SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-13:2019

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Medicinska električna oprema - 2-13. del: Posebne zahteve za osnovno varnost in bistvene lastnosti delovnega mesta za anestezijo (ISO/DIS 80601-2-13:2019)

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO/DIS 80601-2-13:2019)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Anästhesie-Arbeitsplätzen (ISO/DIS 80601-2-13:2019)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie (ISO/DIS 80601-2-13:2019)

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

oSIST prEN ISO 80601-2-13:2019 **en**

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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

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Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

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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.

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 ISO documents 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).

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. 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).

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.

This document 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 62 D, *Electromedical equipment*.

This second edition cancels and replaces the first edition (ISO 80601-2-13:2011 including ISO 80601-2-13:2011/AMD 1:2015 and ISO 80601-2-13:2011/AMD 2:2018), which has been technically revised

The main technical changes compared to the previous edition are as follows:

- incorporation of the texts of the amendments AMD 1:2015 and AMD 2:2018;
- consideration of anaesthetic workstations using Oxygen 93;
- updates of the normative references;
- inclusion of a normative reference to the series of standards ISO 18562 and to the standard ISO 10993-1 on biocompatibility evaluation of breathing gas pathways and on biological evaluation of medical devices respectively;
- amendments of the requirements on test equipment;
- amendments to the requirements on marking on the outside of the equipment;
- amendments to the requirements in the instructions for use, the technical description and design documentation for anaesthetic equipment and its components;

- amendments to the alarm condition for power supply;
- for the determination of the A-weighted sound pressure, replacement of the normative reference ISO 3746 by ISO 3744:2010;
- amendments to the requirements on the internal electrical power source;
- amendments to the requirement on the connection for remote control;
- amendments to the requirements on the flow rate adjustment control;
- revision of the requirements on the reservoir bag connector;
- amendments of the requirements of the circle absorber assembly;
- amendments of the requirements of the accuracy on exhaled volume monitoring equipment;
- amendments to the requirements on timed ventilatory pause (expiratory pause);
- amendments of the pressure and flow-rate characteristics of the inspiratory and expiratory valves;
- addition of requirements on ventilation modes;
- amendments to the requirements on the adjustable pressure limitation *protection device*;
- addition of the normative reference to IEC 60601-1-12 for an anaesthetic workstation that is used in an emergency medical services environment.

A list of all parts in the ISO 80601 series can be found on the ISO website.

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.

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 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 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.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. 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
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

IEC 60601-1:2005 + AMD 1:2012, Clause 1 applies, except as follows:

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;*
- *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 7.2.13 and 8.4.1 of the general standard.

NOTE 3 See also 4.2 of the general standard.

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 201.3.209) 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, IEC 60601-1-9 + AMD 1:2013, IEC 60601-1-11:2010 + AMD 1: 2018 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.

IEC 60601-1:2005 + AMD 1:2012, Clause 2 applies, except as follows:

Replacement:

Replace references to ISO 2878, ISO 7000, ISO 7010, ISO 15223-1, IEC 60601-1-2, IEC 60601-1-6 and IEC 60601-1-8, IEC 62304:2006 by the following references:

ISO 2878:2017, *Rubber, vulcanized or thermoplastic — Antistatic and conductive products — Determination of electrical resistance*

ISO 7000:2014, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010:2011 + AMD 1:2012 + AMD 2:2012 + AMD 3:2012 + AMD 4:2013 + AMD 5:2014 + AMD 6:2014 + AMD7:2016 + AMD8:2017 + AMD9:2018, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 15223-1:2016, corrected version 2017-03, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1-2:2014 + AMD 1:2018, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010 + AMD 1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006 + AMD 2012, *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 60601-1-12:2014, *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 62304:2006 + AMD 1:2015, *Medical device software — Software life cycle processes*

Addition:

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

ISO 594-2:1998, *Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[1]

ISO 3744:2010, *Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Engineering methods for an essentially free field over a reflecting plane*

ISO 5145:2017, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning* [alternative normative reference to ISO 407]

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

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

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 5362:2006, *Anaesthetic reservoir bags*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing tubes intended for use with anaesthetic apparatus and ventilators*

[1] ISO/TC 121/SC 1/JWG 1 will reconsider the reference to ISO 594-2 when ISO 80369-2, *Small bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases applications* becomes available.

ISO 7396-1:2016 + AMD 1:2017, *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 8836:-[2], *Suction catheters for use in the respiratory tract*

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 10079-1:2015 + AMD 1:2018, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements* [alternative normative reference to ISO 10079-3]

ISO 10079-3:2014, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source* [alternative normative reference to ISO 10079-1]

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 18562-2:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter*

ISO 18562-3:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)*

ISO 18562-4:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate*

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*

IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + AMD 1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

[2] Publication of new edition in preparation.