

Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations

The European Standard EN ISO 1180:1997 has the status of a British Standard

ICS 11.040.70

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This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 October 1998

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Amendments issued since publication

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National foreword

This British Standard is the English language version of EN ISO 11980:1997. It is identical with ISO 11980:1997.

The UK participation in its preparation was entrusted by Technical Committee CH/78, Ophthalmic optics, to Subcommittee CH/78/4, Physical properties of contact lenses, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Additional Information

In **Annex C**, Table C.9, visual acuities have been expressed in Snellen form but in Europe it is normal to express them in a metric form, e.g. 6/6 rather than the imperial form given e.g. 20/20.

Textual errors

The textual error set out below was discovered when the English language version of EN ISO 11980:1997 was adopted as the national standard. It has been reported to CEN in a proposal to amend the text of the European Standard.

In **Annex A**, Figure A.1, the numbers on the right hand diagram are incorrect. The 5 and 3 have been reversed, since 3 should represent the nasal side of the cornea and 5 the temporal side. The left hand diagram is correct.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, page 2, the ISO title page, page ii, pages 1 to 14 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

ICS 11.040.70

Descriptors: See ISO document

English version

Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations

(ISO 11980:1997)

Optique ophtalmique — Lentilles de contact et produits d'entretien pour lentilles de contact — Lignes directrices pour les investigations cliniques
(ISO 11980:1997)

Augenoptik — Kontaktlinsen und Kontaktlinsenpflegemittel — Leitfaden für die klinische Prüfung
(ISO 11980:1997)

This European Standard was approved by CEN on 30 November 1997.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

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Foreword

The text of the International Standard ISO 11980:1997 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11980:1997 was approved by CEN as a European Standard without any modification.

NOTE Normative references to International Standards are listed in Annex ZA (normative). A-deviations are given in Annex ZB (informative).

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INTERNATIONAL STANDARD

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Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations

*Optique ophtalmique — Lentilles de contact et produits d'entretien pour
lentilles de contact — Lignes directrices pour les investigations cliniques*



Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 11980 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annex A to Annex D of this International Standard are for information only.

Descriptors: Optics, optical equipment, ophthalmic equipment, contact lenses, care products, tests, clinical testing, estimation, performance, safety, generalities.