

INTERNATIONAL
STANDARD

ISO
9341

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**Optics and optical instruments — Contact
lenses — Determination of inclusions and
surface imperfections for rigid contact
lenses**
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*Optique et instruments d'optique — Lentilles de contact — Détermination
des inclusions et imperfections de surface des lentilles de contact rigides*
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Reference number
ISO 9341:1996(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.

International Standard ISO 9341 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A forms an integral part of this International Standard.

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Optics and optical instruments — Contact lenses — Determination of inclusions and surface imperfections for rigid contact lenses

1 Scope

This International Standard describes a procedure for the assessment of inclusions and surface imperfections for rigid contact lenses. Surface markings intentionally made are not regarded as surface imperfections.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8320:1986, *Optics and optical instruments — Contact lenses — Vocabulary and symbols*.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8320 apply.

4 Test conditions

4.1 Resolution

For an observer with normal visual acuity, the method shall be capable of resolving any inclusion greater than $3\ \mu\text{m}$ in any direction and any surface imperfection greater than $9\ \mu\text{m}$ in any direction.

4.2 Illumination

The illumination of the contact lens to be examined shall be $(350 \pm 35)\ \text{lx}$ including the room illumination.

4.3 Measuring temperature

The contact lens and measuring devices shall be maintained at temperatures of $(20 \pm 5)\ ^\circ\text{C}$.

5 Recommended method

A method for assessing material inclusions (e.g. bubbles, striae, fissures, residual granulates and foreign substances) and surface imperfections (e.g. scratches, matt areas and marginal chips) is described in annex A.

Other methods which fulfil the requirements of clause 4 are also allowed.

Annex A (normative)

Inspection method for assessment of inclusions and surface imperfections of rigid contact lenses

A.1 Principle

The test is effected on a light-dark border with the apparatus according to figure A.1.

A.2 Procedure

Carry out the test with the lens in a dry state. Place the lens on the contact lens support (see figure A.1), ensuring that the lens is not deformed. With the aid of the magnifying device, view the lens at a light-dark border and record the defects as indicated in table A.1.

The observer shall be skilled in the recognition of rigid contact lens defects.

For the observation of inclusions, a $\times 6$ magnifying device shall be used and for the observation of surface imperfections, $\times 2$ magnification shall be used.

A.3 Designation of size of defects

The size and location of any defects shall be designated according to the classification given in table A.1.

Table A.1 — Rating scheme for designating the size of defects (order of magnitude)

Class	Size of defects
0	not visible under $\times 6$ magnification
1	not visible under $\times 2$ magnification
2	visible under $\times 6$ magnification
3	visible under $\times 2$ magnification

A.4 Test report

The test report shall contain at least the following in-

- a) a reference to this International Standard;
- b) the identification of the contact lens tested;
- c) description of defect (surface imperfections or inclusions);
- d) the class of defects;
- e) date of the examination.

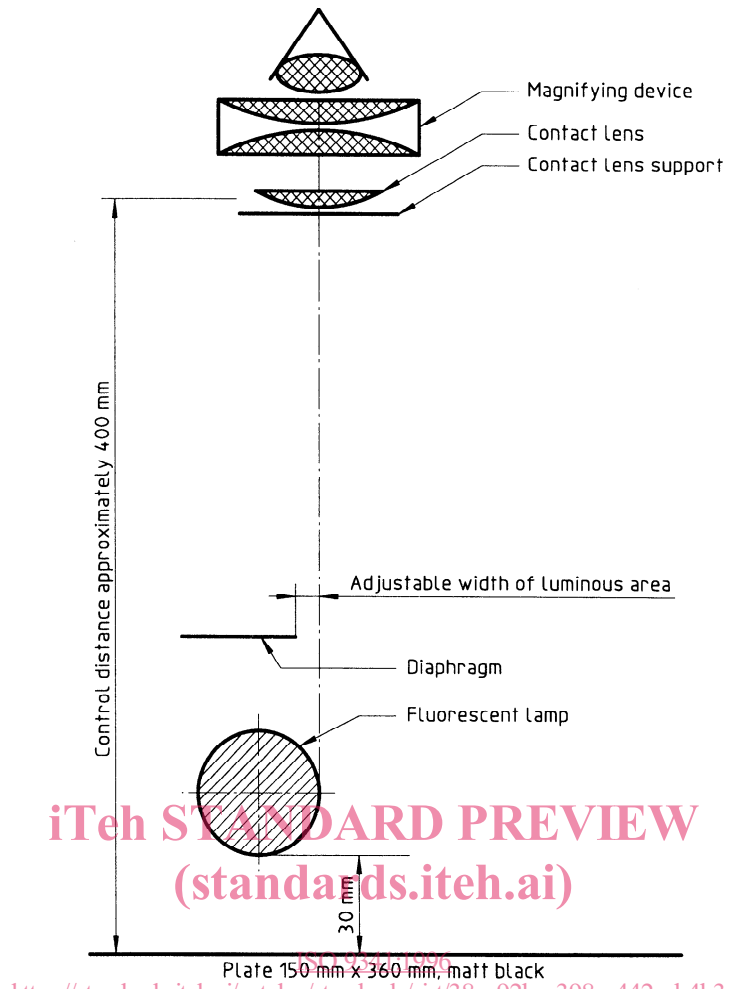


Figure A.1 — Arrangement of apparatus

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