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Medical supply units

Gaines techniques à usage médical

[Revision of second edition (ISO 11197:2004)]

ICS 11.040.10

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the European Committee for Standardization (CEN), and processed under the **CEN-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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Foreword

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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/IEC 11197 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

This second edition cancels and replaces the first edition, clause(s), subclause(s), table(s), figure(s) and annex(es) of which have been technically revised.

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Introduction

Many healthccare facilities use surface-mounted containment systems and enclosures for housing 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, vacuum, anaesthetic gas scavenging and plume extraction systems should be aware of the contents of this document.

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Medical supply units

1 Scope

201.1.1 Scope

Replacement:

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.

NOTE The definition of a MANUFACTURER and guidance on assembly on site can be found in ISO 14971 and ISO 13485.

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 the general standard.

NOTE See also 4.2 of the General Standard.

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201.1.2 Object

Replacement:

The object of this International Standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL SUPPLY UNITS as defined in 201.3.104.

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, IEC 60601-1-8 and IEC 60601-1-9 do not apply.

201.1.4 Particular standards

Replacement:

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In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard 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 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 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 or figures which are additional to those of the general standard 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 the general standard, 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 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.

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201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard and Clause 2 of IEC 60601-1-2 apply, except as follows:

Addition:

IEC 60364-5-54:2001, *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*

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IEC 60601-1-3:2005, *Medical electrical equipment - Part 1: General requirements for safety 3. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment*

IEC 60601-1-8:2006, *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 60529:2001, *Degrees of protection provided by enclosures (IP Code)*

IEC 60598-1:2008, *Luminaires - Part 1: General requirements and tests*

IEC 60669-1:2007, *Switches for household and similar fixed-electrical installations – Part 1: General requirements*

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 32:1977, *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 5359:2008, *Low-pressure hose assemblies for use with medical gases*

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

ISO 9170-2:2008, *Terminal units for medical gas pipeline systems – Part 2: Terminal units for anaesthetic gas scavenging systems*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

201.3 Terms and definitions

For the purpose of this document, the terms and definitions given in IEC 60601-1:2005, ISO 16571 and ISO 7396-1 apply, except as follows:

NOTE An index of defined terms is found beginning on page 31.

Replacement of 3.26:

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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

(See IEC 61950:2007, 3.15)

NOTE An ENCLOSURE can be subdivided into COMPARTMENTS.

Addition:

201.3.101
COMPARTMENT
part of an ENCLOSURE with openings necessary for interconnection, control or ventilation

201.3.102
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 and/or liquids, ANAESTHETIC GAS SCAVENGING SYSTEMS (AGSSs) and PLUME EVACUATION SYSTEMS (PESs) to medical areas of a healthcare facility

NOTE 1 MEDICAL SUPPLY UNITS can include MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL 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 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, and prefabricated walls.

NOTE 2 Examples of configurations are given in Figures 201.103, 201.104 and 201.105.

201.3.103
PLUME EVACUATION SYSTEM
PES

device for capturing, transporting, and filtering plume and exhausting the filtered product

NOTE Plume evacuation systems may also be called smoke evacuators, laser plume evacuators, plume scavengers, and local exhaust ventilators (LEVs).

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201.4 General requirements

Clause 4 of the general standard applies.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.9.2.3 Actuating mechanisms

Addition:

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.

This level of protection to live parts shall not be compromised during maintenance of MEDICAL GAS PIPELINE SYSTEM, ANAESTHETIC GAS SCAVENGING SYSTEM, PLUME EVACUATION SYSTEM 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.

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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.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies except as follows:

201.6.2 Protection against electric shock

Addition:

A MEDICAL SUPPLY UNIT shall be designed and constructed as CLASS I and fulfill the requirements of a TYPE B APPLIED PART according to the degree of protection against electric shock.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies except as follows:

201.7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

Addition:

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.

a) Particular applications

If the MEDICAL SUPPLY UNIT is intended to be used in conjunction with PATIENT monitors for electromyograph and/or electroencephalograph and/or electrocardiograph, the MEDICAL SUPPLY UNIT shall be marked with the particular application as follows:

– for electromyograph EMG

– for electroencephalograph EEG

– for electrocardiograph ECG or EKG

b) Terminal units

– Terminal units for MEDICAL GASES and vacuum shall be marked in accordance with ISO 9170-1 or national regulations. Colour coding, if used, shall be in accordance with ISO 9170-1 or national regulations.

– Terminal units for ANAESTHETIC GAS SCAVENGING SYSTEMS shall be marked in accordance with ISO 9170-2 or national regulations. Colour coding, if used, shall be in accordance with ISO 9170-2 or national regulations.

– Terminal units for liquids shall be marked with the name of the liquid in accordance with Table 201.101 or the equivalent national language.

- Terminal units for plume evacuation shall be marked in accordance with ISO 16571.

NOTE Regional or national regulations which apply to ME EQUIPMENT identification, marking and documents can exist.

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