SLOVENSKI STANDARD
SIST EN ISO 11197:2005

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Enote za oskrbo v medicini (ISO 11197:2004)

Medical supply units (ISO 11197:2004)

Medizinische Versorgungseinheiten (ISO 11197:2004)

Gaines techniques a usage médical (ISO 11197:2004)

Ta slovenski standard je istoveten z: **EN ISO 11197:2004**

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Medical supply units (ISO 11197:2004)

Gaines techniques à usage médical (ISO 11197:2004)

Medizinische Versorgungseinheiten (ISO 11197:2004)

This European Standard was approved by CEN on 23 September 2004.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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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of an identical text or by endorsement, at the latest by June 2005, and conflicting national standards shall be withdrawn at the latest by June 2005.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 relationship with EU Directives, see informative Annex ZA, which is an integral part of this standard.

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: