IEC 60601-2-22

Edition 4.0 2019-11
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

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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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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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.

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 document using a colour printer.

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:~~2007~~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 ~~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~~ LASER PRODUCT of CLASS 1C where the ENCLOSED LASER is of CLASS 3B or 4, or CLASS 3B, or CLASS 4.

~~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.~~

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 ~~2~~1 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~~ 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 ~~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.~~

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.

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

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

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.

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

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.

~~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.~~

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.

~~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 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:~~2007~~2014, *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, 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)~~

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 ~~items~~ labels

See IEC 60825-1:2014, Clause ~~5~~7.

a) General

Laser equipment shall carry labels in accordance with ~~5.5, 5.6, 5.8, 5.9, 5.10, 5.11~~ 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 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.~~ 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 ~~at any time after manufacture added~~ 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;

k) a ~~note~~ statement, saying that laser equipment should be protected against unauthorized use, for example by removal of the key from the key switch;

l) a specification for eye protection; not required for laser equipment of CLASS 1C;

NOTE 2 Refer to 8.4.5.2 of IEC TR 60825-14:2004, Safety of LASER PRODUCTS – Part 14: A user's guide.

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

n) 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 BEAM DELIVERY SYSTEM and/or harm to the PATIENT or LASER OPERATOR;

o) ~~recommendation~~ instructions for checking the integrity of the BEAM DELIVERY SYSTEM, for example as follows: "As the AIMING BEAM passes down the same delivery system as the WORKING BEAM, it provides a good means of checking the integrity of the delivery system. If the AIMING BEAM is not present at the distal end of the BEAM DELIVERY SYSTEM, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or malfunctioning BEAM DELIVERY SYSTEM";

p) ~~a warning~~ information on non-laser HAZARDS, for example as follows: "A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials,

solutions or gases, or in an oxygen enriched environment". The ~~high~~ temperatures produced in NORMAL USE of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases;

q) information on safe procedures which ensure a minimum of acceptable side effects to the PATIENTS, including a list of counter-indications and including a list of all conditions which would render the balance of the expected success of treatment and the non-avoidable side-effects non-acceptable;

r) information on separate equipment which would be useful to assess the favourable conditions which are acceptable for treatment or to assess the unfavourable conditions which would render a treatment unacceptable or HAZARDOUS;

s) checklists and forms which help the user collect the information necessary to assess the favourable conditions of treatment;

t) information about the applicable national regulations, e.g. on professional cosmetic applications of laser equipment;

u) description of procedures to ensure that sterile ACCESSORIES remain sterile;

v) information about ACCESSORIES such as fibre-optics which are compatible with the laser equipment;

w) if the laser equipment is installed with or connected to other medical devices or equipment to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination shall be provided;

x) if the ACCESSORY to the laser equipment is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses shall be provided. Where ACCESSORIES are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization shall be such that, if correctly followed, the ACCESSORY will still comply with the requirements of this document;

y) if the ACCESSORY bears an indication that the ACCESSORY is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used shall be provided. If no instructions for use are needed, the information shall be made available to the user upon request. The possibility of this request and provisions for obtaining the requested information shall be described;

z) details of any further treatment or handling needed before the ACCESSORY can be used (for example sterilization, final assembly, etc.);

aa) precautions to be taken in the event of changes in the performance of the laser equipment;

bb) precautions to be taken, as regards malfunction of laser equipment due to exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

cc) degree of accuracy claimed for ACCESSORIES with a measuring function, such as skin colour detectors or detectors of laser-induced fluorescence or frequency shifted scattered radiation, etc.;

dd) understandable explanation of symbols, controls, instructions, operating or adjustment parameters when required for the operation of the laser equipment.

NOTE 3 If the laser equipment is intended to be used by non-medical professionals, e.g. cosmetic or beauty-care practitioners, they may need information which is additional to the information required in 201.7.9.2.101.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies except as follows:

201.8.5 Separation of parts

Amendment:

If an OEM (Original Equipment Manufacturer) laser and/or OEM ~~laser~~ power supply is incorporated into the laser ~~product~~ equipment and the OEM product complies with IEC 61010-1, then the OEM product is exempt from the differing requirements of ~~IEC 60601-1~~ the general standard. This exemption applies to ~~the means of operator protection (MOOP) and to~~ the requirements of 8.6, 8.8 and 8.9 for MEANS OF OPERATOR PROTECTION. MEANS OF PATIENT PROTECTION are not exempt.

201.8.7 LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS

This subclause of the general standard applies except as follows:

201.8.7.3 *Allowable values

Addition:

Laser equipment is considered as PERMANENTLY INSTALLED equipment if

- it is connected to the SUPPLY MAINS by means of a MAINS PLUG which is mechanically secured against unintentional loosening,
- the POWER SUPPLY CORD is non-detachable, and
- the cross-sectional area of the POWER SUPPLY CORD conductors is not less than 2,5 mm^2 ~~Cu~~.

NOTE Mechanically securing the MAINS PLUG is considered equally safe as using a tool for disconnecting.

Compliance is checked by inspection.

201.8.10 Components and wiring

This subclause of the general standard applies except as follows:

201.8.10.4 Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

Addition:

201.8.10.4.101 Footswitch

Any foot-operated LASER EMISSION CONTROL SWITCH shall be shrouded to prevent unintentional operation. The force required to actuate the switch shall be not less than 10 N, applied over an area of 625 mm^2 anywhere on the operating surface of the footswitch. This force shall not exceed 50 N.

This requirement also applies to wirelessly connected footswitches.

Compliance is checked by measurement of the actuating force.

201.8.11 MAINS PARTS, components and layout

Addition:

201.8.11.101 Use of water for cooling

~~Where water is used in electrical CLASS I equipment for cooling and where the water assumes the role of BASIC INSULATION to MAINS, the conductivity of the water shall be such that the EARTH LEAKAGE CURRENT values required in 201.8.7.3 are not exceeded in NORMAL USE. The manufacturer shall specify periodic maintenance information and methods of measurement.~~

Where liquid is used in laser equipment for cooling and where the liquid assumes the task of BASIC INSULATION to SUPPLY MAINS, the conductivity of the liquid shall be such that the allowable value of the LEAKAGE CURRENT required in 8.7 of the general standard is not exceeded in NORMAL USE. The conductivity of the liquid shall be continuously monitored by the laser equipment. In case of LEAKAGE CURRENT exceeding the values required in 8.7 of the general standard as a result of increased liquid conductivity, the laser equipment shall be switched off automatically from the SUPPLY MAINS.

Compliance is checked by inspection and ~~measurement~~ functional tests.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

201.10.4 Lasers ~~and light emitting diodes (LEDs)~~

Amendment:

Where the general standard refers to IEC 60825-1:2007, IEC 60825-1:2014 shall apply instead.

Amendment:

Add "CLASS 1C" to the listing of the laser classes in the text of the NOTE in 10.4 of the general standard.

Addition:

201.10.4.101 General requirements

NOTE In the context of this document, "light" radiation is understood to cover optical radiation as specified in IEC 60825-1:2014.

~~For the protection of the PATIENT, the LASER OPERATOR and other persons present,~~ The laser equipment shall ~~comply with the following requirements~~ incorporate:

a) REMOTE INTERLOCK CONNECTOR as described in 6.4 of IEC 60825-1:2014

   This requirement does not apply to

   – battery-powered hand-held medical laser equipment

   – CLASS 1C laser equipment

b) Key control as described in 6.6 of IEC 60825-1:2014

c) Viewing optics as described in 6.10 of IEC 60825-1:2014

~~Additionally, the laser equipment shall incorporate:~~

d) LASER READY INDICATOR

Laser equipment shall incorporate a visible LASER READY INDICATOR, which shall be illuminated when emission of the WORKING BEAM is possible upon actuation of the control switch, ~~to allow appropriate safety precautions to be taken~~ i.e. the laser equipment is in the READY mode.

e) LASER EMISSION INDICATOR

~~In addition to the LASER READY INDICATOR,~~ Laser equipment of CLASS 3B and 4, and laser equipment of CLASS 1C incorporating an ENCLOSED LASER of CLASS 3B or 4 shall be equipped with a visible ~~and~~ or an audible signal, which clearly indicates that emission of laser radiation in excess of the AEL for CLASS 3R is taking place. ~~The LASER EMISSION INDICATORS shall be designed as described in 4.7 of IEC 60825-1.~~

Both the LASER READY INDICATOR and the ~~visible~~ LASER EMISSION INDICATOR, if visible, shall be visible through the laser protective eyewear ~~worn by those present in the laser area~~ as specified in the instructions for use, see 201.7.9.2.101.

Provided that one of the LASER EMISSION INDICATORS is clearly visible or audible to the persons in the vicinity of the operational control or laser APERTURE, the 2 m distance requirement in 4.7.3 of IEC 60825-1:2014 is not applicable.

~~NOTE 1 Since this standard requires a LASER READY INDICATOR and two LASER EMISSION INDICATORS, the FAIL SAFE or redundancy requirement in Subclause 4.7.2 of IEC 60825-1 is not applicable.~~

~~NOTE 2 AIMING BEAMS are not considered to be indicator lights.~~

The LASER EMISSION INDICATOR shall be recognizable by the LASER OPERATOR and by the personnel involved in the laser procedure.

The LASER EMISSION INDICATOR shall be FAIL SAFE or redundant.

NOTE An AIMING BEAM is not considered to be a LASER EMISSION INDICATOR.

f) *TARGET INDICATING DEVICE ~~(see 201.15.101)~~

The location where the LASER OUTPUT is to have its effect shall be indicated. Indication shall be prior to emission of the WORKING BEAM.

Possible solutions include:

1) the use of a visible AIMING BEAM;
2) the attachment of a pointer on the hand piece;
3) optical aiming devices;
4) contact application;
5) electronic indication, such as a cursor on a screen.

If the TARGET INDICATING DEVICE is a light beam, the point of impact indicated by the TARGET INDICATING DEVICE shall be concentric with the WORKING BEAM within the following tolerance: The lateral offset of the centres of the two beams shall be less than 50 % of the diameter of the WORKING BEAM. Additionally, the diameter of the AIMING LASER beam shall not be larger than twice the diameter of the working laser beam. For the definition of beam diameter see 3.13 of IEC 60825-1:2014.

If the TARGET INDICATING DEVICE is an electronic indication, its centre shall not deviate from the centre of the WORKING BEAM by more than 50 % of the diameter of the WORKING BEAM.

If a visible AIMING BEAM is chosen, its spot shall be recognizable through the laser protective eyewear, which is specified in the instructions for use, refer to 201.7.9.2.101.

If the TARGET INDICATING DEVICE is in the form of an AIMING BEAM which is emitted from the LASER APERTURE and is generated by an AIMING LASER or ~~is~~ by an attenuated WORKING BEAM, it shall not exceed the AEL for CLASS 3R with the following exception:

For an ophthalmic AIMING LASER, the AIMING BEAM shall not exceed the AEL for CLASS 2 without a deliberate and positive action by the LASER OPERATOR.

The TARGET INDICATING DEVICE is not required for CLASS 1C laser equipment.

g) STAND-BY/READY control

Laser equipment shall be equipped with a STAND-BY/READY device. This device shall be capable of disabling the WORKING BEAM. Upon initial switching the LASER PRODUCT to SUPPLY MAINS it shall by default enter the STAND-BY mode.

Transition from STAND-BY to READY shall not be possible when the LASER EMISSION CONTROL SWITCH is activated.

NOTE The beam stop according to 6.8 of IEC 60825-1:2014 is replaced by the requirement for a STAND-BY/READY device.

h) ENCLOSURES

The following requirements of IEC 60825-1:2014 shall apply:

– 6.2. Protective housing – 6.2.1 General;
– 6.2. Protective housing – 6.2.2 Service;
– 6.3 Access panels and safety interlocks.

i) Limits on LASER OUTPUT

The LASER OUTPUT shall be limited to the amount which is necessary for the laser equipment to enable its intended medical, surgical or diagnostic functions. The considerations about the limits of LASER OUTPUT shall be included in the RISK MANAGEMENT process as described in 4.2 of IEC 60601-1:2005/AMD1:2012.

Compliance is checked by measurement, inspection of the device and inspection of the RISK MANAGEMENT FILE.

~~NOTE The beam stop according to 4.8 of IEC 60825-1 is replaced by the requirement for a STAND-BY/READY device.~~

201.10.4.102 Interlock system of laser equipment of CLASS 1C

A CLASS 1C LASER PRODUCT incorporating an ENCLOSED LASER of CLASS 3B or 4 shall be equipped with an interlock system which is capable of detecting whether GOOD CONTACT with the biological skin tissue is established.

If continuous action by the user is necessary to maintain the enabled status (for example an activation button is continuously depressed) the laser shall keep emitting, unless GOOD CONTACT with the skin is lost. While this continuous action is maintained by the user, any loss of GOOD CONTACT shall be detected by the interlock system and the laser emission shall shut off.

The time interval between loss of GOOD CONTACT with the skin and disabling the triggering of laser emission shall not exceed 0,1 s provided that the requirement for CLASS 1C is met.

The emission may resume automatically if GOOD CONTACT is re-established within a maximum of 10 s. When the loss of GOOD CONTACT exceeds 10 s the laser equipment shall require active retriggering by the user in order to resume emission.

If the interlock system contains a programmable electronic circuit the software shall incorporate measures to control the fault/error conditions specified in 201.13.2, as far as applicable to CLASS 1C laser equipment.

Refer to Clause 14 of the general standard, Programmable eletrical medical systems (PEMS).

NOTE If the laser radiation is coupled into the skin by frustrated internal total reflection due to the match of the refractive indices of the transmitting medium and the skin, and the contact sensors rely on the effect of internal total reflection, this device may not be safe since index matching also takes place when gel or other index matching substance sticks to the output window, allowing emission into free air to take place.

Compliance is checked by the following tests.

The function of the interlock system shall be tested with a cylindrical test specimen, designed to simulate human skin, with the following properties:

– *a cylindrical rod with an outer diameter exceeding the maximal dimension of the applicator footprint by 40 mm and having a smooth surface, made of a flexible material with a Shore hardness not exceeding 25;*

– *the material shall simulate the optical properties of the skin with regard to absorption, reflection and scattering, in order to assess the STRAY OPTICAL RADIATION;*

– *the surface of the artificial skin used for detecting the skin contact is modified in turn as follows:*

  - *dry skin is simulated using the artificial skin without any modification;*
  - *the presence of dried sweat is simulated by using a 0,9 g/l saline solution on the artificial skin surface, that is then air dried;*
  - *the presence of sebum is simulated by using petroleum jelly on the artificial skin surface.*

For laser equipment using an auxiliary material such as a gel as specified in the instructions as the contact means for NORMAL OPERATION, the test shall be performed with and without this material.

The reaction time of the interlock system is tested by placing the output window of the laser equipment applicator on the test specimen, subsequently removing the applicator from the test specimen and the emission of laser radiation shall cease within a time interval of 0,1 s.

The output window of the laser equipment applicator shall be placed on the test specimen and rotated, tilted and raised to test whether the sensors in the interlock system correctly detect GOOD CONTACT with the test specimen.

If STRAY OPTICAL RADIATION from the target skin occurs it shall be measured by placing the applicator in contact with the test specimen at varying positions of orientation. The emission level shall not exceed the AEL of Class 1 as specified in IEC 60825-1:2014 for a maximum emission duration of 10 s, unless the laser equipment is limited to a shorter emission duration.

If compliance with the requirement of 201.10.4.102 relies on the operation of an electronic circuit, the laser equipment is further tested as described in 201.13.1.101 and 201.13.2.102.

201.10.4.103 Laser radiation filter in viewing optics

If the laser equipment incorporates viewing optics such as operating microscopes or endoscopes and the viewing optics transmit radiation from the working laser, the viewing optics shall be equipped with an OPERATOR PROTECTIVE FILTER.

The OPERATOR PROTECTIVE FILTER shall be in place during the time intervals when the working laser is emitting.

The OPERATOR PROTECTIVE FILTER shall not allow radiation of the working laser being transmitted through the eyepiece to exceed the MPE.

The function of the TARGET INDICATING DEVICE shall not be compromised.

ME EQUIPMENT is exempt from these requirements when projectors or monitors are used for viewing.

Compliance is checked by inspection of the equipment, and by measurement or inspection of the filter specifications.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.8 Interruption of the power supply /SUPPLY MAINS to ME EQUIPMENT

Addition:

201.11.8.101 Interruption of emission

CLASS 4 laser equipment shall be provided with a manual reset to enable resumption of laser radiation emission after interruption of emission ~~e.g.~~ caused by the use of a remote interlock on CLASS 4 laser equipment or caused by the unexpected loss of SUPPLY MAINS.

NOTE This manual reset could be removal of the foot from the footswitch and placing it back on again.

201.12 Accuracy of controls and instruments and protection against HAZARDOUS OUTPUTS

~~Clause 12 of the General Standard applies, except as follows:~~

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 Indication of LASER OUTPUT

Laser equipment shall incorporate a means for the indication of the pre-set level of the output of the WORKING BEAM.

The indication shall be in SI units.

The actual LASER OUTPUT measured in the WORKING AREA shall not deviate from the ~~set value~~ pre-set level of output by more than ±20 %. ~~Where the laser equipment is calibrated in watts and incorporates a timer-controlled exposure system, the LASER ENERGY shall not deviate by more than ±20 %.~~

~~This subclause does not apply if the LASER OUTPUT is fixed by the manufacturer and is not adjustable. In this case, the fixed LASER OUTPUT shall be stated by labelling.~~

If the LASER OUTPUT is fixed by the manufacturer and is not adjustable the fixed LASER OUTPUT shall be stated by labelling.

The actual PULSE DURATION shall not deviate from the PULSE DURATION specified by the manufacturer or set by the operator, by more than ±20%. The PULSE DURATION is defined in 3.69 of IEC 60825-1:2014.

Compliance is checked by inspection and measurements.

201.12.4 Protection against HAZARDOUS output

This subclause of the general standard applies, except as follows:

201.12.4.2 *Indication ~~of parameters~~ relevant to safety

Addition:

The ~~indicated~~ LASER OUTPUT emitted by the laser equipment shall not deviate from the pre-set ~~value~~ level of output by more than ±20 %. A ~~measured~~ quantity, electrical or optical, which is directly related to the LASER OUTPUT generated shall be monitored during operation. The monitoring shall be carried out at intervals shorter than the failure tolerance time ~~(see Annex AA, rationale to 201.12.4.4)~~.

Typical solutions are:

- closed-loop system;
- open-loop system with a visible and~~/or~~ audible out-of-tolerance warning.

Compliance is checked by the following test:

During use under NORMAL CONDITIONS, as well as under any reasonably foreseeable SINGLE FAULT CONDITION, the LASER OUTPUT is checked to be within the allowed tolerance or the required warning is given otherwise.

The calibration of the system is to be checked at regular intervals against the LASER POWER (or LASER ENERGY) actually ~~emitted~~ incident on the WORKING AREA. An appropriate method shall be described in the instructions for use in accordance with 201.7.9.2.101 f).

Check the instructions for use and the procedure of calibration for compliance.

201.12.4.4 *Incorrect output

~~*See Annex AA, rationale for Subclause 201.12.4.4.*~~

Addition:

201.12.4.4.101 EMERGENCY LASER STOP

The EMERGENCY LASER STOP shall stop the emission of LASER OUTPUT as fast as possible to prevent a situation where there is an unacceptable risk to any person. The EMERGENCY LASER STOP shall be designed so as to be independent of all other laser ~~stop~~ control systems. The switch shall be a red push-button and be located in such a manner as to be readily visible and easily and quickly reached by the LASER OPERATOR from the operating position. "Laser Stop" or the symbol according to Table D.1, symbol 101, shall be marked on or near the push-button.

If an emergency stop ~~according to~~ as specified in IEC 60947-3 is incorporated in the laser equipment, the EMERGENCY LASER STOP is not required.

~~Exempt from this requirement are~~ CLASS 3B lasers for non-surgical or non-ophthalmic use within the wavelength range of 600 nm to 1 400 nm,

a) emitting less than five times the MPE for the skin and not more than 50 mW average power, or

b) not exceeding the MPE for the skin,

and CLASS 1C laser equipment are exempt from this requirement.

Compliance is checked by inspection and measurements.

201.12.4.4.102 *Spectral impurities

The manufacturer shall address in the RISK MANAGEMENT process the risks associated with spectral impurities of the LASER OUTPUT, such as wavelength shift due to the change of physical parameters, setting of output, temperature and degradation effects.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.1 Specific HAZARDOUS SITUATIONS

Addition:

201.13.1.101 Specific laser considerations

~~The following hazardous situations shall be taken into consideration:~~

~~a) emission of LASER POWER of more than twice the set value for a time period exceeding 100 ms;~~

~~b) emission of pulsed LASER ENERGY, if the preceding pulse of LASER ENERGY exceeded twice the set value.~~

~~c) emission of repeatedly pulsed LASER ENERGY, if consecutive pulses of LASER ENERGY exceed twice the set value and the time period of consecutive emissions exceeds 100 ms.~~

~~d) faulty release of the WORKING BEAM.~~

~~e) failure of the cut-off of the WORKING BEAM.~~

~~Exempt from the requirements a), b) and c) are CLASS 3B LASERS for non-surgical or non-ophthalmic use within the wavelength range of 600 nm to 1 400 nm,~~

~~– emitting less than five times the MPE for the skin and not more than 50 mW average power, if by design this power cannot be exceeded, or~~

~~– not exceeding the MPE for the skin.~~

The MANUFACTURER shall address RISKS resulting from faults which may cause the following situations, taking the specific requirements of this document into account:

a) emission of excessive LASER OUTPUT;

b) faulty release of the WORKING BEAM;

c) failure of the cut-off of the WORKING BEAM;

d) hazardous laser emission into free air for CLASS 1C LASER PRODUCTS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.13.2 SINGLE FAULT CONDITIONS

Addition:

201.13.2.101 *Excessive LASER OUTPUT

~~CLASS 3B or 4 lasers shall be so designed that a single fault condition of any form does not result in an increase in accessible output greater than 50 % beyond nominal (see note), or in an unintended emission of laser radiation. An out-of-tolerance warning shall be given.~~

~~NOTE The value of 50 % may be too high for some applications such as ophthalmology and, in such cases, a smaller value may be required (e.g. 25 %).~~

Laser equipment shall be so designed that if a SINGLE FAULT CONDITION does result in an increase in accessible output, a visible and audible out-of-tolerance warning shall be given when the LASER OUTPUT exceeds the ±20 % tolerance. Then the output shall be restricted to below +50 % unless a risk assessment performed by the manufacturer indicates that a higher

percentage up to 100 % maximum is acceptable. If the LASER OUTPUT exceeds this limit the laser emission shall be terminated.

Compliance is checked by inspection of the manufacturer's technical documentation.

201.13.2.102 Failure of exposure termination

When the exposure is terminated by means of a timer, protection against SINGLE FAULT CONDITIONS shall be provided by a safety device which is independent of the timer and is activated when the set time is exceeded by 20 %. The safety device terminates the laser ~~OUTPUT~~ emission and prevents further timer-dependent operation of the equipment.

NOTE A second timer may be a means of achieving compliance with this requirement.

~~Exempt from this requirement are CLASS 3B LASERS for non-surgical or non-ophthalmic use within the wavelength range of 600 nm to 1 400 nm,~~

~~a) emitting less than five times the MPE for the skin and not more than 50 mW average power, or~~

~~b) not exceeding the MPE for the skin.~~

~~*Compliance is checked by inspection and measurements.*~~

~~This requirement and relevant tests shall not be applied to failures of:~~

~~– components which can be regarded as FAIL SAFE and which are subject to preventive maintenance;~~

~~– components of monitoring circuits which are checked during every start-up procedure of the laser equipment.~~

Exempt from the requirements 201.13.2.101 and 201.13.2.102 are

a) components which can be regarded as FAIL SAFE and which are subject to preventive maintenance;

b) components of monitoring circuits which are checked during every start-up procedure of the laser equipment;

c) CLASS 3B lasers for non-surgical or non-ophthalmic use within the wavelength range of 600 nm to 1 400 nm, emitting less than five times the MPE for the skin and not more than 50 mW average power, or not exceeding the MPE for the skin;

D) CLASS 1C laser equipment with an ENCLOSED LASER below CLASS 4.

Compliance is checked by inspection and measurements.

201.13.2.103 Failure of exposure termination after loss of GOOD CONTACT

For CLASS 1C laser equipment when the exposure is terminated upon loss of GOOD CONTACT, the signal chain towards exposure termination or its components shall be FAIL SAFE or redundant.

Compliance is checked by inspection and measurements.

201.13.2.104 Failure of critical components ~~with limited reliability~~

~~For instance, the following components shall be regarded as having a limited reliability:~~

~~– SHUTTER and/or its means of activation;~~

~~– optical attenuators including the OPERATOR PROTECTIVE FILTER and its mechanism;~~

~~– LASER EMISSION control switch~~

~~– timer for LASER EMISSION;~~

~~– components of monitoring circuits.~~

When evaluating risks, the following components shall be considered:

a) any electronic, opto-electronic and/or mechanical means which allows LASER POWER or LASER ENERGY to be emitted or prevents it from being emitted (e.g. shutter);

b) optical attenuators including the OPERATOR PROTECTIVE FILTER and their mechanisms;

c) LASER EMISSION CONTROL SWITCH;

d) components of monitoring circuits;

e) CLASS 1C laser equipment skin contact sensing interlocks;

f) in systems with exchangeable fibre optic BEAM DELIVERY SYSTEMS, the sensor for detecting the presence of the fibre optic BEAM DELIVERY SYSTEM.

Compliance is checked by inspection of the manufacturer's technical documentation and by inspection of the RISK MANAGEMENT FILE.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies~~, except as follows:~~

~~*Addition:*~~

~~**201.15.101 TARGET INDICATING DEVICE (see Annex AA, rationale to 201.10.4 f))**~~

~~Clearly visible indication of the location where the LASER OUTPUT is to have its effect shall be provided prior to emission of the WORKING BEAM.~~

~~Possible solutions include:~~

~~a) the use of a visible AIMING BEAM which shall be recognisable through the LASER protective eyewear;~~

~~b) the attachment of a pointer on the hand piece;~~

~~c) optical aiming devices;~~

~~d) contact application;~~

~~e) electronic indication, i.e. a cursor on a screen.~~

~~The point of impact indicated by the TARGET INDICATING DEVICE shall be coincident with the WORKING BEAM. The tolerances for coincidence shall be small enough so as to prevent maltreatment due to false aiming.~~

~~The AIMING BEAM and the WORKING BEAM shall be concentric within the following tolerances: at the WORKING AREA the maximum allowable lateral displacement between the centres of the~~

~~two spots shall not exceed 50 % of the diameter of the larger of the two spots. Additionally, the AIMING BEAM spot diameter shall not exceed 1,5 times the WORKING BEAM's spot diameter.~~

~~*Compliance is checked by inspection and measurement.*~~

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT AND ME SYSTEMS

Clause 17 of the general standard applies.

Annexes

The annexes of the general standard apply except as follows:

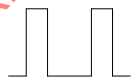
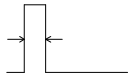
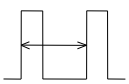
Annex D
(informative)

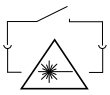
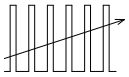
Symbols on marking

Annex D of the general standard applies, except as follows:

Table D.1 – General symbols

Additional symbols:

No.	Symbol [a]	Reference	Description
101			EMERGENCY LASER STOP
102		IEC 60417-5266 (2002-10)	STAND-BY/READY (STAND-BY)
103		IEC 60417-5264 (2002-10)	STAND-BY/READY (READY) [b]
104			Continuous operation. The laser equipment is set to a mode where the exposure duration is limited by the LASER OPERATOR actuating and releasing the footswitch
105			Single exposure. The laser equipment is set to a mode where one single exposure of a given duration is emitted when the footswitch is depressed
106			Repeat exposure. The laser equipment is set to a mode where a series of exposures of a given duration and of a given interval are emitted as long as the footswitch is depressed
107			Exposure duration
108			Repeat exposure pulse repetition time
109			Specialized pulsed mode. A pulsed mode of the laser which, for example in some CO_2 lasers, improves the capability of cutting tissue and may be used as an alternative to the continuously operating mode

No.	Symbol [a]	Reference	Description
110			AIMING BEAM
111			AIMING BEAM, blinking
112			REMOTE INTERLOCK CONNECTOR, as defined in 3.76 of IEC 60825-1:2014
113			Optical fibre applicator
114			PRF, Pulse repetition frequency [rate]

[a] The symbols either concur with the symbols contained in IEC TR 60878~~:2003~~ or are exclusive to IEC 60601-2-22. ~~The above list is not to be considered as an exclusive list.~~ Other symbols may be chosen from IEC TR 60878:2003 if appropriate.

[b] This symbol is listed in Table D.1, No 16 of IEC 60601-1:2012 as "ON" for part of the equipment. Medical laser equipment could make use of this symbol to indicate the "STAND-BY" and "READY" states.

Addition:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This document describes specific requirements for medical laser equipment to ~~prevent~~ protect the PATIENT from hazardous situation(s).

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document~~, with clause and subclause numbers parallel to those in the body of the document~~.

Subclause 201.7.2.101 b)

Medical laser equipment usually incorporates a BEAM DELIVERY SYSTEM. This may either be an articulated arm or an optical fibre, which is attached directly to the main laser cabinet. When the BEAM DELIVERY SYSTEM is regarded as a part of the protective housing, tools should be necessary for the removal of the BEAM DELIVERY SYSTEM and interlocks provided. In this case, there would not be a requirement for labelling the LASER APERTURE proximal to the BEAM DELIVERY SYSTEM. Normally additional applicators including hand pieces, micromanipulators, waveguides, scanners or the like are used, which are attached to the BEAM DELIVERY SYSTEM.

In some cases, the optical fibre itself forms an applicator, for example when it is used as a so-called "bare fibre". In the latter case, the optical fibre assumes two roles, as a protective housing and as an applicator. In this case, all the appropriate requirements should apply including the APERTURE labelling. It is possible that the APERTURE label cannot be placed at the end of the fibre, in which case the standard allows the label to be placed in a position that clearly informs the LASER OPERATOR where the WORKING BEAM emerges from the BEAM DELIVERY SYSTEM.

Laser equipment of CLASS 1C may be conceived, which consists of a remote laser source, a non-detachable BEAM DELIVERY SYSTEM and an applicator, the latter being interlocked using skin contact sensors. An APERTURE label may be placed close to the APERTURE, if APERTURE labelling is chosen.

Subclause 201.8.7.3

A hazardous ~~condition~~ situation may occur if the PROTECTIVE EARTH CONDUCTOR fails allowing the LEAKAGE CURRENT of up to 5 mA to pass through a person's body. It is therefore necessary that particular attention is devoted to the sturdiness of the ~~mains cable~~ POWER SUPPLY CORD and its connections.

Subclause 201.10.4.101 f)

This formulation covers all methods used to date. The term "AIMING LASER" has been replaced by "AIMING BEAM", as ~~cold~~ incoherent light sources are also suitable for use as the aiming light. The requirement that the aiming radiation shall also be directly or indirectly recognizable through safety eyewear is ~~absolutely essential~~ important for safety; it does, however, prove problematic for lasers where the AIMING BEAM is generated by considerable attenuation in the power of the WORKING BEAM. An AIMING BEAM may be superfluous for contact laser scalpels and may constitute a disturbing factor due to the glare effect it produces. As contact laser scalpels can be used as an alternative to non-contact procedures, the option of using the WORKING BEAM without the AIMING BEAM being switched on should also exist.

Laser equipment of CLASS 1C usually has no aiming devices incorporated.

Subclauses 201.12.4.2 and 201.12.4.4

Although continuous measurement of the LASER POWER or LASER ENERGY incident on the PATIENT would be desirable, it is not feasible in some cases as it may nullify the sterility of the hand piece or other beam delivery ACCESSORY end piece, or because suitable measuring technology is not yet available. It would therefore appear adequate to monitor the LASER POWER actually generated in the equipment. The detectors which can be used for this either only emit a relative signal due to variation from component to component (e.g. photodiodes), or they are too slow (thermal detectors). The safety of the equipment is improved if, instead of this, quantities are monitored which constitute an indirect measure of the LASER POWER generated, and which can be quickly and easily measured. Such quantities are, for example, the discharge current or lamp current. With the use of a digital control system, continuous or rapidly repeated monitoring means that the measured quantity is read at regular intervals. This repeat cycle time must be shorter than the time period within which a laser working defectively at full power can cause a dangerous tissue effect (e.g. perforation of a vital structure). This is the failure tolerance time of the system.

Maladjustment or damage to the BEAM DELIVERY SYSTEM can lead to considerable deviations of the LASER POWER incident on the PATIENT from the LASER POWER actually generated. It is therefore imperative that the LASER OUTPUT actually emitted to tissue is checked by means of a calibrated LASER POWER or LASER ENERGY meter during regular inspections of the laser equipment. The laser equipment should allow the LASER OPERATOR to check the delivered LASER OUTPUT at any time, using additional equipment if necessary. Attention should be drawn to this requirement in the ACCOMPANYING DOCUMENTS. See 201.10.4.102

Laser equipment of CLASS 1C incorporates an interlock system. The purpose of the interlock system is to ensure that laser emission from the ENCLOSED LASER source into free air cannot exceed the AEL of Class 1. The practical problems which are to be addressed by the design of the guards and the control software are associated with the tissue contour, surface properties including topical agents and movement of the applicator relative to the tissue target. In addition, the sensing system has intrinsic time delays to react for both, opening and closing functions. An optimum level of sensitivity is desirable in order to be not too restrictive, consistent with the intended function, and to be restrictive enough to provide the safety, by avoiding errant reflected or strayed light.

Although not required, skin colour sensing devices may be incorporated. Their purpose is to automatically adapt the LASER OUTPUT to the absorption properties of the target tissue.

Subclause 201.12.4.4.102

Spectral impurities may be present in the pump source wavelength being transmitted or the original wavelength in frequency-multiplied lasers. Hazards for the eye which are due to the use of inappropriate protective eyewear that does not protect against the radiation at the other contained wavelengths may be overlooked.

Wavelength shifts may alter the biological effect of the treatment, e.g. if the nominal wavelength is chosen to match a particular absorption peak.

Subclause 201.13.2.101

Risks caused by unexpected increase of the LASER OUTPUT will vary according to the wavelength, output level and target tissue type and sensitivity. The mode of operation, including Q-switched pulses, the delivery system and the operator oversight may also influence the level of risk.

Bibliography

The Bibliography of the general standard applies, except as follows:

Addition:

~~IEC 60664-3:2003, *Insulation coordination for equipment within low-voltage systems – Part 3: Use of coating, potting or moulding for protection against pollution*~~

IEC TR 60825-14:2004, *Safety of laser products – Part 14: A user's guide*

IEC 60335-2-113:2016, *Household and similar electrical appliances – Safety – Part 2-113: Particular requirements for cosmetic and beauty care appliances incorporating lasers and intense light sources*

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

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

IEC TR 60878, *Graphical symbols for electrical equipment in medical practice*

Index of defined terms[2] used in this document

[2] Defined terms which appear in the titles of clauses or subclauses of this document and which originate from the general standard, are not necessarily included in this index

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)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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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;

k) a statement, saying that laser equipment should be protected against unauthorized use, for example by removal of the key from the key switch;

l) a specification for eye protection; not required for laser equipment of CLASS 1C;

NOTE 2 Refer to 8.4.5.2 of IEC TR 60825-14:2004, Safety of LASER PRODUCTS – Part 14: A user's guide.

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

n) 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 BEAM DELIVERY SYSTEM and/or harm to the PATIENT or LASER OPERATOR;

o) instructions for checking the integrity of the BEAM DELIVERY SYSTEM, for example as follows: "As the AIMING BEAM passes down the same delivery system as the WORKING BEAM, it provides a good means of checking the integrity of the delivery system. If the AIMING BEAM is not present at the distal end of the BEAM DELIVERY SYSTEM, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or malfunctioning BEAM DELIVERY SYSTEM";

p) information on non-laser HAZARDS, for example as follows: "A risk of fire and/or explosion exists when the LASER OUTPUT is used in the presence of flammable materials, solutions or gases, or in an oxygen enriched environment". The temperatures produced in NORMAL USE of the laser equipment may ignite some materials, for example cotton wool when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases;

q) information on safe procedures which ensure a minimum of acceptable side effects to the PATIENTS, including a list of counter-indications and including a list of all conditions which would render the balance of the expected success of treatment and the non-avoidable side-effects non-acceptable;

r) information on separate equipment which would be useful to assess the favourable conditions which are acceptable for treatment or to assess the unfavourable conditions which would render a treatment unacceptable or HAZARDOUS;

s) checklists and forms which help the user collect the information necessary to assess the favourable conditions of treatment;

t) information about the applicable national regulations, e.g. on professional cosmetic applications of laser equipment;

u) description of procedures to ensure that sterile ACCESSORIES remain sterile;

v) information about ACCESSORIES such as fibre-optics which are compatible with the laser equipment;

w) if the laser equipment is installed with or connected to other medical devices or equipment to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination shall be provided;

x) if the ACCESSORY to the laser equipment is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any restriction on the number of reuses shall be provided. Where ACCESSORIES are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization shall be such that, if correctly followed, the ACCESSORY will still comply with the requirements of this document;

y) if the ACCESSORY bears an indication that the ACCESSORY is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used shall be provided. If no instructions for use are needed, the information shall be made available to the user upon request. The possibility of this request and provisions for obtaining the requested information shall be described;

z) details of any further treatment or handling needed before the ACCESSORY can be used (for example sterilization, final assembly, etc.);

aa) precautions to be taken in the event of changes in the performance of the laser equipment;

bb) precautions to be taken, as regards malfunction of laser equipment due to exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;

cc) degree of accuracy claimed for ACCESSORIES with a measuring function, such as skin colour detectors or detectors of laser-induced fluorescence or frequency shifted scattered radiation, etc.;

dd) understandable explanation of symbols, controls, instructions, operating or adjustment parameters when required for the operation of the laser equipment.

NOTE 3 If the laser equipment is intended to be used by non-medical professionals, e.g. cosmetic or beauty-care practitioners, they may need information which is additional to the information required in 201.7.9.2.101.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies except as follows:

201.8.5 Separation of parts

Amendment:

If an OEM (Original Equipment Manufacturer) laser and/or OEM power supply is incorporated into the laser equipment and the OEM product complies with IEC 61010-1, then the OEM product is exempt from the differing requirements of the general standard. This exemption applies to the requirements of 8.6, 8.8 and 8.9 for MEANS OF OPERATOR PROTECTION. MEANS OF PATIENT PROTECTION are not exempt.

201.8.7 LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS

This subclause of the general standard applies except as follows:

201.8.7.3 *Allowable values

Addition:

Laser equipment is considered as PERMANENTLY INSTALLED equipment if

- it is connected to the SUPPLY MAINS by means of a MAINS PLUG which is mechanically secured against unintentional loosening,
- the POWER SUPPLY CORD is non-detachable, and
- the cross-sectional area of the POWER SUPPLY CORD conductors is not less than 2,5 mm^2.

NOTE Mechanically securing the MAINS PLUG is considered equally safe as using a tool for disconnecting.

Compliance is checked by inspection.

201.8.10 Components and wiring

This subclause of the general standard applies except as follows:

201.8.10.4 Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

Addition:

201.8.10.4.101 Footswitch

Any foot-operated LASER EMISSION CONTROL SWITCH shall be shrouded to prevent unintentional operation. The force required to actuate the switch shall be not less than 10 N, applied over an area of 625 mm^2 anywhere on the operating surface of the footswitch. This force shall not exceed 50 N.

This requirement also applies to wirelessly connected footswitches.

Compliance is checked by measurement of the actuating force.

201.8.11 MAINS PARTS, components and layout

Addition:

201.8.11.101 Use of water for cooling

Where liquid is used in laser equipment for cooling and where the liquid assumes the task of BASIC INSULATION to SUPPLY MAINS, the conductivity of the liquid shall be such that the allowable value of the LEAKAGE CURRENT required in 8.7 of the general standard is not exceeded in NORMAL USE. The conductivity of the liquid shall be continuously monitored by the laser equipment. In case of LEAKAGE CURRENT exceeding the values required in 8.7 of the general standard as a result of increased liquid conductivity, the laser equipment shall be switched off automatically from the SUPPLY MAINS.

Compliance is checked by inspection and functional tests.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

201.10.4 Lasers

Amendment:

Where the general standard refers to IEC 60825-1:2007, IEC 60825-1:2014 shall apply instead.

Amendment:

Add "CLASS 1C" to the listing of the laser classes in the text of the NOTE in 10.4 of the general standard.

Addition:

201.10.4.101 General requirements

NOTE In the context of this document, "light" radiation is understood to cover optical radiation as specified in IEC 60825-1:2014.

The laser equipment shall incorporate:

a) REMOTE INTERLOCK CONNECTOR as described in 6.4 of IEC 60825-1:2014

This requirement does not apply to

– battery-powered hand-held medical laser equipment

– CLASS 1C laser equipment

b) Key control as described in 6.6 of IEC 60825-1:2014

c) Viewing optics as described in 6.10 of IEC 60825-1:2014

d) LASER READY INDICATOR

Laser equipment shall incorporate a visible LASER READY INDICATOR, which shall be illuminated when emission of the WORKING BEAM is possible upon actuation of the control switch, i.e. the laser equipment is in the READY mode.

e) LASER EMISSION INDICATOR

Laser equipment of CLASS 3B and 4, and laser equipment of CLASS 1C incorporating an ENCLOSED LASER of CLASS 3B or 4 shall be equipped with a visible or an audible signal, which clearly indicates that emission of laser radiation in excess of the AEL for CLASS 3R is taking place.

Both the LASER READY INDICATOR and the LASER EMISSION INDICATOR, if visible, shall be visible through the laser protective eyewear as specified in the instructions for use, see 201.7.9.2.101.

Provided that one of the LASER EMISSION INDICATORS is clearly visible or audible to the persons in the vicinity of the operational control or laser APERTURE, the 2 m distance requirement in 4.7.3 of IEC 60825-1:2014 is not applicable.

The LASER EMISSION INDICATOR shall be recognizable by the LASER OPERATOR and by the personnel involved in the laser procedure.

The LASER EMISSION INDICATOR shall be FAIL SAFE or redundant.

NOTE An AIMING BEAM is not considered to be a LASER EMISSION INDICATOR.

f) *TARGET INDICATING DEVICE

The location where the LASER OUTPUT is to have its effect shall be indicated. Indication shall be prior to emission of the WORKING BEAM.

Possible solutions include:

1) the use of a visible AIMING BEAM;

2) the attachment of a pointer on the hand piece;

3) optical aiming devices;

4) contact application;

5) electronic indication, such as a cursor on a screen.

If the TARGET INDICATING DEVICE is a light beam, the point of impact indicated by the TARGET INDICATING DEVICE shall be concentric with the WORKING BEAM within the following tolerance: The lateral offset of the centres of the two beams shall be less than 50 % of the diameter of the WORKING BEAM. Additionally, the diameter of the AIMING LASER beam shall not be larger than twice the diameter of the working laser beam. For the definition of beam diameter see 3.13 of IEC 60825-1:2014.

If the TARGET INDICATING DEVICE is an electronic indication, its centre shall not deviate from the centre of the WORKING BEAM by more than 50 % of the diameter of the WORKING BEAM.

If a visible AIMING BEAM is chosen, its spot shall be recognizable through the laser protective eyewear, which is specified in the instructions for use, refer to 201.7.9.2.101.

If the TARGET INDICATING DEVICE is in the form of an AIMING BEAM which is emitted from the LASER APERTURE and is generated by an AIMING LASER or by an attenuated WORKING BEAM, it shall not exceed the AEL for CLASS 3R with the following exception:

For an ophthalmic AIMING LASER, the AIMING BEAM shall not exceed the AEL for CLASS 2 without a deliberate and positive action by the LASER OPERATOR.

The TARGET INDICATING DEVICE is not required for CLASS 1C laser equipment.

g) STAND-BY/READY control

Laser equipment shall be equipped with a STAND-BY/READY device. This device shall be capable of disabling the WORKING BEAM. Upon initial switching the LASER PRODUCT to SUPPLY MAINS it shall by default enter the STAND-BY mode.

Transition from STAND-BY to READY shall not be possible when the LASER EMISSION CONTROL SWITCH is activated.

NOTE The beam stop according to 6.8 of IEC 60825-1:2014 is replaced by the requirement for a STAND-BY/READY device.

h) ENCLOSURES

The following requirements of IEC 60825-1:2014 shall apply:

– 6.2. Protective housing – 6.2.1 General;
– 6.2. Protective housing – 6.2.2 Service;
– 6.3 Access panels and safety interlocks.

i) Limits on LASER OUTPUT

The LASER OUTPUT shall be limited to the amount which is necessary for the laser equipment to enable its intended medical, surgical or diagnostic functions. The considerations about the limits of LASER OUTPUT shall be included in the RISK MANAGEMENT process as described in 4.2 of IEC 60601-1:2005/AMD1:2012.

Compliance is checked by measurement, inspection of the device and inspection of the RISK MANAGEMENT FILE.

201.10.4.102 Interlock system of laser equipment of CLASS 1C

A CLASS 1C LASER PRODUCT incorporating an ENCLOSED LASER of CLASS 3B or 4 shall be equipped with an interlock system which is capable of detecting whether GOOD CONTACT with the biological skin tissue is established.

If continuous action by the user is necessary to maintain the enabled status (for example an activation button is continuously depressed) the laser shall keep emitting, unless GOOD CONTACT with the skin is lost. While this continuous action is maintained by the user, any loss of GOOD CONTACT shall be detected by the interlock system and the laser emission shall shut off.

The time interval between loss of GOOD CONTACT with the skin and disabling the triggering of laser emission shall not exceed 0,1 s provided that the requirement for CLASS 1C is met.

The emission may resume automatically if GOOD CONTACT is re-established within a maximum of 10 s. When the loss of GOOD CONTACT exceeds 10 s the laser equipment shall require active retriggering by the user in order to resume emission.

If the interlock system contains a programmable electronic circuit the software shall incorporate measures to control the fault/error conditions specified in 201.13.2, as far as applicable to CLASS 1C laser equipment.

Refer to Clause 14 of the general standard, Programmable eletrical medical systems (PEMS).

NOTE If the laser radiation is coupled into the skin by frustrated internal total reflection due to the match of the refractive indices of the transmitting medium and the skin, and the contact sensors rely on the effect of internal total reflection, this device may not be safe since index matching also takes place when gel or other index matching substance sticks to the output window, allowing emission into free air to take place.

Compliance is checked by the following tests.

The function of the interlock system shall be tested with a cylindrical test specimen, designed to simulate human skin, with the following properties:

– *a cylindrical rod with an outer diameter exceeding the maximal dimension of the applicator footprint by 40 mm and having a smooth surface, made of a flexible material with a Shore hardness not exceeding 25;*

– *the material shall simulate the optical properties of the skin with regard to absorption, reflection and scattering, in order to assess the STRAY OPTICAL RADIATION;*

– *the surface of the artificial skin used for detecting the skin contact is modified in turn as follows:*

  - *dry skin is simulated using the artificial skin without any modification;*
  - *the presence of dried sweat is simulated by using a 0,9 g/l saline solution on the artificial skin surface, that is then air dried;*
  - *the presence of sebum is simulated by using petroleum jelly on the artificial skin surface.*

For laser equipment using an auxiliary material such as a gel as specified in the instructions as the contact means for NORMAL OPERATION, the test shall be performed with and without this material.

The reaction time of the interlock system is tested by placing the output window of the laser equipment applicator on the test specimen, subsequently removing the applicator from the test specimen and the emission of laser radiation shall cease within a time interval of 0,1 s.

The output window of the laser equipment applicator shall be placed on the test specimen and rotated, tilted and raised to test whether the sensors in the interlock system correctly detect GOOD CONTACT with the test specimen.

If STRAY OPTICAL RADIATION from the target skin occurs it shall be measured by placing the applicator in contact with the test specimen at varying positions of orientation. The emission level shall not exceed the AEL of Class 1 as specified in IEC 60825-1:2014 for a maximum emission duration of 10 s, unless the laser equipment is limited to a shorter emission duration.

If compliance with the requirement of 201.10.4.102 relies on the operation of an electronic circuit, the laser equipment is further tested as described in 201.13.1.101 and 201.13.2.102.

201.10.4.103 Laser radiation filter in viewing optics

If the laser equipment incorporates viewing optics such as operating microscopes or endoscopes and the viewing optics transmit radiation from the working laser, the viewing optics shall be equipped with an OPERATOR PROTECTIVE FILTER.

The OPERATOR PROTECTIVE FILTER shall be in place during the time intervals when the working laser is emitting.

The OPERATOR PROTECTIVE FILTER shall not allow radiation of the working laser being transmitted through the eyepiece to exceed the MPE.

The function of the TARGET INDICATING DEVICE shall not be compromised.

ME EQUIPMENT is exempt from these requirements when projectors or monitors are used for viewing.

Compliance is checked by inspection of the equipment, and by measurement or inspection of the filter specifications.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.8 Interruption of the power supply /SUPPLY MAINS to ME EQUIPMENT

Addition:

201.11.8.101 Interruption of emission

CLASS 4 laser equipment shall be provided with a manual reset to enable resumption of laser radiation emission after interruption of emission caused by the use of a remote interlock on CLASS 4 laser equipment or caused by the unexpected loss of SUPPLY MAINS.

NOTE This manual reset could be removal of the foot from the footswitch and placing it back on again.

201.12 Accuracy of controls and instruments and protection against HAZARDOUS OUTPUTS

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 Indication of LASER OUTPUT

Laser equipment shall incorporate a means for the indication of the pre-set level of the output of the WORKING BEAM.

The indication shall be in SI units.

The actual LASER OUTPUT measured in the WORKING AREA shall not deviate from the pre-set level of output by more than ±20 %.

If the LASER OUTPUT is fixed by the manufacturer and is not adjustable the fixed LASER OUTPUT shall be stated by labelling.

The actual PULSE DURATION shall not deviate from the PULSE DURATION specified by the manufacturer or set by the operator, by more than ±20%. The PULSE DURATION is defined in 3.69 of IEC 60825-1:2014.

Compliance is checked by inspection and measurements.

201.12.4 Protection against HAZARDOUS output

This subclause of the general standard applies, except as follows:

201.12.4.2 *Indication relevant to safety

Addition:

The LASER OUTPUT emitted by the laser equipment shall not deviate from the pre-set level of output by more than ±20 %. A quantity, electrical or optical, which is directly related to the LASER OUTPUT generated shall be monitored during operation. The monitoring shall be carried out at intervals shorter than the failure tolerance time.

Typical solutions are:

- closed-loop system;

- open-loop system with a visible and audible out-of-tolerance warning.

Compliance is checked by the following test:

During use under NORMAL CONDITIONS, as well as under any reasonably foreseeable SINGLE FAULT CONDITION, the LASER OUTPUT is checked to be within the allowed tolerance or the required warning is given otherwise.

The calibration of the system is to be checked at regular intervals against the LASER POWER (or LASER ENERGY) actually incident on the WORKING AREA. An appropriate method shall be described in the instructions for use in accordance with 201.7.9.2.101 f).

Check the instructions for use and the procedure of calibration for compliance.

201.12.4.4 *Incorrect output

Addition:

201.12.4.4.101 EMERGENCY LASER STOP

The EMERGENCY LASER STOP shall stop the emission of LASER OUTPUT as fast as possible to prevent a situation where there is an unacceptable risk to any person. The EMERGENCY LASER STOP shall be designed so as to be independent of all other laser control systems. The switch shall be a red push-button and be located in such a manner as to be readily visible and easily and quickly reached by the LASER OPERATOR from the operating position. "Laser Stop" or the symbol according to Table D.1, symbol 101, shall be marked on or near the push-button.

If an emergency stop as specified in IEC 60947-3 is incorporated in the laser equipment, the EMERGENCY LASER STOP is not required.

CLASS 3B lasers for non-surgical or non-ophthalmic use within the wavelength range of 600 nm to 1 400 nm,

a) emitting less than five times the MPE for the skin and not more than 50 mW average power, or
b) not exceeding the MPE for the skin,

and CLASS 1C laser equipment are exempt from this requirement.

Compliance is checked by inspection and measurements.

201.12.4.4.102 *Spectral impurities

The manufacturer shall address in the RISK MANAGEMENT process the risks associated with spectral impurities of the LASER OUTPUT, such as wavelength shift due to the change of physical parameters, setting of output, temperature and degradation effects.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.1 Specific HAZARDOUS SITUATIONS

Addition:

201.13.1.101 Specific laser considerations

The MANUFACTURER shall address RISKS resulting from faults which may cause the following situations, taking the specific requirements of this document into account:

a) emission of excessive LASER OUTPUT;

b) faulty release of the WORKING BEAM;

c) failure of the cut-off of the WORKING BEAM;

d) hazardous laser emission into free air for CLASS 1C LASER PRODUCTS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.13.2 SINGLE FAULT CONDITIONS

Addition:

201.13.2.101 *Excessive LASER OUTPUT

Laser equipment shall be so designed that if a SINGLE FAULT CONDITION does result in an increase in accessible output, a visible and audible out-of-tolerance warning shall be given when the LASER OUTPUT exceeds the ±20 % tolerance. Then the output shall be restricted to below +50 % unless a risk assessment performed by the manufacturer indicates that a higher percentage up to 100 % maximum is acceptable. If the LASER OUTPUT exceeds this limit the laser emission shall be terminated.

Compliance is checked by inspection of the manufacturer's technical documentation.

201.13.2.102 Failure of exposure termination

When the exposure is terminated by means of a timer, protection against SINGLE FAULT CONDITIONS shall be provided by a safety device which is independent of the timer and is activated when the set time is exceeded by 20 %. The safety device terminates the laser emission and prevents further timer-dependent operation of the equipment.

NOTE A second timer may be a means of achieving compliance with this requirement.

Exempt from the requirements 201.13.2.101 and 201.13.2.102 are

a) components which can be regarded as FAIL SAFE and which are subject to preventive maintenance;

b) components of monitoring circuits which are checked during every start-up procedure of the laser equipment;

c) CLASS 3B lasers for non-surgical or non-ophthalmic use within the wavelength range of 600 nm to 1 400 nm, emitting less than five times the MPE for the skin and not more than 50 mW average power, or not exceeding the MPE for the skin;

d) CLASS 1C laser equipment with an ENCLOSED LASER below CLASS 4.

Compliance is checked by inspection and measurements.

201.13.2.103 Failure of exposure termination after loss of GOOD CONTACT

For CLASS 1C laser equipment when the exposure is terminated upon loss of GOOD CONTACT, the signal chain towards exposure termination or its components shall be FAIL SAFE or redundant.

Compliance is checked by inspection and measurements.

201.13.2.104 Failure of critical components

When evaluating risks, the following components shall be considered:

a) any electronic, opto-electronic and/or mechanical means which allows LASER POWER or LASER ENERGY to be emitted or prevents it from being emitted (e.g. shutter);

b) optical attenuators including the OPERATOR PROTECTIVE FILTER and their mechanisms;

c) LASER EMISSION CONTROL SWITCH;

d) components of monitoring circuits;

e) CLASS 1C laser equipment skin contact sensing interlocks;

f) in systems with exchangeable fibre optic BEAM DELIVERY SYSTEMS, the sensor for detecting the presence of the fibre optic BEAM DELIVERY SYSTEM.

Compliance is checked by inspection of the manufacturer's technical documentation and by inspection of the RISK MANAGEMENT FILE.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT AND ME SYSTEMS

Clause 17 of the general standard applies.

Annexes

The annexes of the general standard apply except as follows:

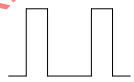
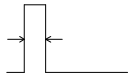
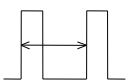
Annex D
(informative)

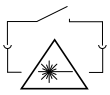
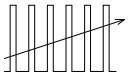
Symbols on marking

Annex D of the general standard applies, except as follows:

Table D.1 – General symbols

Additional symbols:

No.	Symbol [a]	Reference	Description
101			EMERGENCY LASER STOP
102		IEC 60417-5266 (2002-10)	STAND-BY/READY (STAND-BY)
103		IEC 60417-5264 (2002-10)	STAND-BY/READY (READY) [b]
104			Continuous operation. The laser equipment is set to a mode where the exposure duration is limited by the LASER OPERATOR actuating and releasing the footswitch
105			Single exposure. The laser equipment is set to a mode where one single exposure of a given duration is emitted when the footswitch is depressed
106			Repeat exposure. The laser equipment is set to a mode where a series of exposures of a given duration and of a given interval are emitted as long as the footswitch is depressed
107			Exposure duration
108			Repeat exposure pulse repetition time
109			Specialized pulsed mode. A pulsed mode of the laser which, for example in some CO_2 lasers, improves the capability of cutting tissue and may be used as an alternative to the continuously operating mode

No.	Symbol [a]	Reference	Description
110			AIMING BEAM
111			AIMING BEAM, blinking
112			REMOTE INTERLOCK CONNECTOR, as defined in 3.76 of IEC 60825-1:2014
113			Optical fibre applicator
114			PRF, Pulse repetition frequency [rate]

[a] The symbols either concur with the symbols contained in IEC TR 60878 or are exclusive to IEC 60601-2-22. Other symbols may be chosen from IEC TR 60878:2003 if appropriate.

[b] This symbol is listed in Table D.1, No 16 of IEC 60601-1:2012 as “ON” for part of the equipment. Medical laser equipment could make use of this symbol to indicate the “STAND-BY” and “READY” states.

Addition:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This document describes specific requirements for medical laser equipment to protect the PATIENT from hazardous situation(s).

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document.

Subclause 201.7.2.101 b)

Medical laser equipment usually incorporates a BEAM DELIVERY SYSTEM. This may either be an articulated arm or an optical fibre, which is attached directly to the main laser cabinet. When the BEAM DELIVERY SYSTEM is regarded as a part of the protective housing, tools should be necessary for the removal of the BEAM DELIVERY SYSTEM and interlocks provided. In this case, there would not be a requirement for labelling the LASER APERTURE proximal to the BEAM DELIVERY SYSTEM. Normally additional applicators including hand pieces, micromanipulators, waveguides, scanners or the like are used, which are attached to the BEAM DELIVERY SYSTEM. In some cases, the optical fibre itself forms an applicator, for example when it is used as a so-called "bare fibre". In the latter case, the optical fibre assumes two roles, as a protective housing and as an applicator. In this case, all the appropriate requirements should apply including the APERTURE labelling. It is possible that the APERTURE label cannot be placed at the end of the fibre, in which case the standard allows the label to be placed in a position that clearly informs the LASER OPERATOR where the WORKING BEAM emerges from the BEAM DELIVERY SYSTEM.

Laser equipment of CLASS 1C may be conceived, which consists of a remote laser source, a non-detachable BEAM DELIVERY SYSTEM and an applicator, the latter being interlocked using skin contact sensors. An APERTURE label may be placed close to the APERTURE, if APERTURE labelling is chosen.

Subclause 201.8.7.3

A hazardous situation may occur if the PROTECTIVE EARTH CONDUCTOR fails allowing the LEAKAGE CURRENT of up to 5 mA to pass through a person's body. It is therefore necessary that particular attention is devoted to the sturdiness of the POWER SUPPLY CORD and its connections.

Subclause 201.10.4.101 f)

This formulation covers all methods used to date. The term "AIMING LASER" has been replaced by "AIMING BEAM", as incoherent light sources are also suitable for use as the aiming light. The requirement that the aiming radiation shall also be directly or indirectly recognizable through safety eyewear is important for safety; it does, however, prove problematic for lasers where the AIMING BEAM is generated by considerable attenuation in the power of the WORKING BEAM. An AIMING BEAM may be superfluous for contact laser scalpels and may constitute a disturbing factor due to the glare effect it produces. As contact laser scalpels can be used as an alternative to non-contact procedures, the option of using the WORKING BEAM without the AIMING BEAM being switched on should also exist.

Laser equipment of CLASS 1C usually has no aiming devices incorporated.

Subclauses 201.12.4.2 and 201.12.4.4

Although continuous measurement of the LASER POWER or LASER ENERGY incident on the PATIENT would be desirable, it is not feasible in some cases as it may nullify the sterility of the hand piece or other beam delivery ACCESSORY end piece, or because suitable measuring technology is not yet available. It would therefore appear adequate to monitor the LASER POWER actually generated in the equipment. The detectors which can be used for this either only emit a relative signal due to variation from component to component (e.g. photodiodes), or they are too slow (thermal detectors). The safety of the equipment is improved if, instead of this, quantities are monitored which constitute an indirect measure of the LASER POWER generated, and which can be quickly and easily measured. Such quantities are, for example, the discharge current or lamp current. With the use of a digital control system, continuous or rapidly repeated monitoring means that the measured quantity is read at regular intervals. This repeat cycle time must be shorter than the time period within which a laser working defectively at full power can cause a dangerous tissue effect (e.g. perforation of a vital structure). This is the failure tolerance time of the system.

Maladjustment or damage to the BEAM DELIVERY SYSTEM can lead to considerable deviations of the LASER POWER incident on the PATIENT from the LASER POWER actually generated. It is therefore imperative that the LASER OUTPUT actually emitted to tissue is checked by means of a calibrated LASER POWER or LASER ENERGY meter during regular inspections of the laser equipment. The laser equipment should allow the LASER OPERATOR to check the delivered LASER OUTPUT at any time, using additional equipment if necessary. Attention should be drawn to this requirement in the ACCOMPANYING DOCUMENTS. See 201.10.4.102

Laser equipment of CLASS 1C incorporates an interlock system. The purpose of the interlock system is to ensure that laser emission from the ENCLOSED LASER source into free air cannot exceed the AEL of Class 1. The practical problems which are to be addressed by the design of the guards and the control software are associated with the tissue contour, surface properties including topical agents and movement of the applicator relative to the tissue target. In addition, the sensing system has intrinsic time delays to react for both, opening and closing functions. An optimum level of sensitivity is desirable in order to be not too restrictive, consistent with the intended function, and to be restrictive enough to provide the safety, by avoiding errant reflected or strayed light.

Although not required, skin colour sensing devices may be incorporated. Their purpose is to automatically adapt the LASER OUTPUT to the absorption properties of the target tissue.

Subclause 201.12.4.4.102

Spectral impurities may be present in the pump source wavelength being transmitted or the original wavelength in frequency-multiplied lasers. Hazards for the eye which are due to the use of inappropriate protective eyewear that does not protect against the radiation at the other contained wavelengths may be overlooked.

Wavelength shifts may alter the biological effect of the treatment, e.g. if the nominal wavelength is chosen to match a particular absorption peak.

Subclause 201.13.2.101

Risks caused by unexpected increase of the LASER OUTPUT will vary according to the wavelength, output level and target tissue type and sensitivity. The mode of operation, including Q-switched pulses, the delivery system and the operator oversight may also influence the level of risk.

Bibliography

The Bibliography of the general standard applies, except as follows:

Addition:

IEC TR 60825-14:2004, *Safety of laser products – Part 14: A user's guide*

IEC 60335-2-113:2016, *Household and similar electrical appliances – Safety – Part 2-113: Particular requirements for cosmetic and beauty care appliances incorporating lasers and intense light sources*

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

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

IEC TR 60878, *Graphical symbols for electrical equipment in medical practice*

Index of defined terms[2] used in this document

2 Defined terms which appear in the titles of clauses or subclauses of this document and which originate from the general standard, are not necessarily included in this index

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ELECTROMEDICAUX –

Partie 2-22: Exigences particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser

AVANT-PROPOS

1) La Commission Electrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. A cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

La Norme internationale IEC 60601-2-22 a été établie par le sous-comité 76 de l'IEC: Sécurité des rayonnements optiques et matériels laser.

Cette quatrième édition annule et remplace la troisième édition parue en 2007 et l'Amendement 1:2012. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) elle prend en compte l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60825-1:2014, qui ont été publiés depuis la publication de la troisième édition;

b) elle traite des questions techniques et de sécurité soulevées depuis la publication de la troisième édition;

c) le domaine d'application de cette quatrième édition diffère de celui de la troisième édition. Il inclut désormais les appareils à laser de CLASSE 1C, tels que définis dans l'IEC 60825-1:2014, alors que le LASER ENFERME est un laser de CLASSE 3B ou 4;

d) Les appareils à LED (diode électroluminescente) sont à présent exclus du présent document étant donné que les appareils médicaux à LED peuvent être couverts par l'IEC 60601-2-57.

Le texte de cette Norme internationale est issu des documents suivants:

CDV	Rapport de vote
76/580/CDV	76/610/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

- exigences et définitions: caractères romains;
- *modalités d'essais: caractères italiques*;
- les indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères.
- LES TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DE LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme:

- "article" désigne l'une des dix-sept sections numérotées dans le sommaire, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
- "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans le présent document, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2:2018. Pour les besoins du présent document:

- "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité au présent document;
- "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité au présent document;
- "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Une liste de toutes les parties de la série IEC 60601 et IEC 80601, publiées sous le titre général: Appareils électromédicaux, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. A cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

INTRODUCTION

Le présent document modifie et complète l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielle*s.

Le présent document fait également référence à l'IEC 60825-1:2014. Les exigences du présent document sont considérées comme les exigences minimales permettant d'obtenir un niveau raisonnable de sécurité et de fiabilité d'un appareil médical à laser pendant son fonctionnement et son application.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, au début d'un titre d'alinéa ou de tableau, il indique l'existence de recommandations ou d'une justification à consulter à l'Annexe AA. La connaissance des raisons qui ont conduit à ces exigences facilitera non seulement l'application correcte du présent document, mais accélérera, en temps voulu, toute révision rendue nécessaire par des changements dans la pratique clinique ou par suite des développements technologiques.

APPAREILS ELECTROMEDICAUX –

Partie 2-22: Exigences particulières pour la sécurité de base et les performances essentielles des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale[1] s'applique, avec les exceptions suivantes:

201.1.1 Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des appareils à laser pour applications chirurgicales, thérapeutiques, de diagnostic médical, esthétiques ou vétérinaires destinés à être utilisés sur les personnes ou les animaux; ils sont classés comme APPAREILS A LASER DE CLASSE 1C, le LASER ENFERME étant de CLASSE 3B ou 4, ou de CLASSE 3B, ou de CLASSE 4.

LES APPAREILS ELECTROMEDICAUX ou les SYSTEMES ELECTROMEDICAUX intégrant des lasers comme sources d'énergie transférées au PATIENT ou à l'animal, les lasers étant conformes aux spécifications ci-dessus, sont désignés par le terme "appareils à laser" dans le présent document.

NOTE 1 Les APPAREILS A LASER pour ces applications, classés APPAREILS A LASER de Classe 1, Classe 1M, CLASSE 2, Classe 2M ou CLASSE 3R, sont couverts par l'IEC 60825-1:2014 et par la norme générale.

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des appareils à laser dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document à l'exception de 7.2.13, Effets physiologiques, de la norme générale.

NOTE 2 Voir également 4.2, Processus de GESTION DES RISQUES, de la norme générale.

NOTE 3 Si les appareils à laser sont de la CLASSE 1C selon l'IEC 60825-1:2014 et sont utilisés en tant qu'appareil à laser pour un usage domestique, ils sont couverts par l'IEC 60335-2-113:2016.

201.1.2 Objet

Remplacement:

L'objet du présent document est d'établir les exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des appareils chirurgicaux, esthétiques, thérapeutiques et de diagnostic à laser.

[1] Dans le présent document, "la norme générale" signifie l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012.

201.1.3 Normes collatérales

Addition:

Le présent document fait référence aux normes collatérales applicables qui sont données à l'Article 2 de la norme générale et l'Article 201.2 du présent document.

201.1.4 Normes particulières

Addition:

Pour plus de concision, l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012 sont désignées dans le présent document par "norme générale". Les normes collatérales sont citées par leur numéro de document.

La numérotation des sections, articles et paragraphes du présent document correspond à celle de la norme générale ou à celle de la norme collatérale applicable. Les modifications apportées au texte de la norme générale sont précisées en utilisant les termes suivants:

"Remplacement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé en totalité par le texte du présent document.

"Addition" signifie que le texte du présent document est un complément aux exigences de la norme générale ou de la norme collatérale applicable.

"Amendement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué par le texte du présent document.

Les paragraphes ou figures ajoutés à la norme générale sont numérotés à partir de 201.101, les annexes complémentaires notées AA, BB, etc., et les points complémentaires aa), bb), etc.

Les paragraphes ou figures ajoutés à la norme collatérale sont numérotés à partir de 20x, où "x" est le numéro de la norme collatérale, par exemple, 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à la norme générale, à toute norme collatérale applicable et au présent document considérés ensemble.

Si le présent document ne comprend pas de section, d'article ou de paragraphe correspondant, la section, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification; lorsqu'il est prévu qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien qu'éventuellement pertinente, ne s'applique pas, cela est expressément mentionné dans le présent document.

En ce qui concerne la sécurité du rayonnement laser des appareils à laser, l'IEC 60825-1:2014 s'applique, sauf pour les exigences appropriées qui sont spécifiées, modifiées ou corrigées dans le présent document.

201.2 Références normatives

L'Article 2 de la norme générale s'applique, avec l'exception suivante:

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012

IEC 60825-1:2014, *Sécurité des appareils à laser – Partie 1: Classification des matériels et exigences*

201.3 Termes et définitions

L'Article 3 de la norme générale s'applique, avec les exceptions suivantes:

Addition:

201.3.201
LEA
LIMITE D'EMISSION ACCESSIBLE
émission maximale accessible permise dans une CLASSE particulière où l'émission accessible est le niveau de rayonnement déterminé en un point et avec des diaphragmes (lorsque la LEA est donnée en watts ou en joules) ou des OUVERTURES délimitantes (lorsque la LEA est donnée en $W \cdot m^{-2}$ ou en $J \cdot m^{-2}$)

[SOURCE: IEC 60825-1:2014, 3.2 et 3.3, modifié – Les deux définitions ont été combinées en une.]

201.3.202
FAISCEAU DE VISEE
faisceau de rayonnement optique, produisant un repère visible, qui doit indiquer le point d'impact prévu du FAISCEAU DE TRAVAIL

201.3.203
LASER DE VISEE
laser émettant un FAISCEAU DE VISEE

201.3.204
OUVERTURE
orifice du SYSTEME DE TRANSMISSION DU FAISCEAU, à travers lequel est émis un rayonnement laser permettant ainsi l'accès de personnes à un tel rayonnement

[SOURCE: IEC 60825-1:2014, 3.8, modifié. Dans la définition, "tout orifice dans le capot de protection d'un appareil à laser" a été remplacé par "orifice du SYSTEME DE TRANSMISSION DU FAISCEAU".]

201.3.205
SYSTEME DE TRANSMISSION DU FAISCEAU
système optique qui guide le rayonnement laser de son origine au CHAMP DE TRAVAIL

201.3.206
CLASSE 1C
classe de tout APPAREIL A LASER destiné explicitement au contact avec la peau ou avec le tissu non oculaire

[SOURCE: IEC 60825-1:2014, 3.19, modifié – La liste et les notes à l'article ont été supprimées.]

201.3.207
CLASSE 2
classe de tout APPAREIL A LASER dans la gamme de longueurs d'ondes de 400 nm à 700 nm qui, au cours de son fonctionnement, ne permet pas l'accès de personnes à un rayonnement laser excédant la LEA de la Classe 2

[SOURCE: IEC 60825-1:2014, 3.21, modifié – Dans la définition, "pour des longueurs d'ondes et des durées d'émission applicables" et les textes entre parenthèses ont été supprimés.

201.3.208
CLASSE 3B
classe de tout APPAREIL A LASER qui, au cours de son fonctionnement, permet l'accès de personnes à un rayonnement laser excédant la LEA de la Classe 1 et de la CLASSE 2, selon le cas, mais qui, cependant, ne permet pas l'accès de personnes au rayonnement excédant la LEA de la CLASSE 3B pour toute durée d'émission et longueur d'onde

[SOURCE: IEC 60825-1:2014, 3.23, modifié – Le terme et la définition ont été modifiés afin de ne faire référence qu'à la CLASSE 3B. Dans la définition, les textes entre parenthèses ont été supprimés.]

201.3.209
CLASSE 3R
classe de tout APPAREIL A LASER qui, au cours de son fonctionnement, permet l'accès de personnes à un rayonnement laser excédant la LEA de la Classe 1 et de la CLASSE 2, selon le cas, mais qui, cependant, ne permet pas l'accès de personnes au rayonnement excédant la LEA de la CLASSE 3R pour toute durée d'émission et longueur d'onde

[SOURCE: IEC 60825-1:2014, 3.23, modifié – Le terme et la définition ont été modifiés afin de ne faire référence qu'à la CLASSE 3R. Dans la définition, les textes entre parenthèses ont été supprimés.]

201.3.210
CLASSE 4
classe de tout APPAREIL A LASER permettant l'accès de personnes à un rayonnement laser excédant la LEA de la CLASSE 3B

[SOURCE: IEC 60825-1:2014, 3.24, modifié – Dans la définition, les textes entre parenthèses ont été supprimés.]

201.3.211
BOUTON D'ARRET D'URGENCE DU LASER
mécanisme commandé au pied ou à la main, destiné à arrêter immédiatement l'EMISSION LASER en cas d'urgence

201.3.212
LASER ENFERME
laser intégré dans un appareil à laser de CLASSE 1C

201.3.213
CONTACT CORRECT
état établi lorsque l'applicateur des appareils à laser classés comme lasers de CLASSE 1C est positionné au niveau de la peau cible de sorte que celle-ci agisse de manière à éviter avec efficacité toute exposition aux RAYONNEMENTS OPTIQUES PARASITES

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

201.3.214
INTERRUPTEUR DE COMMANDE D'EMISSION LASER
mécanisme commandé au pied ou à la main, destiné à déclencher ou arrêter l'émission du FAISCEAU DE TRAVAIL

201.3.215
INDICATEUR D'EMISSION LASER
signal visible et/ou audible indiquant que le FAISCEAU DE TRAVAIL est en cours d'émission

Note 1 à l'article: voir l'IEC 60825-1:2014, 6.7 Avertissement d'émission de rayonnement laser.

201.3.216
ENERGIE LASER
EMISSION LASER
ENERGIE RAYONNANTE du FAISCEAU DE TRAVAIL frappant le CHAMP DE TRAVAIL, où l'ENERGIE RAYONNANTE est l'intégrale par rapport au temps du flux énergétique Φ pendant une durée donnée Δt

Note 1 à l'article: Le terme EMISSION LASER est un terme plus général qui englobe à la fois PUISSANCE LASER et ENERGIE LASER.

[SOURCE: IEC 60825-1:2014, 3.72, modifié – Dans la définition, "ENERGIE RAYONNANTE du FAISCEAU DE TRAVAIL, frappant le CHAMP DE TRAVAIL, où l'ENERGIE RAYONNANTE est" a été ajouté.]

201.3.217
OPERATEUR LASER
personne qui manipule l'appareil à laser

Note 1 à l'article: Généralement, l'OPERATEUR LASER commande la transmission du rayonnement laser vers le CHAMP DE TRAVAIL. L'OPERATEUR LASER peut nommer d'autres personnes, qui aident à la sélection et/ou au réglage des paramètres.

[SOURCE: IEC 60601-1:2012, 3.73, modifié – Dans le terme et la définition, le mot "laser" a été ajouté.]

201.3.218
PUISSANCE LASER
EMISSION LASER
PUISSANCE RAYONNANTE du FAISCEAU DE TRAVAIL, reçue par le CHAMP DE TRAVAIL où la PUISSANCE RAYONNANTE est la puissance émise, transmise ou reçue sous forme de rayonnement

Note 1 à l'article: Le terme EMISSION LASER est un terme plus général qui englobe à la fois PUISSANCE LASER et ENERGIE LASER.

[SOURCE: IEC 60825-1:2014, 3.74, modifié – Dans le terme, "rayonnante" a été remplacé par "laser". Dans la définition, "PUISSANCE RAYONNANTE du FAISCEAU DE TRAVAIL, reçue par le CHAMP DE TRAVAIL où la PUISSANCE RAYONNANTE est la" a été ajouté.]

201.3.219
INDICATEUR DE DISPONIBILITE DU LASER
moyen qui indique de façon visible que l'appareil à laser est en état de DISPONIBILITE

Note 1 à l'article: Le but de l'INDICATEUR DE DISPONIBILITE DU LASER est d'indiquer au personnel présent dans la zone à laser qu'il faut prendre des précautions contre l'exposition accidentelle à un rayonnement laser dangereux.

201.3.220
EMP
EXPOSITION MAXIMALE PERMISE
niveau du rayonnement laser auquel des personnes peuvent être exposées dans les CONDITIONS NORMALES sans subir des effets nuisibles

[SOURCE: IEC 60825-1:2014, 3.59, modifié – Les notes à l'article ont été supprimées.]

201.3.221
FILTRE DE PROTECTION DE L'OPERATEUR
filtre optique mobile ou fixe incorporé dans le chemin optique du système de visualisation optique permettant de visualiser le CHAMP DE TRAVAIL mais qui bloque les niveaux dangereux de rayonnement du LASER DE TRAVAIL

201.3.222
DISPONIBILITE
mode de fonctionnement dans lequel le RESEAU D'ALIMENTATION est connecté et l'appareil à laser est en service, et dans lequel l'appareil à laser, après activation de l'INTERRUPTEUR DE COMMANDE D'EMISSION LASER, émet le FAISCEAU DE TRAVAIL

201.3.223
VEILLE
mode de fonctionnement dans lequel le RESEAU D'ALIMENTATION est connecté et l'interrupteur de commande du laser est en service, et dans lequel l'appareil à laser n'est pas capable d'émettre de FAISCEAU DE TRAVAIL même si l'INTERRUPTEUR DE COMMANDE D'EMISSION LASER est activé

201.3.224
RAYONNEMENT OPTIQUE PARASITE
rayonnement laser émis de manière non intentionnelle par l'applicateur des appareils à laser de CLASSE 1C, par diffusion autour des bords de l'applicateur ou par tout autre chemin

201.3.225
DISPOSITIF DE DESIGNATION DE CIBLE
dispositif de visée désignant l'emplacement où le FAISCEAU DE TRAVAIL agira pour des besoins chirurgicaux, esthétiques, thérapeutiques ou de diagnostic

201.3.226
CHAMP DE TRAVAIL
zone destinée à être irradiée par le FAISCEAU DE TRAVAIL

201.3.227
FAISCEAU DE TRAVAIL
faisceau de rayonnement laser, autre que le FAISCEAU DE VISEE, émis par l'appareil à laser pour des besoins chirurgicaux, esthétiques, thérapeutiques ou de diagnostic

201.4 Exigences générales

L'Article 4 de la norme générale s'applique.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique, avec les exceptions suivantes:

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou des parties d'APPAREILS EM

Addition:

201.7.2.101 Etiquettes supplémentaires

Voir l'IEC 60825-1:2014, Article 7.

a) Généralités

Les appareils à laser doivent être munis d'étiquettes conformes aux 7.3, 7.6 ou 7.7 de l'IEC 60825-1:2014, selon ce qui est applicable. Ces étiquettes doivent être visibles depuis une position de service normale.

b) *Indication d'OUVERTURE

Sur tout appareil à laser, à l'exception des appareils de CLASSE 1C, une étiquette doit être apposée aussi près que possible en pratique de chaque OUVERTURE laser. L'étiquette spécifiée dans l'IEC 60825-1:2014, 7.8 doit être utilisée. Les applicateurs soumis à une désinfection ou une stérilisation ainsi que les dispositifs fibroniques sont exemptés de ces exigences. Dans un tel cas, une étiquette doit être apposée en un endroit saillant avec soit:

– une indication que l'OUVERTURE laser est à l'extrémité de la fibre/de l'applicateur, soit
– un symbole comme celui figurant au Tableau D.1 sous le numéro 113.

NOTE L'information exigée peut être rassemblée sur une seule étiquette si l'endroit choisi pour l'apposer convient.

c) Les appareils à laser de CLASSE 1C doivent en outre inclure la classe du LASER ENFERME dans l'étiquette explicative.

201.7.9 DOCUMENTS D'ACCOMPAGNEMENT

Le Paragraphe 7.9 de la norme générale s'applique, avec les exceptions suivantes:

201.7.9.1 Généralités

Addition:

Les DOCUMENTS D'ACCOMPAGNEMENT doivent donner des instructions adéquates pour une utilisation correcte, y compris des avertissements clairs concernant les précautions à prendre pour éviter une éventuelle exposition dangereuse au rayonnement laser.

201.7.9.2 Instructions d'utilisation

201.7.9.2.13 Maintenance

Addition:

Les instructions de maintenance doivent inclure des avertissements clairs concernant les précautions à prendre pour éviter une éventuelle exposition au rayonnement laser dangereux.

Addition du paragraphe suivant:

201.7.9.2.101 Informations spécifiques aux LASERS pour l'ORGANISME RESPONSABLE et pour l'OPERATEUR LASER

Les instructions d'utilisation doivent inclure (selon ce qui est applicable):

a) des informations sur la DISTANCE NOMINALE DE RISQUE OCULAIRE (DNRO) pour les appareils à laser en UTILISATION NORMALE avec chacun des ACCESSOIRES appropriés;

NOTE 1 La DNRO ne s'applique pas aux appareils à LASER de CLASSE 1C.

b) une indication en unités SI de la DIVERGENCE DU FAISCEAU, de la DUREE D'IMPULSION, de l'EMISSION LASER maximale du rayonnement laser, ainsi que les ordres de grandeurs de l'incertitude de mesure cumulée et toute augmentation prévisible des quantités mesurées qui peuvent s'ajouter aux valeurs mesurées au moment de la fabrication, signifiant que les appareils fonctionnent différemment que prévu, se reporter au 7.9.2.17 de la norme générale;

c) lorsqu'un choc simple est constitué d'un train d'impulsions, les détails techniques doivent être donnés dans les informations destinées à l'utilisateur du laser. Par exemple, lorsque des impulsions nominales prennent la forme d'une structure de sous-impulsions