
Ophthalmic instruments — Slit-lamp microscopes

Instruments ophtalmiques — Microscopes avec lampe à fente

Sample Document

get full document from standards.iteh.ai



Sample Document

get full document from standards.iteh.ai



COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 General	2
4.2 Optical requirements	2
4.3 Construction and function	4
4.3.1 General	4
4.3.2 High eye point eyepiece	4
4.4 Optical radiation hazard with slit-lamp microscopes	4
5 Accompanying documents	5
6 Marking	5
Bibliography	6

Sample Document

get full document from standards.iteh.ai

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 10939:2007), of which it constitutes a minor revision with the following changes:

- technical correction of inconsistency in [Table 1](#), Item No. 9 “Slit image”: “Parallelism of the sides (for a slit image of 0,2 mm × 8,0 mm)”;
- update of the dated normative reference to IEC 60601-1:2005 to include the Amendment AMD1: 2012, where appropriate.

Ophthalmic instruments — Slit-lamp microscopes

1 Scope

This document, together with ISO 15004-1 and ISO 15004-2, specifies requirements and test methods for slit-lamp microscopes to provide slit illumination and observation under magnification of the eye and its adnexa.

This document is not applicable to microscope accessories, e.g. photographic equipment and lasers.

This document takes precedence over ISO 15004-1 and ISO 15004-2, if differences exist.

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 15004-1, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

ISO 15004-2:2007, *Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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

slit-lamp microscope

instrument consisting of a microscope and a swivelling illumination system providing a slit image

3.2

magnification

ratio of the viewing angle of an object, when observed through a magnifying system with the image at infinity, to that of the object, when observed by the naked eye at a reference viewing distance of 250 mm

Note 1 to entry: The magnification, Γ , can be calculated using the following formula:

$$\Gamma = \frac{\tan \sigma'}{\tan \sigma}$$