Ophthalmic optics and instruments - Optical and electro-optical devices for enhancing low vision (ISO 15253:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 15253:2021 sisaldab Euroopa standardi EN ISO 15253:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15253:2021 consists of the English text of the European standard EN ISO 15253:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 14.07.2021.	Date of Availability of the European standard is 14.07.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.70

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15253

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Supersedes EN ISO 15253:2000, EN ISO 15253:2000/AC:2001, EN ISO 15254:2009

English Version

Ophthalmic optics and instruments - Optical and electro-optical devices for enhancing low vision (ISO 15253:2021)

Optique et instruments ophtalmiques - Dispositifs optiques et électro-optiques pour malvoyants (ISO 15253:2021)

Augenoptik und ophthalmische Instrumente - Optische und elektrooptische vergrößernde Sehhilfen für Sehbehinderte (ISO 15253:2021)

This European Standard was approved by CEN on 28 June 2021.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 15253:2021 E

European foreword

This document (EN ISO 15253:2021) 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 January 2022, and conflicting national standards shall be withdrawn at the latest by January 2022.

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.

This document supersedes EN ISO 15253:2000, EN ISO 15253:2000/AC:2001 and EN ISO 15254:2009.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15253:2021 has been approved by CEN as EN ISO 15253:2021 without any modification.

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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).

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 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*, 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.

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.

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