



**ISO 16971-1**

**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*

**First edition  
2024-11**

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Published in Switzerland

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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.

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Until the early 21<sup>st</sup> 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.