TECHNICAL SPECIFICATION

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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

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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.

ISO/TS 19979 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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 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 nvCJD 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, the working group 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 should consult the scientific literature for any change in processes and procedures that may result.

It is important that industry have available, a guideline in the form of a Technical Specification. If the standard is followed, the risk of patient-to-patient transmission of an infectious micro-organism from trial contact lenses may 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 may 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;

— 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 may 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 referenced documents are indispensable for the application 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 14534:2002, *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

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

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 may 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, 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 should apply in the country/area concerned.

NOTE 2 Local regulations governing the disposal of biohazardous waste may 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 profession'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 [CDC, AAO, Smith and Pepose (see Bibliography)] 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 three hours 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 under 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).

Annex A
(informative)

Example of information to be supplied by the contact lens manufacturer — Hygienic management of multipatient use trial contact lenses

A.1 Handling precautions

A.1.1 Contact lenses used for fitting patients admitting to CJD, herpes simplex, hepatitis, HIV AIDS or adenovirus need to be disposed of after use. Any lens known to be infected needs to be discarded immediately in order to minimize contamination in practice. The use of disposable gloves is recommended.

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

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

A.1.2 Wash and dry your hands **before and after each patient fitting** with a surgical scrub or a liquid soap. Dry your hands on a new paper towel.

NOTE Drying your hands reduces the chances of spreading water-borne organisms such as acanthamoeba.

A.1.3 A biocidal/alcohol hand rub may be used after hand washing.

NOTE Make sure your hands are dry and free from alcohol before touching the contact lens, because a lens contaminated with alcohol will cause ocular tissue irritation.

A.1.4 Clean and rinse the contact lens **before** and **after** use according to the instructions of the manufacturer of the cleaning solution.

The contact lens manufacturer needs to ensure that the specified cleaning and rinsing solutions are compatible with the lens material.

NOTE Removing particulate debris from a contact lens ensures a more effective use of the soaking solution.

A.2 Sterilization/disinfection processes

A.2.1 General

The contact lens manufacturer should specify the methods of sterilization and/or disinfection (e.g., steam sterilization or hydrogen peroxide treatment) to be used during hygienic management. Most RGP lenses can be disinfected using a hydrogen peroxide solution. The manufacturer needs to give appropriate instructions, including labelling the container with sufficient parameters to identify the lens and enable traceability to the manufacturer's lot number, expiry date and number of uses.

A.2.2 Heat management — soft lenses

A.2.2.1 The lens should be placed in a suitable glass vial filled with sterile saline, sealed with a suitable closure and labelled, so that the lens may be identified as to its parameters, manufacturer's lot number and date of heating.

A.2.2.2 The lens should be heated by a moist heat sterilization method to: a) a minimum of 134 °C for at least 3 min or b) a minimum of 121 °C for at least 10 min.

NOTE The manufacturer should state any maximum temperature above which the contact lens may not be exposed.

A.2.3 Chemical management for RGP and soft lenses

A.2.3.1 The use of a 3 % hydrogen peroxide solution including neutralization should be followed by soaking in a preserved solution. RGP lenses may be stored dry in a clean, dry lens container.

A.2.3.2 Use the contact lens case and holder provided by the contact lens solution manufacturer, duly labelled so that the lens may be identified as to its parameters, manufacturer's lot number and date/time of treatment.

A.2.3.3 Fill the case to the upper line with the disinfecting solution.

A.2.3.4 Place a lens in the lens holder and close the case securely.

A.2.3.5 After a minimum soak of 3 h, remove the holder, shake off the residual drops and discard the solution in the case.

A.2.3.6 Refill the case to the lower line with the neutralizing solution and re-insert the contact lens holder. Securely tighten the cap and shake vigorously for 10 s to 15 s.

A.2.3.7 Undo the cap, remove the lens holder, shake off the residual drops and discard the neutralizing solution.

A.2.3.8 Fill the case to the upper line with more neutralizing solution, re-insert the lens holder, secure the cap and leave for a minimum of 1 h.

A.2.3.9 Undo the cap, remove the lens holder, shake off the residual drops and discard the neutralizing solution. Fill the container with any compatible preserved contact lens care soaking solution to the fill line, reinsert the contact lens holder and securely tighten the cap.

NOTE If an RGP/hard lens is to be stored dry, after discarding the neutralizing solution, dry the lens with a clean tissue and store in a suitable closed dry storage container, labelled so that the lens may be identified as to parameters, manufacturer's lot number and date/time of treatment.

A.2.3.10 Repeat the above procedure after each lens use.

A.2.3.11 For lenses stored in soaking solution, repeat the above procedure if the contact lens has not been used for 28 d.

A.3 Number of re-uses or time in use

A.3.1 If the lens is damaged or its physical appearance has changed, the lens should be discarded.

A.3.2 All lenses stored in a soaking solution or in a dry condition should be discarded after X times of use **OR** after Y months from first use, whichever comes first.

NOTE The lens manufacturer should determine the numbers X and Y and any abnormal damage/physical change that may lead to discarding.