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Patient and client eye protectors for use during laser or intense light source (ILS) procedures — Guidance

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94, *Personal safety — Personal protective equipment*, Subcommittee SC 6, *Eye and face protection* in close cooperation with IEC/TC 76, *Optical radiation safety and laser equipment*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Significant eye injuries to patients have been reported in the literature, to national regulatory bodies and in anecdotal reports associated with laser or intense light sources (ILSs) when used in the vicinity of the eye (see Annex A). Such injuries include pupillary distortion, temporary and permanent vision impairment, temporary photophobia and eye pain, ocular fatigue and retinal damage. Many of the reports appear to be associated with a lack of knowledge and understanding by users, and a lack of administrative controls.

Eye protectors are available for patients undergoing procedures involving laser sources or ILS. Some guidance with respect to such eye protectors is given in this document.

This document could be helpful for the responsible person during the process of assessing risks related to eye safety of patients/clients. It may be consulted when setting up a protocol for the purpose of providing safe working conditions and procedures. For further information, see also IEC/TR 60825-8, IEC/TR 60825-14, IEC/TR 62471-3 and ISO 12609-2.

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Patient and client eye protectors for use during laser or intense light source (ILS) procedures — Guidance

1 Scope

This document gives guidelines for and provides information to employers, users and safety advisors on the selection and use of patient eye protectors (PEPs) for lasers and intense light source (ILS) equipment used for medical and cosmetic applications.

This document does not apply to the eye protection of laser/ILS operators or users of the equipment. It also does not apply to PEPs for use with tanning equipment or ophthalmic instruments, either for the user/operator or the patient/client.

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
Class 1C laser product
laser product that is designed explicitly for contact application to the skin or non-ocular tissue and where:

— during operation, ocular hazard is prevented by engineering means, i.e. the accessible emission is stopped or reduced to below the accessible emission limit (AEL) of Class 1 when the laser/applicator is removed from contact with the skin or non-ocular tissue;

— during operation and when in contact with skin or non-ocular tissue, irradiance or radiant exposure levels exceed the skin *MPE* (3.7) as necessary for the intended treatment procedure;

— the laser product complies with applicable vertical standards.

Note 1 to entry: Lasers used in contact mode on the skin that incorporate safety means to ensure that good contact is provided when the laser is emitting and that hazardous leakage radiation is inhibited, as specified in a vertical safety standard, can be classified laser Class 1C.

[SOURCE: IEC 60825-1:2014, 3.19, modified — The three notes (which discussed the classification scheme and tests) have been replaced by a single Note 1 to entry.]

3.2
exposure limit
EL
level of exposure to the eye or skin that is not expected to result in adverse biological effects

[SOURCE: IEC 62471:2006, 3.8]

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3.3
intense light source
ILS
device incorporating one or more non-laser sources of optical radiation of the wavelength range 250 nm to 3 000 nm and intended for creating biological effects in humans

Note 1 to entry: ILS may incorporate continuously emitting or pulsed xenon lamps, incandescent lamps, LEDs or similar.

[SOURCE: ISO 12609-1:2013, 3.4, modified — The phrase "and animals" has been deleted from the definition. Note 1 to entry has been expanded to include examples of light sources.]

3.4
intense pulsed light
IPL
equipment, containing a flash lamp, e.g. xenon or krypton, housed in a handheld device, having an emission window with an area of several cm^2, typically providing a filter that restricts the emission to a band in the visible and infra-red

Note 1 to entry: Pulse lengths are in the order of tens of ms or less and pulse repetition rates are typically two per second or less. The IPL output is on the order of up to 50 J/cm^2. The wavelengths range typically from 400 nm to 1 200 nm. Filters may be incorporated or attachable that cut off portions of the spectrum such as blue-green or IR.

Note 2 to entry: IPL can be covered by trademark rights in certain countries. Generally, users and recipients of IPL treatments comprehend the generic meaning of "IPL" as "intense pulsed light".

[SOURCE: IEC/TR 62471-3:2015, 3.3, modified — The last sentence in Note 1 to entry has been added.]

3.5
laser/ILS user
person who uses the laser/ILS equipment and in general controls the application of the laser/ILS radiation at the working area

Note 1 to entry: The laser/ILS user may appoint other person(s), who assist(s) with the selection and/or setting of the parameters.

[SOURCE: IEC/TR 60825-8:2006, 3.7, modified — The term has been changed from "operator" to "user" and ILS has been added.]

3.6
laser or ILS safety officer
LSO/ILSSO
person who is knowledgeable in the evaluation and control of laser/ILS hazards and has responsibility for oversight of the control of laser/ILS hazards

Note 1 to entry: The LSO/ILSSO may be the *responsible person* (3.11). The acronym "ILSSO" was created for ease of use in this document to provide a parallel definition to that of "LSO" in cases where the risks of *intense light sources* (3.3) are being assessed.

[SOURCE: IEC/TR 60825-8:2006, 3.8, modified — "ILSSO" and Note 1 to entry have been added.]

3.7
maximum permissible exposure
MPE
maximum level of laser radiation to which, in normal circumstances, the skin or eye may be exposed without suffering adverse effects

[SOURCE: IEC/TR 60825-8:2006, 3.9, modified — In the definition, "that level" has been changed to "maximum level" and "laser" has been added. The note has been removed.]

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3.8
optical density
OD
$D(\lambda)$
logarithm to the base 10 of the reciprocal of the spectral transmittance, $\tau(\lambda)$

Note 1 to entry: Optical density is expressed by the formula:

$$D(\lambda) = \log_{10} [1/\tau(\lambda)]$$

Note 2 to entry: For example, when the attenuation value is 1/100, the transmittance = 0,01 and the OD is 2. When the value is 1/100 000, the transmittance = 10^{-5} and the OD is 5.

[SOURCE: ISO 4007:2018, 3.10.1.21, modified — Note 2 to entry has been added.]

3.9
patient
person receiving laser or *ILS* (3.3) treatment

Note 1 to entry: "Patient" includes clients or customers in aesthetic clinics or beauty salons.

3.10
patient eye protector
PEP
eye protector meant to be worn by a *patient* (3.9) or client during laser or *ILS* (3.3) treatment

3.11
responsible person
person who is designated to assess the risks of lasers or *ILS* (3.3) equipment and to determine the safety measures and the local rules

Note 1 to entry: The responsible person will be either the owner/operator of the facility or a person appointed by the owner/operator.

[SOURCE: IEC/TR 62471-3:2015, 3.6, modified — In the definition, "IPL" has been replaced by "lasers or ILS equipment" and who the responsible person will be has been moved to a note to entry.]

3.12
stray optical radiation
optical energy that is unintentionally emitted from the applicator, including scattered, reflected and leakage radiation

[SOURCE: IEC 60335-2-113:2016, 3.107]

4 Risk assessment and selection of patient/client eye protectors

4.1 General

The primary goal of the LSO/ILSSO and/or the responsible person should be to conduct a risk assessment and provide guidance for control measures to reduce ocular risks associated with usage of laser/ILS devices. A risk assessment should be conducted to determine if the output of a laser/ILS device could exceed the MPE/EL and potentially injure a patient/client. The risk assessment should also consider the wavelength(s), the delivery system being used with the laser/ILS device, positioning, the intended use and the body location of the treatment. If there is a risk of ocular injury, then appropriate eye protectors for the patient/client should be selected that are resistant to the energy levels anticipated during the treatment. International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidance or that contained in national regulations may be used to assist in risk assessment.

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