INTERNATIONAL STANDARD

IEC 60601-2-16

Second edition
1998-02

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-16: Règles particulières de sécurité pour les appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
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5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-16 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/254/FDIS	62D/271/RVD

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

Annex AA is for information only.

In this standard, the following print types are used:

– requirements, compliance with which can be tested and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: smaller type;
– *test specifications: italic type*;
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 60601-1: SMALL CAPITALS.

A bilingual version of this standard may be issued at a later date.

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.

MEDICAL ELECTRICAL EQUIPMENT –

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

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, HAEMODIAFILTRATION 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;