Elektrilised meditsiiniseadmed. Osa 2-22: Erinõuded kirurgiliste, kosmeetiliste, terapeutiliste ja diagnostiliste laserseadmete esmasele ohutusele ja olulistele toimimisnäitajatele

Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment (IEC 60601-2-22:2007 + A1:2012)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-22:2013 sisaldab Euroopa standardi EN 60601-2-22:2013 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-22:2013 consists of the English text of the European standard EN 60601-2-22:2013.
Standard on kinnitatud Eesti Standardikeskuse 31.01.2013 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.01.2013 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 18.01.2013.	Date of Availability of the European standard text 18.01.2013.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.01, 31.260

diagnostic and therapeutic laser equipment, fire protection, medical electrical equipment, protection against electric shock, protection against mechanical hazard, radiation protection, safety requirements

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-22

January 2013

ICS 11.040.01; 31.260

Supersedes EN 60601-2-22:1996

English version

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

(IEC 60601-2-22:2007 + A1:2012)

Appareils électromédicaux -
Partie 2-22: Règles particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser
(CEI 60601-2-22:2007 + A1:2012)

Medizinische elektrische Geräte -
Teil 2-22: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für chirurgische, kosmetische, therapeutische und diagnostische Lasergeräte
(IEC 60601-2-22:2007 + A1:2012)

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-22:2013 E

Foreword

The texts of document 76/359/FDIS, future edition 3 of IEC 60601-2-22, and document 76/444/CDV, future amendment 1 to edition 3 of IEC 60601-2-22, prepared by IEC/TC 76 "Optical radiation safety and laser equipment" were submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-22:2013, based on IEC 60601-2-22:2007 + A1:2012.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2013-08-29
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2015-11-29

This document supersedes EN 60601-2-22:1996.

EN 60601-2-22:2013 includes the following significant technical changes with respect to EN 60601-2-22:1996:

This third edition takes account of the recently published new editions of the General Standard EN 60601-1 and Group safety publication EN 60825-1. Additionally, it addresses technical and safety issues which have arisen in the time following the previous second edition.

This standard is to be read in conjunction with EN 60601-1:2006.

In this standard, the following print types are used:

- requirements and definitions: roman type.
- *test specifications: italic type*.
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes Subclauses 7.1, 7.2, etc.),
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standards IEC 60601-2-22:2007 + A1:2012 were approved by CENELEC as a European Standard without any modification.

The Bibliography of EN 60601-1:2006 applies, except as follows:

In the Bibliography of EN 60601-1:2006, the following note has to be added for the standard indicated:

IEC 60664-3:2003	NOTE	Harmonised as EN 60664-3:2003 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year

***Add** to Annex ZA of EN 60601-1:2006 the following new references:*

IEC 60825-1	2007	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1	2007
IEC 60947-3	-	Low-voltage switchgear and controlgear - Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	EN 60947-3	-
IEC 61010-1	-	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements	EN 61010-1	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EU Directive 93/42/EEC, except the following:

- ER 1 to ER 7.1
- ER 7.4
- ER 7.5, Paragraph 2 and 3
- ER 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive[s] concerned.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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INTRODUCTION

This particular standard amends and supplements IEC 60601-1 (third edition, 2005: *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*).

This standard also refers to IEC 60825-1 (2007).

The requirements of this standard are the minimum that need to be complied with, in order to achieve a reasonable level of safety and reliability during operation and application of medical laser equipment.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA. Understanding of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revisions necessitated by changes in clinical practice or by developments in technology.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

201.1 Scope, object and related standards

Clause 1 of the General Standard applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of 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 as defined by 3.22 and 3.23 in IEC 60825-1, hereafter referred to as LASER EQUIPMENT.

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

NOTE 1 Refer to Definition 3.49 in IEC 60825-1.

NOTE 2 Laser products for these applications classified as a CLASS 1, 1M, 2, 2M or CLASS 3R LASER PRODUCT, are covered by IEC 60825-1 and IEC 60601-1.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the General Standard.

NOTE See also 4.2 of the General Standard.

This standard can also be applied to surgical, cosmetic, therapeutic and diagnostic laser equipment used for compensation or alleviation of disease, injury or disability.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the safety of surgical, cosmetic, therapeutic and diagnostic laser equipment.

NOTE Laser classification (IEC 60825-1) must not be confused with electrical classification (IEC 60601-1).

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the General Standard and Clause 2 of this particular standard.

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the General Standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the General Standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the General Standard or applicable collateral 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the General Standard or applicable collateral 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 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the General Standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the General Standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard or applicable collateral 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".

201.2 Normative references

Clause 2 of the General Standard applies, except as follows:

Addition:

IEC 60825-1:2007, *Safety of laser products – Part 1: Equipment classification and requirements*

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

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60825-1:2007 apply, except as follows:

Addition:

201.3.101
ACCESSIBLE EMISSION LIMIT (AEL)
ACCESSIBLE EMISSION LIMIT for CLASS 1M, 2, 2M, 3R, or 3B lasers (see 3.3 and Tables 4 through 9 of IEC 60825-1)

201.3.102
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

201.3.103
AIMING BEAM SPOT
area of impact of the AIMING BEAM within the WORKING AREA

201.3.104
AIMING LASER
LASER emitting an AIMING BEAM

201.3.105
APERTURE
distal opening of the BEAM DELIVERY SYSTEM (see 3.8 of IEC 60825-1)

201.3.106
BEAM DELIVERY SYSTEM
optical system which guides the LASER RADIATION from its origin to the WORKING AREA

201.3.107
CLASS 1, 1M, 2, 2M, 3R, 3B, OR 4 LASER PRODUCT
laser equipment, incorporating a LASER as defined in 3.41 and 3.18 through 3.23 of IEC 60825-1

201.3.108
EMERGENCY LASER STOP
hand- or foot-actuated device intended to stop the LASER OUTPUT immediately in case of emergency