

Safety of laser products —

Part 8: Guidelines for the safe use of medical laser equipment

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The UK participation in its preparation was entrusted to Technical Committee EPL/76, Optical radiation safety and laser equipment, which has the responsibility to:

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Safety of laser products –

Part 8: Guidelines for the safe use of medical laser equipment

Sécurité des appareils à laser –

Partie 8: Lignes directrices pour la sécurité d'utilisation des appareils à laser médicaux



Commission Electrotechnique Internationale
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of medical laser equipment

FOREWORD

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Technical reports do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful by the maintenance team.

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

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

Enquiry draft	Report on voting
76/180/CDV	76/194/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 3.

This document which is purely informative is not to be regarded as an International Standard.

Terms indicated in small capitals are defined in 1.3.

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 (power per unit of area irradiated) 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. Annex A includes descriptions of laser systems and some medical applications.

Lasers may present hazards to patients and staff. 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 USER has direct responsibility for safety during treatment, 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 and maintenance.

SAFETY OF LASER PRODUCTS –

Part 8: Guidelines for the safe use of medical laser equipment

1 General

1.1 Scope and object

This technical report serves as a guide intended to give information to the employer and the USER on the safe use of lasers and laser equipment classified as class 3B or class 4, for diagnostic and therapeutic applications in healthcare facilities. However, particular care should be taken in the use of class 2 and class 3A lasers where the patient's normal aversion response is compromised or absent.

This 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. However, detailed specifications of laser equipment and installation controls are not included in this report, such requirements being separately specified in other standards, e.g. see 1.2.

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.

1.2 Reference documents

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-2-22:1995, *Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment*

IEC 60825-1:1993, *Safety of laser products – Part 1: Equipment classification, requirements and user's guide*

ISO/TR 11991:1995, *Guidance on airway management during laser surgery of upper airway*

1.3 Terminology and definitions

For the purpose of this technical report, the following definitions apply. Reference is also made, as indicated, to IEC 60825-1 and IEC 60601-2-22.

1.3.1

accident

INCIDENT which results in an injury

1.3.2

beam delivery system

fibre optic, handpiece, micromanipulator, scanning device, etc.
See also 2.1.106 of IEC 60601-2-22.

1.3.3

healthcare facility

any hospital, outpatient treatment centre, clinic or the like, where a laser can be used for *in vivo* diagnosis, or surgical or therapeutic purposes on humans

1.3.4

high efficiency particulate-free air filter (HEPA)

porous filter normally used for removing particulate matter from air streams

1.3.5

incident

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

1.3.6

irradiance

radiant flux, in watts per unit irradiated area, W/m^2 . See also 3.35 of IEC 60825-1.

1.3.7

laser controlled area

area where laser safety controls apply. See also 3.37 of IEC 60825-1.

1.3.8

laser operator

person who operates laser controls (e.g. parameter settings, actuation switch). The LASER OPERATOR may also be the LASER USER.

1.3.9

laser user

person who controls the delivery of the laser radiation to the working area

1.3.10

laser safety officer (LSO)

person who has the authority to monitor and enforce the control of laser safety hazards, and to effect knowledgeable evaluation and control of laser hazards. See also 3.43 of IEC 60825-1.

1.3.11

maximum permissible exposure (MPE)

that level of radiation to which, in normal circumstances, the skin or eye may be exposed without suffering adverse effects. See also A.2 of IEC 60825-1.

1.3.12

nominal ocular hazard area (NOHA)

area around the laser beam inside which the IRRADIANCE or RADIANT EXPOSURE is expected to exceed the MPE. See 3.55 of IEC 60825-1.

1.3.13

nominal ocular hazard distance (NOHD)

distance from the laser aperture below which the IRRADIANCE or RADIANT EXPOSURE is expected to exceed the MPE. See 3.56 of IEC 60825-1.

1.3.14

operator

See LASER OPERATOR.

1.3.15

optical density (OD)

negative of the logarithm to base ten of the factor related to the material's property to attenuate light during transmission, e.g. when the transmission factor is 0,01, the OD is 2; when the transmission factor is 0,00001, the OD is 5. See 3.78 of IEC 60825-1.

1.3.16

pulse duration

time increment measured between the half peak power points at the leading and trailing edges of a pulse. See 3.60 of IEC 60825-1.

1.3.17

radiance

radiant flux emitted by a unit area and propagating in a unit solid angle, expressed in W/m^2sr . See also 3.62 of IEC 60825-1.

1.3.18

radiant exposure

radiant energy per unit irradiated area, expressed in J/m^2 . See 3.64 of IEC 60825-1.

1.3.19

radiant power (radiant flux)

power emitted, transferred or received in the form of radiation, expressed in watts. See 3.65 of IEC 60825-1.

1.3.20

remote interlock connector

socket on the laser equipment, allowing for a remotely connected emergency laser switch to make provisions to interrupt the laser's emission with a door interlock or other external safety interlock switches. See also 3.67 of IEC 60825-1.

1.3.21

responsible body

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

1.3.22

user

See LASER USER.

2 Hazards, goals and control measures

2.1 Eye hazards

The retina of the eye is particularly susceptible to injury from laser radiation at wavelengths in the visible and near-infrared regions (wavelengths between 400 nm and 1 400 nm). This is because these wavelengths are readily transmitted through the ocular media and focused onto the retina. Due to the focusing action of the eye, the retina may be exposed to an IRRADIANCE that is over 100 000 times the IRRADIANCE arriving at the cornea. Surgical lasers, e.g. Nd-YAG or argon-ion lasers, thus present a potential threat to the eyesight by direct exposure to the beam or by specular (mirror-like) reflections from flat surfaces. Furthermore, looking at diffuse reflections from rough surfaces can be hazardous with surgical lasers at all wavelengths.

The heat generated in retinal tissues exposed to laser radiation can cause rapid and irreversible damage. Injury is dependent on the total RADIANT POWER passing through the pupil, the laser wavelength and its transmission through the ocular media, the duration of the exposure and the size of the image formed. A precise injury threshold is therefore difficult to define. It should be emphasized that, in contrast to other tissues where tiny lesions may not cause significant loss of function, a retinal lesion can cause irreversible loss of central vision.

Wavelengths above 1 400 nm are absorbed in the anterior components of the eye (cornea and aqueous humour). Beyond 1 900 nm, the cornea is considered the sole absorber. Heat produced in the anterior part of the cornea from, for example, a surgical carbon dioxide (CO₂) laser may be conducted to adjacent tissues causing thermal damage. A surgical CO₂ laser may continuously vaporize surface tissue; the cornea of the eye can easily be injured if accidentally exposed to this laser beam.

Other parts of the eye can also sustain injury, depending on the wavelength of the laser radiation. The ultraviolet (UV) spectrum is divided into three specific regions which are related to different biological responses:

- UV-A (315 nm to 400 nm) is strongly absorbed by the lens of the adult eye. The harmful effects of exposure may not become apparent for many years (small lens opacities can form, which may become clinically significant);
- UV-B (280 nm to 315 nm) and UV-C (100 nm to 280 nm) are mainly absorbed by the cornea and conjunctiva and this can lead to inflammation of the cornea (photokeratitis) and conjunctivitis. Damage limited to the outer layer of the cornea may be temporary. Special considerations should be given to those persons who may be at particular risk from UV exposure, e.g. aphakes or photosensitized persons. Refer to annex A.

2.1.1 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.

2.1.2 Control measures

2.1.2.1 Laser protective eyewear (goggles or glasses)

Unless there is no reasonably foreseeable risk (as assessed by the LSO) 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, LASER USER, LASER OPERATOR, anaesthetists, assisting staff and spectators. It is one of the duties of the LSO to specify appropriate eyewear, resistant to the power or energy levels of the treatment beam expected during reasonably foreseeable hazard conditions. When the treatment region is close to the eye, the patient's eye protection should be selected carefully, since the aiming beam as well as the treatment beam IRRADIANCE or RADIANT EXPOSURE may exceed the MPE. Additionally, the blink reflex may be altered due to anaesthetic drugs.

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.

2.1.2.2 Eye protection with viewing optics

When using viewing optics, e.g. endoscopes, microscopes, colposcopes, laparoscopes, 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 accidental firing of the laser when the fibre is out of the endoscope. A risk assessment should be undertaken by the LSO.

2.1.2.3 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 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.

2.1.2.4 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 like that from the irradiated tissue from class 4 lasers ¹⁾ may also be 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 normally meet this requirement.

b) Room equipment

Glossy surfaces may be found with windows, cupboards, vent frames, fixation frames at tables, infusion stands, 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, or
- anodized.

The USER 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 CO₂ 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 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 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.

2.2 Skin hazards

In general terms, the skin can tolerate a great deal more exposure to laser beam energy than the eye. The biological effect of irradiation of the skin by lasers operating in the visible (400 nm to 780 nm) and infra-red (780 nm to 1 mm) spectral regions may vary from a mild erythema to severe blisters. See annex A.

2.2.1 Goal

Every person should be protected against unintended hazardous laser exposure.

2.2.2 Control measures (protective clothing)

The LSO should recommend or approve the use of appropriate clothing or covers, as determined from the risk assessment, see annex C.

¹⁾ Class 3B laser diffuse reflections are not normally considered hazardous.

2.3 Fire and burn hazards

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

2.3.1 Goal

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

2.3.2 Methods of compliance

2.3.2.1 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, CO₂ can be passed down the fibre at a low rate²⁾ to minimize flammability at the laser target site. Care should be taken to monitor p(O₂).

2.3.2.2 Endogeneous combustion

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

2.3.2.3 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 the wall should be avoided to minimize the risk of thermal damage to adjoining tissue.

The USER should check the proper positioning of the laser delivery fibre (or waveguide) within the endoscope prior to releasing the beam. 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 may become excessively heated during laser transmission and may cause heat damage to the endoscope or (upon contact) to the tissue although the aiming spot looks normal.

²⁾ The anaesthesiologist should be consulted. A typical rate is 250 cm³ per minute.

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

2.3.2.4 Cleaning, disinfecting and anaesthetic agents

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, time should be allowed for complete dispersal of the agent to take place.

2.3.2.5 Drapes and covers

Sponges, gauze pads and swabs located near the operating field should be moistened with saline or sterile water. If class 4 laser equipment is used, surgical drapes may catch fire. The region of the drape near the operating field should be kept moistened with saline or sterile water.

If the laser handpiece is placed on a dry region of the sterile drape, the drape may be ignited if the laser is accidentally operated, or if the handpiece is hot following use. This may go unnoticed. It should, therefore, become a matter of routine either to cover the aperture with a laser-resistant cap or to put the laser handpiece in a safe holder during a treatment pause and/or to set the laser equipment to stand-by. The laser transmission system should never be left lying on the patient or under uncontrolled conditions.