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Oftalmični instrumenti - Temeljne zahteve in preskusne metode - 1. del: Splošne zahteve, uporabne za vse oftalmične instrumente (ISO/DIS 15004-1:2019)

Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO/DIS 15004-1:2019)

Ophthalmische Instrumente - Grundlegende Anforderungen und Prüfverfahren - Teil 1: Allgemeine Anforderungen an ophthalmische Instrumente (ISO/DIS 15004-1:2019)

Instruments ophtalmiques - Exigences fondamentales et méthodes d'essai - Partie 1: Exigences générales applicables à tous les instruments ophtalmiques (ISO/DIS 15004-1:2019)

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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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 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*.

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 were updated;

— change of definition 3.4 manufacturer of <ophthalmic instrument>;

— particular requirements about environmental conditions were replaced by a reference to IEC 60601-1:2005+ A.1:2012;

— Annex A list of product related International Standards for ophthalmic instruments was updated;

— the standard was editorially revised.

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 low-vision aids. 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, 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 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005, *+ A.1:2012, 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:

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

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

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
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.

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 name; whether or not such a ophthalmic instrument is designed and/or manufactured by that person himself or on their behalf by another person(s)

[SOURCE: ISO 13485:2016, 3.10, modified — medical device 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.

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 Information on requirements regarding biocompatibility can be found in 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 Tables 22, 23 and 24 of IEC 60601-1:2005, 11.1.

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+A.1:2012 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 15.3 of IEC 60601-1:2005 + A.1:2012 shall not apply.