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Medical supply units

Gaines techniques à usage médical

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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 fourth edition cancels and replaces the third edition (ISO 11197:2016), which has been technically revised. The main changes compared to the previous edition are as follows:

— editorial revision;

— change in the requirements defining the inclusion of USB outlets within medical supply units;

— addition of methods of internal cabling connections and specific tests including but not limited to impact resistance.

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

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.

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.

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 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 of 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.

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*

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 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.

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* 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 systems*. 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.

201.3.202
junction point
connection point(s) between the *medical supply unit* and the inter-connecting system(s) already installed

201.3.203
compartment
area within an *enclosure* which is created by separating barriers, walls and covers forming its own cellular section

201.4 General requirements

IEC 60601-1:2005+A1:2012, Clause 4 applies.

Addition

201.4.2.3.1 *Hazards* identified in the IEC 60601 series

The *manufacturer* shall undertake all tests as defined or referenced within this standard and Annex BB, and record the results. National standards might also apply which require test and record keeping.

201.5 General requirements for testing *ME equipment*

IEC 60601-1:2005+A1:2012, Clause 5 applies with the following additions:

201.5.9.2.3 Actuating mechanisms

All external surfaces shall conform to a degree of protection against direct contact in *normal use* of at least IP2X or IPXXB. Refer to IEC 60529:1989+AMD1:1999+AMD2:2013 CSV/COR2:2015.

This level of protection to live parts shall not be compromised during maintenance of the *medical gas pipeline systems*, *anaesthetic gas scavenging systems*, *plume evacuation systems* or liquid pipeline systems, e.g. by the provision of covers, barriers or individual protection with a degree of protection of at least IP2X or IPXXB. Refer to IEC 60529:1989+AMD1:1999+AMD2:2013 CSV/COR2:2015.

If requested by the *healthcare facility* (e.g. in psychiatric or paediatric units or prison healthcare facilities), the *manufacturer* shall provide means to prevent inadvertent or unauthorized dismantling of *medical supply units*.

201.5.101 *Medical supply unit* test results

The *manufacturer* shall test each *medical supply unit*. The test results shall be recorded and presented to the *responsible organization* on request.

The *manufacturer* shall maintain legible records of all tests undertaken on each *medical supply unit* according to applicable requirements subject to a minimum period of 5 years for compliance with this document.

201.6 Classification of *ME equipment* and *ME systems*

IEC 60601-1:2005+A1:2012, Clause 6 applies, with the following additions:

201.6.1 Protection against electric shock

A *medical supply unit* shall be designed and constructed as *class i*.

201.7 *ME equipment* identification, marking and documents

IEC 60601-1:2005+A1:2012, Clause 7 applies, with the following additions:

201.7.2.1 Minimum requirements for marking on *ME equipment* and on interchangeable parts

Mains-operated equipment, including separable components thereof which have a *mains part*, shall be provided with permanent and legible marking on the outside of the major part of the equipment indicating the origin and model or type reference.

201.7.2.1.1 *Terminal units*

Terminal units for *gas for medicinal use* and *medical device gas* which are mounted within a *medical supply unit* shall be obvious. Where decorative finishes are applied to the *medical supply unit* (e.g. graphics, where the *terminal unit* is displayed as part of the graphic) the design shall ensure a plain surround to the protrusion hole for the *terminal unit* of not less than 10 mm.

— *terminal units* for *medical gas*, *medical device gas* pipeline systems shall be marked in accordance with ISO 9170-1:2017. Colour coding, if used, shall be in accordance with ISO 9170-1:2017 and ISO 32.

— *terminal units* for *anaesthetic gas scavenging systems* shall be marked in accordance with ISO 9170-2:2008. Colour coding, if used, shall be in accordance with ISO 9170-2:2008.

— *terminal units* for liquids for dialysis shall be marked with the name of the liquid in accordance with Table 201.101 or with the equivalent national language.

— *terminal units* for plume evacuation shall be marked in accordance with ISO 16571:2014.

NOTE Regional or national regulations which apply to *ME equipment* identification, marking and documents might exist.

Table 201.101 — Marking for liquids

Name of liquid
Potable water, cold
Potable water, warm
Cooling water
Cooling water, feed-back
De-mineralized water
Distilled water
Dialysing concentrate
Dialysing permeate

201.7.2.1.1 Minimum requirements for marking on *medical supply units* and attachable parts.

Parts of *medical supply units* designed for additional loads shall be marked to show the maximum *safe working load* specified by the *manufacturer*.

NOTE *Medical supply units* can comprise various attachments such as rail systems for supporting *medical equipment*, shelves, articulated equipment support arms, tracks for monitoring equipment and similar attachments.

201.7.2.6 Connection to the *supply mains*

Due to the possible complexity of external marking, information indicating all electrical and electronic connections to the *medical supply unit* shall be located at the *junction point* inside the equipment.

For electrical connections, the information shall indicate voltages, number of phases, and differentiation of circuits. For electronic connections, the information shall indicate connector numbers and wire identification.

201.7.2.8 Output connectors

201.7.2.8.1 Mains power output

Mains socket-outlets for special purposes (e.g. for x-ray equipment) shall be marked with the type of *supply mains*, rated voltage, rated current and with a label (e.g. "X-RAY").

When a *medical supply unit* is provided with socket-outlets for connection to an essential electrical supply circuit (e.g. uninterruptable power supply (UPS), a Medical IT system as defined in IEC 60364-7-710:2002), these socket-outlets shall comply with the installation rules or be individually identified if not covered by those rules.

If socket-outlets in the same location are supplied from different power sources, each source should be readily identifiable.

NOTE Regional or national regulations can apply to the mains power outlet configurations.

Addition

201.7.2.8.2 USB Charging

Where Universal Serial Bus (USB) charging devices are installed within *medical supply units* they shall not form part of a mains power socket assembly. USB charging devices should be stand-alone units wired on a *final circuit*. The USB charging device shall comply with IEC 62684:2018 and conform to the requirements for dedicated charging ports (DCP) of EN 62680-1-1:2015 to provide a nominal output voltage not exceeding 5 V DC.

The facia plate shall be marked to indicate the following:

— symbol for nature of supply, for direct current only;

— rated current, in milliamperes or amperes;

— rated output voltage;

— labelled "*for non medical use only*" in the local language.

Where a USB charging device is intended to supply a *medical device*, the power supply source shall be resilient, e g: UPS or Medical IT system. The facia plate shall be marked to indicate the following:

— symbol for nature of supply, for direct current only;

— rated current, in milliamperes or amperes;