TECHNICAL REPORT

IEC TR 60825-8

First edition
1999-11

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

SAFETY OF LASER PRODUCTS –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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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Technical reports do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful by the maintenance team.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 (CO_2) laser may be conducted to adjacent tissues causing thermal damage. A surgical CO_2 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, comoscopes, 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.

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