INTERNATIONAL STANDARD

ISO 14729

First edition
2001-04-15

AMENDMENT 1
2010-10-01

Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses

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Optique ophtalmique — Produits d'entretien des lentilles de contact — Exigences microbiologiques et méthodes d'essai des produits et protocoles d'entretien des lentilles de contact

AMENDEMENT 1

Reference number
ISO 14729:2001/Amd.1:2010(E)

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Published in Switzerland

Foreword

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Amendment 1 to ISO 14729:2001 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses

AMENDMENT 1

Page 1, Normative references

Replace references to ISO 8320-1:— and ISO 8320-2:— with the following normative reference, which has replaced them:

> "ISO 18369-1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*"

Delete Footnote 1) at the bottom of page 1.

Page 1, Terms and definitions

Replace the normative reference to ISO 8320 with ISO 18369-1, as follows:

> "For the purposes of this document, the terms and definitions given in ISO 18369-1 and the following apply."

Page 2, 4.1

Add the following paragraph after the second paragraph:

> "For contact lens care products where the instructions for use do not include a requirement to rub (or mechanically clean), or to rinse (pre- or post-soak), or to rub and rinse the lenses, the product shall meet the secondary criteria of the stand-alone test in the presence of organic soil and the requirements of the regimen test in the presence of organic soil."

Renumber the Note at the end of the subclause as Note 1.

Add the following Note 2 after Note 1:

> "NOTE 2 It is advisable that manufacturers evaluate the potential interaction between the solution [e.g. antimicrobial agent(s)] and the contact lens in the contact lens case."

Page 4, 5.1.2

Replace the current subclause with the following:

5.1.2 Moulds and yeasts

The number of each challenge organism recovered per millilitre shall be reduced by an average value of not less than 90 % (1,0 log) within the minimum recommended soaking period. No increase in challenge organism recovery within an experimental error of ±0,5 log shall be observed at greater than or equal to four times the recommended soaking period.

NOTE 1 The value is determined by taking the average of the log reductions for each challenge organism for the individual lots tested.

NOTE 2 An apparent increase in mould and yeast survivors up to 0,5 log units following an incubation time of four times the minimum recommended soaking period addresses the observation that clumps of cells/spores can disperse when exposed to contact lens care solutions with surfactant activity. This can result in an apparent increase in the number of survivors which is not due to cell growth.

Page 4, 5.2

Replace the current subclause with the following:

5.2 Stand alone test: Secondary criteria (see also Table 1)

Products failing to meet the criteria in 5.1.1 or 5.1.2 shall be evaluated by the regimen test procedure described in 6.4, provided the sum of the averages is a minimum of 5,0 log units reduction for the three species of bacteria within the recommended soaking period, with a minimum average of 1,0 log unit reduction for any single bacteria. Stasis or reduction for the yeast and mould shall be observed for the recommended soaking period within an experimental error of ±0,5 log. No increase in challenge organism recovery within an experimental error of ±0,5 log shall be observed at greater than or equal to four times the recommended soaking period.

Page 5, 5.4

After subclause 5.3, add the following new subclause 5.4:

5.4 Test requirements for contact lens care products without rubbing (or mechanical cleaning) and/or rinsing steps

All products meeting the primary or secondary criteria without rubbing (or mechanical cleaning) or without rinsing steps (pre- or post-soak), or without both rubbing and rising steps, shall meet the requirements of the secondary performance criteria of the stand-alone test, with and without organic soil and, additionally, pass the regimen test using organic soil.

An example of inoculum preparation with organic soil is provided in Annex E.

Page 7, 6.2

Replace the second paragraph with the following:

“Organic soil may be included as part of the inoculum. See Annex E for an example.”

Page 7, 6.3.1.1

Replace the current subclause with the following:

6.3.1.1 The test protocol shall state the type of tubes to be used, taking into account any compatibility issues, including any need to precondition the tubes. Prepare one or more tubes (for each lot tested) containing a minimum of 10 ml of test product solution per challenge organism.

NOTE Sample tubes are used rather than lens cases to allow effective technical execution of the test. Since incompatibilities can exist between solution ingredients and tube materials, tubes of an appropriate material, which are compatible with the ingredients, should be used.

Inoculate the sample tube of the product to be tested with a suspension of test organisms sufficient to provide a final count of between $1{,}0 \times 10^5$ and $1{,}0 \times 10^6$ cfu/ml. Ensure that the volume of inoculum does not exceed 1 % of the sample volume. Ensure complete dispersion of the inoculum by adequate mixing.

Page 10, 6.4.1

Replace the current subclause with the following:

6.4.1 Lens inoculation

Carry out the test using lens types representative of those with which the regimen is intended to be used, e.g. low water non-ionic, high water ionic, silicone acrylate, and silicone hydrogel lenses. New and unused lenses should be used for this test. When qualifying a lens care product regimen with a single lens type, inoculate each of eight lenses for each microbial species per lot of test product; this results in testing a total of 24 lenses per formulation per species. When qualifying a lens care product regimen for use with all hydrophilic lens types, including silicone hydrogel lenses, inoculate each of four lenses from Group 1 (low water content non-ionic), four lenses from Group 4 (mid water and high water content ionic), and four lenses from each of three representative silicone hydrogel lens materials for each microbial species per lot of test product; this results in testing a total of 12 lenses per lens type per formulation per species. Additional hydrophilic lens types may be tested; however, a minimum of four lenses per lens type per species per lot of formulation shall be used. In qualifying a lens care product regimen for use with all non-hydrophilic lens types, inoculate four silicone acrylate lenses and four fluorosilicone acrylate lenses per microbial species per lot of test product for a total of 12 lenses per lens type per formulation per species. Qualification of a lens care product regimen with all hydrophilic and all non-hydrophilic lenses requires testing with Group 1 and 4 hydrophilic lens types, three representative silicone hydrogel lens types, and silicone acrylate and fluorosilicone acrylate non-hydrophilic lens types.

The number of lenses required for the test is given in Table 4.

Place test and control lenses, with concave surface uppermost, in a sterile Petri dish. Inoculate each lens by placing 0,01 ml of inoculum on the underside of the lens at the point of contact between the Petri dish and the lens. Also inoculate the upper surface by applying 0,01 ml of the same inoculum directly onto the concave surface of the lens.

Allow the inoculum to adsorb onto each lens for between 5 min and 10 min at 20 °C to 25 °C.

Lenses and lens cases shall not be preconditioned with test product solution prior to testing.

Page 10, Table 4

Replace the current table with the following:

Table 4 — Number of lenses required

Test sample[a]	Number of lenses per microbial species							
	Qualification for a single lens type[b]	Qualification for all non-silicone hydrogel lenses[c,d]		Qualification for all silicone hydrogel (SH) lenses[c,d,e]			Qualification for all non-hydrogel lenses[c,d]	
	(e.g. Group 1)	Group 1	Group 4	SH 1	SH 2	SH 3	Silicone acrylate	Fluoro-silicone acrylate
Solution LOT 1	8	4	4	4	4	4	4	4
Solution LOT 2	8	4	4	4	4	4	4	4
Solution LOT 3	8	4	4	4	4	4	4	4
Total[d]	24	12	12	12	12	12	12	12

[a] Minimum of three lots of lens care product to be tested.

[b] If testing only one lens type, a minimum of eight lenses per lens type per lot of lens care product per microbial species shall be used.

[c] If testing more than one lens type, a minimum of four lenses per lens type per lot of lens care product per microbial species shall be used.

[d] Qualification of a lens care product regimen with all hydrogel lenses, including silicone hydrogel lenses, and all non-hydrogel lenses would require, at a minimum, testing the product with four lenses from each of the following lens types: Group 1 and Group 4 hydrogel lenses, three types of silicone hydrogel lenses, and silicone acrylate and fluorosilicone acrylate non-hydrogel lenses.

[e] Lenses chosen should represent the variety in the currently available silicone hydrogel technologies; the choices shall be justified by the lens care product manufacturer in the risk assessment. At least three representative silicone hydrogel lens materials shall be used. As new silicone hydrogel lens materials are introduced into the market-place, they shall be evaluated for their properties and tested as applicable.

Page 18, Annex E

Delete the first paragraph.

In the fourth paragraph, replace “lipacalin” with “lipocalin” (in line 2) and replace “reference [13]” with “reference [44]” (in line 6).

Replace the penultimate sentence of the seventh paragraph with the following:

> “Therefore, this International Standard encompasses stand-alone and regimen testing conducted either with or without organic soil.”