
British Standard

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.16 Specification for haemodialysis equipment

Appareils électromédicaux

Partie 2. Règles particulières de sécurité

Section 2.16 Equipement d'hémodialyse – Spécifications

Elektromedizinische Geräte

Teil 2. Besondere Sicherheitsanforderungen

Abschnitt 2.16 Hämodialysegeräte

National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with IEC Publication 601-2-16 'Medical electrical equipment' Part 2 'Particular requirements for safety of haemodialysis equipment', published in 1989 by the International Electrotechnical Commission (IEC). This Particular Standard amends and supplements BS 5724 : Part 1 hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of this Particular Standard take precedence over those of the General Standard.

As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc., and additional items are lettered aa, bb), etc. The changes from the text of the General Standard are specified by the use of the following words.

'Replacement' means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.

'Amendment' means that the clause, subclause or specified paragraph of the General Standard is amended as indicated by the text of this standard.

'Addition' means that the text of this standard is additional to the requirements of the General Standard.

A rationale for the most important requirements is given in appendix AA. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. This appendix does not form part of the standard.

Cross-references

International standard	Corresponding British Standard
IEC 601-1 : 1977* (as amended by Amendment No. 1 (1984))	BS 5724 Medical electrical equipment Part 1 : 1979 Specification for general safety requirements (Technically equivalent)
IEC 651 : 1979	BS 5969 : 1981 Specification for sound level meters (Identical)
ISO 594-1 : 1986	BS 3930 Conical fittings with a 6 % (Luer) taper for syringes, needles and other medical equipment Part 1 : 1987 Specification for general requirements (Identical)

The technical committee has reviewed the provisions of IEC 513 : 1976, to which reference is made in Appendix AA, and has decided that they are acceptable for use in conjunction with this standard. The reference to IEC 513 : 1976 is included for information only and does not affect the technical content of this standard.

ISO 594-2, to which reference is made in clause 56, is still in preparation at the time of publication of this British Standard. The technical committee has reviewed the provisions of ISO/DIS 594-2 and has decided that, in the meantime, they are acceptable for use in conjunction with this standard.

Additional information. The following print types are used.

Requirements, compliance with which can be tested, and definitions: in roman type.

Explanations, advice and general statements: in small roman type.

Terms defined in clause 2 of the General Standard and this Particular Standard: SMALL CAPITALS.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

* The 1977 edition of IEC 601-1 has been superseded by IEC 601-1988 and the corresponding British Standard for this revision is BS 5724 : Part 1 : 1989.



AMD 6504

Amendment No. 1
published and effective from 21 December 1990
to BS 5724 : Section 2.16 : 1989

Medical electrical equipment
Part 2. Particular requirements for safety
Section 2.16 Specification for haemodialysis
equipment

Correction

AMD 6504
December 1990

National foreword

Delete the footnote and substitute the following.

‘*Although a second edition of IEC 601-1 was published before IEC 601-2-16, all references to the General Standard in this Section of BS 5724 are to the implementation of the first edition, i.e. to BS 5724 : Part 1 : 1979.’

9012

HCC/23

Amendment No. 2
published and effective from 29 November 1991
to BS 5724 : Section 2.16 : 1989

Medical electrical equipment
Part 2. Particular requirements for safety
Section 2.16 Specification for haemodialysis
equipment

NOTE. This amendment implements CENELEC HD 395.2.16 S1.

Revised text

AMD 6783
November 1991

Front cover

Immediately below the title of Section 2.16 insert the following.
'(Implementation of CENELEC HD 395.2.16 S1)'

AMD 6783
November 1991

National foreword

In paragraph 1, after sentence 2, insert the following.

This Particular Standard also implements Harmonization Document HD 395.2.16 S1 which was published by the European Committee for Electrotechnical Standardization (CENELEC) and approved by the CENELEC Technical Board on 5 December 1988.'

At the end of paragraph 1 insert the following.

'There are no CENELEC modifications in HD 395.2.16 S1.'

CONTENTS

	Page
National foreword	Inside front cover
Committees responsible	Back cover
INTRODUCTION	3

Clause

SECTION ONE — GENERAL

1. Scope and object	3
2. Terminology and definitions	3
6. Identification, marking and documents	5

SECTION TWO — SAFETY REQUIREMENTS

12. SINGLE FAULT CONDITION	7
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SECTION THREE — PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	8
20. Dielectric strength	8

SECTION FOUR — PROTECTION AGAINST MECHANICAL HAZARDS

SECTION FIVE — PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

SECTION SIX — PROTECTION AGAINST THE HAZARDS OF EXPLOSIONS IN MEDICALLY USED ROOMS

SECTION SEVEN — PROTECTION AGAINST EXCESSIVE TEMPERATURES, FIRE AND SAFETY HAZARDS, SUCH AS HUMAN ERRORS

44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	10
45. Pressure vessels and parts subject to pressure	12
46. Human errors	12
49. Interruption of the POWER SUPPLY	12

SECTION EIGHT — ACCURACY OF OPERATING DATA AND PROTECTION AGAINST INCORRECT OUTPUT

50. Accuracy of operating data	13
51. Protection against incorrect output	13

Clause	Page
SECTION NINE — FAULT CONDITIONS CAUSING OVERHEATING AND/OR FUNCTIONAL DAMAGE; ENVIRONMENTAL TESTS	
SECTION TEN — CONSTRUCTIONAL REQUIREMENTS	
56. Components and general assembly	19
57. MAINS PARTS, components and layout	19
APPENDIX AA — Rationale for the particular requirements of this standard	21

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for safety of haemodialysis equipment

INTRODUCTION

The minimum safety and performance requirements specified in this standard are considered to provide for a practical degree of safety in the operation of HAEMODIALYSIS EQUIPMENT.

This Particular Standard amends the General Standard for the safety of MEDICAL EQUIPMENT. 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 sub-clauses 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:

1.1 Scope

Addition:

This Particular Standard specifies the safety requirements for single PATIENT single pass HAEMODIALYSIS EQUIPMENT as defined in Sub-clause 2.1.26. These devices are intended for use either by medical staff or under the supervision of medical expertise, including HAEMODIALYSIS EQUIPMENT operated by the PATIENT. These Particular Requirements do not apply to blood lines, HAEMODIALYSERS, DIALYSING FLUID CONCENTRATE or water purification EQUIPMENT.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

Replacement:

2.1.5 APPLIED PART

The DIALYSING FLUID circuit and all parts permanently and conductively connected to it.

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:

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

where:

$P_{b \text{ in}}$ = pressure of blood on the inlet side of the HAEMODIALYSER

$P_{b \text{ out}}$ = pressure of blood on the outlet side of the HAEMODIALYSER

$P_{d \text{ in}}$ = pressure of DIALYSING FLUID on the inlet side of the HAEMODIALYSER

$P_{d \text{ out}}$ = 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;