INTERNATIONAL STANDARD

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# Ophthalmic instruments — Fundamental requirements and test methods —

## Part 1: General requirements applicable to all ophthalmic instruments



*Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai —*

*Partie 1: Exigences générales applicables à tous les instruments ophtalmiques*



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# 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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.



This document was prepared by Technical Committee ISO/TC 172 *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 170, *Ophthalmic optics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).



This third edition cancels and replaces the second edition (ISO 15004-1:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

— normative references have been updated;

— the definition of 3.4 manufacturer has been aligned with the corresponding definition in ISO 13485;

— particular requirements about environmental conditions have been replaced by a reference to IEC 60601-1:2005 + A1:2012;

— Annex A has been updated;

— some editorial changes have been made.

A list of all parts in the ISO 15004 series can be found on the ISO website.

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.

 

# Ophthalmic instruments — Fundamental requirements and test methods —

# Part 1:
# General requirements applicable to all ophthalmic instruments

## 1 Scope

This document specifies fundamental requirements for non-invasive, active and non-active ophthalmic instruments and to devices for enhancing low vision. This document is also applicable to tonometers, but not to other ophthalmic instruments which are used in contact with the globe of the eye.

This document is not applicable to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

## 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 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005 + A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60695-2-10, *Fire hazard testing — Part 2-10: Glowing/hot-wire based test methods — Glow-wire apparatus and common test procedure*

IEC 60695-2-11, *Fire hazard testing — Part 2-11: Glowing/hot-wire based test methods — Glow-wire flammability test method for end-products*

## 3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

**3.1**
**ophthalmic instrument**
device designed to have an application to the eye, and intended by its manufacturer to be used in the diagnosis, treatment, or monitoring of a patient, or for compensation or alleviation of disease, injury or disability

**3.2**
**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

**3.3**
**active ophthalmic instrument**
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.

**3.4**
**manufacturer**
natural or legal person with responsibility for design and/or manufacture of an ophthalmic instrument with the intention of making the ophthalmic instrument available for use, under his/her name, whether or not such an ophthalmic instrument is designed and/or manufactured by that person himself/herself or on his/her behalf by another person(s)

[SOURCE: ISO 13485:2016, 3.10, modified — The word "medical device" has been replaced by "ophthalmic instrument", neutered.]

# 4 Fundamental requirements



## 4.1 General

This document takes precedence over the corresponding requirements of IEC 60601-1, if IEC 60601-1 is applicable and differences exist.



The general requirements specified in this document for ophthalmic instruments shall be applied in conjunction with those of the relevant product-related International Standard, if it exists. Annex A provides for information the list of relevant product-related International Standards for ophthalmic instruments.

## 4.2 Design

Ophthalmic instruments shall be so designed that, when used for the performance of the intended function(s) in accordance with instructions provided by the manufacturer, the risks associated with such use are reduced to a level compatible with the generally acknowledged state of the art.

NOTE Details of a risk management system for medical devices are provided in ISO 14971.

## 4.3 Performance

The ophthalmic instrument shall achieve the performance stipulated by the manufacturer for the intended function(s) under the intended conditions of use.

## 4.4 Combination of different devices

If another device is intended for use in combination with an ophthalmic instrument, the connecting system shall not impair the specified performance of either instrument.

For coupling with active ophthalmic instruments, the provisions of IEC 60601-1 shall apply.

### 4.5 Materials

**4.5.1** Components of the ophthalmic instrument which are designed to come into direct contact with the skin of the patient or operator shall be made of materials which are neither toxic nor known to create significant allergic reactions, when used as intended by the manufacturer.

NOTE Requirements regarding biocompatibility can be found in the ISO 10993 series, where applicable.

**4.5.2** Materials used shall not ignite. When tested as described in 7.1, combustion shall not continue after withdrawal of the glow-wire.

### 4.6 Protection against contaminants

Parts of the ophthalmic instrument which are designed to come into contact with the patient or the operator shall either be capable of easy disinfection or be protected by a disposable cover.

### 4.7 Scales and displays

Scales and displays of ophthalmic instruments shall be designed and placed in accordance with ergonomic principles, taking into account the intended purpose of the instrument.

### 4.8 Thermal hazards

The temperature of parts of the ophthalmic instrument held by the operator or accessible to the patient shall not exceed the allowable maximum temperatures given in IEC 60601-1:2005 + A1:2012, 11.1, Tables 22, 23 and 24.



### 4.9 Mechanical hazards



The ophthalmic instrument shall be designed so that, when used to perform the intended function(s) in conformance with the user's instructions, the risk of physical injury when using this instrument is reduced as much as is practicable.

## 5 Environmental conditions

For the environmental conditions such as environmental conditions of use, storage conditions and transport conditions, the provisions of IEC 60601-1:2005 + A1:2012 shall apply.

## 6 Particular requirements for active ophthalmic instruments

### 6.1 Electrical safety

With respect to electrical safety, IEC 60601-1 shall apply.

Compliance with the requirements shall be verified as described in 7.4.

### 6.2 Inapplicable clauses of IEC 60601-1

The requirements on mechanical strength as specified in IEC 60601-1:2005 + A1:2012, 15.3 shall not apply.

### 6.3 Optical radiation hazard

ISO 15004-2 specifies the requirements for optical radiation safety for ophthalmic instruments, and the limit values specified therein are considered acceptable with respect to the risks when weighted against the performances intended.

NOTE 1 This clause replaces IEC 60601-1:2005 + A1:2012, 10.4, 10.5, 10.6 and 10.7.

NOTE 2 The possibility of an optical radiation hazard will be present only for those types of ophthalmic instruments with very high levels of radiation output that are capable of causing high irradiance on the retina and other ocular tissues.

## 7 Test methods

### 7.1 General

All tests described in this document are type tests.

### 7.2 Ignitability

Ignitability testing shall be carried out in accordance with IEC 60695-2-11, utilizing the test temperature 650 °C ± 10 °C and using the test equipment specified in IEC 60695-2-10.

### 7.3 Surface temperatures



The requirements given in 4.8 shall be verified at the highest permissible ambient temperature conditions of use specified in the accompanying documents.



### 7.4 Electrical safety

A sequence of tests shall be carried out according to IEC 60601-1:2005 + A1:2012, Annex B, except for the cases excluded by 6.2 of this document.

## 8 Information supplied by the manufacturer

### 8.1 Accompanying documents

The ophthalmic instrument shall be accompanied by user instructions which explain how to use the ophthalmic instrument safely to perform the intended function(s), taking into account the knowledge of the potential user. In particular, this information shall contain:

a) identification of the manufacturer;

b) instructions for effective disinfection of the instrument with particular reference to instruments returned to the manufacturer for repair and maintenance, as appropriate;

c) permissible environmental conditions of use including conditions for transport and storage;

d) the information specified in ISO 15004-2:2007, Clause 7, as appropriate;

e) where appropriate, any additional information as specified in IEC 60601-1:2005 + A1:2012, 7.9.

### 8.2 Marking

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

a) name of manufacturer;

b) where appropriate, trademark or trade name;

c) where appropriate, address of manufacturer, model and serial number;

d) where appropriate, any warnings and/or precautions to be taken;

e) where appropriate, additional marking as required by IEC 60601-1.