SLOVENSKI STANDARD
SIST EN ISO 15004-2:2025

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Oftalmični instrumenti - Osnovne zahteve in preskusne metode - 2. del: Zaščita pred nevarno svetlobo (ISO 15004-2:2024)

Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (ISO 15004-2:2024)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 2: Schutz gegen Gefährdung durch Licht (ISO 15004-2:2024)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 2: Protection contre les dangers de la lumière (ISO 15004-2:2024)

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11.040.70	Oftalmološka oprema	Ophthalmic equipment

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English Version

Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection (ISO 15004-2:2024)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 2: Protection contre les dangers de la lumière (ISO 15004-2:2024)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 2: Schutz gegen Gefährdung durch Licht (ISO 15004-2:2024)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Page

European foreword

This document (EN ISO 15004-2:2024) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2025, and conflicting national standards shall be withdrawn at the latest by June 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 15004-2:2024 has been approved by CEN as EN ISO 15004-2:2024 without any modification.

International Standard

ISO 15004-2

Ophthalmic instruments — Fundamental requirements and test methods —

Part 2: Light hazard protection

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai —

Partie 2: Protection contre les dangers de la lumière

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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 document 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).

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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 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15004-2:2007), which has been technically revised.

The main changes are as follows:

— The terms and definitions include dose limited instruments and time limited instruments;

— The safe exposure limits have been reorganized into 4 tables (Tables 2 to 5), and the associated measurement conditions have been reorganized into a companion table (Table 6);

— A number of Group 1 exposure limits and Group 2 recommended maximum exposures (RMEs) have been updated to conform to recent research and relevant standards;

— The language has been clarified and simplified throughout the document, and a flowchart has been added as a guide to make the standard more accessible to first-time users;

— Clauses and associated exposure limits have been added for long-term repetitive exposures, such as may apply to extensive use of head-mounted displays by people with visual impairments;

— Provisions have been added to ensure that the exposure limits and RMEs applicable to specific devices are easily accessible to end users.

A list of all parts in the ISO 15004 series can be found on the ISO website.

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

Ophthalmic instruments are classified into two groups to distinguish instruments that can present a potential hazard from those that cannot. The two groups are named Group 1 and Group 2. They are defined as follows:

Group 1 instruments: ophthalmic instruments for which no potential light hazard exists when used as intended (see Clause 4).

Group 2 instruments: ophthalmic instruments for which a potential light hazard exists (see Clause 4).

Limits and guidelines for optical radiation exposure of the eye during ophthalmic examination can differ from those of non-ophthalmic applications. They can be more restrictive because of pupils dilation or retinal image stabilization, or less restrictive based on benefit/risk ratios. Furthermore, interruptions of exposure during surgical procedures mitigate the risk.

All group 2 instruments pose a potential risk of injury at the upper emission values of the instrument. This is true for both photochemical (where time is critical) and thermal, where transmission and absorption values can vary. Clinical judgement of individual susceptibility is also required.

NOTE 1 The basic limits and guidelines in this document are based on the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for human exposure to optical radiation. They also cover cases where pupils are dilated, or the image is stabilized on the retina during ophthalmic examinations.

NOTE 2 This document provides exposure limits for ocular tissues. The exposures can be calculated based upon the measured instrument emissions.

The flow chart in Figure 1 at the beginning of Clause 4 provides guidance on how to apply this document to any device to be tested or designed for light hazards conformity.

Ophthalmic instruments — Fundamental requirements and test methods —

Part 2: Light hazard protection

1 Scope

This document specifies fundamental requirements for optical radiation safety for ophthalmic instruments and is applicable to all ophthalmic instruments that direct optical radiation into or at the eye. It is also applicable to all new and emerging ophthalmic instruments that direct optical radiation into or at the eye, as well as to those portions of therapeutic or surgical systems that direct optical radiation into or at the eye for diagnostic, illumination, measurement, imaging or alignment purposes.

NOTE For the purpose of this document, optical radiation relates to the wavelength range of 250 nm to 2 500 nm.

This document does not apply to therapeutic radiation. However, in the case of the treatment beams of therapeutic devices, when conducting risk assessments for non-target tissues, the limits given in this document may be applied to those parts of the treatment beam that strike non-target tissue.

Where vertical (instrument-specific) International Standards contain specific light hazard requirements different from those given in ISO 15004-2, then those in the vertical International Standard take precedence.

This document classifies ophthalmic instruments into either Group 1 or Group 2 to distinguish instruments that are non-hazardous from those that are potentially hazardous.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15004-1 and the following apply.

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

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

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

3.1
aperture
aperture stop
opening that defines the area over which average optical emission is measured

Note 1 to entry: For spectral irradiance measurements this opening is usually the entrance of a small integrating sphere placed in front of the radiometer/spectroradiometer entrance slit.

3.2
continuous exposure
continuous wave
CW
radiant exposure equal to or greater than 0,25 s duration

3.3
continuous wave instrument
CW instrument
ophthalmic instrument that is designed to expose the eye to one or more continuous wave radiation sources

3.4
continuous wave radiation source
CW radiation source
radiation source that is, or can be, operated with a continuous output for a time that can be equal or greater than 0,25 s (i.e. a non-pulsed radiation source)

3.5
dose-limited instrument
ophthalmic instrument whose emission could exceed the Group 1 exposure limits, but through its design and construction and accounting for multiple exposures within a 24-hour period, cannot under reasonably foreseeable conditions expose any given eye to radiation that exceeds the Group 1 cumulative exposure limits given in Table 2 and Table 3

Note 1 to entry: This instrument would otherwise be a Group 2 instrument; for example, some UV-Fluorescent diagnostic instruments.

Note 2 to entry: The maximal exposure duration of dose-limited instruments is 30 000 s.

3.6
effective aperture
portion of the aperture that limits the amount of light delivered to the retina

Note 1 to entry: For an obscured or noncircular aperture, the effective aperture is defined as the uniformly illuminated, unobscured circular aperture that transmits the same radiant flux.

3.7
emission limit
maximum permitted value of optical radiation output to which the eye is potentially exposed

3.8
exposure limit
maximum permitted value of optical radiation exposure to which an ocular tissue is potentially exposed

3.9
endoilluminator
instrument consisting of a light source and an associated fibre optic light guide that is intended for insertion into the eye to illuminate any portion of the interior of the eye

3.10
field-of-view
conical solid angle as “seen” by the detector, such as the eye or the radiometer/spectroradiometer, over which the detector receives radiation

Note 1 to entry: This is also referred to as acceptance angle.

Note 2 to entry: The field-of-view denotes the angle over which radiance is averaged (sampled) and should not be confused with the angular subtense of the source α, which denotes source size.

Note 3 to entry: In this document, a plane angle is used to describe a circular symmetric solid angle field of view.