

Medical electrical equipment —

Part 2: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment

The European Standard EN 60601-2-16:1998 has the status of a
British Standard

ICS 11.040.20

National foreword

This British Standard is the English language version of EN 60601-2-16:1998 including corrigendum December 1999. It is identical with IEC 60601-2-16:1998. It supersedes BS 5724-2-16:1989 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/23, Cardiovascular implants, dialysis systems and oxygenators, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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Summary of pages

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English version

Medical electrical equipment —
Part 2-16: Particular requirements for the safety of
haemodialysis, haemodiafiltration and
haemofiltration equipment

(IEC 60601-2-16:1998)

Appareils électromédicaux —
Partie 2-16: Règles particulières de sécurité pour les
appareils d'hémodialyse, d'hémodiafiltration et
d'hémofiltration
(CEI 60601-2-16:1998)

Medizinische elektrische Geräte —
Teil 2-16: Besondere Festlegungen für die Sicherheit
von Hämodialyse-, Hämodiafiltrations- und
Hämofiltrationsgeräte
(IEC 60601-2-16:1998)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC 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 CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC

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

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Foreword

The text of document 62D/254/FDIS, future edition 2 of IEC 60601-2-16, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-16 on 1998-04-01.

This European Standard supersedes HD 395.2.16 S1:1989.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1999-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-01-01

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Annex AA and Annex ZB are informative.

Annex ZA and Annex ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-16:1998 was approved by CENELEC as a European Standard without any modification.

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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 HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.

This particular standard does not take into consideration the specific safety aspects of systems using regeneration of DIALYSING FLUID.

This particular standard amends and supplements IEC 60601-1 (second edition, 1988): *Medical electrical equipment — Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and amendment 2 (1995), hereinafter referred to as the General Standard (see 1.3).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a “General guidance and rationale” section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

Section 1. General

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This particular standard specifies the minimum safety requirements for single PATIENT HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT (as defined in **2.101**). These devices are intended for use either by medical staff or under the supervision of medical expertise, including HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT operated by the PATIENT. These particular requirements do not apply to

- EXTRACORPOREAL CIRCUITS,
- DIALYSERS,
- DIALYSING FLUID CONCENTRATES,
- water purification EQUIPMENT,
- EQUIPMENT used to perform peritoneal dialysis (see IEC 60601-2-39).

1.3 Particular standards

Addition:

This particular standard refers to IEC 60601-1 (1988): *Medical electrical equipment — Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995).

For brevity IEC 60601-1 is referred to in this particular standard either as the “General Standard” or as the “General Requirement(s)”.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this particular standard.

“Addition” means that the clause or subclause of this particular standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa*), *bb*), etc.

The term “this standard” is used to make reference to the General Standard and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

1.5 Collateral standards

IEC 60601-1-2 applies (see clause **36**).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5

APPLIED PART

Replacement:

the EXTRACORPOREAL CIRCUIT and the DIALYSING FLUID circuit and/or all parts permanently and conductively connected to it

2.2.15

MEDICAL ELECTRICAL EQUIPMENT (hereinafter referred to as EQUIPMENT)

Addition:

under the scope of this particular standard EQUIPMENT means HAEMODIALYSIS, HAEMO-DIAFILTRATION and/or HAEMOFILTRATION EQUIPMENT

Additional definitions:

2.101

HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION EQUIPMENT

a system or combination of units used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION (also refer to **2.2.15**)

2.102

HAEMODIALYSIS (HD)

process whereby solute imbalances in a PATIENT'S blood are corrected mainly by diffusion across a semi-permeable membrane

NOTE This process normally includes fluid removal.

2.103

HAEMOFILTRATION (HF)

a process whereby solute imbalances of a PATIENT'S blood are corrected mainly by filtration across a semi-permeable membrane

NOTE This process includes fluid exchange and normally fluid removal.

2.104

HAEMODIAFILTRATION (HDF)

a process whereby solute imbalances in a PATIENT'S blood are corrected by means of simultaneous filtration and diffusion across a semi-permeable membrane

NOTE This process includes fluid exchange and normally fluid removal.

2.105

BUFFER-FREE HAEMODIAFILTRATION

a specific form of HDF where the buffer is not given to the PATIENT with the DIALYSING FLUID, but with the SUBSTITUTION FLUID

2.106

DIALYSER

for the purpose of this particular standard, the term DIALYSER is used to describe any device containing a semi-permeable membrane that is used to perform HD/HDF/HF

2.107

DIALYSING FLUID

a solution which is intended to exchange solutes and/or water with blood during HD/HDF

NOTE The words "dialysate" and "dialysis fluid" are commonly used as synonyms of DIALYSING FLUID.

2.108

DIALYSING FLUID CONCENTRATE

a solution of chemicals which, when appropriately diluted, produces the DIALYSING FLUID

2.109**SUBSTITUTION FLUID**

a fluid which during HF or HDF is administered to the PATIENT via the EXTRACORPOREAL CIRCUIT

2.110**ULTRAFILTRATION**

the process of fluid removal from the PATIENT'S blood across the DIALYSER

2.111**EXTRACORPOREAL CIRCUIT**

blood lines and any integral ACCESSORY thereof

2.112**TRANSMEMBRANE PRESSURE (TMP)**

hydrostatic PRESSURE exerted across a semi-permeable membrane

NOTE For practical reasons the mean TMP is generally expressed as either

- a) the difference between the arithmetic mean of inlet and outlet PRESSURES of the blood and DIALYSING FLUID compartments of a DIALYSER, 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.

2.113**BLOOD LEAK**

a leakage of blood from the blood compartment to the DIALYSING FLUID compartment of the DIALYSER due to a rupture of the semi-permeable membrane

2.114**ARTERIAL PRESSURE**

the PRESSURE measured in the EXTRACORPOREAL CIRCUIT between the PATIENT and the arterial blood pump

2.115**VENOUS PRESSURE**

the PRESSURE measured in the EXTRACORPOREAL CIRCUIT between the outlet from the DIALYSER and the return to the PATIENT

2.116**VENOUS PART**

part of the EXTRACORPOREAL CIRCUIT between the outlet of the DIALYSER and the PATIENT

2.117**PROTECTIVE SYSTEM**

an automatic system which senses a specified parameter (or parameters), or a constructional feature, specifically designed to protect the PATIENT against SAFETY HAZARDS which may arise

3 General requirements

This clause of the General Standard applies except as follows:

3.6

Addition:

- j) Failure of a PROTECTIVE SYSTEM (see **51.101**);
- k) The following is not regarded as a SINGLE FAULT CONDITION:
Air in the EXTRACORPOREAL CIRCUIT.

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 pointing out the importance of compliance with any local regulation in respect of separation of devices in the water supply, back syphonage and the air clearance between the EQUIPMENT waste connector and the drain.

6.8.2 Instructions for use

Addition:

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

- 1) a statement that it is essential for the EQUIPMENT to be installed and used in compliance with appropriate regulations/recommendations on quality of water and other relevant fluids;
- 2) a statement of the importance of the quality of the protective earth in the installation when CLASS I EQUIPMENT is used;
- 3) a statement of the applications in which a POTENTIAL EQUALIZATION CONDUCTOR should be used;
- 4) a description of the method(s) by which disinfection or sterilization is achieved;
- 5) a statement that the test procedure by which the effectiveness of disinfection or sterilization has been verified is available on request;
- 6) a description of the range of inlet water PRESSURES, DIALYSING FLUID CONCENTRATE supply PRESSURES, temperatures and flows necessary for operation of the EQUIPMENT;
- 7) a definition of TRANSMEMBRANE PRESSURE if the manufacturer makes use of one different from that stated in **2.112**;
- 8) *a statement which draws the OPERATOR'S attention to the precautions necessary to prevent cross-infection between PATIENTS;
- 9) a statement which draws the OPERATOR'S attention to the SAFETY HAZARDS associated with connection and disconnection of the PATIENT;
- 10) a statement which draws the OPERATOR'S attention to the potential SAFETY HAZARDS arising from improper connections of the EXTRACORPOREAL CIRCUIT;
- 11) information on possible deviations from the intended ULTRAFILTRATION rate because of single needle specific parameters as, e.g. phase sensitive PRESSURE variations;
- 12) information on the delivered blood volume per time unit related to the pre-setting of the EQUIPMENT for single needle treatments;
- 13) a statement that comments are available on request, concerning the expected recirculation of the blood flow in the EXTRACORPOREAL CIRCUIT in single needle treatments, if the recommended administration sets, DIALYSERS, fistula needles and catheters are used;
- 14) information on DIALYSING FLUID CONCENTRATES intended to be used together with the EQUIPMENT;
- 15) a statement on the SAFETY HAZARDS related to incorrect choice of DIALYSING FLUID CONCENTRATE(S);

- 16) an explanation of the coloured markings on the concentrate connectors;
- 17) statements on the potential SAFETY HAZARDS related to reverse ULTRAFILTRATION;
- 18) a statement, about the limited sensitivity of a PROTECTIVE SYSTEM employed according to **51.104**;
- 19) an explanation of the adequate OPERATOR action upon an alarm from any PROTECTIVE SYSTEM;
- 20) a statement pointing out that, in override mode, the OPERATOR is responsible for monitoring those parameters of any PROTECTIVE SYSTEM which are being overridden;
- 21) a statement on the possible SAFETY HAZARDS associated with external radio or electromagnetic disturbance which may affect the safe operation of the EQUIPMENT.

6.8.3 Technical description

Addition:

aa) The technical description shall, additionally include, the following:

- 1) the particular measures or conditions to be observed when installing the EQUIPMENT or bringing it into use. These shall include guidance on the type and number of tests to be carried out;
- 2) for EQUIPMENT that includes integral anti-coagulant pump(s): the type of the pump(s), the range and the accuracy of the flow for such pump(s) and the PRESSURES against which this accuracy is maintained;
- 3) for EQUIPMENT that includes integral blood pump(s): the range and accuracy of the flows for such pump(s) and the inlet and outlet PRESSURE range over which this accuracy is maintained;
- 4) *the type, accuracy and limitations of the PROTECTIVE SYSTEM(S) required by **51.101**;
- 5) the type and accuracy of the PROTECTIVE SYSTEM required by **51.102**;
- 6) the method employed, range, accuracy and limitations for the PROTECTIVE SYSTEM required by **51.103**;
- 7) the type and accuracy of the PROTECTIVE SYSTEM required by **51.104.1**;
- 8) the method for the PROTECTIVE SYSTEM required by **51.104.2** and the sensitivity of the PROTECTIVE SYSTEM at the minimum and maximum specified DIALYSING FLUID flow;
- 9) the type of the PROTECTIVE SYSTEM required by **51.104.3**;
- 10) the type and the accuracy of the PROTECTIVE SYSTEM required by **51.105**;
- 11) the method employed and the sensitivity under test conditions specified by the manufacturer for the PROTECTIVE SYSTEM required by **51.106**;
- 12) the type of the PROTECTIVE SYSTEM required by **51.111**;
- 13) the override time(s) for any PROTECTIVE SYSTEM;
- 14) the audible alarm silence period;
- 15) the range of sound PRESSURE levels of any adjustable audible alarm source;
- 16) *a disclosure of all materials intended to come into contact with the water, DIALYSING FLUID and DIALYSING FLUID CONCENTRATE.

Compliance is checked by inspection.

