



SLOVENSKI STANDARD
oSIST prEN ISO 15253:2020
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Očesna optika in instrumenti - Optične in elektrooptične naprave za izboljšanje slabovidnosti (ISO/DIS 15253:2020)

Ophthalmic optics and instruments - Optical and electro-optical devices for enhancing low vision (ISO/DIS 15253:2020)

Augenoptik und ophthalmische Instrumente - Optische und elektro-optische vergrößernde Sehhilfen für Sehbehinderte (ISO/DIS 15253:2020)

Optique et instruments ophtalmiques - Dispositifs optiques et électro optiques pour malvoyants (ISO/DIS 15253:2020)

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Optique et instruments ophtalmiques — Dispositifs optiques pour malvoyants

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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).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics*.

This edition cancels and replaces the first edition (ISO 15253:2000) and the second edition of ISO 15254 (ISO 15254:2009), which both have been technically revised.

The main changes compared to the previous edition are as follows:

- merger of ISO 15253 and ISO 15254;
- revision of normative references;
- revision and re-organisation of terms and definitions;
- addition of new requirements for filters and tints, image relocation, and text to speech;
- editorial revision of the document.

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

This document represents the merger of two earlier related standards for low vision devices – one for optical devices only (previous ISO 15253) and another for electro-optical devices (ISO 15254) – and updating of terms, definitions, and requirements. It also includes new requirements for

- filters and tints, such as for users with extreme light sensitivity or reduced contrast sensitivity, independent of visual acuity or visual field loss;
- image relocation, such as with prisms or mirrors for users with visual field loss or eye- or head-movement restriction; and
- text to speech for electro-optical devices that offer such capability.

The reader is reminded that the requirements within this document apply to the manufacturer of low vision devices. While the requirements can also pertain to how a particular device will function for the low vision user, some factors and variables about the user may not be known to the manufacturer and thus specific requirements cannot be made. For example, the *system* resolution of an electro-optical device is governed by pixel size and density for both the camera and display, while the *spatial* resolution for the user depends on the size of the display and the distance at which the user views the display.

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Ophthalmic optics and instruments — Optical and electro-optical devices for enhancing low vision

1 Scope

This document applies to optical and electro-optical devices specified by the manufacturer for use by visually impaired persons as low vision aids. This document contains requirements and test methods for optical and electro-optical devices specified by the manufacturer for use by visually impaired persons as low vision devices.

Implanted low vision devices are excluded.

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.

EN 55022, *Information technology equipment — Radio disturbance characteristics — Limits and methods of measurement (IEC/CISPR 22:2005, modified + A1:2005)*

EN 60950-1, *Information technology equipment — Safety — Part 1: General requirements*

ISO 12312-1, *Eye and face protection — Sunglasses and related eyewear — Part 1: Sunglasses for general use*

ISO 12870, *Ophthalmic optics — Spectacle frames — Requirements and test methods*

ISO 14889, *Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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

ISO 15004-2, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-3, *Medical Electrical Equipment — Part 1-3: General Requirements for Basic Safety And Essential Performance — Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment*

IEC 60695-2-11, *Fire Hazard Testing — Part 2-11: Glowing/Hot-Wire Based Test Methods — Glow-Wire Flammability Test Method for End-Products (GWEPT)*

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:

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

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

3.1

low vision device

apparatus that alters or enhances the image viewed by a person having low vision

3.1.1

optical low vision device

lens or lens system, prism, or mirror, or combination of such optical components, that alters image characteristics, such as vergence, size, and/or position

Note 1 to entry: Image relocation using a prism, whether ground in or temporary (e.g., Fresnel), is commonly expressed in centimetres per metre or prism dioptres.

Note 2 to entry: Image relocation using a mirror is commonly expressed in degrees.

3.1.2

electro-optical low vision device

opto-electronic low vision device

device or system that produces an altered or enhanced image through the interaction between light from the object and an electronic system

Note 1 to entry: The device minimally consists of a camera and a monitor or display, but can contain additional components such as a computer, display control interface, projector, speakers, tactile output, narrow-beam light source, scanner, and software.

Note 2 to entry: In addition to computer-based systems, common configurations and terms for electro-optical low vision devices are video magnifier and closed-circuit television (CCTV), with which the image is displayed or projected at some distance removed from the user's spectacle plane, and head-mounted (a.k.a. head-up) display, with which the image is presented on a display at or near the user's spectacle plane or projected directly into the user's eye.

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3.1.3

filter

tinted lens

optical component that absorbs and/or reflects light in order to reduce the amount of light transmitted to the user's eye

3.1.3.1

neutral density filter

filter designed to reduce the amount of light by the same percentage for each wavelength across the visible spectrum

3.1.3.2

coloured tint

filter that selectively reduces the amount of light transmitted for some wavelengths relative to that transmitted for other wavelengths

Note 1 to entry: Examples of coloured tints include cut-off, bandpass, and notch filters.

3.2

magnification

ratio between a dimension of the image when a low vision device is in use and the corresponding dimension when the object is viewed without the device

Note 1 to entry: Dimension can be angular or linear.

3.2.1**angular magnification**

ratio of the angle subtended by the image of the object when viewed using a low vision device to the angle subtended by the object alone at a viewing point of reference, such as the entrance pupil of the eye

Note 1 to entry: Angular magnification is used primarily for afocal telescopic low vision devices. It also applies in part to magnifiers that are positioned at distances removed from the spectacle plane.

3.2.2**retinal image magnification**

total magnification that is obtained when using a low vision device and/or viewing technique, calculated as the product of the angular, relative distance, and relative size magnifications.

Note 1 to entry: Viewing techniques include changing viewing distance (i.e., relative distance magnification) and changing font or object size (i.e., relative size magnification). Depending on the low vision device and how it is used, a specific change can result in an increase or decrease in image size compared to that dimension when the device is not used.

3.3**magnifier**

lens system designed to change the size of the image of a near object

Note 1 to entry: The magnifier may be a simple single element or a compound multiple-element system.

3.3.1**hand magnifier**

hand-held magnifier iTeh STANDARD PREVIEW
magnifier intended to be positioned and supported by the user's hand and without artificial support
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3.3.2**stand magnifier**

magnifier in which a support positions the optical system at a fixed or adjustable distance from the object to be viewed
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3.3.3**head-mounted magnifier**

magnifier mounted in a device that is supported on the head

3.3.4**spectacle-mounted magnifier**

magnifier mounted in a device that attaches to a spectacle frame

3.3.5**spectacle magnifier****spectacle microscope**

spectacle lenses having greater power for near focus than found in typical spectacle corrections, creating retinal image magnification primarily by allowing for relative distance magnification

Note 1 to entry: In addition to relative distance magnification, some usually small amount of magnification can result from the parameters of the lens, such as base curve, centre thickness, and refractive index.

3.4**telescope**

optical system composed of two separated lenses (or lens systems), the objective and the eyepiece, that forms a magnified image of a distant object when the eyepiece is the higher powered lens (or system)

Note 1 to entry: In its afocal adjustment, the second (back) focal point of the objective lies at the first (front) focal point of the eyepiece, so that light from a distant object, entering the objective with zero vergence, exits the eyepiece with zero vergence. This is the condition for a user wearing full correction for refractive error viewing a very distant object clearly through the telescope.

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Note 2 to entry: A telescope provides angular magnification, which in its afocal adjustment can be calculated by the negative of the ratio of the equivalent power of the eyepiece to the equivalent power of the objective.

3.4.1**entrance pupil diameter**

clear aperture of the telescopic objective

Note 1 to entry: Entrance pupil diameter is expressed in millimetres.

3.4.2**focusable telescope**

telescope for which the separation between the objective and eyepiece can be changed to compensate for a range of object distances and/or to compensate for uncorrected spherical refractive error

3.5**telemicroscope****near-vision telescope**

telescope adapted for viewing near or intermediate objects

3.5.1**reading cap**

positive optical element placed in front of the telescopic objective to adapt the device for viewing a near or intermediate object

Note 1 to entry: Reading cap power is expressed in dioptres.

Note 2 to entry: In a fixed-focus afocal telescope, the reading cap is a removable lens.

Note 3 to entry: In a fixed-focus telemicroscope, the reading cap is incorporated into the objective power.

Note 4 to entry: In a focusable telescope, a portion of the objective power functions as the reading cap. This reduces the objective power that remains, thus creating a new afocal telescope with slightly greater angular magnification.

3.6**field expander****reverse telescope****minifier**

device that reduces the apparent field of view so that it is smaller than the user's unaided field of view

Note 1 to entry: Apparent field of view is the angle subtended by the field as viewed through a telescope.

3.7**spatial resolution**

smallest separation between two details in the object for which they can be recognised as being separate under a given set of conditions

3.8**field of view**

extent of the object plane visible through, or imaged by, a device

Note 1 to entry: See entries below for definitions of field of view for specific types of devices.

3.8.1**resolvable field of view**

field of view within which the device is capable of resolving required details

3.9 Parameters for magnifiers