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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

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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 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).

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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

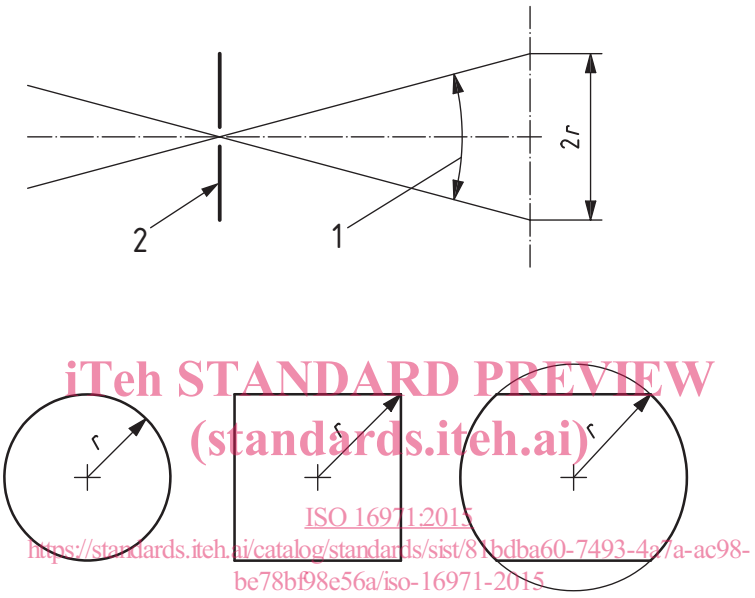
1) Revision to ISO 15004-2:2007. To be published.

3.3
retinal thickness
axial distance between the first inner surface of the retinal nerve and the retinal pigment epithelium (RPE)

3.4
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

3.5
ophthalmic instrument
device designed to have an application to the eye

[SOURCE: ISO 15004-1:2006, 3.1]

3.5.1
non-invasive ophthalmic instrument
ophthalmic instrument which does not in whole or in part penetrate inside the body, either through a body orifice or through the surface of the body

[SOURCE: ISO 15004-1:2006, 3.2]

3.5.2
active ophthalmic instrument
any ophthalmic instrument that depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and that acts by converting this energy

Note 1 to entry: Ophthalmic devices intended to transmit energy, substances, or other elements between an active ophthalmic instrument and the patient, without any significant change, are not considered to be an active ophthalmic instrument.

[SOURCE: ISO 15004-1:2006, 3.3]

3.6
manufacturer
<ophthalmic instrument> natural or legal person who places the ophthalmic instrument on the market

[SOURCE: ISO 15004-1:2006, 3.4]

4 Requirements

4.1 General

4.1.1 General requirements

The OCT shall conform to the requirements specified in ISO 15004-1, IEC 60601-1, IEC 60825-1, and the requirements described in 4.2 to 4.10.

4.1.2 Light hazard protection

The OCT shall conform to all requirements specified in ISO 15004-2 with the exception that if the first edition applies, then for ISO 15004-2:2007, Table 2, 5.4.1.4 and Table 4, 5.5.1.3, a 3,5 mm diameter irradiance averaging aperture rather than a 1 mm diameter aperture should apply.

4.2 Retinal thickness measurement

4.2.1 General

The calculation of the retinal thickness shall be performed assuming refractive indices within the range from n = 1,33 to n = 1,39.[9] [10] [11] [12] [13]

4.2.2 Presentation of retinal thickness maps

To facilitate the interpretation and comparison of retinal thickness maps taken with different OCT instruments, a standardized grey scale display should be used.

OCT instruments that make this display available to the user shall designate it as “standardized display”.

NOTE OCT instruments complying with this International Standard can additionally provide displays using parameters different from these standardized ones, e.g. colour displays.

The standardized grey scale display, if used, shall comply with the following: The display shall employ a continuous grey scale with values related to the ratio of reflected/incident light at each resolvable depth. A representation (key) of the grey scale shall be displayed on the screen with the OCT image. The minimum values and the maximum values of the grey scale shall be indicated.

OCT images of the retina can also be displayed using false colour scales to represent different reflectance values or to delineate different retinal sublayers. Sublayers can be defined manually or derived with the aid of segmentation algorithms.