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Ophthalmic instruments — Fundamental requirements and test methods

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai

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International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

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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.

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.

International Standard ISO 15004 was prepared by ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

Annexes A and B form an integral part of this International Standard. Annexes C and D are for information only.

Ophthalmic instruments – Fundamental requirements and test methods

1 Scope

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

This International Standard takes precedence over the corresponding requirements of the other general standards cited in clause 2, if differences exist.

This International Standard does not apply to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9022-2:1994, *Optics and optical instruments — Environmental test methods — Part 2: Cold, heat, humidity.*

ISO 9022-3:1994, *Optics and optical instruments — Environmental test methods — Part 3: Mechanical stress.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 60601-1-1:1992, *Medical electrical equipment — Part 1: General requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 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.

3.2 active ophthalmic instrument
Any ophthalmic instrument connected with a permanently installed source of electrical power energy.

3.3 manufacturer (of an ophthalmic instrument)
Natural or legal person who places the ophthalmic instrument on the market.

3.4 optical radiation hazard
Possibility of damage to the retina by optical radiation.

NOTE — The effect of the radiance of a source (see 3.6) will decrease as the light beam passes through an optical system due to filtering, absorption or other loss mechanisms. Thus, basing the optical radiation hazard on the source radiance ensures that the radiance at the retina cannot exceed the source radiance.