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Optics and photonics — Environmental requirements —

Part 6: Test requirements for medical optical instruments

Optique et photonique — Exigences environnementales —

Partie 6: Exigences d'essai pour les instruments optiques médicaux

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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 10109-6 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 1, *Fundamental standards*.

This second edition cancels and replaces the first edition (ISO 10109-6:1994), which has been technically revised.

ISO 10109 consists of the following parts, under the general title *Optics and photonics — Environmental requirements*:

— *Part 1: General overview, terms and definitions, climatic zones and their parameters*

— *Part 4: Test requirements for telescopic systems*

— *Part 6: Test requirements for medical optical instruments*

— *Part 7: Test requirements for optical measuring instruments*

— *Part 8: Test requirements for extreme conditions of use*

— *Part 11: Optical instruments for outdoor conditions of use*

— *Part 12: Conditions of transport for optical instruments*

Optics and photonics — Environmental requirements —

Part 6:
Test requirements for medical optical instruments

1 Scope

This part of ISO 10109 is applicable to optical instruments and instruments with optical components in the field of medicine.

It specifies requirements to be met with regard to the resistance of the optical, mechanical, chemical and electrical properties or performance data of instruments to environmental influences and hence determines geographical and technical areas of application. Environmental test methods, as specified in ISO 9022 (all parts), are assigned to the various areas of application for the purpose of ascertaining the suitability of the instruments in their respective area of application.

This part of ISO 10109 is the basis for the specification of environmental requirements and environmental tests in instrument standards. If necessary, these requirements and tests can be amended in the instrument standards.

This part of ISO 10109 does not deal with the requirements to be met by the packaging of the instrument during transport from the manufacturer to the user.

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 9022-1:1994, *Optics and optical instruments — Environmental test methods — Part 1: Definitions, extent of testing*

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 9022-11:1994, *Optics and optical instruments — Environmental test methods — Part 11: Mould growth*

ISO 9022-12:1994, *Optics and optical instruments — Environmental test methods — Part 12: Contamination*

ISO 9022-13:1998, *Optics and optical instruments — Environmental test methods — Part 13: Combined shock, bump or free fall and dry heat or cold*

ISO 10109-1:2005, *Optics and photonics — Environmental requirements — Part 1: General overview, terms and definitions, climatic zones and their parameters*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9022-1 and ISO 10109-1 apply.

4 Subdivision of medical optical instruments

Medical optical instruments are subdivided into instrument types with the type numbers given in Table 1.

NOTE Previously, medical optical instruments were designated as instrument group number 05, however, the use of group numbers is no longer recommended.

Table 1 — Subdivision of medical optical instruments

Type number	Instrument type
01	Field instruments: Instruments which are used in, for example, rescue helicopters or tents. They are generally protected against direct weather influences such as rain, snow or solar radiation.
02	Instruments in weather-protected locations: Locations in which heating or cooling are to be used to ensure that the required conditions (e.g. ambient atmospheric conditions) remain constant during use of the instruments.

5 Designation of environmental requirements and of environmental tests

The relevant specification and other technical documents shall indicate the environmental requirements required by this part of ISO 10109 using the designation specified in ISO 10109-1.

EXAMPLE An example of the designation for the environmental requirements for medical optical instruments of instrument Type 02, and requiring the extent “T” (type or sample testing) is:

Environmental requirements ISO 10109-P06-02-T

In relevant specifications and other technical documentation, tests carried out in accordance with the environmental requirements given in this part of ISO 10109 shall be designated by the environmental test code as specified in ISO 9022-1.

6 Type of testing on the basis of technical requirements

Table 2 specifies the technical requirements and the conditioning methods for the extent of testing, T (type or sample test). Table 3 shows a summary of the tests given in Table 2 as specified in the appropriate part of ISO 9022.

Table 4 specifies the technical requirements and the conditioning methods for the extent of testing, S (series test). Table 5 shows a summary of the tests given in Table 4 as specified in the appropriate part of ISO 9022.

For each of the conditioning methods given in Tables 2 and 4, the instrument is suitable for the technical requirement specified if it is operative without restriction after conditioning.

For the purposes of this part of ISO 10109, the value of g_n is rounded up to the next highest integer, that is 10 m/s^2.

All tests shall be performed as specified in the appropriate part of ISO 9022. The tests may be performed in any order, if not specified otherwise.

Table 2 — Technical requirements and conditioning methods for extent of testing T

Serial No.	ISO 9022		Instrument type			Field instruments			Instruments in weather-protected locations		
	Part	Conditioning method	Type No.			01			02		
			State of operation[a]			0	1	2	0	1	2
1	2	10 Cold	Technical requirement	Temperature °C		–40	–35	—	–40	–10	—
			Degree of severity[a]			08	07	—	08	02	—
2	2	11 Dry heat	Technical requirement	Temperature °C		85	63	10 to 55	70	55	10 to 40
			Degree of severity[a]			06	04	01 and 03	05	03	01[b] and 02[b]
3	2	12 Damp heat	Technical requirement	Temperature °C		—	—	40	—	—	40
				Relative humidity %		—	—	95	—	—	85
			Degree of severity[a]			—	—	01	—	—	01[b]
4	2	14 Slow temperature change	Technical requirement	Temperature °C	t_2	—	63	—	—	—	—
					t_1	—	–35	—	—	—	—
			Degree of severity[a]			—	05	—	—	—	—
5	2	16 Damp heat, cyclic	Technical requirement	Temperature °C/ Relative humidity %		—	40/92	—	40/92	—	—
						—	23/83	—	23/83	—	—
			Degree of severity[a]			—	02	—	01	—	—
6	3	30 Shock	Technical requirement	Acceleration	g	30	30	50	30	10	50
				Duration	ms	6	18	3	6	6	3
			Degree of severity[a]			03	04	05[c]	03	01	05[c]
7	3	31 Bump	Technical requirement	Acceleration	g	10	—	—	10	—	—
				Duration	ms	6	—	—	6	—	—
			Degree of severity[a]			01	—	—	01	—	—
8	3	36 Sinusoidal vibration	Technical requirement	Acceleration	g	2	—	—	0,5	—	—
				Frequency range	Hz	10 to 500	—	—	10 to 500	—	—
			Degree of severity[a]			04	—	—	01	—	—
9	13	66 Combined shock, cold	Technical requirement	Temperature	°C	–40	—	—	–40	—	—
				Acceleration	g	15	—	—	15	—	—
				Duration	ms	11	—	—	11	—	—
			Degree of severity[a]			14	—	—	14	—	—
10	11	85[d] Mould growth	Technical requirement			Ability to be operated for ⩾ 3 years in compliance with stipulated instructions regarding maintenance and care.					
			Degree of severity[a]			—	02	—	—	02	—

Table 2 (*continued*)

Serial No.	ISO 9022		Instrument type	Field instruments			Instruments in weather-protected locations		
	Part	Conditioning method	Type No.	01			02		
			State of operation	0	1	2	0	1	2
11	12	86[e] Basic cosmetic substances and artificial hand sweat	Technical requirements	Ability to be operated for ⩾ 5 years in compliance with stipulated instructions regarding maintenance and care.					
			Degree of severity[a]	—	02	—	—	02	—
12	12	87[e] Laboratory agents	Technical requirements	Ability to be operated for ⩾ 5 years in compliance with stipulated instructions regarding maintenance and care.					
			Degree of severity[a]	—	02	—	—	02	—

[a] See the appropriate part of ISO 9022.

[b] The test is not required if an air-conditioned location is demanded by the manufacturer for operation of the instrument.

[c] For hand instruments only.

[d] Testing of representative samples and components only. The test is not required if tests of identical materials and/or the structure of identical finish coatings have been performed on other instrument types using the same conditioning or if the fungus-resistant properties have been verified. Long-term storage in high relative humidity (> 75 %) and in packaging which is not humidity-proof can also lead to mould contamination in fungus-resistant materials (caused by minor contamination, e.g. fingerprints, on the surface of the material which serves as a culture-medium for fungus spores).

[e] Testing of representative samples only. The test is not required if tests of identical materials and/or the structure of identical finish coatings have been performed on other instrument types using the same or more severe conditioning.

Table 3 — Test summary

Environmental requirement ISO 10109-P06-01-T	Environmental requirement ISO 10109-P06-02-T	Part of ISO 9022
Environmental test ISO 9022		
10-08-0	10-08-0	2
10-07-1	10-02-1	
11-06-0	11-05-0	
11-04-1	11-03-1	
11-01-2	11-01-2	
11-03-2	11-02-2	
12-01-2	12-01-2	
14-05-1	16-01-0	
16-02-1		
30-03-0	30-03-0	3
30-04-1	30-01-1	
30-05-2	30-05-2	
31-01-0	31-01-0	
36-04-0	36-01-0	
66-14-0	66-14-0	13
85-02-1	85-02-1	11
86-02-1	86-02-1	12
87-02-1	87-02-1	

Table 4 — Technical requirements and conditioning methods for extent of testing S

Serial No.	ISO 9022		Instrument type		Field instruments			Instruments in weather-protected locations		
	Part	Conditioning method	Type No.		01			02		
			State of operation		0	1	2	0	1	2
1	2	10 Cold	Technical requirement	Temperature °C	—	−35	—	—	−10	—
			Degree of severity[a]		—	07	—	—	02	—
2	2	11 Dry heat	Technical requirement	Temperature °C	—	63	10 to 55	—	55	10 to 40
			Degree of severity[a]		—	04	01 and 03	—	03	01[b] and 02[b]
3	3	30 Shock	Technical requirement	Acceleration g	—	—	50	—	—	50
				Duration ms	—	—	3	—	—	3
			Degree of severity[a]		—	—	05[c]	—	—	05[c]

[a] See the appropriate part of ISO 9022.

[b] The test is not required if an air-conditioned location is demanded by the manufacturer for operation of the instrument.

[c] For hand instruments only.

Table 5 — Test summary

Environmental requirement ISO 10109-P06-01-S	Environmental requirement ISO 10109-P06-02-S	Part of ISO 9022
Environmental test ISO 9022		
10-07-1	10-02-1	2
11-04-1	11-03-1	
11-01-2	11-01-2	
11-03-2	11-02-2	
30-05-2	30-05-2	3

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