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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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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

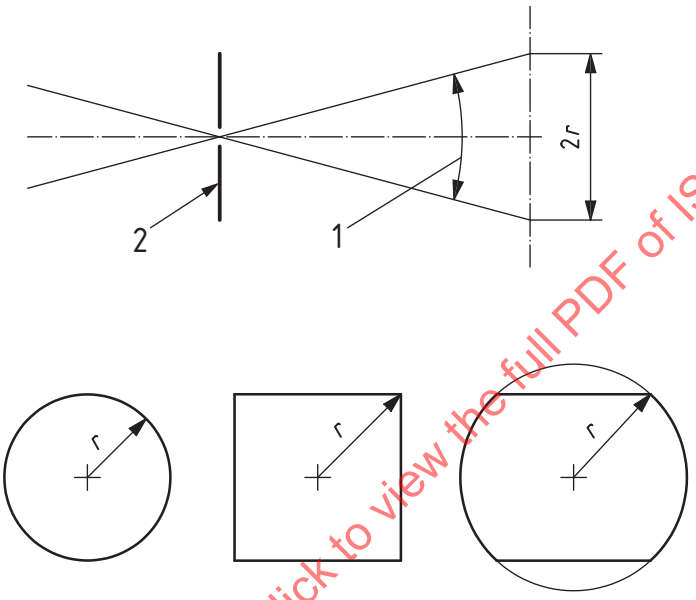
1) Revision to ISO 15004-2:2007. To be published.

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.

4.3 Angular field of view

The tolerance of the angular field of view shall be ± 5 %.

4.4 Depth scaling

The accuracy of the measurement of the thickness of a test target shall be equal to or better than ± 3 %.

4.5 Image quality

The manufacturer shall provide to the user the following parameters for evaluating image quality, together with how they are defined and measured.

a) X resolution (along scan direction);

b) Y resolution (perpendicular to scan direction);

c) Z resolution (axial direction);

d) Signal-to-noise ratio as a function of Z position.

4.6 Axial resolution

Axial resolution shall be specified.

4.7 Signal-to-noise ratio (SNR)

Signal-to-noise ratio shall be specified by the manufacturer.

4.8 Calibration co-alignment of fundus image and OCT scan

If a fundus image is provided, then the co-alignment of any marker on the fundus image and the corresponding OCT scan position shall be within ±100 µm at the centre of the field of view, with the alignment done at a specified ambient temperature, e.g. 21 °C ± 2 °C (recognizing that temperature affects the instrument alignment).

NOTE As an example, if the readout is a two-dimensional fundus image, the position/location can be indicated by a line positioned on the two-dimensional fundus image. Similarly, if the readout is a three-dimensional fundus image, the position/location can be indicated by a plane positioned on the three-dimensional fundus image.

4.9 Normative database

It is recommended that a normative database for typical test parameters is included. The OCT instrument should be capable of comparing the result of each tested location for these parameters with the age-specific normal mean value and distribution of normal values.

NOTE Typical parameters are those that are recommended by the manufacturer for routine use.

The version of the normal value table should be specified by an ordinal version number and the date of issue of this table. Specification shall include the size and the age range of the normative database. The normative database should fulfil the minimum requirements given in Annex A.

Printouts should contain the version number of the normal value table used.

When new normal value table versions are implemented into an instrument by software update or other means, the user should be notified.

4.10 Data export

All diagnostic images shall be exportable, at least as an image.

EXAMPLE Possible formats are portable document format (pdf, see ISO 32000-1) or standard data formats, e.g. tiff, jpg, or DICOM (see ISO 12052).

5 Test methods

5.1 General

All tests described in this International Standard are type tests.

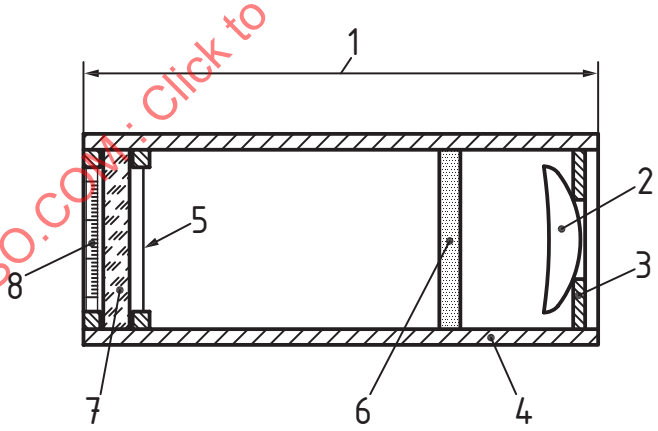
5.2 Test device

Use a test device complying with the specification given in Figure 2. For angular field of view (see 4.3), the test device includes a target at the focus of the lens which has reference marks to indicate field position.

For depth scaling (see 4.4), the test device includes a piece of glass on the order of 1 mm thick whose thickness and refractive index are accurately known (with tolerance significantly less than 3 %). A neutral density (ND) filter should be added between the lens and the glass to prevent detector saturation.

For axial resolution (see 4.6), one surface of the glass used for depth scaling can provide a signal to measure the axial point spread function.

For signal-to-noise ratio (see 4.7), this quantity can be calculated with the intensity of the reflection from one surface of the glass used for depth scaling, along with the known reflectivity of the glass, the known attenuation of the ND filter, and a measurement of the noise level (standard deviation of the background signal level).



Key

1 length approx. 17 mm
2 lens, f = 17 mm
3 aperture, diameter 6 mm
4 tube
5 single filament with 100 µm diameter (has to be tight)
6 neutral density filter
7 glass plane, 1 mm thick
8 scale with reference marks for field size

Figure 2 — Specification of test device

5.3 Co-alignment of preview and OCT scan

5.3.1 Test device

Use a test device complying with the specification given in Figure 2.

5.3.2 Procedure

a) Place the test device in position (equivalent to patient eye).

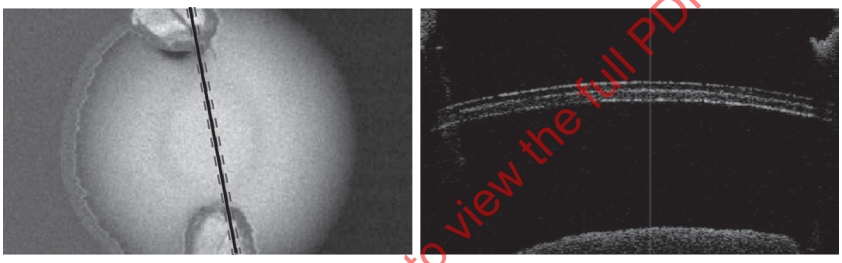
b) Use OCT scan line mode.

c) Position the scan preview line to be congruent with the filament of the test device (including angle, lateral x and y).

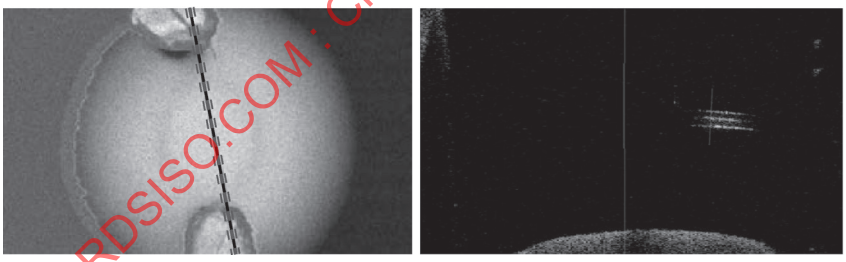
d) Check the resulting OCT scan signal.

— The positioning is in tolerance, if the OCT signal is present on the full scan length, according to the length of filament [see Figure 3 a)];

— The positioning is not in tolerance, if the OCT signal is only in part or even not present [see Figure 3 b)].



a) Co-alignment in tolerance[a]



b) Co-alignment not in tolerance[b]

Key

a Left: Preview scan line (dashed) is congruent with filament (black). Right: OCT signal shows filament in full length.

b Left: Preview scan line (dashed) is congruent with filament (black). Right: OCT signal shows small intersection with filament only or even no signal.

Figure 3 — Illustration of evaluation of OCT scan signal

5.4 Retinal thickness measurement

The kind of measuring procedure to enable and guarantee the required reproducibility and repeatability of the thickness measurement shall be specified by the manufacturer. The manufacturer shall define and describe the measurement procedure of the retinal thickness of his OCT.

