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Optics and photonics — Operation microscopes —

Part 1: Requirements and test methods

Optique et photonique — Microscopes chirurgicaux —

Partie 1: Exigences et méthodes d'essai

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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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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 5, *Microscopes and endoscopes*.

This second edition cancels and replaces the first edition (ISO 10936-1:2000), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the normative references and the title have been updated;

— note from environmental conditions (4.3) has been removed;

— safety requirements (4.4) have been updated;

— the requirement depths of field and total visual magnification (see Table 1) have been clarified.

A list of all parts in the ISO 10936 series can be found on the ISO website.

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Optics and photonics — Operation microscopes —

Part 1: Requirements and test methods

1 Scope

This document specifies requirements and refers to test methods for operation microscopes used for observation during surgical operation and treatment of patients.

It does not apply to accessories, e.g. photographic cameras.

NOTE Specific requirements with regard to optical radiation hazards from operation microscopes used in ocular surgery are given in ISO 10936-2.

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 7944, *Optics and optical instruments — Reference wavelengths*

ISO 8039, *Microscopes — Values, tolerances and symbols for magnification*

ISO 9022 (all parts), *Optics and photonics — Environmental test methods*

ISO 10934 (all parts), *Optics and optical instruments — Vocabulary for microscopy*

ISO 15227, *Optics and optical instruments — Microscopes — Testing of stereomicroscopes*

IEC 60601-1*Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8039, ISO 10934 (all parts) 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 http://www.iso.org/obp

3.1
operation microscope
stereomicroscope used for observation of surgical and other medical procedures, consisting of an illumination system and an observation system, including objective lens, variable or fixed power optical system, observation tube and eyepieces

EXAMPLE Colposcopes.

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