INTERNATIONAL STANDARD

ISO 11197

Fourth edition
2019-11

Medical supply units

Gaines techniques à usage médical

Reference number
ISO 11197:2019(E)

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Published in Switzerland

Contents

Page

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;

— rated output voltage;

— Medical Use Only.

201.7.2.19 *Functional earth terminals*

Facilities for the connection of *protective equipotential bonding* shall be marked with symbol 8 of IEC 60601-1:2005+A1:2012, Annex D, Table D.

201.7.3 Marking on the inside of *ME equipment* or *ME equipment* parts

Junction points and pipelines for *gas distribution systems* shall be marked in accordance with ISO 7396-1:2016. Colour coding, if used, shall be in accordance with ISO 7396-1:2016 or ISO 32.

Junction points and pipelines for *anaesthetic gas scavenging systems* shall be marked in accordance with ISO 7396-2:2007. Colour coding, if used, shall be in accordance with ISO 7396-2:2007, ISO 32.

Junction points and pipelines for liquids shall be marked with the name of the liquid in accordance with Table 201.101 or the equivalent in national language.

Junction points and pipelines for *plume evacuation* shall be marked in accordance with ISO 16571:2014.

If the *medical supply unit* has a terminal connecting the neutral line of the power supply, it shall be clearly identified using the sign A of IEC 60601-1:2005+A1:2012, Annex D.3, the letter N and/or be colour coded blue.

201.7.8.1 Colours of indicator lights

Where electrical components such as indicators, control buttons and the like are incorporated into a *medical supply unit*, the requirements of IEC 60 601-1:2005+A1:2012 shall be maintained.

NOTE 1 Where *supply mains final circuit* socket-outlets are incorporated within *medical supply units*, these are generally only supplied by socket-outlet *manufacturers* from a general range without adaptation for healthcare use. Where lamp/neon/Light Emitting Diode (LED) indicators are supplied as part of that assembly, the illumination colour might not be in accordance with Table 2 of 60601-1:2005+A1:2012.

NOTE 2 The illumination of an indicator might not truly reflect the operational state of the socket-outlet or its *supply mains*.

201.7.9 *Accompanying documents*

201.7.9.1 General

Replace the first dash in IEC 60601-1:2005+A1:2012, 7.9.1 with the following:

The *accompanying documents* shall include the following:

— the name or trade name and address of the *manufacturer* and the authorized representative where the *manufacturer* does not have a registered place of business within the local market;

— a declaration of conformity by the *manufacturer* or on-site *manufacturer* of compliance with this standard and that the *manufacturer* has satisfied the testing requirements.

201.7.9.2 Instructions for use and maintenance

201.7.9.2.1 General

The instructions for use shall contain the date of issue or the latest revision of the instructions for use.

201.7.9.2.16 Reference to the technical description

General information

— Instructions for use shall state which parts of the equipment are capable of bearing additional loads. The maximum *safe working load* shall be stated.

— If flexible hoses and hose assemblies are used as part of the *gas distribution systems* and liquids for dialysis and/or are components of an *anaesthetic gas scavenging system* or a *plume evacuation system* in an *operator*-adjustable system (e.g. a ceiling pendant), the instructions for use shall include a *procedure* for, and the recommended frequency of inspection and replacement.

Responsibility of the *manufacturer*

— The *manufacturer* shall document the manufacturing tests that have been performed on each *medical supply unit* to demonstrate that the requirements of this standard have been met. This documentation shall be retained and made available upon request.

Specifications for installation, use and maintenance

— *Medical supply units* shall be manufactured, tested, installed and used in compliance with this standard and supported by the *manufacturer's* instructions.

NOTE Refer to IEC 60364-7-710:2002 for information on this subject.

Where a *medical supply unit* incorporates a luminaire, it is recommended that consideration is given to the mounting height of the luminaire portion such that it will meet user requirements for (task or general) illumination, viewed luminance and access to services for maintenance or function.

201.7.9.3 Technical description

a) If flexible hoses are used for supplying *gas for medicinal use* and *medical device gases* in an *operator*-adjustable system (e.g. a ceiling pendant), the instructions for use shall state that the following tests given in ISO 7396-1:2016 shall be carried out following modification or replacement of the flexible hose:

— test for leakage;

— test for obstruction;

— test for particulate contamination;

— test of flow and pressure drop;

— test for cross connection;

— test of gas identity.

b) If flexible hoses are used for an *anaesthetic gas scavenging system* in an *operator*-adjustable system (e.g. a ceiling pendant), the instructions for use shall state that the following tests given in ISO 7396-2:2007 shall be carried out following modification or replacement of the flexible hose:

— test for leakage,

— test of flow and pressure drop.

c) If flexible hoses are used for supplying liquids (e.g. for dialysis) in an *operator*-adjustable system (e.g. a ceiling pendant), the instructions for use shall state that the following test shall be carried out following modification or replacement of the flexible hose:

— test for leakage.

— test for cross connections between pipelines for different liquids.

d) If flexible hoses are used for a *plume evacuation system* in an *operator*-adjustable system (e.g. a ceiling pendant), the instructions for use shall state that the following test, given in ISO 16571:2014, shall be carried out following modification or replacement of the flexible hose:

— test for leakage.

201.8 Protection against electrical *hazards* from *ME equipment*

IEC 60601-1:2005+A1:2012, Clause 8 applies, with the following additions:

201.8.1 Fundamental rule of protection against electric shock

Medical supply units shall be constructed so that the mechanisms, operable parts, parts which are live or might become live in the event of a *single fault condition* are not accessible without the use of a key or *tool*.

Luminaires installed in or mounted on *medical supply units* shall comply with IEC 60598-1:2014+A1:2017.

201.8.6 Protection earthing, functional earthing and potential equalization of *ME equipment*

201.8.6.2 *Protective earth terminal*

Typical examples for the earth conductor connection of *medical supply units* are shown in Figure 201.101.

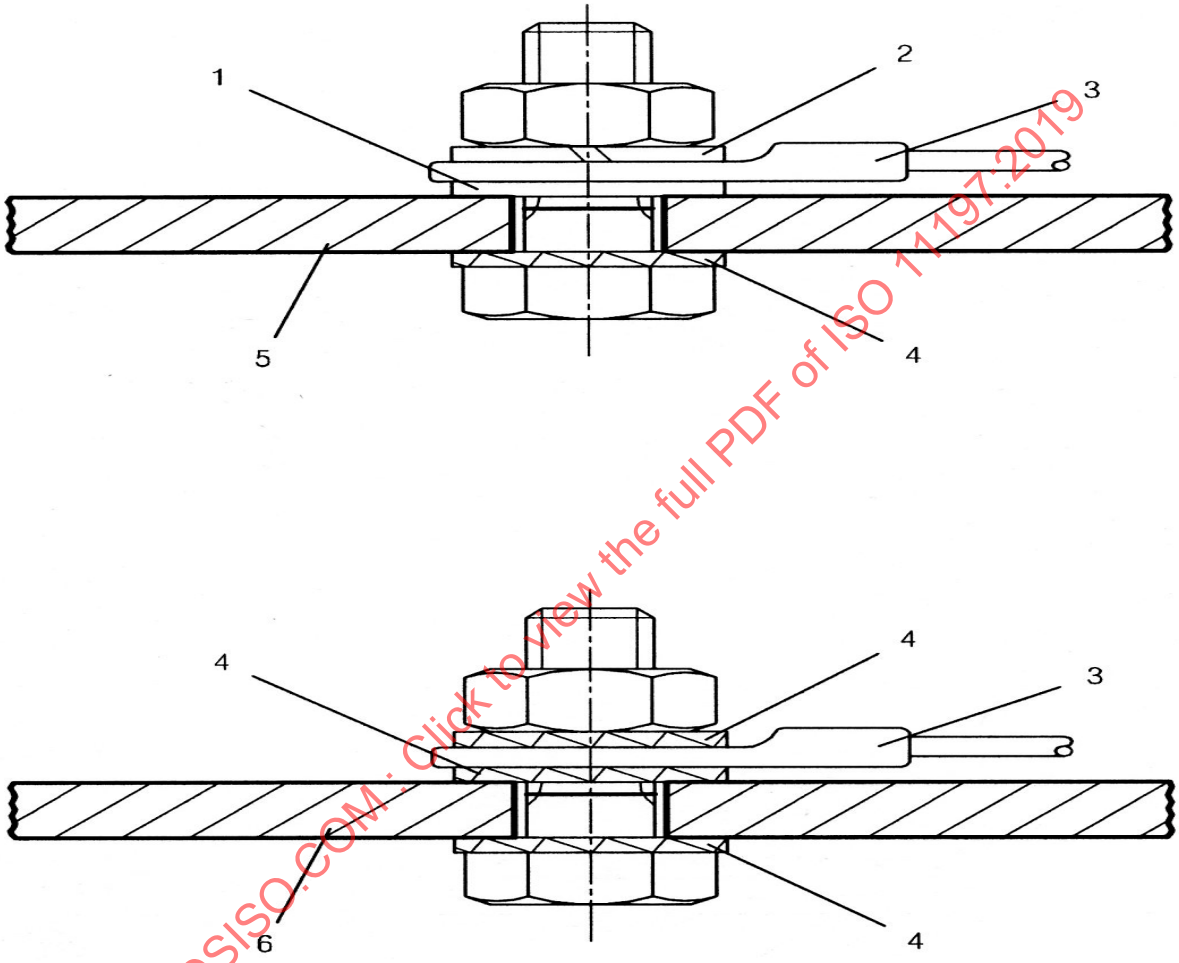
Terminal units installed as part of a compressed *gas distribution system*, *vacuum supply system*, *anaesthetic gas scavenging system* and *plume evacuation system* are not required to be connected to the earth terminal. ISO 7396-1:2016 defines the requirements for earthing of such pipeline systems and their components. If anti-static hoses are used, the electrical resistance of each anti-static hose shall not exceed 1 MΩ.

Where hoses are used, the extraneous metalwork of the *terminal unit* shall be connected to the common earth bar or to the earthed *enclosure* of the *medical supply unit*.

ISO 7396-1:2016 requires that a *medical gas pipeline system* be connected to earth.

Where *medical supply units* incorporate hose assemblies, the pipeline path to earth will be broken. A *terminal unit* with a metallic/electrically conductive surface has to be connected to a *protective earth terminal* or to the earthed *enclosure*.

All earth conductors of circuits from the existing *supply mains* and additional equipotential earth bonding shall be individually connected in the *medical supply unit* to a common earth bar.



Key

1 Cupal (Cu/Al) washer (copper surface uppermost)
2 spring washer
3 cable bracket
4 lock washer
5 *medical supply unit* section (e.g. aluminium)
6 *medical supply unit* section (e.g. ferrous)

Figure 201.101 — Typical examples for protective measures against loosening and corrosion of *potential equalization connectors* and protective earth conductor facilities

201.8.6.7 *Potential equalization conductor*

At each medical location of Group 1 and above at least one *potential equalization conductor*, external connector shall be provided within a *medical supply unit* which shall be attached to an appropriate conductor.

Typical examples for *potential equalization conductor* attachment the *medical supply units* are shown in Figure 201.101.

201.8.6.101 Conductors

Protective earth conductors of *mains socket outlets* shall each have a conductance equivalent to that of the phase conductor with a minimum value of conductance equivalent to 2,5 mm² or AWG 14 of copper and shall be individually connected to the common earth bar.

Protective equipotential bonding conductors connecting extraneous metal parts which form the enclosure of the *medical supply unit* shall have a conductance equivalent to half of that of the phase conductor with a minimum value of conductance equivalent to 2,5 mm² or AWG 14 of copper.

Protective earth conductors supplying other internal components (e.g. lighting) shall each have a conductance equivalent to that of its phase conductor with a minimum value of conductance equivalent to 2,5 mm² or AWG 14 of copper and shall be individually connected to the common earth bar.

The earth bonding conductor of a *potential equalization connector* for the connection of external *ME equipment* shall have a cross section of at least 4 mm² or AWG 12 of copper between this connector and the protective earth bus bar of the *medical supply unit* and shall be individually detachable from the connector (See Figure 201.102).

201.8.6.102 Bus bar

All *protective earth conductors* of circuits from the existing *supply mains* in the *medical supply unit* shall be connected to a bus bar with a conductance at least equivalent to that of 16 mm² or AWG 6 copper.

Each *medical supply unit* shall be provided with a bus bar for the connection of all protective earth connections of *supply mains* circuits and shall

— have a conductance at least equivalent to that of 16 mm² or AWG 6 copper,

— be equipped with a terminal for connection to a protective earth conductor of at least 16 mm² or AWG 6 cross-sectional area,

— provide secure terminals with protection from unintentional loosening,

— provide facilities for connection of *potential equalization connection* conductor terminals (see Figure 201.102 for an example), and

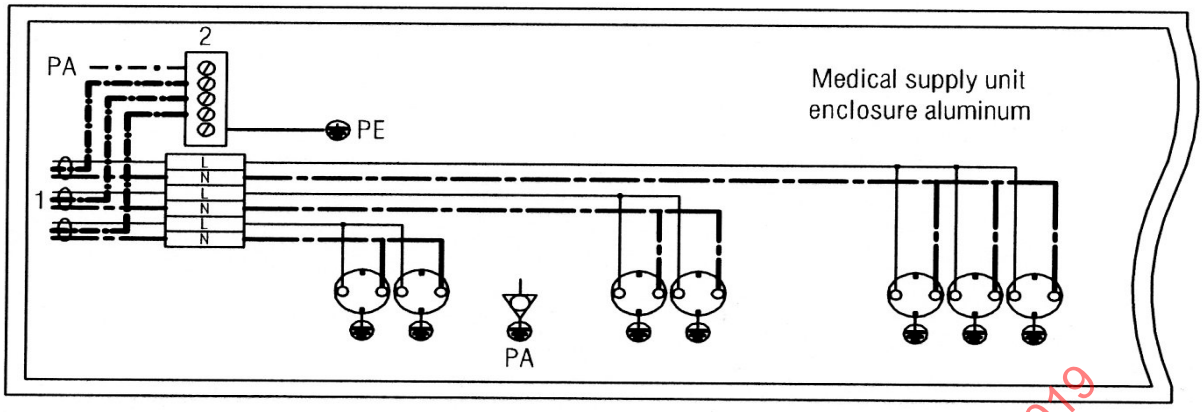
— have a terminal for the electrical installation infrastructure equipotential bonding conductor (PA) connection without any detachable bridge.

The *medical gas pipeline system* shall not be used as a bus bar.

NOTE 1 A metal section of the *medical supply unit* of equivalent conductance can function as a bus bar.

NOTE 2 National regulations can require different wiring configurations.

NOTE 3 Within this document, reference is made to a 'common earth bar' which has the same intention as the 'bus bar' referred to within this sub-section.



Key

L	active line	PE	protective earth conductor
N	neutral line	PA	*potential equalization connector*
1	external power supply for *medical supply unit*		
2	bus bar for protective earth conductor + *potential equalization conductor*		

Figure 201.102 — Example of a terminal connection of a *medical supply unit* according to IEC 60364-5-54:2011

201.8.10 Components and wiring

201.8.10.7 Insulation of internal wiring

If wiring for communication (such as a nurse call system), radio transmission, telephone, signal for biophysical parameters, other data transmission conductors, etc. is provided in a *medical supply unit* together with mains cables or pipelines or flexible hoses for *medical gas distribution systems*, electrically safe operation under *single fault condition* shall be ensured.

Conductors of different *supply mains final circuits* of the same voltage do not require mechanical segregation but they should be electrically separated.

In all departments, at least two separate *supply mains final circuits* supplying *mains socket–outlets* shall be provided for each bed space.

A *final circuit* supplying socket-outlets can serve more than one bed space.

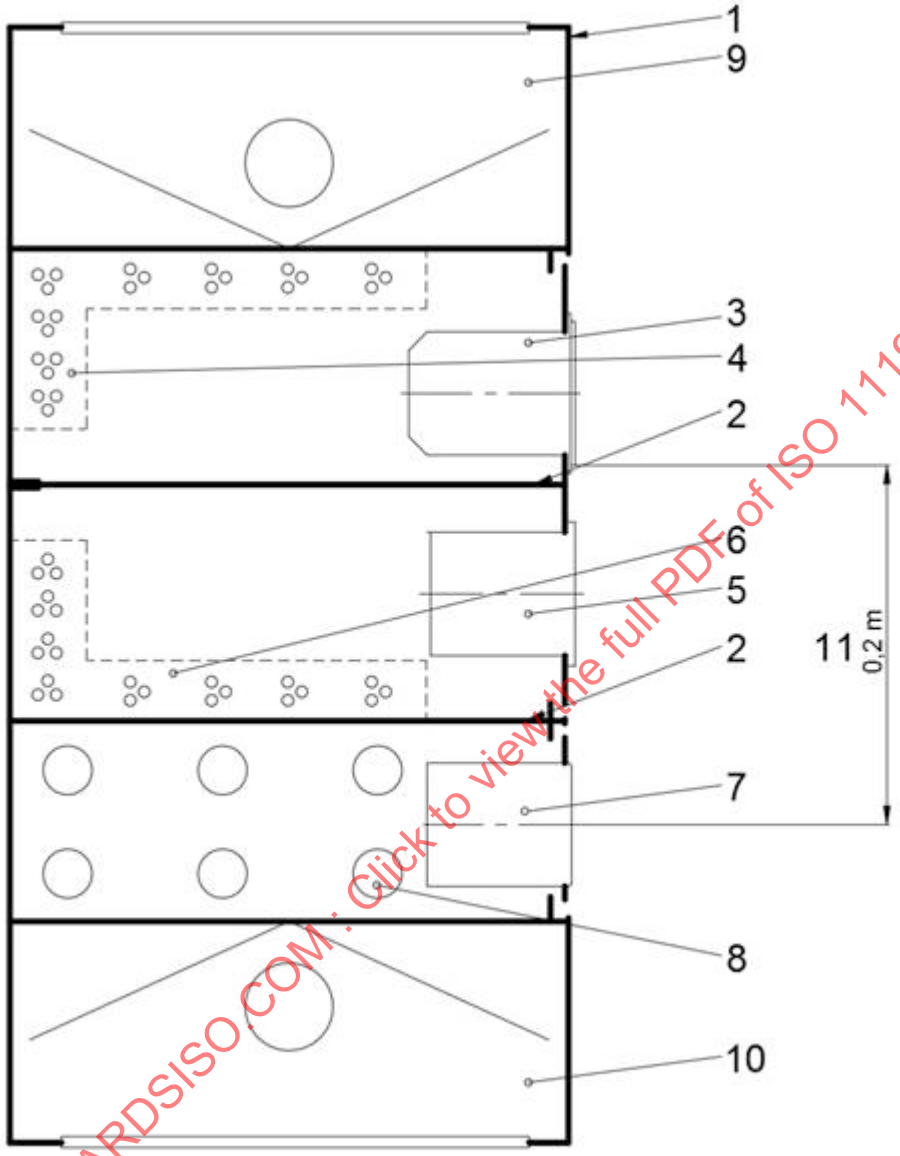
In addition, a separate circuit shall be provided for each haemodialysis machine and for each x-ray machine.

Cabling within a *medical supply unit* shall be insulated and its insulation shall be of low smoke zero halogen compound.

The *medical supply unit* design shall ensure that during maintenance of each *medical gas distribution system* no live parts, or parts which could become live in the event of a *single fault condition* of the electrical system can be touched (see 201.5.9.2.3). The *manufacturer* shall indicate on the removable safety covers to the live parts and/or in the *accompanying documents* how safe maintenance can be ensured. Refer to IEC 60601-1:2005+A1:2012, 8.11.1 i).

NOTE Electrical separation is defined in EN 61140[2].

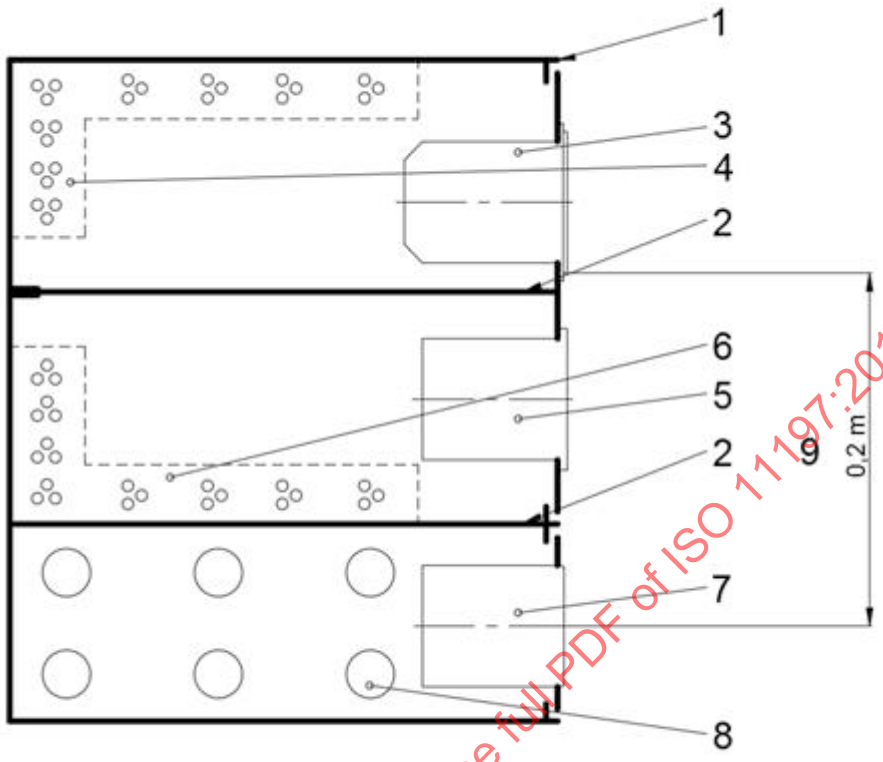
Consideration should be given to EN 50174-2:2018 when power and communication cabling are contained within the same *enclosure*. For examples, see Figure 201.103, Figure 201.104 and Figure 201.105.



Key

1	*enclosure*	7	gas *terminal unit*
2	barrier	8	gas pipes
3	components for mains	9	room light
4	*supply mains* /housing for *supply mains* wiring	10	reading light
5	components for communication purposes	11	safety distance, measured on the surface to midpoint
6	wiring communication/housing for communication wiring		

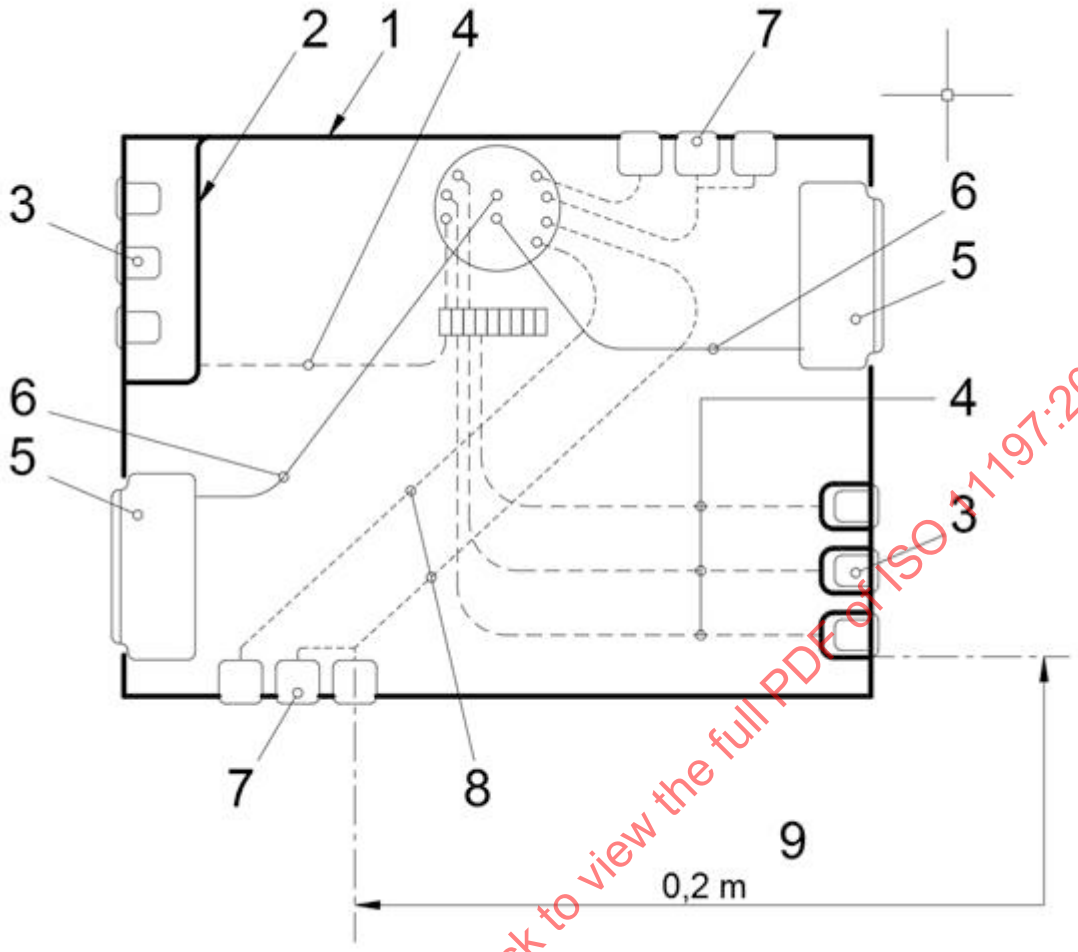
Figure 201.103 — Sectional drawing of typical *medical supply unit* for *patient* care rooms



Key

1	*enclosure*	6	wiring communication/housing for communication wiring
2	barrier	7	gas *terminal unit*
3	components for mains	8	gas pipes
4	*supply mains* /housing for *supply mains* wiring	9	safety distance, measured on the surface to midpoint
5	components for communication purposes		

Figure 201.104 — Sectional drawing of a typical *medical supply unit* for intensive care rooms and operating theatres



Key

1	*enclosure*	6	wiring communication/housing for communication wiring
2	barrier	7	gas *terminal unit*
3	components for mains	8	flexible hoses
4	*supply mains* /housing for *supply mains* wiring	9	safety distance, measured on the surface to midpoint
5	components for communication purposes		

Figure 201.105 — Sectional drawing of typical non-rigid *medical supply unit*

201.8.11 *Mains parts*, components and layout

201.8.11.1 Isolation from the *supply mains*

A *medical supply unit* shall not include externally accessible master switches or fuses capable of isolating a complete electrical circuit.

The general use of switched *mains socket–outlets* is permitted, but consideration shall be given to using only unswitched versions in areas defined as containing life-supporting equipment.

If no particular circuit is designed as "essential" but socket outlets are intended to be supplied from different power sources within the same *medical supply unit*, then the circuit supplying each socket-outlet shall also be readily identifiable.

Spade connections for *supply mains* circuits connecting socket-outlets should not be used. Where they are unavoidable, then they shall be provided with a locking mechanism to prevent inadvertent disconnection and shall be insulated.

NOTE 1 Unintentional operation of mains switches or the removal of mains fuses if integrated in the *medical supply unit* could endanger the *patient*.

NOTE 2 Regional or national regulations can apply to socket-outlet configurations.

Where *mains socket outlets* are supplied from an uninterruptable *supply mains* source, the connected socket-outlets should be unswitched. IEC 60364-7-710 or national regulations might prohibit the use of switched *mains socket–outlets* on *supply mains* from Medical IT systems.

Addition:

201.8.11.101 Layout

Where a *medical supply unit* is provided with an integrated or bolt-on *rail* which can be located higher than 1000 mm from finished floor level, this *rail* should not be used for mounting vacuum collection jars.

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems*

IEC 60601-1:2005+A1:2012, Clause 9 applies, with the following additions:

201.9.1.101 Dynamic forces

Medical supply units shall be subjected to an impact test as described in 201.9.1.102. After the impact, the live parts shall not become accessible, *terminal units* shall continue to meet the leakage and performance requirements of ISO 9170-1:2017, pipelines joints shall not be damaged or leak and existing protective devices shall remain intact.

201.9.1.102 Impact resistance test

The *medical supply unit* shall be subject to a series of tests which replicates forces likely to be encountered in the installed environment.

a) Impact resistance test for the *medical supply unit enclosure only* (e.g.; without *medical gas* and/or *medical device gas terminal units* and electrical outlets).

The *enclosure* of the *medical supply unit* shall be subject to an impact test as defined in 60601-1:2005 +A1:2012, 15.3.3 and maintain intended safety performance after a mechanical impact.

Addition:

At the conclusion of the test the *enclosure* shall be permitted to deform and visible damage might be acceptable, provided that the *enclosure* is not destroyed beyond functionality and maintaining the ingress protection level of IP2X or IPXXB. The pipelines therein shall still operate under *normal condition*.

The second part of the test procedure shall then be performed.

b) Impact resistance test for the *medical supply unit* with *medical gas* and/or *medical device gas terminal units* and electrical outlets.

A bag of 0,50 m width approximately half-filled with sand to give a total weight of 200 N, suspended so as to give a pendulum length of 1 m shall be released from a horizontal deflection of 0,50 m so as to hit the *medical supply unit* that is mounted according to the *manufacturer's* instructions.

The test configuration is shown in Figure 201.106. The test shall be repeated so that at least one more part of the *medical supply unit* is impacted.

The occurrence of cracks in mouldings shall not constitute failure of the test.

In the test sequence 201.9.1.101 b), the external equipment intended to be connected to the *medical supply unit* outlets shall not be connected.

201.9.1.103 Static forces

Parts of *medical supply units* designed for additional loads shall be subjected to a test load of twice the maximum *safe working load* specified by the *manufacturer*.

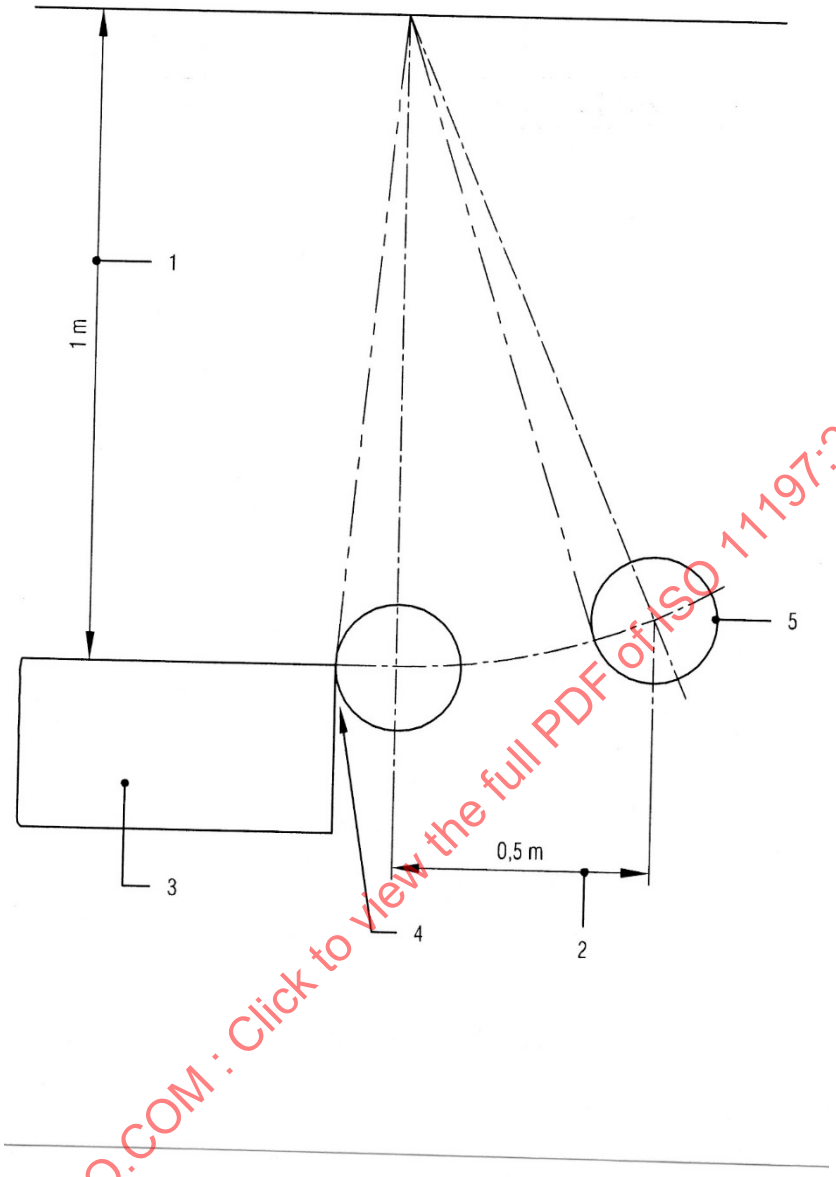
Medical supply unit and their supports designed for additional loads shall not be permanently deformed or deflected by more than 10° with reference to the load-bearing surfaces.

201.9.1.104 Static load test

The test load shall be uniformly distributed over the *medical supply unit* according to the *manufacturer's* specifications.

201.9.1.105 Mechanical damage

Means shall be provided to allow periodic inspection in an *operator*-adjustable system (e.g. a ceiling pendant) to ensure that mechanical joints are free from damage (e.g. cracks and chips).



Key

1 length of pendulum
2 deflection
3 mounted *medical supply unit*
4 most vulnerable point (example)
5 bag of weight 200 N

Figure 201.106 — Impact resistance test as 201.9.1.101 b)

201.9.6 Acoustic energy (including infra- and ultrasound) and vibration

201.9.6.101 Frequency spectrum

Except for noise caused by therapeutic or diagnostic measures or by adjustment of the *medical supply unit*, (e.g. by lifting or lowering) during operation at the rated voltage at *nominal* frequency the *medical supply unit* shall not produce acoustic energies in excess of 30 dB (A) nominal and individual peak noise levels shall not be in excess of 35 dB (A).

The *manufacturer* shall provide evidence upon request that specified sound levels are not exceeded when measured according to ISO 3744:2010.

201.9.8 *Mechanical hazards* associated with support systems

201.9.8.2 *Tensile safety factors*

Medical supply units and parts of which are designed to carry additional mechanical loads shall be tested with a test load. The test load shall be calculated by the *safe working load*, as specified by the *manufacturer*, multiplied by the *tensile safety factors* of IEC 60601-1:2005+A1:2012, 9.8.2 and Table 21.

Compliance is checked by the following test: The test load is applied on the support assembly under test. After 1 min, if the medical supply unit remains in equilibrium, it shall be deemed to have met the requirements of the test.

201.10 Protection against unwanted and excessive radiation *hazards*

IEC 60601-1:2005+A1:2012, Clause 10 applies.

201.11 Protection against excessive temperatures and other *hazards*

IEC 60601-1:2005+A1:2012, Clause 11 applies, with the following additions:

201.11.1 Excessive temperatures in *ME equipment*

201.11.1.101 Temperatures of luminaires

The maximum temperatures of luminaires and their exposed components shall not exceed the maximum temperatures stated in IEC 60598-1:2014+A1:2017.

201.11.2 Fire prevention

The *enclosure* of a *medical supply unit* shall satisfy basic fire safety requirements. *medical supply units* also carry essential emergency circuits and shall present with appropriate fire-resistant properties when constructed. For implementation refer to IEC 60601-1:2005+A1:2012, 11.3.

201.11.2.2 *ME equipment* and *ME systems* used in conjunction with *oxygen-rich environments*

201.11.2.2.101 Venting

Where oxygen, oxygen 93, or nitrous oxide *medical gas* pipelines or *terminal units* are contained within a *medical supply unit*, the specific chamber housing these components shall be vented to atmosphere.

Where these *terminal units* are supplied by copper pipelines, these are not subject to a *single fault condition* and shall be considered a *normal condition*.

Where these *terminal units* are supplied by hoses, the assembly of the completed enclosure shall be supported by a *manufacturer*'s leakage test to demonstrate an appropriate evacuation of oxidising gases under *single fault condition*.

Test outcomes

Compliance is checked by a simulated leakage test as defined in the example test method to show that the oxygen concentration within the medical supply unit is not greater than a volume fraction of 25% once as Table condition under test is achieved.

Example test method

The test shall be conducted using an oxygen supply which is fed through a calibrated regulator, connected to a 3 mm internal diameter hose to provide a continuous flow of 1 l/min at the entry point to the *medical supply unit* under test. The test flow shall be measured at atmosphere.

Compliance with the example test requirements is achievable by using vented openings in the enclosure of the medical supply unit if comprising oxidising gases.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+A1:2012, Clause 12 applies.

201.13 *Hazardous situations* and fault conditions

IEC 60601-1:2005+A1:2012, Clause 13 applies, with the following additions:

201.13.2 *Single fault conditions*

201.13.2.1 * General

An oxidant leak, which is not detected by e.g. an alarm or periodic inspection, shall be considered a *normal condition* and not a *single fault condition*.

Medical supply units shall, when transported, stored, installed, operated in *normal use* and maintained according to the instructions of the *manufacturer*, present no *risks* that have not been reduced to an acceptable level using risk management procedures in accordance with ISO 14971:2019 for their *intended use*, in *normal condition* and in *single fault condition*.

NOTE Maintenance is considered a *normal condition*.

201.13.2.2 *Single fault conditions*

Where these *terminal units* are supplied by copper pipelines, these are not subject to a *single fault condition* and shall be considered a normal operation.

Brazed joints on copper pipelines might be subject to a *single fault condition* if not contained within a *medical supply unit* complying with 201.9.1.102. Appropriate consideration shall be given to the material from which the body of a *medical supply unit* is manufactured to afford suitable protection to copper pipelines and brazed joints.

201.9.1.102 defines an impact resistance test requirement for the *enclosure* of a *medical supply unit*.

The *enclosure* of a *medical supply unit* shall satisfy various tests defined within this standard. It is considered unlikely that a complete *enclosure* manufactured from polymers will afford the level of impact protection to assure against damage to internal pipelines or satisfy other electrical tests required by this standard and therefore is not recommended.

201.14 *Programmable electrical medical systems* (PEMS)

IEC 60601-1:2005+A1:2012, Clause 14 applies.

201.15 Construction of *ME equipment*

IEC 60601-1:2005+A1:2012, Clause 15 applies, with the following additions:

The construction of a *medical supply unit* shall be considered carefully, and be sympathetic to ensure surfaces within a *patient environment* can be cleaned. Where gaps, contours, shallow grooves, grilles and the like are inaccessible for the purposes of cleaning, they should be avoided. Provided such a gap, contours, shallow grooves, grilles and the like can be accessed to be periodically cleaned this shall not ordinarily be considered as presenting an infection control *hazard*/*risk* as its design might be dictated by its function (e.g. mains power socket-outlets, *medical gas terminal outlets*, venting openings, etc.).

201.15.1 Arrangements of controls and indicators of *ME equipment*

Equipment and components incorporated into the *medical supply unit* shall comply with the relevant standard(s) for such equipment or components.

201.15.4 *ME equipment* components and general assembly

201.15.4.1 *Potential equalization connectors*

Potential equalization connectors shall be mounted so as to prevent physical damage to the *operator* or to the connector.

Compliance is checked by inspection.

If power supplies are fitted and are in connection with nurse call systems, they shall comply with IEC 60601-1:2005+A1:2012, *8.9*.

201.15.4.3 Batteries

Where batteries are used (e.g. for emergency lighting), they shall be installed to meet the respective standard for the specific application.

201.15.4.3.5 Excessive current and voltage protection

201.15.4.3.5.101 Pulse relays

If pulse relays are fitted, they shall comply with IEC 60601-1:2005+A1:2012, 8.9.

201.15.4.101 * *Medical gas* supply construction

a) *Medical gas distribution system pipelines* or *hoses* within *medical supply units* shall be constructed to the requirements of ISO 7396-1:2016. Sizing of copper or hoses of *medical gas distribution system pipelines*, *vacuum supply system* and *anaesthetic gas scavenging systems* shall be aligned with the specific project infrastructure pipeline design.

NOTE 1 Copper is the preferred material for all *medical gas distribution system pipelines*.

NOTE 2 Pipes to pressure gauges and other measuring and control equipment can have smaller cross-sections than the pipelines used for *medical gas distribution system pipelines* or *vacuum supply system* distribution.

b) Pipeline joints shall be made in accordance with ISO 7396-1:2016. Cutting ring connections shall not be used.

c) Flexible hoses and hose assemblies shall not be used within *medical supply units* except for *operator*-adjustable portions (e.g. in ceiling pendants).

d) If flexible hoses and hose assemblies are used, the following apply:

— means shall be provided to allow periodic inspection and replacement;

— if hoses are used which are not colour-coded, then each end of the hose shall be labelled;

— they shall comply with ISO 5359:2014, except for

  — ISO 5359:2014, 4.6.4 on resistance to occlusion,

  — ISO 5359:2014:4.6.7 on gas-specificity, and

  — ISO 5359:2014, 4.6.8 on end connectors.

— It shall not be possible to remove the assembled sleeve or ring without the hose, sleeve or ring becoming unsuitable for reuse. The hose may only be clamped once at one and the same point. The areas of the hose that have previously been clamped shall be cut off before a new clamping is performed;

e) If flexible hoses are accessible to the *operator* for removal, they shall be incorporated into hose assemblies which comply with ISO 5359:2014, except for ISO 5359:2014, 4.6.4;

f) Tests for occlusion of hoses are defined in ISO 5359:2014 with the exception of the following:

For hoses of compressed *gas for medicinal use*, *medical device gases* and vacuum:

— test force: 200 N;

g) The *accompanying documents* for the *medical supply unit* shall include a *procedure* for, and the recommended frequency of, inspection and replacement of the flexible hoses and shall specify the tests to be carried out following such replacement [see Annex BB)];

h) If hose assemblies are used, they shall comply with ISO 5359:2014, except for ISO 5359:2014, 4.6.4 and the *accompanying documents* for the *medical supply unit* shall include a *procedure* for, and the recommended frequency of, inspection and replacement of the hose assemblies [see 201.7.9.3 a)].

— Hose assemblies within *medical supply units* are contained within smaller confines than externally accessible hoses. Axial tensile forces for hose assemblies are defined in ISO 5359:2014, 4.6.2.2 but where installed within a *medical supply unit*, these shall be:

  i) Hose assemblies for compressed *gas for medicinal use* and *medical device gases* shall withstand an axial tensile force of 200 N for 60 s following the same procedure as ISO 5359:2014, 4.6.2.2.

ii) Hose assemblies for *vacuum supply systems* shall withstand an axial tensile force of 150 N for 60 s following the same procedure as ISO 5359:2014, 4.6.2.2.

i) The connection to a *medical gas*, *medical device gas*, or *vacuum supply systems* shall be in accordance with ISO 7396-1:2016.

j) Constructional provisions shall be made so that piping is not exposed to temperatures above 50 °C and flexible hoses, if used, are not exposed to temperatures above 40 °C caused by e.g. lighting facilities, transformers, etc.

Hoses and piping are permitted to exceed the temperature requirements given, if the higher temperatures are taken into consideration during the tests according the required standards for both materials.

k) Control knobs and spindles of flow control valves, if fitted, shall be captive such that they cannot be disengaged without the use of a *tool*.

l) Each electrical *compartment* within a *medical supply unit* shall be separated from the gas and liquid *compartments* by a barrier, except where flexible hoses are used for *medical gas* supply. If electrical cables are installed together with flexible hoses or pipes for *medical gas* supply, the cables shall be insulated and sheathed, or installed in a flexible conduit complying with IEC 61386-1:2008+A1:2017, or separated by more than 50 mm. Cables of varying voltages shall be installed in accordance with EN 50174-1:2018 and EN 50174-2:2018.

NOTE 3 A separation of more than 50 mm is in accordance with the requirements of ISO 7396-1:2016.

m) Liquid compartments, when mounted horizontally, shall be located below electrical *compartments*.

n) *Terminal units* connected to a compressed *medical gas distribution system* used for oxidising gases or connection points for liquids, shall be located at least 0,2 m from any electrical component which can spark in *normal condition* or in *single fault condition*. This does not apply to components where the value of the root mean square (RMS) voltage with no load and the RMS value of the short circuit current do not exceed 10 VA (e.g. intercommunication, voice, data, TV components). The distance shall be measured on the surface of the unit from the centre line of the *terminal unit* to the nearest exposed part of the electrical accessory/component.

201.15.4.102 *Anaesthetic gas scavenging system* construction

a) The construction of the *anaesthetic gas scavenging system* shall comply with ISO 7396-2:2007.

b) Flexible hoses for *anaesthetic gas scavenging systems* shall not be used within *medical supply units* except for the *operator*-adjustable portions (e. g. in ceiling pendants) and for measuring and control wiring or hoses (e. g. wiring or hoses between indicators and ejector).

c) If flexible hoses are used for the exhaust air the material of the hoses in contact with the gas shall be compatible with volatile anaesthetic agents and gases.

d) If flexible hoses are used, means shall be provided to allow periodic inspection and replacement.

e) If flexible hoses are used, the *accompanying documents* for the *medical supply unit* shall include a *procedure* for, and the recommended frequency of, inspection and replacement of the flexible hoses and shall specify the tests to be carried out following such replacement [see 201.7.9.3 a)].

f) Measuring and control hoses shall meet the requirements of ISO 5359:2014, 4.6.2, 4.6.3 and 4.6.4.

g) According to ISO 7396-2, *anaesthetic gas scavenging systems* used in ceiling pendants shall comprise plastic hoses for the exhaust air system.

If the exhaust air system can have a negative pressure in *normal use*, the hose shall withstand twice the value of the negative pressure over the service lifetime of the *medical supply unit*. The material of the plastic hoses shall withstand enflurane, sevoflurane, isoflurane, halothane, desflurane and cleaning and disinfection agents and shall have no permanent deformation or cracking after the following:

— 10^4 flexing cycles;

— 150 N tensile loads;

— 60 N pressure load from outside.

Compliance with 201.15.4.102 a) to f) shall be checked by visual inspection and testing.

If the drive system is an exhaust ejector or ventilator and a gauge pressure between 0 kPa and 10 kPa is possible by design, plastic hoses may be used. Where a negative pressure exceeds 10 kPa, a hose in accordance with ISO 5359:2014 shall be used.

If drive system ejectors and hoses are used in an exhaust hose, the ejector shall be placed directly on the connection point of the rigid tubing. If hoses are used according to ISO 5359:2014 the position of the ejector is independent.

201.15.4.103 Liquid supply construction

a) Pipelines for potable water (warm or cold) and cooling water (warm or cold) shall be made of copper or stainless steel.

NOTE Attention is drawn to the antimicrobial properties of copper.

b) Pipelines for demineralized water (cold), distilled water, dialysing concentrate and dialysing permeate shall be made of corrosion-resistant material.

c) Flexible hoses shall not be used within *medical supply units* except for the *operator*-adjustable portions (e.g. in ceiling pendants).

d) If flexible hoses are used, means to allow periodic inspection and replacement shall be provided.

e) If flexible hoses are used, the *accompanying documents* for the *medical supply unit* shall include a *procedure* for, and the recommended frequency of, inspection and replacement of the flexible hoses and shall specify the tests to be carried out following such replacement [see 201.7.9.3 a)].

f) The material selected for flexible hoses for use with any liquid for dialysis shall be compatible with the liquid contained in those hoses with regard to strength, long-term stability and corrosion resistance under the operating conditions specified by the *manufacturer*.

g) Pipes and hoses for *medical gas distribution systems*, *vacuum* and *anaesthetic gas scavenging systems* can be installed together with piping for liquids for dialysis. If mounted together horizontally, gas pipes shall be located above liquid pipes.

h) Pipelines for dialysing solutions should be installed in a single recirculating loop.

i) Hot water or wet steam can be used for pasteurisation of pipelines for dialysing solutions. Means shall be provided to protect other components from excessive temperature.

j) Turbulence and dead spaces should be avoided by design.

k) Connections in metal pipelines and branches to the *terminal units* shall be welded or brazed. Flaring and similar methods shall not be used. Cutting ring connections or compression joints for copper pipes shall not be used. To prevent oxide formation inside the pipes, they shall be filled and purged with a suitable inert gas during welding or brazing. Pipe connections in pipelines for liquids shall be bonded by means of sleeves without changes in internal diameter.

l) The liquid supply system shall be designed and manufactured to minimize health RISKS due to substances leached from the system.

Compliance with 201.15.4.103 a) to l) shall be checked by visual inspection.

201.15.4.104 *Terminal unit* construction

201.15.4.104.1 *Terminal units* for *gases for medicinal use*, *medical device gas*, and vacuum shall comply with ISO 9170-1:2017.

201.15.4.104.2 *Terminal units* for *anaesthetic gas scavenging systems* shall comply with ISO 9170-2:2008.

201.15.4.104.3 *Terminal units* for liquids and dialysis

a) *Terminal units* for liquids and dialysis shall comprise either

- a flow control valve fitted with a check valve and, at the outlet, a hose insert for one of the following:
  - potable water, cold;
  - potable water, warm;
  - cooling water;
  - cooling water, feed-back;
  - de-mineralized water/reverse osmosis;
  - distilled water; or
- a quick-connect socket and probe for the following:
  - dialysing concentrate;
  - dialysing permeate.

b) Control knobs and spindles of flow control valves, if fitted, shall be captive such that they cannot be disengaged without the use of a *tool*.

c) Quick-connect sockets and probes, if fitted, shall both be equipped with a check valve to ensure automatic closure upon disconnection.

d) If probes and sockets are used for dialysing concentrate and dialysing permeates, the probe shall be fitted on the *medical supply unit*.

e) The materials shall be compatible with the liquids for dialysis under the operating conditions specified by the *manufacturer*.

f) If quick-connect sockets and probes are used for the discharge of dialysing solutions, they shall have different dimensions from all the others used.

Compliance with 201.15.4.104.3 a) to 201.15.4.104.3 f) shall be checked by visual inspection.

201.16 *ME systems*

IEC 60601-1:2005+A1:2012, Clause 16 applies.

201.17 *Electromagnetic compatibility* of *ME equipment* and *ME systems*

IEC 60601-1:2005+A1:2012, Clause 17 applies.

Addition:

202 *Medical electrical equipment* — Parts 1-2 General requirements for *basic safety* and *essential performance* — Collateral standard: Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014 applies.

206 *Medical electrical equipment* — Parts 1-6 General requirements for *basic safety* and *essential performance* — Collateral standard: Usability

IEC 60601-1-6:2010+A1:2013 applies.

IEC 60601-1:2005+A1:2012, Annexes A to M, apply.

Annex AA
(informative)

Rationale

NOTE The following corresponds to the clauses and subclauses in this document marked with an asterisk (*). The numbering is, therefore, not consecutive.

AA.201.13.2.1 General

A fault condition which is not detected can exist for a long period of time. Under these circumstances it is not acceptable to regard a further fault as a second fault condition, which can be disregarded. Such a *single fault condition* shall be regarded as a *normal condition*.

AA.201.15.4.101 Medical gas supply construction

Hoses within *medical supply units* are not freely accessible to the *operator* and are protected by the *enclosure*. The resistance to occlusion specified in 4.4.4 of ISO 5359:2014 can only be met by very hard hoses which are relatively inflexible. Hoses within *medical supply units* which are intended to allow movement (e.g. in ceiling pendants) need to be very flexible. Hoses made from materials, which allow such flexibility, have a lower resistance to occlusion. However, since occlusion is not a significant RISK to hoses within *medical supply units*, a lower value of 200 N for the occlusion test is acceptable.

Annex BB
(informative)

Tests during production

The *manufacturer*, including the on-site *manufacturer*, if appropriate, shall perform a routine test on each *medical supply unit*. The test results shall be recorded and presented to the *responsible organization* on request (see Annex CC).

BB.1 Electrical tests

BB.1.1 Impedance of protective earth terminal

The measured impedance of the protective earth terminal shall comply with 8.6.4 a) of the general standard.

Compliance is checked by measurement:

A current of at least 10 A derived from a voltage source having a no-load voltage between 6 V and 12 V AC (50/60 Hz) is passed for 1 s between the earth terminal to each accessible metal part. In no case the contact resistance shall exceed 0,1 Ohm.

BB.1.2 Earth *leakage current*

The allowable values of the earth *leakage current* shall comply with 8.7.3 and 8.7.4 of the general standard.

Compliance is checked by measurement.

Earth *leakage current* shall be measured under *normal condition* and *single fault condition*. The Equipment under test shall be isolated from earth potential. The different circuits have to be connected, all switches have to be closed.

The test shall be carried out with 100 % of the rated voltage.

Under *normal condition* earth *leakage current* shall not exceed 5 mA. Under *single fault condition* earth *leakage current* shall not exceed 10 mA.

BB.1.3 Dielectric strength

The dielectric strength shall comply with 8.5.4 und 8.8.3 of the general standard.

Compliance is checked by measurement,

The test is carried out without humidity pre-conditioning.

Dielectric strength is measured by applying a voltage of 1 500 V AC or 2 120 V DC for at least 1 s.

The maximum current measured shall not exceed 30 mA.