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Medical supply units (ISO/DIS 11197:2018)

Gaines techniques à usage médical (ISO/DIS 11197:2018)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121.

ISO 11197 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with ISO Technical Committee TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 11197:2016), which has been technically revised.

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 International Standard 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 MEDICAL GAS, MEDICAL DEVICE GAS, VACUUM, ANAESTHETIC GAS SCAVENGING and/or PLUME EXTRACTION SYSTEMS should be aware of the contents of this document.

This International Standard 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 COMPATABILITY (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, 201.1.4, and 201.1.5.

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

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 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL SUPPLY UNITS, hereafter also referred to as ME EQUIPMENT.

This International Standard 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 International Standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of IEC 60601-1:2005+A1:2012 (see 201.1.4).

NOTE 2 See also 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 International Standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL SUPPLY UNITS as defined in 201.3.103.

201.1.3 Related standards

201.1.3.1 Collateral standards

IEC 60601-1:2005+A1:2012, 1.3 applies 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, IEC 60601-1-8:2006+A1:2012, IEC 60601-1-9:2007, and IEC 60601-1-10:2007+A1:2013 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the Bibliography on page 25.

IEC 60601-1:2005+A1:2012, Clause 2 applies and IEC 60601-1-2:2014, Clause 2 applies, with the following additions:

IEC 60364-5-54:2011, *Electrical installations of buildings — Part 5-54: Selection and erection of electrical equipment; Earthing arrangements, protective conductors and protective bonding conductors*

IEC 60364-7-710:2002, *Electrical installations of buildings — Part 7-710: Requirements for special installations or locations; Medical locations*

IEC 60529:1989+AMD1:1999 +AMD2:2013 CSV/COR2:2015, *Degrees of protection provided by enclosures (IP Code)*

IEC 60598-1:2014, *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 compatibility – Requirements and tests*

IEC 60601-1-3:2008, *Medical electrical equipment — Part 1: General requirements for safety 3. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment*

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+A1:2012, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, test 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 61386-1:2008, *Conduit systems for cable management — Part 1: General requirements*

IEC 61950:2007, *Cable management systems — Specifications for conduit fittings and accessories for cable installations for extra-heavy duty electrical steel conduit*

ISO 32

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 7396-2:2008, *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 14971:2012, *Medical devices — Application of risk management to medical devices*

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

EN 50174-1:2009 + A2:2014, *Information technology. Cabling installation — Part 1: Installation specification and quality assurance*

EN 50174-2:2009+ A2:2014, *Information technology. Cabling installation — Part 2: Installation planning and practices inside buildings*

201.3 Terms and definitions

For the purpose 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.

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: See 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

MEDICAL SUPPLY UNITS may be connected to more than one SUPPLY MAINS.

Addition:

201.3.67
MULTIPLE SOCKET-OUTLET

Note: MEDICAL SUPPLY UNITS are not considered **MULTIPLE SOCKET OUTLETS**

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 MEDICAL GASES, MEDICAL DEVICE GASES 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 MEDICAL GASES, MEDICAL DEVICE GASES 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, enclosures 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

An 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.

201.4.2.3.1 Hazards identified in the 60601-1 series

The MANUFACTURER shall undertake all tests as defined or referenced within this standard and Annex BB, and record the results. National standards may 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 operation of at least IP2X or IPXXB. See 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. See 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.

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:

