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**Optics and optical instruments —  
Environmental requirements —**

**Part 6:**

**Test requirements for medical optical devices  
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*Optique et instruments d'optique — Conditions d'environnement —*

*Partie 6: Spécifications d'essai pour les appareils optiques médicaux*  
<https://standards.iteh.ai/en/standards/ISO/10109-6-1994>



Reference number  
ISO 10109-6:1994(E)

## Foreword

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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.

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International Standard ISO 10109-6 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 19, *Fundamental standards*.

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

- Part 1: *General information, definitions, climatic zones and their parameters*
- Part 6: *Test requirements for medical optical devices*
- Part 8: *Test requirements for extreme conditions of use*

# Optics and optical instruments — Environmental requirements —

## Part 6:

## Test requirements for medical optical devices

### 1 Scope

This part of ISO 10109 applies 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 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 may 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 standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10109. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based

on this part of ISO 10109 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 9022-1:1994, *Optics and optical instruments — Environmental test methods — Part 1: Definitions, extent of testing.*

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.*

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 9022-13:1994, *Optics and optical instruments — Environmental test methods — Part 13: Combined shock, bump or free fall, dry heat or cold.*

ISO 10109-1:1994, *Optics and optical instruments — Environmental requirements — Part 1: General information, definitions, climatic zones and their parameters.*

### 3 Definitions

For the purposes of this part of ISO 10109, the definitions given in ISO 10109-1.

### 4 Subdivision of the instrument group

The group number of instruments for medicine is 05.

Group number 05 is subdivided into instrument types with the type numbers given in table 1.

**Table 1 — Subdivision of group 05**

Type number	Instrument type
01	<b>Field instruments:</b> 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	<b>Instruments in weather-protected locations:</b> Locations in which heating or cooling must be used to ensure that the required conditions (e.g. ambient atmospheric conditions) remain constant during use of the instruments.
03	<b>Instruments as in type number 02,</b> but which are also sterilizable, e.g. instruments for surgical use.

### 5 Designation of environmental tests

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 Specification of suitability indices on the basis of selected environmental tests

For the purposes of this part of ISO 10109, the acceleration of free fall shall be taken as  $g = 9,81 \text{ m/s}^2$ .

Standard climates are specified in ISO 10109-1.

#### 6.1 Type or sample test (extent of testing T)

Table 2 specifies suitability indices on the basis of selected environmental tests for extent of testing T.

Table 3 shows a summary of the tests given in table 2 as specified in ISO 9022.

#### 6.2 Series test (extent of testing S)

Table 4 specifies suitability indices on the basis of selected environmental tests for extent of testing S.

Table 5 shows a summary of the tests given in table 4 as specified in ISO 9022.

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### 7 Procedure

Tests shall be performed as specified in ISO 9022.

The tests may be performed in any order, if not specified otherwise.

**Table 2 — Suitability indices 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 <sup>1)</sup>		0	1	2	0	1	2	
1	2	10 Cold	Technical requirement	Temperature °C	- 40	- 35	—	- 40	- 10	—	
			Degree of severity <sup>1)</sup>		08	07	—	08	02	—	
			Suitability index for standard climate		1	E	E	—	E	E	—
					2	A	A	—	A	D	—
					3	A	A	—	A	B	—
					4	E	E	—	E	E	—
					5	A	A	—	A	A	—
6	A	A	—	A	B	—					
2	2	11 Dry heat	Technical requirement	Temperature °C	85	63	10 to 55	70	55	10 to 40	
			Degree of severity <sup>1)</sup>		06	04	01 and 03	05	03	01 <sup>2)</sup> and 02 <sup>2)</sup>	
			Suitability index for standard climate		1	A	A	A	A	A	A
					2	A	A	A	A	A	A
					3	A	A	A	A	A	A
					4	A	A	A	A	A	A
					5	A	A	A	A	A	A
6	A	A	A	A	A	A					
3	2	12 Damp heat	Technical requirements	Temperature °C	—	—	40	—	—	40	
				Relative humidity %	—	—	95	—	—	85	
			Degree of severity <sup>1)</sup>		—	—	01	—	—	01 <sup>2)</sup>	
			Suitability index for standard climate		1	—	—	A	—	—	—
					2	—	—	A	—	—	—
					3	—	—	A	—	—	—
					4	—	—	A	—	—	—
5	—	—			A	—	—	A			
6	—	—	A	—	—	—					
4	2	14 Slow temperature change	Technical requirement	Temperature °C	$t_2$	—	63	—	—	—	
				$t_1$	—	- 35	—	—	—	—	
			Degree of severity <sup>1)</sup>		—	05	—	—	—	—	
			Suitability index for standard climate		1	—	E	—	—	—	—
					2	—	A	—	—	—	—
					3	—	A	—	—	—	—
					4	—	E	—	—	—	—
5	—	A			—	—	—	—			
6	—	A	—	—	—	—					

Serial No.	ISO 9022		Instrument type		Field instruments			Instruments in weather-protected locations			
	Part	Conditioning method	Type No.		01			02			
			State of operation <sup>1)</sup>		0	1	2	0	1	2	
5	2	16 Damp heat, cyclic	Technical requirements	Climate °C/% rel. humidity	—	40/92	—	40/92	—	—	
					—	23/83	—	23/83	—	—	
			Degree of severity <sup>1)</sup>		—	02	—	01	—	—	
			Suitability index for standard climate		1	—	A	—	A	—	—
					2	—	A	—	A	—	—
					3	—	A	—	A	—	—
					4	—	A	—	A	—	—
5	—	A			—	A	—	—			
6	—	A	—	A	—	—					
6	3	30 Shock	Technical requirements	Acceleration	g	30	30	50	30	10	50
				Duration	ms	6	18	3	6	6	3
			Degree of severity <sup>1)</sup>		03	04	05 <sup>3)</sup>	03	01	05 <sup>3)</sup>	
			Suitability		The instrument is suitable for the technical requirement if it is operative without restriction after conditioning.						
7	3	31 Bump	Technical requirements	Acceleration	g	10	—	—	10	—	—
				Duration	ms	6	—	—	6	—	—
			Degree of severity <sup>1)</sup>		01	—	—	01	—	—	
			Suitability		The instrument is suitable for the technical requirement if it is operative without restriction after conditioning.						
8	3	36 Sinusoidal vibration	Technical requirements	Acceleration	g	2	—	—	0,5	—	—
				Frequency range	Hz	10 to 500	—	—	10 to 500	—	—
			Degree of severity <sup>1)</sup>		04	—	—	01	—	—	
			Suitability		The instrument is suitable for the technical requirement if it is operative without restriction after conditioning.						
9	13	66 Combined shock, cold	Technical requirements	Temperature	°C	- 40	—	—	- 40	—	—
				Acceleration	g	15	—	—	15	—	—
				Duration	ms	11	—	—	11	—	—
			Degree of severity <sup>1)</sup>		14	—	—	14	—	—	
			Suitability index for standard climate		1	E	—	—	E	—	—
					2	A	—	—	A	—	—
					3	A	—	—	A	—	—
4	E	—			—	E	—	—			
5	A	—	—	A	—	—					
6	A	—	—	A	—	—					

Serial No.	ISO 9022		Instrument type	Field instruments			Instruments in weather-protected locations			
	Part	Conditioning method	Type No.	01			02			
			State of operation <sup>1)</sup>	0	1	2	0	1	2	
10	11	85 4) Mould growth	Technical requirements	Ability to be operated for ≥ 3 years in compliance with stipulated instructions regarding maintenance and care.						
			Degree of severity <sup>1)</sup>	—	02	—	—	02	—	
			Suitability index for standard climate	1	—	A	—	—	B	—
				2	—	B	—	—	B	—
				3	—	B	—	—	B	—
				4	—	A	—	—	B	—
				5	—	B	—	—	B	—
6	—	B	—	—	B	—				
11	12	86 5) 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 <sup>1)</sup>	—	02	—	—	02	—	
			Suitability	The instrument is suitable for the technical requirement if it is operative without restriction after conditioning.						
12	12	87 5) Laboratory agents	Technical requirements	Ability to be operated for ≥ 5 years in compliance with stipulated instructions regarding maintenance and care.						
			Degree of severity <sup>1)</sup>	—	02	—	—	02	—	
			Suitability	The instrument is suitable for the technical requirement if it is operative without restriction after conditioning.						

1) See ISO 9022.  
 2) The test is not required if an air-conditioned location is demanded by the manufacturer for operation of the instrument.  
 3) For hand instruments only.  
 4) 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).  
 5) 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 10109-05-01-T	Environmental requirement ISO 10109-05-02-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	ISO 66-14-0:1994	13
85-02-1	85-02-1	11
86-02-1	86-02-1	12
87-02-1	87-02-1	

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**Table 4 — Suitability indices for extent of testing S**

Serial No.	ISO 9022		Instrument type		Field instruments			Instruments in weather-protected locations			
	Part	Conditioning method	Type No.		01			02/03			
			State of operation <sup>1)</sup>		0	1	2	0	1	2	
1	2	10 Cold	Technical requirements	Temperature °C	—	– 35	—	—	– 10	—	
			Degree of severity <sup>1)</sup>		—	07	—	—	02	—	
			Suitability index for standard climate		1	—	E	—	—	E	—
					2	—	A	—	—	D	—
					3	—	A	—	—	B	—
					4	—	E	—	—	E	—
					5	—	A	—	—	A	—
6	—	A	—	—	B	—					
2	2	11 Dry heat	Technical requirements	Temperature °C	—	63	10 to 55	—	55	10 to 40	
			Degree of severity <sup>1)</sup>		—	04	01 and 03	—	03	01 <sup>2)</sup> and 02 <sup>2)</sup>	
			Suitability index for standard climate		1	—	A	A	—	A	A
					2	—	A	B	—	A	A
					3	—	A	A	—	A	A
					4	—	A	A	—	A	A
					5	—	A	A	—	A	A
6	—	A	A	—	A	A					
3	3	30 Shock	Technical requirements	Acceleration	—	—	50	—	—	50	
				Duration	—	—	3	—	—	3	
			Degree of severity <sup>1)</sup>		—	—	05 <sup>3)</sup>	—	—	05 <sup>3)</sup>	
			Suitability		The instrument is suitable for the technical requirement if it is operative without restriction after conditioning.						

1) See ISO 9022.  
 2) The test is not required if an air-conditioned location is demanded by the manufacturer for operation of the instrument.  
 3) For hand instruments only.

**Table 5 — Test summary**

Environmental requirement ISO 10109-05-01-S	Environmental requirement ISO 10109-05-02-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