भारतीय मानक **IS 13450 (Part 2/Sec 13) : 2024**

Indian Standard

चिकित्सा विद्युत उपकरण

भाग 2 बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन के लिए विशेष अपेक्षाएँ

अनुभाग 13 एनेस्थेटिक वर्कस्टेशन

(ISO 80601-2-13 : 2022, संशोधित)

(पहला पुनरीक्षण)

Medical Electrical Equipment

Part 2 Particular Requirements for the Basic Safety and Essential Performance

Section 13 Anaesthetic Workstation

(ISO 80601-2-13 : 2022, MOD)

(First Revision)

ICS 11.040.10

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Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11

NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 13) (First Revision) which is modified adoption of ISO 80601-2-13 : 2022 'Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard supersedes IS/ISO 80601-2-13 : 2011 'Medical electrical equipment: Part 2 Particular requirements for basic safety and essential performance, Section 13 Anaesthetic workstation'. This first revision has been taken up to align it with latest edition of ISO 80601-2-13 : 2022.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 407 : 2021 Small medical gas cylinders — Pin-index yoke-type valve connections	IS 3745 : 2006 Yoke type valve connections for small medical gas cylinders — Specification (*second revision*)	Not Equivalent
ISO 5356-1 : 2015 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets	IS/ISO 5356-1 : 2015 Anaesthetic and respiratory equipment — Conical connectors: Part 1 Cones and sockets (*first revision*)	Identical
ISO 5356-2 : 2012 + AMD1 : 2019 Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors	IS/ISO 5356-2 : 2012 Anaesthetic and respiratory equipment — Conical connectors: Part 2 Screw -threaded weight — Bearing connectors	Not Equivalent
ISO 7396-2 : 2007 Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems	IS/ISO 7396-2 : 2007 Medical gas pipelines systems: Part 2 Gas scavenging disposal systems	Identical

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 9170-2 : 2008 Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems	IS/ISO 9170-2 : 2008 Terminal units for medical gas pipeline systems: Part 2 Terminal units for anaesthetic gas scavenging systems	Identical
ISO 80369-7 : 2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	IS/ISO 80369-7 : 2016 Small-bore connectors for liquids and gases in healthcare applications: Part 7 Connectors for intravascular or hypodermic applications	Identical

The Committee has reviewed the provisions of the following International Standard referred in this draft standard proposed to be adopted and has decided that it is acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 5145 : 2017	Gas cylinders — Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning
ISO 5359 : 2014 + AMD 1 : 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 + AMD 1 : 2017	Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum
ISO 9170-1 : 2017	Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum
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 + AMD 1 : 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/IEC 80079-20-1 : 2017	Explosive atmospheres — Part 20-1: Material characteristics for gas and vapour classification — Test methods and data
ISO 80601-2-55 : 2018	Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

International Standard	*Title*
IEC 60601-1 : 2005 + AMD 1: 2012 + AMD 2 : 2020	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
IEC 60601-1 10 : 2007 + AMD 1 : 2013 + AMD 2 : 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 + AMD 1 : 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

In this standard, the modification includes references which are not equivalent to referred Indian Standard.

This standard also makes a reference to the BIS Certification Marking of the product, details of which is given in National Annex DD.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2 : 2022 ‘Rules for rounding off numerical values (*second revision*)’

Contents

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

<table>
<tr><td colspan="3">anaesthetic workstation</td></tr>
<tr><td>General requirements
Clauses 201.1 – 201.17, 201.106, 201.107, 202-212</td><td rowspan="3">including associated monitoring equipment, alarm systems and protection devices</td><td rowspan="3">These are mandatory components;
see also Table AA.1</td></tr>
<tr><td>anaesthetic gas delivery system
Clause 201.101</td></tr>
<tr><td>anaesthetic breathing system
Clause 201.102</td></tr>
<tr><td>anaesthetic gas scavenging system (AGSS)
Clause 201.103</td><td rowspan="3">including associated monitoring equipment, alarm systems and protection devices</td><td rowspan="3">These are optional components;
see also Table AA.1</td></tr>
<tr><td>anaesthetic vapour delivery system
Clause 201.104</td></tr>
<tr><td>anaesthetic ventilator
Clause 201.105</td></tr>
</table>

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2 PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE

SECTION 13 ANAESTHETIC WORKSTATION

(ISO 80601-2-13 : 2022, MOD)

(First Revision)

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, CO_2/N_2O), including derived and related parameters such as spontaneous ventilation volume or CO_2 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 *anaesthetic workstation* or generation of a *technical alarm condition*	201.12.4.107.1 (oxygen supply failure alarm) 201.12.4.107.2 (oxygen supply failure *protection device*) 201.101.2 (interruption of the electrical *power supply*) 201.101.8 (oxygen flush)
Delivery of a non-hypoxic gas mixture to the *patient* or generation of a *technical alarm condition*	201.11.8.102 (*alarm condition* for *power supply* failure) 201.11.8.103 (*internal electrical power source*) 201.12.4 (protection against hazardous output) 201.101.4.2.3 (reverse flow and cross flow *protection device*) 201.101.7 (gas mixers) 201.101.8 (oxygen flush)
Non-delivery of excessive concentrations of a volatile anaesthetic agent or generation of a *technical alarm condition*	201.104.2 (delivered vapour concentration) 201.12.4.103.3 (anaesthetic agent *monitoring equipment*)
Airway pressure monitoring and associated alarm	201.12.4.109 (*airway pressure monitoring equipment*)

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 ±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 legibl*e 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

— "O_2 Flush", or

— "O_2 +".

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 cmH_2O.

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 N_2O, CO_2 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 (*m*) of *ME equipment* kg	Pull force N
m ≤ 1	30
1 < m ≤ 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

a) 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

b) 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 cmH_2O), *patient* lung with a compliance of (50 ± 2,5) ml/hPa [(50 ± 2,5) ml/cmH_2O] and resistance of (5 ± 0,5) hPa/(l/s) [(5 ± 0,5) cmH_2O/(l/s)];

   3) *fresh gas* flow (10 ± 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*

Monitoring equipment*, *alarm systems* and *protection device respectively	**According to Subclause**
airway pressure monitoring equipment and alarm system	201.12.4.109
maximum limited pressure protection device	201.102.2.1 (*anaesthetic breathing system*) or 201.105.2.1 (*anaesthetic ventilator*)
*adjustable pressure limit protection devic*e	201.102.2.2 (*anaesthetic breathing system)* or 201.105.2.2 (*anaesthetic ventilator*)
exhaled volume *monitoring equipment and alarm system*	201.12.4.104
alarm system that detects an *anaesthetic breathing system* integrity *alarm condition*	201.12.4.105
carbon dioxide *monitoring equipment*	201.12.4.103.1
oxygen *monitoring equipment*	201.12.4.103.2
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*	201.12.4.103.3
alarm system that detects an *anaesthetic breathing system* continuing-positive-pressure *alarm condition*	201.12.4.106
alarm system that detects an oxygen supply failure condition and *protection device*	201.12.4.107.1 and 201.12.4.107.2 respectively
hypoxic mixture delivery selection *protection device*	201.12.4.107.3
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*	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 ±20 % of the actual reading; displayed minute volumes of 1 l/min and above shall be accurate to within ±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,

recalculated to BTPS, *fresh gas* flows between the minimum setting as specified by the *manufacturer* and 10 l/min oxygen, and the following CO_2-production:

— adults 250 ml/min;

— paediatrics 100 ml/min;

— neonates 50 ml/min.

Check conformity by inspection of the design documentation and, if applicable, by inspection of the instructions for use of the anaesthetic breathing system.

Table 201.105 — Test conditions for expiratory volume tests

Adjustable parameter	Expiratory volume range		
	$V_T > 300$ ml	300 ml ≥ V_T >50 ml	$V_T \leq 50$ ml
Tidal volume, V_T[a]	500 ml	100 ml	30 ml
Frequency in breath per minute, *f*	10/min	20/min	30/min
ratio of the inspiratory time to the expiratory time, I:E	1:1,5 to 1:2,5	1:1,0 to 1:1,5	1:1,0 to 1:1,5
Resistance, *R*[b]	5 hPa/(l/s)± 10 %	20 hPa/(l/s) ± 10 %	50 hPa/(l/s) ± 10 %
Compliance, *C*[b]	50 ml/hPa ± 5 %	20 ml/hPa ± 5 %	1 ml/hPa ± 5 %

[a] V_T is measured by means of a pressure sensor at the test lung, where $V_T = C \times (P_{max})^2$, and

V_T is the volume delivered to the test lung

C is the Compliance of the test lung

P_{max} is the maximum pressure measured in the test lung

[b] The accuracy for *C* and *R* apply over the ranges of the measured parameters.

201.12.4.104.2 *Alarm conditions*

The exhaled volume *monitoring equipment* shall be equipped with an *alarm system* that detects a *physiological alarm condition* of at least *medium priority* that indicates when the *patient's* exhaled volume falls below an *operator*-adjustable *alarm limit*. If the *alarm signal* can be delayed, the *alarm signal generation delay* shall not exceed 90 s. The *alarm signal generation delay* may be *operator*-adjustable.

Check conformity by functional testing.

201.12.4.105 * *Anaesthetic breathing system* integrity *alarm condition*

The *anaesthetic breathing system* shall be equipped with an *alarm system* that detects an *anaesthetic breathing system* integrity *alarm condition* to indicate when the *anaesthetic breathing system* has significant leakage, including disconnection, and shall be of at least *medium priority*. The *anaesthetic breathing system* integrity *alarm condition* may be indicated by other *alarm conditions* including low *airway pressure*, low or zero exhaled carbon dioxide or low exhaled volume.

NOTE The *alarm system* detects specific *alarm conditions* and does not necessarily differentiate between possible causes.

Check conformity by functional testing.

201.12.4.106 * *Anaesthetic breathing system* continuing-positive-pressure *alarm condition*

a) The *anaesthetic breathing system* shall either

1) be equipped with an *alarm system* that detects an *alarm condition* to indicate when the *airway pressure* exceeds the continuing positive pressure *alarm limit,* or

2) if not so equipped, the instructions for use of the *anaesthetic breathing system* shall contain a statement to the effect that the *anaesthetic breathing system* is to be provided with an *alarm system* that detects an *alarm condition* that indicates when the *airway pressure* exceeds the continuing positive pressure *alarm limit* before the *anaesthetic breathing system* is put into service, including information on how to connect it.

b) The maximum *alarm condition delay* shall not exceed 17 s. The *anaesthetic breathing system* continuing positive pressure *alarm condition* shall be at least *medium priority*. The *anaesthetic breathing system* continuing positive pressure *alarm limit* may be *operator*-adjustable.

c) The *anaesthetic breathing system* continuing positive pressure *alarm condition* may be paused during manoeuvres, e. g. automatic lung recruitment or *inspiratory hold*.

Check conformity by functional testing and, if applicable, inspection of the instructions for use of the anaesthetic breathing system.

201.12.4.107 *Anaesthetic gas delivery system* oxygen supply and delivery

201.12.4.107.1 Oxygen supply failure *alarm system*

a) The *anaesthetic gas delivery system* shall be equipped with an *alarm system* that detects a *high priority technical alarm condition* to indicate when the oxygen supply, whether derived from a *medical gas pipeline system* or from a cylinder, is about to fall, or has already fallen, below a value necessary for normal operation.

b) If a pneumatically generated auditory *alarm signal* is used, it shall

— be at least 7 s in duration;

— derive its energy from the oxygen supply source.

c) The A-weighted sound pressure level of the *alarm signal* for the oxygen supply failure *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.

EXAMPLE “Ritchie whistle” or electronically generated (e.g. piezo buzzer supplied by a capacitor).

Check conformity by functional testing.

201.12.4.107.2 * Oxygen supply failure *protection device*

The *anaesthetic gas delivery system* shall be provided with an oxygen supply failure *protection device* that activates whenever the oxygen supply has fallen below a value necessary for normal operation.

EXAMPLE Nitrous oxide cut-off.

The oxygen supply failure *protection device* shall

— cut off the supply of all gases other than oxygen, air and premixed gases with an oxygen content above ambient to the *fresh-gas outlet*, or

— reduce the flow rate of all other gases (except air or premixed gases with an oxygen content above ambient) while maintaining the proportion of oxygen until the supply of oxygen finally fails. When the supply of oxygen fails, the supply of all other gases (except air or premixed gases with an oxygen content above ambient) shall be cut off.

The behaviour of the *anaesthetic gas delivery system* under these conditions shall be disclosed in the instructions for use.

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

201.12.4.107.3 * Hypoxic mixture delivery selection *protection device*

a) The *anaesthetic gas delivery system* shall be provided with a *protection device* to prevent the unintentional selection of an oxygen concentration below that of ambient air (e. g. in a mixture of oxygen/nitrous oxide or a mixture of oxygen/xenon).

b) When a mixture of gases having an oxygen concentration below 19 % is selected, a *clearly legible* indication shall be continuously provided.

EXAMPLE *Information signal* or *low priority alarm signal* indicating presence of override mode.

Check conformity by visual inspection and by functional testing.

NOTE Oxygen 93 can have major influence on the outcome of a hypoxic mixture delivery selection *protection device*, especially as the concentration of Oxygen 93 can be below 93 %.

201.12.4.108 * *Protection device* for the workplace environment

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*, the *anaesthetic workstation* shall either

a) be equipped with an *AGSS* as a *protection device*, or

b) if not so equipped, the instructions for use for the *anaesthetic workstation* shall contain a statement to the effect that the *anaesthetic workstation* is to be provided with an *AGSS* conforming with this document before being put into service. The instructions for use of the *anaesthetic workstation* and the *AGSS* shall disclose how to connect the *AGSS*.

Check conformity by inspection of the instructions for use of the anaesthetic workstation.

201.12.4.109 *Airway pressure monitoring equipment*

a) The *anaesthetic workstation* shall either

   1) be equipped with *airway pressure monitoring equipment*, or

   2) if not so equipped, the instructions for use of the *anaesthetic workstation*, the *anaesthetic breathing system* (if supplied separately) and the *anaesthetic ventilator* (if supplied separately), shall contain a statement to the effect that the *anaesthetic workstation* is to be provided with *airway pressure monitoring equipment* conforming with this document before being put into service; also, it shall describe how to connect that component. *Manufacturers* of the *airway pressure monitoring equipment* shall make available on request information on how to connect that component to the *anaesthetic workstation*, the *anaesthetic breathing system* and the *anaesthetic ventilator*.

b) The *airway pressure monitoring equipment* shall include an *alarm system* that detects an *alarm condition* of at least *medium priority* to indicate when the *airway pressure* exceeds an *operator*-adjustable high pressure *alarm limit*.

c) The *airway pressure monitoring equipment* should include an *alarm system* that detects an *alarm condition* of at least *medium priority* to indicate when the *airway pressure* falls below an *operator*-adjustable *alarm limit*. If the *alarm system* detects an *alarm condition* upon a failure to reach an *operator*-adjustable minimum pressure threshold, that *alarm condition* shall be of at least *medium priority*.

NOTE 1 The failure to reach an *operator*-adjustable minimum pressure threshold *alarm condition* can act as a "failure to cycle" *alarm condition*.

d) The *airway pressure monitoring equipment* shall have a minimum range from 10 hPa (10 cmH_2O) below ambient pressure to 60 hPa (60 cmH_2O) above ambient pressure or to the *maximum limited pressure*, whichever is greater.

e) The *airway pressure monitoring equipment* shall be accurate to within ± (2 % of the full scale reading + 4 % of the actual reading).

NOTE 2 This alarm can indicate a failure to achieve a desired peep level.

Check conformity by functional testing and, if applicable, by inspection of the instructions for use of the anaesthetic workstation.

201.13 *Hazardous situations* and fault conditions

Clause 13 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

Addition:

201.13.101 * Simultaneous failure

A *single fault condition* shall not cause the simultaneous failure of a control function and

— its associated *monitoring equipment* or *alarm system*, or

— its associated *protection device*.

Check conformity by inspection or functional testing.

201.14 *Programmable electrical medical systems (PEMS)*

Clause 14 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.14.6.1 * Identification of known and foreseeable *hazards*

Amendment (add at the end of the subclause):

The *anaesthetic workstation* and its individual components which incorporate radiofrequency (RF) wireless technology should be assessed for the following *risks*:

— performance of wireless functions;

— wireless coexistence;

— wireless quality of service;

— integrity of data transmitted wirelessly;

— security of data transmitted wirelessly;

— wireless network access.

Addition:

201.14.101 Software life cycle *processes*

Programmable electronic sub-systems (PESS) of an *anaesthetic workstation* and its individual components shall be developed with an IEC 62304:2006+AMD1:2015 compliant design *process*. Ventilation control, gas mixture control, and vapour delivery *software items* of *PESS* without an independent *risk control* measure shall be considered as software safety Class C.

EXAMPLE Independent hardware or software measure.

Check conformity by inspection of the documentation required by IEC 62304:2006 for the software safety class C (see IEC 62304:2006+AMD1:2015, 1.4).

201.15 Construction of *ME equipment*

Clause 15 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies except as follows:

201.15.3.5 Rough handling test

Amend as follows:

For an *anaesthetic workstation* with a weight exceeding 125 kg in its *nominal* configuration and only movable manually, the speed in a) ascending step shock, in b) descending step shock and in c) frame-door shock shall be reduced from 0,8 m/s to 0,4 m/s.

Add the following subclause:

201.15.101 *Operator*-detachable, flow-direction-sensitive parts and accessories

Any *operator*-detachable parts and *accessories* of the *anaesthetic workstation* and its components that are flow-direction-sensitive shall be designed in such a way that prevents incorrect assembly.

Check conformity by inspection and functional testing.

201.16 *ME systems*

Clause 16 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

201.16.9.2.1 *Multiple socket-outlet*

Replacement:

Replace 16.9.2.1 a) by the following text:

An *anaesthetic workstation* may provide *multiple socket-outlets* that can accept standard *mains plug*s of the kind specified in IEC/TR 60083:2015.

Addition:

Add the following list item:

ee) The *anaesthetic workstation* and each *multiple socket-outlet* which can accept a standard *mains plug* shall be provided with separate fuses or over-current releases as required for a single piece of *ME equipment* in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 8.11.5.

These fuses or over-current releases shall be designed such that the *anaesthetic workstation* including the *multiple socket-outlets* maintain normal function with each *multiple socket-outlet* loaded to the maximum rating.

If any *multiple socket-outlet* is overloaded by a factor of 7,5 $\pm$ 2,5, all remaining *multiple socket-outlets* and the *anaesthetic workstation* shall maintain normal function.

Check conformity by visual inspection and functional testing.

Replace the 3rd dash of 16.9.2.1 c) by:

— *protective earth terminals* and *protective earth connections* shall conform with IEC 60601-1:2005+AMD1:2012+AMD2:2020, 8.6, except that the total impedance of the protective earth path for an *anaesthetic workstation* may be up to 400 mΩ, or higher if the conditions of IEC 60601-1:2005+AMD:2012+AMD2:2020, 8.6.4 b) are satisfied.

Addition:

201.16.101 Additional requirements for *signal input/output part*

201.16.101.1 General

Basic safety and *essential performance* shall be maintained during the failure of equipment connected to a *signal input/output part* of the *anaesthetic workstation* or its individual components or the disruptions of such connections.

Check conformity by functional testing.

201.16.101.2 Connection to other equipment for *network/data coupling*

An *anaesthetic workstation* or its individual components may be equipped with a *network/data coupling* that permits data transmission from the *anaesthetic workstation* or its individual components to other equipment. If an *anaesthetic workstation* is equipped with such a *signal input/output part* that is intended for clinical applications, the transmission should include at least the parameters for which a corresponding semantic concept exists in the IEEE 11073-10101 series.

If the *anaesthetic workstation* is equipped with a *network/data coupling*, then signal inadequacy shall be included in the data stream.

If the *anaesthetic workstation* is equipped with a *network/data coupling*, then units of measurement shall be included in the data stream either by a separate attribute or as part of parameter data code.

NOTE 1 Other equipment for *network/data coupling* could be e.g. another *ME Equipment*, software as a medical device or electronic health record systems.

The data transmission should be capable of being provided with a *network/data coupling* in accordance with a standardized interoperability architecture and protocol binding.

Check compliance by functional testing.

NOTE 2 Standardized interoperability architectures and protocol binding can be found in ISO/IEEE 11073-20701.

201.16.101.3 Connection to *distributed alarm system/information system*

An *anaesthetic workstation* or its individual components may be equipped with a *signal input/output part* for connection to a *distributed alarm system*.

For an *anaesthetic workstation* or its individual components that is equipped with an *alarm system*, the *anaesthetic workstation* or its individual components may be equipped with a *network/data coupling* that permits connection to a *distributed alarm system/distributed information system*. If the *anaesthetic workstation* or its individual components is equipped with such a *signal input/output part* that is intended to be used in a *distributed alarm system/distributed information system*, the transmission should include at least the alarm data for which a corresponding semantic concept exists in the IEEE 11073-10101 series.

The data transmission should be capable of being provided with a *network/data coupling* in accordance with a standardized interoperability architecture and protocol binding.

Check compliance by functional testing.

NOTE A protocol binding can be found e. g. in ISO/IEEE 11073-20701.

201.16.101.4 * Connection for remote control

A remote control may be an additional control; an *anaesthetic workstation* shall always have an integrated control that cannot be removed completely from the device.

If a *signal input/output part* for connection for remote control is provided, the integrated control of the *anaesthetic workstation* shall have priority over the remote control.

For an *anaesthetic workstation* that is intended for remote control, the *anaesthetic workstation* may be equipped with a *network/data coupling* that allows an external control of the *anaesthetic workstation*. If the *anaesthetic workstation* is equipped with such a *signal input/output part* that is intended for clinical applications, the transmission should include at least the external control commands for which a corresponding semantic concept exists in the IEEE 11073-10101 series.

The transmission of the external control commands should be capable of being provided with a *network/data coupling* in accordance with a standardized interoperability architecture and protocol binding.

NOTE Standardized interoperability architectures and protocol binding can be found in ISO/IEEE 11073-20701.

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems*

Clause 17 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

New clauses:

201.101 Additional requirements for *anaesthetic gas delivery systems*

201.101.1 Identification and documents

201.101.1.1 Instructions for use

The instructions for use shall include the following:

a) a statement to the effect that the *anaesthetic gas delivery system* conforms with this document;

b) unless the *anaesthetic breathing system* is integral to the *anaesthetic gas delivery system* or *anaesthetic workstation*, a statement to the effect that the *anaesthetic gas delivery system* or *anaesthetic workstation* is intended to be used with an *anaesthetic breathing system* that conforms with this document;

c) instructions for testing for correct assembly and connection of each gas supply;

d) if applicable, the *medical gas* supply pressure(s) at which the *anaesthetic gas delivery system* will cease to deliver gas as specified;

e) unless the *anaesthetic breathing system* is an integral part of the *anaesthetic gas delivery system*, information on how to connect an *anaesthetic breathing system*;

f) if the *anaesthetic gas delivery system* is equipped with a means to deliver nitrous oxide or is designed to be equipped with an *anaesthetic vapour delivery system*, a statement to the effect that the *anaesthetic gas delivery system* is to be used with an *AGSS* conforming with this document;

g) if the *anaesthetic gas delivery system* is designed to be equipped with an *interchangeable anaesthetic vapour delivery system*, a statement to the effect that the *interchangeable anaesthetic vapour delivery system* used with the *anaesthetic gas delivery system* shall conform with this document;

h) if the *anaesthetic gas delivery system* is designed to be equipped with an *anaesthetic vapour delivery system*, a statement to the effect that the *anaesthetic gas delivery system* is to be used with halogenated anaesthetic agent *monitoring equipment* conforming with ISO 80601-2-55:2018;

i) if the *anaesthetic gas delivery system* is designed to be equipped with an *anaesthetic ventilator*, a statement to the effect that the *anaesthetic ventilator* shall conform with the requirements of this document;

j) a statement to the effect that the *anaesthetic workstation* is intended for use with non-flammable anaesthetic agents as specified in this document and that flammable anaesthetic agents such as diethyl ether and cyclopropane are not to be used in the *anaesthetic workstation*;

NOTE Annex BB contains the criteria for determining when an anaesthetic agent is non-flammable.

k) the mass in kilograms (kg) in the *nominal* configuration and a definition of the *nominal* configuration. The mass in kilograms (kg) shall be disclosed for each *accessory* with a mass exceeding 1,5 kg;

l) if the *anaesthetic gas delivery system* is equipped with an emergency oxygen flow rate adjustment control the accuracy of the emergency oxygen flow rate adjustment control.

Check conformity by inspection of the instructions for use.

201.101.1.2 Technical description

The technical description shall include the following:

a) pressure and flow rate characteristics of any gas *power supply* outlet throughout the *rated* range of inlet pressure;

b) operating characteristics and location of any pressure relief *protection device*s.

Check conformity by inspection of the technical description.

201.101.2 * Interruption of the electrical *power supply*

The *anaesthetic gas delivery system* shall be so designed that in the event of an electrical *power supply* failure, either the supply of *fresh gas* is unaffected or an alternative means of gas delivery is available.

Check conformity by inspection and functional testing.

201.101.3 Protection against cross-contamination of volatile anaesthetic agents

If an *anaesthetic gas delivery system* provides connectors for more than one *anaesthetic vapour delivery system*, a means shall be provided to prevent contamination of the contents of one *anaesthetic vapour delivery system* with another volatile anaesthetic agent.

EXAMPLE Interlock system allowing the operation of only one vaporizer at a time.

See also 201.104.5.

Check conformity by inspection and functional testing.

201.101.4 Medical gas supply

201.101.4.1 Cylinder supplies

201.101.4.1.1 Inlet connector

Connections to *medical gas* cylinders shall conform with ISO 407:2021 or ISO 5145:2017.

NOTE National or regional regulations might specify a particular connector.

Check conformity by application of the tests of ISO 407:2021 or ISO 5145:2017.

201.101.4.1.2 Inlet filtration

Each *medical gas* supply inlet connection shall be equipped with a means to prevent particles greater than 100 µm from entering the *anaesthetic gas delivery system*. The location at which the supply pressure is monitored (see 201.101.4.3) shall be downstream of the filter.

Check conformity by inspection.

201.101.4.1.3 Pressure regulators

Pressure regulators that are integral parts of the *anaesthetic gas delivery system* intended for use at inlet pressures >1 400 kPa shall conform with ISO 10524-1:2018, 5.4, 6.10, 6.13 and 7.1.

Check conformity by application of the tests of ISO 10524-1:2018.

201.101.4.1.4 * Reserve oxygen supply

In addition to a connection for the main oxygen supply, the *anaesthetic gas delivery system* shall be equipped with a gas inlet to a reserve (back-up) oxygen supply as specified in 201.101.4.1.1 and 201.101.4.2.1

Check conformity by inspection.

201.101.4.2 Pipeline supplies

201.101.4.2.1 Inlet connector

Pipeline inlet connectors for the *anaesthetic gas delivery system* shall be one of the following:

a) a non-interchangeable screw-threaded (NIST) body in accordance with ISO 18082:2014+AMD1:2017, or

b) a *gas-specific* screw-threaded connector in accordance with national or regional standards (e. g. the body of a diameter-index safety system (DISS) [26] or of a sleeve index system (SIS) [25].

Check conformity by inspection.

201.101.4.2.2 Inlet filtration

Each *medical gas* supply inlet connection shall be equipped with a means to prevent particles greater than 100 µm from entering the *anaesthetic gas delivery system*. The location at which the supply pressure is monitored (see 201.101.4.3) shall be downstream of the filter.

Check conformity by inspection.

201.101.4.2.3 Reverse flow and cross-flow *protection device*

a) The *anaesthetic gas delivery system* shall be equipped with a cross-flow *protection device* to limit, under *normal condition*:

   — the reverse gas flow rate between gas input ports of the same gas to 100 ml/min;

   — the flow rate of gas from one input port to an input port of a different gas to less than 10 ml/h.

b) If under *single fault condition* the flow rate of gases between input ports of different gases can exceed 10 ml/h, the *anaesthetic gas delivery system* shall be equipped with a means to indicate this unacceptable *risk*, for example, by means of an *alarm signal*.

Check conformity by functional testing.

201.101.4.3 Pressure or content *monitoring equipment*

The *anaesthetic gas delivery system* shall be equipped with pressure or content *monitoring equipment* for each gas supplied from a *medical gas pipeline system* or at cylinder pressure. The *monitoring equipment* shall display the pressure or content for each gas continuously or on *operator* demand. This display shall be visible from the front of the *anaesthetic gas delivery system*.

NOTE In a cylinder with liquefied gas, cylinder pressure does not reflect cylinder contents.

Displayed values shall be accurate to within $\pm$ (4 % of the full scale reading + 8 % of the actual reading).

Check conformity by inspection and functional testing.

201.101.5 *Anaesthetic gas delivery system* leakage

201.101.5.1 Leakage prior to the flow rate adjustment control element

Except for the venting of air or oxygen from fluidic or pneumatic elements, the gas leakage from that part of the *anaesthetic gas delivery system* piping up to the inlet of the flow rate adjustment control part, and the piping between the inlet connections for cylinders and *pressure regulators*, shall not exceed 75 ml/min when it is pressurized to the maximum design pressure.

NOTE This requirement allows 25 ml/min leakage, each, for the cylinder attachment, the *pressure regulator* assembly and the *anaesthetic gas delivery system* piping.

Check conformity by functional testing.

201.101.5.2 Leakage after the flow rate adjustment control element

The gas leakage to atmosphere between the outlet of the flow rate adjustment control or gas mixer and the *fresh-gas outlet* shall not exceed 50 ml/min at a pressure of 30 hPa (30 cmH_2O).

NOTE An *anaesthetic gas delivery system* can permit a continuous or intermittent basal flow of oxygen. This is not to be confused with leakage to atmosphere.

This requirement shall be met with any *anaesthetic vapour delivery system* specified in the instructions for use when the *anaesthetic vapour delivery system* is

— on,

— off, and

— removed, if it is *operator*-detachable.

Check conformity by functional testing.

201.101.6 Gas flow rate metering

201.101.6.1 Graduations and accuracy

a) All *flowmeters* or flow rate adjustment controls shall be graduated in litres per minute (l/min).

b) For flow rates of 1 l/min or below, the flow rate shall be expressed either in millilitres per minute (ml/min) or in decimal fractions of litres per minute (l/min) (with a zero before the decimal marker). The method of graduation shall be consistent on any one *anaesthetic gas delivery system*.

c) The accuracy of the graduations of any *flowmeter* or flow rate adjustment control used in the *anaesthetic gas delivery system* shall be within $\pm$10 % of the indicated value for flow rates between 10 % and 100 % of full scale when discharged into the ambient atmosphere (see 201.5.101.2).

Check conformity by inspection and functional testing.

201.101.6.2 Flow rate adjustment control

Separate flow rate adjustment controls for each gas, if provided, shall meet the following requirements:

— with the exemption of emergency flow rate adjustment controls, there shall not be more than one flow rate adjustment control for any single gas delivered to the *fresh-gas outlet* under *normal condition*;

NOTE 1 An *anaesthetic gas delivery system* can incorporate an emergency oxygen flow rate adjustment control in addition to the normal oxygen flow rate adjustment control or gas mixer. Such an emergency oxygen flow rate adjustment control is designed for emergency use only, e.g. failure of an electronic controlled gas mixer or flow rate controller. Such an emergency oxygen flow rate adjustment is not required to fulfil the accuracy requirements given in this standard.

NOTE 2 A device that prevents delivery of oxygen at levels below those found in ambient air is not considered to be a flow rate adjustment control.

— a rotary style flow rate adjustment control for oxygen shall have a physical profile in accordance with Figure 201.101 and shall have a diameter not less than the diameter of the knobs controlling all other gases, except for emergency oxygen flow rate adjustment control or flow rate adjustment control for O2 therapy function that shall be discernible;

— all rotary style flow rate adjustment control knobs for gases other than oxygen shall be round and their surface serration shall not exceed a depth of 1 mm;

— if an individual flow rate adjustment control is present for each gas (one knob for each gas), an anticlockwise rotation of the control knob shall cause an increase in flow rate and, conversely, a clockwise rotation shall cause a decrease in flow rate.

NOTE 3 Flow rate adjustment controls being part of an electronical graphical human interface might have a different convention to be consistent throughout the *anaesthetic workstation* and its individual components.

The oxygen *flowmeter* shall be positioned at either end of any bank of *flowmeters*.

Check conformity by inspection.

Dimensions in millimetres

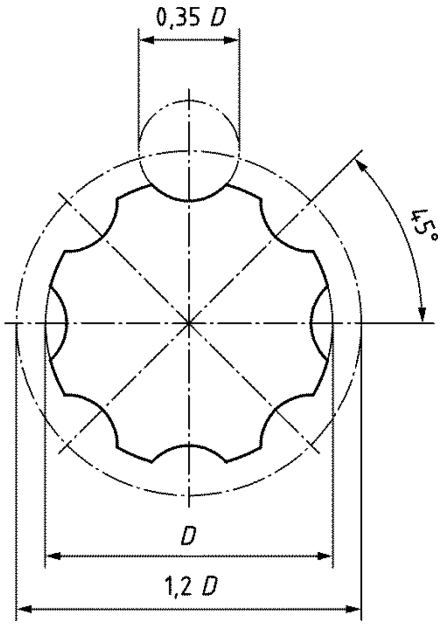


Figure 201.101 — Profile of a mechanical/pneumatic oxygen flow rate adjustment control knob

201.101.6.3 * Carbon dioxide flow rate adjustment control

If carbon dioxide is one of the gases that the *anaesthetic gas delivery system* can deliver, delivery of carbon dioxide shall be limited to a maximum of 600 ml/min.

Check conformity by inspection and functional testing.

201.101.7 Gas mixers

At any flow rate and pressure given in *normal use*, the oxygen concentration shall be within ±5 % volume fraction of the set or indicated value.

Check conformity by inspection and functional testing.

201.101.8 * Oxygen flush

a) The *anaesthetic gas delivery system* shall be equipped with a means to allow the *operator* to supply oxygen or, if applicable, Oxygen 93 at a steady flow rate of between 25 l/min and 75 l/min directly to the *fresh-gas outlet* or *inlet* of the *anaesthetic breathing system*.

b) The oxygen flush shall have only one “Off” position. The oxygen flush shall be operable with one hand and shall be self-closing.

c) It is recommended that the oxygen flush be located such that unintentional operation by equipment or personnel is prevented.

d) Means to supply any single gas other than oxygen or, if applicable, Oxygen 93 directly to the *fresh-gas outlet* or to the *inlet* of the *anaesthetic breathing system* shall not be provided.

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

201.101.9 * *Fresh-gas outlet*

If an *operator*-accessible *fresh-gas outlet* is provided, there shall be not more than one functional *fresh-gas outlet*. The *fresh-gas outlet* shall be a coaxial 22 mm/15 mm conical connector conforming with ISO 5356-1:2015 or ISO 5356-2:2012+AMD1:2019.

Check conformity by inspection and application of the tests of ISO 5356-1:2015 and ISO 5356-2:2012+AMD1:2019.

201.101.10 Interface to *interchangeable anaesthetic vapour delivery systems*

a) For *anaesthetic gas delivery systems* intended to be used with *interchangeable anaesthetic vapour delivery systems* the flow of gas from the oxygen flush shall be delivered to the *fresh-gas outlet* without passing through an anaesthetic vapour delivery module.

b) When the *fresh-gas outlet* is open to atmosphere, the pressure at the outlet from the *anaesthetic vapour delivery system* shall not increase by more than 100 hPa (100 cmH_2O) above its normal working pressure and not decrease by more than 100 hPa (100 cmH_2O) below its normal working pressure when the oxygen flush is operated throughout the *rated* range of inlet pressure.

Conformity is checked by functional testing. For test procedures see 201.104.2.2.

201.102 Additional requirements for an *anaesthetic breathing system*

201.102.1 Identification, marking and documents

201.102.1.1 Marking

201.102.1.1.1 Non-metallic parts

Non-metallic parts of an *anaesthetic breathing system* that are made of antistatic or conductive materials, and the packaging of such parts, shall be marked with the *clearly legible* word “antistatic” or “conductive” or the equivalent in a language that is acceptable to the intended *operator*. These non-metallic parts may additionally bear an indelible yellow coloured mark.

Check conformity by inspection.

201.102.1.1.2 Bag/ventilator control

An *operator*-controlled mechanism that changes from reservoir bag to *anaesthetic ventilator* and vice-versa, if provided, shall be marked with the words “bag” and “ventilator” or the equivalent in a language that is acceptable to the intended *operator* or an appropriate symbol.

Check conformity by inspection.

201.102.1.1.3 Absorbent bypass

An *operator*-controlled mechanism for excluding the absorbent from the gas pathway shall be marked with the following:

— the words “on” and “off” or the equivalent in a language that is acceptable to the intended *operator*; or

— the words “absorber on” and “absorber off” or the equivalent in a language that is acceptable to the intended *operator*; or

— an appropriate symbol.

Check conformity by inspection.

201.102.1.1.4 Inspiratory and expiratory ports of a *circle absorber assembly*

Unless the *circle absorber assembly* is an integral part of the anaesthetic breathing system the inspiratory and expiratory ports of a *circle absorber assembly* shall be marked with an arrow to indicate the intended direction of gas flow.

Check conformity by inspection.

201.102.1.2 Instructions for use

The instructions for use of an *anaesthetic breathing system* and its parts shall include the following:

a) a diagram of the complete *anaesthetic breathing system* identifying its parts and their recommended location(s);

b) a statement to the effect that the *anaesthetic breathing system* or its parts conform with this document;

c) unless the *anaesthetic breathing system* is an integral part of the *anaesthetic gas delivery system* or *anaesthetic workstation*, information on how to connect an *anaesthetic breathing system*;

d) the internal compliance, expressed as a volume in millilitres (ml) at a pressure of 30 hPa (30 cmH_2O), with any reservoir bag excluded;

e) unless permanently mounted, the recommended orientation of the *anaesthetic breathing system* and its parts and details of the effects of other orientations on performance;

EXAMPLE Water trap, *exhaust valve*.

f) information on any means of pressure relief, including pressure/flow-rate characteristics;

g) a statement of known compatibility with gases and anaesthetic agents;

h) a statement regarding the suitability for use with flammable anaesthetic agents, i.e. *category AP* or *category APG*;

i) instructions for use of *anaesthetic breathing system* parts not integrated into the *anaesthetic breathing system*, which shall include a diagram showing the recommended locations of such *anaesthetic breathing system* parts, the location of the *fresh-gas inlet* and the *anaesthetic ventilator* inlet;

j) instructions for use of *exhaust valves* not integrated into the *anaesthetic breathing system*, which shall describe the pressure/flow-rate characteristics of the *exhaust valve* including the opening pressure and the pressure drop at a flow rate of 30 l/min at BTPS;

k) instructions for use of a *circle absorber assembly* and its parts not integrated into the *anaesthetic breathing system*, which shall identify the carbon dioxide absorbent recommended for use and the volume of the absorbent container expressed in millilitres (ml);

l) for breathing *accessories* intended to be assembled by the *operator*, the resistance at 2,5 l/min, 15 l/min and 30 l/min and compliance of those *accessories*;

m) for an *anaesthetic breathing system* supplied separately, a statement to the effect that the *anaesthetic workstation* is to be provided with an *airway pressure monitoring equipment* conforming with this document (see 201.12.4.109) before being put into service and a description on how to connect that component;

n) the inspiratory and expiratory pressure/flow rate characteristics of the *anaesthetic breathing system*, including the pressure at

— 30 l/min if the *anaesthetic breathing system* is intended for adult *patients*;

— 15 l/min if the *anaesthetic breathing system* is intended for paediatric *patients*;

— 2,5 l/min if the *anaesthetic breathing system* is intended for neonatal *patients*;

at a *fresh gas* flow rate of (10 ± 1) l/min oxygen;

o) a statement if the *anaesthetic breathing system* is suitable for neonates;

p) if the *anaesthetic breathing system* is suitable for neonates:

1) the maximum allowed resistance of the *breathing tube* system including filters for neonates; and

2) a method for the *operator* to test a *breathing tube* setup for maximum pressure fluctuation at the *patient connection port;*

q) if the bag connector is a socket (female), a warning in the instructions for use not to use any adaptors for the hoses to prevent any misconnections and not to compromise *patient* safety.

Check conformity by inspection of the instructions for use.

201.102.2 Pressure limitation *protection devices*

NOTE The *anaesthetic workstation* is expected to have one *maximum limited pressure protection device* and one *adjustable pressure limit protection device* which can be located either in the *anaesthetic breathing system* or in the *anaesthetic ventilator* (see 201.102.2.1, 201.102.2.2, 201.105.2.1 and 201.105.2.2).

201.102.2.1 * *Maximum limited pressure protection device*

a) A *protection device* shall be provided to prevent the *airway pressure* from exceeding the *maximum limited pressure* under both:

1) *normal condition*; and

2) *single fault condition*.

b) The *maximum limited pressure* shall not exceed the higher of:

1) 20 hPa (20 cmH_2O) more than the set *inspiratory pressure* but limited to 125 hPa (125 cmH_2O); or

2) 90 hPa (90 cmH_2O).

NOTE 1 This set *inspiratory pressure* can be e. g. the *inspiratory pressure* setting for pressure-controlled ventilation modes or the maximum pressure setting for volume-controlled ventilation modes.

c) A reservoir bag conforming with ISO 5362:2006 may be used for the s*ingle fault condition* pressure limitation *protection device* for an *anaesthetic workstation* without an *anaesthetic ventilator*, or when the *anaesthetic ventilator* is in a manual or spontaneous ventilation mode.

NOTE 2 The pressure limitation effect of a reservoir bag conforming with ISO 5362:2006 has a *nominal* value of 55 hPa (55 cmH_2O).

Check conformity by functional testing.

201.102.2.2 * *Adjustable pressure limit protection device*

a) The *anaesthetic breathing system* shall either

1) be equipped with an *adjustable pressure limit protection device* to limit the pressure at the *patient connection port* to an *operator*-adjustable pressure, or

2) if not so equipped, the instructions for use of the *anaesthetic ventilator* shall contain a statement to the effect that the *anaesthetic ventilator* is to be provided with a *protection device* to limit the pressure at the *patient connection port* to an *operator*-adjustable pressure conforming with this document before the *anaesthetic workstation* is put into service and shall describe how to connect that component to the *anaesthetic workstation* available (e.g. in integration instructions) upon request.

b) The *adjustable pressure limit protection device* shall

1) ensure that the pressure at the *patient connection port* does not exceed the *operator*-set maximum value by more than 15 % or 10 hPa (10 cmH_2O), whichever is greater, in *normal condition*;

2) be capable of releasing the maximum flow that can be delivered by an O_2 flush without exceeding the limits as given above.

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

201.102.3 Packaging of parts of *anaesthetic breathing systems*

Parts of the *anaesthetic breathing system* shall be packaged in such a way as to reduce the *risk* of the incomplete removal of the packaging before use to acceptable levels.

NOTE This is to prevent accidental retention of the packaging, e.g. transparent wrapper, caps, lids, covers, and to ensure its removal by the *operator* prior to use.

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

201.102.4 * Electrical conductivity

An *anaesthetic breathing system* or its parts marked as “antistatic” or “conductive” shall have a maximum electrical resistance of 1,0 MΩ when tested according to ISO 2878:2017.

When evaluating tubing, the resistance limit should be considered to be 1,0 MΩ/m.

Check conformity by inspection and application of the tests of ISO 2878:2017.

201.102.5 Ports and connectors

201.102.5.1 *Patient connection port*

The *patient connection port* shall be a coaxial 22 mm cone/15mm socket conforming with ISO 5356-1:2015. The *patient connection port* may swivel.

Check conformity by inspection and application of the test of ISO 5356-1:2015.

201.102.5.2 **Exhaust port* connector

If an *exhaust port* connector is a separate connector which is *operator*-detachable without the use of a *tool*, it shall be

a) marked with the word "exhaust" or "AGS" or the equivalent in a language that is acceptable to the intended *operator*, or an appropriate symbol, and

b) one of the following:

1) a 30 mm cone conforming with ISO 5356-1:2015 with a means to prevent connection of the orifice to any *anaesthetic breathing system* port or component, or
2) a proprietary connector that does not engage with connectors conforming with ISO 5356-1:2015 and *breathing tubes* conforming with ISO 5367:2014.

Check conformity by inspection, functional testing and application of the tests in ISO 5356-1:2015 and ISO 5367:2014.

201.102.5.3 * Reservoir bag connector

201.102.5.3.1 Arrangement and connector

a) The connector of a reservoir bag shall be a 22 mm socket conforming with ISO 5356-1:2015 if

1) the reservoir bag port is located adjacent to the inspiratory or the expiratory port, or
2) the reservoir bag is intended to be connected using a *breathing tube* according to ISO 5367:2014 between the reservoir bag and the reservoir bag connector.

This connection shall be within 20 ° of the vertical axis.

NOTE 1 See Figure 201.102 a).

b) The connector of a reservoir bag may be a 22 mm cone conforming with ISO 5356-1:2015, if

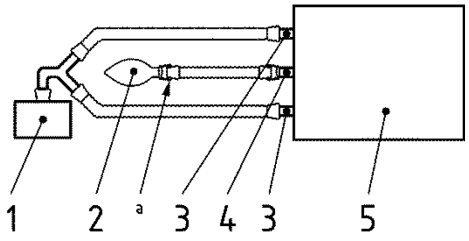
1) the reservoir bag is intended to be connected directly (without a *breathing tube*) to the reservoir bag connector, and
2) the reservoir bag connector is separated from the inspiratory and the expiratory port by the use of a flexible bag arm or a bag swivel mount.

NOTE 2 A flexible bag arm and a swivel mount substitutes the connecting tube of a reservoir bag.

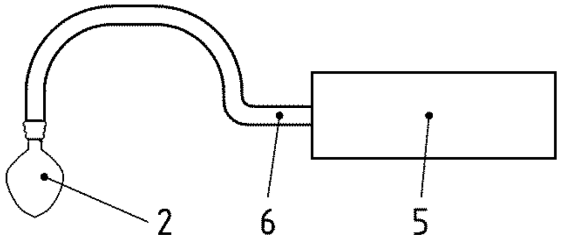
NOTE 3 See Figure 201.102 b).

c) The reservoir bag connection port shall not be on the *patient* side of the *inspiratory* or *expiratory valve*(s).

Check conformity by inspection, functional testing and application of the tests of ISO 5356-1:2015.



a) 22 mm socket reservoir bag connector



b) 22 mm cone reservoir bag connector

Key to a) and b)
1 *Patient* with a 15/22 mm cone/socket connector
2 Reservoir bag [22 mm socket]
3 *Breathing tube*, inspiratory and expiratory connection respectively
4 *Breathing tube* with cones at both ends
5 *Circle absorber assembly*
6 Flexible bag arm or bag swivel mount with a cone (direct connection to the reservoir bag)
a cone on both ends of the connecting tube

Figure 201.102 — Schematic representation of the connectors and the arrangement of the reservoir bag connection port

201.102.5.3.2 Marking

The reservoir bag connection port shall be marked with the word “bag” or the equivalent in a language that is acceptable to the intended *operator*, or an appropriate symbol.

Check conformity by inspection.

201.102.5.3.3 Connectors of the reservoir bag connecting tube

The connectors at both ends of the reservoir bag connecting tube, if used, shall be a 22 mm cone. They shall not have a 15 mm socket that connects to a 15 mm cone according to ISO 5356-1:2015.

Check conformity by inspection, functional testing and application of the tests of ISO 5356-1:2015.

201.102.5.4 *Anaesthetic ventilator* port connector

If the *anaesthetic ventilator* port connector is *operator*-detachable without the use of a *tool*, it shall be:

a) marked with the word “ventilator” or the equivalent in a language that is acceptable to the intended *operator* or an appropriate symbol; and

b) one of the following:

1) a 22 mm cone conforming with ISO 5356-1:2015 or ISO 5356-2:2012+AMD1:2019 or

2) a proprietary fitting that does not engage with connectors conforming with ISO 5356-1:2015 and *breathing tubes* conforming with ISO 5367:2014.

Check conformity by inspection, functional testing and application of the tests of ISO 5356-1:2015, ISO 5356-2:2012+AMD1:2019 and ISO 5367:2014.

201.102.5.5 *Anaesthetic breathing system* port connector

If an *anaesthetic breathing system port* connector is *operator*-detachable without the use of a *tool*, it shall be

a) a 22 mm cone (male) with coaxial 15 mm socket conforming with ISO 5356-1:2015, or

b) a proprietary fitting that does not engage with connectors conforming with ISO 5356-1:2015 and *breathing tubes* conforming with ISO 5367:2014.

Check conformity by functional testing and application of the tests of ISO 5356-1:2015 and ISO 5367:2014.

201.102.5.6 * Inspiratory and expiratory port connectors of a *circle absorber assembly*

If the connections to inspiratory or expiratory ports of a *circle absorber assembly* are *operator*-detachable without the use of a *tool*, the ports shall be a 22 mm cone with or without coaxial 15 mm socket conforming with ISO 5356-1:2015 or ISO 5356-2:2012+AMD1:2019. The axis of these ports shall be within $\pm 50°$ of the horizontal plane.

Check conformity by inspection and application of the tests of ISO 5356-1:2015 and ISO 5356-2:2012+AMD1:2019.

201.102.5.7 Other port connectors

a) Port connectors used for other specific purposes (e.g. pressure measurement, gas sample return) shall not engage with connectors as specified in ISO 5356-1:2015, ISO 5356-2:2012+AMD1:2019 or ISO 80369-7:2016.

b) The port connectors shall be provided with a means of securing closure when not in use. The means of closure shall be non-detachable from the corresponding part/device.

NOTE 1 Attention is drawn to the ISO 80369 series.

c) A gas sample return port shall be marked with the words “gas return” or symbol ISO 7000-0795 and a gas sample port shall be marked with the words “gas sample” or symbol ISO 7000-0794.

NOTE 2 Other particular standards, e.g. ISO 80601-2-84 for respiratory humidifying equipment, that might be added to an *anaesthetic breathing system* also contain requirements for specific ports, e.g. temperature probe.

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

201.102.6 * Leakage

The leakage from an *anaesthetic breathing system* shall not exceed 150 ml/min at 30 hPa (30 cmH_2O) internal pressure.

Check conformity by functional testing.

201.102.7 * Inspiratory and expiratory pressure/flow rate characteristics

The pressure, either positive or subatmospheric, generated at the *patient connection port*, in any combination of the *anaesthetic breathing system* and *accessories* such as *breathing tubes*, water traps, microbial filters and *y-pieces* as recommended by the *manufacturer*, shall not exceed 6 hPa (6 cmH_2O) at the peak flow rate of

— 30 l/min if the *anaesthetic breathing system* and the *accessories* are intended for adult *patients*;

— 15 l/min, if the *anaesthetic breathing system* and the *accessories* are intended for paediatric *patients*;

— 2,5 l/min, if the *anaesthetic breathing system* and the *accessories* are intended for neonatal *patients*;

at a *fresh gas* flow rate of (10 ± 1) l/min oxygen.

Check conformity by functional testing of any combination of the anaesthetic breathing system and accessories such as breathing tubes, water traps, microbial filters and y-pieces as recommended by the manufacturer under the worst case scenario and inspection of the instructions for use.

201.102.8 *Anaesthetic breathing system* parts and accessories

201.102.8.1 * *Y-piece*

The connectors of a *y-piece*, not permanently attached to a *breathing tube*, shall be either

a) 22 mm cone, with a recess, conforming with ISO 5356-1:2015, or

b) other connectors compatible with a *breathing tube* conforming with ISO 5367:2014.

Check conformity by inspection and application of the tests of ISO 5356-1:2015 or ISO 5367:2014, as applicable.

201.102.8.2 * *Exhaust valve*

a) An *exhaust valve* shall not be placed between the *inspiratory valve* and the *y-piece.*

b) An *operator*-adjustable *exhaust valve* with a rotary control shall progressively increase the opening pressure with movement of the control in a clockwise direction. Movement of the control to a fully clockwise position need not close the *exhaust valve* completely.

c) For an *exhaust valve* not integrated into the *anaesthetic breathing system*, the instructions for use shall disclose:

   — the opening pressure;

   — the pressure/flow-rate characteristics;

   — the pressure drop with any *exhaust valve* control fully open at a flow rate of 30 l/min;

   — for an *exhaust valve* that can be fully closed, the leakage to atmosphere in the fully closed position at a pressure of 30 hPa (30 cmH_2O).

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

201.102.8.3 * *Breathing tubes*

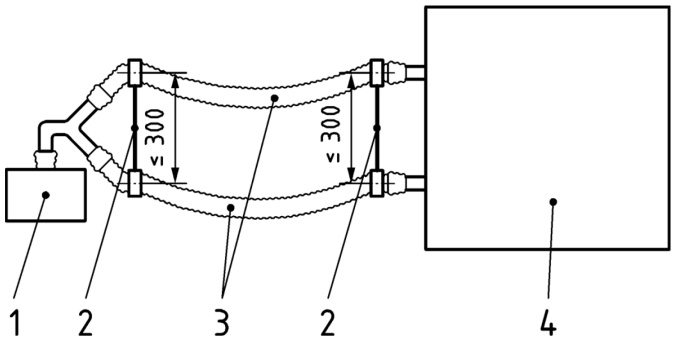
Breathing tubes connecting the *patient* with the inspiratory and expiratory port connectors of a *circle absorber assembly* shall prevent a misconnection of the *patient* or make it detectable.

This may be done by e.g.

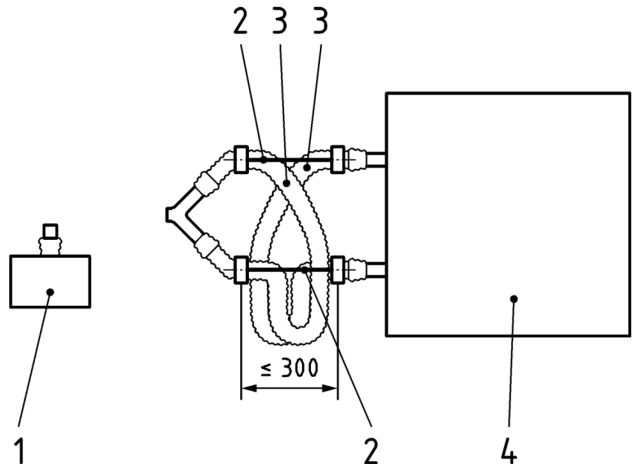
— a pre-assembled set of *breathing tubes* that cannot be disassembled by the *operator* (this includes e.g. co-axial systems, double-D-systems)*;*

— creating a fixed connection of both ends of a pair of *breathing tubes*, where the distance between the ends of this pair of *breathing tubes* then shall not exceed 300 mm, see (Figure 201.103).

Dimensions in millimetres



a) Correct connection



b) Short circuit and the principle of "handcuffs" – *patient* is not connected

Key to a) and b)

1 Patient with a 15/22 mm cone/socket connector
2 Fixed connection ("handcuffs") between the two breathing tubes
3 Inspiratory and expiratory breathing tubes with 22 mm sockets on both ends
4 *Anaesthetic workstation*

Figure 201.103 — Example of arrangement of *breathing tubes* and connections

Alternative technical solutions are possible to prevent this type of tube short circuit. The fixed connection may be a solution mainly for re-usable breathing sets.

Check conformity by inspection of the risk management file.

201.102.9 Circle absorber assemblies

201.102.9.1 * Constructional requirements

a) A *circle absorber assembly* not integrated into the *anaesthetic breathing system* shall incorporate *inspiratory* and *expiratory valves* or other means of ensuring unidirectional gas flow. If these valves or means can be detached from the *circle absorber assembly*, the method of attachment shall be by means of connectors which are non-interchangeable with each other and which do not engage with any of the connectors specified in ISO 5356-1:2015 and ISO 5356-2:2012+AMD1:2019.

b) The carbon dioxide absorbent shall have a visual indicator to indicate the state of exhaustion. The indicator may be qualitative or quantitative. The *anaesthetic workstation* shall permit the visual indicator, e. g. colour change, of the absorbent to be visible from the *operator's* intended position. A *circle absorber assembly* may include means to permit changing the absorbent without opening the gas pathway to the atmosphere.

NOTE Not all technologies use colour change as a visual indicator.

Check conformity by inspection, functional testing and application of the tests of ISO 5356-1:2015 and ISO 5356-2:2012+AMD1:2019.

201.102.9.2 * Absorbent bypass mechanism

a) Unless the absorbent bypass mechanism is intended to function at one or more intermediate settings, its control shall have only "on" and "off" positions. The position marked "off" shall mean that the gas does not pass through the absorbent. The instructions for use shall disclose the proportion of gas that does not pass through the absorbent with the bypass control at intermediate settings, if so equipped, and at the "on" setting.

b) The requirements for leakage (201.102.6) and resistance to flow rate (201.102.9.3) shall be met in the "on" and "off" positions and, if provided, any intermediate position of the bypass mechanism.

c) Indication of the absorbent bypass mechanism setting shall be *clearly legible* from the intended *operator*'s position.

d) A *circle absorber assembly* with an *operator*-controlled absorbent bypass mechanism shall permit changing the absorbent without opening the gas pathway to the atmosphere when the control is in the "off" position.

Check conformity by inspection, functional testing and the tests of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.

201.102.9.3 Resistance to flow rate

a) A *circle absorber assembly* not integrated into an *anaesthetic breathing system*, when assembled with other parts and *accessories* according to the instructions for use to form a complete *anaesthetic breathing system*, shall meet the resistance to flow rate requirements of 201.102.7.

b) The instructions for use shall describe the inspiratory and expiratory pressure/flow rate characteristics of the *circle absorber assembly*, including the pressure at 2,5 l/min, 15 l/min and 30 l/min.

Check conformity by the tests of 201.102.7 with the circle absorber assembly connected to each anaesthetic breathing system indicated in the instructions for use.

201.102.10 Inspiratory and *expiratory valves*

201.102.10.1 * Constructional requirements

a) Unless a means of indicating a malfunction is provided, *inspiratory* and *expiratory valves* shall be designed and located such that their action is visible to the *operator*. *Inspiratory valve*s and *expiratory valves* shall not be located in the *y-piece*.

b) The instructions for use shall disclose information as to how the *operator* can check the function of these valves.

Check conformity by inspection and functional testing as disclosed in the instructions for use.

201.102.10.2 Opening pressure

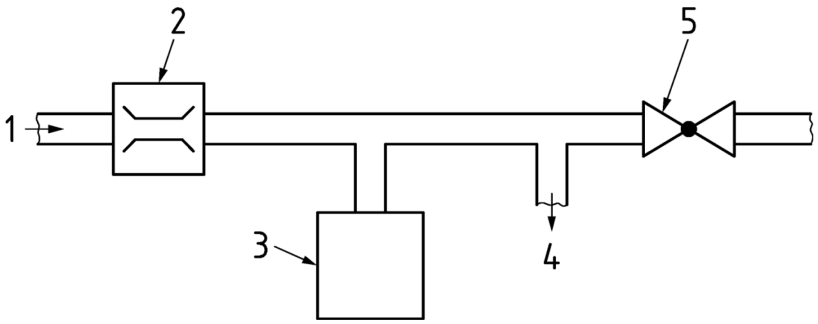
At a flow rate of 20 ml/min the pressure to open a dry valve shall not exceed 1,2 hPa (1,2 cmH_2O).

Check conformity with the following test or an equivalent:

a) *Utilize a flow rate-measuring device capable of indicating a flow rate of 60 ml/min, and a pressure-measuring device, accurate to within ±0,1 hPa (±0,1 cmH_2O) at a pressure of 15 hPa (15 cmH_2O).*

b) *Connect a pressure source on the upstream side of the valve and connect the pressure-measuring device to record the pressure generated at the input side of the valve, as shown in Figure 201.104.*

c) *Allow the valve to close and determine the opening pressure by adjusting the flow rate of gas to 20 ml/min and recording the peak pressure attained on the upstream side of the valve.*



Key

1 from pressure source
2 flow rate-measuring device
3 rigid container
4 to pressure-measuring device
5 *inspiratory* or *expiratory unidirectional valves*

Figure 201.104 — Arrangement for test of opening pressure of *inspiratory* or *expiratory valves*

201.102.10.3 Pressure flow-rate characteristics

For *inspiratory* and *expiratory valves* that are not integrated in the *anaesthetic breathing system*, the instructions for use shall disclose the pressure/flow-rate characteristics of the valves under both wet and dry conditions, including the pressure drop at a flow rate of 2,5 l/min, 15 l/min and 30 l/min.

Check conformity by inspection of the instructions for use and the following test or an equivalent:

a) Utilize a flow-rate-measuring device capable of indicating a flow rate of 2,5 l/min, 15 l/min and 30 l/min, and a pressure-measuring device, accurate to within ±0,1 hPa (±0,1 cmH_2O) at a pressure of 1,5 hPa (1,5 cmH_2O).

b) Connect the pressure source on the input side of the valve, connect the pressure-measuring device to record the pressure generated at the input side of the valve, and connect the flow-rate-measuring device between the pressure source and the pressure-measuring device. Adjust the flow rate to 2,5 l/min, 15 l/min and 30 l/min respectively. Record the pressure generated.

201.102.10.4 * Reverse flow rate and dislocation

The reverse flow rate through the *inspiratory* or *expiratory* valve shall not exceed 60 ml/min at a pressure up to 5,0 hPa (5,0 cmH_2O). The valve disc or flap shall not become dislocated on application of a reverse

pressure of 50 hPa (50 cmH_2O) and following the application of this pressure, the reverse flow rate through the *inspiratory* or *expiratory valve* shall not exceed 60 ml/min at a pressure up to 5,0 hPa (5,0 cmH_2O).

NOTE Typically the most significant reverse flow rate with disc-type valves is at pressures of less than 0,5 hPa (0,5 cmH_2O), whereas with flap valves it can be at a higher pressure.

Check conformity by functional testing.

201.102.11 * *Fresh-gas inlet*

An *operator*-accessible *fresh-gas inlet* should have a means to prevent unintentional disconnection of the *anaesthetic breathing system*.

In a *circle absorber assembly*, it is recommended that the *fresh-gas inlet* be placed between the absorbent container and the *inspiratory valve*.

201.102.12 Ventilation modes

An *anaesthetic breathing system* shall at least provide

a) manual ventilation by the means of a reservoir bag and an *adjustable pressure limit protection device*;

b) spontaneous breathing of the *patient*.

Check conformity by inspection.

201.103 Additional requirements for an *AGSS*

201.103.1 Identification, marking and documents

201.103.1.1 Marking

a) The *receiving system* of an *AGSS*, if physically discrete, shall have *clearly legible* marking that indicates its suitability for use with a high-flow-rate or low-flow-rate *disposal system*.

EXAMPLE 1 >75 l/min, high-flow-rate or <50 l/min, low-flow-rate.

b) If colour coding is used to identify parts and *accessories* as being specific for use with an *AGSS*, it shall be magenta.

EXAMPLE 2 10P hue/4/10 specified in Reference [27].

Check conformity by inspection.

201.103.1.2 Instructions for use

The instructions for use shall include the following:

a) a statement to the effect that the *AGSS* conforms with this document;

b) for *active AGSS*, the *rated* maximum disposal flow rate and *rated minimum disposal flowrate* of the *disposal system* with which the *transfer system* and *receiving system* are intended to be used.

Check conformity by inspection of the instructions for use.

201.103.2 Pressure relief *protection device*

The pressure relief *protection device*, if provided, shall be accessible for cleaning and/or servicing.

NOTE When the pressure relief *protection device* is actuated, gases can be spilled into the atmosphere.

Check conformity by inspection.

201.103.3 General requirements

201.103.3.1 *Normal condition*

201.103.3.1.1 *AGSS* inlet pressure

The pressure at the inlet to the *AGSS* shall not exceed 3,5 hPa (3,5 cmH_2O):

— with a flow of air of 75 l/min into the inlet of the *AGSS*;

— for an *active AGSS*, with the *rated minimum disposal flowrate* and the *rated maximum disposal flowrate* as indicated in the instructions for use.

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

201.103.3.1.2 *Induced flow rate* for *active AGSS*

The *induced flow rate* at the inlet to the *active AGSS* shall not exceed 50 ml/min at the *rated maximum disposal flowrate* indicated in the instructions for use of the *transfer* and *receiving system*.

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

201.103.3.1.3 Flow resistance for *active AGSS*

a) The pressure drop across a *low-flow transfer and receiving system* shall be

   — not less than 10 hPa (10 cmH_2O) at 50 l/min;

   — not greater than 20 hPa (20 cmH_2O) at 25 l/min.

b) The pressure drop across a *high-flow transfer and receiving system* shall be

   — not less than 10 hPa (10 cmH_2O) at 80 l/min;

   — not greater than 20 hPa (20 cmH_2O) at 50 l/min.

Check conformity by functional testing.

201.103.3.1.4 *Spillage* to atmosphere

Spillage to atmosphere shall not exceed 100 ml/min under the following conditions:

a) a breathing pattern in the *anaesthetic breathing system* or *anaesthetic ventilator* of

   — frequency of 20 cycles/min;

   — I:E ratio 1:1;

   — *tidal volume* of 1 l;

   — *fresh gas* flow of 10 l/min oxygen

b) for *active AGSS,* at the *rated minimum disposal flowrate* indicated in the instructions for use;

c) for *active AGSS* at *disposal flowrates* between 25 l/min and 50 l/min for a *low-flow transfer and receiving system*;

d) for *active AGSS* at *disposal flowrates* between 50 l/min and 80 l/min for a *high-flow transfer and receiving system*.

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

201.103.3.1.5 Leakage

The leakage of gas from the *transfer* and *receiving system* shall be less than 100 ml/min at a gas flow rate of (10 $\pm$ 0,5) l/min. The technical description shall describe how to measure the leakage of the *transfer* and *receiving system*.

NOTE 1 For an open reservoir system, the leakage cannot be measured directly. The value of leakage and *spillage* would be identical so the measured value for *spillage* is relevant for an open reservoir system.

NOTE 2 Leakage can be greater under *single fault condition*.

Check conformity by inspection of the technical description and testing according to the technical description.

201.103.3.2 *Single fault condition*

201.103.3.2.1 Pressure

Under *single fault conditions*, the pressure at the inlet to the *AGSS* shall not exceed 20 hPa (20 cmH_2O) with a *disposal flowrate* of 75 l/min.

Check conformity by functional testing.

201.103.3.2.2 *Induced flow rate* for *active AGSS*

Under *single fault conditions*, the *induced flow rate* at the inlet to the *AGSS* shall not exceed 500 ml/min at the *rated maximum disposal flowrate* indicated in the instructions for use of the *transfer system* and *receiving system*.

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

201.103.3.2.3 Subatmospheric pressure at the input of the *receiving system* for *active AGSS*

Under *single fault conditions*, the pressure at the input of the *receiving system* shall not be more than 0,5 hPa (0,5 cmH_2O) below ambient pressure at the *rated maximum disposal flowrate* indicated in the instructions for use of the *transfer* and *receiving system*.

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

201.103.4 Connectors

201.103.4.1 Hose connectors

Connectors fitted to hoses shall be permanently attached, i.e. not *operator*-detachable without the use of a *tool*.

Check conformity by inspection.

201.103.4.2 Connections between parts of *transfer systems* and *receiving systems*

Connectors between subassemblies of *transfer systems* and *receiving systems*:

a) shall be either:

— 30 mm conical connectors conforming with ISO 5356-1:2015; or

— designed to prevent mis-assembly;

b) shall not engage with:

— *terminal units* as specified in ISO 9170-1:2017 and ISO 9170-2:2008;

— *low-pressure hose assemblies* as specified in ISO 5359:2014+AMD1:2017;

— conical connectors conforming with ISO 5356-1:2015 or ISO 5356-2:2012+AMD1:2019, other than size 30 mm.

Check conformity by inspection and by application of the tests of ISO 5356-1:2015, ISO 5356-2:2012+AMD1:2019, ISO 5359:2014+AMD1:2017, ISO 9170-1:2017 and ISO 9170-2:2008.

201.103.4.3 Connections to diverting respiratory gas monitors

If provided, connectors on the *AGSS* intended for the scavenging of sample gas from a diverting respiratory gas monitor shall not engage with connectors according to ISO 80369-7:2016.

NOTE Attention is drawn to the ISO 80369 series.

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

201.103.5 *Transfer system*

201.103.5.1 Inlet

If an inlet connector of a *transfer system* is *operator*-detachable without the use of a *tool*, it shall be either

a) a 30 mm diameter socket conforming with ISO 5356-1:2015 and the *transfer system* shall include a means of pressure relief at the inlet, or

b) a proprietary connector that conforms with 201.103.4.2 b).

Check conformity by inspection and by application of the tests of ISO 5356-1:2015, ISO 5356-2:2012+AMD1:2019, ISO 5359:2014+AMD1:2017, ISO 9170-1:2017 and ISO 9170-2:2008, as applicable.

201.103.5.2 Outlet

If an outlet connector of a *transfer system* is *operator*-detachable without the use of a *tool*, it shall be either

a) a 30 mm diameter cone (male) conforming with ISO 5356-1:2015, or

b) a proprietary connector that conforms with 201.103.4.2 b).

Check conformity by inspection and by application of the tests of ISO 5356-1:2015, ISO 5356-2:2012+AMD1:2019, ISO 5359:2014+AMD1:2017, ISO 9170-1:2017 and ISO 9170-2:2008, as applicable.

201.103.6 *Receiving system*

201.103.**6.1** Inlet connectors

If an inlet connector of a *receiving system* is *operator*-detachable without the use of a *tool*, it shall be **either**

a) a 30 mm diameter socket (female) conforming with ISO 5356-1:2015, or

b) a proprietary connector that conforms with 201.103.4.2 b).

Check conformity by inspection and by application of the tests of ISO 5356-1:2015, ISO 5356-2:2012+ AMD1:2019, ISO 5359:2014+AMD1:2017, ISO 9170-1:2017 and ISO 9170-2:2008, as applicable.

201.103.6.2 * Outlet connectors

If the outlet connector is *operator*-detachable without the use of a *tool*, it shall be either

a) a connector 1L conforming with ISO 9170-2:2008, for a *low-flow transfer and receiving system*, or

b) a connector 1H conforming with ISO 9170-2:2008, for a *high-flow transfer and receiving system*.

NOTE In some countries, alternative designs with equivalent levels of *risk control* are required.

Check conformity by inspection and by application of the tests of ISO 9170-2:2008.

201.103.6.3 Hoses

If hoses are used in the *receiving system* to connect to the *disposal system*, they shall conform with the following requirements for vacuum services:

— resistance to kinking, as specified in ISO 5359:2014+AMD1:2017, 4.6.6;

— resistance to occlusion, as specified in ISO 5359:2014+AMD1:2017, 4.6.4.

Check conformity by inspection and by application of the tests of ISO 5359:2014+AMD1:2017 using the conditions specified in ISO 5359:2014+AMD1:2017, 5.1.

201.103.6.4 Particle filter for *active AGSS*

If provided, a particle filter shall be located on the *disposal system* side of the *receiving system*. It shall be *operator*-detachable without the use of a *tool*.

Check conformity by inspection.

201.103.7 *Transfer systems* and *receiving systems* with integral *power device* for *active AGSS*

If the *power device* is an integral part of the *transfer system* or *receiving system*, the *power device* shall conform with the applicable requirements of ISO 7396-2:2007 and the outlet of the *receiving system* or the *disposal hose* shall be a Type 2 connector as specified in ISO 9170-2:2008.

Check conformity by application of the tests of ISO 7396-2:2007 and ISO 9170-2:2008.

201.103.8 Visual indicator for *active AGSS*

The *AGSS* shall visually indicate when the *disposal flowrate* is within the appropriate range for the *transfer* and *receiving system*.

EXAMPLE Quantitative information such as flow rates or pressure values or qualitative devices such as reservoir bags filling and discharging or go/no-go indicators.

Check conformity by inspection.

201.104 Additional requirements for interchangeable and non-*interchangeable anaesthetic vapour delivery systems*

201.104.1 Identification, marking and documents

201.104.1.1 * Marking

a) Unless the *anaesthetic vapour delivery system* is an integral part of the *anaesthetic workstation*, the *anaesthetic vapour delivery system* shall be marked with the safety sign for the mandatory action: "follow instructions for use", ISO 7010-M002 (see IEC 60601-1:2005/COR1:2006, Table D.2, number 10). Such marking shall be *clearly legible* from the intended *operator's* position.

b) The control activating the delivery of a specific vapour of a volatile anaesthetic agent shall be marked with the generic name in full spelling or in abbreviated form as given in the following list:

— Desflurane – "DES"

— Enflurane – "ENF"

— Halothane – "HAL"

— Isoflurane – "ISO"

— Sevoflurane – "SEV"

c) If colour coding is used, it shall be in accordance with ISO 5360:2016.

d) Either the maximum and minimum filling levels shall be marked on the liquid level indicator, or the actual usable volume shall be displayed.

Check conformity by inspection.

201.104.1.2 Instructions for use

The instructions for use shall include the following:

a) a statement to the effect that the *anaesthetic vapour delivery system* conforms with this document;

b) a statement to the effect that an *anaesthetic workstation* used with this *anaesthetic vapour delivery system* needs to conform with this document;

c) a statement to the effect that the *anaesthetic vapour delivery system* is to be used with halogenated anaesthetic agent *monitoring equipment* conforming with ISO 80601-2-55:2018;

d) a statement to the effect that the *anaesthetic vapour delivery system* is to be used with an *anaesthetic gas delivery system* conforming with this document;

e) a statement to the effect that the *anaesthetic vapour delivery system* is to be used with an *AGSS* conforming with this document;

f) the performance of the *anaesthetic vapour delivery system* including the effects of variation in ambient temperature, ambient pressure, resistance, tilting, back pressure, subatmospheric pressure, input flow rate and gas composition over the range of operating conditions specified in the instructions for use;

g) the carrier gas, gas flow rate(s) and analytical technique(s) recommended for measuring the output of the *anaesthetic vapour delivery system*;

h) a statement to the effect that the vaporizer should not be used between zero and the first calibration, if applicable;

i) the volume at the maximum and minimum fill levels and the total capacity.

Check conformity by inspection of the instructions for use.

201.104.2 Delivered vapour concentration

201.104.2.1 Controls

a) The control of an *anaesthetic vapour delivery system* shall be vapour concentration calibrated for each intended *anaesthetic gas*.

b) The set concentration as well as the units of measurement shall be marked on the *anaesthetic vapour delivery system* or its display for the calibrated range.

c) It shall not be possible to set the control above the calibrated range.

d) The controls shall be marked with "0" or "Off", or with both, if the "0" position is not also the "Off" position, or with "Standby" if "Off" is not provided.

e) If a rotary control is provided, the *anaesthetic gas* concentration shall increase when the control is turned anticlockwise.

f) Means to prevent the unintentional operation of the *anaesthetic vapour delivery system* control shall be provided.

NOTE 1 Electronic flow adjustment controls being part of an electrical graphical human interface can have a different convention to be consistent throughout the *anaesthetic workstation*.

NOTE 2 When the *anaesthetic vapour delivery system* is marked with "Off" or "Standby" this indicates that no anaesthetic vapour is intentionally being added to the output flow. "Standby" on an electrically operated *anaesthetic vapour delivery system* indicates that the *anaesthetic vapour delivery system* is enabled. "0" indicates that no more than the prescribed tolerance as indicated in the instructions for use is being added to the output flow.

Check conformity by inspection and functional testing

201.104.2.2 * Accuracy

When the *anaesthetic vapour delivery system* is tested with the carrier gas and the analytical technique recommended in the instructions for use [see 201.104.1.2 g)]:

— the delivered concentration at all graduations other than "Off", "standby", or the "0" position if this is also the "Off" position, from the *anaesthetic vapour delivery system* shall not deviate by more than +30 % or −20 % from the concentration setting or by more than +7,5 % or −5 % of the maximum setting, whichever is greater;

— the delivered concentration when the *anaesthetic vapour delivery system* control is in the "Off" position, the "standby" position or the "0" position if this is also the "Off" position, shall not exceed 0,1 % volume fraction.

Check for conformity by visual inspection, functional testing and with the following test.

a) *Test the anaesthetic vapour delivery system on a calibrated test rig capable of supplying the necessary gas flow rates and pressures required by the test conditions, or on an anaesthetic workstation, with the anaesthetic ventilator and anaesthetic breathing system recommended in the instructions for use.*

b) *Connect an anaesthetic vapour analyser to the fresh-gas outlet of the anaesthetic workstation. If there is no fresh-gas outlet connect it to the inlet of the anaesthetic breathing system, or if applicable, to the inspiratory port of the anaesthetic ventilator. Ensure that the parts downstream of the anaesthetic vapour delivery system do not affect the test results, for example, either by absorbing the volatile anaesthetic agents, by causing delays in the response time, or by leakage.*

c) *Place the calibrated test rig or the anaesthetic workstation, as applicable, with the specified test equipment and volatile anaesthetic agent in the test room for at least 3 h at (20 $\pm$ 3) °C and maintain this temperature throughout the test.*

d) *Fill the anaesthetic vapour delivery system with the appropriate liquid anaesthetic agent to approximately half of the maximum usable volume, and leave it to stand for at least 45 min.*

e) *If the instructions for use recommend that when power is applied to the anaesthetic vapour delivery system, a warm-up period be allowed before use, apply power for at least that period before continuing. This period may be within the 45 min mentioned in d).*

f) *With the anaesthetic vapour delivery system control in the "Off", "0" or, if applicable, the "Standby" position, set the gas flow rate through the anaesthetic workstation to (2 $\pm$ 0,2) l/min and adjust the anaesthetic ventilator to give (15 $\pm$ 2) breaths/min at an I:E ratio of 1:2 $\pm$ 20 % with the inspiratory flow rate control set to maximum. For an anaesthetic workstation in which the fresh gas flow rate is determined by the anaesthetic ventilator settings, set the anaesthetic ventilator to give a minute volume of (2 $\pm$ 0,2) l.*

g) *Introduce a maximum pressure fluctuation of (20 $\pm$ 3) hPa [(20 $\pm$ 3) cmH_2O], above ambient, at the fresh-gas outlet ensuring that the decay time during the expiration period (from 100 % of the fresh-gas outlet pressure at the end of the inspiration period to 33 % of this pressure) is less than 0,6 s.*

NOTE This can be achieved by using a test lung having a compliance of 20 ml/hPa and an appropriate resistance.

h) *Maintain the pressure fluctuations for 3 min and after that time measure the concentration of anaesthetic vapour delivered over a further 1 min period while maintaining the pressure fluctuation. Calculate the average vapour concentration in the total delivered gas flow.*

i) *Repeat f) to h) with the anaesthetic vapour delivery system set to each of the other settings and in the order given in Table 201.105. If the anaesthetic vapour delivery system is not marked with the concentration settings given in Table 201.105, use the nearest settings on the anaesthetic vapour delivery system. If any setting given in Table 201.105 is equidistant between settings on the anaesthetic vapour delivery system, use the lower setting on the anaesthetic vapour delivery system.*

Table 201.106 — Settings to be used for testing delivered concentration

Order of test	Setting (%volume fraction of anaesthetic vapour)
1	off, standby, and zero, if separately marked
2[a]	lowest graduation above zero
3	10 % FS
4	20 % FS
5	50 % FS
6	75 % FS
7	maximum graduation (full scale)

[a] If 10 % of full scale (FS) is the lowest graduation, step 2 is omitted.

j) *Repeat f) to i) using a fresh gas flow rate of (8 ± 0,8) l/min and a pressure fluctuation at the fresh-gas outlet of (50 ± 4) hPa [(50 ± 4) cmH_2O]. For an anaesthetic workstation in which the fresh gas flow rate is determined by the anaesthetic ventilator settings, set these to give a minute volume of (8 ± 0,8) l.*

201.104.3 * Vapour concentration during and after oxygen flush

During and after oxygen flush, the anaesthetic vapour concentration delivered by the *anaesthetic vapour delivery system* shall not increase by more than 20 %.

a) For interchangeable anaesthetic vapour delivery systems, check conformity with the following test:

1) Set up the interchangeable anaesthetic vapour delivery system according to 201.104.2.2 a) through e).

— *Set the fresh gas flow rate through the interchangeable anaesthetic vapour delivery system to (8 ± 0,8) l/min.*

— *To simulate activation of the O_2 flush, apply a steady pressure at the anaesthetic vapour delivery system outlet of (100 ± 5) hPa [(100 ± 5) cmH_2O] for 10 s.*

— *Measure the concentration at the outlet for 1 min before, during the application of the pressure and for 30 s after relief of the pressure.*

— *Repeat this for each of the settings given in Table 201.105.*

2) Set up the interchangeable anaesthetic vapour delivery system according to 201.104.2.2 a) through e).

— *To simulate activation of the O_2 flush, apply a steady subatmospheric pressure of 100 hPa (100 cmH_2O) for 10 s.*

— *Measure the concentration at the outlet for 1 min before, during the application of the pressure and for 30 s after relief of the pressure.*

— *Repeat this for each of the settings given in Table 201.105.*

b) For non-interchangeable anaesthetic vapour delivery systems, check conformity with the following test:

— *Set up the anaesthetic workstation according to the instructions for use.*

— *Set the fresh gas flow rate to (8 ± 0,8) l/min.*

— *Activate the O_2 flush for 10 s.*

— *Measure the concentration at the fresh-gas outlet for 1 min before, during activation of the O_2 flush and for 30 s after releasing the O_2 flush.*

NOTE Concentration values can be filtered with a 5 s moving average for evaluation.

— *Repeat this for each of the settings given in Table 201.105.*

201.104.4 Connectors

If a conical connector that is *operator*-detachable without the use of a *tool* is used at the inlet or outlet of an *anaesthetic vapour delivery system*, it shall be 23 mm in size conforming with ISO 5356-1:2015. The connector at the inlet shall be a cone and that at the outlet shall be a socket (female). Any other means of connection for an *anaesthetic vapour delivery system* shall ensure that the *anaesthetic vapour delivery system* can only be fitted so that the gas flow through it is in the intended direction.

Check conformity by visual inspection and by application of the tests of ISO 5356-1:2015.

201.104.5 Cross-contamination

For an *anaesthetic workstation* capable of delivering more than one vapour of a volatile anaesthetic agent, means shall be provided to prevent the simultaneous delivery of more than one vapour of a volatile anaesthetic agent to the *fresh gas* and to prevent cross-contamination of the content of one *anaesthetic vapour delivery system* with a vapour of another volatile anaesthetic agent.

See also 201.101.3.

Check conformity by inspection and functional testing.

201.104.6 *Anaesthetic vapour delivery system* filling

a) The filling port shall be marked with the generic name of the anaesthetic agent in full spelling or in abbreviated form as specified in 201.104.1.1.

b) Means to prevent filling the *anaesthetic vapour delivery system* with the incorrect liquid anaesthetic agent shall be provided. If a rectangular agent-specific keyed filling system is used, it shall conform with ISO 5360:2016.

c) The volume of liquid anaesthetic agent required to fill the reservoir of the *anaesthetic vapour delivery system* to the maximum filling level, and the total capacity shall be disclosed in the instructions for use. The anaesthetic agent bottle may be used as the anaesthetic agent reservoir.

d) In *normal use*, it shall not be possible to overfill the *anaesthetic vapour delivery system* such that

   1) its performance is affected, or

   2) the fluid level is no longer evident.

Check conformity by inspection, functional testing and application of the tests of ISO 5360:2016.

201.104.7 Packaging of *anaesthetic vapour delivery system* parts and accessories

Anaesthetic vapour delivery system parts and *accessories* shall be packaged in such a way as to reduce the *risk* of the incomplete removal of the packaging before use to acceptable levels.

NOTE This is to prevent accidental retention of the packaging, e.g. transparent wrapper, caps, lids, covers, and to ensure its removal by the *operator* prior to use.

Check conformity by inspection.

201.105 Additional requirements for an *anaesthetic ventilator*

201.105.1 Instructions for use

The instructions for use shall include the following:

a) a statement to the effect that the *anaesthetic ventilator* conforms with this document;

b) a statement to the effect that the *anaesthetic ventilator* is intended to be used with an *anaesthetic breathing system* that conforms with this document;

c) unless the *anaesthetic ventilator* is an integral part of the *anaesthetic workstation*, information on how to connect to an *anaesthetic workstation* and *anaesthetic breathing system*;

d) the operational characteristics of the *anaesthetic ventilator* including, where applicable, the following:

1) range of *delivered volumes* (tidal and minute);

2) range of cycling frequency,

3) range of I:E ratios,

4) range of values that can be set as the maximum pressure at the *patient connection port* during *normal use* in the inspiratory phase and the means by which that maximum pressure is ensured (e.g. pressure cycling, pressure limitation),

5) inspiratory flow rate and pressure characteristics,

6) ventilation modes,

7) the minimum *airway pressure* (during *normal use* and under *single fault condition*),

NOTE This minimum pressure can be subatmospheric.

8) PEEP range,

9) if there is a facility for subatmospheric pressure in the *expiratory hold*, the limiting pressure and generated pressure,

10) characteristics of the means used for initiation of the *inspiratory hold*, e.g. *patient- trigger event*,

11) interdependence of controls,

12) if applicable, a statement that the *anaesthetic ventilator* compensates for *anaesthetic breathing system* compliance and a description of the method of this compliance compensation;

e) any restrictions on the location and/or sequence of parts within the *anaesthetic breathing system* as they relate to the *anaesthetic ventilator*;

EXAMPLE Where such components are flow-direction-sensitive.

f) the range of internal volume of any *anaesthetic breathing system accessories* or other parts or subassemblies recommended by the *manufacturer*;

g) for an *anaesthetic ventilator* supplied separately, a statement to the effect that the *anaesthetic workstation* is to be provided with an *airway pressure monitoring equipment* conforming with this document (see 201.12.4.109) before being put into service and a description on how to connect that component.

Check conformity by inspection of the instructions for use.

201.105.2 Pressure limitation *protection device*

NOTE The *anaesthetic workstation* is expected to have one *maximum limited pressure protection device* and one *adjustable pressure limit protection device* which can be located either in the *anaesthetic breathing system* or in the *anaesthetic ventilator* (see 201.102.2.1, 201.102.2.2, 201.105.2.1 and 201.105.2.2).

201.105.2.1 *Maximum limited pressure protection device*

a) A *protection device* shall be provided to prevent the *airway pressure* from exceeding the *maximum limited pressure* under both:

1) *normal condition*; and

2) *single fault condition*.

b) The *maximum limited pressure* shall not exceed the higher of:

1) 20 hPa (20 cmH_2O) more than the set *inspiratory pressure* but limited to 125 hPa (125 cmH_2O); or

2) 90 hPa (90 cmH_2O).

NOTE 1 This set *inspiratory pressure* can be e. g. the *inspiratory pressure* setting for pressure-controlled ventilation modes or the maximum pressure setting for volume-controlled ventilation modes.

c) A reservoir bag conforming with ISO 5362:2006 may be used for the s*ingle fault condition* pressure limitation *protection device* for an *anaesthetic workstation* without an *anaesthetic ventilator*, or when the *anaesthetic ventilator* is in a manual or spontaneous ventilation mode.

NOTE 2 The pressure limitation effect of a reservoir bag conforming with ISO 5362:2006 has a *nominal* value of 55 hPa (55 cmH_2O).

Check conformity by functional testing.

201.105.2.2 * *Adjustable pressure limit protection device*

a) The *anaesthetic ventilator* shall either

1) be equipped with an *adjustable pressure limit protection device* to limit the pressure at the *patient connection port* to an *operator*-adjustable pressure, or

2) if not so equipped, the instructions for use of the *anaesthetic ventilator* shall contain a statement to the effect that the *anaesthetic breathing system* is to be provided with a *protection device* to limit the pressure at the *patient connection port* to an *operator*-adjustable pressure conforming with this document before the *anaesthetic workstation* is put into service and shall describe how to connect that component to the *anaesthetic workstation* available (e.g. in integration instructions) upon request.

b) The *adjustable pressure limit protection device* shall

1) ensure that the pressure at the *patient connection port* does not exceed the maximum *operator*-set value by more than 15 % or 10 hPa (10 cmH_2O), whichever is greater, in *normal condition*.

2) be capable of releasing the maximum flow that can be delivered by an O_2 flush without exceeding the limits as given above.

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

201.105.3 Activation of automatic ventilation

If the *anaesthetic ventilator* is integral to the *anaesthetic workstation*, only one control shall be provided to change from automatic ventilation to spontaneous or manually assisted breathing and vice versa.

Check conformity by functional testing.

201.105.4 *Anaesthetic breathing system* port connector

If a conical *operator*-accessible port that connects the *anaesthetic ventilator* to the *anaesthetic breathing system* is provided, that port shall be a 22 mm cone (male) connector conforming with ISO 5356-1:2015 or ISO 5356-2:2012+ AMD1:2019.

Check conformity by application of the tests of ISO 5356-1:2015 or ISO 5356-2:2012+ AMD1:2019.

201.105.5 Interruption of the electrical or pneumatic *power supply*

a) The *anaesthetic ventilator* shall either

1) be so designed that in the event of an electrical or pneumatic *power supply* failure, the supply of *fresh gas* to the *anaesthetic breathing system* is either unaffected, or

2) an alternative means of *fresh gas* delivery is available. The status of flow delivery of the alternative *fresh gas* delivery shall be indicated at any time.

EXAMPLE An external flow-metering device directly connected to the *medical gas* supply.

b) Under *power supply* failure conditions, it shall be possible to ventilate the *patient* manually. This may be achieved with an *operator*-powered *resuscitator*. See e. g. ISO 10651-4.

c) Under *power supply* failure conditions, *operator* actions necessary to ensure the continued supply of *fresh gas* to or ventilation of the *patient* shall be disclosed in the instructions for use. *Verification* of these capabilities shall be included in the pre-use checklist (see 201.7.9.2.8).

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

201.105.6 *Exhaust port* connector

If an *exhaust port* connector is *operator*-detachable without the use of a *tool*, the *exhaust port* connector shall be:

a) marked with the word “exhaust” or “AGS” or the equivalent in a language that is acceptable to the intended *operator* or an appropriate symbol;

b) one of the following:

1) for an *anaesthetic ventilator* intended to connect to an *AGSS* conforming with 201.103, a 30 mm cone conforming with ISO 5356-1:2015 with means to prevent connection of the orifice to any *anaesthetic breathing system* port or *anaesthetic ventilator* port or component port, or

2) a proprietary connector that does not engage with connectors conforming with ISO 5356-1:2015 and *breathing tubes* conforming with ISO 5367:2014.

Check conformity by inspection, functional testing and application of the tests of ISO 5356-1:2015 and ISO 5367:2014.

201.105.7 * Timed ventilatory hold

201.105.7.1 *Expiratory hold*

An *anaesthetic ventilator* may be equipped with an *operator*-controlled means to hold the *anaesthetic ventilator* in expiration.

The following applies to an *expiratory hold*.

a) The *expiratory-hold time* may be *operator*-configurable or *operator*-adjustable.

b) More than one *expiratory hold* function may be provided.

c) During the *expiratory hold*, any apnoea-related ventilatory *alarm condition* that would be caused by this *expiratory hold* shall be automatically *audio paused* or *alarm paused* for the *expiratory-hold time*.

d) In addition to the requirements for *alarm signal* inactivation of IEC 60601-1-8:2006+AMD1:2012, 6.8.5, the *anaesthetic ventilator* shall indicate the presence of the *expiratory hold* with an *information signal* or *low priority alarm condition*.

e) The normal *expiratory-hold time* shall not exceed 60 s. Increasing this time to a maximum of 120 s shall require a deliberate second action of the *operator* and shall not be configurable as a default holdtime.

f) A means may be provided to initiate the *expiratory hold* from a *signal input part/signal output part*. The *anaesthetic ventilator* should communicate information related to the *expiratory hold* via a *network/data coupling*.

NOTE 1 An *expiratory hold* can be equivalent to placing the *anaesthetic ventilator* into manual or spontaneous ventilation and automatically resuming automatic ventilation after a predetermined duration.

NOTE 2 The *expiratory hold* can be used to synchronize radiographic imaging with a deflated lung.

Check conformity by inspection and functional testing.

201.105.7.2 *Inspiratory hold*

An *anaesthetic ventilator* may be equipped with an *operator*-controlled means to hold automatic ventilation at end-inspiration.

The following applies to an *inspiratory hold* function.

a) The *inspiratory-hold time* may be non-adjustable, *responsible organization*-configurable or *operator*-adjustable.

b) The high-pressure *alarm condition* of 201.12.4.109 and the *protection device* of 201.105.2 shall remain active during an *inspiratory hold*.

c) More than one *inspiratory hold* function may be provided.

d) During the *inspiratory hold*, any apnoea or sustained *airway pressure alarm condition* that would be caused by this *inspiratory hold* should be *audio paused* or *alarm paused* for the *inspiratory-hold time*.

e) In addition to the requirements for *alarm signal* inactivation of IEC 60601-1-8:2006+AMD1:2012, 6.8.5, the *anaesthetic ventilator* shall indicate the presence of the *inspiratory hold* with an *information signal* or *low priority alarm condition*.

f) The maximum *inspiratory-hold time* of a non-adjustable *inspiratory hold* shall be 10 s; the maximum allowable *inspiratory-hold time* of a configurable or adjustable *inspiratory hold* shall be 40 s.

g) A means may be provided to initiate the *inspiratory hold* from a *signal input part/signal output part*. The *anaesthetic ventilator* should communicate information related to the *inspiratory hold* via a *network/data coupling*.

NOTE The *inspiratory hold* can be used to synchronize radiographic imaging with lung inflation or for recruitment.

Check conformity by inspection and functional testing.

201.105.8 * Subatmospheric pressure

a) A *high priority alarm signal* shall be activated when the *airway pressure* falls 10 hPa (10 cmH_2O) below atmospheric pressure for more than 1 s.

Check conformity by functional testing.

b) The *anaesthetic ventilator* shall continue to function normally after application of negative pressure.

Check conformity by the following test.

1) Connect a suction system (9), as shown in Figure 201.104, leaving the patient connection port (4) of the closed-suction catheter adaptor (5) open to air and the anaesthetic ventilator disconnected. Utilize a closed-suction catheter (6) of minimum inside diameter of 2,95 mm [French (Charriere) equivalent size 14 F].

2) Adjust the suction equipment as follows:

— *Close the flow control valve (7) and adjust the vacuum regulator of the suction equipment to an occluded vacuum of 200 hPa (200 cmH_2O) below ambient atmospheric pressure.*

— *Open and set the flow control valve (7) to give a free air flow (suction flow) of:*

i) 30 l/min, for an anaesthetic ventilator intended to provide a delivered volume, $V_{del} \geq 300$ ml;

ii) 15 l/min, for an anaesthetic ventilator intended to provide a delivered volume, 300 ml ≥ $V_{del} \geq 50$ ml;

iii) *5 l/min, for an anaesthetic ventilator intended to provide a delivered volume, $V_{del} \leq 50$ ml.*

3) Disable the suction flow without affecting the flow control valve setting.

4) Connect the anaesthetic ventilator to an anaesthetic breathing system conforming with this document as shown in Figure 201.105 and as indicated in the instructions for use. Connect the anaesthetic breathing system to the closed-suction catheter adaptor as shown in Figure 201.105

5) Connect a test lung to the patient connection port of the closed-suction catheter adaptor. Utilize a test lung with compliance:

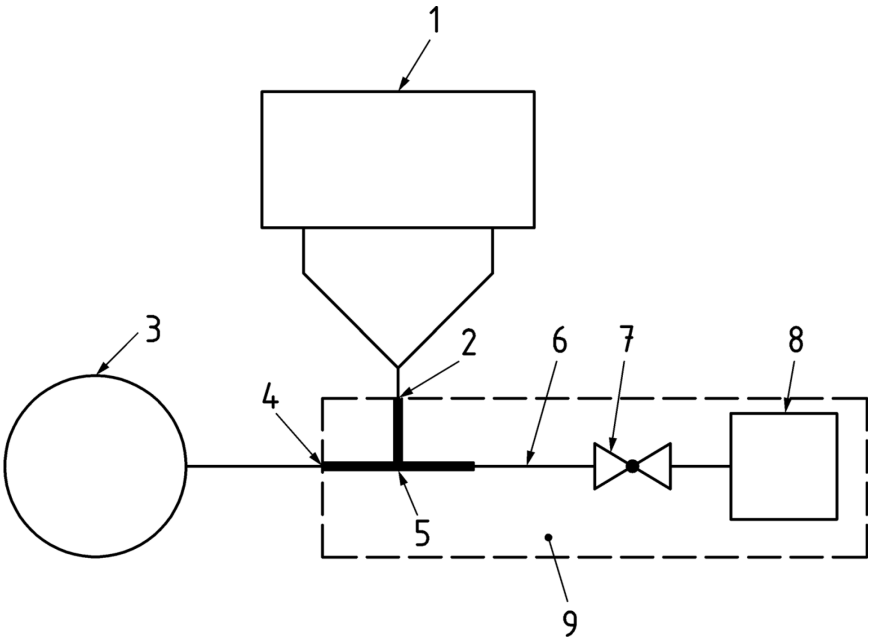
— *10 ml/hPa $\pm$ 10 %, for an anaesthetic ventilator intended to provide a delivered volume, $V_{\mathrm{del}} \geq 300$ ml;*

— *3 ml/hPa ± 10 %, for an anaesthetic ventilator intended to provide a delivered volume, 300 ml ≥ V_{del} ≥ 50 ml;*

— *0,5 ml/hPa ± 10 %, for an anaesthetic ventilator intended to provide a delivered volume, V_{del} ≤ 50 ml.*

6) Do not enable any special suction procedure mode and retract the closed-suction catheter.

7) Perform any Compliance correction as indicated in the instructions for use.



Key
1 *anaesthetic ventilator* under test
2 *patient connection port* of an *anaesthetic breathing system* before adding the closed-*suction catheter* adaptor
3 test lung
4 *patient connection port* of an *anaesthetic breathing system* after adding the closed-*suction catheter* adaptor
5 closed-*suction catheter* adaptor
6 2,95 mm (14 F) closed-*suction catheter* conforming with ISO 8836:2019
7 flow control valve (can be incorporated in 8)
8 *suction* equipment conforming with ISO 10079-1:2015+AMD1:2018 or ISO 10079-3:2014
9 *suction* system

Figure 201.105 — Typical closed-suctioning test setup

8) Select a volume-controlled breath type with the following parameters:

— *minimum delivered volume for the intended delivered volume range;*

— *ventilatory frequency of 10 min^{-1};*

— *trigger off or, if not so equipped, the most insensitive method and setting.*

9) Wait until stability is achieved.

10) Advance the closed-suction catheter between 1 cm and 2 cm beyond the patient connection port (4).

11) *Enable the flow control valve (7), without affecting the flow control valve setting, and maintain for 30 s.*

NOTE 1 Some *alarm conditions* might become active and this is an expected possibility.

12) *Terminate the suction flow by closing the flow control valve (7) and retract the suction catheter.*

NOTE 2 Retracting the *suction catheter* into its supplied sleeve can be important to seal the gas pathway and reduce gas leakage.

13) *Wait until stability is achieved.*

14) *Verify that the anaesthetic ventilator continues to function as intended.*

EXAMPLE The *delivered volume* is within specification.

15) *Repeat 1) to 14) for each intended delivered volume range.*

16) *Repeat 1) to 15) using a pressure-controlled breath type with the following parameters in lieu of 8):*

— *ventilation pressure of 5 hPa (5 cmH_2O) or if the anaesthetic ventilator cannot be set that low, the lowest setting;*

— *ventilatory frequency of 10 min^{-1};*

— *trigger off or, if not so equipped, the most insensitive setting.*

17) *Repeat 1) to 15) using the recommended ventilation mode and settings for use with a closed-suction catheter in lieu of 8) unless the recommended ventilation mode and settings have already been tested.*

201.106 Display of pressure-volume loops

If an *anaesthetic workstation* is provided with the display of pressure-volume loops, the loop graph shall have:

— *delivered volume* on the vertical axis;

— *airway pressure* on the horizontal axis.

Positive values shall be represented to the top and the right of the display. Increases in *delivered volume* shall be represented as a positive value. The volume shall be reset to the origin at the beginning of each breath.

NOTE During controlled ventilation the loop will move anticlockwise. During spontaneous breathing the loop will move clockwise.

Check conformity by inspection.

201.107 Clinical evaluation

A clinical evaluation shall be performed and documented.

Check conformity by inspection of the manufacturer's documentation.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014+AMD1:2020 applies.

203 General requirements for radiation protection in diagnostic X-ray equipment

IEC 60601-1-3 does not apply.

206 *Usability*

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 applies except as follows:

206.6.2.2.2 *Primary operating functions*

Addition

For the *anaesthetic workstation* and its individual components, if provided, the following shall be considered *primary operating functions*:

aa) observing monitored ventilation parameters such as *airway pressure*s and volumes;

bb) observing respiratory gas concentrations such as inspired oxygen concentration (FiO_2), end-tidal carbon dioxide ($etCO_2$) and anaesthetic agent concentration;

cc) setting volatile anaesthetic agent concentration;

dd) setting *fresh gas* flow and concentration;

ee) operating the O_2 flush;

ff) manually ventilating the *patient*;

gg) setting the *operator*-adjustable *airway pressure* control;

hh) setting *alarm limits*;

ii) inactivating *alarm signals;*

jj) switching between ventilation modes;

kk) setting ventilation control parameters;

EXAMPLE *Set rate*, *tidal volume*, *inspiratory pressure* settings

ll) suctioning the *patient*;

mm) connecting the *patient* to the *patient connection port*;

nn) starting the *anaesthetic workstation* from power off;

oo) starting the *anaesthetic workstation* from standby mode;

pp) starting the *anaesthetic ventilator*;

qq) connecting the *anaesthetic breathing system* to the *fresh-gas outlet*;

rr) if present, operation of a *fresh-gas outlet* switch (not more than one functional *fresh-gas outlet*);

ss) operation of the hypoxic mixture delivery selection *protection device*.

208 General requirements, tests and guidance for *alarm systems* in *medical electrical equipment* and *medical electrical systems*

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 applies except as follows:

208.5.2.2 * Technical description

Addition

The technical description shall include:

— a list of *alarm systems* and *alarm conditions* to be tested by the *operator*;

— the methods of verifying their correct function, e.g. by a built-in self test;

— the recommended frequency of *verification*.

208.6.8.3 * Global indefinite *alarm signal* inactivation states

Addition:

An *anaesthetic workstation* and its individual components shall not be equipped with a means to initiate a global *alarm off* while connected to a *patient*.

208.6.8.4 * Termination of inactivation of *alarm signals*

Addition:

The duration of *audio paused* for the *high priority alarm condition*s required by this document shall not exceed 120 s without *operator* intervention.

Other priority *alarm conditions* (*low* and *medium priority alarm conditions*) may have longer *audio paused* durations.

208.6.12 * *Alarm system* logging

Amendment:

Replace the introductory sentence to the list by the following:

An *alarm system* shall be equipped with an *operator alarm system* log for at least *high priority* and *medium priority alarm conditions* and should be equipped with a *responsible organization alarm system* log.

NOTE This logging can be *operator*-configurable.

209 Requirements for environmentally conscious design

IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 does not apply.

210 *Process* requirements for the development of physiologic closed-loop controllers

IEC 60601-1-10:2007+AMD1:2013+AMD2:2020 applies.

211 Requirements for *medical electrical equipment* and *medical electrical systems* used in the home healthcare environment

IEC 60601-1-11:2010 does not apply.

212 Requirements for *medical electrical equipment* and *medical electrical systems* intended for use in the *emergency medical services environment*

For an *anaesthetic workstation* to be used in an *emergency medical services environment*, IEC 60601-1-12:2014+AMD1:2020 applies.

The annexes of IEC 60601-1:2005+AMD1:2012+AMD2:2020 apply, except as follows.

Annex C
(informative)

Guide to marking and labelling requirements for *ME equipment* and *ME systems* or their parts

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

Addition:

201.C.1 Marking on the outside of *ME equipment* and *ME systems* or their parts

Additional requirements for marking on the outside of the *anaesthetic workstation* and its individual components, parts and *accessories* are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of the *anaesthetic workstation* and its individual components, parts and *accessories*

Description of marking	Subclause
For the *anaesthetic workstation* and its individual components, marking with the safety sign for the mandatory action: "follow instructions for use", ISO 7010-M002 (see IEC 60601-1:2005/COR1:2006, Table D.2, number 10)	201.7.2.3
For the *anaesthetic workstation* and its *operator*-detachable components, or their packaging, marking with: — the year of manufacture or — if applicable, use-by date (symbol 5.1.4 in ISO 15223-1:2016)	201.7.2.101, a) b)
For an *operator*-accessible *gas-specific* inlet and outlet, the gas name or chemical symbol in accordance with ISO 5359:2014+AMD1:2017, Table 6; if colour coding is used, conformity with ISO 5359:2014+AMD1:2017, Table 6	201.7.2.102
For *operator*-accessible gas *power supply* outlets, the *rated* output pressure and *rated* flow rate	201.7.2.103
If relevant, marking of parts and *accessories* of the *anaesthetic workstation* or its individual components that are in contact with gas to be inhaled by the *patient* and that contain phthalates, which are known to be carcinogenic, mutagenic or toxic to reproduction (see symbol in EN 15986)	201.7.2.104
For cylinder and pipeline pressure indicators, identification of the gas name or chemical symbol in accordance with ISO 5359:2014+AMD1:2017, Table 6; if colour coding is used, conformity with ISO 5359: 2014+AMD1:2017, Table 6	201.7.2.105
The direction of the movement of a moving part where the direction of movement needs to be known in order to avoid a *hazardous situation*	201.9.2.1
For non-metallic parts made of antistatic or conductive materials, the *clearly legible* word "antistatic" or "conductive" or the equivalent in a language that is acceptable to the intended *operator*; these non-metallic parts may additionally bear an indelible yellow coloured mark	201.102.1.1.1
Unless the *circle absorber assembly* is an integral part of the *anaesthetic breathing system*, marking of the inspiratory and expiratory ports of a *circle absorber assembly* to indicate the intended direction of gas flow	201.102.1.1.4

Description of marking	Subclause
For an *exhaust port* connector that is a separate connector an is *operator*-detachable without the use of a *tool*, the word "exhaust" or "AGS" or the equivalent in a language that is acceptable to the intended *operator* or an appropriate symbol	201.102.5.2
For a reservoir bag connection port, the word "bag" or the equivalent in a language that is acceptable to the intended *operator* or an appropriate symbol	201.102.5.3.2
For an *anaesthetic ventilator* port connector that is *operator*-detachable without the use of a *tool*, the word "ventilator" or the equivalent in a language that is acceptable to the intended *operator* or an appropriate symbol	201.102.5.4
For a gas sample return port, the word "gas return" or symbol ISO 7000-0795	201.102.5.7 c)
For a gas sample port, the words "gas sample" or symbol ISO 7000-0794	201.102.5.7 c)
Marking that indicates that the *receiving system* of an *AGSS* is suitable for use with a high-flow-rate or low-flow-rate *disposal system*, if the *receiving system* is physically discrete If colour coding is used to identify parts as being specific for use with an *AGSS*, it shall be magenta	201.103.1.1
Unless the *anaesthetic vapour delivery system* is an integral part of the anaesthetic workstation, marking of the *anaesthetic vapour delivery system* with the safety sign for the mandatory action: "follow instructions for use", ISO 7010-M002 (see IEC 60601-1:2005+TC1, Table D.2, number 10); such marking shall be *clearly legible* from the intended *operator's* position	201.104.1.1
For the *anaesthetic vapour delivery system*, the maximum and minimum filling levels on the liquid level indicator, if the actual usable volume is not displayed	201.104.1.1
For the filling port of the *anaesthetic vapour delivery system*, the generic name of the anaesthetic agent in full spelling or in abbreviated form	201.104.6 a)
For an *exhaust port* connector that is *operator*-detachable without the use of a *tool*, the word "exhaust" or "AGS" or the equivalent in a language that is acceptable to the intended *operator* or an appropriate symbol	201.105.6 a)
Mass of *mobile ME equipment* in kg	201.7.2.21
Marking of the *anaesthetic workstation* and its components regarding use in an magnetic resonance (MR) environment: 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*.	201.7.2.106

201.C.3 Marking of controls and instruments

Additional requirements for marking of controls are found in Table 201.C.102.

Table 201.C.102 — Marking of controls

Description of marking	Subclause
For *gas-specific* flow rate adjustment controls of an *anaesthetic gas delivery system*: — identification of 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, conformity with ISO 5359:2014+AMD1:2017, Table 6 — indication on how to increase and decrease the gas flow rate; if applicable, the identification of the point of reference for reading the flow-rate indication	201.7.4.2
Marking of the oxygen flush control with one of the following: — "Oxygen Flush" — "O2 Flush" — "O2 +"	201.7.4.2
For an *operator*-controlled mechanism that changes from reservoir bag to *anaesthetic ventilator* and vice-versa, marking of the words "bag" and "ventilator" or the equivalent in a language that is acceptable to the intended *operator* or an appropriate symbol	201.102.1.1.2
Marking the *operator*-controlled mechanism for excluding the absorbent from the gas pathway with the following: — the words "on" and "off", or the equivalent in a language that is acceptable to the intended *operator*, or — the words "absorber on" and "absorber off" or the equivalent in a language that is acceptable to the intended *operator*.	201.102.1.1.3
Graduation of *flowmeters* or flow rate adjustment controls in litres per minute (l/min)	201.101.6.1
For the control activating the delivery of a specific vapour of a volatile anaesthetic agent, the generic name in full spelling or in abbreviated form as given in the following list: — Desflurane — "DES" — Enflurane — "ENF" — Halothane — "HAL" — Isoflurane — "ISO" — Sevoflurane — "SEV" For colour coding, see ISO 5360:2016	201.104.1.1
On the *anaesthetic vapour delivery system* or its display for the calibrated range, the set concentration as well as the units of measure In addition, marking of the controls with "0" or "Off", or with both, if the "0" position is not also the "Off" position, or with "Standby" if "Off" is not provided	201.104.2.1

201.C.4 *Accompanying documents*, general

Additional requirements for general information to be included in the *accompanying documents* of an *anaesthetic workstation* and its individual components and *accessories* are found in Table 201.C.103.

Table 201.C.103 — *Accompanying documents*, general

Description of requirement	Subclause
The 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	201.7.9.1
For an *anaesthetic workstation* not supplied complete, in the instructions for use, as far as applicable, information about the *monitoring equipment*, *alarm systems* and *protection devices* required by this document and how to connect them	201.7.9.2.1
A statement to the effect that in case of a failure of the *anaesthetic workstation*, the lack of immediate access to appropriate alternative means of ventilation can result in *patient* injury; and to the effect that alternative means of ventilation during the use of an *anaesthetic workstation* shall be available	201.7.9.2.2
A provision of at least one *operator* pre-use checklist	201.7.9.2.8
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	201.7.9.2.101 aa)
Conditions under which the measured values are displayed	201.7.9.2.101 bb)
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*	201.7.9.2.101 cc)
Where applicable, a statement to the effect that a malfunction of the *medical gas pipeline system* can cause one or more *anaesthetic workstations* and other *anaesthetic workstation* components connected to the *medical gas pipeline system* to stop their operation simultaneously; this is not applicable to *anaesthetic workstation*s that only use cylinders for the gas supply	201.7.9.2.101 dd)
Where applicable, disclosure of the presence of all natural rubber latex-based parts and *accessories* and their location (see symbol 5.4.5 in ISO 15223-1:2016)	201.7.9.2.101 ee)
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 including the maximum safe magnetic field strength	201.7.9.2.101 ff)
If an *anaesthetic workstation* or its individual components 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	201.7.9.2.101 gg)
For single-use *accessories* to the *anaesthetic workstation* or its individual components, a disclosure of the *risks* associated with reusing; this information may be given upon request	201.7.9.2.101 hh)
the type(s) of oxygen the *anaesthetic workstation* or its individual components are compatible with (oxygen, oxygen and Oxygen 93 or only Oxygen 93)	201.7.9.2.101 ii)
If the *anaesthetic workstation* or its individual components is/are suitable for Oxygen 93, restrictions and consequences of the use of Oxygen 93, e. g. possible argon accumulation.	201.7.9.2.101 jj)
A description of 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* outlets under these circumstances	201.11.8.101
If the *anaesthetic workstation* or its individual components has/have an *internal electrical power source*: — the conditions under which the back up time is maintained — the operational time of the *internal electrical power source* when fully charged — the behaviour after a switchover to the *internal electrical power source* — the behaviour while the *internal electrical power source* is recharging	201.11.8.103 c)

Description of requirement	Subclause
If the *anaesthetic workstation* is not equipped with the following *monitoring equipment*, *alarm systems*, and *protection devices,* a statement to the effect that the *anaesthetic workstation* is to be equipped with these components, before being put into service and a description of how to connect these components: — *airway pressure monitoring equipment* conforming with 201.12.4.109 — *maximum limited pressure protection device* conforming with 201.102.2.1 (*anaesthetic breathing system*) or 201.105.2.1 (*anaesthetic ventilator*) — *adjustable pressure limit protection device* conforming with 201.102.2.2 (*anaesthetic breathing system*) or 201.105.2.2 (*anaesthetic ventilator*) — exhaled volume *monitoring equipment* conforming with 201.12.4.104 — *alarm system* with *anaesthetic breathing system* integrity *alarm condition* conforming with 201.12.4.105 — carbon dioxide *monitoring equipment* conforming with 201.12.4.103.1 — oxygen *monitoring equipment* conforming with 201.12.4.103.2 — 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* conforming with 201.12.4.103.3 — *anaesthetic breathing system* continuing-positive-pressure *alarm condition* conforming with 201.12.106 — oxygen supply failure *alarm system* and *protection device* conforming with 201.12.4.107.1 and 201.1.24.107.2 respectively — hypoxic mixture delivery selection *protection device* conforming with 201.12.4.107.3 — *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* conforming with 201.12.4.108 From *manufacturers* of individual components information regarding how to connect these components to the *anaesthetic workstation*	201.12.4.102, Table 201.104
A statement to the effect that the *anaesthetic workstation* is to be provided with halogenated anaesthetic agent *monitoring equipment* complying with ISO 80601-2-55:2018 before the *anaesthetic workstation* is put into service and a description of how to connect it, if the *anaesthetic gas delivery system* is not so equipped From *manufacturers* of halogenated anaesthetic agent *monitoring equipment*, information regarding how to connect that components to the *anaesthetic workstation*, upon request	201.12.4.103.3
For exhaled volume *monitoring equipment*, the accuracy of the displayed exhaled volume, if the accuracy of the displayed exhaled volume exceeds the values specified in this document	201.12.4.104.1
A statement to the effect that the *anaesthetic breathing system* is to be provided with an *alarm system* that includes an *alarm condition* that indicates when the *airway pressure* exceeds the continuing positive pressure *alarm limit* before the *anaesthetic breathing system* is put into service, if the *anaesthetic breathing system* is not so equipped Unless the *alarm system* that includes an *alarm condition* that indicates when the *airway pressure* exceeds the continuing positive pressure *alarm limit* is integral to the *anaesthetic breathing system*, information on how to connect it	201.12.4.106
Disclosure of the behaviour of the *anaesthetic gas delivery system* under the conditions specified in this document	201.12.4.107.2
For the *anaesthetic workstation* a statement to the effect that the *anaesthetic workstation* is to be provided with an *anaesthetic gas scavenging system* complying with this document before being put into service The instructions for use of the *anaesthetic workstation* and the *anaesthetic gas scavenging system* shall disclose how to connect the *anaesthetic gas scavenging system*	201.12.4.108

Description of requirement	Subclause
If the *anaesthetic workstation* is not equipped with an *airway pressure monitoring equipment,* a statement in the instructions for use of the *anaesthetic workstation*, the *anaesthetic breathing system* (if supplied separately) and the *anaesthetic ventilator* (if supplied separately), to the effect that the *anaesthetic workstation* is to be provided with *airway pressure monitoring equipment* complying with this document before being put into service; also, a description of how to connect that component. *Manufacturers* of the *airway pressure monitoring equipment* shall make available on request information on how to connect that component to the *anaesthetic workstation*, the *anaesthetic breathing system* and the *anaesthetic ventilator.*	201.12.4.109
For the *anaesthetic gas delivery system*: a) a statement to the effect that the *anaesthetic gas delivery system* conforms with this document b) unless the *anaesthetic breathing system* is integral to the *anaesthetic gas delivery system* or *anaesthetic workstation*, a statement to the effect that the *anaesthetic gas delivery system* or *anaesthetic workstation* is intended to be used with an *anaesthetic breathing system* that conforms with this document c) instructions for testing for correct assembly and connection of each gas supply d) if applicable, the *medical gas* supply pressure(s) at which the *anaesthetic gas delivery system* will cease to deliver gas as specified e) unless the *anaesthetic breathing system* is an integral part of the *anaesthetic gas delivery system*, information on how to connect an *anaesthetic breathing system* f) if the *anaesthetic gas delivery system* is equipped with a means to deliver nitrous oxide or is designed to be equipped with an *anaesthetic vapour delivery system*, a statement to the effect that the *anaesthetic gas delivery system* is to be used with an *AGSS* conforming with this document g) if the *anaesthetic gas delivery system* is designed to be equipped with an *interchangeable anaesthetic vapour delivery system*, a statement to the effect that the *interchangeable anaesthetic vapour delivery system* used with the *anaesthetic gas delivery system* needs to conforming with this document h) if the *anaesthetic gas delivery system* is designed to be equipped with an *anaesthetic vapour delivery system*, a statement to the effect that the *anaesthetic gas delivery system* is to be used with halogenated anaesthetic agent *monitoring equipment* conforming with ISO/IEC 80601-2-55:2018 i) if the *anaesthetic gas delivery system* is designed to be equipped with an *anaesthetic ventilator*, a statement to the effect that the *anaesthetic ventilator* shall conform with the requirements of this document j) a statement to the effect that the *anaesthetic workstation* is intended for use with non-flammable anaesthetic agents as specified in this document and that flammable anaesthetic agents such as diethyl ether and cyclopropane are not to be used in the *anaesthetic workstation* k) the mass in kilograms (kg) in the *nominal* configuration and a definition of the *nominal* configuration. The mass in kilograms (kg) shall be disclosed for each *accessory* with a mass exceeding 1,5 kg; l) if the gas delivery system is equipped with an emergency oxygen flow rate adjustment control the accuracy of the emergency oxygen flow rate adjustment control.	201.101.1.1

Table 201.C.103 (*continued*)

Description of requirement	Subclause
For the *anaesthetic breathing system* and its individual parts: a) a diagram of the complete *anaesthetic breathing system* identifying its parts and their recommended location(s) b) a statement to the effect that the *anaesthetic breathing system* or its parts conform with this document c) unless the *anaesthetic breathing system* is an integral part of the *anaesthetic gas delivery system* or *anaesthetic workstation*, information on how to connect an *anaesthetic breathing system* d) the internal Compliance, expressed as a volume in millilitres (ml) at a pressure of 30 hPa (30 cmH_2O), with any reservoir bag excluded e) unless permanently mounted, the recommended orientation of the *anaesthetic breathing system* and its parts and details of the effects of other orientations on performance f) information on any means of pressure relief, including pressure/flow rate characteristics g) a statement of known compatibility with gases and anaesthetic agents h) a statement regarding the suitability for use with flammable anaesthetic agents, i.e., *category AP* or *category APG* i) the instructions for use of *anaesthetic breathing system* parts not integrated into the *anaesthetic breathing system* shall include a diagram showing the recommended locations of such *anaesthetic breathing system* parts, the location of the *fresh-gas inlet* and the ventilator inlet j) the instructions for use of *exhaust valves* not integrated into the *anaesthetic breathing system* shall describe the pressure/flow-rate characteristics of the *exhaust valve* including the opening pressure and the pressure drop at a flow rate of 30 l/min at BTPS k) the instructions for use of a *circle absorber assembly* and its parts not integrated into the *anaesthetic breathing system* shall identify the carbon dioxide absorbent recommended for use and the volume of the absorbent container expressed in millilitres (ml) l) for breathing *accessories* intended to be assembled by the *operator*, their resistance at 2,5 l/min, 15 l/min and 30 l/min and compliance of those *accessories* m) for an *anaesthetic breathing system* supplied separately, a statement to the effect that the *anaesthetic workstation* is to be provided with an *airway pressure monitoring equipment* conforming with this document (see 201.12.4.109) before being put into service and a description on how to connect that component n) the inspiratory and expiratory pressure/flow rate characteristics of the *anaesthetic breathing system*, including the pressure at 30 l/min if the *anaesthetic breathing system* is intended for adult *patients*; 15 l/min if the *anaesthetic breathing system* is intended for paediatric *patients*; 2,5 l/min if the *anaesthetic breathing system* is intended for neonatal *patients* at a *fresh gas* flow rate of 10 l/min ± 1 l/min oxygen o) if applicable, a statement that the *anaesthetic breathing system* is suitable for neonates; p) if the *anaesthetic breathing system* is suitable for neonates: the maximum allowed resistance of the *breathing tube* system including filters for neonates; and a method for the *operator* how to test a *breathing tube* setup for maximum pressure fluctuation at the *patient connection port* q) if the bag connector is a socket (female), a warning in the instructions for use not to use any adaptors for the hoses to prevent any misconnections and not to compromise *patient* safety.	201.102.1.2 see also 201.102.8.2 (at item k)
For an *exhaust valve* not integrated into the *anaesthetic breathing system*, disclosure of the following: — the opening pressure — the pressure/flow-rate characteristics — the pressure drop with any *exhaust valve* control fully open at a flow rate of 30 l/min — for an *exhaust valve* that can be fully closed, the leakage to atmosphere in the fully closed position at a pressure of 30 hPa (30 cmH_2O)	201.102.8.2 c) see also 201.102.1.2 j)

Description of requirement	Subclause
For the absorbent bypass mechanism, disclosure of the proportion of gas that does not pass through the absorbent with the bypass control at intermediate settings, if so equipped, and at the "on" setting	201.102.9.2
Description of the inspiratory and expiratory pressure/flow rate characteristics of the *circle absorber assembly*, including the pressure at 2,5 l/min, 15 l/min and 30 l/min	201.102.9.3 b)
Information as to how the *operator* can check the function of *inspiratory* and *expiratory valves*	201.102.10.1 b)
For *inspiratory* and *expiratory valves* that are not integrated in the *anaesthetic breathing system*, disclosure of the pressure/flow-rate characteristics of the valves under both wet and dry conditions, including the pressure drop at a flow rate of 2,5 l/min, 15 l/min and 30 l/min.	201.102.10.3 b)
For the *AGSS*: a) a statement to the effect that the *AGSS* conforms with this document b) for *active AGSS,* the *rated maximum* and *minimum disposal flowrate* of the *disposal system* with which the *transfer system* and *receiving system* are intended to be used	201.103.1.2
For the *anaesthetic vapour delivery system*: a) a statement to the effect that the *anaesthetic vapour delivery system* conforms with this document b) a statement to the effect that an *anaesthetic workstation* used with this *anaesthetic vapour delivery system* needs to conform with this document c) a statement to the effect that the *anaesthetic vapour delivery system* is to be used with halogenated anaesthetic agent *monitoring equipment* conforming with ISO 80601-2-55:2018 d) a statement to the effect that the *anaesthetic vapour delivery system* is to be used with an *anaesthetic gas delivery system* conforming with this document e) a statement to the effect that the *anaesthetic vapour delivery system* is to be used with an *AGSS* conforming with this document f) the performance of the *anaesthetic vapour delivery system* including the effects of variation in ambient temperature, ambient pressure, resistance, tilting, back pressure, subatmospheric pressure, input flow rate and gas composition over the range of operating conditions specified in the instructions for use g) the carrier gas, gas flow rate(s) and analytical technique(s) recommended for measuring the output of the *anaesthetic vapour delivery system* h) a statement to the effect that the vaporizer should not be used between zero and the first calibration, if applicable i) the volume at the maximum and minimum fill levels and the total capacity	201.104.1.2 201.12.4.103.3
A disclosure of the volume of liquid anaesthetic agent required to fill the reservoir of the *anaesthetic vapour delivery system* to the maximum filling level, and the total capacity	201.104.6
A description of the combination of the *anaesthetic breathing system* and *accessories* under the worst case scenario for determination of inspiratory and expiratory pressure/flow rate characteristics.	201.102.7

Description of requirement	Subclause
For the *anaesthetic ventilator*: a) a statement to the effect that the *anaesthetic ventilator* conforms with this document b) a statement to the effect that the *anaesthetic ventilator* is intended to be used with an *anaesthetic breathing system* that conforms with this document c) unless the *anaesthetic ventilator* is an integral part of the *anaesthetic workstation*, information on how to connect to an *anaesthetic workstation* and *anaesthetic breathing system* d) the operational characteristics of the *anaesthetic ventilator* including, where applicable, the following: 1) range of *delivered volumes* (tidal and minute) 2) range of cycling frequency 3) range of I:E ratios 4) range of values that can be set as the maximum pressure at the *patient connection port* during *normal use* in the inspiratory phase and the means by which that maximum pressure is ensured (e.g. pressure cycling, pressure limitation) 5) inspiratory flow rate and pressure characteristics 6) ventilation modes 7) the minimum *airway pressure* at the *patient connection port* (during *normal use* and under *single fault condition*) 8) PEEP range 9) if there is a facility for subatmospheric pressure in the *expiratory hold*, the limiting pressure and generated pressure 10) characteristics of the means used for initiation of the *inspiratory hold*, e.g. *patient-trigger event* 11) interdependence of controls 12) if applicable, a statement that the *anaesthetic ventilator* compensates for *anaesthetic breathing system* compliance and a description of the method of compliance compensation e) any restrictions on the location and/or sequence of parts within the *anaesthetic breathing system* as they relate to the *anaesthetic ventilator* f) the range of internal volume of any *anaesthetic breathing system accessories* or other parts or subassemblies recommended by the *manufacturer* g) for an *anaesthetic ventilator* supplied separately, a statement to the effect that the *anaesthetic workstation* is to be provided with an *airway pressure monitoring equipment* conforming with this document (see 201.12.4.109) before being put into service and a description on how to connect that item	201.105.1
A disclosure of *operator* actions necessary to ensure the continued supply of *fresh gas* to or ventilation of the *patient* under *power supply* failure conditions	201.105.5 c)
For the subatmospheric pressure test, Compliance correction, as appropriate	201.105.8, 7)

201.C.4 *Accompanying documents*, technical description

Additional requirements for information to be included in the technical description of an *anaesthetic workstation* and its individual components are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
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, 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."; any additional handling instructions necessary to allow transport with an acceptable *risk* according to the *risk management file*	201.7.9.3.102
Description of 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	201.7.9.3.101
For the *anaesthetic gas delivery system*, a) pressure and flow-rate characteristics of any gas *power supply* outlet throughout the *rated* range of inlet pressure b) operating characteristics and location of any pressure relief *protection devices*	201.101.1.2
For the *AGSS*, description of how to measure the leakage of the *transfer* and *receiving system*	201.103.3.1.5
For alarms, — a list of *alarm systems* and *alarm conditions* to be tested by the *operator* — the methods of verifying their correct function, e.g. by a built-in self test — the recommended frequency of *verification*	208.5.2.2
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)	201.7.9.3.1

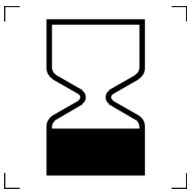
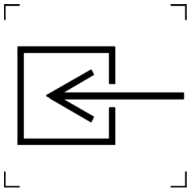
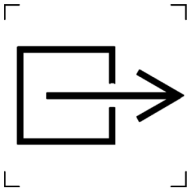
Annex D
(informative)

Symbols on marking

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

Addition:

Table 201.D.2.101 — Additional symbols on marking

No.	Symbol	Reference	Title and description
1		ISO 7000-2607 ISO 15223-1:2016, 5.1.4	Use-by date On packaging. To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging. The expiration date can be a year, year and month, or year, month, day. The date shall be shown adjacent to the symbol. The date may for example be given as follows: 1997-06-12. The date shall be expressed as in ISO 8601[5] as four digits for the year and, where appropriate, two digits for the month and two digits for the day. For some medical devices [e.g. in vitro diagnostics (IVDs)], this date is only valid when the medical device is unopened.
2		ISO 7000-2725 ISO 15233-1:2016, 5.4.5	Contains or presence of natural rubber latex On medical devices: to indicate that the equipment contains the identified product or substance.
3		Application of ISO 7000-2725 EN 15986:2011	Contains or presence of [XXX] On medical devices: to indicate that the equipment contains the identified product or substance. Replace with the symbol or other identification of the substance that is contained or present, where PHT is used for phthalates
4		ISO 7000-0794	Input; entrance
5		ISO 7000-0795	Output; exit

No.	Symbol	Reference	Title and description
6		option one, IEC 62570:2014, 7.3.1	MR safe To identify an item which poses no unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the symbol may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.
7		option two IEC 62570:2014, 7.3.1	MR safe Alternative graphical symbol representation. Same meaning as IEC 62570-7.3.1, option one.
8		IEC 62570:2014, 7.3.2	MR conditional To identify an item which poses no unacceptable *risks* within defined conditions to the *patient*, medical staff or other persons within the MR environment. When color reproduction is not practical, the symbol may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. The MR Conditional symbol may be supplemented by supplementary marking that describes the conditions for which the item has been demonstrated to be MR Conditional.
9		IEC 62570:2014, 7.3.3	MR Unsafe To identify an item which poses unacceptable *risks* to the *patient,* medical staff or other persons within the MR environment. When color reproduction is not practical, the symbol may be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.

Additional annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

Subclause 201.1.1 Scope

Table AA.1 illustrates the configuration of an *anaesthetic workstation* and provides a summary of *risk control* measures for an *anaesthetic workstation* for various actuators and associated *monitoring equipment*, *alarm systems* and *protection devices*. They allow easy reference of applicable subclauses and shows prerequisite conditions for specific applications.

Table AA.1 — Summary of *risk control* measures for an *anaesthetic workstation*

***Risk control* measure**	***Monitoring equipment* and *alarm systems***										
	Power supply failure	Oxygen supply failure	Oxygen concentration		Anaesthetic agent concentration			*Airway pressure*			
	A	A	M	L[f]	M	L[f]	H[f]	M	L	H	A: CPP[e]
Subclause 201.x	11.8.102	12.4.102 12.4.107.1	12.4.102 12.4.103.2	12.4.102 12.4.103.2	12.4.102 12.4.103.3	12.4.102 12.4.103.3	12.4.102 12.4.103.3	12.4.102 12.4.109	12.4.102 12.4.109	12.4.102 12.4.109	12.4.102 12.4.106
Actuator											
Driving power - electric - pneumatic	 + +	 - -	 - -	 - -	 - -	 - -	 - -	 - -	 - -	 - -	 - -
anaesthetic gas delivery system											
- oxygen	-	+[c]	+	+	-	-	-	-	-	-	-
- air	-	+[c]	+	+	-	-	-	-	-	-	-
- premixed[a]	-	+[c]	+	+	-	-	-	-	-	-	-
- others[b]	-	-	+	+	-	-	-	-	-	-	-
Anaesthetic breathing system	-	-	+	+	-	-	-	+	R	+	+
Circle breathing system	-	-	+	+	-	-	-	+	R	+	+
Anaesthetic vapour delivery system	-	-	-	-	+	+	+	-	-	-	-
Anaesthetic ventilator	+	+	-	-	-	-	-	+	R	+	+

Key

\+ always mandatory; R recommendation; - no requirement;

A *alarm condition*; H high level *alarm condition*; L low level *alarm condition*

M *monitoring equipment*; P *protection device*

[a] Premixed gases of 50 % N_2O and 50 % O_2.

[b] Others might include N_2O.

[c] Mandatory only if primary or sole source of oxygen/oxygen-enriched air.

[d] Inspiratory volume monitoring permissible with manual or spontaneous ventilation.

[e] Continuous positive pressure *alarm condition*.

[f] Alarm conditions according to ISO 80601-2-55:2018.

Table AA.1 (continued)

***Risk control* measure**	***Monitoring equipment* and *alarm systems***							***Protection devices***				
	Exhaled volume		*Anaesthetic breathing system*	Carbon dioxide concentration			Subatmospheric pressure limit	Oxygen supply failure	Hypoxic mixture selection	*AGSS*	*Maximum limited pressure*	*Adjustable pressure limiton*
	M	L	A	M	L[f]	H[f]	A	P	P	P	P	P
Subclause 201.x	12.4.102 12.4.104.1	12.4.102 12.4.104.2	12.4.102 12.4.105	12.4.102 12.4.103.1	12.4.102 12.4.103.1	12.4.102 12.4.103.1	105.8	12.4.102 12.4.107.2	12.4.102 12.4.107.3	12.4.102 12.4.108	12.4.102 102.2.1 105.2.1	12.4.102 102.2.2 105.2.2
Actuator												
Driving power - electric - pneumatic	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -
anaesthetic gas delivery system												
- oxygen	-	-	-	-	-	-	-	-	-	-	-	-
- air	-	-	-	-	-	-	-	-	-	-	-	-
- premixed[a]	-	-	-	-	-	-	-	-	-	+	-	-
- others[b]	-	-	-				-	+	+	+	-	-
Anaesthetic breathing system	+[d]	+	+	+	+	+	-	-	-	-	+	+
Circle breathing system	+	+	+	+	+	+	-	-	-	-	+	+
Anaesthetic vapour delivery system	-	-	-	-	-	-	-	-	-	+	-	-
Anaesthetic ventilator	+	+	+	+	+	+	+	-	-	-	+	+

Key

+ always mandatory; R recommendation; - no requirement;

A *alarm condition*; H high level *alarm condition*; L low level *alarm condition*

M *monitoring equipment*; P *protection devic*e

[a] Premixed gases of 50 % N_2O and 50 % O_2.

[b] Others might include N_2O.

[c] Mandatory only if primary or sole source of oxygen/oxygen-enriched air.

[d] Inspiratory volume monitoring permissible with manual or spontaneous ventilation.

[e] Continuous positive pressure *alarm condition*.

[f] *Alarm conditions* according to ISO 80601-2-55:2018.

In order to clarify the applicability of this document, Table AA.2 identifies typical use environments of *anaesthetic workstations* with the corresponding resources and use scenarios.

Table AA.2 — Use environments

Use environment	Resources	Use scenario	Applicable standard
Hospital	Central gas supply with O_2, N_2O and air backup Electrical power with backup *Anaesthetic workstation* with backup, ventilator, vaporizers, etc. Extensive *patient* monitoring In-house medical faculty Climate control *Anaesthetic gas* scavenging In-house pharmacy Cardiopulmonary resuscitation (CPR) equipment and *operators* Hospital supply stockroom	Anaesthetist/anaesthesiologist or nurse anaesthetist Multi-tasking when supervising registered nurse anaesthetists (CRNA) or residents	ISO 80601-2-13
Physician's office	Gas supply with limited backup Electrical power Anaesthetic equipment *Patient monitoring equipment* In-house surgeon CPR equipment and *operator* Climate control Limited pharmacy and supplies	Anaesthetist/anaesthesiologist or nurse anaesthetist	ISO 80601-2-13
Dental office	Gas supply (premixed O_2/N_2O or O_2-N_2O mixer) Electrical power Analgesic apparatus Climate control	Dentist Multi-tasking *Patient* interaction	ISO 80601-2-13
Emergency areas/ rescue vehicles	Portable gas supply (O_2) Portable electrical power Consultant via phone CPR equipment and *operator* Portable anaesthesia machine Mask and self-inflating bag Portable ventilator Portable *patient* monitors Portable pharmacy	Paramedic Multi-tasking Stressed High workload Time pressure	ISO 80601-2-13
Civil emergencies, disaster areas and areas with limited logistical support	Electric power via diesel/gasoline generator *Oxygen concentrator* and bottled O_2 Oxygen *flowmeter* Anaesthesia system Non-rebreathing anaesthetic system Draw-over vaporizer Ventilator (manual or mechanical) Limited pharmacy Limited *patient* and machine monitoring	Anaesthetist/anaesthesiologist or trained technician Single-tasking Adverse environment	ISO 8835-7 ISO 18835

Administering an anaesthetic is in itself hazardous. *Risks* associated with administering an anaesthetic are not covered by this document

The use of flammable anaesthetics, as determined by Annex BB, has diminished to a point where it was agreed not to consider adding specific requirements to this document to address the associated *hazards*.

Subclause 201.1.4 Particular standards

IEC 80601-2-49 specifies requirements for multiparameter monitors, i.e. devices that monitor more than one parameter with more than one *applied part* (= sensor) on one *patient*. In detail these are

a) electrical safety of devices with more than one *applied part* in contact with the *patient*;

b) multi-parameter *alarm systems*;

c) ingress protection (IP class) requirements;

d) electromagnetic compatibility.

Even if this basic definition seems to apply to *anaesthetic workstations*, all of these aspects are covered by IEC 60601-1:2005+AMD1:2012+AMD2:2020. *Anaesthetic workstations* are exempt from the requirements of IEC 80601-2-49 to allow *manufacturers* to fully integrate any component considered useful into the *anaesthetic workstation*. They are encouraged to develop a consistent user interface for all integrated functions, especially regarding the *alarm system*. However, the required *risk management process* has to fully address any *risks* arising from integration of additional components.

Subclause 201.3.225 *Interchangeable anaesthetic vapour delivery system*

Currently, two designs of anaesthetic vapour delivery devices are known. They are either an integral part of the *anaesthetic workstation* and cannot be exchanged by *operators* at all or only between *anaesthetic workstation*s of the same type.

The other, allows the use of a non-integral vaporizer that may be exchanged by the clinician not requiring *tool*s.

Subclause 201.4.3 *Essential performance*

The loss of oxygen delivery could result in an unacceptable *risk* to the *patient*. The *anaesthetic workstation* needs to make every attempt to continue oxygen delivery as long as possible under as many fault conditions as possible.

All *patients* who receive gas delivered by an *anaesthetic workstation* depend on a sufficient amount of oxygen in this gas. When an *anaesthetic gas delivery system* is used with a non-rebreathing system, it is sufficient to ensure non-hypoxic concentrations in the delivered *fresh gas*. In certain configurations of circle systems used with low flow techniques only measuring the inspired oxygen concentration provides a sufficient means to ensure this *essential performance*.

There is no dispute that delivering excessive concentrations of volatile anaesthetic agents poses a *risk* to the *patient*. Therefore, avoiding delivery of high concentrations is considered to be *essential performance* for an *anaesthetic workstation* to ensure that the delivery of high concentrations is avoided.

The loss of controlled ventilation to the *patient* may result in an unacceptable *risk* to the *patient*. Identifying *airway pressure* monitoring (and associated alarms) as *essential performance* will provide the *operator* with indications of ventilation. In addition to the designation of these items as *essential performance*, this document requires that the instructions for use 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. This document also provides examples of an alternative means of ventilation as well as an accompanying rationale.

The combination of *risk* mitigation methods described above is believed to be sufficient enough to make the *residual risk* level acceptable.

Attention is drawn to additional *essential performance* requirements given in other particular standards.

Subclause 201.4.10.101 Requirements for pneumatic power input

An *anaesthetic workstation* designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its *rated* range of supply pressures; these pressures can only be maintained if the *anaesthetic workstation* in *normal condition* does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that these *anaesthetic workstations* will be designed to prevent an unacceptable *risk* under possible *single fault conditions* of the pressurized gas supply.

Pressurized *medical gas* supplies, including *medical gas pipeline systems* and cylinder *pressure regulators* conforming to current relevant standards, supply *gas-specific* terminal outlets at a pressure that is within an internationally agreed pressure range of 280 kPa to 600 kPa under *normal condition*. It is expected that *anaesthetic workstation*s will operate to their declared specification with any supply pressure within this range.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, *medical gas pipeline systems* supplying compressed *medical gas* through *gas-specific* terminal outlets are designed so that they can maintain this pressure at the input connection of gas-powered devices whilst supplying steady-state flows up to 60 l/min at a single outlet connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, at 60 l/min, across the *terminal unit* and the hose assembly connecting the device to the pipeline.

The *medical gas pipeline system* is also required to be capable of supplying sufficient gas so that this flow can be drawn from a predetermined number of adjacent *terminal units* simultaneously. The actual number will have been determined during the design and installation of the *medical gas pipeline system* by the application of a "diversity factor", a factor agreed between the supplier and *responsible organization* to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the *medical gas pipeline system* is capable of supplying an average flow of 60 l/min to the required proportion of terminal outlets. However, if the flow demand from many adjacent *anaesthetic workstations* exceeds 60 l/min there is an increased possibility that the *anaesthetic workstation* input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the *terminal unit* and input hose (also because of the flow-drop characteristic in the case of *pressure regulators* supplying a single terminal outlet).

In addition to steady-state flows of 60 l/min, the switching of the internal pneumatic system and the operation of a *patient* demand system can result in an *anaesthetic workstation* requiring fast transient input flows far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimize pressure drop, such fast transient demands can generally be accommodated from the gas stored locally within the pipework of the *medical gas pipeline system*. There can be temporary pressure drops of the input pressure at the inlet of the *anaesthetic workstation*, to below 280 kPa, due to any transient flows in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the *manufacturer*. *Manufacturers* need to evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their *anaesthetic workstation* when used with recommended supply hose configurations and when connected to alternative *gas-specific* terminal outlets such as those fitted to cylinder *pressure regulators* conforming to ISO 10524-1:2018.

The permitted maximum average flow of 60 l/min stated in this document is greater than the test flow used during the commissioning of *medical gas pipeline systems*. In itself, this should be of no concern because the specific conditions specified for the test do not allow a direct comparison between the two values. The Technical Committee responsible for standards on *medical gas pipeline systems*, ISO TC 121/SC 6, in consultation with ISO TC 121/SC 1 and ISO TC 121/SC 3, agreed to the 60 l/min average flow value, and also the 200 l/min for up to 3 s transient flows, during the preparation of the first edition of the current series of documents for *medical gas pipeline systems* and were aware of the need to satisfy that specification when finalizing the *medical gas pipeline system* test requirements.

Manufacturers should be aware that other standards on medical gas supply systems permit the fitting of *gas-specific terminal units* to spur systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their *terminal units*.

Subclause 201.5.101.3 Gas flow rate and leakage specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally one atmosphere (101,3 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,2 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (~ 37 °C) irrespective of the temperature of the gas delivered by an *anaesthetic ventilator*. The volume of a given amount of gas increases by about 13,5 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurized gas to medical equipment, including *anaesthetic ventilators*, follow engineering conventions and specify gas quantities and flow rates at STPD conditions. This practice is followed in this document for all requirements concerning gas input.

However, *anaesthetic ventilators* conforming with this document are likely to be inflating the *patient's* lungs relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered from an *anaesthetic ventilator*. With a standard temperature of 0 °C, 1 l of gas referenced to STPD can expand the lungs by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different *anaesthetic ventilators*, it is essential that the information for all *anaesthetic ventilators* be referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the lungs, BTPS is the appropriate set of reference conditions to use.

In *anaesthetic ventilators* a variety of flow transducers are used. Whereas a heated-wire anemometer measures the rate of mass flow of the gas independent of pressure, a pneumotachograph measures the flow of gas at the actual pressure. Therefore, the necessary corrections depend on the type of flow transducer. When a pressure correction is required, this can be adequately estimated. The necessary corrections also depend on the location of the flow transducer in the *anaesthetic breathing system*. The humidity of the gas can be zero when the transducer measures the inspired flow inside the *anaesthetic ventilator*. When, however, the flow transducer is located at the *y-piece,* the relative humidity can be anything up to 100 %. When a heat and moisture exchanger is used for humidification, the output of the flow-transducer depends on whether it is located distal or proximal to the heat and moisture exchanger. With a turbine-based *anaesthetic ventilator* that uses ambient air, the humidity of the drawn-in air can be unknown to the *anaesthetic ventilator*. All these effects together will inevitably introduce some errors in the conversion of the measured flow signal to BTPS reference conditions. However, these errors are only in the range of several percent.

The recalculation from STPD to BTPS depends on a number of factors, in particular CO_2 production that has an influence on temperatures and humidity within the *anaesthetic breathing system*. This mainly depends on *anaesthetic breathing system* architectures and ventilator implementation. This document therefore requests the *manufacturer* to provide the appropriate evidence with the design documentation where it is not possible to completely specify all of the test conditions. See e. g. accuracy of the exhaled volume *monitoring equipment*.

Subclause 201.7.2.3 Consult *accompanying documents*

Following the instructions for use is considered a mandatory action for the safe operation of an *anaesthetic workstation* and its individual components.

Subclause 201.7.2.21 Mass of *mobile ME equipment*

Modern *anaesthetic workstation*s are quite heavy, especially if fully equipped with various components required in this document and other devices needed for routine clinical use. *Anaesthetic workstation*s are usually *mobile* devices that are intended to be moved between operating rooms and taken to maintenance locations by the clinical user or hospital technicians. Marking the device with its mass allows *operators* to select a route more convenient for heavy equipment or to call for assistance to help with the transport.

Subclause 201.7.2.103 *Operator*-accessible gas *power supply* outlet

Connecting pneumatically driven equipment to a gas *power supply* outlet of an *anaesthetic workstation* can cause the internal pressure in the *anaesthetic workstation* to fall below a level where it might not function properly.

Subclause 201.7.4.2 Control devices

The marking of *gas-specific* flow rate adjustment controls is required to be consistent with that used on the corresponding gas supplies and pressure indicators. This minimizes the likelihood of confusion.

In an *anaesthetic workstation*, especially with controls for the flow of gases, it is important that the *operator* is able to identify immediately what gas flow setting he/she is about to change. Colour coding is helpful and should conform with International Standards.

Traditionally, the direction to increase a setting is different for mechanical (anticlockwise) and electronic (clockwise) functions. This requirement aims to avoid confusing *operators*.

Subclause 201.7.4.3 Unit of measure

Additional information can be found in the rationale to 201.5.101.3.

Subclause 201.7.9.2.2 Warnings and safety notices

Even with *anaesthetic workstations* that are safe under *single fault conditions*, a failure to ventilate the *patient* with adequate concentrations and volumes is possible. Protection of the *patient* in such an infrequent but possibly fatal situation requires the immediate access to an alternative means of ventilation.

Subclause 201.7.9.2.101 - Additional requirements for the instructions for use

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The commonly agreed maximum level of volatile anaesthetic agents in the breathing gas is 5 ppm. The *manufacturer* should be aware that several restrictions might be necessary for the operation to prevent a re-bound of agent concentration to above 5 ppm again.

Subclause 201.7.9.2.8 Start-up *procedure*

For many years, pre-use checklists described those checks necessary for safe operation. These checks are to be performed by the *operator* prior to use either every day or before each case. The less integrated an *anaesthetic workstation* is, the more important a thorough pre-use check becomes to ensure that all necessary equipment is present, correctly connected, switched on and fully functional. An essential part is verifying that *alarm systems* function properly.

Most modern *anaesthetic workstation*s incorporate *programmable electrical medical systems (PEMS)* that perform some of the pre-use checks. Almost all *monitoring equipment* test all its *alarm systems*. Here it is important to inform the *operator* or *responsible organization* which checks are automatically performed by the *anaesthetic workstation* to enable the *operator* to adapt checklists.

Additional, important information is the situation, frequency or point in time when automatic test *procedures* have to be started by the *operator*.

Subclause 201.8.11.3.101 Additional requirements for *power supply cords*

Designing an *anaesthetic workstation* or its individual components with a fixed *power supply cord* mitigates the *risk* of unintentional interruptions of *supply mains*, which could result in interruption of the operation of the *anaesthetic workstation* or its individual components. If such interruption persists too long or restarting the *anaesthetic workstation* or its individual components requires considerable *operator* interaction, the *patient* is exposed to additional *risk*. However, a fixed *power supply cord* raises other *risks* like damaging the *power supply cord*, the *mains connector* or the *appliance inlet*, or injuries due to falls of personnel.

As many modern *anaesthetic workstation*s are equipped with uninterruptable *power supply* (UPS), backup batteries or quick start *procedure*s, the *risks* from *supply mains* interruptions are greatly reduced. If such features are provided, a *detachable power supply cord* is considered to increase the overall safety.

Subclause 201.9.2.102 Lighting

Insufficient illumination of work areas, overly bright light, reflections and flashing effects can stress *operators* more than necessary, thus leading to more frequent use errors and *hazard*s for the *operators* themselves.

Subclause 201.9.2.103 Integrated seating

Even if unlikely, it is not unthinkable that an *anaesthetic workstation* might include a seat for the *operator*. As already standard for common machinery, certain minimum safety requirements also apply here.

Subclause 201.9.2.104 Arrangement of control positions

Even if unlikely today, it can be imagined that ceiling pendants, on which an *anaesthetic workstation* is mounted, might be moved electrically. This would be an example for a system where a *risk* would arise if more than one control for the movement were provided.

Subclause 201.11.8.101 General requirements

To continue adequate ventilation and therapy of the *patient*, it is important that the *operator* understands the behaviour of the *anaesthetic workstation* or its individual components after interruption of the *power supply*.

When a gas *power supply* fails, it is vital to know whether gas delivery from the *anaesthetic gas delivery system* or an auxiliary means stops, or is switched to alternative supplies like gas cylinders.

Subclause 201.11.8.102 *Alarm condition* for *power supply* failure

The requirement for the duration of this *alarm signal* is consistent with the pneumatic loss of pressure *alarm signal* ("Ritchie whistle"). See also 201.12.4.107.1.

Subclause 201.11.8.103 *Internal electrical power source*

Many contemporary *anaesthetic workstation*s and their individual components have built-in *internal electrical power sources*. It is mandatory for the *operator* to be able to determine whether sufficient power is available for the task at hand. Otherwise the *risks* from unexpectedly running out of power would be unacceptably high, even if backup power is immediately available.

Operators of an *anaesthetic workstation* and its individual components, running on internal power, have to be made aware that this supply is nearing depletion to allow them to make provisions for the *anaesthetic workstation* and its individual components failing to operate.

Subclause 201.12.4.101 Accidental adjustment of operating controls

Unacceptable *risks* to the *patient* can occur when accidental adjustments of operating controls or accidental turning off of the *anaesthetic workstation* or its individual components occur. To control this *risk*, the design of the *operator-equipment interface* needs to prevent accidental adjustments. The *usability engineering process* is used to ensure that these *risks* are reduced to acceptable levels. Examples of methods could include mechanical control techniques such as locks, shielding, friction-loading and detents, as well as for pressure-sensitive finger pads, capacitive finger switches and microprocessor-oriented "soft" controls.

When mechanical controls are used, it is important to ensure that controls are firmly engaged in the intended positions to prevent an undefined and potentially hazardous intermediate state. For controls with more than two intended positions, bi-stable should be interpreted to mean stable in each position and not stable in any intermediate position.

Subclause 201.12.4.102 Additional requirements for *anaesthetic workstation*s

This document provides specific requirements for individual components which, although individual devices in their own right, can be utilized, in conjunction with other relevant devices, to form an *anaesthetic workstation*.

Subclause 201.12.4.104.1 Accuracy

With regard to accuracy of expired volume measurement, although current technology allows for much higher accuracies, these cannot be met under every condition. Low prices and increased robustness might require less accuracy. Therefore, the accuracy requirement is maintained at this level.

The CO_2 production contributes to temperatures and humidity within the *anaesthetic breathing system* and thus alters the recalculations from STPD to BTPS. This mainly depends on *anaesthetic breathing system* architectures and ventilator implementation. Thus this test cannot be completely specified in this document.

Table 201.104

In previous standards, the expiratory volume ranges in Table 201.104 were referenced by the terms "adult", "paediatric", and "neonatal". In this document, those terms were replaced with the relevant *delivered volume* ranges because there is no international agreement as to what the terms "adult", "paediatric", and "neonatal" mean.

Subclause 201.12.4.105 *Anaesthetic breathing system* integrity *alarm condition*

The committee generally agreed that currently there is no way to indicate reliably the failure of *anaesthetic breathing system* integrity (for example, partial or even complete disconnection of the *anaesthetic breathing system*). Under certain circumstances, the monitoring of abnormal or low values of carbon dioxide, pressure, exhaled volume, concentration of vapour or oxygen can individually or in combination indicate or contribute to the detection of loss of *anaesthetic breathing system* integrity. It is for these reasons that a *medium priority alarm condition* is required, but that a specific method of determining or labelling of that *alarm condition* is not specified.

Subclause 201.12.4.106 *Anaesthetic breathing system* continuing-positive pressure *alarm condition*

A minimum of 17 s delay is a compromise between immediately alarming to annunciate a *hazardous situation* and avoidance of nuisance alarms.

Interruption of ventilation caused, for example, by an occlusion of the expiratory limb, is a major *risk* that is mitigated by an *anaesthetic breathing system* continuing-positive-pressure *alarm condition*.

Subclause 201.12.4.107.2 Oxygen supply failure *protection device*

The oxygen supply failure *protection device* permits the remaining oxygen, when the oxygen supply is below the *rated* pressure, to be safely delivered to the *patient* in this emergency situation. The oxygen supply failure *protection device* should attempt to maintain an oxygen concentration above 19 %. The oxygen supply failure *technical alarm condition* would have already generated a warning prior to the operation of this *protection device*.

Subclause 201.12.4.107.3 Hypoxic mixture delivery selection *protection device*

An hypoxic *protection device* has been mandated, as an alarm alone is not considered sufficient to prevent such accidents. A potential use error is closing of, for example, the oxygen delivery valve instead of the nitrous oxide valve. An hypoxic mixture delivery selection *protection device* either prevents this by not allowing the selection of hypoxic mixtures or via a pneumatic element that proportionally reduces the carrier gas fraction when the oxygen flow is reduced.

Subclause 201.12.4.108 *Protection device* for the workplace environment

Both nitrous oxide and halogenated volatile anaesthetic agents create potential occupational health *hazard*s. Therefore, the *manufacturer* of an *anaesthetic workstation* has to provide means to reliably route excess gases to an *AGSS*.

Subclause 201.13.101 Simultaneous failure

The purpose of this requirement is to ensure that failure of the *anaesthetic workstation* control function can be detected by the corresponding *monitoring equipment* or *alarm system* or prevented by a *protection device*. When, for example, a single sensor is used both as feedback for a control function and as input for the *alarm system*, a single failure or degradation can allow an undetected hazardous output. As a result, such construction is not permitted.

Subclause 201.14.6.1 Identification of known and foreseeable *hazard*s

RF wireless technology is increasingly being incorporated into *ME equipment* and *ME systems.* There are concerns, which should be addressed, about the potential effects of the use of this technology on the ability of the *anaesthetic workstation* and its individual components to function properly and the resultant safety of *patients* and *operators*.

Subclause 201.16.101.4 Connection for remote control

Control of the *anaesthetic workstation* from a distance can reduce the exposure of *operators* to *hazards*, for example radiation during a radiological *procedure*.

The *manufacturer* has to do a careful *risk analysis* to prevent technical failure and use errors.

Subclause 201.101.2 Interruption of the electrical *power supply*

Most mechanical/pneumatic *anaesthetic gas delivery system*s are independent from electrical power. These devices do not need any special precautions. For an electronically operated *anaesthetic gas delivery system* an "alternative means of gas delivery" can be, for example:

— an automatic switch-over to pure oxygen and a *technical alarm*, or

— a *technical alarm* and an alternative, manual gas delivery unit, or

— a *technical alarm* and an external oxygen cylinder with *pressure regulator* and flow-metering device and labelling advising the *operator* to have this ready.

Subclause 201.101.4.1.4 Reserve oxygen supply

This is to protect the *patient* in case of a failure of the primary source of oxygen.

Subclause 201.101.6.3Carbon dioxide flow rate adjustment control

The first time the 600 ml/min limit for carbon dioxide appeared in a standard was in the December 1990 amendment to BS 4272-3 [21]. This requirement was in response to reports of over delivery of carbon dioxide.

Subclause 201.101.8 Oxygen flush

Oxygen flush is used to rapidly fill the *anaesthetic breathing system* with oxygen and flush other *anaesthetic gases* out of the *anaesthetic breathing system*.

Subclause 201.101.9 *Fresh-gas outlet*

An *operator*-accessible *fresh-gas outlet* should have a means to prevent unintentional disconnection of the *fresh-gas outlet* connector.

Subclause 201.102.2.1*Maximum limited pressure protection device*

This *protection device* provides the ultimate fail-safe pressure protection in the case of failure of the adjustable pressure limitation (see 201.102.2.2).

Subclause 201.102.2.2*Adjustable pressure limit protection device*

The committee chose to include a requirement for an *operator-adjustable pressure limit protection device* to ensure that the *operator* has better control of maximum pressure. The adjustable pressure limitation can be used as the functional pressure limitation during normal operation in some modes of operation.

Subclause 201.102.4 Electrical conductivity

Burns can occur if antistatic or electrically conductive *breathing tubes* are used while high-frequency electric surgery equipment is in use. Therefore, such *breathing tubes* are not recommended.

Subclause 201.102.5.2 *Exhaust port* connector

For an integrated *anaesthetic breathing system*, the connectors may be proprietary and not even accessible for the *operator*, i.e. misconnection is prevented by design. Therefore it makes no sense to require markings for proprietary connectors in order to prevent misconnections.

Subclause 201.102.5.3Reservoir bag connector

During the development of this document, the requirement for the reservoir bag connection port to be "within 20° of the vertical axis" was questioned. Some members of the working group felt the requirement was unnecessarily design-restrictive. In the end, the majority of the working group members concluded that this requirement is an important and effective deterrent against accidental misconnections of other parts of the *anaesthetic breathing system* to the reservoir bag connection port if the reservoir bag connector is adjacent to the inspiratory or expiratory port and not separated by a flexible bag arm or a bag swivel mount.

A reservoir bag on the *patient* side of either the *inspiratory* or *expiratory valve* fills with exhaled gas, which is then re-breathed on subsequent inhalation.

As a reservoir bag often is used as a test lung for testing the *anaesthetic workstation*, the connector of a reservoir bag should still be a socket.

This requires a *breathing tube* with cones at both ends, if the reservoir bag connector at the *anaesthetic workstation breathing system* is a socket. If the reservoir bag is intended to be connected directly to the reservoir bag connector, the connector must be a cone. To prevent misconnections, this may only be done if the reservoir bag is directly connected to e.g. a flexible bag arm or a bag swivel mount that separates this connector from the inspiratory and expiratory connector.

Subclause 201.102.5.3.3 Connectors of the reservoir bag connecting tube

The requirement that the connectors at both ends of the reservoir bag connecting tube shall not have a 15 mm socket that connects to a 15 mm cone according to ISO 5356-1:2015 has been set in order to prevent a misconnection to a *patient connection port*.

Subclause 201.102.5.6 Inspiratory and expiratory port connectors of a *circle absorber assembly*

During the development of this document, the requirement for the "axis of these ports to be within $\pm$50 ° of the horizontal plane" was questioned. Some of the working group members felt the requirement was unnecessarily design-restrictive. In the end, the majority of the working group members concluded that this requirement is an important and effective deterrent against accidental misconnections of other parts of the *anaesthetic breathing system* to the inspiratory or expiratory port connectors of a *circle absorber assembly*. It also prevents kinking of the *breathing tubes*.

Subclause 201.102.6 Leakage

The limit of 150 ml/min for an entire *anaesthetic breathing system* was established for two reasons:

— to restrict the loss of gas volume intended to be delivered to the *patient*, and

— to limit *anaesthetic gas* pollution in the area of the *anaesthetic workstation*.

This limit was considered to be the maximum acceptable in view of all the other potential sources of gas leaks. Today the *manufacturer* of an *anaesthetic workstation* usually provides an integrated *anaesthetic breathing system* with the *anaesthetic workstation*. *Operators* frequently assemble breathing attachments, such as hoses, water traps, filters, and *y-pieces,* as they need from different *manufacturers*. The split of the leakage into 75 ml/min for each the *anaesthetic breathing system* and the external *accessories* was introduced to encourage the use of specified combinations that meet at least minimum requirements.

Subclause 201.102.7 Inspiratory and expiratory pressure/flow rate characteristics

Total expiratory and total inspiratory resistance are established at a maximum of 6 hPa (6 cmH_2O) each in order to limit the work of breathing for the spontaneously breathing *patient* and to restrict positive end-expiratory pressure. In setting the maximum, the Committee considered the resistances of commercially available components and selected a value between those considered and the ideal of zero resistance. This limit is considered to be the generally acceptable maximum physiological value by clinicians.

Subclause 201.102.8.1 *Y-piece*

The recess is a *risk control* measure against the accidental disconnection of the *y-piece* and the *breathing tube*.

Subclause 201.102.8.2 *Exhaust valve*

An open *exhaust valve* between the *inspiratory valve* and the *y-piece* permits free return of exhaled gas into the inspiratory pathway with subsequent rebreathing.

Although evaluating the performance of an *exhaust valve* under wet conditions would be a better model of real usage with a *patient*, wet condition testing yields inconsistent results that are not reproducible. Consequently, the disclosure requirement is based on testing performed under dry conditions.

Subclause 201.102.8.3 ****Breathing tubes*

Despite proper descriptions in the *accompanying documents* on how to connect the *breathing tubes* several critical incidents have happened.

An example has been, where the 1st *breathing tube* connected the inspiratory and the expiratory port connector of the *circle absorber assembly* and the 2nd *breathing tube* connected two ports of the *y-piece*. This results in a short circuit at the *y-piece* and the *circle absorber assembly* without connecting the *patient* to the *anaesthetic breathing system*. When the *breathing tubes* are long and/or have additional water traps integrated, this error might not be easily visible to the *operator*. By pre-assembling the *breathing tube* system without giving the *operator* the possibility to disassemble it again, this error can be prevented. This option can be appropriate for e. g. non-reusable sets of *breathing tubes*.

Another possibility to prevent this error is to flexibly connect both ends of a pair of *breathing tubes* to each other (see Figure 201.102). This will make visible the short circuit of a circle circuit at both the *patient* end and the inspiratory and expiratory ports. This option can be appropriate for reusable sets of *breathing tubes*.

Subclause 201.102.9.1 Constructional requirements

Ensuring unidirectional flow prevents undesirable rebreathing. Misassembling the *anaesthetic breathing system* into hazardous configurations is prevented by requiring valves to be non-interchangeable.

To prevent operation with exhausted, desiccated or no absorbent, the *operator* needs to be able to readily see the presence and visual indicator of the absorbent and the absorbent needs to indicate the state of exhaustion by a visual indicator.

Subclause 201.102.9.2 Absorbent bypass mechanism

Ensuring that the absorbent bypass control is firmly engaged and obvious to the *operator* prevents unintended, undesirable rebreathing including undefined and potentially hazardous intermediate states. Ensuring that gas does not flow to the absorbent when the control is in the "off" position permits changing the absorbent without polluting the local atmosphere or interrupting the flow of gases to the *patient*.

Subclause 201.102.10.1 Constructional requirements

A malfunction of these valves can cause rebreathing that is difficult to correct. Requiring that the *operator* be able to see the action of these valves is the most practicable means of *risk control*. Many valve designs are orientation-sensitive. Consequently, they need to be placed in a fixed orientation and that makes the *y-piece* an inappropriate location for such valves.

A *y-piece* with valves could be placed in reverse orientation to another set of *non-return valves* on a *circle absorber assembly*, making ventilation impossible.

Subclause 201.102.10.4 Reverse flow rate and dislocation

Reverse flow, dislocation, or ineffectiveness of *inspiratory* or *expiratory valves* can result in rebreathing of expired gases that causes a reduction of carbon dioxide elimination. The most significant leak with disk-type valves can be at low pressures, whereas with flap valves, the most significant leak can be closer to a pressure of 5 hPa (5 cmH_2O). A 60 ml/min reverse flow rate is considered clinically acceptable and attainable using current manufacturing techniques.

Subclause 201.102.11 *Fresh-gas inlet*

If the *fresh-gas inlet* is placed on the *patient* side of the *expiratory valve*, loss of *fresh gas* through the *exhaust valve* will occur. If the *fresh-gas inlet* is placed between the *expiratory valve* and the absorbent, the humidification of the *fresh gas* mixture will be enhanced; however, with this arrangement, loss of *fresh gas* through the *exhaust valve* can occur if the *exhaust valve* is not placed at a sufficient distance from the *fresh-gas inlet*. Placement of the *fresh-gas inlet* on the *patient* side of the *inspiratory valve* permits the *fresh gas* flow to pass by the *y-piece* during exhalation. This prevents the use of a spirometer in the expiratory limb of the *anaesthetic breathing system*.

Subclause 201.103.6.2 Outlet connectors

The use of differing connectors is intended to prevent connection to an inappropriate *disposal system*. See also ISO 7396-2:2007 and ISO 9170-2:2008.

Subclause 201.104.1.1 Marking

The delivery of the vapour of a volatile anaesthetic agent can be hazardous to the *patient*, *operator* and others in the vicinity. The *operator* needs to understand the proper operation and the maintenance of an *anaesthetic vapour delivery system* prior to operating it. Consequently, following the instructions for use is considered as a mandatory action for the safe operation of an *anaesthetic vapour delivery system*.

Subclause 201.104.2.2 Accuracy

To control the *risk* associated with under or over delivering the vapour of a volatile anaesthetic agent, agent-specific calibrated controls are required on an *anaesthetic vapour delivery system*.

Subclause 201.104.3 Vapour output during and after oxygen flush

There are *hazard*s that can arise from interaction between a conventional *anaesthetic vapour delivery system* and the oxygen flush on an *anaesthetic workstation*, for example:

— if the *anaesthetic vapour delivery system* is mounted downstream of the oxygen flush, the high flow rate (75 l/min) during a flush can cause the mass output from the *anaesthetic vapour delivery system* to increase; in some cases, this could force liquid anaesthetic agent out of the *anaesthetic vapour delivery system*;

— if the *anaesthetic gas delivery system* piping has a high resistance to flow, the pressure at the *anaesthetic vapour delivery system* during a flush can be high enough to cause a so-called "pumping effect" which can increase the output concentration of the *anaesthetic vapour delivery system*.

ISO 5358:1980[2] had requirements to address these *hazards* in that 19.4 required the flow of gas from the oxygen flush to be delivered to the *fresh-gas outlet* without passing through any *anaesthetic vapour delivery system*. It also required that the pressure at the *anaesthetic vapour delivery system* not be greater than 100 hPa (100 cmH_2O) during a flush. This 100 hPa (100 cmH_2O) helped determine the safety of an *anaesthetic vapour delivery system* in that 15.10 required the *anaesthetic vapour delivery system* to be tested with a pressure fluctuation of 100 hPa (100 cmH_2O) without the output changing by more than 20 %.

ISO 5358:1992[3] kept the requirement that the flow of gas from the oxygen flush be delivered to the *fresh-gas outlet* without passing through an *anaesthetic vapour delivery system* and that the pressure at the *anaesthetic vapour delivery system* not be greater than 100 hPa (100 cmH_2O) during a flush, but the pressure fluctuation test for the *anaesthetic vapour delivery system* was changed to 50 hPa (50 cmH_2O). This meant the 100 hPa (100 cmH_2O) test was no longer matched to an *anaesthetic vapour delivery system* test. This was probably an oversight, as the pressure fluctuation test was mainly concerned with the effects of *anaesthetic ventilators*.

The first *anaesthetic vapour delivery system* test proposed provided a 100 hPa (100 cmH_2O) pressure fluctuation test for an *anaesthetic vapour delivery system* to ensure that it was compatible with an *anaesthetic workstation* that was designed to accept an *interchangeable anaesthetic vapour delivery system*.

This provided pneumatic requirements for *manufacturers* of *anaesthetic vapour delivery systems* and *manufacturers* of *anaesthetic workstations* which would ensure compatibility if different *manufacturers*' products were connected together. This is equivalent to the original requirements found in ISO 5358:1980.

This test does not specify pressures or locations of *anaesthetic vapour delivery system* but specifies that the output of the *anaesthetic vapour delivery system* does not vary by more than a specified amount both during and after use of the oxygen flush. This gives greater flexibility for new designs (which can be insensitive to high pressure and high flow rates) without risking compatibility problems with older designs.

Subclause 201.105.2.2 *Adjustable pressure limit protection device*

The relationship between the *operator-adjustable pressure limit protection device* and the pressure *monitoring equipment* and its *alarm limits* is not addressed in this document. This is because of the differing ways in which pressure limitation can be used in clinical practice.

Subclause 201.105.7 Timed ventilatory hold

Holding mechanical ventilation is necessary for certain clinical *procedures*.

EXAMPLE Chest x-ray at *operator*-chosen level of inflation, chest x-ray at end expiration, measuring central venous pressure or cardiac output, measuring respirophasic blood pressure variation, suctioning the airway, turning the *patient*.

Currently, in order to avoid nuisance *alarm signals* and to avoid cycling the *anaesthetic ventilator* while the *anaesthetic breathing system* is disconnected from the *patient*, *operators* usually turn off the

anaesthetic ventilator and thereby incur the *risk* of undetected prolonged apnoea by subsequently forgetting to turn the *anaesthetic ventilator* back on.

Alternatively, the x-ray technician manually attempts to synchronize chest x-ray exposure to ventilatory hold through hand-eye coordination, with varying effectiveness. Automated synchronization of x-ray exposure and ventilation would provide clinical benefits.

In addition, there are situations where, to permit the minimum disruption of ventilation, the initiation of the ventilatory hold needs to come from external equipment. This is particularly important for those *procedures* where the *operator* needs to evacuate the immediate area or when manual synchronization would be less effective, such as with high doses of radiation.

As part of the *risk management process,* special attention should be paid to ensuring that the *patient's* lungs remain adequately ventilated when either externally generated or repetitive ventilatory holds occur.

Subclause 201.105.8 Subatmospheric pressure

During closed suctioning *procedure*s, where an external suctioning device is introduced into the airway to remove secretions while the *anaesthetic ventilator* is connected to the *patient*, high subatmospheric pressures can develop. Suctioning *procedure*s are regarded as expected *normal use* by an *operator*. It is recommended that the *anaesthetic breathing system* and the pressure transducers be able to withstand a pressure of 100 hPa to 400 hPa (100 cmH_2O to 400 cmH_2O) below ambient pressure. The suctioning is hazardous itself but should not have a negative impact on the *anaesthetic breathing system* during the suctioning *procedure*. There are known to have been deaths when pressure transducers have failed after closed suctioning.

Subclause 208.5.2.2 Technical description

Testing of *alarm systems* and *alarm conditions* helps to prevent unnoticed failure of important monitoring functions. If not performed automatically by the *anaesthetic workstation* or its individual components, the *responsible organization* has to ensure regular testing. Therefore, detailed information about these tests is necessary. Such tests will usually be too complex to be performed by the *operator*, and providing the information in the technical description is therefore considered sufficient.

Subclause 208.6.8.3 Global indefinite *alarm signal* inactivation states

Incidents can go undetected when *alarm signals* are permanently disabled.

Subclause 208.6.8.4 Termination of inactivation of *alarm signals*

Permitting very long pauses of *alarm signals* can be hazardous for the *patient* since the *operator* will not be notified of the existence of an *alarm condition*. However, *patient* management often requires delicate *procedure*s that can be disrupted by auditory *alarm signals.* Therefore, extending *audio paused* by *operator* action is useful to prevent the *anaesthetic workstation*s from disturbing the *operator* or others in the vicinity (e.g. surgeon).

Subclause 208.6.12 *Alarm system* logging

Optimal management of a *patient* requires the ability to review the history of important *alarm conditions*. This is a more reasonable means of *risk control* in the clinical environment for a *life-supporting ME equipment* or *ME system* than *latching alarm signals.* Additional information is also found in IEC 60601-1-8:2006+AMD1:2012, Annex A, for 6.12.

Annex BB
(normative)

Test for flammability of anaesthetic agent

BB.1 General

The following tests can be used to determine whether anaesthetic agents shall be regarded as non-flammable.

NOTE Cyclopropane and diethyl-ether are known to be flammable agents. Halothane, desflurane, sevoflurane, enflurane, and isoflurane have been found to be non-flammable agents.

BB.2 Spark ignition tests

Spark ignition tests shall be carried out with the most ignitable concentration of the anaesthetic agent mixed with the gases oxygen and/or nitrous oxide in which the anaesthetic agent is more ignitable using the test apparatus described in IEC 60601-1:2005, Annex G.

With an ignition probability of less than 10^{-3}, ignition shall not occur:

— in a resistive circuit at a d.c. voltage of 20 V with a current of 1,0 A and at a d.c. voltage of 100 V with a current of 0,15 A;

— in an inductive circuit at a d.c. current of 200 mA with an inductance of 10 mH and at a d.c. current of 60 mA with an inductance of 1 000 mH;

— in a capacitive circuit at a d.c. voltage of 100 V with a capacity of 1 μF and at a d.c. voltage of 20 V with a capacitance of 20 μF.

The measuring circuits are illustrated in IEC 60601-1:2005, Figures G.4 and G.6.

BB.3 Surface temperature ignition tests

Determination of the ignition temperature shall be carried out with apparatus and *procedures* based on ISO/IEC 80079-20-1:2017, with the following additional requirements:

— fill the test vessel with a mixture of oxygen and nitrous oxide in different proportions in successive tests, and

— cover the vessel with a lid which prevents diffusion but lifts easily if an explosion occurs.

The ignition temperature shall not be less than 300 °C.

Annex CC
(informative)
Terminology — alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP) and the IEC Electropedia provide access to many of these terms and definitions.

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NATIONAL ANNEX DD
(*National Foreword*)

DD-1 BIS CERTIFICATION MARKING

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