INTERNATIONAL STANDARD

ISO 80601-2-13

First edition
2011-08-01

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 performance essentielle pour les systèmes d'anesthésie

Reference number
ISO 80601-2-13:2011(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 80601-2-13 was prepared by a joint working group of 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 D, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-13 cancels and replaces the following:

— ISO 8835-2:2007, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems*

— ISO 8835-3:2007, *Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

— ISO 8835-4:2004, *Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices*

— ISO 8835-5:2004, *Inhalational anaesthesia systems — Part 5: Anaesthetic ventilators*

— IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

This edition constitutes a major technical revision of the material that was contained in the previous standards by consolidating it into a single document, removing duplications and inconsistencies as well as harmonization with the third edition of IEC 60601-1.

Introduction

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— 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.

— Terms defined in Clause 3 of the general standard, in this particular standard or as noted: small capitals.

In referring to the structure of this standard, the term

— “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

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

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

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

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

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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.

The attention of Member Bodies and National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

This International Standard considers both an ANAESTHETIC WORKSTATION supplied complete and its individual components. 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 International Standard identifies particular

requirements pertinent to specific ANAESTHETIC WORKSTATION components, and to their associated MONITORING EQUIPMENT, ALARM SYSTEM(S) and PROTECTION DEVICE(S), and defines the interfaces.

Figure 201.101 is a graphical representation of the structure of this International Standard and is provided for informational purposes only.

<table>
<tr><td colspan="3">ANAESTHETIC WORKSTATION</td></tr>
<tr><td>General requirements
Clauses 201.1 – 201.17, 201.106, 201.107, 202-211</td><td rowspan="3">MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES</td><td rowspan="3">Mandatory elements;
see also Table AA.1</td></tr>
<tr><td>ANAESTHETIC GAS DELIVERY SYSTEM
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Clause 201.103</td><td rowspan="3">MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES</td><td rowspan="3">Optionally present;
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Clause 201.104</td></tr>
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Clause 201.105</td></tr>
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Figure 201.101 — Configuration of an ANAESTHETIC WORKSTATION and corresponding organization of this International Standard

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

IEC 60601-1:2005, Clause 1 applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard 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 International Standard 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;

— 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 International Standard is indicated in Table AA.2.

This International Standard 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 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, as relevant.

HAZARDS inherent in the intended physiological function of an ANAESTHETIC WORKSTATION and its individual components within the scope of this International Standard are not covered by specific requirements in this International Standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 3 See also 4.2 of the general standard.

This International Standard 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 particular standard 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 201.3.211) and its ACCESSORIES.

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-3:2008 and IEC 60601-1-11:2010 do not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 206.4 in this particular standard 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 particular standard.

“Addition” means that the text of this particular standard 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 particular standard.

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 3.139, additional definitions in this standard 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 standard" 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 particular standard, 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 particular standard.

201.2 Normative references

The following referenced documents are indispensable for the application 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.

IEC 60601-1:2005, Clause 2 applies, except as follows:

Replacement:

Replace references to ISO 2878, ISO 15223, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 by the following:

ISO 2878:2005, *Rubber — Antistatic and conductive products — Determination of electrical resistance*

ISO 15223-1:—[1], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

ISO 407:2004, *Small medical gas cylinders — Pin-index yoke-type valve connections* [alternative normative reference to ISO 5145]

ISO 594-2:1998[2] , *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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1) To be published.

2) To be revised by ISO 80369-7, *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*, which is under preparation.

ISO 5145:2004, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning* [alternative normative reference to ISO 407]

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2:2006, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

ISO 5360:2006, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5362:2006, *Anaesthetic reservoir bags*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7396-1:2007, *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 8836, *Suction catheters for use in the respiratory tract*

ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

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

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements* [alternative normative reference to ISO 10079-3]

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source* [alternative normative reference to ISO 10079-1]

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 80601-2-55:—[3)], *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60079-11, *Explosive atmospheres — Part 11: Equipment protection by intrinsic safety "i"*

IEC 60079-20-1, *Explosive atmospheres — Part 20-1: Material characteristics for gas and vapour classification — Test methods and data*

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

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

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3) To be published.

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *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 62304:2006, *Medical device software — Software life cycle processes*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-8:2006 and the following apply.

NOTE An index of defined terms is found at the end of this document.

Addition:

201.3.201
ACTIVE ANAESTHETIC GAS SCAVENGING SYSTEM
ANAESTHETIC GAS SCAVENGING SYSTEM in which gas flow in the DISPOSAL SYSTEM results from a POWER DEVICE

NOTE Adapted from ISO 4135:2001, definition 7.1.2.

201.3.202
AIRWAY PRESSURE
pressure at the PATIENT CONNECTION PORT

201.3.203
ANAESTHETIC BREATHING SYSTEM
inspiratory and expiratory pathways through which ANAESTHETIC GAS flows at respiratory pressure between the FRESH-GAS INLET, the PATIENT CONNECTION PORT and an EXHAUST VALVE or EXHAUST PORT

NOTE Adapted from ISO 4135:2001, definitions 3.1.6 and 4.1.1.

201.3.204
ANAESTHETIC GAS
gases and, if present, vapour of a volatile anaesthetic agent, used in anaesthesia

NOTE In parts of an ANAESTHETIC BREATHING SYSTEM, ANAESTHETIC GAS includes gases exhaled by the PATIENT.

201.3.205
ANAESTHETIC GAS DELIVERY SYSTEM
ANAESTHETIC WORKSTATION component that receives separate supplies of MEDICAL GAS(ES) and delivers mixed gases in concentrations or individual flow rates adjustable by the OPERATOR

NOTE 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.

201.3.206
ANAESTHETIC GAS DELIVERY SYSTEM PIPING
all piping, including unions, from the UNIDIRECTIONAL VALVES in the pipeline inlets and from the outlets of the PRESSURE REGULATOR(S) to the means of flow rate adjustment control, as well as the piping connecting the

means of flow rate adjustment control and the piping connecting the ANAESTHETIC VAPOUR DELIVERY SYSTEM to the FRESH-GAS OUTLET

NOTE ANAESTHETIC GAS DELIVERY SYSTEM PIPING includes piping leading to and from pneumatic loss of pressure ALARM SIGNAL generators, pressure indicators, the oxygen flush and gas power outlets.

201.3.207
ANAESTHETIC GAS SCAVENGING SYSTEM
PROTECTION DEVICE that is connected to an ANAESTHETIC BREATHING SYSTEM or to associated equipment for the purpose of conveying excess ANAESTHETIC GAS to an appropriate place of discharge

NOTE 1 Adapted from ISO 4135:2001, definition 7.1.1.

NOTE 2 Functionally, an ANAESTHETIC GAS SCAVENGING SYSTEM comprises three different parts: a TRANSFER SYSTEM, a RECEIVING SYSTEM and a DISPOSAL SYSTEM. These three functionally discrete parts can be either separate or sequentially combined in part or in total. In addition, one or more parts of an ANAESTHETIC GAS SCAVENGING SYSTEM can be sequentially combined with an ANAESTHETIC BREATHING SYSTEM or an ANAESTHETIC VENTILATOR, to include the TRANSFER SYSTEM or the TRANSFER and RECEIVING SYSTEM.

201.3.208
ANAESTHETIC PATIENT VALVE
valve at the PATIENT end of an ANAESTHETIC BREATHING SYSTEM that has three operating functions:

— as a UNIDIRECTIONAL VALVE to prevent flow towards the vaporizer during exhalation,

— as an inflating valve to permit intermittent positive-pressure ventilation, and

— as a unidirectional EXHAUST VALVE to prevent inhalation of air through the EXHAUST PORT during spontaneous ventilation

201.3.209

ANAESTHETIC VAPOUR DELIVERY SYSTEM
ANAESTHETIC WORKSTATION component that provides the vapour of a volatile anaesthetic agent in a calibrated concentration

NOTE Adapted from ISO 4135:2001, definition 2.2.2.

201.3.210
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

201.3.211
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 The ANAESTHETIC WORKSTATION can also include, but is not limited to, one or more of the following: ANAESTHETIC VAPOUR DELIVERY SYSTEM, ANAESTHETIC VENTILATOR, ANAESTHETIC GAS SCAVENGING SYSTEM, and any associated MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES.

201.3.212
BREATHING TUBE
non-rigid tube used to convey ANAESTHETIC GAS between components of an ANAESTHETIC BREATHING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.1.2.

201.3.213
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

201.3.214
CIRCLE BREATHING SYSTEM
ANAESTHETIC BREATHING SYSTEM in which the direction of gas flow through inspiratory and expiratory pathways is unidirectional and in which the two pathways form a circle

201.3.215
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

201.3.216
DELIVERED VOLUME
V_{DEL}
volume of gas delivered through a PATIENT CONNECTION PORT during a breath

NOTE 1 Adapted from ISO 4135:2001, definition 3.4.2.

NOTE 2 DELIVERED VOLUME is also referred to as 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.

201.3.217
DISPOSAL HOSE
part of an ANAESTHETIC GAS SCAVENGING SYSTEM that conveys excess ANAESTHETIC GAS from the RECEIVING SYSTEM to the DISPOSAL SYSTEM

201.3.218
DISPOSAL SYSTEM
part of an ANAESTHETIC GAS SCAVENGING SYSTEM by means of which the excess ANAESTHETIC GAS is conveyed to the point of discharge

NOTE The point of discharge can be, for example, the exterior of a building or a non-recirculating extract ventilation system.

201.3.219
EXHAUST PORT
port through which waste or excess ANAESTHETIC GAS is discharged to the atmosphere or to an ANAESTHETIC GAS SCAVENGING SYSTEM

NOTE Adapted from ISO 4135:2001, definition 4.2.1.6.

201.3.220
EXHAUST VALVE
valve connected to an EXHAUST PORT

NOTE An ADJUSTABLE PRESSURE-LIMITING (APL) VALVE can be an EXHAUST VALVE.

201.3.221
EXHAUST FLOW RATE
flow rate of gas from the RECEIVING SYSTEM at the entry to the DISPOSAL SYSTEM