SLOVENSKI STANDARD
SIST EN 60601-2-22:1995

01-maj-1995

Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment (IEC 601 2 22:1992)

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

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von diagnostischen und therapeutischen Lasergeräten

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité pour les appareils thérapeutiques et de diagnostic à laser

Ta slovenski standard je istoveten z: **EN 60601-2-22:1992**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-22:1995 **en**

EUROPEAN STANDARD

NORME EUROPEENNE

EUROPÄISCHE NORM

EN 60601-2-22

September 1992

UDC 615.849.19:621.373.826:614.8

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

Ref. No. EN 60601-2-22:1992 E

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 of an identical national standard (dop) 1993-05-01

- latest date of withdrawal of conflicting national standards (dow) 1993-05-01

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.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-2-22:1992 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC Publication	Date	Title	EN/HD	Date
601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
664	1980	Insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment	-	-
825 + A1 (mod)	1984 1990	Radiation safety of laser products, equipment classification, requirements and user's guide	EN 60825	1991

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-2-22

Première édition
First edition
1992-05

Appareils électromédicaux

Partie 2:
Règles particulières de sécurité pour les appareils thérapeutiques et de diagnostic à laser

Medical electrical equipment

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

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

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

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

This Particular International Standard has been prepared by IEC Technical Committee No. 76: Laser equipment, in close cooperation with Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

DIS	Report on Voting
76/62D(CO)21/65	76/62D(CO)24/70

Full information on the voting for the approval of this standard can be found in the Voting Report indicated in the above table.

In this standard, the following print types are used:

- requirements and definitions: in roman type;
- NOTES: in smaller roman type;
- *compliance: in italic type;*
- TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AS WELL AS THOSE DEFINED IN IEC 601-1 AND IEC 825: SMALL ROMAN CAPITALS.

INTRODUCTION

This Particular International Standard amends and supplements IEC 601-1 (second edition, 1988): Medical Electrical Equipment - Part 1: General requirements for safety, hereinafter referred to as the General Standard.

As stated in 1.3 of the General Standard, a requirement of this Particular Standard takes priority over the corresponding requirement of the General Standard.

Clauses or subclauses which are supplementary to the General Standard are numbered 101 and beyond.

This standard also refers to IEC 825 (1984) including its Amendment 1 (1990).

The requirements of this Standard have to be taken as the minimum to comply with, in order to achieve a reasonable level of safety and reliability during operation and application of medical laser equipment.