International Standard

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First edition
2024-11

Ophthalmic instruments — Optical coherence tomographs —

Part 1: Optical coherence tomographs for the posterior segment of the human eye

Instruments ophtalmiques — Tomographe à cohérence optique —

Partie 1: Tomographe à cohérence optique du segment postérieur de l'oeil humain

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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

This first edition of ISO 16971-1 cancels and replaces the first edition (ISO 16971:2015), which has been technically revised.

The main changes are as follows:

— revision of the dated references;

— document restructured;

— definitions added with particular emphasis on performance parameters;

— added example performance parameters;

— clarified requirements for presentation of OCT images;

— clarified minimum requirements for data exchange; DICOM required;

— test methods not mandatory anymore; added additional test methods;

— extended requirements for the information to be supplied by the manufacturer;

— deleted annex on *Minimum requirements for a normative database;*

— Annex A *Example for test device* added.

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

Until the early 21st century, it was impossible to obtain clinically relevant depth-resolved information of the inner structures of the human eye, including those of the retina. With optical coherence tomography (OCT), eye care practitioners now have an available non-invasive method that allows the rapid generation of high-resolution three-dimensional in vivo images of the eye. Before the first edition of ISO 16971 was published, there were no well-defined and widely accepted requirements for either OCT instruments or the data collected and displayed with them. Consequently, it was very difficult to compare the instruments, their measurement results, and clinically relevant diagnostic findings based on them.

The first edition of ISO 16971 was an important first step towards defining the necessary terminology and performance requirements for OCT instruments and to establishing standardized framework conditions for the application of OCT technology to ophthalmic imaging.

This edition continues the task by extending the requirements of ISO 16971 and specifying a more comprehensive set of characteristics for OCT instruments. To facilitate this, ISO 16971 has been divided with this document serving as the first part addressing OCT instruments for the posterior segment of the human eye.

Ophthalmic instruments — Optical coherence tomographs —

Part 1:
Optical coherence tomographs for the posterior segment of the human eye

1 Scope

This document is applicable to optical coherence tomography (OCT) instruments, systems, and methods that are intended to image and measure the biological tissue of the posterior segment of the human eye.

This document specifies characteristics and minimum requirements for OCT instruments and systems. It specifies type tests and procedures to verify that a system or instrument qualifies as an OCT instrument or system in accordance with this document.

NOTE In this document the term OCT refers to ophthalmic applications.

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*

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 60825-1, *Safety of laser products — Part 1: Equipment classification and requirements*

NEMA PS3/ISO 12052, *Digital Imaging and Communications in Medicine (DICOM) Standard*, National Electric Manufacturers Association, Rosslyn, VA, USA (available free at https://www.dicomstandard.org/).

3 Terms, definitions and symbols

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 General

3.1.1
A-scan
one-dimensional axial profile of sample reflectance

Note 1 to entry: axial is the direction of incidence of the measuring beam.

Note 2 to entry: An A-scan is typically depicted either as a plot of reflectance versus depth or as a column in a B-scan image with intensity corresponding to reflectance.

3.1.2
B-scan
two-dimensional cross-sectional measurement of sample reflectance, typically depicted on a display as intensity as a function of depth and transverse position

Note 1 to entry: A B-scan is often constructed by transverse scanning and placing neighbouring A-scans side by side.

3.1.3
en-face OCT image
2D transverse OCT image derived from the OCT signal between transverse surfaces in an OCT volume, where these transverse surfaces are usually derived by image processing that identifies boundaries between layers in the tissue

Note 1 to entry: Typically, an en-face OCT images is associated with a transverse volume slab of a given layer of tissue, e.g. retinal nerve fibre layer (RNFL), retinal pigment epithelium (RPE) or choroid.

3.1.4
manufacturer
natural or legal person with responsibility for design or manufacture of an ophthalmic instrument with the intention of making the ophthalmic instrument available for use, under their name, whether or not such an ophthalmic instrument is designed or manufactured by themselves or on their behalf by another person

[SOURCE: ISO 13485:2016, 3.10, modified — The word "medical device" has been replaced by "ophthalmic instrument" and the original notes to entry have been deleted. Text has been made gender-neutral.]

3.1.5
OCT volume
three-dimensional (spatial) representation of the results of a volume scan

Note 1 to entry: An OCT cube is a subtype of an OCT volume.

3.1.6
ophthalmic instrument
device designed to have an application to the eye, and intended by its *manufacturer* (3.1.4) to be used in the diagnosis, treatment, or monitoring of a patient, or for compensation or alleviation of disease, injury or disability

[SOURCE: ISO 15004-1:2020, 3.1]

3.1.7
optical coherence tomograph
OCT instrument
medical device or system that measures, processes, and displays OCT images of target objects

3.1.8
optical coherence tomography
OCT
optical interferometric measurement technique for obtaining cross-sectional images of a target object, using partially coherent optical radiation to determine the relative depths of backscattering structures within the object

EXAMPLE Biological tissue of the human eye is an example of a target object.

3.1.9
standard eye
emmetropic eye that has a focal length of 17 mm in air and with retinal tissue with an index of refraction of n = 1,33 to n = 1,39

Note 1 to entry: The manufacturer specifies the index of refraction.

3.1.10
structural OCT image
two-dimensional image representing the reflectance of the sample tissue along a surface

Note 1 to entry: Typically, the representation of results of one or multiple B-scans.

3.1.11
volume scan
three-dimensional sampling of the reflectance of the sample tissue

Note 1 to entry: Often realised as a sequence of spatially adjacent B-scans.

3.1.12
volume slab
slab
contiguous region of interest in an OCT volume, roughly in the form of a layer or slice

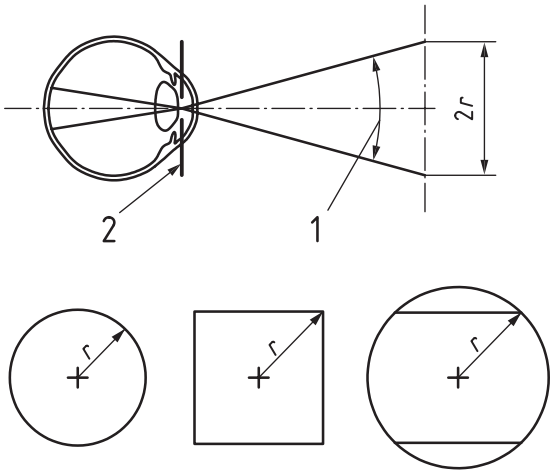
Note 1 to entry: A slab can follow an anatomical structure or can be plane. It can be as thick as the retina or as thin as a single surface.

3.2 Optical properties

3.2.1
angular field of view
FOV
angular extent from which an image can be taken, expressed as the angle subtended at the exit pupil of the eye by the maximum dimension 2r

[SOURCE: ISO 10940:2009, 3.2, modified]

Note 1 to entry: See Figure 1.



Key
1 angular field of view
2 entrance pupil of instrument/exit pupil of eye

Figure 1 — Meaning of dimension r for various formats

3.2.2
axial range
measuring range of the OCT instrument in the axial direction in tissue in a *standard eye* (3.1.9)

Note 1 to entry: This corresponds to the length of an A-scan.

Note 2 to entry: The axial range can be calculated by dividing the optical path length range by the assumed refractive index of the tissue.

3.2.3
axial resolution
full width half maximum of the OCT signal of a single punctiform reflector in axial direction, given in tissue in a standard eye

3.2.4
transverse range
transverse extent of an OCT image at the image plane in a standard eye

3.2.5
transverse optical resolution
full width at half maximum of the OCT signal of a single punctiform reflector in transverse direction, given in tissue in a standard eye

3.3 Signal characteristics

3.3.1
axial sampling density
distance between the corresponding locations in tissue for two adjacent OCT image pixels in axial direction

3.3.2
axial signal roll-off
attenuation in OCT signal with axial depth in tissue, specified by the decrease in sensitivity at a given axial location in the image window relative to the maximum sensitivity

3.3.3
sensitivity
ratio between irradiated optical power and minimum detectable optical power reflected back from the sample to the system

Note 1 to entry: Sensitivity is typically expressed in decibels.

Note 2 to entry: Sensitivity of OCT instruments is not the same as the term sensitivity used to describe clinical accuracy for clinical performance testing.

Note 3 to entry: In the OCT literature, 'sensitivity' is frequently used to denote 'maximum sensitivity.'

3.3.4
maximum sensitivity
sensitivity (3.3.3) measured at the axial depth of the greatest signal

3.3.5
minimum sensitivity
sensitivity (3.3.3) measured at the axial depth of the least signal

3.3.6
transverse sampling density
displacement of the OCT beam between neighbouring A-scans or B-scans