INTERNATIONAL STANDARD

ISO 15004-1

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

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.

ISO 15004-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition together with ISO 15004-2 cancels and replaces ISO 15004:1997, which has been technically revised as follows:

a) all reference to light hazard (definitions 3.4 to 3.9, 6.3, 7.5, Annexes A, C and D of ISO 15004:1997) has essentially been moved to ISO 15004-2;

b) ignitability requirement/testing changed (4.5.2 and 7.1 of ISO 15004:1997);

c) environmental requirements/testing partly changed [Table 1; 5.2.2 and 8.1 f) of ISO 15004:1997];

d) normative Annex B (now informative Annex A) entirely updated;

e) normative (dated) reference updated to use IEC 60601-1:2005 edition.

ISO 15004 consists of the following parts, under the general title *Ophthalmic instruments — Fundamental requirements and test methods*:

— *Part 1: General requirements applicable to all ophthalmic instruments*

— *Part 2: Light hazard protection*

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Ophthalmic instruments — Fundamental requirements and test methods —

Part 1:
General requirements applicable to all ophthalmic instruments

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1 Scope

This part of ISO 15004 specifies fundamental requirements for non-invasive, active and non-active ophthalmic instruments. This part of ISO 15004 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 part of ISO 15004 is not applicable to operation microscopes, endoscopes and devices intended for laser investigation or laser treatment of the eye.

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.

ISO 9022-2:2002, *Optics and optical instruments — Environmental test methods — Part 2: Cold, heat and humidity*

ISO 9022-3:1998, *Optics and optical instruments — Environmental test methods — Part 3: Mechanical stress*

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

IEC 60695-2-10:2000, *Fire hazard testing — Part 2-10: Glowing/hot-wire based test methods — Glow-wire apparatus and common test procedure*

IEC 60695-2-11:2000, *Fire hazard testing — Part 2-11: Glowing/hot-wire based test methods — Glow-wire flammability test method for end-products*

1) To be published. (Revision of ISO 15004:1997)

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3 Terms and definitions

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

3.1
ophthalmic instrument
device designed to have an application to the eye

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 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
〈ophthalmic instrument〉 natural or legal person who places the ophthalmic instrument on the market

4 Fundamental requirements (for non-active and active ophthalmic instruments)

4.1 General

This part of ISO 15004 takes precedence over the corresponding requirements of IEC 60601-1:2005 and IEC 60601-1-1:1992, if differences exist.

The general requirements specified in this part of ISO 15004 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.

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 60601-1-1 shall apply.

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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.

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 non-active and active ophthalmic instruments)

NOTE The requirements specified in 5.1, 5.2 and 5.3 are verified as described in 7.3.

5.1 Environmental conditions of use

The ophthalmic instrument shall conform to all safety, optical, mechanical and accuracy requirements under the environmental conditions given in Table 1.

Table 1 — Environmental conditions of use

Criterion	Environmental conditions
Temperature	+ 10 °C to + 35 °C
Relative humidity	30 % to 90 %
Atmospheric pressure	800 hPa to 1 060 hPa
Shock (without packing)[a]	10 g, duration 6 ms
a Applicable to hand-held instruments only.	

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5.2 Storage conditions

5.2.1 After being stored under the conditions given in Table 2, the ophthalmic instrument shall conform to all safety, optical, mechanical and accuracy requirements under the environmental conditions of use given in Table 1 after being fully adapted to these conditions.

Table 2 —Storage conditions

Criterion	Environmental conditions
Temperature	– 10 °C to + 55 °C
Relative humidity	10 % to 95 %
Atmospheric pressure	700 hPa to 1 060 hPa

5.2.2 Certain ophthalmic instruments may have components, critical for them to perform their design function, that are not able to meet the temperature requirement of 5.2.1 for storage because the temperature extreme would degrade their operating characteristics. When this is the case, the instrument may still fulfil the requirements of this standard if the manufacturer states in bold extra large writing on the shipping container and again in the instructions accompanying the instrument, as required by 8.1 the following:

> THIS INSTRUMENT DOES NOT MEET THE TEMPERATURE REQUIREMENTS OF ISO 15004-1 FOR STORAGE. DO NOT STORE THIS INSTRUMENT IN CONDITIONS WHERE THE TEMPERATURE MAY RISE ABOVE _____ °C OR FALL BELOW _____ °C.

5.3 Transport conditions

It is recommended that the instrument, in its original packaging, be tested for ability to withstand transport conditions.

If ability to withstand exposure to the transport conditions listed in Table 3 of this part of ISO 15004 is claimed [see 8.1 c)], the following shall apply:

After exposure of the ophthalmic instrument in its original packaging to the range of transport conditions given in Table 3, the ophthalmic instrument shall conform to all safety, optical, mechanical and accuracy requirements under the environmental conditions of use given in Table 1 after being fully adapted to these conditions.

Table 3 — Transport conditions

Criterion	Environmental conditions
Temperature	– 40 °C to + 70 °C
Relative humidity	10 % to 95 %
Atmospheric pressure	500 hPa to 1 060 hPa
Vibration, sinusoidal	10 Hz to 500 Hz: 0,5 g
Shock	30 g, duration 6 ms
Bump	10 g, duration 6 ms

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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 60601-1:2005

The requirements on mechanical strength as specified in 15.3 of IEC 60601-1:2005 shall not apply.

6.3 Optical radiation hazard

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

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 tissue. 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.

7 Test methods

All tests described in this part of ISO 15004 are type tests.

7.1 Ignitability

Ignitability testing shall be carried out in accordance with IEC 60695-2-11:2000, utilizing the test temperature 650 °C ± 10 °C and using the test equipment specified in IEC 60695-2-10:2000.

7.2 Surface temperatures

The requirements given in 4.8 shall be verified at the highest ambient temperature specified in Table 1.

7.3 Environmental conditions

The requirement specified in Clause 5 shall be verified by the tests according to the appropriate part of ISO 9022 given in Table 4.

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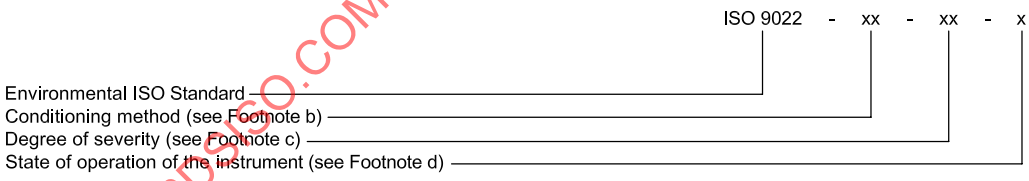
Table 4 — Environmental tests

Conditions	Test[a b c d]	According to ISO 9022 Part	Comment[b]
Environmental conditions of use	ISO 9022-11-01-2[e]	2	dry heat
	(10 ± 2) °C / 16 h		
	ISO 9022-11-02-2[e]		dry heat
	(40 ± 2) °C / 16 h		
	ISO 9022-12-01-2[e]		damp heat
	(40 ± 2) °C (90 to 95)% R.H. / 16 h		
Storage conditions	ISO 9022-10-02-1	2	cold
	(–10 ± 3) °C / 16 h		
	ISO 9022-11-03-1		dry heat
	(55 ± 2) °C / 16 h		
	ISO 9022-12-06-1		damp heat
	(55 ± 2) °C (90 to 95)% R.H. / 6 h		
Transport conditions	ISO 9022-14-06-0	2	slow temperature change
	(–40 ± 3) °C / (+70 ± 2) °C / 5×		
	ISO 9022-30-03-0	3	shock
	30 *g* / 6 ms		
	ISO 9022-31-01-0		bump
	Bump 10 *g* / 6 ms / 1 000×		
	ISO 9022-36-01-0		sinusoidal vibration
	0,5 *g* / 10 Hz to 500 Hz / 2×		

a The environmental code reads as follows:



b The numbers in the conditioning methods listed in this table have the following meaning:

10: cold
11: dry heat
12: damp heat
14: slow temperature change
30: mechanical stress - shock
31: mechanical stress - bump
36: mechanical stress - sinusoidal vibration

c Degrees of severity are given in the appropriate part of ISO 9022.

d The numbers for the state of operation mean:

0: Specimen in its normal transport and/or storage container as provided by the manufacturer.
1: Specimen unprotected, ready for operation, power supply not connected.
2: Specimen in operation during the test as specified in the relevant specification.

e Deviations from these standardized values as given in Table 1 are permissible for ophthalmic instruments. The actual values shall be stated in the test report.

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7.4 Checking electrical safety

A sequence of tests shall be carried out according to Annex B of IEC 60601-1:2005 except for the cases excluded by this part of ISO 15004 (see 6.2).

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) if appropriate, a statement that the instrument in its original packaging is able to withstand the range of transport conditions given in this part of ISO 15004 (see 5.3);

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

e) where appropriate, any additional documents as specified in 7.9 of IEC 60601-1:2005.

f) if appropriate, a statement that the instrument is not able to fulfil the temperature requirements of 5.2.1 as required by 5.2.2.

8.2 Marking

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

a) name of manufacturer and/or trademark or trade name;

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

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

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

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