SLOVENSKI STANDARD
SIST EN 50072:1995

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Medical electrical equipment - Particular requirements for the safety of peritoneal dialysis equipment

Medical electrical equipment - Particular requirements for the safety of peritoneal dialysis equipment

Medizinische elektrische Geräte - Besondere Festlegungen für die Sicherheit von Peritoneal-Dialyse-Geräte

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Appareils électromédicaux - Règles particulières de sécurité pour le matériel de dialyse péritonéale

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Ta slovenski standard je istoveten z: **EN 50072:1992**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

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2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 50072

September 1992

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English version

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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Foreword

This standard was prepared by the working group for peritoneal dialysis equipment of TC 62, Electrical equipment in medical practice.

The draft standard was submitted to the CENELEC Unique Acceptance Procedure in July 1991 and was approved by CENELEC as EN 50072 on 24 March 1992.

The following dates are applicable:

- latest date of publication of an identical national standard	(dop)	1993-03-01
- latest date of withdrawal of conflicting national standards	(dow)	1993-03-01

For products which have complied with the relevant national standard before 1993-03-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1998-03-01.

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Introduction

The minimum safety requirements specified in this Particular Standard are considered to provide for a practical degree of safety in the operation of PERITONEAL DIALYSIS EQUIPMENT.

This Particular Standard amends the General Standard, EN 60601-1, Medical electrical equipment - Part 1: General requirements for safety, below called the General Standard. As stated in Sub-clause 1.3 of the General Standard, the requirements of this Particular Standard take priority, where indicated, over those of the General Standard.

As in the General Standard, the requirements are followed by specifications for the relevant tests. The numbers of clauses and subclauses of this Particular Standard refer to the relevant clauses of the General Standard.

As in the General Standard, terms defined in this standard are written in capitals.

SECTION ONE — GENERAL

1 Scope and object

This clause of the General Standard applies except as follows:

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1.1 *Scope*

Addition:

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This Particular Standard specifies the minimum safety requirements for PERITONEAL DIALYSIS EQUIPMENT as defined in Sub-clause 2.1.102. These devices are intended for use either by medical staff or under the supervision of medical expertise, including PERITONEAL DIALYSIS EQUIPMENT operated by the PATIENT. These particular requirements do not apply to DIALYSING SOLUTION, the PATIENT CIRCUIT or continuous ambulatory peritoneal dialysis equipment.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

To the first paragraph, add the following:

The PATIENT CIRCUIT and all parts permanently and conductively connected to it shall be considered as an APPLIED PART.

Addition:

2.1.101 *PERITONEAL DIALYSIS*

A process whereby DIALYSING SOLUTION is introduced into the peritoneal cavity of the PATIENT and subsequently removed.

2.1.102 *PERITONEAL DIALYSIS EQUIPMENT*

A system or combination of units used to perform PERITONEAL DIALYSIS.

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2.1.103 *PATIENT CIRCUIT*

The tubing set which conveys DIALYSING SOLUTION from a reservoir via the PERITONEAL DIALYSIS EQUIPMENT to the peritoneal cavity of the PATIENT and subsequently to a drainage bag or drain.

2.1.104 *DIALYSING SOLUTION*

Commercially available pharmaceutical preparation (solution) for use with PERITONEAL DIALYSIS EQUIPMENT.

NOTE: The composition of this solution is prescribed in the relevant Pharmacopeia

2.1.105 *INFLOW*

The phase during which the peritoneal cavity is filled.

2.1.106 *OUTFLOW*

The phase during which the peritoneal cavity is emptied.

2.1.107 *PROTECTIVE SYSTEM*

An automatic system which senses a specified parameter (or parameters), or a constructional feature, specially designed to protect the PATIENT against hazards which may arise.

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3 General requirements

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This clause of the General Standard applies except as follows:

3.6 *Addition:*

j) Failure of any PROTECTIVE SYSTEM

Leakage from the PATIENT CIRCUIT shall not be regarded as a SINGLE FAULT CONDITION.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 *Other conditions*

Addition:

f) The initial temperature of the DIALYSING SOLUTION used for test shall be 1 °C ± 0,5 °C or the minimum temperature specified by the manufacturer in the ACCOMPANYING DOCUMENTS.

5 Classification

This clause of the General Standard applies.

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6 Identification, marking and documentation

This clause of the General Standard applies except as follows:

6.1 *Marking on the outside of the EQUIPMENT or EQUIPMENT parts*

Replace the test specification for the determination of durability after item z) by the following:

For determination of durability, markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then either:

- *for 15 s with a cloth rag soaked with methylated spirit at ambient temperature and then for 15 s with a cloth rag soaked with isopropy alcohol, or*
- *for 15 s with any cleaning solution recommended by the manufacturer, applied with a cloth rag or as specified by the manufacturer.*

6.8.2 *Instructions for use*

Addition:

j) The instructions for use shall additionally include the following:

- the method(s) by which any necessary disinfection or sterilization is achieved;
- a statement that the test procedure by which the effectiveness of any necessary sterilization or disinfection has been verified is available on request;
- a list of recommended PATIENT CIRCUITs for use with the equipment.

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6.8.3 *Technical description*

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Addition:

e) The technical description shall additionally include the following:

- the type and accuracy of the PROTECTIVE SYSTEM required by Sub-clause 51.101
- the range and accuracy of any DIALYSING SOLUTION temperature measuring equipment.

7 Power input

This clause of the General Standard applies.

SECTION TWO — ENVIRONMENTAL CONDITIONS

Clauses 8 to 12 of the General Standard apply.

8 (Not used)

9 (Not used)

10 Environmental conditions

11 (Not used)

12 (Not used)

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SECTION THREE — PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

Clauses 13 to 20 of the General Standard apply.

13 General

14 Requirements related to classification

15 Limitation of voltage and/or energy

16 ENCLOSURES and PROTECTIVE COVERS

17 Separation

18 Protective earthing, functional earthing and potential equalization

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

20 Dielectric strength

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SECTION FOUR — PROTECTION AGAINST MECHANICAL HAZARDS

Clauses 21 to 28 of the General Standard apply.

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21 Mechanical strength

22 Moving parts

23 Surfaces, corners and edges

24 Stability in NORMAL USE

25 Expelled parts

26 (Not used)

27 Pneumatic and hydraulic power

28 Suspended masses

SECTION FIVE — PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

Clauses 29 to 36 of the General Standard apply.

29 X-Radiation

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

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31 Microwave radiation

32 Light radiation (including lasers)

33 Infra-red radiation

34 Ultra-violet radiation

35 Acoustical energy (including ultra-sonics)

36 Electromagnetic compatibility

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

Clauses 37 to 41 of the General Standard apply.

37 Locations and basic requirements

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38 Marking and ACCOMPANYING DOCUMENTS

39 Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT

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40 Requirements and tests for CATEGORY AP EQUIPMENT, parts and components thereof

41 Requirements and tests for CATEGORY APG EQUIPMENT; parts and components thereof

SECTION SEVEN — PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

Clauses 42 and 43 of the General Standard apply.

42 Excessive temperatures

43 Fire prevention

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

This clause of the General Standard applies except as follows:

44.1 *General*

Addition:

All the provisions of the Sub-clause 44.2 to 44.4 shall be applied using DIALYSING SOLUTION of conductivity 13 mS x cm^{-1} ± 0,5 mS x cm^{-1}, measured at a reference temperature of 25 °C, and containing 15 g/l glucose.