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Ophthalmic optics and instruments — Instruments to measure axial distances in the eye

Optique et instruments ophtalmiques — Appareil pour le mesurage de la longueur axiale de l'oeil

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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Introduction

The measurement of the axial length of the human eye is one of the pre-requisites for the calculation of the necessary power of an artificial lens that is to be implanted in the eye during cataract and/or refractive surgery.

Since the 1950s ultrasound biometry instruments have been used for ocular distance measurements. Depending on how the sound waves are coupled into the eye, two different measurement methods are applied in ultrasound biometry: immersion and contact techniques. In recent years, optical biometry instruments based on partial coherence interferometry have established themselves as an alternative to echometry.

Neither instrument is calibrated against a common standard. As a result, there are systematic differences between measurements taken with different biometers. The resulting errors can affect surgical outcomes for patients.

Ophthalmic optics and instruments — Instruments to measure axial distances in the eye

1 Scope

This International Standard is applicable to instruments and methods used for measuring the axial length of the human eye.

It defines minimum requirements for such instruments and systems and defines test methods and procedures to verify that a system or instrument qualifies as an axial length measuring device in accordance with this International Standard.

2 Normative references

The following referenced documents are indispensable for the application 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.

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
axial length
distance along the axis of a human eye between the anterior corneal surface to either the inner limiting membrane (ILM) of the retina or the retinal pigment epithelium (RPE) of the retina

NOTE The separation between the ILM (anterior retina) and RPE (posterior retina) is approximately 100 µm at the centre of the fovea and 300 µm immediately outside the fovea. Different methods exist to assess axial length, e.g. peak and rising edge detection of fundus echoes in ultrasound instruments (using ILM) or determination of the optical path length to the RPE in optical biometry.

3.2
aphakic mode
measurement mode and/or instrument setting for an axial length measuring device which is to be used for the measurement of an aphakic eye (eye without lens)

3.3
contact ultrasound
contact mode
coupling technique in echo biometry by which the measuring transducer probe is in direct contact with the cornea

3.4
echo biometry
method to determine the axial length of a human eye by measuring the time of flight of an ultrasound pulse between two echo-generating structures in the eye

3.5
group refractive index
ratio c_0/c_g between the speed of light in vacuum (c_0) and the group velocity of light propagation (c_g) through a medium or a biological tissue

3.6
immersion ultrasound
immersion mode
coupling technique in echo biometry by which the measuring transducer probe is separated from the cornea by a water or liquid standoff

3.7
optical biometry
optical method to measure the axial length of a human eye

3.8
phakic mode
measurement mode and/or instrument setting for an axial length measuring device which is to be used for the measurement of a phakic eye (eye with a crystalline lens)

3.9
acoustical impedance
Z
material property defined as the product of the velocity of sound in that material with its density:

$$Z = \upsilon \times \rho$$

where

υ is the velocity of sound in the material;

ρ is the density of the material.

4 Requirements

The axial length measuring device shall conform to the requirements given below. Conformity shall be verified as described in Clause 5.

The radial and axial dimensions of three test bodies conforming to the requirements of Annex A shall be determined using the instrument under test and shall be compared to the true dimensions. All measured values shall lie within ± 100 µm of the true dimensions.

5 Test methods

5.1 General

The measurements aim at comparing axial and radial dimensions of the test cylinders.

All test bodies shall be placed in a position relative to the measuring instrument or sensor (transducer) which is comparable to the patient's eye position during clinical measurements. Axial measurements are to be performed along the cylinder axis, radial measurements along a diameter. In each orientation, 10 independent measurements shall be carried out and averaged to give the respective test cylinder dimension.

To perform independent measurements it is necessary to adjust the measuring device anew for each new single measurement.

5.2 True parameters of the test bodies

The true dimensions of the test bodies shall be determined using a mechanical calliper with an accuracy of at least or better than 10 µm, preferably at the same temperature at which the measurements with the axial length measuring devices were performed. Test results shall be evaluated according to the general rules of statistics.

The group refractive index and the velocity of sound and their temperature dependences, as well as the acoustical impedance of the material, are to be specified.

5.3 Measurements with ultrasound biometry instruments

Measurements using ultrasound instruments shall be performed in contact mode as well as in immersion mode. For immersion measurements, the test cylinders are to be immersed in distilled water in a suitable cuvette and oriented according to the desired dimension to be measured.

To prevent excessive uptake of water, the test bodies shall only be immersed in water for the duration of the measurements.

The ultrasound instrument has to be set up to operate in the aphakic mode.

The temperature of the test bodies shall be determined in order to allow a temperature correction for the propagation speed of sound through the test body material.

The measured values are transformed into times of flight and then reconverted into geometrical distances by means of the temperature-corrected velocity of sound for the test body material. For details, see Annex A.

5.4 Measurements with optical biometry instruments

The optical biometry instrument has to be set up to operate in a mode which allows the optical path length of the test body to be obtained.

The temperature of the test bodies shall be determined in order to allow a temperature correction for the group refractive index of the test body material.

The measured values are then reconverted into geometrical distances by means of the temperature-corrected group refractive index for the test body material. For details, see Annex A.

6 Accompanying documents

The instrument shall be accompanied by documents containing instructions for use and any necessary precautions. In particular, these documents shall contain the following information:

a) name and address of the manufacturer or his authorized representative as required by legislation;

b) instructions as to effective disinfection of the components of the axial length measuring device which are in contact with the patient with particular reference to instruments returned to the manufacturer for repair and maintenance;

c) any additional documents as specified in IEC 60601-1;

d) a reference to this International Standard, i.e. ISO 22665:2012, if the manufacturer or supplier claims compliance with it;

e) instructions for use, if not already specified by IEC 60601-1.

7 Marking

The instrument shall be permanently marked with at least the following information:

a) name and address of manufacturer or supplier;

b) name, model, serial number;

c) additional marking as required by IEC 60601-1.

Annex A
(normative)

Test bodies and evaluation of measurements

A.1 Test bodies

A.1.1 General

The test bodies are cylinders made of a suitable material that represent the distances of small, medium and long eyes; they shall be manufactured with a tolerance ≤ 0,01 mm.

PMMA has been used in a variety of ultrasound applications as an echo-generating material; millions of PMMA lenses have been implanted in human eyes, the axial length of which is measured by ultrasound. Therefore, A.1.2 gives the specification of a test body on the basis of the relevant material parameters for test bodies made from PMMA.

Other suitable materials may be used and will be necessary, e. g. for ultrasound biometry instruments that may not be sensitive enough to display echoes with a long travel time through PMMA.

When selecting an appropriate material, it is recommended to consider the material's acoustical impedance to cause changes similar to those at the tissue margins to be detected in the human eye.

NOTE 1 Otherwise, the detection mechanism will be different from that of the human eye, thereby causing a non-negligible impact on the measured axial lengths.

NOTE 2 Consideration may be given to selecting a combination of more than one material.

If a material other than PMMA is to be used, the specification of the test body and evaluation of results shall follow along the lines of the approach with PMMA, but with the appropriate parameters of the selected material and the calculations made based on them.

A.1.2 Material properties

The following material properties are used for the measurement evaluation:

T temperature of the test body (in °C);

$c(T)$ temperature-dependent velocity of sound at working frequency for the test body material (in m/s);

$n_g(T)$ temperature-dependent group refractive index at laser wavelength for the test body material.

For PMMA:

The temperature-dependence of the ultrasound velocity is assumed to be the same as given by Asay et al[1] for 6 MHz:

$$c(T) = 2751{,}9 - 2{,}647(T - 25) - 8{,}631 \cdot 10^{-3}(T - 25)^2 \quad \text{(A.1)}$$

The temperature-dependence of the group refractive index is assumed to be the same as the respective relation for the phase refractive index[2] and can be expressed as:

$$n_g(T) = n_0 - 8 \cdot 10^{-5} \cdot (T - T_0) \quad \text{(A.2)}$$

with n_0 = 1,498 at T_0 = 20 °C[3].

For materials other than PMMA, the relations given in Equations (A.1) and (A.2) will need to be replaced with the respective relations for the selected material.

A.1.3 Geometry of test cylinders

The lengths l of the test cylinders shall be equal to their diameters d (see Figure A.1).

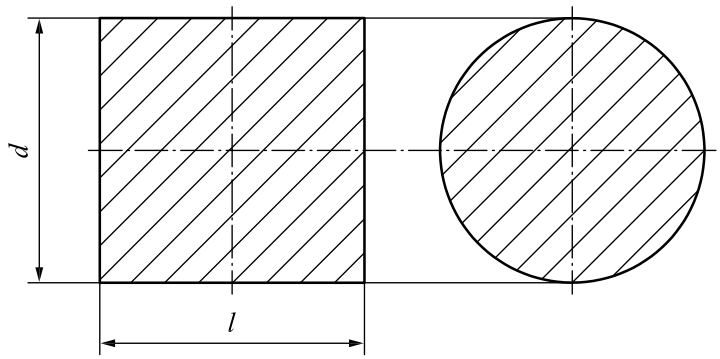

Figure A.1 — Test cylinders with axial length l and diameter d ($l = d$)

Different cylinder dimensions are required for ultrasound and optical biometry to represent small, medium and long eyes.

The relation between cylinder lengths l_{MAT} and corresponding eye lengths l_{EYE} is given by:

$$\frac{l_{MAT}}{l_{EYE}} = \frac{c_{MAT}}{c_{EYE}} \quad \text{and} \quad \frac{l_{MAT}}{l_{EYE}} = \frac{n_{EYE}}{n_{MAT}} \quad \text{respectively.}$$

where

c_{MAT} is the temperature-dependent velocity of sound of the test cylinders;

n_{MAT} is the temperature-dependent group refractive index of the test cylinders;

c_{EYE} is the temperature-dependent velocity of sound of the eye;

n_{EYE} is the group refractive index of the eye.

EXAMPLE Table A.1 provides a set of test cylinder dimensions allowing short, medium and long eyes to be represented by 5 PMMA cylinders. Their lengths are 15 mm, 20 mm, 30 mm, 40 mm and 60 mm. The values were calculated using an average ultrasound velocity of 1550 m/s[4] for the phakic eye at body temperature (37 °C) and an average group refractive index of 1,3574[5] apart from the PMMA material properties given in Equations (A.1) and (A.2). The dimensions of the test cylinders actually used, especially of those representing short and long eyes, may deviate from those in Table A.1 according to the measurement range of the instrument under test.

Table A.1 — Test cylinder dimensions $l = d$ made from PMMA and representing small, medium and long axial eye lengths

Ultrasound biometry		Optical biometry	
PMMA cylinder l mm	Eye length mm	PMMA cylinder l mm	Eye length mm
30,0	17,04	15,0	16,55
40,0	22,72	20,0	22,07
60,0	34,08	30,0	33,11