INTERNATIONAL STANDARD

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Medical electrical equipment —

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

Appareils électromédicaux —

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

Reference number
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Foreword

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

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives or www.iec.ch/members_experts/refdocs).

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

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

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

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

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

The main changes are as follows:

— update of normative references;

— update of terms and definitions;

— consideration of *anaesthetic workstations* using Oxygen 93;

— addition of requirements for *expected service life*;

— amendment of the requirements on test equipment;

— amendment of the requirements on warning and safety notices, on the instructions for use and on the technical description as well as design documentation;

— addition of marking requirements regarding the suitability of *anaesthetic workstations* and its components for use in a magnetic resonance environment;

— amendment of the requirements on compatibility with substances used with the *anaesthetic workstation* and its components;

— amendment of the requirements on *internal electrical power source*;

— amendment of the requirements on the exhaled volume *monitoring equipment*;

— amendment of the requirements on detachable, flow-direction-sensitive parts and accessories;

— amendment of the requirements on *multiple socket-outlets*;

— amendment of the requirements and recommendations for signal input/signal output part;

— amendment of the requirements on the flow-rate adjustment control;

— amendment of the requirements on the *maximum limited pressure protection device*;

— amendment of the requirements on the reservoir bag port connection port connector;

— amendment of the requirements on the inspiratory and expiratory pressure/flow rate characteristics

— amendment of the requirements on *breathing tubes* and *breathing tube* sets;

— amendment of the requirements on circle absorber assemblies;

— addition of requirements on ventilation modes;

— amendment of the requirements on *anaesthetic gas scavenging systems* by differentiation between active and non-active systems;

— amendment of the requirements on *anaesthetic ventilators* in case of interruption of the electrical or pneumatic *power supply*.

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

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

Introduction

In this document, the following print types are used:

— Requirements and definitions: roman type.

— Terms defined in Clause 3 of the general standard, in this particular standard and test specifications: italic type.

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term

— “clause” means one of the eight numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.12 are all subclauses of Clause 201.7).

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

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

For the purposes of this document, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformity with this document;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” is used to describe permission (e. g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

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

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

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

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

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

<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>

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

201.1 Scope, object and related standards

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

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

201.1.1 * Scope

Replacement:

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

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

— *anaesthetic gas delivery system;*

— *anaesthetic breathing system;*

— *anaesthetic gas scavenging system (AGSS);*

— *anaesthetic vapour delivery system;*

— *anaesthetic ventilator;*

— *monitoring equipment;*

— *alarm system;*

— *protection device.*

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

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

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

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

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

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

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

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

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

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

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

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

201.1.4 *Particular standards

Addition:

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

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

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

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

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

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

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

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

If an *anaesthetic workstation* is supplied with physiological monitoring, having more than one *applied part* on the *patient*, then IEC 80601-2-49:2018 applies. Measured parameters related to the inherent function of an *anaesthetic workstation* (i.e. *airway pressure*, ventilation volume, oxygen concentration, volatile anaesthetic agent concentration, 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*

