DRAFT INTERNATIONAL STANDARD

ISO/DIS 10938.2

ISO/TC **172**/SC **7**	Secretariat: **DIN**
Voting begins on: **2015-10-22**	Voting terminates on: **2015-12-22**

Ophthalmic optics — Chart displays for visual acuity measurement — Printed, projected and electronic

Optique ophtalmique — Dispositifs d'affichage de tableaux d'optotypes destinés au mesurage de l'acuité visuelle — Tableaux d'optotypes imprimés, projetés et affichés par des moyens électroniques

ICS: 11.040.70

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO/DIS 10938.2:2015(E)

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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.

ISO 10938 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments* and by Technical Committee CEN/TC 170, *Ophthalmic optics* in collaboration.

This second edition cancels and replaces the first edition (ISO 10938:1998) which has been technically revised.

Introduction

This International Standard applies to displays of optotypes by chart projectors and all other clinical visual acuity measurement systems that use recognition of high-contrast optotypes and that are designed for general use including optotypes printed on opaque media, those intended for transillumination, electronically generated or projected displays.

The principles of standardized visual acuity measurement are presented in standards adopted by the National Academy of Sciences in the United States and the Consilium Ophthalmologicum Universal as referenced in the Bibliography.

Due to practical design considerations and physical limitations of most general-purpose clinical visual acuity measurement systems, the chart design features specified in these reference standards can only be met for a limited range of acuity presentations. Specialized chart displays are often required for special clinic visual acuity measurements, such as for low-vision patients or for research purposes. The purpose of this International Standard is to provide for standardized visual acuity charts for general measurement, which will enable the measurement of visual acuity over a limited, but clinically useful, range of acuities according to the principles contained in the reference standards.

Ophthalmic optics — Chart displays for visual acuity measurement — Printed, projected and electronic

1 Scope

This International Standard applies to high-contrast optotypes that are designed for general use. It applies to optotypes generated by either printed media, optical chart projectors or electronic displays.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8596, *Ophthalmic optics — Visual acuity testing — Standard optotype and its presentation*

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

3 Terms and definitions

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

3.1
optotype
symbol used in the measurement of visual acuity

3.2
standard optotype
Landolt ring for which the gap can be oriented in eight different positions

Note 1 to entry: The Landolt ring is specified in ISO 8596.

3.3
Snellen fraction
notation for specifiying the angular subtense of an optotype, expressed as a fraction with the numerator nominally being the distance at which visual acuity is tested, commonly in meters or feet, and the denominator being the distance at which the critical detail (limbs of the optotype) within the optotype subtends 1’ of arc

EXAMPLE A 6/6 letter has limbs that subtend 1’ of arc at 6 m.

Note 1 to entry: For projected charts and electronic acuity displays, it is common to calibrate the size of the optotype to subtend the desired minutes of arc at test distances other than 6 m. For example, for a short 4 m room, the letter equivalent in angular subtense to the 6/6 letter is 2/3 the size of a true 6/6 letter. However, such a reduced letter is still labelled as 6/6. In this convention, the label 6/6 implies the limbs of the letter subtend 1’ of arc at the reduced test distance.

3.4
decimal acuity
reciprocal of the minimum angle of resolution in minutes of arc

Note 1 to entry: This method of noting the angular subtense of a limb of an optotype is also found by writing the Snellen fraction as a decimal. For example, Snellen visual acuities 6/6 and 6/12 are decimal acuities 1,0 and 0,5, respectively.

3.5
resolution
smallest separation between 2 lines for which the lines can be distinguished as two separate lines

3.6
focus range
distances from a projector at which a focused image of the visual acuity chart can be displayed with characteristics meeting the specifications of this International Standard

4 Requirements

4.1 Optotypes

4.1.1 Size of Optotypes

Each size of a set of optotypes shall be specified in terms of the size of some critical dimension common to that set of optotypes e. g. for the Landolt ring, the critical detail is the gap size.

NOTE 1 If letters or figures are used for visual acuity measurement, then it should be acknowledged that these normally show large differences in legibility, even if the size and width of stroke are identical. The impact of this variability can be reduced by choosing letters or figures that are comparable to one another. Comparability can be established for each letter or figure by showing that its effective resolution is equivalent to that of the standard optotype in a direct comparative test.

NOTE 2 See ISO/TR 19498 for description of a method for the correlation of optotypes.

4.1.2 Luminance of background

The luminance of the background surrounding the optotype, as viewed by the patient, shall be between 80 cd/m^2 and 320 cd/m^2 and shall be specified by the manufacturer.

NOTE The recommended luminance is 200 cd/m^2.

The luminance of the background within 2 character diameters of the optotype shall vary by more than 30 %. Across the entire area of the illuminated field it shall not vary by more than 50 %.

4.1.3 Contrast of optotypes

Optotypes shall be specified by the background luminance in cd/m^2 and by the luminance of the optotype as a percentage of the background luminance. The luminance of the optotype shall be not more than 15 % of that of the test area, taking into account the room illumination.

The optotypes shall have sharply defined edges as perceived by an observer with a decimal visual acuity of at least 1,0 at an observation distance of 1/3 the distance at which the optotypes are designed to be used. Optypes in a series shall not differ noticeably in contrast or contour.

4.2 Printed charts

4.2.1 Test distance

The distance for which the optotypes are designed to be used shall be specified.

4.3 Projector charts

4.3.1 Resolution

For optically projected charts, the minimum resolution on the screen (expressed in lines per millimetre) shall be 4 times the line separation corresponding to the limb width on the 1,0 decimal acuity grade optotype.

If an observation distance of 1/3 the distance at which the optotypes are designed to be used, as described in 4.1.3, is not applicable, the optotypes shall be viewed with a magnification of 3x.

4.3.2 Focus range

For projector charts, the minimum focus range shall be 2,9 m to 6,1 m.

4.3.3 Projector screens

Screens which are suitable for use with the projector shall be specified by the manufacturer.

4.4 Electronic displays

4.4.1 Resolution

Electronic displays shall have pixel size sufficiently small, such that there is no performance difference between the electronically displayed optotype and an optotype that meets the requirements of 4.1.3.

NOTE For electronic displays, the use of grey scaling (i.e., adding a border of partially illuminated pixels) is sometimes used to smooth the naturally occurring jagged edge formed by pixels. Grey scaling may add or subtract from the width of the detail and may change the calibration. This potential change should not cause a change in the perceived size of the optotype outside of the 5 % variability in optotype size allowed by ISO 8596.

4.5 Range of compliance

The manufacturer shall specify the range of test distances and visual acuity grades over which the chart complies with this International Standard.

NOTE It is recommended that a minimum range of 0,1 to 1,25 decimal visual acuity be included.

4.6 Conformity to ISO 15004-1

Chart displays for acuity measurement that are active ophthalmic instruments, as defined by ISO 15004-1, shall conform to the requirements of ISO 15004-1.

5 Test methods

5.1 Type tests

All tests described in this International Standard are type tests.

5.2 Conformity

The conformity with the requirements in this document shall be verified using measuring devices for which the measuring error is less than 10 % of the smallest value to be determined.