INTERNATIONAL STANDARD

ISO 11197

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Medical electrical equipment — Particular requirements for safety of medical supply units

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Appareils électriques médicaux — Prescriptions particulières relatives à la sécurité des systèmes de distribution médicaux

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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.

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.

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

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Annexes M and N of this International Standard are for information only.

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Medical electrical equipment — Particular requirements for safety of medical supply units

Section 1: General

1.1 Scope

ISO 11197 is one of a series of International Standards based on IEC 601-1; in IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1.

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The scope and object given in clause 1 of IEC 601-1:1988 apply, with the following addition:

This International Standard applies to medical supply units as defined in 1.3.4 of ISO 11197.

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Other medical equipment, such as devices for nurse call systems, monitoring, etc., which can be incorporated in or mounted on medical supply units, are not covered by this International Standard. Such medical equipment may be the subject of additional Particular Standards.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane.*

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

ISO 7396:1987, *Non-flammable medical gas pipeline systems.*

ISO 9170:1990, *Terminal units for use in medical gas pipeline systems.*

IEC 79-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.*

IEC 598-1:1992, *Luminaires — Part 1: General requirements and tests.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 601-1-1:1992, *Medical electrical equipment — Part 1: General requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems.*

IEC 601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility — Requirements and tests.*

IEC 884-1:1994, *Plugs and socket-outlets for household and similar purposes — Part 1: General requirements.*

1.3 Definitions

For the purposes of this International Standard, the definitions given in clause 2 of IEC 601-1:1988 and the following definitions apply.

1.3.1 equipment: Single self-contained unit or combination of units provided with one or more permanently fixed connections to the building services, e.g. electrical, gas(es), liquid and anaesthetic gas scavenging systems.

NOTE 1 This definition replaces the definition of equipment given in 2.2.11 of IEC 601-1:1988.

1.3.2 junction point: Connection point between the medical supply unit and the fixed building services.

1.3.3 medical gas: Any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for surgical tool application.

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1.3.4 medical supply unit: Prefabricated equipment of Class I, Type B for application in medical areas such as general wards and special purpose areas (e.g. operating theatres, induction rooms, recovery wards, intensive care or therapy units and other intermediate care areas) that is intended to supply electric power and/or gases and/or liquids.

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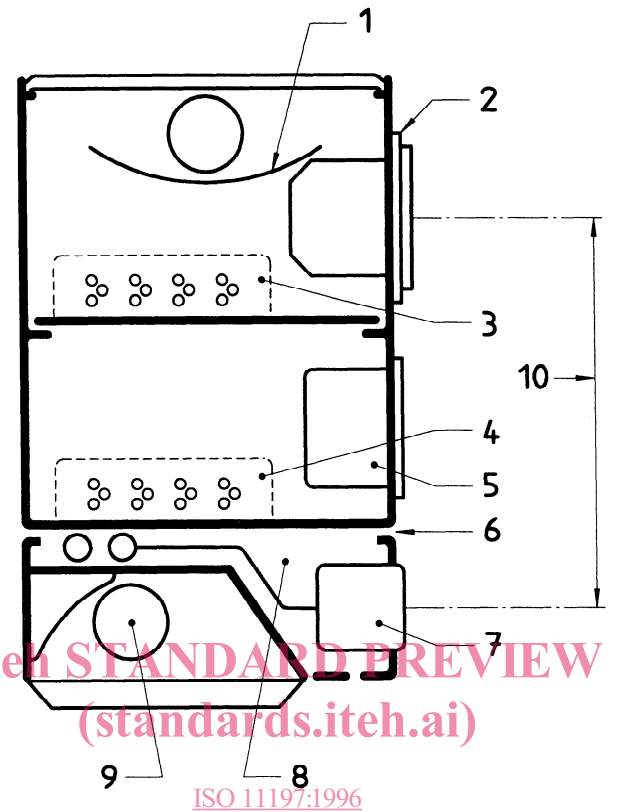
NOTE 2 Medical supply units may include medical electrical equipment or systems or parts of such equipment or systems which might be applied to diagnosis, therapeutics and communications. Medical supply units may consist of modular sections for electrical supply, lighting for therapy or illumination for communications for the supply of medical gases and liquids and for anaesthetic gas scavenging systems. Typical examples of medical supply units are given in figures 1, 2 and 3.

1.3.5 oxidizing medical gas: Oxygen, nitrous oxide or gas mixtures in which the total concentration of oxygen and nitrous oxide exceeds 25 % volume fraction.



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1 Ambient lighting fitting

2 Electrical socket

3 Mains supply

4 Intercommunication, safety extra-low voltage

5 Recessed equipment

6 Barrier

7 Terminal unit

8 Pipeline installation

9 Reading light

10 Safety distance as distance from centre to centre = 0,2 m

Figure 1 — Sectional drawing of typical medical supply unit for patient care rooms

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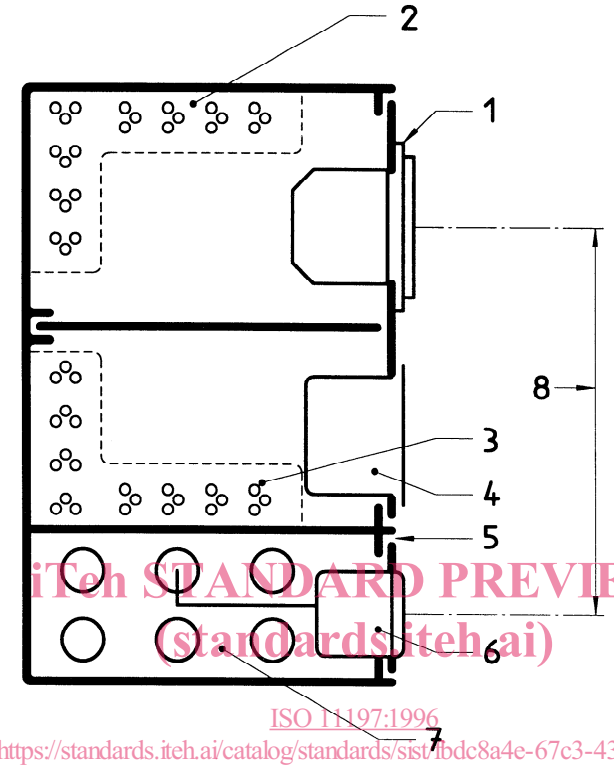

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1 Electrical socket

2 Mains supply

3 Intercommunication, safety extra-low voltage

4 Recessed equipment

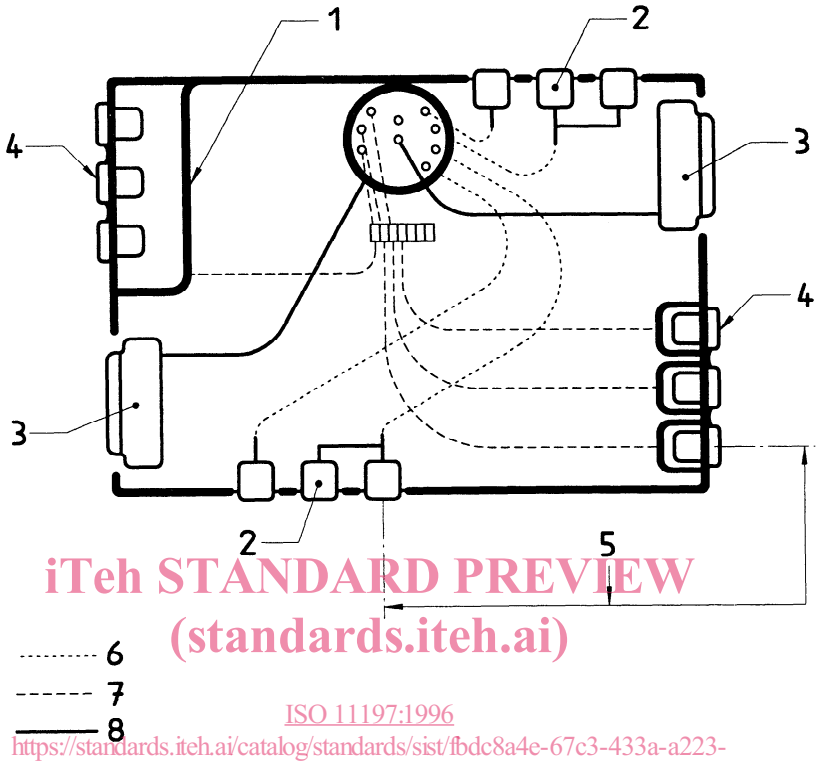
5 Barrier

6 Terminal unit

7 Pipeline installation

8 Safety distance as distance from centre to centre = 0,2 m

Figure 2 — Sectional drawing of typical medical supply unit for intensive care rooms and operating theatres



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1 Barrier

2 Terminal units

3 Recessed equipment, low current electroinstallation, intercommunication safety extra-low voltage

4 Electrical socket

5 Safety distance measured on the surface as distance from centre to centre = 0,2 m

6 Flexible hoses

7 Mains installation

8 Low current installation

Figure 3 — Sectional drawing of typical non-rigid medical supply unit

1.4 General requirements

The requirements given in clause 3 of IEC 601-1:1988 apply with the following addition:

— To **3.6** add the following:

k) An oxidant leak which remains undetected shall be considered a normal condition and not a single-fault condition.

A rationale for this subclause is provided in annex N.

1.5 General requirements for tests

The requirements given in clause 4 of IEC 601-1:1988 apply.

1.6 Classification

The requirements given in clause 5 of IEC 601-1:1988 apply.

1.7 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1:1988 apply with the following amendments:

— Replace **6.1 a)** with the following:

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Mains-operated equipment, including separable components thereof which have a mains part, shall be provided at least with permanently affixed and clearly legible marking on the outside of the major part of the equipment as described in 6.1 c).

— Replace **6.1 g)** with the following:

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Due to the possible complexity of external marking, diagrams indicating all electrical and electronic connections to the medical supply units shall be located at the junction point inside the equipment. For electrical connections the diagram shall indicate voltages, number of phases and number of circuits. For electronic connections, the diagram shall indicate connector numbers and wire identification.

— Replace **6.1 k)** with the following:

NOTE — Mains socket outlets for special-purpose areas should be colour-coded according to national regulations of the nation where the equipment is to be installed. Mains socket outlets for special-purpose areas which are fused in a single circuit may be marked with identical numbers.

— Under **6.1 l)**, replace text after third dash with the following:

Medical supply units shall be designed and constructed as Class I, Type B equipment according to the degree of protection against electric shock. A marking for this degree of protection is not required. Built-in units of Type BF or CF and outlets forming part of them, contained in medical supply units, shall be clearly marked with the relevant symbols according to Appendix D, Table D II.

— To **6.1 y)** add the following:

Facilities for the connection of a potential equalization conductor, if provided, shall be marked with symbol 9 of Table D I of Appendix D.

— After **6.1 z)**, add the following:

aa) Particular applications

If the medical supply unit is intended to be used in conjunction with patient monitors, for electromyogram and/or electroencephalogram and/or electrocardiogram, the medical supply unit shall be marked with the particular application as follows:

- for electromyogram EMG
- for electroencephalogram EEG
- for electrocardiogram ECG or EKG

bb) Terminal units

Terminal units for medical gases shall be marked in accordance with ISO 9170:1990, clause 6. Colour coding, if used, shall be in accordance with ISO 32.

An International Standard covering the marking of terminal units for anaesthetic gas scavenging equipment is under development.

Terminal units for liquids shall be marked with the name of the liquid in accordance with table 1 or the national equivalent.

Colour coding, if used, shall be in accordance with national standards.

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Table 1 — Names of liquids for marking of terminal units

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Potable water, COLD
Potable water, WARM
Cooling water
Cooling water, feedback
Demineralized water
Distilled water
Dialysing concentrate
Dialysing permeate

— To **6.2**, add the following:

o) Junction points and pipelines for medical gases shall be marked in accordance with ISO 7396:1987, clause 10.

p) Junction points and pipelines for liquids shall be marked with

- the name of the liquid in accordance with table 1;
- the direction of flow;
- (optionally) colour coding in accordance with national standards.

q) An International Standard covering the marking of junction points and pipelines for anaesthetic gas scavenging systems is under development.