excess gases" and by adding note 2 to entry.]

201.3.208

anaesthetic vapour delivery system

anaesthetic vapourizer

anaesthetic workstation component that provides the vapour of a volatile anaesthetic agent in a controllable concentration

[SOURCE: ISO 4135:2022, 3.3.2.2, modified by adding “anaesthetic” before “agent”.]

201.3.209

anaesthetic ventilator

anaesthetic workstation component that is connected via the *anaesthetic breathing system* to the *patient's* airway and automatically augments or provides ventilation during anaesthesia

[SOURCE: ISO 4135:2022, 3.4.1.3]

201.3.210

anaesthetic workstation

system for administering inhalational anaesthesia that contains an *anaesthetic gas delivery system*, an *anaesthetic breathing system* and any required *monitoring equipment*, *alarm systems*, and *protection devices*

Note 1 to entry: An *anaesthetic workstation* can also include, but is not limited to, one or more of the following: *anaesthetic vapour delivery system*, *anaesthetic ventilator*, parts of an *anaesthetic gas scavenging system*, and any associated *monitoring equipment*, *alarm systems* and *protection devices*.

[SOURCE: ISO 4135:2022, 3.3.1.2]

201.3.211

breathing tube

non-rigid tube used to convey gases between parts of an *anaesthetic breathing system*

201.3.212

circle absorber assembly

part of a *circle breathing system* that comprises one or more carbon-dioxide-absorbent containers, *inspiratory* and *expiratory valves* or other means of ensuring unidirectional gas flow, two ports for connection to *breathing tubes*, a *fresh-gas inlet*, and a reservoir bag port or an *anaesthetic ventilator* port or both

[SOURCE: ISO 4135:2022, 3.6.1.8.2]

201.3.213

circle breathing system

anaesthetic circle breathing system

breathing system in which the direction of gas flow through inspiratory and expiratory pathways is unidirectional and in which the two pathways form a loop

Note 1 to entry: In context of anaesthesia, the breathing system is a *circle breathing system*.

[SOURCE: ISO 4135:2022, 3.6.1.8.1]

201.3.214

danger zone

any zone within and/or around an *anaesthetic workstation* in which a person is subject to a *risk* to their health or safety from the powered movement of the *anaesthetic workstation* or its components

201.3.215**delivered volume** V_{DEL}

volume of gas delivered through a *patient connection port* during a breath

Note 1 to entry: *Delivered volume* is also referred to as inspiratory *tidal volume* when all of the *delivered volume* enters the *patient's* respiratory tract. This is frequently not the case when there is significant tracheal tube cuff leakage (as in neonates) or in non-invasive ventilation.

201.3.216**disposal flowrate**

flow rate of gas from the *receiving system* at the entry to the *AGSS disposal system*

[SOURCE: ISO 4135:2022, 3.9.1.3.6]

201.3.217**disposal hose**

part of an *AGSS* that is intended to convey gas from the *receiving system* to the *AGSS disposal system*

[SOURCE: ISO 4135:2022, 3.9.1.3.1, modified by replacing "flexible tube that conveys" by "part of an *AGSS* that is intended to convey" and by removing "exhaust" before "gas".]

201.3.218**exhaust port**

port of the medical equipment or device from which gas is discharged to the atmosphere during *normal use*, either directly or via an *anaesthetic gas scavenging system*

[SOURCE: ISO 19223:2019, 3.14.2]

201.3.219**exhaust valve**

valve with an outlet connected to an *exhaust port*

EXAMPLE An adjustable pressure-limiting valve.

[SOURCE: ISO 4135:2022, 3.1.4.12]

201.3.220**fresh gas**

respirable gas delivered to a breathing system

Note 1 to entry: In a circle system, the *fresh gas* is all respirable gas delivered into the circle system (including *anaesthetic gases* and vapours).

[SOURCE: ISO 4135:2022, 3.1.1.16, modified by deleting the last sentence in Note 1 to entry and by deleting Note 2 to entry.]

201.3.221**fresh-gas inlet**

port through which *fresh gas* enters the *anaesthetic breathing system*

[SOURCE: ISO 4135:2022, 3.1.4.20, modified by adding "anaesthetic" before "breathing system".]

201.3.222**fresh-gas outlet**

port through which *fresh gas* is delivered from the *anaesthetic gas delivery system*

[SOURCE: ISO 4135:2022, 3.3.2.6]

201.3.223

high-flow transfer and receiving system

transfer system and *receiving system* that connects to a high-flow-rate disposal system

[SOURCE: ISO 4135:2022, 3.9.1.3.8, modified by deleting note 1 to entry.]

201.3.224

induced flow rate

flow rate at the inlet of the *transfer system*, that is generated by the *disposal system* in an AGSS

***201.3.225**

interchangeable anaesthetic vapour delivery system

anaesthetic vapour delivery system that

- by design is intended to be used with different *anaesthetic workstations*, and
- can be exchanged by the clinical user without the use of *tools* and without the need for specific tests

201.3.226

low-flow transfer and receiving system

transfer system and *receiving system* that connects to a low-flow-rate disposal system

Note 2 to entry: *Terminal units* of type 1L (as specified in ISO 9170-2 are intended for use with *low-flow transfer and receiving systems*.

[SOURCE: ISO 4135:2022, 3.9.1.3.10, modified by deleting Note 1 to entry.]

201.3.227

maximum disposal flowrate

DEPRECATED: maximum exhaust flow rate

largest *disposal flowrate* that can be accommodated without exceeding the specified limitations for *induced flow rate*

[SOURCE: ISO 4135:2022, 3.9.1.3.6.1, modified by adding "for *induced flow rate*" after "specified limitations".]

201.3.228

maximum limited pressure

highest *airway pressure* that can occur during *normal use* or under a *single fault condition*

201.3.229

minimum disposal flowrate

disposal flowrate that ensures that the specified limit of *spillage* to atmosphere is not exceeded

201.3.230

monitoring equipment

medical electrical equipment or part that continuously or continually measures and indicates the value of a variable to the *operator*

[SOURCE: ISO 4135:2022, 3.11.1.3, modified by replacing "equipment" with "medical electrical equipment", adding "continuously or continually" before "measures" and by replacing "user" with "operator".]

201.3.231**patient connection port**

port of a breathing system intended for connection to an airway device

EXAMPLE A tracheal tube, tracheostomy tube, face mask and supraglottic airway are all airway devices

Note 1 to entry: The *patient connection port* is the end of the breathing system proximal to the *patient*.

[SOURCE: ISO 4135:2022, 3.1.4.41, modified by removing Notes to entry 2, 3 and 4, and by adding an example.]

201.3.232**power device**

part of the *disposal system* of an *active AGSS* that generates the *disposal flowrate*

201.3.233**power supply**

source of energy other than that generated directly by the human body or by gravity that makes the device function

EXAMPLE *Supply mains, internal electrical power source, compressed gas from a medical gas pipeline system or cylinder.*

201.3.234**protection device**

part or function of a medical device or *accessory* that, without intervention by the *operator*, protects the *patient*, other people or the environment from hazardous output due to incorrect delivery of energy or substances

[SOURCE: ISO 4135:2022, 3.1.4.48, modified by replacing "user" by "operator".]

201.3.235**receiving system**

part of an *AGSS* that conveys gases from an interface of the breathing system to a *disposal hose*

[SOURCE: ISO 4135:2022, 3.9.1.3.4, modified by removing Notes to entry 1 and 2.]

201.3.236**spillage**

volume of *anaesthetic gas* that cannot be accommodated by the *AGSS* over a specified period

201.3.237**transfer system**

part of an *AGSS*, which can incorporate a transfer tube, that transfers *anaesthetic gas* from the *exhaust port* of an *anaesthetic breathing system*, or associated equipment to the *receiving system*

[SOURCE: ISO 4135:2022, 3.9.1.3.5, modified by replacing "transfer hose" with "transfer tube" and by replacing "exhaust gas" with "anaesthetic gas".]

201.3.238**y-piece**

adaptor comprising a *patient connection port* and two ports for connection to *breathing tubes*

[SOURCE: ISO 4135:2022, 3.1.4.53]

201.4 General requirements

Clause 4 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.4.3 * *Essential performance*

Addition:

Additional *essential performance* requirements are identified in the subclauses listed in Table 201.102.

Table 201.102 — Distributed *essential performance* requirements

Requirement	Subclause
Oxygen flow under all conditions except the failure of the oxygen supply (pipeline or cylinder) to the <i>anaesthetic workstation</i> or generation of a <i>technical alarm condition</i>	201.12.4.107.1 (oxygen supply failure alarm) 201.12.4.107.2 (oxygen supply failure <i>protection device</i>) 201.101.2 (interruption of the electrical <i>power supply</i>) 201.101.8 (oxygen flush)
Delivery of a non-hypoxic gas mixture to the <i>patient</i> or generation of a <i>technical alarm condition</i>	201.11.8.102 (<i>alarm condition</i> for power supply failure) 201.11.8.103 (<i>internal electrical power source</i>) 201.12.4 (protection against hazardous output) 201.101.4.2.3 (reverse flow and cross flow <i>protection device</i>) 201.101.7 (gas mixers) 201.101.8 (oxygen flush)
Non-delivery of excessive concentrations of a volatile anaesthetic agent or generation of a <i>technical alarm condition</i>	201.104.2 (delivered vapour concentration) 201.12.4.103.3 (anaesthetic agent <i>monitoring equipment</i>)
<i>Airway pressure</i> monitoring and associated alarm	201.12.4.109 (<i>airway pressure monitoring equipment</i>)

201.4.4 Additional requirements for *expected service life*

Amendment (add as a second paragraph):

In the design documentation, the *manufacturer* shall:

- aa) state the probability of component failure that results in the *anaesthesia workstation* to be taken out of service during the *expected service life* assuming that the preventative inspection, maintenance and calibration is performed according to the *accompanying documents*; and
- bb) summarize the methodology used to determine this probability.

201.4.10 *Power supply*

Addition:

201.4.10.101* Requirements for pneumatic power input

- a) The *anaesthetic workstation* or its individual components including *accessories* shall operate and meet the requirements of this document throughout the *rated* range of inlet pressures and shall not cause an unacceptable *risk* under a *single fault condition* to a maximum pressure of 1 000 kPa.

Check conformity by functional testing.

b) If the *anaesthetic workstation* or its individual components including *accessories* is/are intended to be connected to either

- a *medical gas pipeline system* conforming with ISO 7396-1:2016+AMD1:2017 and flexible hose connections conforming with ISO 5359:2014+AMD1:2017, or
- a *pressure regulator* conforming with ISO 10524-1:2018,

then

- the *rated* range of inlet pressures shall cover the range specified in ISO 7396-1:2016+AMD1:2017 and ISO 10524-1:2018 respectively,
- the time-weighted average input flow (over 10 s) required by the *anaesthetic workstation* or all individual *anaesthetic workstation* components for each gas shall not exceed 60 l/min at a pressure of 280 kPa measured at the gas inlet port, with the oxygen flush not activated,
- the transient input flow shall not exceed the equivalent of 200 l/min for 3 s.

NOTE 1 Internal *pressure regulators* can be required to accommodate the *rated* range of inlet pressure and the *single fault condition* of maximum inlet pressure.

NOTE 2 Flow values are expressed under STPD (Standard Temperature and Pressure Dry) conditions, see 201.7.4.3.

Check conformity by functional testing in normal use and under normal condition with the most adverse operating settings (e.g. highest driving gas consumption, highest fresh gas delivery and highest rated gas consumption at any gas power supply output, if provided, but without activating the oxygen flush).

201.5 General requirements for testing *ME equipment*

Clause 5 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Addition:

201.5.101 Additional general requirements for testing of *anaesthetic workstations* and *anaesthetic workstation components including accessories*

201.5.101.1 Test conditions

The ambient temperature for the duration of each test should be between 20 °C and 25 °C, except where otherwise stated.

201.5.101.2 Test equipment

The accuracy of the test equipment used to carry out measurements shall be better than or equal $\pm 5\%$ of the variable to be measured for each device in the measurement setup, except where otherwise stated. Dry air should be used as the test gas, except where otherwise stated.

Pressure measuring equipment for functional testing at the *patient connection port* shall have a response time of 200 ms maximum (200 ms to reach 90% of the final reading) and a minimum sample rate of 10 ms.

201.5.101.3 * Gas flow rate and leakage specifications

Gas flow rate, volume and leakage specifications in this document are expressed at STPD except for those associated with the *anaesthetic breathing system*, which are expressed at BTPS (Body Temperature and Pressure Saturated).

NOTE 1 For the purposes of this document, STPD is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this document, BTPS is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

Correct all test measurements to STPD or BTPS, as appropriate.

201.5.101.4 Test consideration regarding oxygen

Conformity checks and tests as specified in this document shall be performed using the type(s) of oxygen the *anaesthetic workstation* has been designed for and as specified by the *manufacturer* in the instructions for use (see 201.7.9.2.101 ii), i.e.

- with oxygen if the *anaesthetic workstation* is suitable for use with oxygen;
- with oxygen and Oxygen 93 if the *anaesthetic workstation* is suitable for use with oxygen and Oxygen 93;
- with Oxygen 93 if the *anaesthetic workstation* is suitable for use with Oxygen 93.

201.6 Classification of ME equipment or ME systems

Clause 6 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

201.7 ME equipment identification, marking and documents

Clause 7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.7.2 Marking on the outside of ME equipment or ME equipment parts

201.7.2.3 * Consult accompanying documents

Replace the existing subclause by the following:

The *anaesthetic workstation* and its individual components shall be marked with the safety sign for the mandatory action: “follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, number 10).

One safety sign on the *anaesthetic workstation* is sufficient to cover all components that are described in the instructions for use of the *anaesthetic workstation*.

Add the following subclause:

201.7.2.21 * Mass of mobile ME equipment

Replace the existing subclause by the following:

The *anaesthetic workstation* shall be *clearly legible* marked with its maximum mass in kilograms [see also 201.101.1.1 k)].

Addition:

201.7.2.101 Marking with year of manufacture or use-by date

The *anaesthetic workstation* and its *operator-detachable* components or their packaging shall be marked with the following:

- a) year of manufacture or
- b) use-by date, if applicable, symbol 5.1.4 of ISO 15223-1:2016 (see Table 201.D.2.101, symbol 1).

NOTE The *manufacturer's* attention is drawn to the importance of consistent use of indication for single-use devices.

Check conformity by visual inspection.

201.7.2.102 Operator-accessible gas-specific inlet and outlet

Each *operator-accessible gas-specific* inlet and outlet shall be marked with the gas name or chemical symbol in accordance with ISO 5359:2014+AMD1:2017, Table 6. If colour coding is used it shall be in accordance with ISO 5359:2014+AMD1:2017, Table 6.

Check conformity by visual inspection.

201.7.2.103 * Operator-accessible gas power supply outlet

Each *operator-accessible gas power supply* outlet shall be marked with the *rated* output pressure and *rated* flow rate.

EXAMPLE 1 280 kPa - 600 kPa, 20 l/min.

EXAMPLE 2 280 kPa - 600 kPa, 20 l/min - 40 l/min.

Check conformity by visual inspection.

201.7.2.104 Components, parts and accessories containing phthalates

If parts of the *anaesthetic workstation* or its individual components in contact with gas to be inhaled by the *patient* contain phthalates, which are known to be carcinogenic, mutagenic or toxic to reproduction, the *anaesthetic workstation* and its individual components shall be marked accordingly.

NOTE 1 The symbol given in Reference [20] can be used.

NOTE 2 For information, see Directive 1272/2008/EC, Annex VI, part 3 ^[28].

Check conformity by visual inspection.

201.7.2.105 Cylinder and pipeline pressure indicators

All cylinder and pipeline pressure indicators shall be identified with the gas name or the chemical symbol in accordance with ISO 5359:2014+AMD1:2017, Table 6. If colour coding is used it shall be in accordance with ISO 5359:2014+AMD1:2017, Table 6.

Check conformity by visual inspection.

201.7.2.106 Magnetic resonance environment

The *anaesthetic workstation* and its components shall be *clearly legible* marked in accordance with IEC 62570:2014, using the following symbol, as applicable:

- a) the symbol 7.3.1-1 (Table 201.D.2.101, symbol 6) or Symbol 7.3.1-2 (Table 201.D.2.101, symbol 7) of IEC 62570:2014 for an 'MR Safe' *anaesthetic workstation*, or

- b) the symbol 7.3.2 of IEC 62570:2014 (Table 201.D.2.101, symbol 8) for an ‘MR Conditional’ *anaesthetic workstation*, or
- c) the symbol 7.3.3 of IEC 62570:2014 (Table 201.D.101, symbol 9) for an “MR Unsafe” *anaesthetic workstation*.

See also 201.7.9.2.101 ff).

NOTE National or regional regulations might require textual information in addition to the markings.

201.7.4.2 * Control devices

Addition:

- a) Each *gas-specific* flow rate adjustment control of an *anaesthetic gas delivery system* shall be identified with the gas that it controls by the gas name or the chemical symbol in accordance with ISO 5359:2014+AMD1:2017, Table 6. If colour coding is used it shall be in accordance with ISO 5359:2014+AMD1:2017, Table 6.
- b) Each flow rate adjustment control of an *anaesthetic gas delivery system* shall be marked with an indication of how to increase and decrease the gas flow rate. If applicable, the point of reference for reading the flow rate indication shall be identified.

NOTE A multifunctional control that can be used to control multiple items is not considered a *gas-specific* control.

- c) The oxygen flush control shall be marked with one of the following:

- “Oxygen Flush”, or
- “O₂ Flush”, or
- “O₂ +”.

201.7.4.3 * Unit of measure

Addition:

All specifications, displayed values and settings regarding volume, flow and leakage shall be expressed as STPD, except those associated with the *anaesthetic breathing system*, which shall be expressed as BTPS.

NOTE 1 For the purposes of this document, STPD is 101,3 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this document, BTPS is local atmospheric pressure and a relative humidity of 100 % at an operating temperature of 37 °C.

NOTE 3 For the purposes of this document pressures related to the *anaesthetic breathing system* are expressed in hectopascals (hPa) whereas 1 hPa approximately corresponds to 1 cmH₂O.

201.7.9.1 General

Replacement:

Replace the first dash with:

- name or trade name and address of
 - the *manufacturer*, and

- where the *manufacturer* does not have an address within the locale, an authorized representative within the locale, to which the *responsible organization* can refer.

Addition:

The instructions for use shall be provided with every device.

The instructions for use shall be provided either printed or as an electronic copy.

If no complete printed manual has been provided, the availability of information in an emergency case shall be considered and documented in the *risk management file*.

201.7.9.2.1 General

Addition:

For *anaesthetic workstations* not supplied complete, the instructions for use shall contain, as far as applicable, information about the *monitoring equipment*, *alarm systems* and *protection devices* required by this document and how to connect them (see 201.12.4.102).

201.7.9.2.2 * Warnings and safety notices

Addition:

The instructions for use shall contain a statement to the effect that, in case of *anaesthetic workstation* failure, the lack of immediate access to appropriate alternative means of ventilation can result in *patient* injury and shall require the availability of an alternative means of ventilation during the use of an *anaesthetic workstation*.

EXAMPLE An alternative means of ventilation would be a self-inflating, manually-powered *resuscitator* (see ISO 10651-4:2002) with mask.

201.7.9.2.8 * Start-up procedure

Amendment:

Delete the given EXAMPLE and add the following text at the end of the subclause:

The instructions for use shall contain at least one *operator* pre-use checklist.

EXAMPLE 1 Beginning of day or shift pre-use checklist

EXAMPLE 2 Between *patients* pre-use checklist

NOTE Attention is drawn to additional pre-use checklists that might be required by regional or national medical associations or authorities with jurisdiction.

Electronic displays integral to, or provided with, the *anaesthetic workstation* or its individual components may be used to provide such a pre-use checklist.

201.7.9.2.101 Additional requirements for the instructions for use

Addition:

The instructions for use of the *anaesthetic workstation* and its individual components shall include the following:

- aa) information on the method of enabling the *anaesthetic workstation* or its individual components, including the *monitoring equipment*, *alarm systems* and *protection devices*, required by this document; this information may form part of the pre-use checklist (see 201.7.9.2.8);
- bb) the conditions under which the measured values are displayed, e.g. BTPS, STPD;
- cc) where an *anaesthetic workstation* is not supplied complete, a statement to the effect that whoever assembles the *anaesthetic workstation* from individual components shall provide the pre-use checklist for the *anaesthetic workstation* (see 201.7.9.2.8);
- dd) where applicable, a statement to the effect that a malfunction of the *medical gas pipeline system* can cause one or more *anaesthetic workstations* or *anaesthetic workstation* components connected to the *medical gas pipeline system* to stop their operation simultaneously; this is not applicable to *anaesthetic workstations* that only use cylinders for gas supply;
- ee) where applicable, disclosure of the presence of all natural rubber latex-based parts and *accessories* and their location (see also Symbol 5.4.5 in ISO 15223-1:2016);
- ff) information about the suitability of an *anaesthetic workstation* or its individual components and *accessories* for use in a magnetic resonance imaging (MRI) environment and any related restrictions and, where applicable, the maximum safe magnetic field strength;
- gg) if an *anaesthetic workstation* or its individual components and *accessories* is/are used for the treatment of neonates or treatment of pregnant or nursing women, the *residual risk* from phthalates that are carcinogenic, mutagenic or toxic to reproduction;
- hh) for single-use *accessories* to the *anaesthetic workstation* or its individual components and *accessories* disclosure of the *risks* associated with re-usage; this information may be given upon request;
- ii) the type(s) of oxygen the *anaesthetic workstation* or its individual components are compatible with (oxygen, oxygen and Oxygen 93 or only Oxygen 93);
- jj) if the *anaesthetic workstation* or its individual components is/are suitable for use with Oxygen 93, the restrictions and consequences of the use of Oxygen 93, e.g. possible argon accumulation;
- kk) the influence of ambient conditions (in particular ambient pressure and ambient temperature) on the performance of the *anaesthetic workstation*;
- ll) the backup time and the operating conditions with *internal electrical power source*;
- mm) if the flow and volume measurement and the flow and volume delivery are corrected for influences of N₂O, CO₂ and volatile anaesthetic agents;
- nn) list of any component or function that is not included or limited during the power back-up by the *internal electrical power source* (see 201.11.8.103);
- oo) * recommendations on how to prepare the *anaesthetic workstation* for use with a malignant hyperthermia susceptible *patient* and any restrictions in using the *anaesthetic workstation* after the preparation given (e. g. minimum *fresh gas* flow, minimum minute volume, *patient* population, ventilation modes, time between preparation and start of the case).

Check conformity by inspection of the instructions for use.

201.7.9.3 Technical description

Addition:

201.7.9.3.1 General

Addition:

The technical description shall include information to allow the *responsible organization* to assess when the *anaesthetic workstation* and its individual components is approaching the end of its *expected service life* (e.g. in terms of years of service or number of uses), assuming that the preventative inspection, maintenance and calibration is performed according to the *accompanying documents*.

Check conformity by inspection of the technical description.

201.7.9.3.101 Components

The technical description shall describe the maximum weight of components, as well as the height of and length of arms on which these components may be mounted on the *anaesthetic workstation* or its individual components so as not to compromise the stability requirements tested in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 9.

Check conformity by inspection of the technical description.

201.7.9.3.102 Anaesthetic workstations intended to be mounted to a wall or ceiling pendant

For *anaesthetic workstations* intended to be mounted to a wall or a ceiling pendant and that are not considered *mobile ME equipment* and consequently need not conform with the requirement on moving over a threshold in 201.9.4.2.4.3, the technical description shall contain a warning to the effect of: "Warning: This device, when removed from its wall or ceiling mount, does not meet the stability requirements of ISO 80601-2-13 and IEC 60601-1 respectively. Special caution has to be taken." The technical description shall contain any additional handling instructions necessary to allow transport with an acceptable *risk* according to the *risk management file*.

Check conformity by inspection of the technical description.

201.8 Protection against electrical hazards from ME equipment

Clause 8 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.8.11.3 Power supply cords

Addition:

201.8.11.3.101 * Additional requirements for power supply cords

Unless the *anaesthetic workstation* or its individual components automatically switch over to an *internal electrical power source* (see 201.11.8.102) or the functionality of the complete *anaesthetic workstation* can be restored in less than 30 s following the restoration of power, the *power supply cord* of the *anaesthetic workstation* or its individual components shall be a non-detachable cord or shall be protected against accidental disconnection.

Check conformity by inspection. For an anaesthetic workstation and its individual components provided with an appliance coupler, subject the detachable power supply cord to an axial pull of force for 1 min as shown in Table 201.103. During the test, the mains connector shall not become disconnected from the appliance inlet, and the anaesthetic workstation and its individual components shall continue to function normally.

Table 201.103 — Force of axial pull

Mass (<i>m</i>) of ME equipment kg	Pull force N
$m \leq 1$	30
$1 < m \leq 4$	60
$m > 4$	100

201.9 Protection against *mechanical hazards of ME equipment and ME systems*

Clause 9 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.9.2 Hazards associated with moving parts

201.9.2.1 General

Addition:

Where the direction of movement of a moving part needs to be known in order to avoid a *hazardous situation*, the direction of movement shall be marked on the moving part or its housing.

Check conformity by visual inspection.

Additional subclauses:

201.9.2.101 Maintenance points

- Any maintenance points shall be located outside *danger zones* and adjustment, maintenance, repair, cleaning and servicing operations shall be possible when the *anaesthetic workstation* is not being operated, or
- where this is not achievable, alternative means of *risk* mitigation, e.g. alarming and information of safety and training, shall be provided to reduce the *risk* to acceptable levels.

Check conformity by inspection of the risk management file and usability engineering file.

201.9.2.102 * Lighting

Anaesthetic workstations shall be supplied with lighting where the absence thereof causes an unacceptable *risk*.

NOTE Attention is drawn to areas of shadows likely to cause nuisance, irritating dazzles, dangerous stroboscopic effects on moving parts, to internal parts requiring frequent inspection and adjustment, and to maintenance areas.

Check conformity by inspection of the risk management file and usability engineering file.

201.9.2.103 * Integrated seating

Where a seat for the *operator* is an integral part of the *anaesthetic workstation*, the seat shall

- enable the *operator* to maintain a stable position,
- be adaptable for the *operator's* distance from the control device,
- be adaptable for the *operator*, e.g. arm length, height, etc.,

- be designed to minimize transmission of vibrations to the *operator*,
- withstand maximum operational stresses, and
- be provided with slip-resistant footrests where no floor is underneath the *operator*.

Check conformity by visual inspection and functional testing.

201.9.2.104 * Arrangement of control positions

For *anaesthetic workstations* which contain one or more *danger zones*

- the *operator* shall be able to ensure, from each control position, that no one is in the *danger zone(s)*, or
- the control system shall be designed in such a way that starting is prevented while someone is in the *danger zone*, or
- an audible or visual *alarm signal* shall be given long enough before the *anaesthetic workstation* is started to allow anyone wholly or partially in a *danger zone* to leave the area.

Where there is more than one control position for an *anaesthetic workstation*, the control systems shall be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When an *anaesthetic workstation* has two or more operating positions, each position shall be provided with all the required control devices without the *operators* hindering or putting each other into a *hazardous situation*.

Check conformity by visual inspection and functional testing.

201.9.4 Instability hazards

201.9.4.2.4.3 Movement over a threshold

Addition:

Anaesthetic workstations that are intended only to be used when mounted to a wall or pendant, but may need to be removed from the wall or pendant for service or at initial installation, are not considered *mobile ME equipment* and the threshold test specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 9.4.2.4.3 does not apply. Such non-*mobile anaesthetic workstations* can use small casters to aid service and installation of the device. See also 201.7.9.3.102.

201.10 Protection against unwanted and excessive radiation hazards

Clause 10 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

201.11 Protection against excessive temperatures and other hazards

Clause 11 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.11.6.3 Spillage on ME equipment and ME systems

Replacement:

The *anaesthetic workstation* and its individual components, parts and *accessories* shall be so constructed that *spillage* does not wet parts which, when wetted, pose an unacceptable risk.

Check conformity by the following test:

Test the anaesthetic workstation and its individual components, parts and accessories under the least favourable specified working conditions, but in accordance with the instructions for use. Pour a quantity of 200 ml of normal tap water steadily on an arbitrary point on the top surface of the anaesthetic workstation and its individual components, parts and accessories, for approximately 15 s, from a height not exceeding 5 cm. After the test, the anaesthetic workstation and its individual components, parts and accessories shall conform with all the requirements of this document for normal condition.

201.11.6.8 Compatibility with substances used with the ME equipment

Addition:

The *anaesthetic workstation* and its individual components, parts and *accessories* shall be designed and manufactured to minimize health risks due to particles and substances leached or leaking from the *anaesthetic workstation* or its individual components, parts and *accessories* during *normal use*. Particular attention shall be paid to the toxicity of materials and their compatibility with substances and gases with which they come into contact during *normal use*.

NOTE 1: Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction (CMR substances).

Check conformity by the requirements given in ISO 18562-1:2017 and ISO 10993-1:2018.

NOTE 2: Attention is drawn to *anaesthetic gases* that might contribute to leaching.

201.11.8 Interruption of the power supply/supply mains to ME equipment

Addition:

201.11.8.101 * General requirements

The instructions for use shall describe the functioning of the *anaesthetic workstation* or its individual components after interruption of the *power supply*, and where applicable following a switchover to an *internal electrical power source*. Particular emphasis shall be placed on the flow rate and composition of the *fresh gas* and the behaviour of any *operator-accessible gas power supply* outlet under these circumstances.

Check conformity by inspection of the instructions for use.

201.11.8.102 * Alarm condition for power supply failure

- a) The *anaesthetic workstation* shall be equipped with an *alarm system* to detect a *power supply* failure *technical alarm condition* when the *power supply* is outside the range specified by the *manufacturer*. The *alarm signals* for the *power supply* failure *technical alarm condition* shall be
- generated for at least 7 s if pneumatically generated, or
 - generated for at least 7 s if generated by basic electronics (e.g. piezo buzzer supplied by a capacitor) or
 - at least 5 bursts of a *high priority* alarm that conforms with IEC 60601-1-8+AMD1:2012, if electronically generated.

EXAMPLE The Ritchie Whistle is a pneumatic alarm sound generator.

NOTE 1 The *power supply failure technical alarm condition* applies to the *supply mains*, an *internal electrical power source* or *pneumatic (driving) power supply*.

NOTE 2 The 7 s duration of the *alarm signals* for the *power supply failure technical alarm condition* is measured exclusive of any *interburst interval*.

- b) The A-weighted sound pressure level of the *alarm signal* for the *power supply failure technical alarm condition* shall be at least 55 dB(A) when tested as described in IEC 60601-1-8:2006+AMD1:2012, 6.3.3.2.
- c) If the normal operation of the *anaesthetic workstation* or its individual components is maintained by the automatic switchover to an *internal electrical power source* or alternate *pneumatic power supply*, the *power supply failure high priority technical alarm condition* shall not occur. Any such switchover to an *internal electrical power source* or alternate *pneumatic power supply* shall be indicated by an *information signal* or a *low priority technical alarm condition*.

Check conformity by functional testing.

201.11.8.103 * *Internal electrical power source*

If the *anaesthetic workstation* or its individual components has/have an *internal electrical power source*,

- a) it shall provide at least 30 min of back-up time with the following conditions, applied within the given ambient conditions as specified by the *manufacturer* in the instruction for use:
 - 1) controlled ventilation;
 - 2) *tidal volume* = (500 ± 10) ml, frequency = 10/min, I:E -ratio = 1:1,5 to 1:2,5, positive end-expiratory pressure (PEEP) = 5 hPa (5 cmH₂O), *patient* lung with a compliance of $(50 \pm 2,5)$ ml/hPa [$(50 \pm 2,5)$ ml/cmH₂O] and resistance of $(5 \pm 0,5)$ hPa/(l/s) [$(5 \pm 0,5)$ cmH₂O/(l/s)];
 - 3) *fresh gas flow* $(10 \pm 0,5)$ l/min oxygen;
 - 4) where applicable, volatile anaesthetic agent dosing with at least one agent at 1 MAC according to ISO 80601-2-55;
 - 5) complete monitoring of all *anaesthesia workstation* related functions [see 201.7.9.2.101 nn)].

NOTE 1 This does not include functions of separate multiparameter *patient* monitors if not part of the *anaesthetic workstation*.

- b) it/they shall be equipped with:
 - 1) a means of determining the state of the *internal electrical power source*; this means may be qualitative;

EXAMPLE 1 An indication of the remaining time provided by the *internal electrical power source*.

EXAMPLE 2 An indication of the percentage of the remaining capacity provided by the *internal electrical power source*.

EXAMPLE 3 A gauge of the remaining capacity provided by the *internal electrical power source*.

NOTE 2 An uncalibrated gauge that only indicates the state of the power source could be qualitative.

- 2) an *alarm system* that detects a *technical alarm condition* generating an *alarm signal* with *medium priority*, at least 10 min prior to the loss of function, and *high priority* at least 5 min prior to the loss of function
- c) the instructions for use shall include the following:

- 1) the operational time of a new *internal electrical power source* when fully charged;

NOTE 3 With the passage of time, the operational time might decrease.

- 2) the conditions under which 201.11.8.103 a) is maintained;
- 3) the behaviour after a switchover to the *internal electrical power source*;
- 4) the behaviour while the *internal electrical power source* is recharging.

Check conformity by functional testing and inspection of the instructions for use.

201.11.101 Packaging systems for components intended to be sterilized

Packaging systems shall be designed to maintain components at their intended level of cleanliness and to reduce the *risk* of microbial contamination.

Check conformity by inspection.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.12.4 Protection against hazardous output

Addition:

201.12.4.101 * Accidental adjustment of operating controls

- a) A means of protection against accidental adjustment of operating controls that can create a *hazardous situation* shall be provided. This includes the accidental turning off of the *anaesthetic workstation* or its individual components.
- b) If a selector switch or control is provided to change from one mode to another, it shall be bi-stable.

EXAMPLE 1 Requiring a confirmation step can be one method.

EXAMPLE 2 Manual/automatic ventilation selector switch, vaporiser selector switch, *circle absorber assembly* bypass mechanism.

- c) The *usability* of the means of protection shall be evaluated in the *usability engineering process* according to IEC 60601-1-6:2010+AMD1:2013.

Check conformity by functional testing and inspection of the usability engineering file.

201.12.4.102 * Additional requirements for *anaesthetic workstations*

The *anaesthetic workstation* shall either

- a) be equipped with the *monitoring equipment*, *alarm systems*, and *protection devices* in accordance with Table 201.104, or
- b) if not so equipped, the instructions for use of the *anaesthetic workstation* or the component, as indicated in subclauses 201.12.4.103 to 201.12.4.109, 201.102.2.1, 201.102.2.2, 201.105.2.1 and 201.105.2.2, shall contain a statement to the effect that the *anaesthetic workstation* or the component is to be equipped with the *monitoring equipment*, *alarm systems*, and *protection devices* according to Table 201.104, before being put into service and shall describe how to connect these components.

Manufacturers of individual components shall make available information in the instructions for use regarding how to connect these items to the anaesthetic workstation.

Table 201.104 — Monitoring equipment, alarm systems, and protection devices of anaesthetic workstations

<i>Monitoring equipment, alarm systems and protection device respectively</i>	According to Subclause
<i>airway pressure monitoring equipment and alarm system</i>	201.12.4.109
<i>maximum limited pressure protection device</i>	201.102.2.1 (<i>anaesthetic breathing system</i>) or 201.105.2.1 (<i>anaesthetic ventilator</i>)
<i>adjustable pressure limit protection device</i>	201.102.2.2 (<i>anaesthetic breathing system</i>) or 201.105.2.2 (<i>anaesthetic ventilator</i>)
<i>exhaled volume monitoring equipment and alarm system</i>	201.12.4.104
<i>alarm system that detects an anaesthetic breathing system integrity alarm condition</i>	201.12.4.105
<i>carbon dioxide monitoring equipment</i>	201.12.4.103.1
<i>oxygen monitoring equipment</i>	201.12.4.103.2
<i>anaesthetic agent monitoring equipment with halogenated agent monitoring equipment, if the anaesthetic gas delivery system is designed to be equipped with an anaesthetic vapour delivery system</i>	201.12.4.103.3
<i>alarm system that detects an anaesthetic breathing system continuing-positive-pressure alarm condition</i>	201.12.4.106
<i>alarm system that detects an oxygen supply failure condition and protection device</i>	201.12.4.107.1 and 201.12.4.107.2 respectively
<i>hypoxic mixture delivery selection protection device</i>	201.12.4.107.3
<i>protection device for the workplace environment (AGSS) if the anaesthetic gas delivery system is equipped with means to deliver nitrous oxide or is designed to be equipped with an anaesthetic vapour delivery system</i>	201.12.4.108

Check conformity by inspection and, if applicable, inspection of the instructions for use.

NOTE See also Table AA.1.

201.12.4.103 Respiratory gas monitoring equipment

201.12.4.103.1 Carbon dioxide monitoring equipment

The *anaesthetic workstation* shall either

- a) be equipped with a carbon dioxide *monitoring equipment* conforming with ISO 80601 2 55:2018, or
- b) if not so equipped, the instructions for use of the *anaesthetic breathing system* shall contain a statement to the effect that the *anaesthetic workstation* is to be provided with a carbon dioxide *monitoring equipment* conforming with ISO 80601-2-55:2018 before the *anaesthetic workstation* is put into service; also, it shall describe how to connect it.

Check conformity by application of the tests of ISO 80601-2-55:2018 and, if applicable, inspection of the instructions for use of the anaesthetic breathing system.

201.12.4.103.2 Oxygen monitoring equipment

The *anaesthetic workstation* shall either

- a) be equipped with an *monitoring equipment* conforming with ISO 80601-2-55:2018, or
- b) if not so equipped, the instructions for use of the *anaesthetic breathing system* shall contain a statement to the effect that the *anaesthetic workstation* is to be provided with an oxygen *monitoring equipment* conforming with ISO 80601-2-55:2018 before the *anaesthetic workstation* is put into service; also, it shall describe how to connect it.

Check conformity by application of the tests of ISO 80601-2-55:2018 and, if applicable, inspection of the instructions for use of the anaesthetic breathing system.

201.12.4.103.3 Anaesthetic agent monitoring equipment

If the *anaesthetic gas delivery system* is designed to be equipped with an *anaesthetic vapour delivery system*, the *anaesthetic workstation* shall either

- a) be equipped with a halogenated anaesthetic agent *monitoring equipment* conforming with ISO 80601-2-55:2018, or
- b) if not so equipped, the instructions for use of the *anaesthetic gas delivery system* shall contain a statement to the effect that the *anaesthetic workstation* is to be provided with a halogenated anaesthetic agent *monitoring equipment* conforming with ISO 80601-2-55:2018 before the *anaesthetic workstation* is put into service; also, it shall describe how to connect it.

Check conformity by application of the tests of ISO 80601-2-55:2018 and, if applicable, inspection of the instructions for use of the anaesthetic gas delivery system.

201.12.4.104 Exhaled volume monitoring equipment

201.12.4.104.1 * Accuracy

Displayed *tidal volumes* of 100 ml and above shall be accurate to within $\pm 20\%$ of the actual reading; displayed minute volumes of 1 l/min and above shall be accurate to within $\pm 20\%$ of the actual reading. The accuracy of displayed exhaled volumes below *tidal volumes* of 100 ml and below minute volumes of 1 l/min shall be disclosed in the instructions for use.

In the design documentation, the *manufacturer* shall prove the accuracy of the displayed exhaled volume based on tests performed under the test conditions as described in Table 201.105 using oxygen dry,