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TECHNICAL REPORT

Safety of laser products –
Part 8: Guidelines for the safe use of lasers on humans

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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.

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- withdrawn,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.

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.

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