IEC 60601-2-22

Edition 3.1 2012-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). 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 organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of IEC 60601-2-22 consists of the third edition (2007) [documents 76/359/FDIS and 76/363/RVD] and its amendment 1 (2012) [documents 76/444/CDV and 76/477/RVC]. It bears the edition number 3.1.

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

International standard IEC 60601-2-22 has been prepared by IEC subcommittee 76: Optical radiation safety and laser equipment.

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

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

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

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date 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.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests.

It is the recommendation of the committee that the content of the amendment 1 be adopted for implementation nationally not earlier than 12 months from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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

201.3.109
LASER EMISSION CONTROL SWITCH
hand- or foot-actuated device intended to initiate and stop WORKING BEAM emission through any APERTURE

201.3.110
LASER EMISSION INDICATOR
visible and/or audible signal which indicates that the WORKING BEAM is being emitted through any APERTURE

NOTE The LASER EMISSION INDICATOR is different from the LASER RADIATION EMISSION warning requirement 4.7 of IEC 60825-1.

201.3.111
LASER ENERGY
RADIANT ENERGY of the WORKING BEAM, incident on the WORKING AREA (see 3.70 of IEC 60825-1)

201.3.112
LASER OPERATOR
the person who handles the laser equipment. In general, the LASER OPERATOR controls the delivery of the laser radiation to the WORKING AREA. The LASER OPERATOR may appoint other person(s), who assist with the selection and/or setting of the parameters.

Refer to Definition 3.73 in IEC 60601-1.

NOTE The safety requirements in this standard apply to all above persons.

201.3.113
LASER OUTPUT
either LASER POWER or LASER ENERGY

201.3.114
LASER POWER
RADIANT POWER of the WORKING BEAM, incident on the WORKING AREA, see 3.72 of IEC 60825-1

201.3.115
LASER READY INDICATOR
visible means which indicate that the laser equipment is in the READY condition, and the purpose of which is to make all persons present in the laser area aware of the need to take precautions against hazardous LASER RADIATION, as detailed in the ACCOMPANYING DOCUMENTS (instructions for use). See 201.7.9.

201.3.116
OPERATOR PROTECTIVE FILTER
a moveable or fixed filter which does not allow radiation in excess of the MAXIMUM PERMISSIBLE EXPOSURE (MPE) to the LASER OPERATOR

NOTE For the definition of MPE, see 3.56 of IEC 60825-1.

201.3.117
SHUTTER
electronic, opto-electronic and/or mechanical means which allows or prevents LASER OUTPUT to be emitted from the APERTURE

201.3.118
STAND-BY/READY
modes of operation when mains supply is connected and the mains switch activated, where the STAND-BY mode means that the laser is not capable of emitting the WORKING BEAM even if the laser control switch is activated, and where the READY mode keeps the laser equipment enabled, so that it is capable of emitting LASER OUTPUT when the control switch is activated

201.3.119
TARGET INDICATING DEVICE
an aiming device which designates the position where the WORKING BEAM will perform its surgical, cosmetic, therapeutic or diagnostic purpose

201.3.120
WORKING AREA
area which is intended to be irradiated with WORKING BEAM

201.3.121
WORKING BEAM
beam of LASER RADIATION emitted by the laser equipment for surgical, cosmetic, therapeutic or diagnostic purposes (other than the AIMING BEAM)

201.4 General requirements

Clause 4 of the General Standard applies.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the General Standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the General Standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the General Standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Addition:

201.7.2.101 Additional items

See Clause 5 of IEC 60825-1.

a) General

Laser equipment shall carry labels in accordance with 5.5, 5.6, 5.8, 5.9, 5.10, 5.11 of IEC 60825-1, as applicable.

b)* Aperture label

Laser equipment shall have a label positioned as close as practicable to each laser aperture. The label shall be similar to the laser hazard symbol as specified in IEC 60825-1, Figure 1, with the exception that the size can be adjusted as appropriate or alternatively be similar to the label described in 5.7 of IEC 60825-1. Hand-pieces and other applicators are exempt from these requirements. In this case, a label is to be affixed in a prominent position with either:

– a statement that the laser aperture is on the end of the fibre/applicator, or

– a symbol as detailed in Table D.1, number 113.

NOTE The required information can be combined into one single label if the area where the label is to be affixed is suitable.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall give adequate instructions for proper operation, including clear warnings concerning precautions to avoid possible exposure to hazardous LASER RADIATION.

201.7.9.2 Instructions for use

201.7.9.2.13 Maintenance

Addition:

The instructions for maintenance shall include clear warnings concerning precautions to avoid possible exposure to hazardous laser radiation.

201.7.9.2.101 Laser specific information for the responsible organization and for the LASER OPERATOR

The instructions for use shall include (as applicable):

– information on the NOMINAL OCULAR HAZARD DISTANCE (NOHD) for the laser equipment in NORMAL USE with each appropriate ACCESSORY;

– a statement in SI units of BEAM DIVERGENCE, PULSE DURATION, maximum LASER OUTPUT of the LASER RADIATION, with the magnitudes of the cumulative measurement uncertainty and any expected increase in the measured quantities at any time after manufacture added to the values measured at the time of manufacture;

– legible reproductions (colour optional) of all required LASER labels and hazard warnings affixed to the laser equipment;

– information and guidance for regular calibration of the LASER OUTPUT in accordance with 201.12.1 of this standard. The information shall include a specification for the measuring equipment and frequency of calibration and clarification requirements concerning regular calibration of LASER OUTPUT;

– a clear indication of all locations of laser APERTURES;

– a listing of controls, adjustments and procedures for operation and maintenance by the RESPONSIBLE ORGANISATION, including the warning "Caution – Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure";

– a description of the BEAM DELIVERY SYSTEMS including the characteristics of the LASER OUTPUT;

– A note, saying that laser equipment should be protected against unauthorized use, for example by removal of the key from the key switch;

– a specification for eye protection;

NOTE Refer to 8.4.5.2 of IEC/TR 60825-14 (2004), Safety of laser products – Part 14: A user's guide.

– a specification for fume and plume extraction, including a cautionary statement: "Caution – Laser fume and/or plume may contain viable tissue particulates";

– information about the potential hazards when inserting, sharply bending or improperly securing the fibre optics, stating that not following the recommendations of the manufacturer may lead to damage to the fibre or delivery system and/or harm to the patient or LASER OPERATOR;