INTERNATIONAL STANDARD

ISO 16971

First edition
2015-04-15

Ophthalmic instruments — Optical coherence tomograph for the posterior segment of the human eye

Instruments ophtalmiques — Tomographe à cohérence optique du segment postérieur de l'oeil humain

Reference number
ISO 16971:2015(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Introduction

Until recently, it was impossible to obtain medically 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. Currently, there exist no well-defined and widely accepted requirements for either OCT instruments or the data collected and displayed with them. Consequently, it is very difficult to compare the instruments, their measurement results, and medically relevant diagnostic findings based on them. This International Standard aims to define the necessary terminology and performance requirements for OCT instruments and to establish standardized framework conditions for the application of OCT technology to ophthalmic imaging.

Ophthalmic instruments — Optical coherence tomograph for the posterior segment of the human eye

1 Scope

This International Standard 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 International Standard defines certain terms that are specific to this diagnostic procedure.

This International Standard specifies minimum requirements for OCT instruments and systems. It specifies tests and procedures that will verify that a system or instrument complies with this International Standard and so qualifies as an OCT in the meaning of this International Standard. It specifies type test methods and procedures that will allow the verification of capabilities of systems that are beyond the minimum required for OCTs.

NOTE It is anticipated that this International Standard can, in a future revision, be expanded to include all segments of the human eye.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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[1)], *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15004-1 and the following apply.

3.1
optical coherence tomography
OCT
optical interferometric measurement technique for obtaining cross-sectional images of a target object, using a partially coherent narrow scanning beam to determine the relative depths of reflective surfaces within the object

EXAMPLE Biological tissue of the human eye.

3.2
optical coherence tomograph
instrument or system that measures, processes, and displays OCT images of target objects

1) Revision to ISO 15004-2:2007. To be published.