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Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses

Optique ophtalmique — Lentilles de contact et produits d'entretien des lentilles de contact — Détermination de la compatibilité physique des produits d'entretien des lentilles de contact avec les lentilles de contact

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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

This third edition cancels and replaces the second edition (ISO 11981:2009), which has been revised for clarity and to update all normative references.

Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses

1 Scope

This document describes the general procedure and performance criteria for assessing the physical compatibility of contact lens care products with contact lenses and for determining whether the observed changes are reversible.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 18369-1:2017, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-2, *Ophthalmic optics — Contact lenses — Part 2: Tolerances*

ISO 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
cycle
sequence of events, following instructions for use or recommendations by the manufacturer of the contact lens care product, to occur between the time the contact lens is removed from the eye and before it is placed back into the eye

3.2
standard saline solution
specific phosphate buffered saline at a pH of 7,4 ± 0,1 and a nominal osmolarity of 310 ± 5 mOsm

Note 1 to entry: The provisions for formulation and preparation of standard saline solution are given in ISO 18369-3:2017, 4.9.

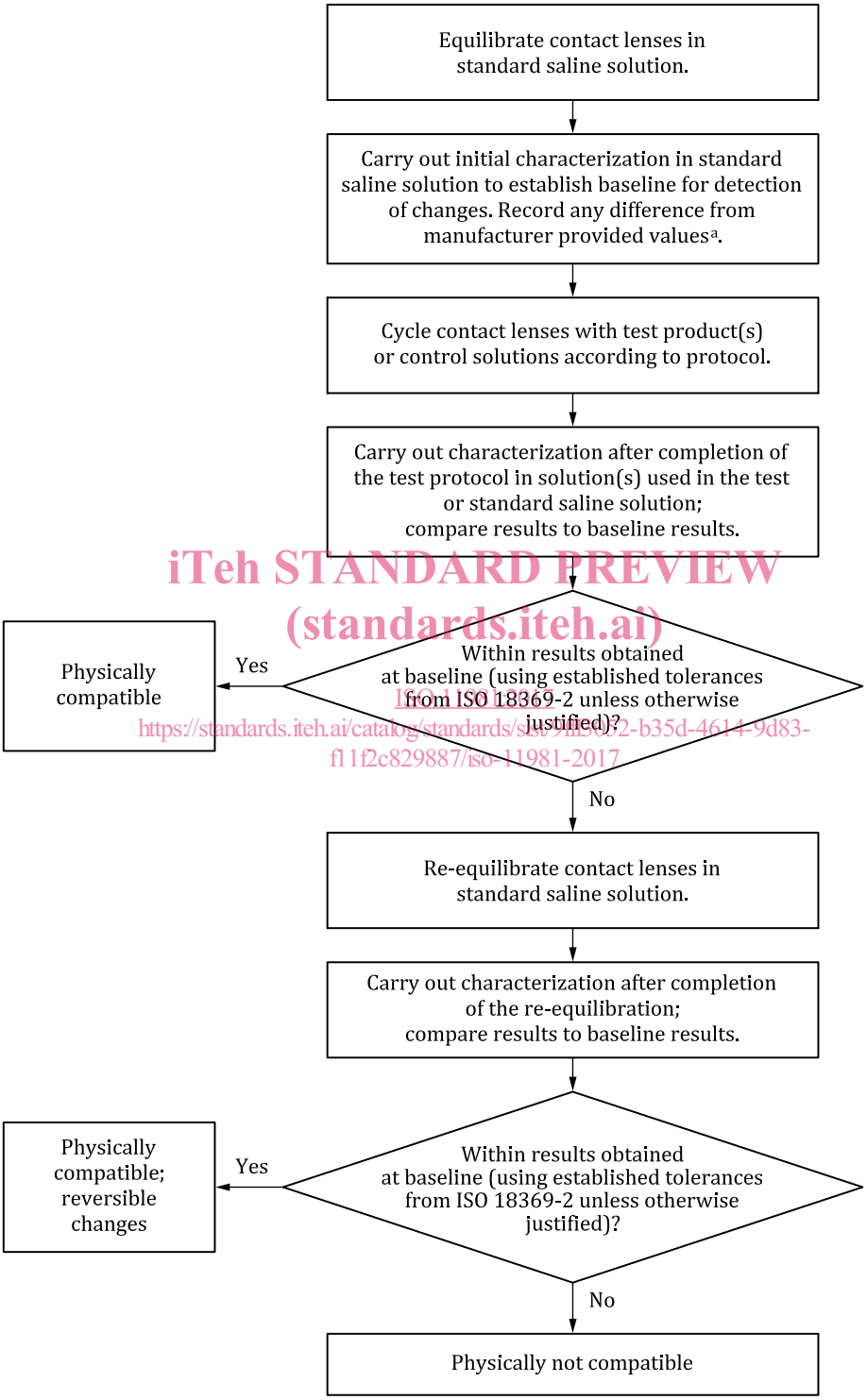
3.3
control solution
standard saline solution or appropriate justified alternative solution used to cycle contact lenses

Note 1 to entry: Control solutions are not required to comply with this document, but can be used to gain further information about the test.

4 Principle

4.1 Detection of changes in contact lens characteristics

See Figure 1.



a If the parameters are different from the values provided by the contact lens manufacturer, the new baseline values should be used to compare results of test product.

Figure 1 — Flowchart for determination of physical compatibility of contact lens care products with contact lenses

4.1.1 Before cycling, contact lenses shall be equilibrated in standard saline solution for sufficient time so that the contact lens parameters to be measured remain constant. Document the volume and temperature used for equilibration. ISO 18369-3 shall be used for methods of measurement for contact lenses.

NOTE An equilibration time of up to 24 h can be required for some hydrogel lenses.

4.1.2 Contact lenses shall be cycled in a manner which simulates the procedures given in the manufacturer's instructions for use of the contact lens care product(s), and tested in volumes in accordance with the manufacturer's instructions.

During the cycles, temperature should be considered. Unless otherwise specified the temperature should be 20 °C to 25 °C.

Volumes for soaking should be at least the amount used to fill a standard lens case used for the care product(s).

NOTE Use of organic soil (0,1 ml per contact lens as per ISO 18259:2014, Annex A) or other specified artificial tear fluid can be considered for in-eye simulation.

In evaluating product(s) being used during on-eye wear, justification of cycling parameters should be documented with regard to simulation of real world conditions.

4.1.3 Where a range of contact times is permitted, the cycle giving rise to the worst case conditions should be used.

4.1.4 Lens characteristics shall be measured after cycling, in the contact lens care product or standard saline solution to determine any changes. Changes in the average results shall be evaluated with reference to values obtained at baseline and tolerances given in ISO 18369-2 unless other tolerances have been justified. See Table 1 for properties and test methods.

It might be advisable to check contact lens parameters mid-way through the test cycles.

4.1.5 If the average results from 4.1 are within the tolerances, the contact lens care solution and contact lens are compatible. If the average results from 4.1 are not within tolerances, proceed to 4.2.

4.2 Method to distinguish reversible from irreversible changes in contact lens characteristics

4.2.1 This method applies only to contact lens care products for which the changes observed in the contact lens characteristics are outside the baseline values obtained by equilibration in standard saline solution (see 4.1.1) and tolerances given in ISO 18369-2 unless other tolerances have been justified after following the test method given in 4.1.

4.2.2 Re-equilibrate the same contact lenses measured in test solution in 4.1 in standard saline solution and measure to distinguish reversible from irreversible changes. See Table 1 for properties and test methods.

4.2.3 Evaluate contact lens characteristics measured in standard saline solution with baseline values and tolerances given in ISO 18369-2. Differences should be reported.

NOTE For certain types of contact lens material, e.g. ionic, the ionic strength of standard saline solution can affect the parameters compared to the label values.

5 Selection of test lenses

5.1 A suitable number of contact lenses, for test and where necessary for controls, is required for each type of contact lens material to be studied. The average of the contact lens characteristics shall be based on a minimum of at least 10 test contact lenses for each combination of contact lens material and contact lens care product.

5.2 Contact lens material groups tested shall represent those types of contact lenses for which the contact lens care product is intended to be used. Contact lens material groups are described in ISO 18369-1.

Contact lenses from at least groups 1 through 4 should be tested if the care product(s) are used with non-hydrogel contact lenses (see ISO 18369-1:2017, Table 2). Contact lenses from at least groups 1, 4, 5A, 5B, and 5C should be tested if the care product(s) are used with hydrogel contact lenses (see ISO 18369-1:2017, Table 3).

6 Procedure

6.1 Test method to detect changes in contact lens characteristics

6.1.1 Record in detail both the characteristics of the contact lenses to be tested and the regimen to be followed. The record shall include contact lens care products and test methods to be used, and the sequence and method of their use. Pass/fail criteria shall be specified.

6.1.2 For contact lens care products intended for use on a daily basis, perform 30 cycles on each material.

6.1.3 For products recommended for use on a scheduled basis as part of a contact lens care regimen (e.g. enzymatic cleaners), the number of cycles shall represent one month's use of the product or at least five exposures to the product.

6.1.4 For lubricating and rewetting drops intended for on-eye use, assess the contact lens characteristics before and after use of the test product. The protocol shall define the method and time of exposure, and shall represent the simulated use of the test product over a month.

6.1.5 For each contact lens care regimen being evaluated, test a minimum of 10 test contact lenses for each combination of lens material and contact lens care product(s).

6.1.6 Allow the contact lenses to equilibrate in standard saline solution for sufficient time so that the parameter to be measured remains constant. Document the time and temperature utilized for equilibration.

Determine the contact lens characteristics and record the data. As a minimum, the properties listed in Table 1 should be determined.

Table 1 — Properties and test methods

Property	Standard test method in accordance with
Diameter (hydrogel lenses only)	ISO 18369-3:2017, 4.4
Curvature (rigid lenses only)	ISO 18369-3:2017, 4.2
Back vertex power (all lens materials)	ISO 18369-3:2017, 4.3
Spectral transmittance (cosmetic tinted and UV-absorbing lenses only)	ISO 18369-3:2017, 4.8
Physical appearance (e.g. surface defects, colour)	ISO 18369-3:2017, 4.6, 4.7

6.1.7 Cycle the contact lenses and record the time of each cycle.

Particular attention should be given to recording the times allocated to each of the components of the regimen.

6.1.8 After cycling, measure the contact lens characteristics in the test solution or standard saline solution. Control contact lenses (if any) should be measured in the control solution.

6.1.9 Determine changes in contact lens characteristics and compare to baseline parameters obtained after equilibration in standard saline solution.

6.2 Test method to distinguish reversible from irreversible changes in contact lens characteristics

6.2.1 This test is to be performed if the changes observed in the characteristics of the test lenses having undergone the test method in 6.1 are outside baseline values. These baseline values are obtained after equilibration in standard saline solution and relevant specifications and tolerances given in ISO 18369-2.

6.2.2 Soak the same contact lenses used in 6.1 in standard saline solution and allow to equilibrate at least for the time necessary to stabilize the contact lens parameters. Record the time, volume and temperature utilized for equilibration, and provide justification for conditions used.

6.2.3 After equilibration and while soaking in standard saline solution, measure the contact lens characteristics.

6.2.4 Determine the changes compared to the baseline results (see 4.1.1).

6.3 Interpretation of results

6.3.1 If the changes observed in the contact lens characteristics are within the baseline results with respect to tolerances defined in ISO 18369-2 after completing the test described in 6.1, the test product(s) is/are judged to be physically compatible with the contact lens material.

6.3.2 If the changes observed in the contact lens characteristics are within the baseline results and tolerances defined in ISO 18369-2 after completing the test described in 6.2, the test product(s) is/are judged to be physically compatible with reversible changes to the contact lens material.

6.3.3 If the changes observed in the contact lens characteristics are outside the baseline results and tolerances defined in ISO 18369-2 after completing the test described in 6.2, the test product(s) is/are judged to be physically incompatible with the contact lens material.

7 Test report

The test report shall include at least the following information:

a) description of the contact lens material, the base curve, power, lot number and the expiry date of the contact lenses;

b) description of the contact lens care product(s), the lot number(s) and expiry date(s);

c) test protocol;

d) test results describing changes in the average of the contact lens characteristics from baseline and, when necessary, changes after equilibration in standard saline solution;

