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Ophthalmic optics — Contact lenses — Hygienic management of multipatient use trial contact lenses

Optique ophtalmique — Lentilles de contact — Entretien de l'hygiène des lentilles de contact d'essai à usage multipatient

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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).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: 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 first edition of ISO 19979:2018 cancels and replaces ISO/TS 19979:2014, which has been technically revised. In addition to the change in document type from a Technical Specification to an International Standard, the main changes compared to ISO/TS 19979:2014 are as follows:

— the specific processes of hygienic management have been presented as tables;

— a flow chart of the hygienic management process has been introduced;

— the example of disinfection procedure using hydrogen peroxide has been moved to Annex A;

— editorial revisions have been implemented.

Introduction

Wherever possible, a trial contact lens should be used only on one individual. While the current trend in contact lens development is toward disposable and extended wear lenses, conventional lenses including rigid gas-permeable (RGP) contact lenses, composite contact lenses and hydrogel contact lenses in special designs and parameters are necessary to meet individual patient needs.

The reconditioning of multipatient use contact lenses involves cleaning, disinfection and storage of the contact lenses. The cleaning step is not specified in this document, as it does not differ from the cleaning of contact lenses for end-users.

The hygienic management for multipatient use differs from the requirements of hygienic management for contact lenses for individual use and from surface disinfection used in hospitals.

This document gives guidance for the development of instructions for manufacturers of multipatient use contact lenses, in order to mitigate the risk of pathogen transfer between patients.

Ophthalmic optics — Contact lenses — Hygienic management of multipatient use trial contact lenses

1 Scope

This document provides guidance to manufacturers for the development of information to be provided to eye care practitioners for the hygienic management of trial hydrogel, composite and rigid gas-permeable (RGP) contact lenses intended for multipatient use.

This document does not apply to:

— labelling of contact lenses;

— the inactivation of prions and viruses since there are no standardised methods available for contact lenses.

This document can be used as guidance for the development of a hygienic management procedure for multipatient use.

NOTE ISO 14729 does not cover multipatient use.

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 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 18369-1 and the following apply.

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

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

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

3.1
trial contact lens
diagnostic contact lens
contact lens only used by a practitioner or fitter for the purpose of selecting the appropriate contact lens parameters for the intended wearer

[SOURCE: ISO 18369-1:2017, 3.1.10.8]

3.2
multipatient use trial contact lens
trial contact lens permitted to be used on more than one person

[SOURCE: ISO 18369-1:2017, 3.1.10.9, modified — Note 1 to entry has been deleted.]

3.3
competent personnel
personnel, qualified or trained for the hygienic conditioning of contact lenses

3.4
composite contact lens
contact lens composed of two or more different materials

[SOURCE: ISO 18369-1:2017, 3.1.1.11, modified — The example has been deleted.]

4 Methods of hygienic management for multipatient use trial contact lenses

The ideal approach for trial contact lenses is to use the lens a single time, after which the lens is dispensed to the same individual or discarded. Where reuse is necessary, moist heat management is preferred over chemical management whenever applicable.

The manufacturer shall provide instructions for the hygienic management of multipatient use trial contact lenses appropriate to the type of lens being used.

The instructions shall include advice on the process to be applied and on how to maintain the processed contact lens in a suitable condition (e.g. container choice, container closure).

Ocular irritation due to use of a chemical disinfection method should be considered.

When using this document as guidance for the development of a hygienic management procedure for multipatient use, the disinfection performance shall be appropriate to meet at least the requirements in Clause 5.

5 Options for hygienic management of multipatient use trial contact lenses

5.1 General

Table 1 gives general information on relevant items for the hygienic management of multipatient use trial contact lenses.

Table 1 — General information

	Content	Action	NOTE
1	**Precautions against infections**	Dispose of contact lenses used in persons known to be infected with — Herpes simplex cornea; — Hepatitis; — Human Immunodeficiency Virus (HIV); — Adenovirus.	Use disposable/single use gloves. Dispose of trial contact lenses immediately after use. There is a possibility that National Regulations add other infectious diseases to this list. Practitioners should be instructed to monitor Health Authority communications for emerging risks related to outbreaks of unknown or little known infectious diseases, and associated advice.
2	**Waste disposal**	When it is necessary to dispose of any lenses, containers, or solutions due to reasons mentioned in 1, the items need to be treated as "biohazardous" waste. Use disposable/single use powder-free, latex-free gloves to remove the infected lenses from patient eyes. If necessary, dispose of containers and solutions used in contact with the infected lenses. The lenses, containers and solutions shall be treated as "biohazardous waste".	The local requirements for the disposal of biohazardous waste apply.
3	**Workbench surface**	Shall be cleaned and disinfected on a daily basis with a suitable surface disinfectant.	
4	**Hand washing**	Wash your hands before and after each patient fitting with a surgical scrub or a liquid soap. Dry your hands on a new paper towel.	Drying the hands reduces the chances of spreading water-borne organisms such as *Acanthamoeba.*
a)		Hand washing is required even before the use of gloves.	Information on hygienic hand wash is provided on the poster by WHO: www.who.int/gpsc/5may/How_To_HandWash_Poster.pdf.
5	**Cleaning of contact lenses**	Rub and rinse the contact lens **before** (RGP only) **and after** use according to the instructions of the manufacturer.	Removing particulate debris from a contact lens ensures a more effective use of the disinfecting solution.
6	**Applicable procedures**	The manufacturer shall specify the methods of disinfection (e.g. moist heat disinfection or an ophthalmic hydrogen peroxide treatment) to be used during hygienic management.	Moist heat disinfection is applicable for hydrogel lenses. (See Table 2). Most contact lens types can be disinfected using an ophthalmic hydrogen peroxide solution.
7	**Number of re-uses or time in use**	All lenses stored in a soaking solution or in a dry condition shall be discarded after X times of use **or** after Y months from first use, or if the lens is damaged, whichever comes first.	For lenses stored in soaking solution, repeat the disinfection procedures if the contact lens has not been used for 28 d. The lens manufacturer shall determine the numbers X and Y. If the manufacturer is aware of particular changes/damages that may occur, the manufacturer shall provide guidance on related criteria for discarding the lens.

Table 1 *(continued)*

	Content	Action	NOTE
8	**Re-use of contact lenses**	The contact lens shall be inspected before and after every use. If the lens is damaged or its physical appearance has changed, the lens shall be discarded.	
9	**Contact lens container**	The manufacturer shall state the type of container suitable for the hygienic management of multi-patient use trial contact lenses. The methods shall be stated by which the container can be cleaned, properly closed, and relabelled, if appropriate.	
a)		Information on regular replacement and care of the containers shall be given by the contact lens manufacturer.	
10	**Documentation**	The manufacturer shall specify: — lot number; — lens parameters; — expiry date; — if appropriate maximum number of uses.	Enough lens parameters should be given to sufficiently identify the lens and enable traceability.
11	**Record of each disinfection procedure**	Type of procedure, e.g. chemical management, moist heat disinfection.	
a)		Practitioners shall record: — patient's reference; — date of use; — date of hygienic management; — contact lens details.	
b)		Person performing disinfection	Competent personnel only, with supporting training records.
12	**Storage container labelling**	— parameters of contained contact lens; — lot number; — date of disinfection; — lens identification (for future tracking).	Add sufficient information to identify individual lens.

5.2 Disinfection procedure with moist heat

Table 2 gives guidance on factors to be considered for disinfection with moist heat.

NOTE Only after a properly validated sterilization process, according to ISO/TS 17665-2:2009, Table 1, can the lens be described as sterile.

Table 2 — Disinfection procedure with moist heat (applicable for hydrogel lenses only)

	Procedure step	Example
Preparation	Choice of medium, in which to place the lens.	Saline (0,9 % sodium chloride solution).
	Choice of container.	Borosilicate glass vial with crimped seal.
Procedure	Choice of disinfection process conditions.	Target temperature 134 °C for dwell time of at least 3 min, or Target temperature 121 °C for dwell time of at least 15 min.

5.3 Disinfection procedures using an 3 % ophthalmic hydrogen peroxide for 3 h or equivalent

The recommended disinfection solution shall have intrinsic disinfecting efficacy equivalent to a 3 h exposure to 3 % ophthalmic hydrogen peroxide. Equivalence may be demonstrated empirically.

NOTE An example of a disinfection procedure using hydrogen peroxide is provided in Annex A.

5.4 Storage of disinfected lenses

Table 3 gives additional information on the storage of disinfected lenses.

Table 3 — Storage of disinfected lenses

	Step	Procedure	Information
1	**Preparation for storage**	Fill appropriate container with stipulated preserved soaking solution.	Hydrogel contact lenses should not be stored dry.
a)		To avoid skin contact, use disinfected tweezers.	This is not appropriate for moist heat processed lenses.
b)		Re-insert lens/holder and close the container.	Container of moist heat processed lenses shall not be opened until use.
2	**Duration of storage**	The contact lens manufacturer shall state the maximum number of times of re-use and the maximum duration of time from the first use as a multipatient use trial contact lens.	Applicable for hydrogel, composite, and RGP lenses.
3	**Wet storage**	The validation of the system used defines the storage time.	Applicable for hydrogel, composite, and RGP lenses.
4	**Dry storage**	Dry contact lens with a clean lint-free paper tissue.	Applicable for RGP lenses only.
a)		Insert lens in an appropriate container and close securely. A dry stored lens should be prepared for reuse.	

6 Flowchart to describe the use of multipatient use trial contact lenses

See Figure 1.

Disinfection procedure applicable for RGP lenses, hydrogel and composite lenses.

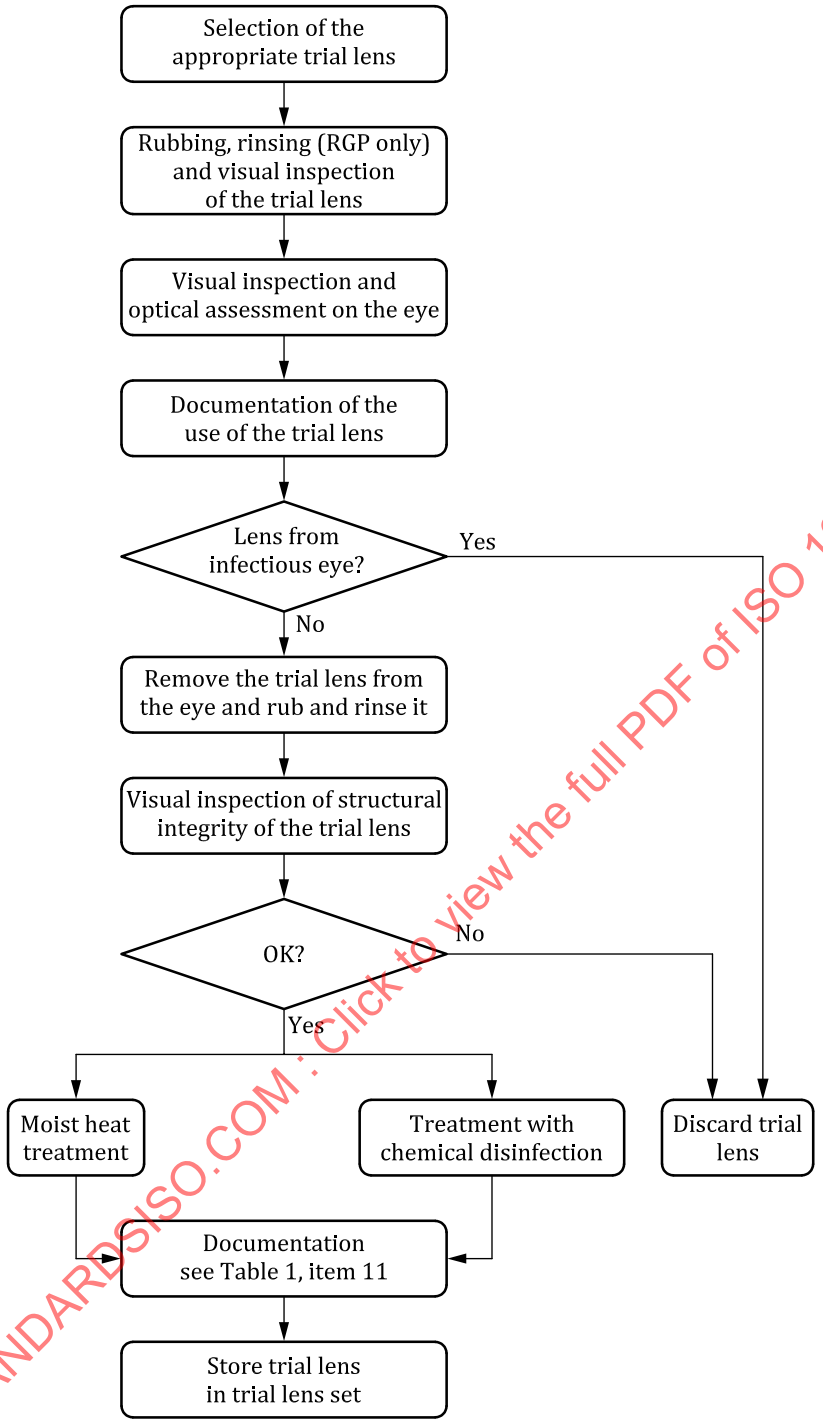

Figure 1 — Use of multipatient use trial contact lenses