1990 Perimetry Standards

FIRST CODICIL, 1990

AUTOMATED FIELD EXAMINATION STANDARD

Preface

This section is intended to clarify the intent of the first codicil to the established standards of the International Perimetric Society (IPS). The codicil adds to but does not supersede the previously established standards. The Preface is not a part of the Standard.

Automated perimetry has made perimetric examination simpler, more accessible, and more repeatable, and has therefore become a major screening and diagnostic tool serving the ophthalmic professions. Automated perimeters may be used in a variety of settings in addition to clinical practice, e.g. job selection (police, fire-fighters, lifeguards, pilots, train engineers, truck drivers),l visual competence assessment, school or community screenings, military selection, disability classifications, etc.

There is a need to advance standardization in automated perimetry while retaining latitude for innovation in future hardware and software design. Therefore, these standards do not address specific details of test strategies, which are still in an active phase of development.

This document represents the first standard for clinical automated screening perimetry, and mainly addresses clinical applications of automated perimetry in screening situations. As stated in this document, screening tests are not intended for use in establishing a diagnosis. Rather, they are meant to alert the practitioner to the existence of a possible abnormality for which further evaluation is indicated. Since such tests will by nature include false positives and negatives, it is important to minimize each of these types of response.

Screening programs are used by eye care practitioners, nurses, and technical assistants. Even lay persons without qualifications may use automated perimeters in various screening situations. Therefore, instructions for the use of such instruments must be clear and explicit, i.e. very "user friendly". Individuals using these devices may not be knowledgeable about calibration techniques; therefore, devices should be easily calibrated or self-calibrating.

Parameters for the test should be selected so that modest errors in calibration or variability of test conditions do not invalidate the test results. The printout of the test should be simple in format, and should include a l information useful in test interpretation, e.g. age, sex, general health, ocular history, medications, pupi and corrective lens provided.

The standards are directed both to users and manufacturers of automated perimeters. It is recommended that all instruments be provided with at least one screening program which provides parameters and procedures as described. These parameters should be clearly described in the instruction manual and indicated on the printouts of the visual field data.

1. Background Illumination

The IPS standards adopted for the background luminance of manual perimeters apply also for automated perimeters.

2. Stimulus Parameters

The size of the stimulus should always be specified. It is advisable to use sizes compatible with the sizes employed on the Goldmann perimeter. Ideally, stimuli should be round, although elliptical stimuli can be accepted, provided that the elliptic deformation does not exceed that of the stimuli used on the Goldmann perimeter.

Diameter of the stimuli should be expressed in angular notation, i.e. in minutes of arc (1 min. of arc = pr/10.800) or milliradians (1 mrad = r/1000), e.g.:

Goldmann stimuli

size diameter

_____

N. mm2 min of arc milliradians

I 1/4 6.5 1.85

II 1 13 3.75

III 4 26 7.5

IV 16 52 15

V 64 104 30

It is advisable to take into account the effect of stray light when determining the maximal contrast between background and stimulus luminances.

3. Examination Strategies

Presently there are three types of strategies commonly available:

1. Constant luminance suprathreshold testing.

2. Threshold-related suprathreshold testing.

3. Threshold determination testing.

Strategy #1 should not be used for clinical purposes, but only for medicolegal or disability screening or similar purposes.

4. Density of Test Points

Density of test points should be appropriate for the width of defects to be detected. A pattern of points separated by 6 degrees or less in the central field is advisable.

It is desirable that a sufficient number of points be arranged on either side of the horizontal (0-180 degree) and vertical (90-270 degree) meridians in order not to miss a nasal step or an early hemianopic defect.

5. Data Presentation

Manufacturers should provide data either in luminance values in candelas/meter2 (cd/m2) or in relative values in decibels (dB). If relative values are used, they should be related by the manufacturer to the maximum luminance of the stimulus, and this luminance should be specified.

It is highly desirable that manufacturers provide a stimulus equivalency table to assist in comparison of results from their perimeter with those from other similar perimeters.

6. Gradient of Sensitivity

It is desirable that manufacturers disclose the normal sensitivity gradient used in the development of their software. Without such information, the user of the automated perimeter cannot properly determine the quality of patient performance.

7. Representation of Results

If a gray scale or other interpolated representation of results is used by the manufacturer, actual measured numerical data should be available for reference by the user.

8. Size of the Printout

The graph for representation of the visual field should be legible and allow easy interpretation of the test results by the user.

OPTICS AND OPTICAL INSTRUMENTS - OPHTHALMIC INSTRUMENTS-PERIMETERS

1. OPTICS

This international standard specifies requirements and test methods for instruments designed to measure differential light sensitivity in the visual field by the subjective detection of the presence of test targets on a defined background. This standard does not apply to clinical methodologies and other psychophysical tests of the visual field.

This International Standard takes priority over the semi-horizontal standard ISO..., if differences exist.

2. NORMATIVE REFERENCES

The following standard contain provisions which, through reference in this text, constitute provisions of International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO Optics and optical instruments - Fundamental requirements and test methods

ISO/DIS 9022-2 Optics and optical instruments - Environmental test methods

Part 2: Cold, heat humidity

ISO/DIS 9022-3 Optics and optical instruments - Environmental test methods

Part 3: Mechanical stresses

IEC 601-1 Safety of medical electrical equipment

Part 1: General requirements because of the fundamental

3. DEFINITIONS

For the purpose of this International Standard, the following definitions apply.

3.1 Visual Field: *The 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:** The visual field of a single eye.

3.1.2 **Binocular:** The visual field of an individual with both eyes open.

3.1.3 **Central:** The visual field extending up to 30 degrees from fixation *in all directions.*

3.1.4 **Peripheral:** The visual field beyond 30 degrees from fixation *in all directions.*

3.2 Perimeter: An instrument to measure differential light sensitivity in the visual field by the detection of the presence of test targets on a defined background.

3.2.1 **Fixed Location Stimulus:** A perimeter which utilizes test stimuli that are at permanent, locations on the background.

3.2.2 **Projection:** A perimeter which utilizes a projection system to create the test stimuli on the background.

3.2.3 **Kinetic:** A perimeter which utilizes moving test targets.

3.2.4 **Static:** A perimeter which utilizes non-moving test targets.

3.3 Test stimulus: The stimulus used to estimate differential light sensitivity at each test location in the visual field.

3.13 Goldmann stimulus size: A set of sizes which can be used to specify test stimuli. See Annex A.

3.xx **Stimulus duration:** The time from the defined on-set to the defined off-set of the stimulus.

3.xxx **Inter-stimulus Interval:** The duration between the defined off-set of a given stimulus and the defined on-set of the next stimulus.

3.4 Stimulus Luminance Ls: The luminance of the presented stimulus.

3.5 Threshold Stimulus Luminance LT: The estimated luminance of the test stimulus which has a 50% detection rate for a given set of test parameters.

3.6 Background Luminance LB: The luminance of the surround within which the test stimuli are presented.

3.7 Differential Luminance L: The difference between threshold stimulus luminance **LT** and the background luminance **LB,** i.e. **LT - LB**

3.12 Goldmann Differential Luminances: A set of differential luminances which can be used to specify test stimulus differentials which can be used to specify stimulus differential luminance. See Annex A.

3.8 Differential Light Sensitivity S: The ratio of the background luminance LB to the differential luminance L, i.e. L**B**/L.

3.8.1 **Perimeter decibel scale (dB):** A logarithmic scale used to express the differential light sensitivity, S, where the value of the background luminance, LB, is replaced within the formula, by the defined maximum stimulus luminance of the specific instrument, Lmax, where 0 dB represents the brightest stimulus.

dB = 10 log10 Lmax/L

The same scale is used to express stimulus luminance by replacing the differential luminance L within the formula, with the absolute value of the stimulus luminance.

dB = 10 log10 Lmax/Ls.

3.10 Suprathreshold (supraliminal) Strategy: An examination strategy which is designed to determine whether sensitivities in test locations of the visual field depart from defined criteria relating to the chosen purpose of the examination.

3.11 Threshold Strategy: An examination strategy which is designed to quantify the sensitivity at each test location by estimation of the threshold target luminance.

3.14 Fixation Target(s): The target(s) used to locate the point where the patient should look during testing.

3.15 Normative Data: A representative sample of visual fields from clinically healthy individuals used to assess and/or interpret individual patient data.

3.16 Eccentricity (F): Angle from fixation point to a position in the visual field. See Annex B.

4. REQUIREMENTS

The requirements of this standard are to be verified through type testing.

4.1 General:

4.1.1 The luminance of the background and test targets shall be specified in photometric units measure[illegible]e designed position of the centre of the entrance pupil of the patient's eye.

4.1.2 The perimeter shall conform to requirements for stimulus presentation given in Table 1.

NOTE - These requirements are verified as described in Section 5.

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

4.1.4 The location of each test target shall be given, either in a polar co-ordinate or Cartesian system, as the angle subtended at the entrance pupil of the patient's eye between the fixation target and the test target. See Annex B.

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

4.1.6 The viewing distance to the fixation target shall be specified.

4.1.7 Provision for the optical correction of patient refractive error/target viewing distance shall be made.

4.1.8 Provision for proper head positioning within the instrument shall be made.

4.1.9 Means for monitoring fixation shall be provided. This may be by operator observation or by automatic means.

4.1.10 Provision shall be made for making a measurement of the visual field at central fixation.

4.1.11 Perimeters designed to measure the central field, mid-peripheral field and full field shall have minimum test target extension and minimum total number of target locations as specified in Tables 2 and 3 respectively.

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

4.1.13 The test record shall have provision for recording the following data: requirements of 4.1.13, patient identification, date, examined eye, corrective lenses used, stimulus/background options, and pupil size.

Table 1: REQUIREMENTS FOR STIMULUS PRESENTATION

Criteria Requirement Test Method

Background luminance, LB +/- 25% of specified value 5.1

Target luminance +/- 25% of specified value 5.2

Target location within 1 degree of specified location 5.3

for stimuli within 30 degrees of the

centre, within 2 degrees for stimuli

beyond 30 degrees

Target size +/- 20% of the specified value 5.4

converted to solid angle

Target presentation time +/- 20% of specified value 5.5

Extent of background beyond not less than 2 target diameters beyond

the stimulus the edge of the stimulus test target

Table 2: MINIMUM TEST TARGET PATTERN EXTENSION

Central field (F) Mid-peripheral field (F) Full field (F)

nasal 25 40 45

temporal 25 50 70

superior 25 40 45

inferior 25 50 60

Table 3: MINIMUM TOTAL NUMBER OF POTENTIAL TARGET LOCATIONS

F Central field Mid-peripheral field Full field

instrument instrument instrument

0 - 25 60 60 60

>25 - 50 30 30

>50 - 70 15

total points 60 90 105

4.2 Kinetic Perimeters

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

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

4.3 Static Perimeters

4.3.1 The temporal characteristics of the test target presentation shall be specified.

4.4 Environmental Conditions

The perimeter shall comply with the requirements for environmental conditions of ISO.....Section 4. "Environmental conditions" and Section 7.2 "Checking the environmental conditions".

4.5 Electrical Safety

The perimeter shall comply with the requirements for electrical safety as specified in ISO.....Section 6.1 "Spatial requirements for active ophthalmic instruments" and Section 7.3 "Checking electrical safety".

5. TEST METHODS

5.1 Checking The Background Luminance

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

5.2 Checking Target Luminance

Measure the luminance of the test target from the design pupil position using a luminance meter and seek the difference between the measurements and the specified value. If the test target 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. (See 5.6.2). Table 4 gives the positions and luminance values to be used in making this test.

5.3 Checking The Test Target Location

Measure the position of the centre of the test target and seek 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 Target Size

Measure the area of the test target, A. Measure the distance, d, between the eye pupil position and the surface of the perimeter. Convert the area into a solid angle, W. Seek the difference between the measured and the specified solid angle.

$W = A/d2$

5.5 Checking The Test Target Presentation Duration

Measure the duration of the test target presentation and seek the difference between the measured duration and the specified value.

5.6 Type Tests

5.6.1 **Projection Perimeters**

To fulfill the requirements of this 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 alternate locations removed from the specified locations by no more than 2 degrees in any direction. The stimulus intensities and test target sizes to be tested at each location are given in the table. The test shall be conducted three times at each location.

5.6.2 **Fixed Position Stimulus Perimeters**

To fulfill the requirements of this standard during type testing, the test specified in 5.2, 5.3 and 5.4 sha 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**.**

Table 4

(degrees) (degrees) Target size Test target intensity (dB)

0 15/40 III 10/20

45 15/40 III 10/20

90 2 all available Lmax to 10 dB less

than LB in 1 dB steps

90 15/40 III 10/20

135 15/40 III 10/20

180 15/40 III 10/20

225 15/40 III 10/20

270 15/40 III 10/20

315 15/40 III 10/20

NOTE: Perimeters which are designed to measure only in the central field need only check at the F = 15 locations. If a size III target is not available, the nearest target size to a size III target shall be used.

6. ACCOMPANYING DOCUMENTS

The perimeter shall be accompanied by documents containing instruction for use. In particular this information shall contain:

(a) - name and address of the manufacturer

(b) - any additional documents as specified in 6.8 of IEC 601-1: 1988

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 601-1: 1988 and, if applicable, IEC 825: 1984

IPS SECOND CODICIL

Preface - stands along side ISO Standard - **scope** of ISO -

DIVISIONS

PREFACE

SCOPE - Goal: clinical quality improvement or good practice. Collection of definitions, recommendations, minimal requirements on behalf of the IPS involving instruments, examination methods data handling, and the practical applications (covering QA of instrument - ISO & also examination procedure - IPS)

DEFINITIONS LOGICAL & ALPHABETICAL (NO TRANSLATIONS)

INSTRUMENTS

EXAMINATIONS METHODS

DATA STORAGE

DATA DISPLAY

DATA ANALYSIS/INTERPRETATION

DATA TRANSMISSION

EDUCATION & TRAINING - hot lines - INTERNET

PRODUCT LIABILITY

FUTURE DEVELOPMENT