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Ophthalmic instruments — Perimeters

AMENDMENT 1

Instruments ophtalmiques — Périmètres

AMENDEMENT 1

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Foreword

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

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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*

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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.

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