IEC 60601-2-22

Edition 4.0 2019-11

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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: Exigences particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser

IEC 60601-2-22:2019-11(en-fr)

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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

This fourth edition cancels and replaces the third edition published in 2007 and Amendment 1:2012. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) it takes account of IEC 60601-1:2005/AMD1:2012 and IEC 60825-1:2014, which have been published since publication of the third edition;
b) it addresses technical and safety issues which have arisen since publication of the third edition;

c) the scope of this fourth edition differs from the scope of the third edition. It now includes CLASS 1C laser equipment, as defined in IEC 60825-1:2014, when the ENCLOSED LASER is CLASS 3B or 4;

d) LED (light emitting diode) products are now excluded from this document as medical LED products may be covered by IEC 60601-2-57.

The text of this International Standard is based on the following documents:

CDV	Report on voting
76/580/CDV	76/610/RVC

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

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

In this document, 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 document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

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

A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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

INTRODUCTION

This document amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

This document also refers to IEC 60825-1:2014. The requirements of this document 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 the reasons for these requirements will not only facilitate the proper application of this document 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[1] applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of laser equipment for surgical, therapeutic, medical diagnostic, cosmetic or veterinary applications, intended for use on humans or animals, classified as LASER PRODUCT of CLASS 1C where the ENCLOSED LASER is of CLASS 3B or 4, or CLASS 3B, or CLASS 4.

MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS which incorporate lasers as sources of energy being transferred to the PATIENT or animal and where the lasers are specified as above, are referred to as "laser equipment" in this document.

NOTE 1 LASER PRODUCTS for these applications classified as a Class 1, Class 1M, CLASS 2, Class 2M or CLASS 3R LASER PRODUCT, are covered by IEC 60825-1:2014 and by the general standard.

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 to ME EQUIPMENT and to ME SYSTEMS, as relevant.

Hazards inherent in the intended physiological function of laser equipment within the scope of this document are not covered by specific requirements in this document except in 7.2.13, Physiological effects, of the general standard.

NOTE 2 See also 4.2, RISK MANAGEMENT process, of the general standard.

NOTE 3 If the laser equipment is CLASS 1C according to IEC 60825-1:2014 and is used as a laser appliance in a household, it is covered by IEC 60335-2-113:2016.

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

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[1] In this document, "the general standard" means IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

201.1.4 Particular standards

Addition:

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this document as "the general standard". Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this document 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 document.

"Addition" means that the text of this document 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 document.

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 document" is used to make reference to the general standard, any applicable collateral standards and this document taken together.

Where there is no corresponding section, clause or subclause in this document, 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 document.

Concerning laser radiation safety of laser equipment, IEC 60825-1:2014 applies, except for the relevant requirements that are specified, changed or amended in this document.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60825-1:2014, *Safety of laser products – Part 1: Equipment classification and requirements*

201.3 Terms and definitions

Clause 3 of the general standard applies, except as follows:

Addition:

201.3.201
AEL
ACCESSIBLE EMISSION LIMIT
maximum accessible emission permitted within a particular class where the accessible emission is the level of radiation determined at a position and with APERTURE stops (when the AEL is given in units of watts or joules) or limiting APERTURES (when the AEL is given in units of $W \cdot m^{-2}$ or $J \cdot m^{-2}$)

[SOURCE: IEC 60825-1:2014, 3.2 and 3.3, modified – The two definitions have been combined into one.]

201.3.202
AIMING BEAM
beam of optical radiation, producing a visible spot, intended for indication of the anticipated point of impact of the WORKING BEAM

201.3.203
AIMING LASER
laser emitting an AIMING BEAM

201.3.204
APERTURE
opening of the BEAM DELIVERY SYSTEM through which laser radiation is transmitted, thereby allowing human access to such radiation

[SOURCE: IEC 60825-1:2014, 3.8, modified – In the definition, "any opening in the protective housing of a laser product" has been replaced by "opening of the BEAM DELIVERY SYSTEM".]

201.3.205
BEAM DELIVERY SYSTEM
optical system which guides the laser radiation from its origin to the WORKING AREA

201.3.206
CLASS 1C
class of any LASER PRODUCT which is designed explicitly for contact application to the skin or non-ocular tissue

[SOURCE: IEC 60825-1:2014, 3.19, modified – The list and notes to entry have been deleted.]

201.3.207
CLASS 2
class of any LASER PRODUCT in the wavelength range from 400 nm to 700 nm which during operation does not permit human access to laser radiation in excess of the AEL of CLASS 2

[SOURCE: IEC 60825-1:2014, 3.21, modified – In the definition, "for applicable wavelengths and emission durations" and the text in parentheses have been deleted.]

201.3.208
CLASS 3B
class of any LASER PRODUCT which during operation permits human access to laser radiation in excess of the AEL of Class 1 and CLASS 2, as applicable, but which does not permit human access to laser radiation in excess of the AEL of CLASS 3B for any emission duration and wavelength

[SOURCE: IEC 60825-1:2014, 3.23, modified – The term and definition have been modified to refer only to CLASS 3B. In the definition, the text in parentheses has been deleted.]

201.3.209
CLASS 3R
class of any LASER PRODUCT which during operation permits human access to laser radiation in excess of the AEL of Class 1 and CLASS 2, as applicable, but which does not permit human access to laser radiation in excess of the AEL of CLASS 3R for any emission duration and wavelength

[SOURCE: IEC 60825-1:2014, 3.23, modified – The term and definition have been modified to refer only to CLASS 3R. In the definition, the text in parentheses has been deleted.]

201.3.210
CLASS 4
class of any LASER PRODUCT which permits human access to laser radiation in excess of the AEL of CLASS 3B

[SOURCE: IEC 60825-1:2014, 3.24, modified – In the definition, the text in parentheses has been deleted.]

201.3.211
EMERGENCY LASER STOP
hand- or foot-actuated device intended to stop the LASER OUTPUT immediately in case of emergency

201.3.212
ENCLOSED LASER
laser which is incorporated in laser equipment of CLASS 1C

201.3.213
GOOD CONTACT
state that is established when the applicator of the laser equipment which is classified laser CLASS 1C is positioned at the target tissue so that the tissue surface acts to effectively prevent hazardous eye exposure to STRAY OPTICAL RADIATION

[SOURCE: IEC 60335-2-113:2016, 3.104, modified]

201.3.214
LASER EMISSION CONTROL SWITCH
hand- or foot-actuated device intended to initiate and stop WORKING BEAM emission

201.3.215
LASER EMISSION INDICATOR
visible and/or audible signal which indicates that the WORKING BEAM is being emitted

Note 1 to entry: Refer to IEC 60825-1:2014, 6.7 Laser radiation emission warning.

201.3.216
LASER ENERGY
LASER OUTPUT
RADIANT ENERGY of the WORKING BEAM, incident on the WORKING AREA, where the RADIANT ENERGY is the time integral of the radiant flux Φ over a given duration Δt

Note 1 to entry: LASER OUTPUT is a more general term which covers both LASER POWER and LASER ENERGY.

[SOURCE: IEC 60825-1:2014, 3.72, modified – In the definition, "RADIANT ENERGY of the WORKING BEAM, incident on the WORKING AREA, where the RADIANT ENERGY is the"]

201.3.217
LASER OPERATOR
person handling the laser equipment.

Note 1 to entry: 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.

[SOURCE: IEC 60601-1:2012, 3.73, modified – The word "laser" has been added in the term and definition.]

201.3.218
LASER POWER
LASER OUTPUT
RADIANT POWER of the WORKING BEAM, incident on the WORKING AREA where the RADIANT POWER is the power emitted, transferred, or received in the form of radiation

Note 1 to entry: LASER OUTPUT is a more general term which covers both LASER POWER and LASER ENERGY.

[SOURCE: IEC 60825-1:2014, 3.74, modified – In the term, "radiant" has been replaced by "laser". In the definition, "RADIANT POWER of the WORKING BEAM, incident on the WORKING AREA where the RADIANT POWER is the" has been added.]

201.3.219
LASER READY INDICATOR
means which visibly indicates that the laser equipment is in the READY condition

Note 1 to entry: The purpose of the LASER READY INDICATOR is to make the personnel present in the laser area aware of the need to take precautions against inadvertent hazardous laser radiation.

201.3.220
MPE
MAXIMUM PERMISSIBLE EXPOSURE
level of laser radiation to which, under normal circumstances, persons may be exposed without suffering adverse effects

[SOURCE: IEC 60825-1:2014, 3.59, modified – The notes to entry have been deleted.]

201.3.221
OPERATOR PROTECTIVE FILTER
moveable or fixed optical filter incorporated in the optical pathway of viewing optics which allows viewing of the WORKING AREA but blocks hazardous levels of the radiation of the WORKING LASER

201.3.222
READY
mode of operation when SUPPLY MAINS is connected and the laser equipment is switched on, and in which upon activation of the LASER EMISSION CONTROL SWITCH the laser equipment emits the WORKING BEAM

201.3.223
STAND-BY
mode of operation when SUPPLY MAINS is connected and the laser equipment is switched on, and in which the laser equipment is not capable of emitting the WORKING BEAM even if the LASER EMISSION CONTROL SWITCH is activated

201.3.224
STRAY OPTICAL RADIATION
laser radiation that is unintentionally emitted from the applicator of the laser equipment of CLASS 1C, either by scattering around the edges of the applicator or by any other pathway

201.3.225
TARGET INDICATING DEVICE
aiming device which designates the position where the WORKING BEAM will perform its surgical, cosmetic, therapeutic or diagnostic purpose

201.3.226
WORKING AREA
area which is intended to be irradiated with the WORKING BEAM

201.3.227
WORKING BEAM
beam of laser radiation, other than the AIMING BEAM, emitted by the laser equipment for surgical, cosmetic, therapeutic or diagnostic purposes

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 labels

See IEC 60825-1:2014, Clause 7.

a) General

Laser equipment shall carry labels in accordance with 7.3, 7.6 or 7.7 of IEC 60825-1:2014, as applicable. These labels shall be visible from the normal operating position.

b) *APERTURE label

Laser equipment except CLASS 1C shall have a label positioned as close as practicable to each laser APERTURE. The label as specified in IEC 60825-1:2014, 7.8 shall be used. Applicators which are subject to disinfection or sterilizing and fibre-optics 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.

c) CLASS 1C laser equipment shall in addition include the class of the ENCLOSED LASER in the explanatory label.

201.7.9 ACCOMPANYING DOCUMENTS

Subclause 7.9 of the general standard applies except as follows:

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.

Addition of the following subclause:

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):

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

NOTE 1 The NOHD does not apply to laser equipment of CLASS 1C.

b) 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 which may add to the values measured at the time of manufacture, meaning that the equipment performs differently than expected, refer to 7.9.2.17 of the general standard;

c) where a single pulse is made up of a pulse train, the technical details shall be described in the information for the laser user. For example, where nominal pulses are comprised of a predetermined sub-pulse structure or pulse-train, the number of sub-pulses and approximate duration of each sub-pulse shall be stated;

d) the potential variation in wavelength shall be stated;

e) legible reproductions (colour optional) of all required laser labels and HAZARD warnings affixed to the laser equipment;

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

g) a clear indication of all locations of laser APERTURES;

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

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

j) when the laser equipment is of CLASS 1C, a detailed technical description of the interlocks, a description of possible limitations and malfunction following false positioning of the applicator, a comprehensive description of how to position the applicator properly, a warning about possible usage conditions which may result in hazardous STRAY OPTICAL RADIATION;