BRITISH STANDARD

BS EN ISO
12866:1999
+A1:2008

Ophthalmic instruments — Perimeters

ICS 11.040.70

BSi
British Standards

National foreword

This British Standard is the UK implementation of EN ISO 12866:1999+A1:2008. It is identical with ISO 12866:1999, incorporating amendment 1:2008. It supersedes BS EN ISO 12866:1999 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/172, Ophthalmic optics, to Subcommittee CH/172/6, Ophthalmic instruments.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 September 1999

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Ophthalmic instruments - Perimeters (ISO 12866:1999)

Instruments ophtalmiques - Périmètres (ISO 12866:1999)

Ophthalmische Instrumente - Perimeter (ISO 12866:1999)

This European Standard was approved by CEN on 13 May 1999.

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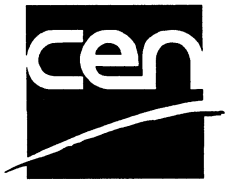

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Foreword

The text of the International Standard ISO 12866:1999 has been prepared by Technical Committee ISO/TC 172 “Optics and optical instruments” in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 1999, and conflicting national standards shall be withdrawn at the latest by December 1999.

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The text of the International Standard ISO 12866:1999 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

Foreword to amendment A1

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BS EN ISO 12866:1999+A1:2008
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INTERNATIONAL STANDARD

ISO 12866

First edition
1999-06-01

Ophthalmic instruments — Perimeters

Instruments ophtalmiques — Périmètres

Reference number
ISO 12866:1999(E)

Contents

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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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.

A1 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* A1

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.

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.

5 Test methods

5.1 Checking the background luminance

Measure the background luminance at the approximate midpoint of each quadrant of the background surface using a luminance meter, and determine the difference between the measurements and the specified value.

5.2 Checking stimulus luminance

Measure the luminance of the test stimulus from the designated pupil position using a luminance meter and calculate the difference between the measurements and the specified value. If the test stimulus luminance can vary with direction, the measured values shall meet the requirements of Table 1 at all positions within one centimetre of the design pupil position. Table 4 gives the positions and luminance values to be used in making this test.

5.3 Checking the test stimulus location

Measure the position of the centre of the test stimulus and calculate the difference between the measured location and the specified location. Table 4 gives the positions to be used in making this test.

5.4 Checking the test stimulus size

Measure the area, A, of the test stimulus. Measure the distance, z, between the eye pupil position and the surface of the perimeter. Convert the area into a solid angle, Ω. Calculate the difference between the measured and the specified solid angles.

$$\Omega = A/z^2$$

5.5 Checking the stimulus shape

Measure the maximum and minimum widths of the stimulus along the four oblique half-meridians at 25° eccentricity. The shape is defined as the ratio of minimum to maximum widths.

5.6 Checking the stimulus duration

Measure the duration of the test stimulus presentation and calculate the difference between the measured duration and the specified value.

5.7 Type tests

5.7.1 Projection perimeters

To fulfill the requirements of this International Standard during type testing, the tests specified in 5.2, 5.3 and 5.4 shall be conducted at the locations specified in Table 4. If because of the design of the perimeter it is not possible to test at the exact locations given in the table, the testing may be conducted at alternative locations separated from the specified locations by no more than 2° in any direction. The stimulus intensities and test stimulus sizes to be tested at each location are given in Table 4. The test shall be conducted three times at each location.

5.7.2 Fixed position stimulus perimeters

To fulfill the requirements of this International Standard during type testing, the tests specified in 5.2, 5.3 and 5.4 shall be conducted at each point (or the closest available point) and intensity specified in Table 4. Light-emitting diodes (LEDs) and optical fibres, which are typically used as stimuli in fixed-stimulus perimeters, can vary greatly one from another and tend to be directional in their output intensity patterns. Therefore, in addition to intensity, the homogeneity and directionality of the light in the area of the pupil of the tested eye shall be checked (see 5.2).

5.7.3 Checking the mechanical and functional requirements

The requirements described in 4.2.6, 4.2.7, 4.2.8, 4.2.9, 4.2.11, 4.2.12 shall be checked by observation.

Table 4 — Test locations and stimulus values

Azimuth Θ	Eccentricity Φ	Stimulus size	Stimulus luminance
0°	15° and 40°	III	10 dB and 20 dB
45°	15° and 40°	III	10 dB and 20 dB
90°	2°	all available	0 dB to 20 dB in steps of 5 dB
			22 dB to 30 dB in steps of 2 dB
			31 dB to a luminance equal to 0,1 L_B (measured with background equal to zero) in steps of 1 dB
90°	15° and 40°	III	10 dB and 20 dB
135°	15° and 40°	III	10 dB and 20 dB
180°	15° and 40°	III	10 dB and 20 dB
225°	15° and 40°	III	10 dB and 20 dB
270°	15° and 40°	III	10 dB and 20 dB
315°	15° and 40°	III	10 dB and 20 dB

NOTE Perimeters which are designed to measure only in the central field need only be checked at the $\Phi = 15°$ locations. If a size III stimulus is not available, the stimulus size nearest to a size III stimulus shall be used.

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.

7 Marking

The perimeter shall be permanently marked with at least the following information:

a) name and address of manufacturer or supplier;

b) name and model of the perimeter;

c) additional marking as required by IEC 60601-1 and IEC 60601-1-1;

d) a reference to this International Standard, ISO 12866, if the manufacturer or supplier claims compliance with it.

e) In a software-driven perimeter, the date and identification of the software release shall be displayed.

Annex A
(informative)

Goldmann test stimulus specifications

A.1 Goldmann differential luminances

The original Goldmann differential luminances were specified in apostilbs and used a background luminance of 31,5 apostilbs (10 cd/m^2). The SI unit of luminance is candela per square metre (cd/m^2). To convert from apostilbs to cd/m^2, the apostilb value is divided by π (see Table A.1). The values in candela per square metre represent the standard Goldmann values.

Table A.1 — Goldmann differential luminances

CODE	Differential luminance apostilbs	Differential luminance cd/m^2
1a	12,6	4,01
1b	15,8	5,03
1c	20,0	6,37
1d	25,1	7,99
1e	31,6	10,1
2a	39,8	12,7
2b	50,1	15,9
2c	63,1	20,1
2d	79,4	25,3
2e	100	31,8
3a	126	40,1
3b	158	50,3
3c	200	63,7
3d	251	79,9
3e	316	101
4a	398	127
4b	501	159
4c	631	201
4d	794	253
4e	1 000	318

A.2 Goldmann test stimulus sizes

The Goldmann test stimulus sizes (see Table A.2) are for round stimuli presented at a viewing distance of 300 mm. The angular values can be used to represent Goldmann sizes at viewing distances differing from 300 mm.

Table A.2 — Goldmann test stimulus sizes

CODE	Area mm^2	Diameter minutes of arc	Diameter mrad
I	0,25	6,5	1,88
II	1,0	13,0	3,75
III	4,0	26,0	7,5
IV	16,0	52,0	15,0
V	64,0	104	30,0

NOTE A number of national requirements for perimetric assessment of disability and/or legal blindness specify Goldmann stimulus size III, Goldmann differential luminance 4e (see Table A.1) and a background of 10 cd/m^2.

Annex B
(informative)

Perimetric coordinate systems

B.1 Reference system (polar coordinates)

The recommended reference system for designating locations in the visual field is a spherical coordinate system whose origin is the pupil of the eye. The location is specified by

a) the half-meridian Θ and

b) the eccentricity Φ of the centre of the test stimulus, both expressed in degrees (Θ,Φ).

The zero-degree half-meridian is defined to the right of the patient (as seen by the patient). The specified half-meridian then proceeds anticlockwise through 360° about the fixation stimulus (as seen by the patient). The fixation point is defined as having 0° eccentricity. Figure B.1 shows a typical two-dimensional representation of this system.

Angles in degrees

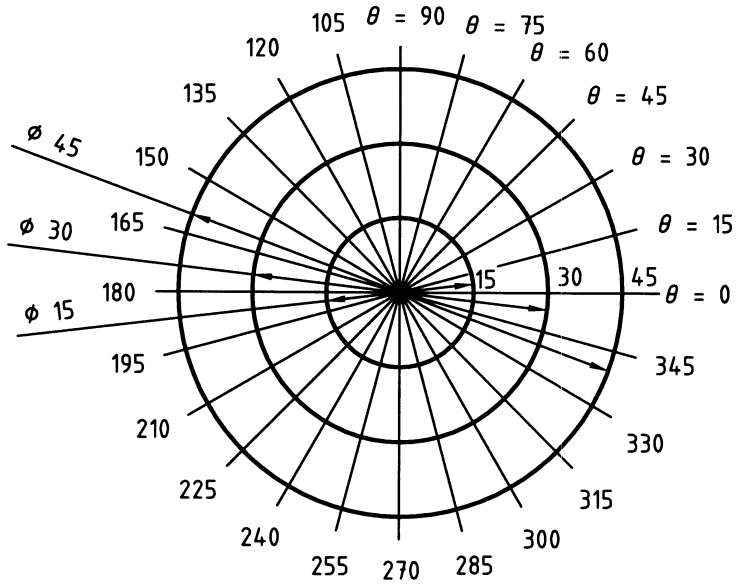

Figure B.1 — Recommended reference system for designating locations in the visual field

B.2 Cartesian coordinate system

A widely used system for representing visual field data uses a rectangular coordinate system. This system is related to the reference system by the following equations:

$$x = \Phi \cos \Theta \qquad \Theta = \arctan (y/x)$$

$$y = \Phi \sin \Theta \; \Phi = (x^2 + y^2)^{0,5}$$

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.

ANNEX ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 15004	1997	Ophthalmic instruments - Fundamental requirements and test methods	EN ISO 15004	1997

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