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

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Foreword

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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.

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.

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]

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.]

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.

The PEP should be labelled, if applicable, and conform to the relevant standards. Additional guidance about the safe usage of laser and ILS equipment can be found in IEC/TR 60825-8 (lasers) or IEC/TR 62471-3 (ILS).

NOTE If it is determined that there is additionally a potential risk to the user or staff member, refer to ISO 12609-1 and ISO 12609-2 for ILS, and IEC 60825-14 for lasers, for guidance on the selection of eye protection for these individuals.

4.2 When the laser/ILS is used on parts of the body below the face/neck

This is the least restrictive condition and the PEP used for the patient/client can be identical to that worn by the user. To avoid accidental exposure if the laser/ILS beam is inadvertently directed towards the eyes, the user should ensure that the PEP maintains a good fit with the periorbital region. The user should check for light leakage around the edges of the PEP once it is in place to ensure a good fit. In some cases, a close-fitting PEP may be required in place of an operator style PEP due to the particular treatment being performed away from the head and neck or the behavioural characteristics of the patient/client.

If the patient/client does not need or want to observe the procedure, then the PEP may be opaque (non-transparent) and have an appropriate attenuation over the wavelength region of concern.

If any topical compound is applied to the skin that could increase the specular reflection of laser/ILS radiation, then this should be taken into consideration when deciding on the appropriate attenuation of the PEP. Also, any metallic items near the application site, such as piercings, should be removed prior to laser treatment.

The resistance of the PEP to intense radiation is also less critical in this situation because the laser/ILS radiation is not likely to be directed into or near the eye. See PEP type a), b) or c) in Annex B.

NOTE If PEP type c) is used, skin damage or allergic reaction from the adhesive can occur.

4.3 When the laser/ILS is used on the face/neck, but not in the periorbital region

Under this condition, it is critical that the PEP has a good fit with the area around the eyes to prevent any stray optical radiation from entering the eye. The PEP should be opaque (non-transparent) or have an appropriate OD/attenuation over the wavelength region of concern. See PEP type b) or c) in Annex B. It is also critical that the PEP has sufficient resistance to intense radiation from the laser or ILS.

NOTE If PEP type c) is used, skin damage or allergic reaction from the adhesive can occur.

4.4 When the laser/ILS is used in the periorbital region

Under this condition, it is also critical that the PEP have a good fit (see also 4.2 regarding light leakage) with the area around the eyes to prevent any stray optical radiation from entering the eye. The PEP should be opaque (non-transparent) or have an appropriate OD/attenuation over the wavelength region of concern. It is also critical that the PEP have sufficient resistance to intense radiation from the laser or ILS. Consideration should be given to asking that the patient/client look down to avoid potential injury due to Bell's phenomenon (see NOTE 2 for more information). See PEP types b), c) or d) in Annex B.

NOTE 1 If PEP type c) is used, skin damage or allergic reaction from the adhesive can occur.

NOTE 2 When closing their eyelids, individuals tend to unconsciously rotate the eyes upwards. This reaction is called "Bell's phenomenon". This phenomenon is considered when assessing the possible ways that direct or scattered light could enter the pupil or be incident on the vulnerable anterior segments of the eye.

Some of the more common procedures that require a PEP, as specified above, include:

a) laser/ILS application on wrinkles adjacent to the eye;

b) laser/ILS application on spider naevi adjacent to the eye, e.g. nose;

c) laser/ILS application on pigmented spots adjacent to the eye;

d) laser/ILS application on scars adjacent to the eye;

e) laser/ILS application on artificially injected colours, such as tattoos adjacent to the eye;

f) laser/ILS application of permanent makeup on the eyebrow;

g) laser/ILS application on the eyebrow for hair removal.

The PEP as specified should also be applied in cases where a Class 1C laser product is used. Since the radiation level that is emitted onto the skin in the periorbital region can be up to a Class 4 laser, intense levels of scattered light can be transmitted through the bulk tissue onto the eye, particularly if the wavelengths are in the visible red and/or near infrared. No physical shield is available that inhibits light from propagating through the bulk periorbital tissue and reaching the sclera and the adjacent retina or the anterior segment of the eye. The user should consider that the effect of the Class 1C laser is comparable to that of the enclosed laser as far as the safety of the patient's/client's eye is concerned. It is recommended that no Class 1C, 3B or 4 laser in the 800 nm to 1 200 nm wavelength range in used within 10 mm of the eye. This precautionary measure is needed in addition to a PEP.

In addition, where the applicator is used in contact with the target area, ILS equipment of Risk Group 3 should incorporate a means that prevents radiation being emitted from the applicator in a direction other than intended for the treatment. The same advice regarding the use of Class 1C products applies in the case of ILS equipment used in a contact mode in the periorbital region. Some ILS equipment is intended to be used not in contact, but at a fixed distance from the target tissue. Because of this, there is an increased risk of stray radiation reaching the eye. Thus, it is recommended that the user keeps the margin of 10 mm from the eye mentioned above, in addition to using a PEP that has a good fit to the area around the eye of the patient/client.

4.5 When the laser/ILS is used on the eyelid

Due to its mobility and limited thickness, the eyelid offers inadequate protection against most laser/ILS procedures. As the iris behaves like a light-absorbing chromophore, it heats up considerably when trans-illuminated by light sources of intensities such as those needed for the intended procedure.

In this situation, corneal eye shields similar to type d) of Annex B should be applied with a high viscosity water-based ocular lubricant and, if a general anaesthetic is not being used, an appropriate topical ophthalmic anaesthetic solution. However, corneal eye shields can themselves be absorbers that can heat up upon exposure, potentially leading to corneal damage. Therefore, care should be taken to avoid excessive heating of the eye shield, which may require the operator to apply cooling strategies between pulses.[28] Also, the size of the corneal shield needs to match the orbit of the eye to prevent inadvertent radiant exposure into the eye. Care should be taken upon the removal of the corneal eye shields to avoid corneal injury or abrasion.

NOTE There have been reports of corneal abrasions caused by the corneal eye shield heating up and sticking to the cornea. However, these corneal abrasions were probably caused by the inappropriate/inadvertent use of topical skin anaesthetics on the cornea and were, in fact, chemical not thermal burns.

Another option is to use an eye spatula [see e) in Annex B] with an appropriate lubricant. Physicians/medical professionals who have experience using this device have reported success in using this type of PEP when treating the eyelid with laser radiation, usually by having an assistant hold the spatula in place under the eyelid, but not in direct contact with the cornea, during the procedure.

It is recommended that any laser/ILS procedure to be performed on the eyelid is done by a medical professional. The user should be trained and experienced with the proper application of corneal eye shields and should be aware of the potential factors that can lead to adverse heating effects. These factors include irradiance or radiant exposure and the duration and frequency of pulses that can lead to the need for additional cooling or other appropriate protective measures.