INTERNATIONAL STANDARD

ISO 19979

First edition
2018-03

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

Reference number
ISO 19979:2018(E)

© ISO 2018



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2018 – All rights reserved

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Methods of hygienic management for multipatient use trial contact lenses ... **2**
5 Options for hygienic management of multipatient use trial contact lenses ... **2**
5.1 General ... 2
5.2 Disinfection procedure with moist heat ... 4
5.3 Disinfection procedures using an 3 % ophthalmic hydrogen peroxide for 3 h or equivalent ... 5
5.4 Storage of disinfected lenses ... 5
6 Flowchart to describe the use of multipatient use trial contact lenses ... **5**
Annex A (informative) **Disinfection procedure using an 3 % ophthalmic hydrogen peroxide solution** ... **7**
Bibliography ... **8**

© ISO 2018 – All rights reserved

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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.

© ISO 2018 – All rights reserved

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.

© ISO 2018 – All rights reserved

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.]

© ISO 2018 – All rights reserved

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.

© ISO 2018 – All rights reserved