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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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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 11981 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO 11981:1999) as well as ISO 11981:1999/Cor.1:2005, which has undergone minor revision to update all normative references and to add a NOTE 2 to subclause 5.2.

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

1 Scope

This International Standard 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 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 18369-1, *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 18369-3:2006, *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.

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
active control
contact lens that is cycled according to the test procedure using standard saline solution or appropriate justified contact lens care product(s) instead of the contact lens care product under evaluation

NOTE Active controls are not required to comply with this International Standard, 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.

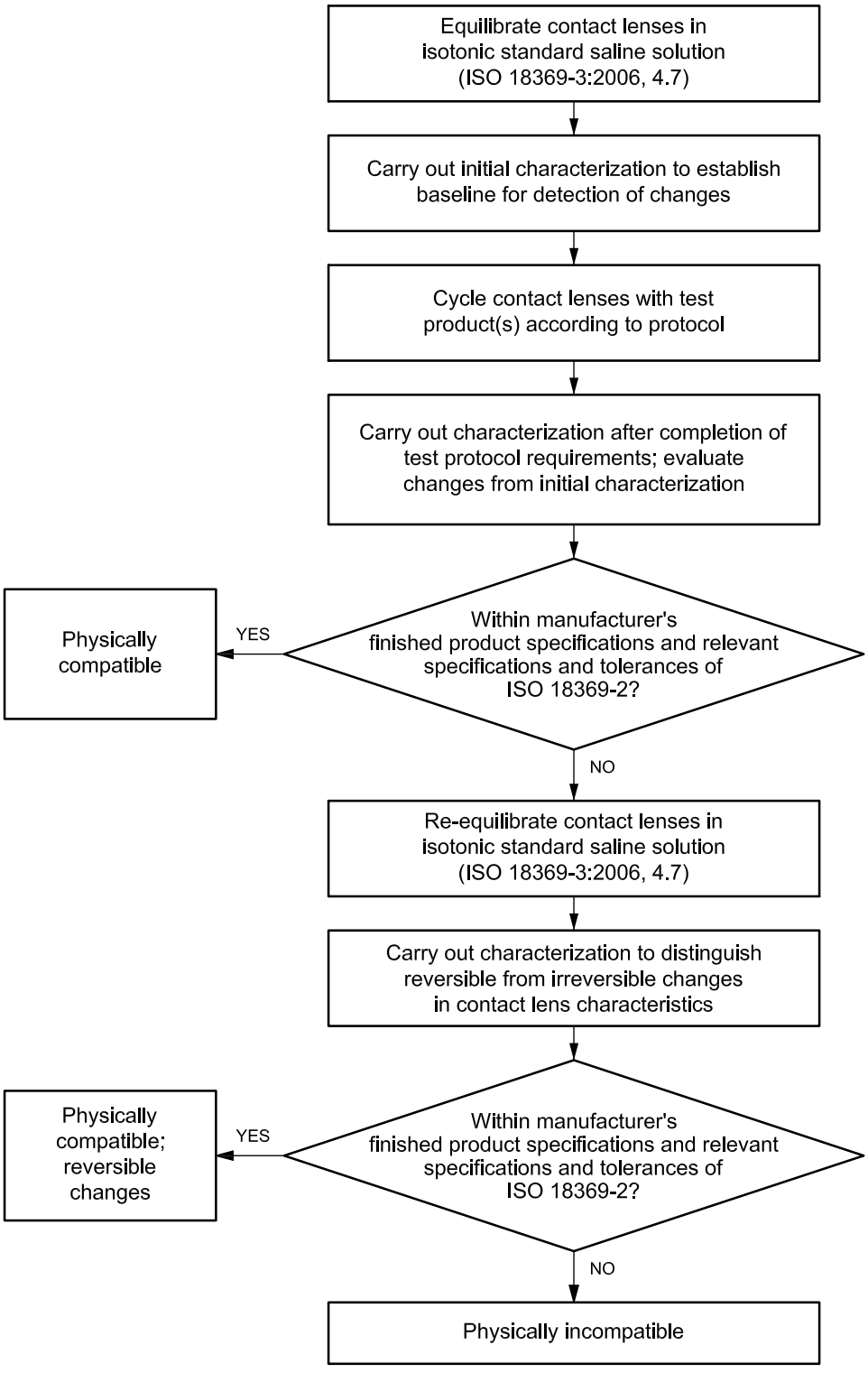

Figure 1 — Flowchart

4.1.1 Before cycling, contact lenses shall be equilibrated in isotonic standard saline solution (see ISO 18369-3:2006, 4.7) for at least 15 min or for the time necessary to stabilize the contact lens parameters.

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 product(s) to be tested.

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

4.1.4 Before and after cycling, certain physical parameters shall be measured to determine any changes. Changes shall be evaluated with reference to the manufacturer's finished product specifications and relevant specifications and tolerances given in ISO 18369-2.

NOTE 1 Contact lens care products should be tested using types of material representative of those with which these products are intended to be used.

NOTE 2 It may be advisable to check contact lens parameters mid-way through the test cycles.

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 manufacturer's finished product specifications and relevant specifications and tolerances given in ISO 18369-2 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 isotonic standard saline solution (see ISO 18369-3:2006, 4.7) and measure to distinguish reversible from irreversible changes.

4.2.3 Evaluate contact lens parameters measured in isotonic standard saline solution (see ISO 18369-3:2006, 4.7) with respect to the manufacturer's finished product specifications and relevant specifications and tolerances given in ISO 18369-2.

NOTE For certain types of contact lens material, e.g. ionic, the ionic strength of standard saline solution (see ISO 18369-3:2006, 4.7) may affect the parameters, compared to the label claim.

5 Selection of test lenses

5.1 A suitable number of contact lenses for test and, where necessary, for active controls is required for each type of contact lens material to be studied. The average of the results shall be based on a minimum of at least ten contact lenses for each lens group tested.

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.

NOTE 1 The study should include test lenses of the extreme powers available within the total of a minimum of ten contact lenses tested for each lens group.

NOTE 2 Based on recent reports of the incompatibility of some silicone-containing hydrogels with some contact lens care systems, consideration should be given for separate compatibility testing of these types of material with contact lens care systems.

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/test methods to be used and the sequence and method of their use.

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 each contact lens care regimen being tested, test a minimum of ten contact lenses for each lens group tested, and when required, a minimum of ten contact lenses with the active-control regimen.

6.1.5 Allow the contact lenses to equilibrate in isotonic standard saline solution before testing for a minimum of 15 min or the time necessary to stabilize the contact lens parameters. 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 18369-3:2006, 4.3
Curvature (rigid lenses only)	ISO 18369-3:2006, 4.1
Back vertex power (spherical lenses)	ISO 18369-3:2006, 4.2
Spectral transmittance (cosmetic tinted and UV-absorbing lenses only)	ISO 18369-3:2006, 4.6
Physical appearance (e.g. surface defects, colour)	ISO 18369-3:2006, 4.5

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

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

6.1.7 After cycling, measure the contact lens characteristics in the test solution. Active-control contact lenses should be measured in the active-control solution.

6.1.8 Determine changes in contact lens characteristics and compare to the manufacturer's finished product specifications and relevant specifications and tolerances defined in ISO 18369-2.

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

6.2.1 Perform this test if the changes observed in the characteristics of the test lenses having undergone the test method in 6.1 fall outside the manufacturer's finished product specifications and relevant specifications and tolerances given in ISO 18369-2.

6.2.2 Soak the same contact lenses used in 6.1 in isotonic standard saline solution (see ISO 18369-3:2006, 4.7) and allow to equilibrate at least for 15 min or the time necessary to stabilize the contact lens parameters.

6.2.3 After equilibration and while soaking in isotonic standard saline solution (see ISO 18369-3:2006, 4.7), measure the contact lens characteristics.

6.2.4 Determine the changes from the initial values obtained in isotonic standard saline solution and compare to the manufacturer's finished product specifications and relevant specifications and tolerances defined in ISO 18369-2.

6.3 Interpretation of results

6.3.1 If the changes observed in the contact lens characteristics are within the manufacturer's finished product specifications and relevant specifications and 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 manufacturer's finished product specifications and relevant specifications 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 with the contact lens material.

6.3.3 If the changes observed in the contact lens characteristics are outside the manufacturer's finished product specifications and relevant specifications 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.

NOTE Pass/fail criteria for this study should be specified in the test plan.

7 Test report

The test report shall include at least the following information:

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

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

c) test protocol;

d) test results;

e) name and address of the test laboratory;

f) name of the person responsible;

g) date of testing and an approved signature.

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