PD ISO/TR 22463:2019

BSI Standards Publication

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

bsi.

# National foreword

This Published Document is the UK implementation of ISO/TR 22463:2019.

The UK participation in its preparation was entrusted to Technical Committee PH/2, Eye protection.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.


Published by BSI Standards Limited 2019

ISBN 978 0 580 97838 8

ICS 13.340.20

**Compliance with a British Standard cannot confer immunity from legal obligations.**

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 April 2019.

**Amendments/corrigenda issued since publication**

| Date | Text affected |
|---|---|

PD ISO/TR 22463:2019

TECHNICAL REPORT

# ISO/TR 22463

First edition
2019-04-30

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

Reference number
ISO/TR 22463:2019(E)

**COPYRIGHT PROTECTED DOCUMENT**



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

# Contents

Page

# 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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

*This page deliberately left blank*

**TECHNICAL REPORT** **ISO/TR 22463:2019**

# 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]