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Ophthalmic instruments — Endoilluminators — Fundamental requirements and test methods for optical radiation safety

Instruments ophtalmiques — Sondes endolumineuses — Exigences fondamentales et méthodes d'essai relatives à la sécurité vis-à-vis des rayonnements optiques

Reference number
ISO 15752:2000(E)

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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.

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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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15752 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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

Ophthalmic instruments — Endoilluminators — Fundamental requirements and test methods for optical radiation safety

1 Scope

This International Standard specifies optical radiation safety aspects of endoilluminators which are used to illuminate the interior of the eye during ocular surgery. This International Standard is not applicable to other active and non-active ophthalmic instruments and operating microscopes.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document 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.

IEC 60601-1:1988, *Medical Electrical Equipment — Part 1: General requirements for safety*.

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply:

3.1
aperture
opening, usually circular, through which light enters an optical system

3.1.1
effective aperture
portion of the aperture that limits the amount of light delivered to the retina

NOTE For an obscured or noncircular aperture, it is the equivalent nonobscured circular aperture.

3.1.2
numerical aperture
NA
fibre aperture given by the index of refraction (of the medium in which the illuminated object lies) times the sine of the half angle of the cone of illumination

$NA = n' \sin u'$

where

n' is the index of refraction (of the medium in which the illuminated object lies) and

u' is the half angle of the cone of illumination