

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.18 Specification for endoscopic equipment

The European Standard EN 60601-2-18:1996, with the incorporation of amendment A1:2000, has the status of a British Standard

ICS 11.040.50

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/3, Endoscopic equipment, upon which the following bodies were represented.

- Association of Anaesthetists of Great Britain and Ireland
- British Institute of Surgical Technologists
- British Surgical Trades Association
- Department of Health
- Institute of Physics and Engineering in Medicine and Biology

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 April 1997

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National foreword

This British Standard has been prepared by Technical Committee CH/3 and is the English language version of EN 60601-2-18:1996 *Medical electrical equipment Part 2: Particular requirements for the safety of endoscopic equipment*, including amendment A1:2000, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 60601-2-18:1996, including amendment A1:2000, published by the International Electrotechnical Commission (IEC).

It supersedes BS 4824:1972 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags **A1** **A1**. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1**.

This particular standard amends and supplements BS 5724-1:1989 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, sub-clauses 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, sub-clause or specified paragraph of the General Standard is replaced by the text of this standard.

“Amendment” means that the clause, sub-clause 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.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

Textual errors. When adopting the text of the international standard, the textual errors listed below were discovered. They have been marked in the text and have been reported to IEC in a proposal to amend the text of the international standard.

In **6.1 aa)**, line 3, the text “those preferred symbols which shall be used” should be read as “those preferred symbols which may be used”.

Additional information. The following print types are used in this standard.
Requirements, with which compliance can be tested, and definitions: in roman type.

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

Test procedures: in *italic* type.

Terms defined in clause 2 of BS 5724-1 or in BS 6641: in SMALL CAPITALS.

For the purpose of this British Standard, any references to IEC page numbers in the text should be ignored.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 21 and a back cover.

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Descriptors: Medical electrical equipment, endoscopy, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

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

(includes amendment A1:2000)
(IEC 60601-2-18:1996 + A1:2000)

Appareils électromédicaux
Partie 2: Règles particulières de
sécurité pour appareils d'endoscopie
(inclut l'amendement A1:2000)
(CEI 60601-2-18:1996 + A1:2000)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von endoskopischen Geräten
(enthält Änderung A1:2000)
(IEC 60601-2-18:1996 + A1:2000)

This European Standard was approved by CENELEC on 1996-07-02.
Amendment A1 was approved by CEN on 2000-08-01.

CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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.

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

CENELEC

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

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Ref. No. EN 60601-2-18:1996 + A1:2000 E

Foreword

The text of document 62D/191/FDIS, future edition 2 of IEC 601-2-18, 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 60601-2-18 on 1996-07-02.

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) 1997-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-05-01

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 is informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-2-18:1996 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A1

The text of document 62D/360/FDIS, future amendment 1 of IEC 60601-2-18:1996, 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 amendment A1 to EN 60601-2-18:1996 on 2000-08-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2001-06-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2003-08-01

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.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of amendment 1:2000 to the International Standard IEC 60601-2-18:1996 was approved by CENELEC as an amendment to the European Standard without any modification.

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