

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.122 Specification for diagnostic and therapeutic laser equipment

The European Standard EN 60601-2-22:1996 has the status of a
British Standard

ICS 11.040.50; 11.040.60

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee EPL/76, Optical radiation safety and laser equipment, upon which the following bodies were represented:

- Association of University Radiation Protection Officers
- BLWA Ltd. (The Association of the Laboratory Supply Industry)
- British Medical Laser Association
- British Railways Board
- British Telecommunications plc
- Department of Health
- DTI (Consumer Safety Unit, CA Division)
- Engineering Equipment and Materials Users' Association
- Federation of the Electronics Industry
- Health and Safety Executive
- Institute of Physics
- Institution of Electrical Engineers
- Machine Tool Technologies Association
- Ministry of Defence
- National Radiological Protection Board
- Royal College of Ophthalmologists
- Royal Institute of Chartered Surveyors
- SIRA Ltd.
- Trades Union Congress
- UK Laser and Electro-optic Association
- UK Optical Sensors Collaborative Association

This British Standard, having been prepared under the direction of the Electrotechnical Sector Board, was published under the authority of the Standards Board and comes into effect on 15 July 1996

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National foreword

This British Standard has been prepared by Technical Committee EPL/76 and is the English language version of EN 60601-2-22:1996 *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 601-2-22:1995 published by the International Electrotechnical Commission (IEC).

BS EN 60601-2-22:1996 supersedes BS EN 60601-2-22:1993 which is withdrawn. 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, 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 annex 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.

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.

Cross-references

Publication referred to	Corresponding British Standard
EN 60601-1:1990 (IEC 601-1:1988)	BS 5724: <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i>
EN 60601-1-1:1993 (IEC 601-1-1:1992)	BS EN 60601 <i>Medical electrical equipment</i> BS EN 60601-1 <i>General requirements for safety</i> BS EN 60601-1-1:1993 <i>Collateral standard. Safety requirements for medical electrical systems</i>
EN 60601-1-2:1993 (IEC 601-1-2:1993)	BS EN 60601-1-2:1993 <i>Collateral standard. Electromagnetic compatibility. Requirements and tests</i>
EN 60825-1:1994 (IEC 825-1:1993)	BS EN 60825 <i>Safety of laser products</i> Part 1:1994 <i>Equipment classification, requirements and user’s guide</i>

EN 60947-3:1992
(IEC 947-3:1990)

BS EN 60947 *Specification for low-voltage switchgear
and controlgear*

BS EN 60947-3:1992 *Switches, disconnectors,
switch-disconnectors and fuse-combination units*

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their 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 16, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

ICS 11.040.50; 11.040.60

Descriptors: Medical electrical equipment, diagnostic and therapeutic laser equipment, 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 diagnostic and therapeutic laser equipment

(IEC 601-2-22:1995)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour
les appareils thérapeutiques et de diagnostic à
laser
(CEI 601-2-22:1995)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von diagnostischen und
Lasengeräten
(IEC 601-2-22:1995)

This European Standard was approved by CENELEC on 1995-11-28. 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.

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CENELEC

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

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

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Foreword

The text of document 76/104/DIS, future edition 2 of IEC 601-2-22, prepared by IEC TC 76, Laser equipment, was submitted to the IEC-/CENELEC parallel vote and was approved by CENELEC as EN 60601-2-22 on 1995-11-28.

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) 1996-09-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-09-01

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, annexes D and ZA are normative and annex AA is informative.

Annex ZA has been added by CENELEC

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