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oSIST prEN ISO 11197:2024
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Enote za oskrbo v medicini (ISO/DIS 11197:2024)

Medical supply units (ISO/DIS 11197:2024)

Medizinische Versorgungseinheiten (ISO/DIS 11197:2024)

Gaines techniques à usage médical (ISO/DIS 11197:2024)

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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 Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas supply systems*.

This fifth edition cancels and replaces the fourth edition (ISO 11197:2019), which has been technically revised. The main changes compared to the previous edition are as follows:

- editorial revision;
- concerning the transition of temporary healthcare facilities to those which will become permanent installations;
- inclusion in the requirements defining the use of anti-static hoses within medical supply units;
- inclusion of amendments following a scope gap assessment conducted against IEC 60601-1:2005+A1:2012

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.

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Introduction

Many healthcare facilities use surface-mounted or recessed containment systems and *enclosures* for accommodating and displaying essential *patient* care services. These are known as *medical supply units*.

This document specifies requirements for *medical supply units* manufactured in factories or assembled from components on site.

It is intended for use by those persons involved in the design, construction, inspection, testing, maintenance and operation of healthcare facilities as well as those manufacturing, assembling and installing *medical supply units*.

Persons involved in the design, manufacture, installation, maintenance and testing of equipment intended to be connected to *gas for medicinal use, medical device gas, vacuum, anaesthetic gas scavenging* and/or *plume extraction systems* should be aware of the contents of this document.

This document is a particular standard, based on IEC 60601-1:2005+A1:2012. IEC 60601-1:2005+A1:2012 is the basic standard for the safety of all *medical electrical equipment* used by or under the supervision of qualified personnel in the general medical and *patient environment*; it also contains certain requirements for reliable operation to ensure safety.

In order to fully understand this Particular Standard the reader is guided to read the Collateral Standard IEC 60601-1:2005+A1:2012 in parallel.

IEC 60601-1:2005+A1:2012 has associated collateral standards and particular standards. The collateral standards include requirements for specific technologies and/or *hazards* and apply to all applicable equipment, such as medical systems, *electromagnetic compatibility* (EMC), radiation protection in diagnostic X-ray equipment, software, etc. The particular standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

Where a healthcare facility is developed for temporary use, such as in a pandemic or other natural disaster, the basic principles of this standard shall apply. Once the stage of critical use of the facility has normalised the product remaining in use shall fulfil the requirements of this standard.

NOTE Definitions of collateral standard and particular standard can be found in IEC 60601:2005+A1:2012.

For an explanation of the special numbering in this document and more on the terms “collateral”, “particular” and “general” standards, see 201.1.3, 201.1.3.1, 201.1.3.2.

Annex AA contains rationale statements for some of the requirements of this document. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this document. The clauses and subclauses marked with (*) after their number have a corresponding rationale contained in Annex AA.

In this document, the following print types are used:

- requirements, compliance with which can be verified, and definitions: roman type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller roman type. Normative text of tables is also in a smaller roman type;
- *test methods: italic type;*
- *terms defined in clause 3 of the general standard, in this document or as noted: italic type.*

Medical supply units

201.1 Scope, object and related standards

IEC 60601-1:2005+A1:2012, Clause 1 applies except as follows:

201.1.1 Scope

IEC 60601-1:2005+A1:2012, 1.1 is replaced by:

This document applies to the *basic safety* and *essential performance* of MEDICAL SUPPLY UNITS, hereafter also referred to as *ME equipment*.

This document applies to MEDICAL SUPPLY UNITS manufactured within a factory or assembled on site, including joinery, cabinetry and other *enclosures*, which incorporate *patient* care services.

NOTE 1 A party that assembles on site various components intended for *patient* care services into an *enclosure* is considered the *manufacturer* of the MEDICAL SUPPLY UNIT.

Hazards inherent in the intended function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this standard, except in IEC 60601-1:2005+A1:2012, 7.2.13 and 8.4.1 (see 201.1.4).

NOTE 2 Refer to IEC 60601-1:2005+A1:2012, 4.2.

201.1.2 Object

IEC 60601-1:2005+A1:2012, 1.2 is replaced by:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for *MEDICAL SUPPLY UNITS* as defined in 201.3.201.

201.1.3 Related standards

201.1.3.1 General and Collateral standards

IEC 60601-1:2005+A1:2012, 1.3 applies as the *General Standard* with the following addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005+A1:2012, Clause 2 as well as 201.2 of this particular standard.

IEC 60601-1-3:2008+A1:2013, IEC 60601-1-8:2006+A1:2012, IEC 60601-1-9:2007, IEC 60601-1-10:2007+A1:2013 and IEC 60601-1-11 and IEC 60601-1-12 do not apply.

NOTE Collateral standards are referred to by their document numbers.

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201.1.3.2 Particular standards

IEC 60601-1:2005+A1:2012, 1.4 applies with the following additions:

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005+A1:2012 with the prefix “201” (e.g. 201.1 in this standard addresses the content of IEC 60601-1:2005+A1:2012 Clause 1) 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, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005+A1:2012 are specified by the use of the following words:

- “Replacement” means that the clause or subclause of IEC 60601-1:2005+A1:2012 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 IEC 60601-1:2005+A1:2012 or applicable collateral standard.
- “Amendment” means that the clause or subclause of IEC 60601-1:2005+A1:2012 or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of IEC 60601-1:2005+A1:2012 are numbered starting from 201.101. 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, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to IEC 60601-1:2005+A1:2012, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of IEC 60601-1:2005+A1:2012 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+A1:2012 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 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 60364-7-710:2002, *Electrical installations of buildings — Part 7-710: Requirements for special installations or locations - Medical locations*

IEC 60598-1:2014+A1:2017 *Luminaires — Part 1: General requirements and tests*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

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IEC 60601-1-3:2008+A1:2013, *Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-Ray equipment*

IEC 60601-1-6:2010+A1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 61386-1:2008+A1:2017, *Conduit systems for cable management — Part 1: General requirements*

IEC 62684:2018, *Interoperability specifications of common external power supply (EPS) for use with data-enabled mobile telephones*

ISO 32, *Gas cylinders for medical use - Marking for identification of content*

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

ISO 5367:2023, *Anaesthetic and respiratory equipment – Breathing sets and connectors*

ISO 7396-1:2016, *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 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 16571:2014, *Systems for evacuation of plume generated by medical devices*

EN 50174-1:2018, *Information technology. Cabling installation — Part 1: Installation specification and quality assurance*

EN 50174-2:2018, *Information technology. Cabling installation — Part 2: Installation planning and practices inside buildings*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, ISO 16571:2014, ISO 7396-1:2016 and the following apply.

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

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

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

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Replacement of 3.26:

201.3.26 enclosure

surrounding case constructed to provide a degree of protection to personnel against accidental contact with live parts and also the enclosed equipment against specified environmental conditions

Note 1 to entry: The environmental conditions are referenced in IEC 61950:2007, 3.15.

Note 2 to entry: An ENCLOSURE can be subdivided into *compartments*.

Addition:

201.3.63 medical electrical equipment ME equipment

Note 1 to entry: MEDICAL SUPPLY UNITS may be connected to more than one *supply mains*.

Addition:

201.3.67 multiple socket-outlet

Note 1 to entry: MEDICAL SUPPLY UNITS are not considered as a *multiple socket outlet*.

201.3.201 medical supply unit

permanently installed *ME equipment* intended to supply electric power, communication means (telephone, call systems, etc.), data transmission, lighting, and/or *gas for medicinal use, medical device gas* and/or liquids, an ANAESTHETIC GAS SCAVENGING SYSTEM and/or a *plume evacuation system*, low level waste gas extract ductwork systems and vents/grilles to medical areas of a *healthcare facility*.

Note 1 to entry: *medical supply units* can include *ME equipment* or *ME systems* or parts thereof. *medical supply units* can also consist of modular sections for electrical supply, lighting for therapy or illumination, communication, supply of *gas for medicinal use, medical device gas* and liquids, *plume evacuation systems* and ANAESTHETIC GAS SCAVENGING SYSTEM. Some typical examples of *medical supply units* are bed head service modules, ceiling pendants, beams, booms, columns, pillars, wall mounted *enclosure* for area shut-off valve boxes of the *medical gas pipeline system*, joinery, cabinetry, concealed *compartments* on or in a wall and prefabricated walls.

Note 2 to entry: Examples of configurations are given in Figures 201.103, 201.104 and 201.105.

Note 3 to entry: Where in-patient care locations (bed spaces) are required within an acute healthcare facility for dedicated purposes, for example mental health patients, prisons etc, care should be taken to provide bedhead services arrangements including medical supply units which limit ligature points or ease of access to services therein.

201.3.202 junction point

connection point(s) between the *medical supply unit* and the inter-connecting system(s) already installed