

INTERNATIONAL STANDARD

ISO
12866

First edition
1999-06-01

AMENDMENT 1
2008-11-15

Ophthalmic instruments — Perimeters AMENDMENT 1

Instruments ophtalmiques — Périmètres
AMENDEMENT 1

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 12866:1999/Amd 1:2008](https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008)
<https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008>



Reference number
ISO 12866:1999/Amd.1:2008(E)

© ISO 2008

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 12866:1999/Amd 1:2008](https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008)

<https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2008

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 12866 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 12866:1999/Amd 1:2008](https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008)

<https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 12866:1999/Amd 1:2008

<https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008>

Ophthalmic instruments — Perimeters

AMENDMENT 1

Page 1, Normative references

Update the dated normative references to ISO 15004-1 and IEC 60601-1 with their new editions:

ISO 15004-1:2006, *Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments*

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

Page 5

After 4.4.2, add the following new paragraphs:

4.4.3 For typical stimulus and background parameters the instrument shall be capable of comparing the result of each tested location with the age-specific normal value.

NOTE Typical parameters are those that are recommended by the manufacturer for routine use.

4.4.4 The version of the normal value table shall be specified by an ordinal version number and the date of issue of this table. Specification shall include the size and the age range of the normative database. The normative database shall fulfill the minimum requirements given in Annex C.

4.4.5 Printouts shall contain the version number of the normal value table used.

4.4.6 When new normal value table versions are implemented into an instrument by software update or other means, the user shall be notified.

Page 7, Clause 6

Change Clause 6 as follows:

6 Accompanying documents

The perimeter shall be accompanied by documents containing instructions for use. In addition to the requirements laid down in 4.2.3, 4.2.4, 4.2.5, 4.4.1, 4.4.2 and 4.4.4 this information shall contain:

- a) name and address of the manufacturer;
- b) if appropriate, a statement that the perimeter in its original packaging conforms to the transport conditions as specified in 5.3 of ISO 15004-1:2006;
- c) any additional documents as specified in 7.9 of IEC 60601-1:2005;
- d) specification of examination strategies.

After page 10

Add a new Annex C:

Annex C (normative)

Minimum requirements for a normative database

Normal values for perimeters shall be based on a study that fulfils the following criteria:

- a) Predefined criteria for healthy eyes that are included in the database, covering at least the following items:
 - minimum visual acuity;
 - maximum spherical and cylindrical correction;
 - pathological conditions that lead to exclusion, independent of whether they are previously known or detected in the course of examination, and that are based on findings other than the visual field;
- b) predefined criteria for the minimum experience in perimetric testing;
- c) predefined method to choose the eye to be examined; only one eye of each subject can be included;
- d) predefined criteria of unreliable examinations, which may cover the following items:
 - fixation behaviour;
 - false positive responses;
 - false negative responses;
- e) no exclusion of examinations for reasons other than the predefined criteria;

NOTE Exclusion of examinations based only on the results is not allowed. The exclusion of examinations based on pathological conditions that are found with the help of the result and that fulfil predefined criteria of exclusion is allowed.

- f) a minimum sample size of 60 eyes;
- g) a minimum of ten eyes of subjects younger than 30 years;
- h) a minimum of ten eyes of subjects older than 60 years.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 12866:1999/Amd 1:2008](https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008)

<https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[ISO 12866:1999/Amd 1:2008](https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008)
<https://standards.iteh.ai/catalog/standards/sist/6c5245e7-e5fb-4438-9e0e-cfced277c5e5/iso-12866-1999-amd-1-2008>

ICS 11.040.70

Price based on 2 pages