SLOVENSKI PREDSTANDARD

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Medicinska električna oprema – 2-22. del: Posebne zahteve za varnost in bistvene lastnosti kirurške, terapevtske in diagnostične laserske opreme

Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, therapeutic and diagnostic laser equipment

ICS 11.040.50; 11.040.55; 11.040.60

Referenčna številka
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76/314/CDV

COMMITTEE DRAFT FOR VOTE (CDV)
PROJET DE COMITÉ POUR VOTE (CDV)

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Titre du CE/SC:	Title of TC/SC: OPTICAL RADIATION SAFETY AND LASER EQUIPMENT	
Secretary: Gerald Glen Secrétaire:		
Also of interest to the following committees Intéresse également les comités suivants	Supersedes document Remplace le document 76/287/CD, 76/300/CC	
Functions concerned Fonctions concernées ☒ Safety / Sécurité ☐ EMC / CEM ☐ Environment / Environnement ☐ Quality assurance / Assurance qualité		

Titre :

Title : IEC 60601-2-22 Ed.3: MEDICAL ELECTRICAL EQUIPMENT –
Part 2: Particular requirements for the safety and essential performance of surgical, therapeutic and diagnostic laser equipment

Note d'introduction

Introductory note IEC TC76/WG4 foreword to the CDV only.
This draft incorporates all changes due to the comments received prior to the WG4 Valbella meeting in October 2004 and observed at the meeting. The document was 76/287/60601-2-22/comments. This document was distributed by IEC as 76/300/CC. The old numbering of clauses and Definitions were retained in order to facilitate reviewing. The Numbering will be brought in an order editorially in the FDIS stage.
March 2005, The convener
The French version will be circulated later.

ATTENTION	ATTENTION
CDV soumis en parallèle au vote (CEI) et à l'enquête (CENELEC)	**Parallel IEC CDV/CENELEC Enquiry**

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety and essential performance of surgical, therapeutic and diagnostic laser equipment

FOREWORD

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International Standard IEC 60601-2-22 has been prepared by technical committee No. 76: Optical radiation safety and laser equipment of IEC.

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

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date[1)] indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

1) The National Committees are requested to note that for this publication the maintenance result date is ....

In this Particular Standard, the following print types are used:

– requirements and definitions: in Arial type;

– NOTES: in smaller Arial type;

– *compliance: in italic type*;

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 3 AS WELL AS THOSE DEFINED IN IEC 60601-1 AND IEC 60825-1: SMALL CAPITALS

INTRODUCTION

This Particular Standard amends and supplements IEC 60601-1 (third edition, xxxx, see Note): *Medical Electrical Equipment – Part 1: General requirements for safety and essential performance*.

This Standard also refers to IEC 60825-1 (2001).

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.

WG4 note for IEC: This document has been prepared by IEC/TC76 Working Group 4 using the Committee Drafts of IEC 60601-1 3rd edtion, 62A/389/CDV (Rockville) and 62A/449/CDV (Valbella).

TC76/WG4 has produced a table listing the clause and subclause numbering of the second and third editions (CD) which follows below and is included in this Part-2 standard. The table should only facilitate navigating and is not meant to be finally published.

When the third edition of 60601-1 is issued as an FDIS, this standard will be reviewed for possible changes.

Old clause number	New clause number	Old clause number	New clause number	Old clause number	New clause number
Appendix L	2	19.3	8.7.3	52.4.101	13.1.101
2.x.x	3.1xxx	32	10.4/10.6	52.5.9	13.2.101
3	4	36	17	55	16.4
3.6	13.2.101	45	9.7	56.11	8.10.4.101

6	7	49	11.8	56.101	10.4.g)
6.1	7.2	50.2	12.1	57.10	8.9
6.3	7.4	51.2	12.4.4	57.101	8.9.101
6.8	7.9	51.5	12.4.6	59.101	15.101
6.8.2	7.9.2	51.101	12.4.101		

This note together with the table are for review purposes only. They will be omitted from the final publication.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety and essential performance of surgical, therapeutic and diagnostic laser equipment

SECTION ONE – GENERAL

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

1 Scope, object and related standards

This clause of the General Standard applies except as follows:

1.1 *Scope*

Addition:

This Particular International Standard applies to laser equipment for either surgical, therapeutic, medical diagnostic, cosmetic, or veterinary APPLICATIONS, intended for its use on humans or animals, classified as a CLASS 3B or CLASS 4 LASER PRODUCT according to 3.21 and 3.22 in IEC 60825-1, hereinafter referred to as laser equipment.

Throughout this document light emitting diodes (LED) are included whenever the word “laser” is used.

NOTE – Laser equipment classified as a CLASS 1, 1M, 2, 2M or CLASS 3R LASER PRODUCT, is covered by IEC 60825-1 and IEC 60601-1.

1.2 *Object*

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

NOTE - Laser classification (IEC 60825-1) is not to be confused with electrical classification (IEC 60601-1)

1.3 *Particular Standards*

Addition:

This Particular Standard refers to IEC 60601-1, 3rd edition (xxxx).

For brevity, Part 1 of IEC 60601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The numbering of 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.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa), bb),* etc.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding clause or subclause in this Particular Standard, the clause or subclause of the General Standard, although possibly not relevant, applies without modification. Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

Concerning LASER RADIATION safety of laser equipment, IEC 60825-1 applies, except that the relevant requirements are specified, changed or amended in this Particular Standard.

Clauses and subclauses of the General Standard and IEC 60825-1, which are not applicable to laser equipment for medical applications, are not necessarily indicated as "not applicable".

2. Normative references

Addition:

IEC 60601-1: xxxx, *Medical electrical equipment – Part 1: General requirements for safety and essential performance*

IEC 60664-1: 1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60664-3: 1992, *Insulation coordination for equipment within low-voltage systems – Part 3: Use of coatings to achieve insulation coordination of printed board assemblies*

IEC 60825-1, Ed. 1.2: 2001-08, *Safety of laser products – Part 1: Equipment classification, requirements and user's guide*

IEC 60947-3: 1990, *Low-voltage switchgear and controlgear – Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units*

3. Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

3.1001 *ACCESSIBLE EMISSION LIMIT (AEL)*

ACCESSIBLE EMISSION LIMIT for Class 1 (1M, 2, 2M, 3R, 3B) lasers. See 3.2 and tables 1 through 4 of IEC 60825-1.

3.1002 *AIMING BEAM*

Beam of optical radiation, producing a visible AIMING BEAM spot, intended for indication of the anticipated point of impact of the WORKING BEAM.

3.1003 *AIMING BEAM POSITION*

Area of impact of the AIMING BEAM within the WORKING AREA.

3.1004 *AIMING LASER*

LASER emitting an AIMING BEAM.

3.1005 *APERTURE*

See 3.8 of IEC 60825-1.

3.1006 *BEAM DELIVERY SYSTEM*

Optical system which guides the LASER RADIATION from its origin to a LASER APERTURE.

3.1007 *CLASS 1 (1M, 2, 2M, 3R, 3B, 4) LASER PRODUCT*

Laser equipment, incorporating a LASER as defined in 3.17 through 3.22 and 3.40 of IEC 60825-1.

3.1008 *EMERGENCY LASER STOP*

Hand- or foot-actuated device intended to stop the LASER OUTPUT immediately in case of emergency.

3.1009 *LASER EMISSION INDICATOR*

Visible and/or audible signal which indicates that the WORKING BEAM is being emitted through any APERTURE.

3.1010 *LASER ENERGY*

RADIANT ENERGY of the WORKING BEAM, incident on the WORKING AREA, see 3.68 of IEC 60825-1.

3.1012 *LASER OUTPUT*

Either LASER POWER or LASER ENERGY.

3.1013 *LASER POWER*

RADIANT POWER of the WORKING BEAM, incident on the WORKING AREA, see 3.70 of IEC 60825-1.

3.1014 *LASER READY INDICATOR*

Visible means which indicates that the laser equipment is in the READY condition.