INTERNATIONAL STANDARD

ISO 12866

First edition
1999-06-01

Corrected and reprinted
1999-12-01

Ophthalmic instruments — Perimeters

Instruments ophtalmiques — Périmètres

Reference number
ISO 12866:1999(E)

Contents

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Printed 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 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.

International Standard ISO 12866 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

Annexes A and B of this International Standard are for information only.

Ophthalmic instruments — Perimeters

1 Scope

This International Standard specifies requirements and test methods for instruments designed to assess differential light sensitivity in the visual field by the subjective detection of the presence of test stimuli on a defined background.

It does not apply to clinical methodologies and other psychophysical tests of the visual field.

This International Standard takes precedence over ISO 15004, if differences exist.

2 Normative references

The following normative documents contain 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 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 15004:1997, *Ophthalmic instruments — Fundamental requirements and test methods.*

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

IEC 60601-1-1:1992, *Medical electrical systems — Part 1: General requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems*.

3 Terms and definitions

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

3.1
visual field
sum of all directions from which the eye may perceive visual stimulation at a defined moment in time and the performance of the perception of this stimulation

3.1.1
monocular field
visual field of an individual perceived with a single eye

3.1.2
binocular field
visual field of an individual perceived with both eyes open

3.1.3
central field
visual field in all directions extending up to 30° from fixation

3.1.4
peripheral field
visual field in all directions beyond 30° from fixation

NOTE It is possible to discriminate between midperipheral and full-field.

3.2
perimeter
instrument to assess differential light sensitivity in the visual field by detection of the presence of test stimuli on a defined background

3.2.1
fixed-location stimulus perimeter
perimeter which utilizes test stimuli that are at permanent locations on the background

3.2.2
projection perimeter
perimeter which utilizes a projection system to create the test stimuli on the background

3.2.3
kinetic perimeter
perimeter which utilizes moving test stimuli

3.2.4
static perimeter
perimeter which utilizes stationary test stimuli

3.3
test stimulus
stimulus used to determine differential light sensitivity in each tested location of the visual field

3.3.1
Goldmann test stimulus
set of sizes which can be used to specify test stimuli

See annex A.

3.3.2
stimulus duration
time from the defined onset to the defined end of the stimulus

3.3.3
test stimulus pattern
local distribution of a set of test stimuli

3.4
stimulus luminance
L_S
luminance of the presented stimulus

NOTE The stimulus luminance includes the background luminance.

3.5
threshold stimulus luminance
L_T
luminance of the test stimulus which has a 50 % detection rate for a given set of test parameters

3.6
background luminance
L_B
luminance of the surround within which the test stimuli are presented

3.7
differential luminance
ΔL
difference between stimulus luminance L_S and the background luminance L_B

$\Delta L = L_S - L_B$

3.7.1
threshold differential luminance
ΔL_T
difference between the threshold stimulus luminance L_T and the background luminance

$\Delta L_T = L_T - L_B$

3.7.2
Goldmann differential luminances
Set of luminance differentials which can be used to specify test stimulus differential luminance

See annex A.

3.8
contrast
ratio of the differential luminance ΔL to background luminance L_B

$\Delta L / L_B$

3.9
differential light sensitivity
S
ratio of the background luminance L_B to the threshold differential luminance ΔL_T

$S = L_B/\Delta L_T$

3.10
perimeter decibel scale
logarithmic scale used to express, in decibels, the differential light sensitivity, S, where the value of the background luminance, L_B, is replaced within the formula by the defined maximum stimulus luminance of the specific instrument, L_{max}, and where 0 dB represents this maximum stimulus luminance

$$S \text{ (in dB)} = 10 \log_{10} [L_{max}/\Delta L_T]$$

NOTE The same scale is used to express stimulus luminance, L_S, by replacing the threshold differential luminance ΔL_T within the formula with the differential luminance ΔL.

3.11
suprathreshold strategy
supraliminal strategy
examination strategy designed for screening purposes, in which stimulus luminances of a defined amount above the presumed threshold stimulus luminance are applied

3.12
threshold strategy
examination strategy which is designed to quantify the sensitivity in each test location by estimation of the threshold stimulus luminance

3.13
fixation
direction in which the patient is required to look during the test

3.14
fixation target
target used to locate the point where the patient should look during testing

3.15
eccentricity
Φ
angle from fixation to a position in the visual field

See annex B.

4 Requirements

4.1 General

The requirements of this International Standard shall be verified through type testing. All tests described in this International Standard are type tests.

The perimeter shall conform to the general requirements specified in ISO 15004. The perimeter shall conform to the specific requirements described in 4.2 to 4.4.

NOTE These requirements are verified as described in clause 5.

4.2 Specific requirements

4.2.1 The test stimuli shall be presented within the tolerances specified in Table 1.

4.2.2 The luminance of the background and test stimuli shall be specified in candela per square metre (cd/m^2), measured at the designated position of the centre of the entrance pupil of the patient's eye.

4.2.3 The spectral distribution(s) of the background and the test stimuli shall be specified by the manufacturer.

4.2.4 The test stimulus size(s) and shape, including variation within the central visual field, shall be specified.

4.2.5 The viewing distance from the designated position of the centre of the entrance pupil of the eye to the fixation target shall be specified.

4.2.6 Provision for the optical correction of patient's refractive error for the fixation-target viewing distance shall be made.

4.2.7 Provision for adequate head positioning within the instrument shall be made.

4.2.8 Means for monitoring fixation and eye position at the instrument shall be provided. This may be by operator observation or by automatic means.

4.2.9 Provision shall be made for measuring the differential light sensitivity at fixation.

4.2.10 Central-field perimeters, midperipheral-field perimeters and full-field perimeters shall have minimum test stimulus eccentricities and minimum total number of stimulus locations as specified in Tables 2 and 3 respectively.

4.2.11 The instrument shall be capable of defining the position of and quantifying the results from each tested location.

4.2.12 The test record shall have provision for recording the following data: requirements of 4.2.11, patient identification, date, examined eye, corrective lenses used, stimulus/background parameters used, age or birth date of patient, and pupil size.

Table 1 — Requirements for stimulus presentation

Criteria	Tolerances	Test method according to
Background luminance, L_B	+25 %/−20 % of specified value	5.1
Contrast, $\Delta L/L_B$	+25 %/−20 % of specified value	5.1, 5.2
Stimulus location	within 0,5° of specified location for stimuli within 10° of the centre, within 1° for stimuli between 10° and 30° of the centre, within 2° for stimuli beyond 30°	5.3
Stimulus size	+20 %/−15 % of the specified value converted to solid angle	5.4
Stimulus duration	+/−20 % of specified value	5.6
Extent of background	not less than 2° beyond the edge of the most peripheral stimulus	

Table 2 — Minimum test stimulus pattern extension

	Central field Φ	Midperipheral field Φ	Full field Φ
Nasal	25°	40°	45°
Temporal	25°	50°	70°
Superior	25°	40°	45°
Inferior	25°	50°	60°

Table 3 — Minimum total number of potential stimulus locations

Eccentricity Φ	Central-field instrument	Midperipheral field instrument	Full-field instrument
0° to 25°	60	60	60
> 25° to 50°		30	30
> 50° to 70°			15
Total locations	60	90	105

4.3 Kinetic perimeters

4.3.1 If movement of the test stimulus is automatically controlled by the instrument, the movement shall be smooth, the presentation of the stimulus shall be continuous, and the speed and characteristics of stimulus movement shall be specified.

4.3.2 If the movement of the stimulus is manually controlled, the instrument mechanism shall allow the test stimulus to be moved smoothly in any direction.

4.4 Static perimeters

4.4.1 The temporal characteristics of the test stimulus presentation shall be specified.

4.4.2 The total number of stimuli for each available stimulus pattern shall be specified, together with the location of each test stimulus given in either polar or Cartesian coordinates referenced to the designated position of the centre of the entrance pupil of the patient's eye between the fixation target and the test stimulus. See annex B.