SLOVENSKI STANDARD
SIST EN 60601-2-22:2001

01-julij-2001

Nadomešča:

SIST EN 60601-2-22:1995

Medicinska električna oprema - 2. del: Posebne varnostne zahteve za lasersko diagnostično in terapevtsko opremo (IEC 60601-2-22:1995)

Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment (IEC 60601-2-22:1995)

Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von diagnostischen und therapeutischen Lasergeräten (IEC 60601-2-22:1995)

Appareils électromédicaux - Partie 2: Règles particulières de sécurité pour les appareils thérapeutiques et de diagnostic à laser (CEI 60601-2-22:1995)

Ta slovenski standard je istoveten z: EN 60601-2-22:1996

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-22:2001 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-22

January 1996

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 therapeutischen Lasergeräten
(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.

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 76/104/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.

Endorsement notice

The text of the International Standard IEC 601-2-22:1995 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

Addition:

Publication	Year	Title	EN/HD	Year
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2[1)] A12 + corr. July	1995 1993 1994
IEC 601-1-1	1992	1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
IEC 601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 664-1	1992	Insulation coordination for equipment within low-voltage systems Part 1: Principles, requirements and tests	-	-
IEC 664-3	1992	Part 3: Use of coatings to achieve insulation coordination of printed board assemblies	-	-
IEC 825-1	1993	Safety of laser products Part 1: Equipment classification, requirements and user's guide	EN 60825-1 + corr. February	1994 1995
IEC 947-3 (mod)	1990	Low-voltage switchgear and controlgear Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	EN 60947-3[2)] + corr. March	1992 1993

1) A2 to EN 60601-1 includes corrigendum June 1995.

2) EN 60947-3 includes corrigendum December 1991.

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-2-22

Deuxième édition
Second edition
1995-11

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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CONTENTS

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organization liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) 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.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

International Standard IEC 601-2-22 has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment, in close cooperation with sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1992 and constitutes a technical revision.

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

DIS	Report on voting
76/104/DIS	76/121/RVD

Full information on the voting for the approval of this Particular Standard can be found in the report on voting indicated in the above table.

Annex AA is for information only.

In this Particular 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 PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AS WELL AS THOSE DEFINED IN IEC 601-1 AND IEC 825-1: SMALL CAPITALS

INTRODUCTION

This Particular Standard amends and supplements IEC 601-1 (second edition, 1988): *Medical Electrical Equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995), and its Collateral Standards IEC 601-1-1 and IEC 601-1-2 (see 1.3).

This Standard also refers to IEC 825-1 (1993).

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.

Clauses or subclauses for which there are explanatory notes in annex AA: Rationale are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as result of developments in technology. However, this annex does not form part of the requirements of this Standard.

MEDICAL ELECTRICAL EQUIPMENT

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

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

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 APPLICATIONS, as defined in 2.1.111 classified as a CLASS 3B or CLASS 4 LASER PRODUCT according to 3.17 and 3.18 in IEC 825-1, hereinafter referred to as LASER EQUIPMENT.

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

1.2 *Object*

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

1.3 *Particular Standards*

Addition:

This Particular Standard refers to IEC 601-1, as amended by its amendment 1 (1991) and its amendment 2; it also refers to its Collateral Standards IEC 601-1-1 and IEC 601-1-2.

For brevity, Part 1 together with the Collateral Standards mentioned above are referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.