INTERNATIONAL STANDARD

ISO 10936-2

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Optics and optical instruments — Operation microscopes —

Part 2:

Light hazard from operation microscopes used in ocular surgery

Optique et instruments d'optique — Microscopes chirurgicaux —

Partie 2: Danger de la lumière provenant des microscopes opératoires utilisés en chirurgie oculaire



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 10936 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 10936-2 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

ISO 10936 consists of the following parts, under the general title *Optics and optical instruments* — *Operation microscopes*:

- Part 1: Requirements and test methods
- Part 2: Light hazard from operation microscopes used in ocular surgery

Annexes A and B form a normative part of this part of ISO 10936. Annex C is for information only.

Optics and optical instruments — Operation microscopes —

Part 2:

Light hazard from operation microscopes used in ocular surgery

1 Scope

This part of ISO 10936 specifies requirements and test methods for optical radiation hazards from operation microscopes which are used during ocular surgery.

NOTE General requirements for operation microscopes and test methods for these requirements are specified in ISO 10936-1.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 10936. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10936 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10936-1:2000, Optics and optical instruments — Operation microscopes — Part 1: Requirements and test methods.

IEC 60601-1:1988, Medical electrical equipment — Part 1: General requirements for safety, including Amendment 1:1991, including Amendment 2:1995.

3 Terms and definitions

For the purposes of this part of ISO 10936, the following terms and definitions apply.

3.1

auxiliary beam

off-axis beam attached to or an integral part of the microscope and intended to illuminate the eye

3.2

corneal plane

plane that is perpendicular to the optical axis of the instrument and that is tangential to the corneal surface closest to the instrument when in normal use

3.3

photoretinitis

retinal photochemically induced injury resulting from intense retinal radiant exposure

NOTE Photic maculopathy is a term also used to describe photoretinitis in the fovea-macular area of the retina.

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