PD IEC/TR 60825-8:2022

BSI Standards Publication

Safety of laser products

Guidelines for the safe use of laser beams on humans

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National foreword

This Published Document is the UK implementation of IEC TR 60825-8:2022. It supersedes PD IEC/TR 60825-8:2006, which is withdrawn.

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A list of organizations represented on this committee can be obtained on request to its committee manager.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of lasers on humans

FOREWORD

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IEC TR 60825-8 has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment. It is a Technical Report.

This third edition cancels and replaces the second edition published in 2006. This edition constitutes a technical revision.

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

a) Recent medical laser equipment classified as laser class 1C is now included. Equipment of laser class 1C incorporates sensors which ensure good contact, so that laser emission into free space is inhibited.
b) More emphasis is given to protective eyewear of patients or clients, to the burning of materials close to the skin and to collateral hazards such as from internal or external fire and from noxious gases.
c) General technical update.

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The text of this Technical Report is based on the following documents:

Draft	Report on voting
76/640/DTR	76/658/RVDTR

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Report is English.

Terms written in small capitals in this document are defined in Clause 3.

A list of all parts in the IEC 60825 series, published under the general title *Safety of laser products*, can be found on the IEC website.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under 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.

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INTRODUCTION

Lasers emit visible or invisible optical radiation or both. In some cases, this radiation is a parallel beam with almost no divergence. This means that the inherently high IRRADIANCE of the laser is maintained over considerable distances. Due to the laser irradiation properties, injuries to the eye and skin can occur. Annex A includes descriptions of laser systems and some medical applications.

Lasers present hazards to anyone present during the operation of the laser. Serious risks of injury, particularly to the eye, or undesired effects can result from lack of protective measures, the use of faulty laser equipment, misdirected beams or inappropriate laser controls or settings.

Lasers which are used in contact mode on the skin may be classified as laser class 1C. These laser systems incorporate safety means which ensure that laser radiation can only be emitted if the interlocks detect good contact with the skin so that free space emission above the AEL of class 1 is prohibited. When used correctly, class 1C laser systems are considered safe for the eyes.

This document is intended to give direction as to how aspects of laser safety are incorporated into medical laser practice. It is not intended to take precedence over existing or proposed national guidance. However, where none exists, this document is intended to provide helpful information.

Although the LASER USER has direct responsibility for safety during laser use, the employer, referred to in this document as RESPONSIBLE PERSON, bears the responsibility for the setting up of a framework for the safe use of the system. A LASER SAFETY OFFICER (LSO) can be appointed to provide expert advice to the RESPONSIBLE PERSON and all personnel concerned with the laser operation. This document emphasizes the need for appropriate laser safety training for all staff involved in providing practical guidance on installation, operation, maintenance and servicing.

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SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of lasers on humans

1 Scope

This part of IEC 60825, which is a Technical Report, serves as a guide to the employer, the RESPONSIBLE PERSON, the LASER SAFETY OFFICER, the LASER USER and other persons involved, on the safe use of lasers and laser equipment classified as laser class 1C, 3B or 4 in interventional applications of laser beams on humans, excluding use of consumer products.

NOTE Premises where lasers are used include, but are not limited to, health-care facilities, dental-care practices, physiotherapy, beauty-care and cosmetic facilities.

This document explains the control measures recommended for the safety of the LASER USER, patients, clients, staff, maintenance personnel and others. Engineering controls which form part of the laser equipment or the installation are also briefly described to provide an understanding of the general principles of protection.

The subject areas covered in this document include

– BEAM DELIVERY SYSTEMS;
– biological effects of laser radiation;
– reporting of ACCIDENTS and dangerous situations, and
– checklists.

The object of this document is to enhance the protection of persons from laser radiation and other associated hazards by providing guidance on how to establish safety procedures, precautions and user control measures.

Medically relevant advice such as about treatment indications, counter-indications, patient or client condition, medical or beauty-care treatment procedures, patch testing, medication, adverse tissue or skin conditions and follow-up controls is beyond the scope of this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accident
unforeseen situation which results in an injury to any individual

3.2
beam delivery system
mechanism or device which delivers the laser output to the target site

EXAMPLE fibre optics, handpiece, micromanipulator, scanning device

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3.3
incident
potentially dangerous situation which could result in an injury to any individual

3.4
irradiance
RADIANT POWER per unit irradiated area

Note 1 to entry: IRRADIANCE is expressed in $W \cdot m^{-2}$.

3.5
laser controlled area
area where laser safety controls apply

3.6
laser user
user
person who controls the delivery of the laser radiation

Note 1 to entry: An assistant may control the settings such as output level, timing and stand-by or ready functions. The responsibility for the treatment is however with the USER. When in this document any action is attributed to the USER, it should also be understood that the action is performed by an assistant under the responsibility of the USER.

3.7
laser safety officer
LSO
person who is knowledgeable in the evaluation and control of laser hazards and has responsibility for oversight of the control of laser hazards

Note 1 to entry: Functions and responsibilities of the LSO are regulated differently in different countries.

3.8
maximum permissible exposure
MPE
maximum level of radiation to which, under normal circumstances, persons can be exposed without suffering permanent adverse effects

3.9
nominal ocular hazard area
NOHA
area within which the IRRADIANCE or RADIANT EXPOSURE can exceed the MPE

[SOURCE: IEC 60825-1:2014 [3], 3.64, modified – In the definition, "exceeds the appropriate corneal maximum permissible exposure (MPE), including the possibility of accidental misdirection of the laser beam" has been replaced by "can exceed the MPE".]

3.10
nominal ocular hazard distance
NOHD

distance from the output aperture beyond which the IRRADIANCE or RADIANT EXPOSURE remains below the MPE

[SOURCE: IEC 60825-1:2014 [3], 3.65, modified – In the definition, "beam" has been deleted and "appropriate corneal maximum permissible exposure (MPE)" has been replaced by "MPE".]

3.11
pulse duration
time increment measured between the half-peak power points at the leading and trailing edges of a pulse

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[SOURCE: IEC 60825-1:2014 [3], 3.69]

3.12
radiant exposure
radiant energy per unit irradiated area

Note 1 to entry: For the purpose of this document, the area of the spot size on the target tissue is considered to be the irradiated area which receives the RADIANT ENERGY. A spatially uneven distribution of the RADIANT ENERGY across the spot is neglected. See also IEC 60826-1:2014, 3,73. RADIANT EXPOSURE is expressed in $J \cdot m^{-2}$.

3.13
radiant power
power emitted, transferred or received in the form of radiation

Note 1 to entry: RADIANT POWER is expressed in W.

[SOURCE: IEC 60825-1:2014 [3], 3.74]

3.14
remote interlock connector
connector which permits the connection of external controls placed apart from other components of the laser product

Note 1 to entry: Medical laser equipment usually has a REMOTE INTERLOCK CONNECTOR incorporated which is used to attach an external switch or door switch which interrupts the laser emission when activated.

[SOURCE: IEC 60825-1:2014 [3], 3.76]

3.15
responsible person
person legally responsible for assuring safe working conditions

Note 1 to entry: The RESPONSIBLE PERSON is usually the owner of the premises, the Chief Executive Officer (CEO) or a person in a leading position who is liable in case of an ACCIDENT in the premises.

4 Hazards and preventive measures

4.1 Risks to eyes

4.1.1 General

The eye is at risk of injury from laser radiation exceeding the MAXIMUM PERMISSIBLE EXPOSURE (MPE). Laser radiation at wavelengths between 400 nm and 1 400 nm is focused onto the retina resulting in permanent damage to vision. Refer to Annex A.

Any person who is present within the NOHA should be protected against unintended laser exposure above the MPE.

Laser equipment of laser class 1C is considered safe for the eyes, as the accessible emission is stopped or reduced to the accessible emission limits of class 1 when the laser applicator is removed from contact with the skin or tissue. Lasers of class 1C have no NOHA. However, the eye of the patient or client is at risk from the incorporated laser, when the laser is applied to an area which is close to the eye.

4.1.2 Laser protective eyewear of personnel

Unless there is no reasonably foreseeable risk (as assessed by the LSO) that any person can be exposed to laser radiation exceeding the MPE, eye protection specifically designed for the wavelength(s) and output in use should be worn in addition to any other controls that are in place. Eyewear should be selected and approved by the LSO. When the eyes of any person

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including the treated individual are within the NOHA, then the appropriate eye protection should be selected.

Laser protective eyewear should conform with ISO 19818-1[1].

NOTE Information on safety eyewear can be found in the manufacturer's documentation.

In addition to the required marking according to eyewear standards and when different lasers are available, an unambiguous and robust method of marking the laser safety eyewear should be employed to ensure that there is a clear link to the laser in use and wavelength (if selectable) for which it has been specified. The type of marking should be sufficiently permanent.

Subclause 4.1.2 does not apply to lasers of class 1C.

4.1.3 Laser protective eyewear of patients or clients

Patient eye protection can include corneoscleral eye shields (see the manufacturer's instruction for use for possible risks), overlay external eye shields, moistened opaque cotton, pads or towels, eye protectors, and laser protective eyewear (glasses, spectacles or goggles). Protective eyewear should be chosen which reduces the radiant energy below the MPE.

More information can be found in ISO/TR 22463 [5][2].

Laser devices of class 1C incorporate engineering controls which prevent hazardous eye exposure to the USER and to personnel. However, the technical engineering controls possibly do not prevent eye damage to the patient when the laser is applied to a skin area close to the patient's or client's eye.

The extent of the NOHA will vary according to the type of laser used and the optical properties of the applicators used. Positioning of the treatment setting in a part of the treatment room can reduce the risk of exposure to errant beams.

4.1.4 Eye protection with viewing optics

When using viewing optics such as microscopes, colposcopes, slit lamps and other optical devices, the person(s) looking through the eyepiece(s) should be protected with a suitable filter or a shutter fitted to reduce the risk from radiation reflected through the vision channel. In case of monocular optics, consideration should be given to protecting the unshielded eye.

The use of a video endoscope can overcome the problems of reflected radiation in the viewing optics; however, it is still advisable for all persons present to wear eye protection when there is a risk of fibre breakage, or possible firing of the laser when the fibre is retracted from the endoscope. A risk assessment should be undertaken.

4.1.5 Eye protection of persons behind room windows

When the NOMINAL OCULAR HAZARD DISTANCE (NOHD) extends further than the nearest window, and the wavelength of the laser is less than 2 500 nm, protection should be provided to persons behind the window. Persons behind windows can be adequately protected by means of a window barrier which reduces transmission to a value below the MPE. Window barriers should meet infection control standards. For carbon dioxide lasers or other lasers which emit at wavelengths longer than approximately 2 500 nm, glass or plastics can provide sufficient absorption. Windows and shields should provide sufficient protection against the maximum IRRADIANCE for

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[1] EN 207 [2] and ANSI Z136.7 [1] are current standards in use, although new safety eyewear conforms with ISO 19818-1 [9].

[2] Numbers in square brackets refer to the Bibliography.

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the exposure duration likely to be encountered in normal use, as identified in the risk assessment carried out by the LSO.

For more information, see Annex B.

4.1.6 Reflecting surfaces

Reflections from glossy surfaces such as surgical instruments, mirrors, shiny jewellery, lubricating or cooling gels or tissue surfaces can be hazardous, particularly to the unprotected eyes. Depending on the wavelength and beam configuration, diffuse reflection of radiation from class 4 lasers from the irradiated tissue can also be hazardous. The probability for inadvertent exposure by reflected light should be assessed, for example in the case that eye protection is inadequate or is not worn or is temporarily put aside. Technical means for minimizing this probability may consist of the following:

d) Wall and ceiling surface or texture

   The surface of the wall and ceiling should be chosen such that specular reflections are minimized. A matt finish of any colour will minimize specular reflections.

e) Room equipment

   Glossy surfaces are found with windows, cupboards, vent frames, sterilization cases, X-ray viewing screens, video monitors, operating room lights, etc. Glossy surfaces reflect laser radiation unexpectedly and unpredictably. Unless concave in shape, glossy surfaces do not normally present a risk greater than that already present within the LASER CONTROLLED AREA. The checklist as described in Annex C may be used.

f) Instrumentation

   Care should be taken to prevent the unintentional reflection of the laser beam from an instrument. If the laser beam is likely to hit an instrument, for instance when it is placed in the beam path or adjacent to it, any such instruments should have a roughened surface to diffuse the beam. Instruments which have convex shape with radii in the millimetre range are suitable too as they also diverge the beam.

   The USER should be aware that a rough surface which does not specular reflect visible light reflects long-wavelength infra-red laser radiation such as that from a carbon dioxide laser. Black or dark-coloured instruments become hot when the absorbed radiant energy is sufficiently high, causing unintended patient burns. These instruments can also be significantly reflective at infra-red wavelengths. When working in the upper respiratory digestive tract, the USER should consider that a reflected beam or a hot instrument can perforate the endotracheal tube, possibly igniting it, with the risk of a severe endotracheal fire, see also 4.3.3 and Annex F.

Instruments with reflective surfaces are sometimes used to deflect the laser output onto an otherwise inaccessible operating site. Mirrors or other reflective devices should be checked for suitability at the laser wavelength and laser output employed.

When using laser equipment of laser class 1C, reflecting surfaces are of no concern.

4.2 Risks to skin

4.2.1 General

Depending on the radiation parameters of errant beam exposure, skin damage can occur such as erythema, burns, blistering, and scarring. Besides the fire hazard, a collateral skin burn of personnel, of the patient or the client can be caused by the ignition of material.

NOTE Risks to the skin of the patient or client due to unsuitable skin treatment parameters or other adverse treatment conditions are not covered in 4.2.

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4.2.2 Skin protection against laser radiation

Treatment procedures should be determined which minimize the probability for unintended skin exposure of personnel to the treatment beam or errant or reflected radiation.

In cutaneous application, when manipulation of the tissue is necessary, protective measures should be considered such as tongue depressors, templates or wet gauze.

4.2.3 Protection against burning of materials close to the skin

The LSO should recommend or approve the use of appropriate non-flammable or fire-retardant materials as determined by the risk assessment. The LSO should consider using patient covers such as drapes which are claimed by the manufacturer to be laser resistant.

NOTE Laser-resistant drapes usually conform with ISO 11810 [7].

Lasers can produce sufficient energy to ignite flammable materials particularly in an oxygen-enriched environment. Oxygen can possibly accumulate under patient drapes or covers.

Any new agent used with a laser should be checked for flammability before use. The USER should consider the use of non-flammable agents (e.g. water-based). If the use of flammable agents cannot be avoided, the drying times determined by the manufacturer should be adhered to, allowing complete dispersal of the agent to take place.

Dry or flammable materials, including sponges, gauze pads and swabs, located near the operating field should be moistened and then kept moistened with saline or sterile water, throughout the use of class 4 laser equipment due to the risk of fire. Prior to releasing or placing the delivery systems (handpiece, fibre, etc.) on the instrumentation table, the laser should be set to stand-by mode, to avoid unintended irradiation and ignition. If available, the storage means, as provided by the manufacturer, should be used. The delivery system should always be under direct control of the USER. Placement of the unprotected delivery system directly on the patient should be avoided.

Protective measures may include

a) use of wet drapes and materials to protect tissues adjacent to the target site, or in the path of the beam;
b) if oxygen is likely to accumulate under covers or cloths, changing the location of oxygen exhaust or providing means for ventilation;
c) eliminating flammable solutions and preparations from the target site;
d) adherence to manufacturer's drying times of skin preparations and solutions;
e) all staff be knowledgeable of location and operation of fire extinguisher appropriate for electrical equipment and flammable materials;
f) availability of water or saline that is easily accessible to the LASER USER.

4.3 Risk of internal combustion

4.3.1 General

Fire hazards within the patient body cavities are associated with the presence of combustible material, oxygen and energy which is capable of ignition.

4.3.2 Protection against combustion of endogenous gases

To avoid combustion of endogenous gases like methane in the gastro-intestinal tract, localized ventilation and gas scavenging techniques should be employed.

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4.3.3 Protection against airway fire

Airway fires are the most devastating and patient life-threatening events that can happen. Such events have been caused by lasers being focused or laser fibres being inserted.

For instance, materials which can burn include endotracheal tubes, flexible endoscopes, the laser fibre itself including tubular sheaths, inserted pads or sponges. Under increased oxygen concentration, the ignition takes place instantly and the flames are abundant even extending through the mouth of the patient to the exterior.

When, during airway laser surgery, oxygen concentrations higher than the normal 21 % are likely to be inhaled by the patient, a written medical airway management protocol should be followed. The USER, surgeon, and anaesthesia personnel should have received education and training.

Only endotracheal tubes specially specified for use with lasers should be used. The endotracheal tube chosen should be labelled for use with the intended wavelength and range of output parameters, in conformity with ISO 11990 [6]. If an adequate product is not available, the LASER USER together with the anaesthetist should consider other means to avoid airway fire and describe them in the written medical airway management protocol.

Since combustion can be initiated in the respiratory digestive tract in high oxygen concentrations, the lowest clinically acceptable concentration of oxygen should be chosen in laryngotracheal procedures. Jet ventilation should be considered.

4.3.4 Protection against burning of an endoscope

Care should be taken to avoid laser beam exposure of the sheaths of flexible fibre optic endoscopes since most of the sheaths are flammable.

The USER should check the proper positioning of the laser delivery fibre within the endoscope prior to placing the laser in a READY mode. Means include

– checking the integrity of the aiming spot;
– introducing the fibre far enough so that the tip can be seen through the endoscope. It should be realized that the tip of the fibre possibly becomes excessively heated during laser transmission and can cause heat damage to the endoscope or (upon contact) to the tissue although the aiming spot looks normal.

Care should be taken when endoscopy is performed in an oxygen enriched atmosphere, see 4.3.3.

Cases have been reported that fibres or fibre tips have broken within body cavities and endoscopes. Therefore, upon removal, the USER should confirm that the BEAM DELIVERY SYSTEM is intact and not compromised or broken.

Inadvertent pulling on the fibre during a laser procedure can cause damage to endoscopes, loss of part of the fibre inside the body, breakage of the fibre outside of the body with risk of inadvertent emission of radiation including cause of fire. If the fibre bridges a gap between the laser system and the treatment area, nobody should be allowed to enter that gap.

4.4 Risks due to inhalation of noxious fumes and plumes

4.4.1 General

When lasers are used to disrupt cells through the process of vaporization, noxious airborne contaminants are produced which can enter the breathing zones of all personnel present in the operating and treatment rooms, as well as the patient. Surgical plume contains carbon, gases, bio-aerosols, cellular material, blood, viruses and ultrafine particles (UFP).

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