TECHNICAL REPORT

IEC TR 60825-8

Second edition
2006-12

Safety of laser products –

Part 8: Guidelines for the safe use of laser beams on humans

Reference number
IEC/TR 60825-8:2006(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE W

For price, see current catalogue

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SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of laser beams on humans

FOREWORD

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IEC 60825-8, which is a technical report, has been prepared by IEC technical committee 76: Optical radiation safety and laser equipment.

This second edition cancels and replaces the first edition published in 1999. It constitutes a technical revision. This second edition, which is the result of continued maintenance work on the previous edition, reflects more thorough consideration of the hazards involved. It also takes into account newer laser technology and laser radiation supply instrumentation, and addresses refined application procedures. Additionally, this second edition implements more recent information available from other standards relevant to safety procedures, which have been revised in recent years. Further technical developments in this area will be reflected on an ongoing basis in future amendments or editions of this technical report.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
76/316/DTR	76/329/RVC

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

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

Terms indicated in small capitals are defined in Clause 3.

A list of all parts of the IEC 60825-8 series, published under the general title *Safety of laser products,* can be found on the IEC website.

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

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

A bilingual version of this technical report may be issued at a later date.

INTRODUCTION

Lasers emit visible and/or invisible optical radiation. In some cases, this radiation is a parallel beam with almost no divergence. This means that the inherently high IRRADIANCE of the laser may be maintained over considerable distances. Because of this, the beam may be focused to a very small area, which may be hazardous to the eye or skin. Annex A includes descriptions of laser systems and some medical applications.

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

This guide is intended to give direction as to how aspects of laser safety may be incorporated into medical laser practice. Its publication as a technical report indicates that it is not intended to take precedence over existing or proposed national guidance. However, where none exists, this guide should prove helpful.

Although the LASER OPERATOR has direct responsibility for safety during laser use, the employer bears the responsibility for the setting up of a framework for the safe use of the system. This guide strongly advocates the appointment of a LASER SAFETY OFFICER to provide expert advice to the employer and all personnel concerned with the laser operation. This guide emphasizes the need for appropriate laser safety training for all staff involved in providing practical guidance on installation, operation, maintenance and servicing.

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of laser beams on humans

1 Scope and object

This part of IEC 60825 serves as a guide to the employer, the RESPONSIBLE ORGANISATION, the LASER SAFETY OFFICER, the LASER OPERATOR and other persons involved, on the safe use of lasers and laser equipment classified as class 3B or class 4. It covers all applications of laser beams on humans in, but not limited to, health-care facilities, cosmetic and hair removal centres and dental practices, including applications in vehicles and domestic premises.

NOTE Although the scope excludes laser classes lower than class 3B and 4, it is appropriate to state, that particular care should be taken when levels of laser energy are used below the Class 3B and 4 limits when the individual's normal AVERSION RESPONSES are compromised or absent.

This technical report explains the control measures recommended for the safety of patients, 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 guide include

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

The object of this report 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.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

None.

3 Terms and definitions

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

NOTE Reference is also made, as indicated, to individual terms and definitions in IEC 60825-1 and IEC 60601-2-22.

3.1
accident
unforeseen situation which results in an injury to the patient and/or other personnel

3.2
aversion response
movement of the eyelid or the head to avoid an exposure to a noxious stimulant or bright light

NOTE For visible lasers the AVERSION RESPONSE is assumed to occur within 0,25 s.

3.3
beam delivery system
optical system which delivers the laser beam to the target area, focuses or shapes the laser beam and makes it manoeuvrable

NOTE 1 Examples of a beam delivery system include fibre optic, handpiece, micromanipulator or scanning device.

NOTE 2 See also 2.1.106 of IEC 60601-2-22.

3.4
incident
potentially dangerous situation which could result in an injury to the patient and/or other personnel

3.5
irradiance
RADIANT POWER divided by the irradiated area

NOTE See also 3.39 of IEC 60825-1. IRRADIANCE is expressed in Wm^{-2}.

3.6
laser controlled area
area where laser safety controls apply

NOTE See also 3.41 of IEC 60825-1.

3.7
laser operator
person who handles the laser equipment and in general controls the application of the laser radiation at the working area

NOTE The LASER OPERATOR may appoint other person(s), who assist with the selection and/or setting of the parameters.

3.8
laser safety officer
LSO
one who is knowledgeable in the evaluation and control of laser hazards and has responsibility for oversight of the control of laser hazards

[IEC 60825-1, definition 3.47]

3.9
maximum permissible exposure
MPE
that level of radiation to which, in normal circumstances, the skin or eye may be exposed without suffering adverse effects

NOTE See also 3.55 and A.2 of IEC 60825-1.

3.10
nominal ocular hazard area
NOHA
area within which the IRRADIANCE or RADIANT EXPOSURE can exceed the MPE

NOTE See also 3.59 of IEC 60825-1.

3.11
nominal ocular hazard distance
NOHD
distance from the laser aperture within which the IRRADIANCE or RADIANT EXPOSURE can exceed the MPE

NOTE See also 3.60 of IEC 60825-1.

3.12
operator
See LASER OPERATOR.

3.13
optical density
OD
value that defines the attenuation property of a filter

NOTE For example, when the attenuation value is 1/100, the OD is 2; when the value is 100 000, the OD is 5. See 3.86 of IEC 60825-1.

3.14
pulse duration
time increment measured between the half peak power points at the leading and trailing edges of a pulse

[IEC 60825-1, definition 3.65]

3.15
radiant exposure
radiant energy divided by the irradiated area

NOTE See also 3.69 of IEC 60825-1. RADIANT EXPOSURE is expressed in Jm^{-2}.

3.16
radiant power
power emitted, transferred or received in the form of radiation

[IEC 60825-1, definition 3.70]

NOTE RADIANT POWER is expressed in watts.

3.17
remote interlock connector
socket or terminal on the laser equipment, allowing for connection of a remote interlock to make provisions to interrupt the laser's emission with a door interlock or other external safety switches

NOTE See also 3.72 of IEC 60825-1.

3.18
responsible organisation
individual or group responsible for the use and maintenance of equipment, and for assuring that LASER OPERATORS are adequately trained

3.19
ultra low penetration air filter
ULPA
porous filter normally used for removing particulate matter from the laser plume

4 Hazards, goals and control measures

4.1 Risks to eyes

The eye is at risk of injury from laser radiation in excess of the MAXIMUM PERMISSIBLE EXPOSURE (MPE). In particular, laser radiation at wavelengths between 400 nm and 1 400 nm may be focussed onto the retina resulting in permanent damage to vision. Refer to Annex A.

4.1.1 Goal

Any person who is present within the NOMINAL OCULAR HAZARD AREA (NOHA) should be protected against unintended laser exposure above the MAXIMUM PERMISSIBLE EXPOSURE (MPE) for the cornea.

4.1.2 Control measures

4.1.2.1 Laser protective eyewear (goggles or glasses)

Unless there is no reasonably foreseeable risk (as assessed by the LSO, see Clause C.4) that personnel may be exposed to laser radiation in excess of the MPE, eye protection specifically designed for the wavelength(s) and output in use should be worn in addition to any other controls that may be in place. “Personnel” includes the patient, the LASER OPERATOR, the anaesthetist, assisting staff and others. It is one of the duties of the LSO to specify appropriate eyewear, resistant to the power or energy levels of the working beam expected during reasonably foreseeable hazard conditions. When the target area is close to the eye, the patient’s eye protection should be selected carefully, since the aiming beam as well as the working beam IRRADIANCE or RADIANT EXPOSURE may exceed the MPE. Additionally, the AVERSION RESPONSE may be altered due to anaesthesia or sedation.

Laser protective eyewear should be clearly marked with the wavelength(s) and corresponding OPTICAL DENSITY. Additionally, it is recommended that an unambiguous and robust method of marking the laser safety eyewear be employed to ensure that there is a clear link to the particular laser for which it has been specified.

The extent of the NOHA will vary according to the type of laser used and the optical properties of the applicators used. Placement of the laser equipment and the patient within the room can do much to control the direction and reduce the risk of exposure to errant beams.

As an alternative to having many people in the NOHA, which would require many pairs of goggles to be available, consideration should be given to installing a remote video monitor outside the NOHA.

NOTE There is concern that eyewear with correct OPTICAL DENSITY may shatter, if subjected to laser radiation with very high IRRADIANCE or RADIANT EXPOSURE. The European Standard EN 207:2002 contains the requirement, that the eyewear has to withstand such high IRRADIANCE or RADIANT EXPOSURE as long as 10 s. In many EU member countries, laser eyewear has to comply with this standard, In other countries, laser eyewear may not necessarily comply.

4.1.2.2 Eye protection with viewing optics

When using viewing optics, e.g. endoscopes, 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 out of the endoscope. A risk assessment should be undertaken by the LSO.

4.1.2.3 Windows

Persons behind windows can be adequately protected by means of an opaque material temporarily attached or unfolded at the window inside the room. For carbon dioxide lasers or other lasers which emit at wavelengths longer than approximately 4 000 nm, glass or plastics may provide sufficient absorption. Windows and shields should provide sufficient protection against IRRADIANCE for the exposure duration likely to be encountered in normal use, as identified in the risk assessment carried out by the LSO. For possible technical solutions, see Annex B.

4.1.2.4 Reflecting surfaces

Reflections from shiny surfaces such as surgical instruments may focus the laser beam, which can be hazardous, particularly to the eyes. Depending on the wavelength and beam configuration, diffuse reflections from the irradiated tissue from class 4 lasers may also be hazardous. In order to reduce hazards due to reflected laser radiation the following should be considered:

NOTE Class 3B laser diffuse reflections are not normally considered hazardous.

a) Wall and ceiling surface or texture

The surface of the wall and ceiling should be chosen such that reflections are minimized. The LSO should consider the risks due to possible reflections. A matt finish of any colour will minimize the reflections.

b) Room equipment

Glossy surfaces may be found with windows, cupboards, vent frames, sterilization cases, X-ray viewing screens, video monitors, operating room lights, etc. Shiny surfaces may reflect laser radiation in an unpredictable way. The LSO should identify the hazards involved and decide on the appropriate measures to be taken. The checklist as described in Annex C may be used.

c) 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, any such instruments which may be used with a laser should either be

– convex with small radii, if polished, or

– roughened.

The OPERATOR should be aware that a surface which does not reflect visible light may reflect long-wavelength infra-red laser radiation such as that from a CO_2 laser. Black instruments may absorb sufficient energy to become hot, causing unintended patient burns. These instruments may also be significantly reflective at infra-red wavelengths. When working in the upper respiratory/digestive tract, the OPERATOR 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 Annex F.

Reflective surfaces are sometimes used to deflect the laser energy into an otherwise inaccessible operating site. Mirrors or other reflective devices should be suitable for the laser wavelengths and powers or energies employed.

NOTE Glass mirrors may shatter if used at high laser powers.

4.2 Risks to skin

Although an acute skin injury resulting from exposure to laser radiation is less likely to affect the individual's quality of life, it should be recognised that the skin presents a much larger target than the eye and therefore the probability of exposure may be higher. Of particular concern is exposure of the skin to laser radiation below 400 nm, which may increase the risk of skin cancer. Refer to Annex A.

4.2.1 Goal

All personnel including the patient/client should be sufficiently protected against unintended hazardous laser exposure.

4.2.2 Control measures

The LSO should recommend or approve the use of appropriate clothing or drapes of low flammability, as determined from the risk assessment, see Annex C. When working with lasers in the UV region, a protective skin cream should be considered to be used, in order to avoid an erythema.

4.3 Fire and burn hazards

Lasers of class 4 may produce sufficient energy to ignite flammable materials particularly in oxygen enriched atmospheres.

4.3.1 Goal

All personnel including the patient/client should be sufficiently protected against burns.

4.3.2 Methods of compliance

4.3.2.1 Endotracheal fires

When performing airway laser surgery in the presence of endotracheal tubes, the tube should have adequate protection or be specially designed to reduce the likelihood of fire. For more detailed information on this subject, reference is made to ISO/TR 11991. Fire hazards related to endotracheal tubes, plastics, adhesive tapes, ointment and surgical preparatory solutions can be controlled by various methods. These include (but are not confined to) the use of non-combustible surgical instrumentation, Venturi (jet) ventilation techniques, shielding with wet substances and the use of low-combustion gas mixtures. Anaesthetics personnel should use non-flammable, specially manufactured or adequately protected laser resistant tubes. Standard plastic and rubber tubes are particularly hazardous and should be avoided, unless there is no practical alternative. There have been ACCIDENTS involving spirally wound metal tapes and these should be avoided. If there is no medical contra-indication, the endotracheal tube cuffs should be inflated with liquid and externally protected with wet swabs.

Since combustion may be initiated in the respiratory/digestive tract in high oxygen concentrations, or in the presence of oxidizing gases (nitrous oxide), the lowest possible concentration of oxygen should be used in laryngo-tracheal procedures. In some cases where co-axial fibres are used, CO_2 can be passed down the fibre at a low rate to minimize flammability at the laser target site. Care should be taken to monitor $p(O_2)$.

NOTE The anaesthesiologist should be consulted. A typical rate is 250 cm^3 per minute.

4.3.2.2 Endogeneous combustion

In order to avoid combustion of endogeneous gases like methane in the gastro-intestinal tract, localized ventilation techniques should be employed.

4.3.2.3 Endoscope burns

Care should be taken to avoid laser beam exposure of the sheaths of flexible fibre optic endoscopes since most of the sheaths are flammable. For metallic tubular delivery systems (i.e. bronchoscopes, laparoscopes, laryngoscopes), heating of the wall should be avoided to minimize the risk of thermal damage to adjoining tissue.

The OPERATOR should check the proper positioning of the laser delivery fibre (or waveguide) within the endoscope prior to releasing the beam. Means include