INTERNATIONAL STANDARD

ISO 11197

Second edition
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Medical supply units

Gaines techniques à usage médical

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

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...".

This second edition cancels and replaces the first edition (ISO 11197:1996), which has been technically revised.

Annex ZB provides a list of corresponding International and European Standards for which equivalents are not given in the text.

For the purposes of this International Standard, the CEN annex regarding fulfilment of European Council Directives has been removed.

Contents

Foreword

This document (EN ISO 11197:2004) has been prepared by CEN /TC 215, "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with ISO/TC121/SC6 "Medical gas systems".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2005, and conflicting national standards shall be withdrawn at the latest by June 2005.

This document supersedes EN 793: 1997.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive(s).

For special national conditions for Clauses 6.1 k), 6.1 bb), 6.2 aa) and 57.1, see Annex AA.

For a list of International Standards identical to the European Standards referred to in this European Standard, see informative Annex ZB.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This particular standard applies in conjunction with EN 60601-1 "Medical electrical equipment — Part 1: General requirements for safety".

As stated in EN 60601-1 the requirements of this Particular Standard take priority over those of EN 60601-1.

As in EN 60601-1 the requirements are followed by the relevant tests. The structure of this particular standard corresponds to that of EN 60601-1 and the sections, clauses and sub-clauses refer to those of EN 60601-1.

Clauses, subclauses, Tables and Figures additional to those in EN 60601-1 are numbered beginning at "101". Additional annexes are lettered beginning at "AA" except for annexes "ZA" and "ZB".

Additional items in lettered lists are lettered beginning "aa)".

Annex BB contains rationale statements for some of the requirements of EN ISO 11197. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into EN ISO 11197. The clauses and subclauses marked with **R** after their number have corresponding rationale contained in Annex BB. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this standard, but will expedite any subsequent revision.

In any health care facility it is strongly recommended that terminal units of only one type (i.e. with the same set of specific dimensions) are used for each medical gas system, anaesthetic gas scavenging system and liquid system.

SECTION ONE - GENERAL

1 Scope

Clause 1 of EN 60601-1:1990 applies with the following addition:

This document applies to medical supply units as defined in 3.5.

This particular document applies in conjunction with EN 60601-1.

The requirements of this particular document take priority over those of EN 60601-1.

2 Normative references

The following referenced documents are indispensable for the application 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.

EN 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum.*

EN 737-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems – Basic requirements.*

EN 737-3, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum.*

EN 737-4, *Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems.*

EN 739:1998, *Low-pressure hose assemblies for use with medical gases.*

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

EN ISO 14971, *Medical devices - Application of risk management to medical devices (ISO 14971:2000).*

IEC 60079-4, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.*

EN 60529, *Degrees of protection provided by enclosures (IP code) (IEC 60529:1989).*

EN 60598-1, *Luminaires — Part 1: General requirements and tests (IEC 60598-1:1999, modified).*

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1988).*

EN 60601-1-2, *Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility; Requirements and tests (IEC 60601-1-2:2001).*

EN 60669-1, *Switches for household and similar fixed electrical installations — Part 1: General requirements (IEC 60669-1:1998, modified).*

EN 61386-1, *Conduit systems for electrical installations – Part 1: General requirements (IEC 61386-1:1996+A1:2000).*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 60601-1:1990 and the following apply.

3.1
compartment
part of an enclosure with openings necessary for interconnection, control or ventilation

3.2
enclosure
surrounding case constructed to provide a degree of protection to personnel against accidental contact with live parts and also the equipment enclosed against specified environmental conditions (IEC 61950:1997)

NOTE An enclosure can be subdivided into compartments.

3.3
junction point
connection point(s) between the medical supply unit and the system(s) already installed

3.4
medical gas
any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, or for driving surgical tools

NOTE In some applications this term includes medical vacuum.

3.5
medical supply unit
fixed equipment intended to supply electric power and/or medical gases and/or liquids and anaesthetic gas scavenging systems to medical areas of a health-care facility

NOTE 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, anaesthetic gas scavenging systems. Some typical examples of medical supply units are bed head services modules, ceiling pendants, beams, booms, columns and pillars. Examples of configurations are given in Figures 101, 102 and 103.

4 General requirements and requirements for tests

4.1 Modifications to clause 3 of EN 60601-1:1990

Clause 3 of EN 60601-1:1990 applies with the following addition:

3.6 Add the following items:

3.6 aa) **R** 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.

3.6 bb) Medical supply units shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with EN ISO 14971 and which is connected with its intended application, in normal condition and in single fault condition.

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

4.2 Clause 4 of EN 60601-1:1990

Clause 4 of EN 60601-1:1990 applies.

5 Classification

Clause 5 of EN 60601-1:1990 applies.

6 Identification, marking and documents

Clause 6 of EN 60601-1:1990 applies with the following amendments:

6.1 Marking on the outside of equipment or equipment parts

a) Mains-operated equipment

Replace with the following:

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.

g) Connection to the supply

Replace with the following:

Due to the possible complexity of external marking, diagrams 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 diagram shall indicate voltages, number of phases and number of circuits. For electronic connections, the diagram shall indicate connector numbers and wire identification.

k) Mains power output

Replace with the following:

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

See Annex AA for Special National Conditions

NOTE 1 Mains socket-outlets for special purpose areas which are fused in a single circuit can be marked with identical numbers.

Add the following:

When a medical supply unit is provided with socket-outlets for connection to an essential electrical supply circuit [e.g. uninterruptable power supply (UPS)], these socket-outlets shall comply with the national installation rules or be individually identified if not covered by those rules.

See Annex AA for Special National Conditions.

NOTE 2 If socket-outlets in the same location are supplied from different power sources, each source should be readily identifiable.

l) Classification

Replace dash three with the following:

Medical supply units shall be designed and constructed as CLASS I, Type B equipment according to degree of protection against electric shock. 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 of EN 60601-1:1990.

NOTE The term “Type B (BF, CF) equipment (unit)” used in this standard is equivalent to the term “Type B (BF, CF) applied part” used in EN 60601-1.

y) Earth terminals

Add the following:

Facilities for the connection of supplementary equipotential earth bonding (if provided) shall be marked with symbol 9 of appendix D, Table D I of EN 60601-1:1990.

NOTE The term "equipotential earth bonding" used in this standard is equivalent to the term "potential equalisation conductor" used in EN 60601-1.

Add the following:

aa) 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

bb) Terminal units

— Terminal units for medical gases and vacuum shall be marked in accordance with EN 737-1 or national regulations. Colour coding, if used, shall be in accordance with EN 737-1 or national regulations.

See Annex AA for Special National Conditions.

— Terminal units for anaesthetic gas scavenging systems shall be marked in accordance with EN 737-4 or national regulations. Colour coding, if used, shall be in accordance with EN 737-4 or national regulations.

— Terminal units for liquids shall be marked with the name of the liquid in accordance with Table 101 or the equivalent national language.

Table 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

6.2 Marking on the inside of equipment and equipment parts

Add the following:

aa) Junction points and pipelines for medical gases shall be marked in accordance with EN 737-3 or national regulations. Colour coding, if used, shall be in accordance with EN 737-3 or national regulations.

See Annex AA for Special National Conditions.

bb) Junction points and pipelines for anaesthetic gas scavenging systems shall be marked in accordance with EN 737-2 or national regulations. Colour coding, if used, shall be in accordance with EN 737-2 or national regulations.

cc) Junction points and pipelines for liquids shall be marked with the name of the liquid in accordance with Table 101 or the equivalent in national language.

dd) The neutral connection point within the medical supply unit shall be clearly identified using the letter N and/or colour coded blue (See appendix D, Table D I, symbol 8 of EN 60601-1:1990, IEC 60364-5-51 and IEC 60446).

6.8 Accompanying documents

Clause 6.8 of EN 60601-1:1990 applies with the following amendments:

6.8.2 Instructions for use

a) General information

Add the following:

— 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 for supplying medical gases, anaesthetic gas scavenging or liquids 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.

— If flexible hoses are used for supplying medical gases in an operator-adjustable system (e.g. a ceiling pendant), the instructions for use shall state that the following tests given in EN 737-3 shall be carried out following modification or replacement of the flexible hose:

- test for leakage;
- test for obstruction;
- test for particulate contamination;
- test of gas identity.

— If flexible hoses are used for supplying anaesthetic gas scavenging in an operator-adjustable system (e.g. a ceiling pendant), the instructions for use shall state that the following tests given in EN 737-2 shall be carried out following modification or replacement of the flexible hose:

- test for leakage;
- test of flow and pressure drop.

— If flexible hoses are used for supplying liquids in an operator-adjustable system (e.g. a ceiling pendant), the instructions for use shall state that the following test, given in clause 59.103.2 b), shall be carried out following modification or replacement of the flexible hose:

- test for leakage

b) Responsibility of the manufacturer

Replace with the following:

The manufacturer shall provide evidence that the following production tests have been performed for each medical supply unit and that the specified requirements are met:

i) Impedance of protective earthing in accordance with 18 f) of EN 60601-1:1990;

ii) Earth leakage current in accordance with 19.3 and 19.4 of EN 60601-1:1990;

iii) Dielectric strength in accordance with 20.3 and 20.4 of EN 60601-1:1990;

iv) The following requirements and tests:

— requirements as in 59.101.1, 59.102.1 and 59.103.1;

— flow and pressure drop in accordance with 59.101.2 a) and 59.102.2 a);

— no cross-connections in accordance with 59.101.2 b), 59.102.2 b) and 59.103.2 a);

— leakage in accordance with 59.101.2.c), 59.102.2 c) and 59.103.2.b);

— pressure tests in accordance with 59.101.2.d) and 59.102.2.d).

Add the following:

aa) Specifications for installation and use

Medical supply units shall be installed, tested and used in compliance with EN 737-2, EN 737-3 and the manufacturer's instructions.

NOTE 1 An IEC document has been prepared on this subject. (See IEC 60364-7-710)

NOTE 2 Consideration should be given to the mounting height of medical supply units in order to satisfy user requirements for illumination and viewed luminance and access to services.

6.8.3 Technical description

Add the following:

aa) Disclosure by the manufacturer

— The manufacturer shall provide evidence that the noise levels of clause 26 are not exceeded.

— The manufacturer shall specify the flow and pressure drop characteristics of the medical supply unit for both medical gases and anaesthetic gas scavenging, if fitted.

— The manufacturer shall submit upon request evidence of any residual hydrocarbon content on the inner surface of the medical gas pipes.

NOTE The maximum permissible level of residual hydrocarbon content on the inner surface of medical gas pipes is given in EN 13348.

7 Power input

Clause 7 of EN 60601-1:1990 applies.

SECTION TWO - ENVIRONMENTAL CONDITIONS

8 Basic safety categories

Clause 8 of EN 60601-1:1990 applies.

9 Removable protection means

Not used. Replaced by sub-clause 6.1.z).

10 Environmental conditions

Clause 10 of EN 60601-1:1990 applies.

11 Not Used

12 Not Used

SECTION THREE - PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

13 General

Clause 13 of EN 60601-1:1990 applies with the following addition:

Luminaires, built in or mounted on medical supply units shall comply with EN 60598-1.

14 Requirements related to classification

Clause 14 of EN 60601-1:1990 applies.

15 Limitation of voltage and/or energy

Clause 15 of EN 60601-1:1990 applies.

16 Enclosures and protective covers

Clause 16 of EN 60601-1:1990 applies with the following addition:

All external surfaces shall conform to a degree of protection against direct contact in normal operation of at least IP2X or IPXXB (see EN 60529).

This level of protection to live parts shall not be compromised during maintenance of medical gas, anaesthetic gas scavenging 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.

17 Separation

Clause 17 of EN 60601-1:1990 applies.

18 Protective earthing, functional earthing and potential equalization

Clause 18 of EN 60601-1:1990 applies with the following additions:

aa) Terminal units for compressed medical gases and vacuum and for anaesthetic gas scavenging systems are not required to be connected to the earth terminal.

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

19 Continuous leakage current and patient auxiliary currents

Clause 19 of EN 60601-1:1990 applies with the following amendments:

19.3 Allowable values

Add to examples of such equipment in Note 3 of Table IV of EN 60601-1:1990:

— "Medical supply units"

20 Dielectric strength

Clause 20 of EN 60601-1:1990 applies.

SECTION FOUR - PROTECTION AGAINST MECHANICAL HAZARDS

21 Mechanical strength

Clause 21 of EN 60601-1:1990 applies with the following additions:

21.101.1 Dynamic forces

Medical supply units shall be subjected to an impact as described in 21.101.2. After the impact, the live parts shall not become accessible, terminal units shall continue to meet the requirements of EN 737-1 and existing protective devices shall remain intact.

21.101.2 Impact resistance test

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 instruction. The test configuration is shown in Figure 104. 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.

21.101.3 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 as described in 21.101.4.

The medical supply units 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.

21.101.4 Static load test

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

22 Moving parts

Clause 22 of EN 60601-1:1990 applies.

23 Surfaces, corners and edges

Clause 23 of EN 60601-1:1990 applies.

24 Stability in normal use

Clause 24 of EN 60601-1:1990 applies.

25 Expelled parts

Clause 25 of EN 60601-1:1990 applies.

26 Vibration and noise

Add the following:

26.101

Within the frequency spectrum, individual peak noise levels shall not be in excess of 35 dB (A).

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 1,1 times the rated voltage at nominal frequency the medical supply unit shall not produce acoustic energies in excess of 30 dB (A).

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

27 Pneumatic and hydraulic power

Clause 27 of EN 60601-1:1990 applies.

28 Suspended masses

Clause 28 of EN 60601-1:1990 applies.

SECTION FIVE - PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

29 X-Radiation

Clause 29 of EN 60601-1:1990 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

Clause 30 of EN 60601-1:1990 applies.

31 Microwave radiation

Clause 31 of EN 60601-1:1990 applies.

32 Light radiation (including lasers)

Clause 32 of EN 60601-1:1990 applies.

33 Infra-red radiation

Clause 33 of EN 60601-1:1990 applies.

34 Ultraviolet radiation

Clause 34 of EN 60601-1:1990 applies.

35 Acoustical energy (including ultrasonics)

Clause 35 of EN 60601-1:1990 applies.

36 Electromagnetic compatibility

Replace Clause 36 with the following:

EN 60601-1-2 shall apply with the following amendments to all components incorporated into the medical supply unit which can generate magnetic (inductive) interferences:

36.101 Magnetic (inductive) interferences

Medical supply units shall be designed to minimize the emission of magnetic flux. The peak-to-peak values of the magnetic flux generated by the medical supply unit at a distance of 0,75 m shall not exceed the values for specific applications as follows:

— electromyograph application: $0{,}1 \times 10^{-6}$ T;

— electroencephalograph application: $0{,}2 \times 10^{-6}$ T;

— electrocardiograph application: $0{,}4 \times 10^{-6}$ T.

NOTE 1 In addition to the system components, other peripheral electrical components (e.g. nurse call systems, computers) can be installed in medical supply units.

NOTE 2 An example of a circuit for measuring magnetic flux is given in Figure 107.

SECTION SIX - PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

37 Locations and basic requirements

Clause 37 of EN 60601-1:1990 applies.

38 Marking and accompanying documents

Clause 38 of EN 60601-1:1990 applies.

39 Common requirements for Category AP and Category APG Equipment

Clause 39 of EN 60601-1:1990 applies.

40 Requirements and tests for Category AP Equipment, parts and components thereof

Clause 40 of EN 60601-1:1990 applies.

41 Requirements and tests for Category APG Equipment, parts and components thereof

Clause 41 of EN 60601-1:1990 applies.

SECTION SEVEN - PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42 Excessive temperatures

Clause 42 of EN 60601-1:1990 applies with the following amendments:

Add the following:

42.101

The maximum temperatures of luminaires and their exposed components shall not exceed the maximum temperatures stated in EN 60598-1.

43 R Fire prevention

Clause 43 of EN 60601-1:1990 applies with the following amendment:

43.2

Replace with the following:

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault condition, shall not, at the same time, be subjected to conditions in which:

— the temperature of the material is raised to its minimum ignition temperature and

— an oxidant is present

Determine the minimum ignition temperature in accordance with IEC 60079-4 using the oxidizing conditions present under the normal and single fault condition.

Compliance is checked by determining the temperature the material is raised to under normal and single fault condition.

If sparking can occur under normal or single fault conditions, the material subjected to the energy dissipation of the spark shall not ignite under the oxidising conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

Clause 44 of EN 60601-1:1990 applies.

45 Pressure vessels and parts subject to pressure

Clause 45 of EN 60601-1:1990 does not apply.

46 Human errors

Not used.

47 Electrostatic charges

Not used.

48 Material in applied parts in contact with the body of the patient

Clause 48 of EN 60601-1:1990 does not apply.

49 Interruption of the power supply

Clause 49 of EN 60601-1:1990 applies.

SECTION EIGHT - ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 Accuracy of operating data

Not used.

51 Protection against hazardous output

Clause 51 of EN 60601-1:1990 applies.

SECTION NINE - ABNORMAL OPERATION AND FAULT CONDITIONS, ENVIRONMENTAL TESTS

52 Abnormal operation and fault conditions

Clause 52 of EN 60601-1:1990 applies.

53 Environmental tests

Clause 53 of EN 60601-1:1990 applies.

SECTION TEN - CONSTRUCTIONAL REQUIREMENTS

54 General

Clause 54 of EN 60601-1:1990 applies.

55 Enclosures and covers

Clause 55 of EN 60601-1:1990 applies with the following amendment:

Add the following:

55.101

To prevent the build-up of oxidizing medical gases, the lowest part of the enclosure of the medical supply unit shall have ventilation openings.

Compliance is checked by inspection.

56 Components and general assembly

Clause 56 of EN 60601-1:1990 applies with the following amendments:

56.1 General

Add the following:

aa) Connectors for equipotential earth bonding conductors, if provided, shall be mounted so as to prevent physical damage to the operator or to the connector.

Compliance is checked by inspection.

57 Mains parts, components and layout

Clauses 57.1 a) to m) of EN 60601-1:1990 are replaced by the following:

57.1 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.

Mains socket-outlets shall not be provided with mains switches.

See Annex AA for Special National Conditions

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

57.2 Mains connectors, appliance inlets and the like

Clause 57.2 of EN 60601-1:1990 applies.

57.6 Mains fuses and over-current releases

Clause 57.6 of EN 60601-1:1990 does not apply. See Clause 57.1 in this document.

58 Protective earthing - terminals and connections

Clause 58 of EN 60601-1:1990 applies with the following amendments:

58.2

Add the following:

Two examples are given in Figure 105.

Add the following:

58.101 Conductors

Protective earth conductors shall each have a conductance equivalent to that of the associated phase conductor with a minimum value of conductance equivalent to 2,5 mm^2 of copper and shall be individually connected to a common earth bar.

Equipotential earth bonding conductors for the connection of external equipment, if provided, shall each have a cross-section of at least 4 mm^2 of copper and shall be individually detachable from the equipotential earth bonding connectors.

Add the following:

58.102 Bus bar

All protective earth conductors of circuits from the existing mains supply shall be connected in the medical supply unit to a bus bar with a conductance at least equivalent to that of 16 mm^2 copper.

The bus bar for protective earth conductors shall also be equipped with a terminal for connection to a protective earth conductor of at least 16 mm^2 cross sectional area. Facilities for potential equalization conductors shall be connected to the bus bar of the protective earth conductor if there is no bus bar for potential equalization. See Figure 106 for an example. All terminals shall be secured against unintentional loosening.

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

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

59 Construction and layout

Clause 59 of EN 60601-1:1990 applies with the following amendments:

59.1 Internal wiring

c) Insulation

Replace with the following:

NOTE 1 Conductors of different mains circuits of the same voltage do not require mechanical segregation but they should be electrically separated. A separate circuit should be provided for each haemodialysis machine and for each x-ray machine. In general wards one mains circuit supplying socket-outlets can serve more than one bed. In all other departments, at least two separate mains circuits supplying socket-outlets should be provided for each bed.

NOTE 2 Electrical separation is defined in EN 61140.

Add the following:

aa) Communication circuits

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

NOTE 3 Consideration should be given to EN 50174-2 when power and communication cabling are contained within the same enclosure. For an example see Figure 101.

bb) Maintenance

The design features shall ensure that during maintenance of each piping system no live parts of the electrical system can be touched (see Clause 16). The manufacturer shall indicate on the removable safety covers to the live parts and/or in accompanying documents how safe maintenance can be ensured. See Clause 16 d) of EN 60601-1:1990.

59.3 Excessive current and voltage protection

Add the following:

If pulse relays are fitted, they shall comply with EN 60669-1 and EN 60601-1:1990 Clause 57.10.

Add the following new subclauses:

59.101 Medical gas supply construction

59.101.1 Requirements

a) Medical gas pipelines in medical supply units shall be constructed to the requirements of EN 737-3.

NOTE 1 Copper is the preferred material for all medical gas pipelines including vacuum.

NOTE 2 The dimensions of pipes which supply terminal units for compressed medical gases and vacuum should permit the system to function in accordance with EN 737-3.

NOTE 3 Pipes to pressure gauges and other measuring and control equipment can have small cross-sections.

b) Pipeline joints shall be made in accordance with EN 737-3. Cutting ring connections and compression joints shall not be used.

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

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

If flexible hoses are used, they shall comply with EN 739:1998 except for Clauses 5.4.4, 5.4.7, 5.4.8 and 5.4.9.

Evidence shall be provided by the manufacturer.

If flexible hoses are accessible to the operator for removal, they shall be incorporated in hose assemblies which comply with EN 739:1998 except for Clause 5.4.4.

Evidence shall be provided by the manufacturer.

The reduction of a flow of 20 l/min shall not exceed 10 % and the hose shall show no visible deformation in the following condition:

— for hoses for compressed medical gases:
test pressure: 320 kPa
test force : 200 N

— for hoses for vacuum:
test pressure: 10 kPa absolute pressure
test force : 200 N

Evidence shall be provided by the manufacturer.

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 Clause 6.8.2 a).

If hose assemblies are used, they shall comply with EN 739:1998 except for Clause 5.4.4 and the accompanying documents for the medical supply units shall include a procedure for, and the recommended frequency of, inspection and replacement of the hose assemblies (see Clause 6.8.2 a).

d) 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 e.g. by lighting facilities, transformers, etc.

e) 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.

f) Each electrical compartment within a medical supply unit shall be separated from the gas and liquid compartments by a partition wall except where flexible hoses are used for medical gas supply. If electrical cables are installed together with flexible hoses for medical gas supply, the cables shall be insulated and sheathed or installed in a flexible conduit complying with EN 61386-1. Liquid compartments, when mounted horizontally, shall be located below electrical compartments.

g) Terminal units for oxidizing medical gases, for anaesthetic gas scavenging systems and 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 RMS no load voltage and the RMS value of the short circuit current does 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 first exposed part of the electrical accessory/component.

59.101.2 Production tests

The compressed medical gases and vacuum systems shall be tested at ambient temperature to ensure the following:

a) that the portion of the medical gas supply system within the medical supply unit meets the manufacturer's specified flow and pressure drop performance (see clause 6.8.3 aa).

b) that there are no cross connections between pipelines for different gases.

NOTE 1 Test procedure for cross-connections are given in EN 737-3.

c) that when pressurized with clean, oil free, dry air or nitrogen at the nominal distribution pressure specified in EN 737-3, the leakage from the portion of the pipeline for each compressed medical gas and vacuum included in the medical supply unit does not exceed the value of 0,296 ml/min (equivalent to 0,03 kPa l/min) times the number of terminal units connected to that portion of pipeline.

NOTE 2 For the vacuum supply, the test can be carried out at 400 kPa positive pressure.

d) that each portion of pipeline can withstand a pressure of 2 times the nominal distribution pressure specified in EN 737-3.

e) that pipelines are made of copper and joints are in accordance with EN 737-3.

59.102 Anaesthetic gas scavenging system construction

59.102.1 Requirements

f) The construction of the anaesthetic gas scavenging system shall comply with EN 737-2.

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

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

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 Clause 6.8.2 a).

59.102.2 Production test

The anaesthetic gas scavenging system installed on each medical supply unit shall be tested to ensure the following:

a) that the portion of the anaesthetic gas scavenging system within the medical supply unit meets the manufacturer's specified flow and pressure drop performance (see Clause 6.8.3 aa);

b) that there are no cross-connections between pipelines for different gases.

c) that when pressurized with clean, oil free, dry air or nitrogen at the nominal operating pressure specified in EN 737-2, the leakage of the portion of the pipeline for the anaesthetic gas scavenging system included in the medical supply unit does not exceed the value of 2,96 ml/min (equivalent to 0,3 kPa l/min) times the number of terminal units connected to that portion of pipeline.

d) that each portion of the pipeline that is exposed to positive pressure under normal condition can withstand a pressure of 2 times the maximum operating pressure.

59.103 Liquid supply construction

59.103.1 R Requirements

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

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

NOTE 1 Stainless steel (with a corrosion resistance at least equivalent to CrNiMoTi 18 10 - ISO 683-13: 1986, Type 15) or appropriate PVC or appropriate polypropylene should be used for dialysing concentrate and dialysing permeate pipelines.

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

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

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 Clause 6.8.2 a).

The material selected for flexible hoses for use with any liquid supply 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.

Evidence shall be provided by the manufacturer.

d) Pipes and hoses for medical gases can be installed together with piping for liquids. If mounted together horizontally, gas pipes shall be located above liquid pipes.

NOTE 2 Pipelines for dialysing solutions should be installed in a single recirculating loop.

NOTE 3 Hot water or wet steam can be used for pasteurisation of pipelines for dialysing solutions. Means should be provided to protect other components from excessive temperature.

NOTE 4 Turbulence and dead spaces should be avoided by design.

e) 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.

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

Evidence shall be provided by the manufacturer.

59.103.2 Production tests

Each liquid supply unit shall be tested to ensure the following:

a) that there are no cross-connections between pipelines for different liquids;

b) that when pressurized with clean, oil free, dry air or nitrogen at 1,5 times the operating pressure specified by the manufacturer, the leakage from the portion of the pipeline for each liquid included in the medical supply unit does not exceed the value of 0,296 ml/min (equivalent to 0,03 kPa l/min) times the number of terminal units connected to that portion of pipeline.

c) that the requirements of Clause 59.103.1 are met.

59.104 Terminal unit construction

59.104.1 Terminal units for medical gases shall comply with EN 737-1.

59.104.2 Terminal units for anaesthetic gas scavenging systems shall comply with EN 737-4.

59.104.3

a) Terminal units for liquids shall comprise either:

— a flow control valve fitted with a check valve and at the outlet a hose insert for the following:

- potable water, cold
- potable water, warm
- cooling water
- cooling water, feed-back
- de-mineralized water
- 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 during release.

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

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

NOTE Stainless steel (with a corrosion resistance at least equivalent to CrNiMoTi 18 10 - ISO 683-13: 1986, Type 15) should be used for terminal units for dialysing solutions.

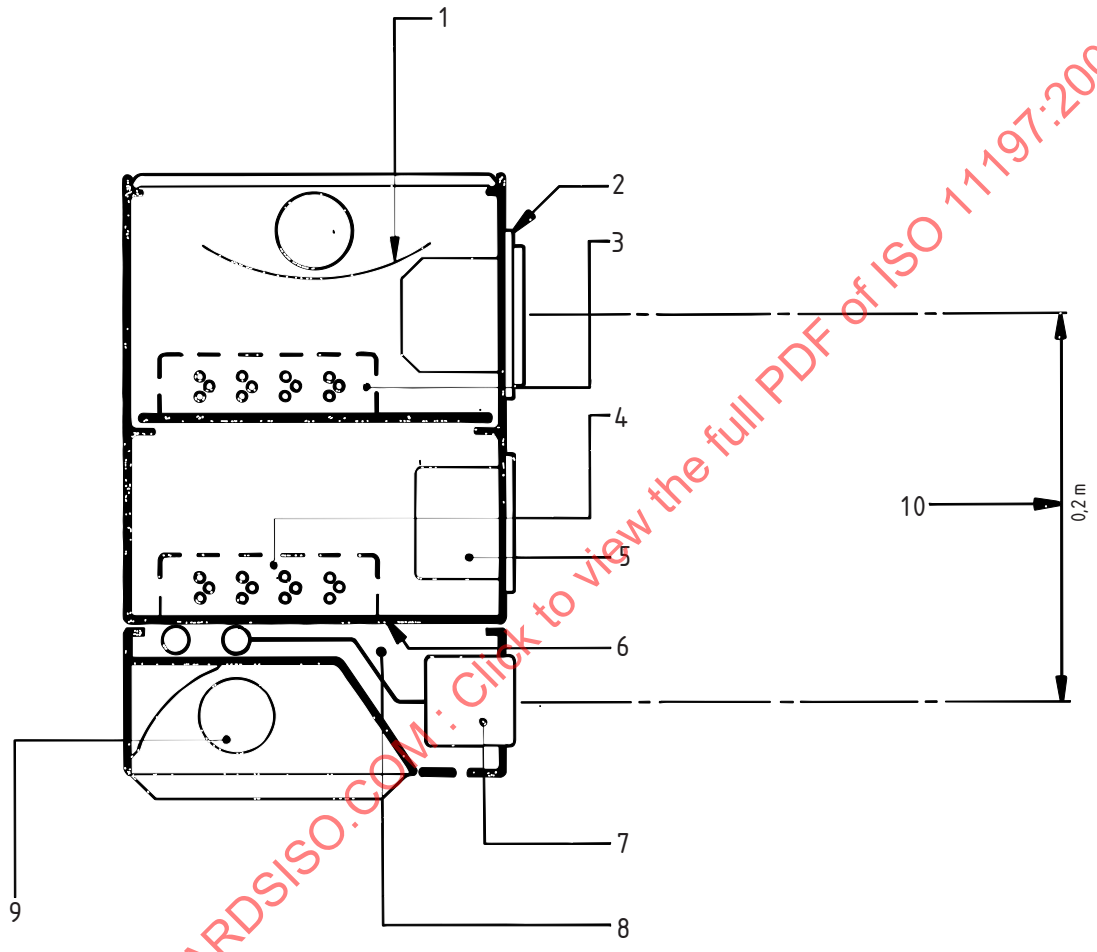
Evidence shall be provided by the manufacturer.

f) The nominal internal diameters for quick-connect sockets and probes, if fitted, shall be as follows:

- Dialysing concentrate 4 mm
- Dialysing permeate 6 mm

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

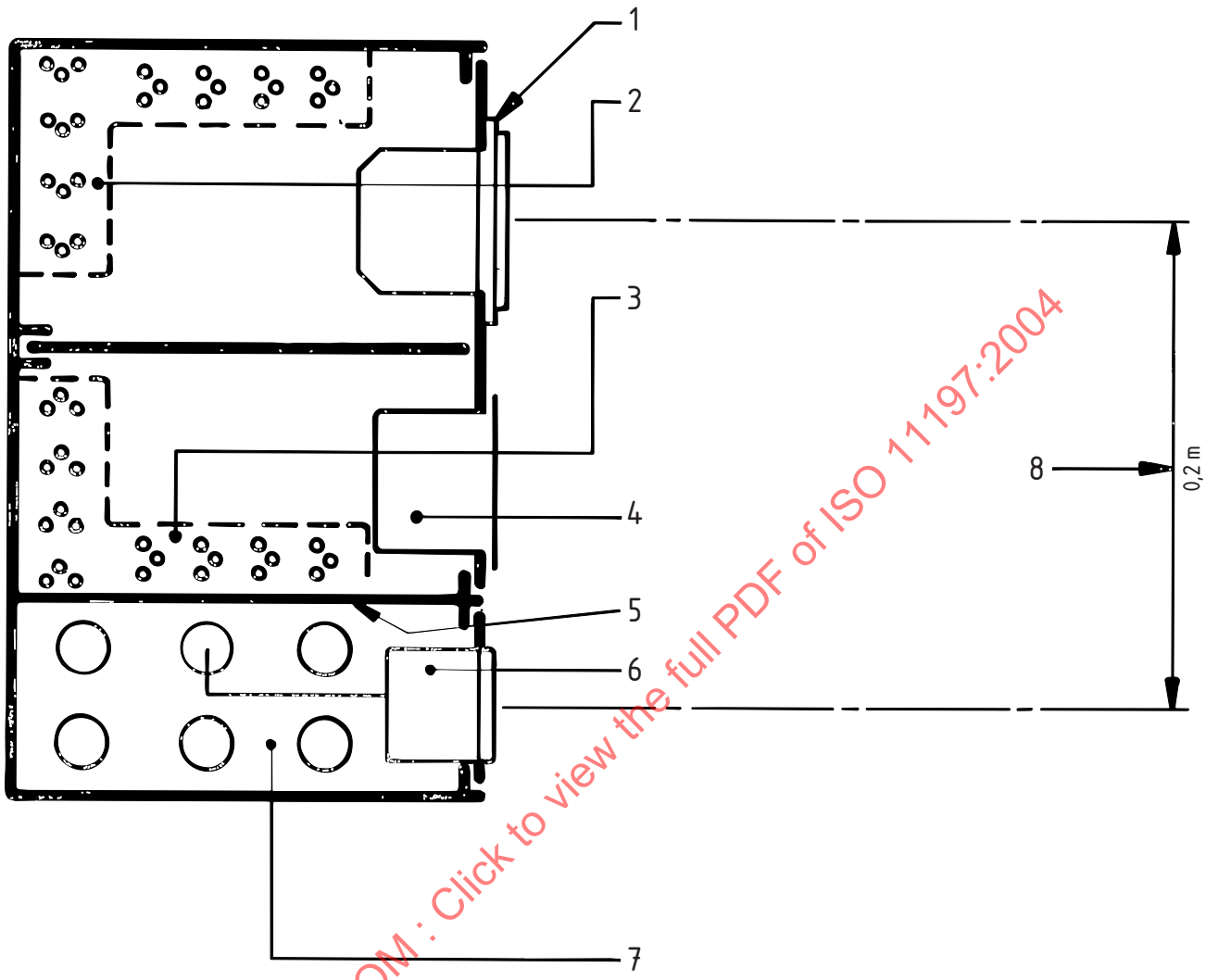
h) Compliance with clauses 59.104.3 a) to d) and f) and g) shall be checked by visual inspection.



Key

1 Ambient light fitting
2 Electrical socket
3 Mains supply
4 Communication, safety extra-low voltage
5 Recessed equipment
6 Barrier
7 Terminal unit
8 Pipeline installation
9 Reading light
10 Minimum distance from centre to centre

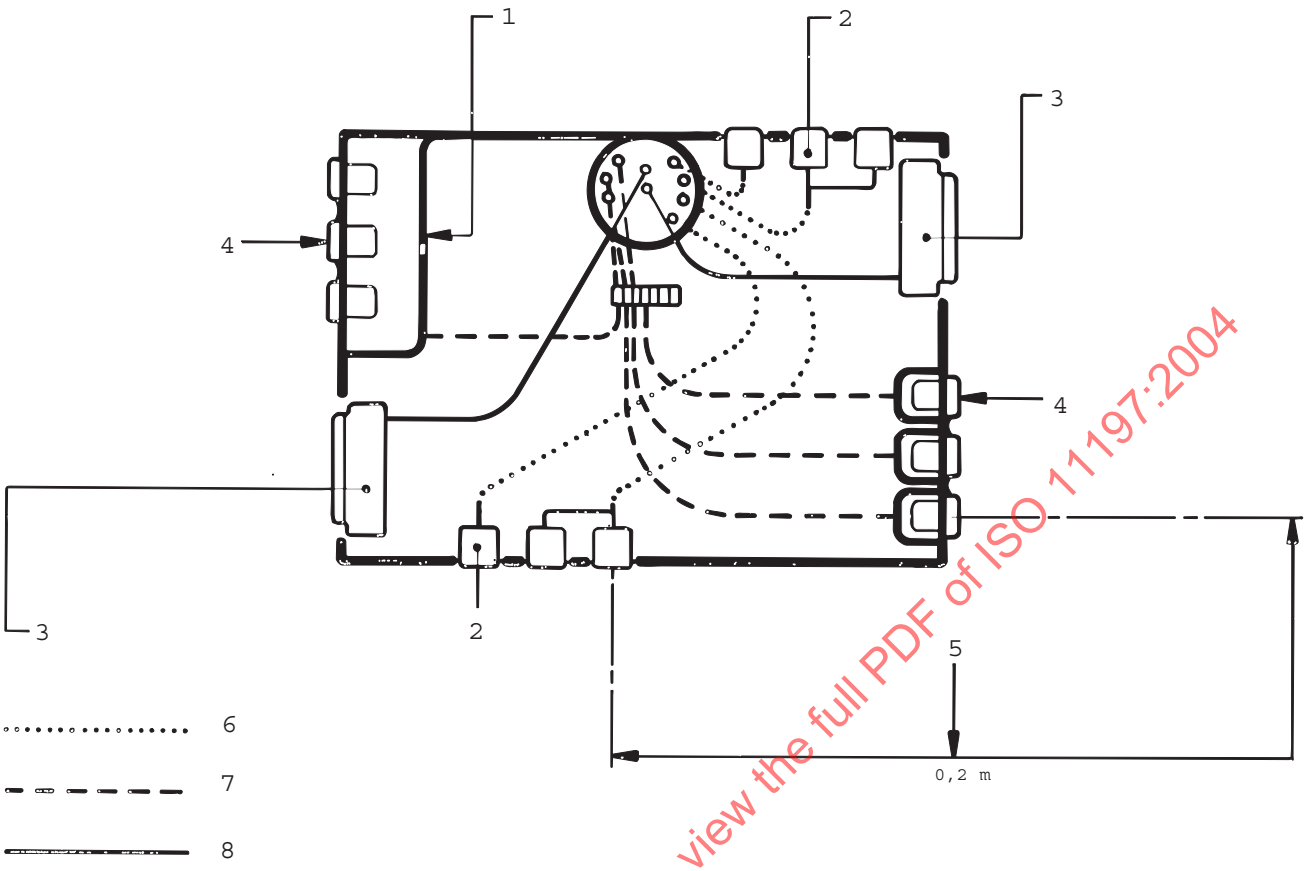
Figure 101 — Sectional drawing of typical medical supply unit for patient care rooms



Key

1 Electrical socket
2 Mains supply
3 Communication, safety extra-low voltage
4 Recessed equipment
5 Barrier
6 Terminal unit
7 Pipeline installation
8 Minimum distance from centre to centre

Figure 102 — Sectional drawing of typical medical supply unit for intensive care rooms and operating theatres



Key

1 Barrier

2 Terminal units

3 Recessed equipment, low current electro installation, icommunication safety extra-low voltage

4 Electrical socket

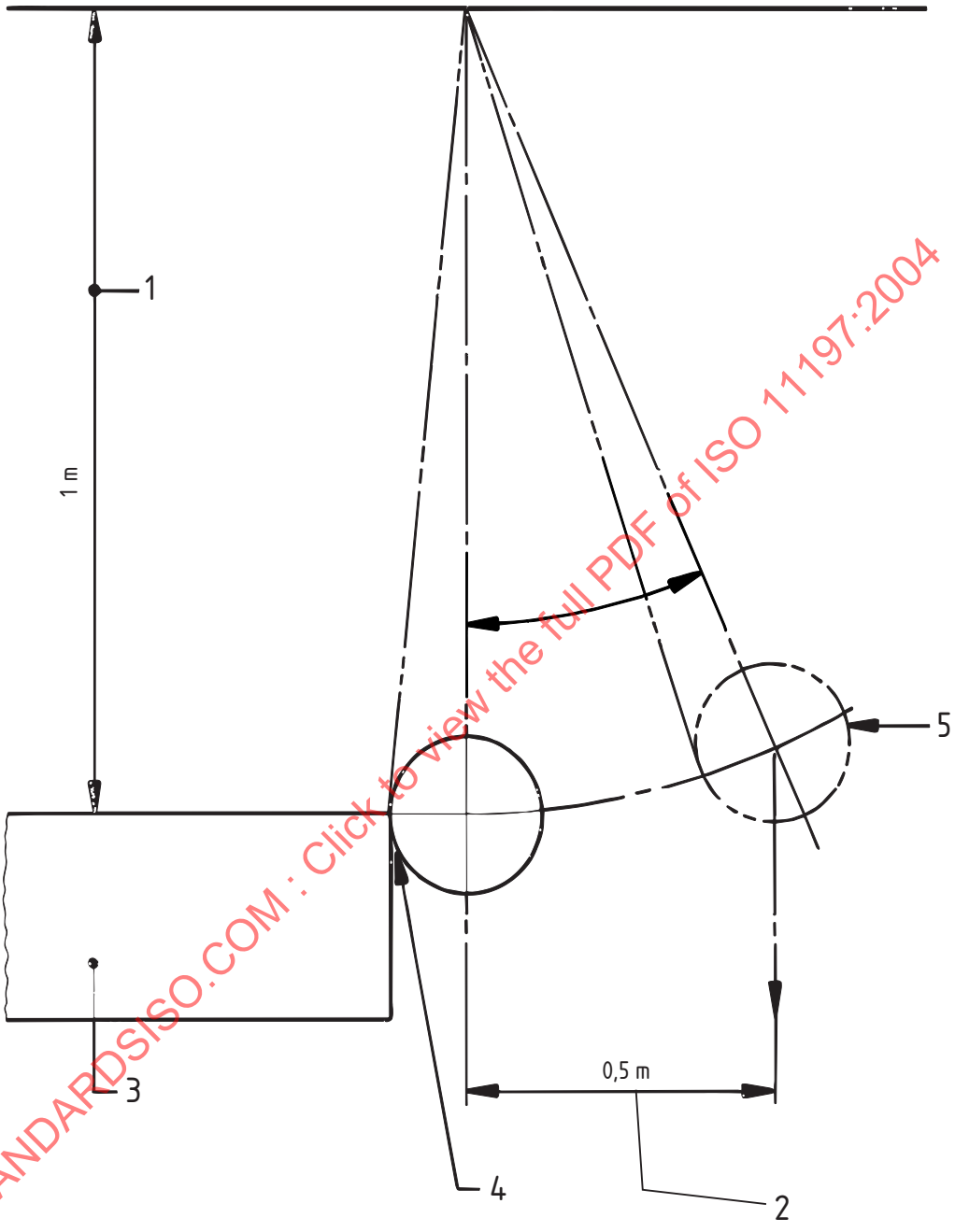
5 Minimum distance measured on the surface from centre to centre

6 Flexible hoses

7 Mains installation

8 Low current installation

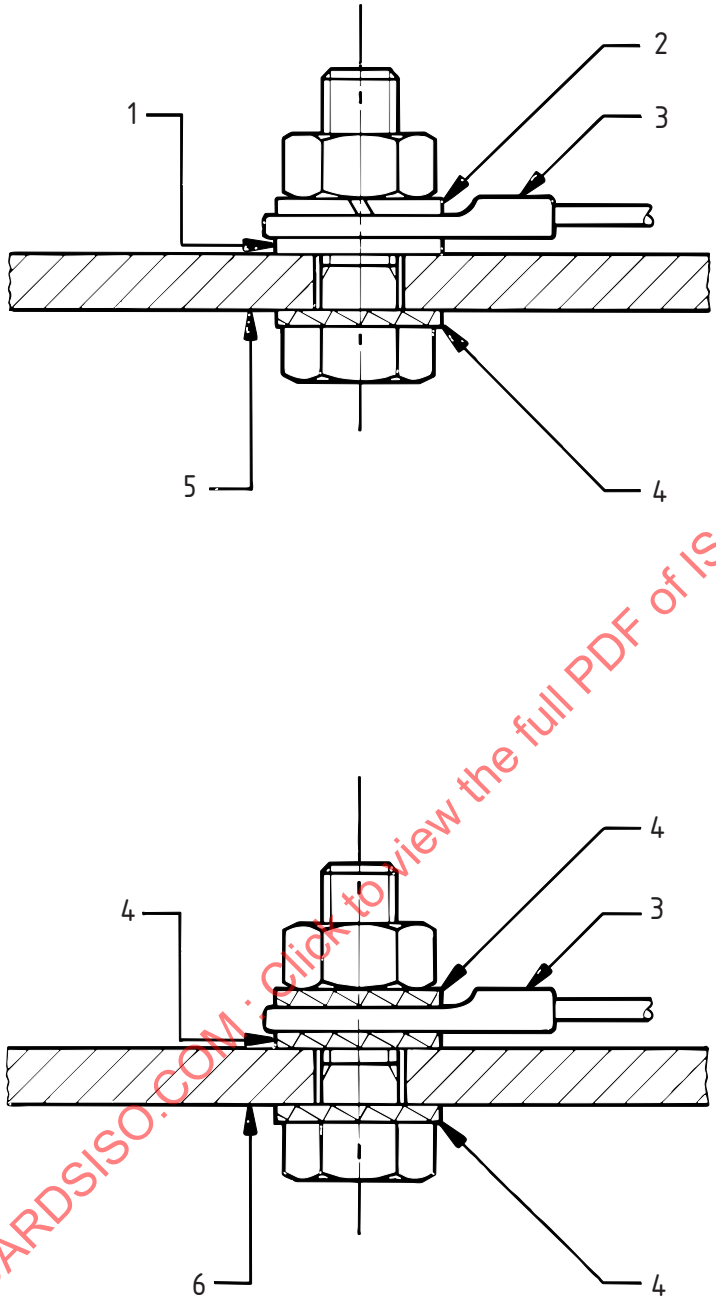
Figure 103 — Sectional drawing of typical non-rigid medical supply unit



Key

1 Length of pendulum
2 Deflection
3 Mounted medical supply unit
4 Most vulnerable point (example)
5 Bag of weight 200 N

Figure 104 — Impact resistance test



Key

1 Cupal washer (Cu/Al) (Copper surface uppermost)
2 Spring washer
3 Cable bracket
4 Lock washer
5 Supply unit section (e.g. aluminium)
6 Supply unit section (e.g. ferrous)

Figure 105 — Typical examples for protective measures against loosening and corrosion of potential equalization and earth-conductor facilities