International Standard

ISO 16971-1

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

Reference number
ISO 16971-1:2024(en)

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Published in Switzerland

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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 document 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 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.

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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.

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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/

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