

BS 5724 :
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1988

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.12 Specification for lung ventilators

Appareils électromédicaux
Partie 2. Règles particulières de sécurité
Section 2.12 Ventilateurs pulmonaires

Elektromedizinische Geräte
Teil 2. Besondere Sicherheitsanforderungen
Abschnitt 2.12 Beatmungsgeräte

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/46, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health Care Industries
Association of Veterinary Anaesthetists of Great Britain and Ireland
British Anaesthetic and Respiratory Equipment Manufacturers' Association
British Paediatric Association
Department of Health
Electro Medical Trade Association Limited
Industrial Safety (Protective Equipment) Manufacturers' Association
Intensive Care Society
Medical Sterile Products Association

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 31 July 1990

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The following BSI references relate to the work on this standard:
Committee reference HCC/46
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Amendments issued since publication

Amd. No.	Date	Text affected

Amendment No. 1
published and effective from 15 January 1993
to BS 5724 : Section 2.12 : 1990

Medical electrical equipment
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NOTE. This amendment implements CENELEC HD 395.2.12 S1.

Revised text

MD 7446
January 1993

Front cover

Immediately below the title of Section 2.12 insert the following.
'(Implementation of CENELEC HD 395.2.12 S1)'

MD 7446
January 1993

National foreword

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

'This Particular Standard also implements Harmonization Document HD 395.2.12 S1 which was published by the European Committee for Electrotechnical Standardization (CENELEC) and approved by the CENELEC Technical Board on 6 December 1988.'

At the end of paragraph 1 insert the following.

'There are no CENELEC modifications in HD 395.2.12 S1.'

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is identical with IEC Publication 601-2-12 : 1988 'Medical electrical equipment' Part 2 'Particular requirements for the safety of lung ventilators for medical use', prepared by Technical Committee 62, Electrical equipment in medical practice, of the International Electrotechnical Commission (IEC). This Particular Standard amends and supplements BS 5724 : Part 1 : 1979, 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 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.

BS 5724 : Part 1 : 1979 has now been revised and this Particular Standard will be revised in due course to refer to the new edition, BS 5724 : Part 1 : 1989. BS 5724 : Part 1 : 1979 is expected to remain in effect until at least 1991.

Additional information. The following print types are used in this standard.

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

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

Text procedures: in italic type

Terms defined in clause 2 of the General Standard, in BS 6015 and this Particular Standard: SMALL CAPITALS

Cross-references

International standard	Corresponding British Standard
IEC 601-1 : 1977	BS 5724 Medical electrical equipment Part 1 : 1979 Specification for general safety requirements (Technically equivalent)
IEC 601-2-13 : 1989	BS 5724 Medical electrical equipment Section 2.13 : 1990 Specification for anaesthetic machines (Identical)

ISO 4135 : 1979

BS 6015 : 1980 Glossary of terms used in anaesthesiology
(Identical)

The Technical Committee has reviewed the provisions of ISO 5369 : 1987 and IEC 65 : 1985, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

NOTE. *Textual errors.* When adopting the text of the international standard, the textual errors given below were discovered. They have been marked in the text and have been reported to the IEC Central Office in a proposal to amend the text of the International Standard.

In clause 1.1, line 3, for '1977' read '1987'. In clause 57.2 aa), paragraph 2, line 1, for 'ANAESTHETIC MACHINE' read 'LUNG VENTILATOR'.

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