SLOVENSKI STANDARD
SIST HD 395.2.16 S1:1998

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Medical electrical equipment - Part 2: Particular requirements for the safety of haemodialysis equipment (IEC 60601-2-16:1989)

Medical electrical equipment -- Part 2: Particular requirements for the safety of haemodialysis equipment

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von Hämodialysegeräte

Appareils électromédicaux -- Partie 2: Règles particulières relative à la sécurité de l'équipement d'hémodialyse

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MEDICAL ELECTRICAL EQUIPMENT
PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF HAEMODIALYSIS EQUIPMENT

Appareils électromédicaux
Deuxième partie:
Règles particulières relatives
à la sécurité de l'équipement
d'hémodialyse

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen
für die Sicherheit von
Hämodialysegeräte

BODY OF THE HD

The Harmonization Document consists of:

- IEC 601-2-16 (1989) ed 1; IEC/SC 62D, not appended

This Harmonization Document was approved by CENELEC on 6 December 1988. -09- 1998

The English and French versions of this Harmonization Document are provided by the text of the IEC publication and the German version is the official translation of the IEC text.

According to the CENELEC Internal Regulations the CENELEC member National Committees are bound:

to announce the existence of this Harmonization Document at national level **by or before 1989-07-01**

to publish their new harmonized national standard **by or before 1990-01-01**

to withdraw all conflicting national standards **by or before 1992-01-01.**

Harmonized national standards are listed on the HD information sheet, which is available from the CENELEC National Committees or from the CENELEC Central Secretariat.

The CENELEC National Committees are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
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Première édition
First edition
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Appareils électromédicaux

Deuxième partie:
Règles particulières relatives à la sécurité de l'équipment d'hémodialyse

Medical electrical equipment

Part 2:
Particular requirements for safety of haemodialysis equipment

Numéro de référence
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CEI/IEC: 601-2-16: 1989

CONTENTS

Clause Page

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for safety of haemodialysis equipment

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This standard has been prepared by Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

The text of this standard is based upon the following documents:

Six Months' Rule	Report on Voting
62D(CO)34	62D(CO)39

Full information on the voting for the approval of this standard can be found in the Voting Reports, indicated in the above table.

The following IEC publications are quoted in this standard:

Publications Nos. 513 (1976): Basic aspects of the safety philosophy of electrical equipment used in medical practice.
601-1 (1977): Safety of medical electrical equipment. Part 1: General requirements.
651 (1979): Sound level meters.

Addition:

2.1.22 *HAEMODIALYSER*

A device for the purpose of performing HAEMODIALYSIS, containing semi-permeable material alongside which extracorporeal blood and DIALYSING FLUID flow on opposite sides and usually in the opposite direction.

2.1.23 *DIALYSING FLUID*

A solution used as an exchange fluid during HAEMODIALYSIS.

2.1.24 *DIALYSING FLUID CONCENTRATE*

A solution of chemicals which, when appropriately diluted, produces DIALYSING FLUID.

2.1.25 *HAEMODIALYSIS*

Treatment utilizing a HAEMODIALYSER in which imbalances in a patient's blood are corrected by means of diffusion and/or ULTRAFILTRATION.

2.1.26 *HAEMODIALYSIS EQUIPMENT*

A system or combination of units used to perform HAEMODIALYSIS.

2.1.27 *VENOUS PRESSURE*

The pressure measured in the blood line between the outlet from the HAEMODIALYSER and the return to the PATIENT.

2.1.28 *BLOOD LEAK*

A leakage of blood within the HAEMODIALYSER from the blood compartment to the DIALYSING FLUID compartment.

2.1.29 *TRANSMEMBRANE PRESSURE*

Pressure calculated as a mean from the expression:

$$\frac{P_{b\,in} + P_{b\,out}}{2} - \frac{P_{d\,in} + P_{d\,out}}{2}$$

where:

$P_{b\,in}$ = pressure of blood on the inlet side of the HAEMODIALYSER
$P_{b\,out}$ = pressure of blood on the outlet side of the HAEMODIALYSER
$P_{d\,in}$ = pressure of DIALYSING FLUID on the inlet side of the HAEMODIALYSER
$P_{d\,out}$ = pressure of DIALYSING FLUID on the outlet side of the HAEMODIALYSER

2.1.30 *ULTRAFILTRATION*

The process of fluid removal from the extracorporeal circuit across the HAEMODIALYSER.

2.1.31 *ULTRAFILTRATE*

Fluid removed from the extracorporeal circuit by ULTRAFILTRATION.

2.1.32 *PROTECTIVE SYSTEM*

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

Clauses 3 to 5 of the General Standard apply.

3. General requirements

4. General requirements for tests

5. Classification

6. Identification, marking and documents

This clause of the General Standard applies except as follows:

6.8.1 *General*

Addition:

The ACCOMPANYING DOCUMENTS shall additionally include:

– a statement that USERS should ensure compliance with any local regulation in respect of back syphonage and the air clearance between the EQUIPMENT's waste connector and the drain.

6.8.2 *Instructions for use*

Addition:

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

– a statement that it is essential for this HAEMODIALYSIS EQUIPMENT to be installed and be used in compliance with appropriate recommendations on water quality for HAEMODIALYSIS use;

– a statement of the importance of the quality of the protective earth in the installation when CLASS I EQUIPMENT is used;

Note. — Attention is drawn to the existence in many countries of additional requirements of their national authorities.

– a statement of the applications in which a POTENTIAL EQUALIZATION CONDUCTOR should be used;

– a warning of the possibility of hazards arising from other equipment being connected to the HAEMODIALYSIS EQUIPMENT which may cause allowable EARTH LEAKAGE CURRENTS to be exceeded;

– the method(s) by which disinfection or sterilization is achieved;

- a statement that the test procedure by which the effectiveness of sterilization or disinfection has been verified is available on request;
- the range of inlet water pressures, DIALYSING FLUID concentrate supply pressure, temperature and flow rates necessary for operation of the HAEMODIALYSIS EQUIPMENT;
- the definition of TRANSMEMBRANE PRESSURE if the manufacturer makes use of one different from that stated in Sub-clause 2.1.29;
- the precautions necessary to prevent cross-infection between PATIENTS, caused by the blood pressure transducer.

6.8.3 *Technical description*

Addition:

e) The technical description shall additionally include the following:

- the particular measures or conditions to be observed when installing or bringing the HAEMODIALYSIS EQUIPMENT into use. These shall include guidance on the type and number of tests to be carried out. Particular guidance shall be given in respect of checking all alarms and safeguards and also the correct composition of the DIALYSING FLUID;
- a description of the methods of calibration of the control and indication of DIALYSING FLUID concentration;
- an explanation of the relationship between the DIALYSING FLUID concentration and the DIALYSING FLUID concentration alarm set points;
- for HAEMODIALYSIS EQUIPMENT that includes heparin infusion pumps: the range and accuracy of the infusion rates for such pumps and the pressures against which this accuracy is maintained;
- for HAEMODIALYSIS EQUIPMENT that includes integral blood pumps: the range and accuracy of the flow rates for such pumps and the inlet and outlet pressure range over which this accuracy is maintained;
- a specification for the extracorporeal circuit, HAEMODIALYSER and the conditions necessary to comply with the requirement of Sub-clause 49.5;
- the accuracy of the PROTECTIVE SYSTEM required by Sub-clause 51.5;
- the type and accuracy of the PROTECTIVE SYSTEM required by Sub-clause 51.6;
- the range and accuracy of any DIALYSING FLUID temperature measuring instrument;
- the method employed, range, accuracy and limitations for the PROTECTIVE SYSTEM required by Sub-clause 51.7;
- the range and accuracy of the alarm limits for the PROTECTIVE SYSTEM required by Sub-clause 51.7 and the conditions under which Sub-clause 51.1 of the General Standard applies;
- the accuracy of the PROTECTIVE SYSTEM required by Sub-clause 51.8;
- the method for the PROTECTIVE SYSTEM required by Sub-clause 51.8.2 and the sensitivity of the PROTECTIVE SYSTEM at the maximum specified DIALYSING FLUID flowrate;

- a statement on the possibility of a time delay occurring in the operation of the PROTECTIVE SYSTEM required by Sub-clause 51.8.2 under conditions of zero DIALYSING FLUID flow or during sequential dialysis and ULTRAFILTRATION (isolated ULTRAFILTRATION);
- the method employed for the PROTECTIVE SYSTEM and the conditions necessary to comply with the requirements of Sub-clause 51.9;
- the method of detection for any air detector and its sensitivity over the specified range of blood flow rates and the physical configuration of the gas detected;
- the override time(s) for any PROTECTIVE SYSTEM;
- the audible alarm silence period;
- a disclosure of all materials which come into contact with the treated water, DIALYSING FLUID and DIALYSING FLUID CONCENTRATE.

Compliance is checked by inspection.

7. **Power input**

This clause of the General Standard applies.

SECTION TWO — SAFETY REQUIREMENTS

Clauses 8 to 11 of the General Standard apply.

8. **Basic safety categories**

9. **Removable protective means**

10. **Special environmental conditions**

11. **Special measures with respect to safety**

12. SINGLE FAULT CONDITION

This clause of the General Standard applies except as follows:

Addition:

- failure of a PROTECTIVE SYSTEM (see Sub-clause 51.11).

The following is not regarded as a SINGLE FAULT CONDITION:

- air in the extracorporeal circuit.