SLOVENSKI STANDARD
oSIST prEN ISO 11980:2024

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Očesna optika - Kontaktne leče in izdelki za vzdrževanje kontaktnih leč - Navodilo za klinične raziskave (ISO/DIS 11980:2024)

Ophthalmic optics - Contact lenses and contact lens care products - Guidance for clinical investigations (ISO/DIS 11980:2024)

Augenoptik - Kontaktlinsen und Kontaktlinsenpflegemittel - Leitfaden für die klinische Prüfung (ISO/DIS 11980:2024)

Optique ophtalmique - Lentilles de contact et produits d'entretien pour lentilles de contact - Directives pour les investigations cliniques

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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 — Directives pour les investigations cliniques

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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.

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This fourth edition cancels and replaces the third edition (ISO 11980:2012), which has been technically revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Currently, contact lenses and contact lens care products are regulated in different ways in different countries. This International Standard has been developed to encourage global alignment. Widespread adoption of this International Standard can represent yet another step toward universal recognition. This International Standard can also be used as a basis to fulfil design elements of ISO 9001 and/ or (EN) ISO 13485 as well as related national laws.

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

1 Scope

This document gives guidelines for the clinical investigation (CI) to establish the safety and performance of contact lenses and contact lens care products.

NOTE 1 This document attempts to align the recognised regulatory requirements for the conduct of a CI to meet the marketing and labelling requirements for contact lenses and contact lens care products around the world. However, national requirements vary greatly. Wherever national practice or regulations dictate some legal requirement, this requirement takes precedence over this document.

NOTE 2 For indications beyond correction of refractive error, additional considerations for safety and performance should be included in the clinical investigation plan (CIP).

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 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14534, *Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements*

ISO 18369-1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14155, ISO 14534 and ISO 18369-1 apply.

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

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

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

4 Clinical investigational requirements

4.1 General

The general requirements for a CI and for a CIP given in ISO 14155 shall apply, with additional requirements given below.

4.2 Additional requirements

4.2.1 Study design

4.2.1.1 General

a) The inclusion criteria for participant selection shall relate to the study objectives and should include:

   1) participants with eyes appropriate for the study being conducted;

   2) participants of appropriate age for the study being conducted (age range to be specified);

   3) participants requiring lens powers within the range available for the study lenses;

   4) the manifest cylinder less than or equal to 1,00 D (for a study with only spherical power correcting soft lenses. For rigid contact lenses, the suitable manifest cylinder may be higher and shall be defined in the inclusion criteria);

   5) best spectacle corrected visual acuity greater than or equal to 20/25 (less than or equal to LogMAR 0,1).

b) The exclusion criteria for participant selection shall relate to the study objectives and should include, but not be limited to:

   1) anterior segment infection, inflammation or abnormality;

   2) any active anterior segment ocular disease that would contraindicate contact lens wear;

   3) the use of systemic or ocular medications that would contraindicate contact lens wear;

   4) history of herpetic keratitis;

   5) history of refractive surgery or irregular cornea (except when the contact lens or contact lens care product under investigation is indicated for ocular conditions such as irregular cornea, keratoconus or refractive surgery);

   6) slit lamp findings that are more serious than grade 1 (refer to Annex B containing grading scales);

   7) inactive (i.e. ghost) vessels greater than 1 mm of penetration into the cornea;

   8) participation of the participant in a contact lens or contact lens care product clinical trial within the previous 90 days (orthokeratology), 30 days (extended wear, rigid gas permeable corneal and scleral lenses) or 15 days (daily disposable, daily wear).

c) The CIP shall provide a description of the monitoring procedure to ensure consistent quality of data collection and recording based on the chosen intended purpose.

d) The CIP shall include a statistical analysis plan. Sample size shall be statistically justified.

4.2.1.2 Contact lenses

4.2.1.2.1 General

A CI of contact lenses, including daily wear and extended wear hydrogel, silicone hydrogel, and rigid gas-permeable contact lenses, shall be designed as one of 4.2.1.2.2 or 4.2.1.2.3.

For CIPs to demonstrate safety and performance based on the chosen intended purpose, as well as special claims (e.g., comfort), labelling or additional indications, the following is required per wearing modality to be investigated: a pre-determined statistical analysis plan (including sample size calculations) shall be

specified in the clinical protocol. Where feasible, the CIP shall define objective endpoints to help support such claims.

NOTE 1 Bilateral studies are preferred to contralateral studies, due to the potential dependence between the two eyes and concerns regarding participant compliance.

NOTE 2 Annex A provides guidance for the design of a CI.

4.2.1.2.2 As a prospective, concurrently controlled study. For investigations evaluating hydrogel, silicone hydrogel or rigid gas-permeable contact lenses, a prospective, concurrent control study design shall be followed. Either a (i) bilateral crossover design, or (ii) parallel groups (inter-participant controls) design, or (iii) contra-lateral eye (i.e., intra-participant controlled) design shall be utilised. If parallel groups/inter-participant controls are utilised, the ratio of test participants to control participants may be either 2:1 or 1:1.

The control lens shall be a currently cleared, registered, or approved contact lens in use for the same modality, in all countries where the study is performed. Randomisation and masking (participant, investigator, and evaluator) shall be employed where possible to minimise the potential for bias. Participants shall be divided evenly between study investigators.

NOTE A single arm study is acceptable for orthokeratology studies (overnight or daily wear).

4.2.1.2.3 As an uncontrolled study. Here, results are compared to a historical control. Alternative investigational study designs, such as historical controls, shall be utilised when a sponsor has a clinical database on a cleared, registered, or approved contact lens to use as a comparator. If any historical control is used, the control group shall be defined and adequately characterised for comparison to the test group. Compatibility of test and control groups shall be demonstrated by comparison of the selection criteria, demographics, refractive characteristics, contact lens wearing history and in the CIPs used.

4.2.1.3 Contact lens care products

For investigations evaluating contact lens care products, a prospective concurrent control study design shall be followed. It is recommended that the ratio of test to control participants be either 2:1 or 1:1. The control care product shall be a currently cleared, registered, or approved contact lens care product in all countries where the study is performed. Randomisation and masking (participant, investigator, and evaluator) shall be employed where possible to minimise the potential for bias. Participants shall be divided evenly between study investigators. Alternative investigational study designs, such as use of historical controls, may be utilised when a sponsor has a clinical database on a cleared, registered, or approved care product to use for comparison. If any historical control is used, the control group should be defined and adequately characterised for comparison to the test group. Compatibility of test and control groups should be demonstrated by comparison of the selection criteria and CIPs used.

For CIPs to demonstrate safety and performance, as well as special claims (e.g., comfort), labelling or additional indications, the following is required for the care products: a pre-determined statistical analysis plan (including sample size calculations) shall be specified in the clinical protocol. Where feasible, the protocol should define objective endpoints to help support such claims.

NOTE 1 Bilateral studies are preferred to contralateral studies, due to the potential dependence between the two eyes and concerns regarding participant compliance.

In a contact lens care product investigation, a daily wear schedule shall be followed for most products in order to maximise the participant's exposure to those products. However, a study of a lens or a periodic cleaner, used at weekly intervals, may provide more valuable clinical data concerning effectiveness when extended wear participants are enrolled than a similar investigation with daily wear participants.

When a daily wear schedule is used and safety is a primary objective, one post-dispensing visit should be done 1 h to 2 h after lens insertion in order to permit observation of corneal and conjunctival staining, and redness caused by an immediate toxicity reaction.

A contact lens care product with a cleaning indication shall have an objective measure of lens deposits on at least one lens collected from each participant at the end of the clinical study.