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1992**

Medical electrical equipment

Part 2. Particular requirements for safety

Section 2.122 Specification for diagnostic and therapeutic laser equipment

The European Standard EN 60601-2-22 : 1992 has the status of a
British Standard

Appareils électromédicaux
Partie 2. Conditions particulières de sécurité
Section 2.122 Spécification pour les appareils
thérapeutiques et de diagnostic à laser

Elektromedizinische Geräte
Teil 2. Besondere Anforderungen an die
Sicherheit
Abschnitt 2.122 Spezifikation für
diagnostischen und therapeutischen
Lasergeräten

UDC 615.849.19 : 621.3 : 620.1 : 614.8

Cooperating organizations

The European Committee for Electrotechnical Standardization (CENELEC), under whose supervision this European Standard was prepared, comprises the national committees of the following countries:

Austria	Italy
Belgium	Luxembourg
Denmark	Netherlands
Finland	Norway
France	Portugal
Germany	Spain
Greece	Sweden
Iceland	Switzerland
Ireland	United Kingdom

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 January 1993

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee. It is the English language version of EN 60601-2-22 : 1992 *Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-22 : 1992 published by the International Electrotechnical Commission (IEC).

This Particular Standard amends and supplements BS 5724 : Part 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, 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 more 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.

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 and general statements: in small roman type.

Test procedures: *in italic type*.

Terms defined in clause 2 of the General standard: in SMALL CAPITALS.

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

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Descriptors: Electromedical equipment, laser product, diagnosis, safety requirements, equipment specifications, equipment protection, tests

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of
diagnostic and therapeutic laser equipment

(IEC 601-2-22 : 1992)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité
pour les appareils thérapeutiques et de
diagnostic à laser
(CEI 601-2-22 : 1992)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von diagnostischen und
therapeutischen Lasergeräten
(IEC 601-2-22 : 1992)

This European Standard was approved by CENELEC on 1992-03-24. 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

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of document 76/62D(CO)21/65, as prepared by IEC Technical Committee N° 76: Laser equipment, in close cooperation with Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee N° 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in June 1991.

The reference document was approved by CENELEC as EN 60601-2-22 on 24 March 1992.

The following dates were fixed:

- latest date of publication (dop) 1993-05-01
of an identical national
standard
- latest date of withdrawal (dow) 1993-05-01
of conflicting national
standards

For products which have complied with the relevant national standard before 1993-05-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1998-05-01.

Annexes designated 'normative' are part of the body of the standard. In this standard, annex ZA is normative.

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MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment

SECTION ONE - GENERAL

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular International Standard applies to LASER EQUIPMENT FOR MEDICAL APPLICATION, as defined in 2.1.112, classified as a CLASS 3B or CLASS 4 LASER PRODUCT according to 3.12 and 3.13 in IEC 825, hereinafter referred to as LASER EQUIPMENT.

NOTE - LASER EQUIPMENT for medical application classified as a CLASS 1, 2, or CLASS 3A LASER PRODUCT, is covered by IEC 601-1 and IEC 825.

1.2 Object

The object of this Particular International Standard is to specify particular requirements for the safety of LASER EQUIPMENT classified as a CLASS 3B or CLASS 4 LASER PRODUCT.

1.3 Particular Standards

1.3.101 Relation to the General Standard

This Particular Standard amends and supplements IEC 601-1, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard.

Where there is no corresponding clause or subclause in this Particular Standard, the clause or subclause of the General Standard applies.

Concerning LASER RADIATION safety of LASER EQUIPMENT, IEC 825 applies, except that the relevant requirements are specified, changed or amended in this Particular Standard.

Clauses and subclauses of the General Standard and of IEC 825 which are not applicable to LASER EQUIPMENT FOR MEDICAL APPLICATION are not necessarily indicated as "not applicable".