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Ophthalmic instruments — Fundamental requirements and test methods

Instruments ophtalmiques — Exigences fondamentales et méthodes d'essai

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Contents

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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.

3.5 irradiance, E
Radiant flux $d\Phi$ incident on an element of a surface of unit area dA.

NOTE — Irradiance is expressed in milliwatts per square centimetre (mW/cm²).

3.6 radiance, L
In a given direction at a given point, the quotient of the radiant flux $d\Phi$ passing through that point and propagating within the solid angle $d\Omega$ in a direction θ divided by the product of the area of a section of that beam on a plane perpendicular to this direction containing the given point and the solid angle $d\Omega$ (see C.1).

NOTE Radiance is expressed in milliwatts per square centimetre per steradian [mW/(cm² · sr)].

3.7 spectral radiance, $L_\lambda(\lambda)$
Value of the radiance (see 3.6) of an infinitesimal wavelength interval, at any given wavelength in the spectrum, divided by the range of that interval.

NOTE Spectral radiance is expressed in milliwatts per square centimetre per steradian per nanometer [mW/(cm² · sr · nm)].

3.8 spectrally weighted photochemical aphakic source radiance, L_A
Spectral radiance of the source integrated over the aphakic spectrum range 305 nm to 700 nm and weighted by $A(\lambda)$ as given by the equation:

$$L_A = \sum_{305}^{700} L_\lambda(\lambda) \cdot A(\lambda) \cdot \Delta\lambda \quad \ldots (1)$$

where $A(\lambda)$ is the spectral weighting function for the aphakic retinal hazard analysis (see annex A).

3.9 spectrally weighted photochemical phakic source radiance, L_B
Spectral radiance of the source integrated over the phakic spectrum range 380 nm to 700 nm and weighted by $B(\lambda)$ as given by the equation:

$$L_B = \sum_{380}^{700} L_\lambda(\lambda) \cdot B(\lambda) \cdot \Delta\lambda \quad \ldots (2)$$

where $B(\lambda)$ is the spectral weighting function for the phakic retinal hazard analysis (see annex A).

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

4.1 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.

4.2 Performance

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

In addition to the requirements of this International Standard, the supplementary or modified requirements specified in the relevant product-related International Standards listed in annex B apply.

4.3 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 60601-1-1shall apply.

4.4 Materials

4.4.1 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.

4.4.2 Materials used shall not ignite. When tested as described in 7.1, combustion shall not continue after withdrawal of the test rod.

4.5 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.

4.6 Scales and displays

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

4.7 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 table Xa of IEC 60601-1:1988, clause 42.1.

4.8 Mechanical hazards

The ophthalmic instrument shall be designed so that, when used to perform the intended function(s) in conformance with the user 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.

5.2 Storage conditions

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 1 — Environmental conditions of use

Criterion	Environmental condition
Temperature	+ 10°C to + 35°C
Relative humidity	30 % to 75 %
Atmospheric pressure	800 hPa to 1060 hPa
Shock (without packing) *)	10 *g* duration 6 ms
*) Applicable to hand-held instruments only.	

Table 2 — Storage conditions

Criterion	Environmental condition
Temperature	– 10°C to + 55°C
Relative humidity	10 % to 95 %
Atmospheric pressure	700 hPa to 1060 hPa

5.3 Resistance to transport conditions

NOTE 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 International Standard is claimed [see 8.1 c)], the following shall apply:

After exposure of the ophthalmic instrument in its original packing 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	Transport conditions
Temperature	– 40°C to + 70°C
Relative humidity	10 % to 95 %
Atmospheric pressure	500 hPa to 1060 hPa
Sinusoidal vibration	10 Hz to 500 Hz: 0,5 *g*
Shock	30 *g*, duration 6 ms
Bump	10 *g*, duration 6 ms

6 Particular requirements for active ophthalmic instruments

6.1 Electrical safety

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

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

6.2 Inapplicable clauses of IEC 60601-1:1988

The requirements on mechanical strength as specified in clause 21.6 of IEC 60601-1:1988 shall not apply.

6.3 Optical radiation hazard

6.3.1 General

NOTE — This clause replaces clauses 32, 33 and 34 of IEC 60601-1:1988.

The possibility of an optical radiation hazard will be present only for those types of ophthalmic instruments with very high level of radiation output which is capable of causing high irradiance on the retina. The limiting values given in 6.3.2 are considered acceptable with respect to the risks when weighted against the performances intended.

Where appropriate, each specific instrument standard expressly states that the requirements given in 6.3.2 to 6.3.4 shall apply.

6.3.2 Limiting values

The limiting values given in items a) and b) shall apply to the radiation from the ophthalmic instrument used to illuminate, view or photograph the human eye with light from 380 nm to 700 nm and in which the full beam homogeneously illuminates a circular pupil of diameter 8 mm (see notes 1 to 6).

a) Short wavelength limit: The amount of radiant power exiting the instrument in the portion of the spectrum from 305 nm to 400 nm shall have an irradiance no greater than 0,05 mW/cm² as measured in the corneal plane when the instrument is operating at maximum intensity[1] and, if the aperture can be varied, at maximum aperture.

b) Long wavelength limit: The amount of energy exiting the instrument in the wavelength range 700 nm to 1100 nm shall not exceed 100 mW/cm², nor shall it exceed the amount of energy exiting the instrument in the range between 380 nm and 700 nm. The energy shall be measured in the corneal plane when the instrument is operating at maximum intensity[1] and maximum aperture.

NOTES

1 If due to stops or other obstructions of the beam, a circular area of less than 8 mm diameter is illuminated, the limiting values may be increased by the ratio of the area of an 8 mm diameter pupil to the true area illuminated.

2 It is recommended that the energy in the range of the spectrum below 420 nm be attenuated as much as possible.

3 For instruments with a large illuminating solid angle Ω over the designated spectral range 305 nm to 400 nm, i.e. $\Omega > 0{,}031$ sr, the limiting values may be increased by the ratio of the true solid angle, expressed in steradians, divided by 0,031 (e.g. valid for instruments such as fundus cameras).

4 For instruments with a small illuminating solid angle Ω over the designated spectral range 305 nm to 400 nm, i.e. $\Omega << 0{,}031$ sr, the limiting value of illumination is given by the radiance L = 1,6 mW/(cm² · sr) instead of an irradiance value in the corneal plane (e.g. valid for instruments like retinoscopes).

5 For instruments with non-pulsed radiation, the assumptions used to set the limiting value for radiation shorter in wavelength than 400 nm are based on considerations of the typical spectral distribution of a 3000 K standard black-body source, an illuminating solid angle at the corneal plane of 0,031 sr, a maximum exposure time of 5 min and the weighting factors for L_A (see annex A). The limit is set to ensure that the fraction of the photochemical hazard dose due to radiation shorter in wavelength than 400 nm is no greater than 1/8 of the total photochemical hazard dose over all wavelengths when that total dose is at the threshold limit for an 8 mm diameter pupil.

[1] Maximum intensity is the highest brightness the instrument is capable of delivering, including the highest brightness achievable if overvoltage is provided.

Using the ACGIH (American Conference of Governmental Industrial Hygienists) guidelines, that threshold limit is 14 J/(cm² · sr). To convert from photochemical hazard weighted radiance to irradiance, over the designated spectral range 305 nm to 400 nm, the conversion factor 0,276 is used. Thus the limit is then found by the formula

$$14\ \text{J/(cm}^2 \cdot \text{sr)} \times (0{,}031\ \text{sr}) \times [(0{,}276/(300\ \text{s} \cdot 8)] = 0{,}05\ \text{mW/cm}^2$$

6 For instruments with pulsed radiation, the limit is a total dose expressed in J/cm², and is found by the formula:

$$14\ \text{J/(cm}^2 \cdot \text{sr)} \times (0{,}031\ \text{sr}) \times (0{,}276/8) = 15\ \text{mJ/cm}^2$$

For multiple pulses, the limit per pulse is then 15 mJ/cm² divided by the number of pulses.

6.3.3 Variable brightness

For instruments where provision is made to vary the brightness, the manufacturer shall provide indications of the proportions of the maximum intensity[1].

6.3.4 Particular information

The manufacturer shall provide the user with a graph showing the relative spectral output of the instrument between 305 nm and 1100 nm when the instrument is operating at maximum light intensity[1] and maximum aperture. The spectral output shall be shown for the beam after it exits the instrument.

The manufacturer shall provide the user with the values for the spectrally weighted photochemical source radiance, both phakic L_B and aphakic L_A, measured in the beam exiting from the instrument when operating at maximum intensity[1] and maximum aperture and determined by using the spectral weighting values given in annex A.

The manufacturer shall provide information on the meaning of L_B and L_A to the user.

NOTE — An example of such information is given in annex D.

7 Test methods

All tests described in this International Standard are type tests.

7.1 Ignitability

7.1.1 Apparatus

The test device consists of

a) steel rod 300 mm ± 3 mm long and 6 mm nominal diameter with end faces which are flat and perpendicular to its longitudinal axis;

b) heat source;

c) thermocouple with temperature-indicating device.

[1] Maximum intensity is the highest brightness the instrument is capable of delivering, including the highest brightness achievable if overvoltage is provided.

7.1.2 Procedure

Heat one end of the steel rod over a length of at least 50 mm to a temperature of 650°C ± 10°C. Measure the temperature of the rod by means of the thermocouple attached at a distance of 20 mm from the heated end of the rod. With the rod positioned vertically, press the heated face of the rod against the surface of the test sample (the contact force being equal to the weight of the rod) for a period of 5 s, and then remove. Repeat this test on every component of the instrument made from different organic material. Following each stage, visually inspect to establish whether combustion continues after removal of the rod from the test sample.

7.2 Surface temperatures

The requirements given in 4.7 shall be verified at the highest ambient temperature specified in table 1.

7.3 Environmental conditions

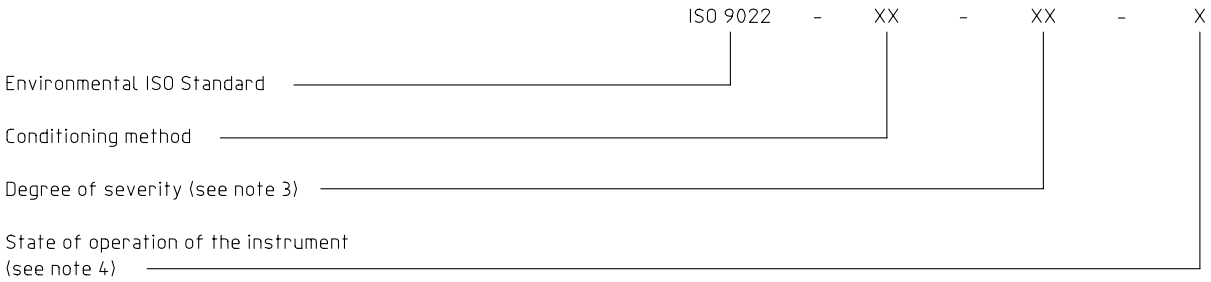
The requirement specified in clause 5 shall be verified by the tests according to the appropriate part of ISO 9022 given in table 4.

Table 4 — Environmental tests

Conditions	Test (see note 1 below)	According to ISO 9022 Part	Comment (see note 2 below)
Environmental conditions of use	ISO 9022-11-01-2 *) (10±2)°C / 16 h	2	Dry heat
	ISO 9022-11-01-2 *) (40±2)°C / 16 h		Dry heat
	ISO 9022-12-01-2 *) (40±2)°C (90 to 95)% R.H. / 16 h		Damp heat
Storage conditions	ISO 9022-10-01-1 (-10±3)°C / 16 h	2	Cold
	ISO 9022-11-02-1 (55±2)°C / 16 h		Dry heat
	ISO 9022-12-06-1 (55±2)°C (90 to 95)% R.H. / 6 h		Damp heat
Transport conditions	ISO 9022-14-06-0 (-40±3)°C / (+70±2)°C / 5x	2	Slow temperature change
	ISO 9022-30-03-0 30 *g* / 6 ms		Shock
	ISO 9022-31-01-0 Bump 10 *g* / 6 ms / 1000x	3	Bump
	ISO 9022-36-01-0 0,5 *g* / 10 Hz to 500 Hz / 2x		Sinusoidal vibration

*) 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.

NOTE 1 The environmental code reads as follows:



NOTE 2 The numbers in the conditioning methods listed above 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

NOTE 3 Degrees of severity are given in the appropriate part of ISO 9022.

NOTE 4 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.

7.4 Checking electrical safety

A sequence of tests shall be carried out according to appendix C of IEC 60601-1:1988 except for the cases excluded by this International Standard (see 6.2).

7.5 Checking optical radiation safety

7.5.1 Determination of spectral irradiance

Spectral irradiance shall be measured with an uncertainty of less than ± 30 % at regular intervals over the effective range of the spectrum. For aphakic photochemical hazard (L_A), the effective range is 305 nm to 700 nm. For phakic photochemical hazard (L_B), the effective range is 380 nm to 700 nm.

NOTE — The intervals for spectral irradiance measurement should be centred on the values given in annex A with a recommended bandwidth of 5 nm or 10 nm as indicated. The recommended measurement unit is milliwatts per square centimetre per nanometre [mW/(cm² · nm)]. The values should be recorded and, after being multiplied by the bandwidth, recorded as milliwatts per square centimetre (mW/cm²) for that interval (see also annex C).

7.5.2 Determination of irradiance

Irradiance shall be measured with an uncertainty of less than ± 30 % over the effective ranges of the spectrum. For the short wavelength limit, the effective range of the spectrum is from 305 nm to 400 nm. For the long wavelength limits, the effective ranges of the spectrum are from 380 nm to 700 nm and from 700 nm to 1100 nm.

NOTE — A spectroradiometer can be used to make these measurements.

7.5.3 Determination of beam cross-section

When determining the area of the beam cross-section, which is required for several calculations, the measuring method used shall be capable of an accuracy of ± 30% (see C.2).

NOTE — For irregular cross-sections, it may be appropriate to measure the area by exposing a piece of film and then measuring the exposed area on the negative.

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 International Standard (see 5.3);

d) the information specified in 6.3.4, as appropriate;

e) where appropriate, any additional documents as specified in 6.8 of IEC 60601-1:1988.

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.

Annex A
(normative)

Optical radiation hazard

A.1 List of spectral weighting functions for retinal hazard analysis

Wavelength, λ nm	**Photochemical** (blue-light) **hazard function**, B (λ)	**Photochemical aphake hazard function**, $A(\lambda)$
305 to 335	-	6,00
340	-	5,88
345	-	5,71
350	-	5,46
355	-	5,22
360	-	4,62
365	-	4,29
370	-	3,75
375	-	3,56
380	0,006	3,19
385	0,012	2,31
390	0,025	1,88
395	0,050	1,58
400	0,10	1,43
405	0,20	1,30
410	0,40	1,25
415	0,80	1,20
420	0,90	1,15
425	0,95	1,11
430	0,98	1,07
435	1,00	1,03
440	1,00	1,00
445	0,97	0,97
450	0,94	0,94
455	0,90	0,90
460	0,80	0,80
465	0,70	0,70
470	0,62	0,62
475	0,55	0,55
480	0,45	0,45
485	0,40	0,40
490	0,22	0,22
495	0,16	0,16
500	0,10	0,10
510	0,063	0,063
520	0,040	0,043
530	0,025	0,025
540	0,016	0,016
550	0,010	0,010
560	0,006	0,006
570	0,004	0,004
580	0,002	0,002
590	0,001	0,001
600	0,001	0,001
610	0,001	0,001
620	0,001	0,001
630	0,001	0,001
640	0,001	0,001
650	0,001	0,001

660	0,001	0,001
670	0,001	0,001
680	0,001	0,001
690	0,001	0,001
700	-	-

A.2 Determination of spectrally weighted source radiance

If spectral radiance $L_\lambda(\lambda)$ can only be measured relatively, but the total source radiance L can be measured absolutely, the following equation determines the spectrally weighted photochemical aphakic source radiance L_A.

$$L_A = \frac{\sum_{305}^{700} L_\lambda(\lambda) \cdot A(\lambda) \cdot \Delta\lambda}{\sum_{305}^{700} L_\lambda(\lambda) \cdot \Delta\lambda} \cdot L \quad \ldots \text{(A.1)}$$

If spectral radiance $L_\lambda(\lambda)$ can only be measured relatively, but the total source radiance L can be measured absolutely, the following equation determines the spectrally weighted photochemical phakic source radiance L_B.

NOTE — $\Delta\lambda$ should be taken as 5 nm or 10 nm.

$$L_B = \frac{\sum_{380}^{700} L_\lambda(\lambda) \cdot B(\lambda) \cdot \Delta\lambda}{\sum_{380}^{700} L_\lambda(\lambda) \cdot \Delta\lambda} \cdot L \quad \ldots \text{(A.2)}$$

NOTE— $\Delta\lambda$ should be taken as 5 nm or 10 nm.

Annex B
(normative)

Product-related International Standards for ophthalmic instruments

The International Standards listed below shall follow the fundamental requirements given in this International Standard.

ISO 9801:1997, *Ophthalmic instruments — Trial case lenses.*

ISO 10341:1997, *Ophthalmic instruments — Refractor heads.*

ISO 10342:1997, *Ophthalmic instruments — Eye refractometers.*

ISO 10343:1997, *Ophthalmic instruments — Ophthalmometers.*

ISO 10938:—[2], *Ophthalmic instruments — Chart projectors.*

ISO 10939:—[2], *Ophthalmic instruments — Slit-lamp microscopes.*

ISO 10940:—[2], *Ophthalmic instruments — Fundus cameras.*

ISO 10942:—[2], *Ophthalmic instruments — Direct ophthalmoscopes.*

ISO 10943:—[2], *Ophthalmic instruments — Indirect ophthalmoscopes.*

ISO 10944:—[2], *Ophthalmic instruments — Synoptophores.*

ISO 12865:—[2], *Ophthalmic instruments — Retinoscopes.*

ISO 12866:—[2], *Ophthalmic instruments — Perimeters.*

ISO 12867:—[2], *Ophthalmic instruments — Trial frames.*

NOTE — The above list is not necessarily complete. New International Standards will be incorporated during the next review of annex B.

[2] To be published.