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

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

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50; 11.040.60; 31.260

ISBN 978-2-8322-7650-1

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.]