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

Optique et instruments ophtalmiques — Dispositifs optiques et électro-optiques pour malvoyants

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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).

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics*, 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 of ISO 15253:2000 and the second edition of ISO 15254:2009, which 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 (first edition of 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 is applicable to optical and electro-optical devices specified by the manufacturer for use by visually impaired persons as low vision aids. This document specifies requirements and test methods for optical and electro-optical devices specified by the manufacturer for use by visually impaired persons as low vision devices.

Implantable 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.

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:

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

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

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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
optical 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
electro-optical 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 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 (also known as 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.

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 (3.1.3) 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 (3.1.3) 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* (3.1) 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.

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3.2.1
angular magnification
ratio of the angle subtended by the image of the object when viewed using a *low vision device* (3.1) 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.

3.3
magnifier
lens system designed to change the size of the image of a near object

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

3.3.1
hand magnifier
hand-held magnifier
magnifier (3.3) intended to be positioned and supported by the user's hand and without artificial support

3.3.2
stand magnifier
magnifier (3.3) in which a support positions the optical system at a fixed or adjustable distance from the object to be viewed

3.3.3
head-mounted magnifier
magnifier (3.3) mounted in a device that is supported on the head

3.3.4
spectacle-mounted magnifier
magnifier (3.3) 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.

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.

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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

3.9.1
optical dimensions
zone of optical dimensions
optical zone of magnifier
linear size of the lens of a magnifier that is visible when mounted

Note 1 to entry: Optical dimensions are expressed in millimetres.

3.9.2
magnifier optical axis
line connecting the centres of curvature of the surfaces of an optical system, along which there is symmetry and zero induced prism

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3.9.3
equivalent focal length
distance between a focal point and the corresponding principal plane, measured along the optical axis

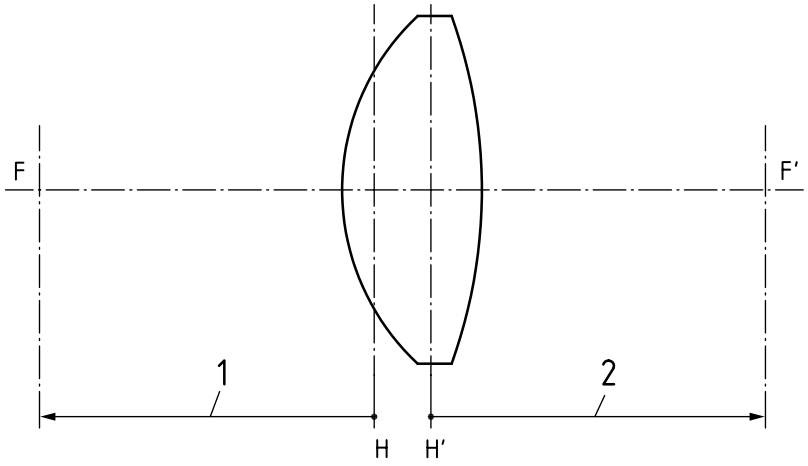
Note 1 to entry: See Figure 1.

Note 2 to entry: First focal length is measured from the first principal plane to the first (front) focal point.

Note 3 to entry: Second focal length is measured from the second principal plane to the second (back) focal point.

3.9.4
equivalent power
reciprocal of the equivalent focal length in air measured in metres

Note 1 to entry: Equivalent power is expressed in dioptres, or reciprocal metres.



Key

1	first focal length	F	first (front) focal point
2	second focal length	F'	second (back) focal point
		H	first principal plane
		H'	second principal plane

Figure 1 — Illustration of focal lengths

3.9.5
magnifier working distance
distance between the front vertex of the magnifier and the object being viewed

Note 1 to entry: See Figure 2.

3.9.6
exit image distance
vertex image distance
distance between the back vertex of the magnifier and the virtual image formed by the magnifier when the object is placed in the designated position

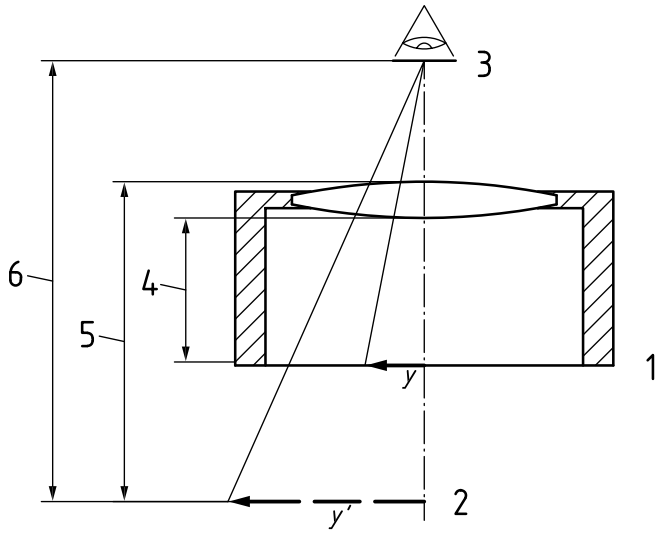
Note 1 to entry: See Figure 2.

Note 2 to entry: Exit image distance is especially useful for stand magnifiers.

3.9.7
viewing distance
distance between the image formed by the magnifier and the spectacle plane of the user

Note 1 to entry: See Figure 2.

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Key

1	object plane	*y*	object size
2	image plane	*y'*	image size
3	spectacle plane		
4	working distance		
5	exit image distance		
6	viewing distance		

Figure 2 — Illustration of object plane, image plane, spectacle plane, working distance, exit image distance and viewing distance for magnifiers

3.9.8
transverse magnification
TM
lateral magnification
enlargement ratio
ER
ratio of the linear image size to the corresponding linear object size, both measured perpendicular to the optical axis of the magnifier

Note 1 to entry: Transverse magnification is used primarily for magnifiers, especially stand magnifiers.

Note 2 to entry: Referring to Figure 2, transverse magnification can be calculated with the equation TM = *y'*/*y*.

3.9.9
lateral variation of magnification
distortion
change in magnification as distance from the optical axis increases

Note 1 to entry: For converging (plus) lenses with an aperture behind the lens, such as the pupil of the user's eye, the magnification change is positive, resulting in pincushion distortion.

Note 2 to entry: For diverging (minus) lenses with an aperture behind the lens, such as the pupil of the user's eye, the magnification change is negative, resulting in barrel distortion.

Note 3 to entry: If the aperture of the system is placed in front of the lens (that is, the user's pupil is not the limiting aperture), a plus lens will produce barrel distortion while a minus lens will produce pincushion distortion.

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3.9.10
nominal magnification
effective magnification
M_{nominal}
ratio of the retinal image size with zero exit image vergence when using the magnifier to the retinal image size when the object is viewed at the reference seeing distance without the magnifier

Note 1 to entry: Reference seeing distance is the distance between the spectacle plane and the object or image observed that is assumed to be the closest that a typical corrected eye can focus clearly and comfortably.

Note 2 to entry: Exit image vergence, expressed in dioptres, is the reciprocal of the exit image distance measured in metres.

Note 3 to entry: Nominal magnification can be calculated from the product of the reference seeing distance, in metres, and the equivalent power, in dioptres.

EXAMPLE With a reference seeing distance of 0,25 m the nominal magnification is calculated from the formula

$$M_{\text{nominal}} = 0{,}25\ F = F/4.$$

3.9.11
trade magnification
conventional magnification
M_{trade}
ratio of the retinal image size when the magnifier is placed at the spectacle plane, and the object is placed such that the image is at the reference seeing distance, to the retinal image size when the object is viewed at the reference seeing distance without the magnifier

Note 1 to entry: Trade magnification can be calculated from the nominal magnification using the formula:

$$M_{\text{trade}} = M_{\text{nominal}} + 1$$

3.9.12
linear field of view
field of view at the viewing distance stated by the manufacturer

Note 1 to entry: Linear field of view is expressed in millimetres at a specified viewing distance.

3.10 Parameters for telescopes, telemicroscopes and minifying field expanders

3.10.1
telescope optical axis
line on which the elements or components of an optical system are centred

Note 1 to entry: A lens system that incorporates a prism or mirror can have a folded or nonlinear optical axis.

3.10.2
telescope object field of view
field of view at the working distance specified by the manufacturer

Note 1 to entry: Object field of view is denoted in either metres at a specified distance or degrees.

3.10.3
telescope working distance
distance between the telescope objective and the object being viewed

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3.10.4
telemicroscope equivalent power
<for a telemicroscope> product of the reading cap power and telescope magnification

Note 1 to entry: Equivalent power is expressed in dioptres, or reciprocal metres.

3.11 Parameters for electro-optical devices

3.11.1
display size
horizontal and vertical dimensions of the display within which the image is visible, i.e., active area

Note 1 to entry: Many displays are labelled by their oblique size, i.e., linear distance between diagonally opposite corners.

3.11.2
electro-optical device working distance
working space
distance between the front of the camera of the system and the object being imaged

3.11.3
system resolution
spatial resolution of the system, limited by the component that has the lowest resolution

Note 1 to entry: System resolution is expressed in pixels horizontal by pixels vertical.

Note 2 to entry: Spatial resolution for the user will depend on and vary with display size and working distance. Thus, it typically cannot be set or controlled by the manufacturer.

3.11.4
display magnification
ratio between any linear dimension of the displayed image and the corresponding dimension of the object

3.11.5
electro-optical device object field of view
field of view that is imaged by the system for conditions of use stated by the manufacturer

Note 1 to entry: Object field of view is expressed in millimetres.

3.11.6
contrast ratio
ratio of the luminance of the brightest colour (e.g., white) to that of the darkest colour (e.g., black) produced by a display

Note 1 to entry: Contrast ratio is commonly normalised to a minimum value of 1 and reported, for example, as 300:1.

Note 2 to entry: Displays capable of producing zero luminance would have a contrast ratio of infinity.

3.11.8
object table
XY table
device used to support and position the object being viewed

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3.11.9
text to speech system
text to speech device
video magnifier or CCTV that incorporates optical character recognition (OCR) to convert text to audio output recognizable to the user as speech

Note 1 to entry: Optical character recognition (OCR) is the conversion of typed, printed, or handwritten text into machine-encoded text, which can then be used in other applications, such as searchable text, speech, and braille.

4 Classification

4.1 Optical devices

4.1.1 Distance vision

Telescopes, field expanders, and devices for image relocation.

4.1.2 Near and intermediate vision

Magnifiers, telemicroscopes, focusable telescopes, and devices for image relocation.

4.1.3 Retinal illumination reduction or contrast enhancement

Neutral density filter, coloured tint, cut-off, bandpass, and notch filters.

4.2 Electro-optical devices

Electronic systems for viewing objects at distance, intermediate, and/or near. Such devices capture images and display them on a screen either directly or indirectly via projection, or by projecting directly into the eye.

5 Requirements

5.1 General

5.1.1 Risk assessment and management

Manufacturers shall assess and manage potential risks that may pose harm to the user using, when applicable, the steps provided in ISO 14971, ISO 62366-1, and IEC 60601-1.

A device that projects an image directly onto the retina shall meet the requirements of ISO 15004-2. The manufacturer shall assess and manage potential light hazards related to intended long-term repetitive daily use of the device.

5.1.2 Materials

Materials comprising the device and its components shall conform to the relevant clauses of ISO 15004-1 and, when applicable, ISO 12870.

5.1.3 Dimensions and weight

The dimensions and weight of each component of the device shall be within ±10 % of the stated values.

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