SLOVENSKI STANDARD
SIST EN 793:2000

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Posebne zahteve za varnost enot za oskrbo z medicinskim materialom

Particular requirements for safety of medical supply units

Besondere Anforderungen für die Sicherheit von medizinischen Versorgungseinheiten

Prescriptions particulieres relatives a la sécurité des gaines techniques a usage médical

Ta slovenski standard je istoveten z: **EN 793:1997**

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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English version

Particular requirements for safety of medical supply units

Prescriptions particulières relatives à la sécurité des gaines techniques à usage médical

Besondere Anforderungen für die Sicherheit von medizinischen Versorgungseinheiten

This European Standard was approved by CEN on 30 October 1997.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents **Page**

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Anaesthetics and respiratory equipment" the secretariat of which is held by BSI.

For special national conditions for clauses 6.1 bb) and 6.2 aa) see annex AA.

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 relationship with EU Directives, see informative annex ZA which is an integral part of this standard.

Annex AA is a normative part, and annexes BB, CC and ZA are informative parts, of this standard.

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 May 1998, and conflicting national standards shall be withdrawn at the latest by May 1998.

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

Introduction

This Particular Standard amends EN 60601-1: 1990 "Medical electrical equipment, Part 1: General requirements for safety".

As stated in EN 60601-1: 1990 the requirements of this Particular Standard take priority over those of EN 60601-1: 1990.

As in EN 60601-1: 1990 the requirements are followed by the relevant tests. The structure of this Particular Standard corresponds to that of EN 60601-1: 1990 and the sections, clauses and subclauses refer to those of EN 60601-1: 1990.

Clauses, subclauses, tables and figures additional to those in EN 60601-1: 1990 are numbered beginning at '101'. Additional annexes are lettered beginning at 'AA' except for annex 'ZA'.

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

Rationales for some of the requirements of this standard are given in annex CC. Such requirements are indicated by the letter 'R' after the clause number.

Section one - General

1 Scope

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

This standard applies to medical supply units as defined in 3.4.

1.3 Particular standards

This Particular Standard amends EN 60601-1: 1990.

The requirements of this Particular Standard take priority over those of EN 60601-1: 1990.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references subsequent amendment to or revisions of any of these apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Appendix L of EN 60601-1: 1990 applies with the following additions:

EN 737-1	*Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum*
prEN 737-2	*Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems - Basic requirements*
prEN 737-3	*Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum - Basic requirements*
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 1441	*Medical devices - Risk analysis*
EN ISO 3744	*Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially freefield condition over a reflecting plane (ISO 3744: 1994)*

EN 60598-1	*Luminaires - Part 1: General requirements and tests (IEC 598-1: 1992, modified)*
EN 60601-1 : 1990	*Medical electrical equipment - Part 1: General requirements for safety*
EN 60601-1-2	*Medical electrical equipment - Part 1: General requirements for safety - Electromagnetic compatibility - Requirements and tests*
EN 60669-1	*Switches for household and similar fixed electrical installations - Part 1: General requirements (IEC 669-1: 1993, modified)*
IEC 79-4	*Electrical apparatus for explosive gas atmospheres - Part 4: Method of test for ignition temperature*
IEC 884-1	*Plugs and socket-outlets for household and similar purposes - General requirements*

3 Terminology and definitions

Clause 2 of EN 60601-1: 1990 applies with the following additions:

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. electricity, medical gas(es), liquid(s) or anaesthetic gas scavenging systems.

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

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 applications.

3.4 medical supply unit: Prefabricated permanently installed 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 of therapy units and other intermediate care areas. It is intended to supply electric power and/or medical gases and/or liquids.

NOTE: Medical supply units can 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 can consist of modular sections for electrical supply, lighting for therapy or illumination, communication, supply of medical gases and liquids, anaesthetic gas scavenging systems. Typical examples of medical supply units are given in figures 101, 102 and 103.

4 General requirements and requirements for test

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

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

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 1441 and which is connected with their 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 Particular 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 at least with permanently affixed and clearly legible marking on the outside of the major part of the equipment with an indication of 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 purpose areas (e.g. x-ray equipment) shall be marked with type of mains, rated voltage, rated current and the label "x-ray".

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

l) **Classification**

Replace dash three 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. 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 annex D, table D II of EN 60601-1 : 1990.

y) **Earth terminals**

Add the following:

- Facilities for the connection of a potential equalization conductor (if provided) shall be marked with symbol 9 of annex D, table DI of EN 60601-1 : 1990.

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 EN 737-1. Colour coding, if used, shall be in accordance with EN 737-1.

See annex AA for special national conditions.

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

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

NOTE: Colour coding, if used, should be in accordance with national standards if available.

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 prEN 737-3. Colour coding, if used, shall be in accordance with prEN 737-3.

See annex AA for special national conditions.

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

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 the national language.

NOTE: Colour coding, if used, should be in accordance with national standards if available.

6.8 Accompanying documents

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

6.8.2 *Instruction 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 safe working load shall be stated.

- Instructions for use shall state that in any health care facility, terminal units of only one type (i.e. with the same set of dimensions for probe and socket) should be used for the same liquid.

- If flexible hoses and hose assemblies are used for medical gas supply, anaesthetic gas scavenging and liquid supply for operator adjustable systems, e.g. ceiling pendants, the instructions for use shall include a procedure for and the frequency of inspection and replacement.

- If flexible hoses are used for medical gas supply for operator adjustable systems, e.g. ceiling pendants, the instructions for use shall state that the following tests given in prEN 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 anaesthetic gas scavenging for operator adjustable systems, e.g. ceiling pendants, the instructions for use shall state that the following tests given in prEN 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 liquid supply for operator adjustable systems, e.g. ceiling pendants, the instructions for use shall state that the following test, given in 59.103.2 b), shall be carried out following modification or replacement of the flexible hose:

- test for leakage

- If live parts of the electrical system can be touched during maintenance of the piping systems, the manufacturer shall state the precautions required for safe maintenance when safety covers have been removed.