SLOVENSKI STANDARD
SIST EN 1283:2000

01-januar-2000

Hemodializatorji, hemodiafiltri, hemofiltri, hemokoncentratorji in izventelesni pretoļ ni sistemi

Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits

Hämodialysatoren, Hämodiafilter, Hämofilter, Hämokonzentratoren und dazugehörige Blutschlauchsysteme

Hémodialyseurs, hémodiafiltres, hémofiltres, hémoconcentrateurs et leurs circuits extracorporels

Ta slovenski standard je istoveten z: **EN 1283:1996**

ICS:

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

SIST EN 1283:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1283

April 1996

ICS 11.040.20

Descriptors: medical equipment, dialysis apparatus, haemodialysers, filters, disposable equipment, definition, specifications, performance evaluation, physical properties, tests, information

English version

Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits

Hémodialyseurs, hémodiafiltres, hémofiltres, hémoconcentrateurs et leurs circuits extracorporels

Hämodialysatoren, Hämodiafilter, Hämofilter, Hämokonzentratoren und dazugehörige Blutschlauchsysteme

This European Standard was approved by CEN on 1996-03-14. 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.

The European Standards exist 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

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

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

Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 205 "Non-active medical devices" of which the Secretariat is held by BSI.

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 October 1996, and conflicting national standards shall be withdrawn at the latest by October 1996 .

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

0 Introduction

This European Standard contains requirements and acceptance criteria (including testmethods)for safety-related parameters for haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the extracorporeal circuits for these devices.

This European Standard contains only those requirements that are specific to the devices concerned. Non-specific requirements are covered by references to other European or International Standards, listed in the normative references section. Since non-toxicity is anticipated to be the subject of a future standard, this standard does not cover non-toxicity.

1 Scope

This European Standard specifies requirements for sterile, single use haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the extracorporeal circuits for these devices (including any integral accessory lines, such as fluid and infusion lines and lines for connection to pressure monitors) intended for renal care and cardiovascular use on humans.

This European Standard does not apply to extracorporeal circuits for cardiovascular use or to other extracorporeal blood exchange devices, such as plasmafilters, haemoperfusion devices, vascular access devices, oxygenators, active medical devices or devices for peritoneal dialysis.

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 amendments to or revisions of any of these publications 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.

EN 556	Sterilization of medical devices - Requirements for medical devices to be labelled "sterile"
prEN 980	Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
prEN 1041	Terminology, symbols and information provided with medical devices - Information supplied by the manufacturer with medical devices
EN 30993-1	Biological evaluation of medical devices Part 1: Guidance on selection of tests (ISO 10993-1: 1992 + Technical Corrigendum 1: 1992)
prEN 30993-7	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals (ISO/DIS 10993-7: 1994)
prEN 30993-11	Biological evaluation of medical devices Part 11: Test for systemic toxicity (ISO 10993-11: 1993)
EN 46001	Quality systems - Medical devices - Particular requirements for the application of EN 29001

EN 46002	Quality systems - Medical devices - Particular requirements for the application of EN 29002
HD 395-2-16	Medical electrical equipment - Part 2: Particular requirements for the safety of haemodialysis equipment (IEC 601-2-16: 1989)
ISO 594-2: 1987	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
ISO 7864: 1988	Sterile hypodermic needles for single use

3 Definitions

For the purposes of this European Standard, the following definitions apply:

3.1 blood compartment: Part of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators through which blood is intended to pass.

3.2 clearance: Volume of a solution from which a solute is completely removed per unit time.

3.3 dialysing fluid; dialysate; dialysis fluid: Solution which is intended to exchange solutes and/or water with blood during haemodialysis or haemodiafiltration.

3.4 dialysing fluid compartment: Part of a haemodialyser or haemodiafilter through which dialysing fluid is intended to pass.

3.5 haemoconcentration: Process whereby excess fluid, and possibly electrolytes, are removed from diluted blood across a semipermeable membrane.

3.6 haemoconcentrator: Device intended to perform haemoconcentration.

3.7 haemodiafilter: Device intended to perform haemodiafiltration.

3.8 haemodiafiltration: Process whereby solute imbalances in a patient's blood are corrected by means of simultaneous filtration and diffusion across a semipermeable membrane and replacement with an appropriate physiological fluid.

NOTE: This process normally includes fluid removal.

3.9 haemodialyser: Device intended to perform haemodialysis.

3.10 haemodialysis: Process whereby solute imbalances in a patient's blood are corrected, mainly by diffusion across a semipermeable membrane.

NOTE: This process normally includes fluid removal.

3.11 haemofilter: Device intended to perform haemofiltration.

3.12 haemofiltration: Process whereby solute imbalances in a patient's blood are corrected, mainly by filtration across a semipermeable membrane and replacement with an appropriate physiological fluid.

NOTE: This process normally includes fluid removal.

3.13 transmembrane pressure: Hydrostatic pressure exerted across a semipermeable membrane.

NOTE: For practical reasons the mean transmembrane pressure is generally expressed as either:

a) the difference between the arithmetic means of inlet and outlet pressures of the blood and dialysing fluid compartments of a haemodialyser or a haemodiafilter; or

b) the difference between the arithmetic mean of the inlet and outlet pressures of the blood compartment and the filtrate pressure of a haemofilter or a haemoconcentrator.

3.14 access port: Component intended to provide access to the interior of the extracorporeal circuit.

NOTE: Access can be for sampling and/or injection purposes.

3.15 sieving coefficient: Ratio of a solute concentration in the filtrate to the simultaneous concentration of the same solute in the plasma.

4 Requirements

4.1 Biological characteristics

4.1.1 *Sterility and non-pyrogenicity*

Pathways for blood and other fluids shall be sterile and non-pyrogenic.

NOTE: The fact that it is common practice to make aseptic connections to blood compartments and/or pathways should be considered.

Compliance shall be verified in accordance with 5.2.1.

4.1.2 *Biocompatibility*

Parts of haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the extracorporeal circuit that will come into direct or indirect contact with blood during their intended clinical use shall be biocompatible with respect to their intended use.

Compliance shall be verified in accordance with 5.2.2.

4.2 Physical characteristics

4.2.1 *Structural integrity*

When tested in accordance with 5.3.1, haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and extracorporeal circuits shall not leak.

NOTE: This requirement refers to the external integrity of the device.

4.2.2 *Blood compartment integrity*

When tested in accordance with 5.3.2 the blood compartments of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators shall not show leakage under the transmembrane pressures stated by the manufacturer for their intended clinical use (see 7.2.11).

4.2.3 *Connectors and ports*

4.2.3.1 *Connections to the blood compartment*

Except if haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the extracorporeal circuit are designed as an integral system, the dimensions of the blood inlet and outlet connectors of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators shall be as given in figures 1 and 3 and the dimensions of the connectors of the extracorporeal circuit shall be as given in figures 2 and 3.

Compliance shall be verified by inspection.

4.2.3.2 *Connections for dialysing fluid or filtrate*

Except if haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the dialysing fluid and/or filtrate lines are designed as an integral system, the dimensions of the ports of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators shall be as given in figure 4.

Compliance shall be verified by inspection.

4.2.3.3 *Connections to vascular access devices*

Except if the extracorporeal circuit and the vascular access device are designed as an integral part, the extracorporeal circuit shall terminate in a male 6 % (Luer) taper lock fitting in accordance with ISO 594-2.

Compliance shall be verified by inspection.

4.2.3.4 *Connections to ancillary components*

Except if the extracorporeal circuit and any ancillary components are designed as integral parts and except for connectors for substitution fluid containers, the extracorporeal circuits shall terminate in a female 6 % (Luer) taper lock fitting in accordance with ISO 594-2.

Compliance shall be verified by inspection.

4.2.3.5 *Access ports*

When tested in accordance with 5.3.3, any access ports which incorporate a membrane intended to be pierced by a needle and which are incorporated in the extracorporeal circuit, shall not leak.

Any access ports shall be designed so as to minimize the risk of the needle piercing the extracorporeal circuit completely and/or causing potential leakage.

Access ports shall not be located downstream of the intended location for any air detection device.

4.2.4 *Volume*

When tested in accordance with 5.3.4, the volume of the blood compartments of haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the volume of the extracorporeal circuit shall be within the range of values stated by the manufacturer (see 7.2.2).

4.2.5 *Pressure drops*

When tested in accordance with 5.3.5, the pressure drops across the blood compartments of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators and the dialysing fluid compartments of haemodialysers and haemodiafilters shall be within the range of values stated by the manufacturer (see 7.2.7).

4.3 Performance characteristics

4.3.1 *Clearance of haemodialysers and haemodiafilters*

When measured in accordance with 5.4.1, the clearance rates of urea, creatinine, phosphate, cyanocobalamin and, for haemodiafilters, inulin shall be within the range of values stated by the manufacturer (see 7.2.6a)).

4.3.2 *Sieving coefficient for haemodiafilters, haemofilters and haemoconcentrators*

When measured in accordance with 5.4.2, the sieving coefficients for albumin, inulin, myoglobin and cyanocobalamin shall be within the range of values stated by the manufacturer (see 7.2.6).

4.3.3 *Ultrafiltration rate*

When measured in accordance with 5.4.3, the ultrafiltration rate shall be within the range of values stated by the manufacturer (see 7.2.6).