
**Ophthalmic optics — Contact lenses —
Determination of shelf-life**

*Optique ophtalmique — Lentilles de contact — Détermination de la
durée de conservation*

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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 11987 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 11987:1997), which has been technically revised. It also incorporates the Technical Corrigendum ISO 11987:1997/Cor.1:1998.

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Introduction

The tests included in this International Standard are designed to obtain information that enables proposals to be made for the shelf-life of a contact lens, and storage conditions to be recommended. However, in practical terms, it is the stability of the material from which the contact lens is made that is being tested, along with the integrity of the packaging that maintains the environment necessary for the contact lens.

The purpose of the stability studies is to ascertain how the quality of the contact lens varies as a function of time and under the influence of a variety of environmental factors. On the basis of the information thus obtained, storage conditions can be recommended that guarantee the maintenance of the quality of the contact lens in relation to its safety, efficacy and acceptability throughout the proposed shelf-life (i.e. during storage and distribution until the moment of dispensing).

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Ophthalmic optics — Contact lenses — Determination of shelf-life

1 Scope

This International Standard specifies test procedures for determining the stability of contact lenses once they are placed in their final packaging during storage and distribution.

NOTE The results obtained can be used for determining the expiry date.

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, *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 apply.

4 Principle

The stability of contact lenses, packaging solution and packaging is established under controlled storage conditions in order to determine their shelf-life under those conditions.

The design of the stability tests is based on the known properties of the material from which the contact lens is made, the packaging system, and the recommendations for storing the contact lens.

5 General requirements and recommendations

A risk assessment shall be performed to evaluate the critical properties and parameters, and a test protocol prepared.

NOTE 1 A knowledge of the quantity and identity of extractable substances (see ISO 18369-4) is of particular help in evaluating new contact lens materials and in determining the information that needs to be obtained from the stability testing.

The specifications of the properties and parameters evaluated in the stability study, which are claimed at the time of manufacture and to the end of the proposed shelf-life, should reflect, as far as possible, the results of the stability studies, particularly in relation to any parameters which could have a bearing on efficacy, safety and product acceptability.

In designing stability tests, the manufacturer should consider any sterility requirements.

NOTE 2 Requirements for the development, validation and routine control of sterilization processes are described in other International Standards. Additionally, sterility testing is described in monographs in various pharmacopoeias.