TECHNICAL SPECIFICATION

ISO/TS 19979

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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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Contents

Page

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO/TS 19979:2004), of which it constitutes a minor revision.

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) and soft contact lenses in special designs and parameters are necessary to meet individual patient needs.

The subject of transmission of diseases such as variant Creutzfeld-Jakob Disease (vCJD) via multipatient use of trial contact lenses has recently become a topic of discussion. It is anticipated that the discussions will be ongoing for some time, making it impossible to reach agreement on an International Standard. Therefore, it was decided that the publication of a Technical Specification for the hygienic management of multipatient use trial contact lenses would be appropriate at this time. However, this Technical Specification does not address the inactivation of prions since there are no reported cases of transmission of prions by contact lenses. The user of this Technical Specification has to consult the scientific literature for any change in processes and procedures that might result.

It is important that the industry have an available guideline in the form of a Technical Specification. If the guideline is followed, the risk of patient-to-patient transmission of an infectious microorganism from trial contact lenses can be reduced.

This Technical Specification is not to be regarded as an International Standard. Its proposed application is provisional so that information and experience based on its use in practice can be gathered.

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

1 Scope

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

See Annex A for an example of labelling information.

This Technical Specification does not address

— national regulations for labelling of contact lenses; and

— the inactivation of prions since there are no reported cases of transmission of prions by contact lenses.

NOTE This Technical Specification acknowledges that risk factors for possible transmission of specific diseases by use of trial contact lenses on multiple patients can vary by country or other political or geographical barriers. Legal requirements involving national practices or regulations take precedence over this Technical Specification.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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 18369-1:2006, 2.1.10.8]

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

[SOURCE: ISO 18369-1:2006, 2.1.10.8.1]

4 Methods of hygienic management for multipatient use of trial contact lenses

4.1 General

The contact lens manufacturer's instructions for the hygienic management of multipatient use trial contact lenses should ensure that the performance criteria of methods of heat or chemical management are not compromised by the instructions. Manufacturers of contact lenses and contact lens care products should consider the issues that could arise when specifying a system for the hygienic management of multipatient use trial contact lenses (e.g. incompatibilities between a specific contact lens, lens care system, chemical agents, and/or storage container).

4.2 Single-use conditions

All trial contact lenses used with patients identified as potential carriers of infectious diseases such as CJD, herpes simplex, hepatitis, Human Immunodeficiency Virus (HIV), or adenovirus shall be disposed of after use. Any lens known to be infected shall be discarded immediately to minimize contamination in practice. In this case, the use of disposable gloves is necessary.

NOTE 1 If any country's regulations require other infectious diseases to be added, these apply in the country/area concerned.

NOTE 2 Local regulations governing the disposal of biohazardous waste can apply.

4.3 Hand washing

Instructions should be given to wash the hands in accordance with the eye care professional's recommendations.

NOTE For those countries without an eye care professional's recommendation on hand washing, see A.1.2 and A.1.3.

4.4 Adjunctive solutions

All solutions used in the hygienic management of contact lenses or contact lens containers shall meet the requirements of ISO 14534. Water from the tap should not be used to hygienically manage the contact lens or its container.

4.5 Use of a contact lens cleaner

The use of a cleaning and rinsing solution(s) shall be part of the procedure of reprocessing of multipatient use trial contact lenses, as specified by the manufacturer. All multipatient use trial contact lenses should be cleaned and rinsed **just prior** to use as well as **after** use.

4.6 Containers

The contact lens manufacturer should state the type of container suitable for the hygienic management of multipatient use trial contact lenses. Consideration should be given to the recommendations of the manufacturer of the contact lens care system. The methods should be stated by which the container can be cleaned, properly closed, and relabelled, if appropriate.

4.7 Frequency and lifetime of hygienic management of multipatient use trial contact lenses

The physical performance criteria for discontinuation of use should be given by the contact lens manufacturer. Unless otherwise justified, the contact lens manufacturer should 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 (e.g. not more than 25 trial uses and/or a 12-month duration for hydrogel trial lenses; for nonhydrogel trial lenses, the duration could be extended indefinitely). These times should not be

exceeded. The manufacturer should encourage the practitioner to ensure that the multipatient use trial contact lens is examined to confirm that the lens is suitable for use (e.g. undamaged, free from deposits, and within tolerance for dimensions).

4.8 Options for hygienic management of multipatient use trial contact lenses

4.8.1 General

The preference for trial contact lenses is to use the lens a single time, after which the lens is dispensed to the same individual or discarded in accordance with the procedures outlined in 4.2. If single use is not/cannot be followed, heat management is preferred over chemical management. Current scientific literature [Centers for Disease Control (CDC),[4] American Academy of Ophthalmology (AAO), Smith and Pepose[6]] suggests the use of steam sterilization or a soak in 3 % hydrogen peroxide for sterilization or disinfection of trial lenses between patient fittings. Other chemical systems may be qualified as equivalent to 3 % hydrogen peroxide by a comparison of D-values obtained for a variety of challenge organisms, including bacteria, fungi, and viruses.

4.8.2 Heat management

For lenses that are compatible with heat, the preferred method is to sterilize the lenses, packed in appropriate solution and a sealed vial, such that the sterility assurance level will be less than or equal to 10^{-6} (e.g. 10^{-7}, 10^{-8}, etc.). For further information, consult the relevant standards in sterilization. In the absence of a properly validated process, the lens cannot be described as sterile, only disinfected.

4.8.3 Chemical management

Chemical management is achieved by soaking the lens. In the case of a 3 % hydrogen peroxide contact lens solution, the soaking period is for a minimum of 3 h prior to neutralization of the hydrogen peroxide. Following neutralization of the hydrogen peroxide, the lens should be stored in a preserved solution.

4.8.4 Dry storage

After completing the neutralization step described in 4.8.3, instead of storage in a preserved solution, an RGP contact lens may be stored in a dry condition in a dry closed storage container. See the Note in A.2.3.9.

4.9 Records

The manufacturer shall draw attention to the retention of appropriate records (e.g. patient reference, use of appropriately trained staff, date of use, hygienic management, and relevant contact details).