TECHNICAL ISO/TS

Second edition
2014-09-01

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/TS 19979:2014(E)

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Published in Switzerland

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Foreword

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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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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.