INTERNATIONAL STANDARD

ISO 10938

Second edition 2016-10-01

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

Jaum Jes, pro Jen the full click to view the full standards is occur. Click to view the full standards is occur.



STANDARDS & O.COM. Click to view the full PDF of the O.COM.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Ch. de Blandonnet 8 • CP 401 CH-1214 Vernier, Geneva, Switzerland Tel. +41 22 749 01 11 Fax +41 22 749 09 47 copyright@iso.org www.iso.org

Contents		Page
eword		iv
oductio	on	v
Scop	oe	1
-		
4.2	4.1.1 Size of optotypes 4.1.2 Luminance of background 4.1.3 Contrast of optotypes 4.1.4 Quality of presentation 4.1.5 Resolution Requirements specific to optically projected displays 4.2.1 Focus range 4.3.2 Projector screens	
4.5	Conformity to ISO 15004-1	4
5.1	Conformity	4
Acco	ompanying documents	4
Marl	king lahalling and nackaging	5
	king, labelling and packaging	
	eword Scop Norr Terr Requ 4.1 4.2 4.3 4.4 4.5 Test 5.1 5.2 5.3 Accommand	roduction Scope Normative references Terms and definitions Requirements 4.1 Optotypes 4.1.1 Size of optotypes 4.1.2 Luminance of background 4.1.3 Contrast of optotypes 4.1.4 Quality of presentation 4.1.5 Resolution 4.2 Requirements specific to optically projected displays 4.2.1 Focus range 4.2.2 Projector screens 4.3 Requirements specific to printed charts 4.4 Range of compliance 4.5 Conformity to ISO 15004-1 Test methods 5.1 Type tests 5.2 Conformity 5.3 Resolution Accompanying documents Marking, labelling and packaging Miography

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.so.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 102, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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

Introduction

The purpose of this International Standard is to provide for standardization of certain characteristics of displays of optotypes used for measurement of visual acuity in general clinical practice. These characteristics include size specification, luminance, contrast, and resolution of the optotypes. It applies to displays intended for measurement of visual acuity over a limited, but clinically useful, range of acuities.

The principles of standardized visual acuity measurement, including the arrangement of optotypes on the display, are presented in standards adopted by the National Academy of Sciences in the United States of America and the Consilium Ophthalmologicum Universal as referenced in the Bibliography. This International Standard is not intended to address these principles, but they are included in an annex in ISO 8596.

Due to practical design considerations and physical limitations of most general propose clinical visual acuity measurement systems, the chart design features specified in the reference standards can usually be met for only a limited range of acuity presentations. Other chart display designs are often required for special clinic visual acuity measurements, such as for low-vision patients or for research purposes.

STANDARDS ISO COM. Click to view the full PDF of ISO 10938:2016

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

1 Scope

This International Standard applies to displays of optotypes generated by chart projectors and all other visual acuity measurement systems that use recognition of high-contrast optotypes and that are designed for general use, including optotypes printed on media (either opaque optintended for transillumination), those generated electronically, and those produced by optical projection.

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 specifying the angular subtense of an *optotype* (3.1), expressed as a fraction with the numerator being the distance at which visual acuity is tested, commonly in metres or feet, and the denominator being the distance at which the *critical detail* (3.9) (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 (3.5) in minutes of arc

Note 1 to entry: This method of noting the angular subtense of a limb of an *optotype* (3.1) is also found by writing the *Snellen fraction* (3.3) 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 two lines for which the lines can be distinguished as two separate lines

3.6

focus range

maximum and minimum distances from a projector at which a focused image of the visual acrity chart can be displayed

3.7

line

group of optotypes (3.1) having the same size arranged in a straight row across the display

3.8

pixel

smallest element, or point sample, that can be individually processed on an electronic display

3.9

critical detail

smallest feature in an *optotype* (3.1) that is considered necessary to distinguish the optotype from the other optotypes

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 critical detail common to that set of optotypes. For example, for the Candolt ring, the critical detail is the gap. The permissible deviation is 5 %.

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 1 The recommended luminance is 200 cd/m².

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

NOTE 2 See <u>Clause 6</u> e) for ambient illumination requirements needed to ensure compliance with background luminance specifications.

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 the luminance of the background upon which the optotype is located. Optypes in a series shall not differ noticeably in contrast.

4.1.4 Quality of presentation

Optotypes as presented shall appear with sharply defined contours to an observer with a binocular visual acuity of 1,0 to 1,25 at an observation distance of 1/3 of the distance at which the optotypes are designed to be used. Similar optotypes in a size series shall not differ noticeably in shape or edge sharpness.

For electronic displays, if anti-aliasing (i.e. modifying the brightness of pixels at the borders of optotypes) is used to smooth the naturally occurring jagged edge formed by pixels at curved edges, it shall not cause a change in the perceived size of the optotype outside of the 5 % variability in optotype size allowed by ISO 8596. Furthermore, there shall be no performance difference between the electronically displayed optotype and a printed display of standard optotypes that meets the requirements of ISO 8596.

NOTE Anti-aliasing may add or subtract from the width of the detail and may change the calibration.

Optotypes presented in displays for which the design prevents viewing at 1/3 the normal distance shall be observed with a magnification of 3× in order to verify the quality of presentation.

4.1.5 Resolution

For optically projected charts, the minimum resolved spatial frequency on the screen shall be at least 2 cycles per minute of arc measured from the minimum test distance specified by the manufacturer.

For electronically generated charts, the pixel size shall be sufficiently small that there is no performance difference between the electronically displayed optotype and an optotype that meets the requirements of <u>4.1.4</u>. Ideally, the pixel size should be not larger than 0,25 min of arc measured from the minimum test distance specified by the manufacturer

4.2 Requirements specific to optically projected displays

4.2.1 Focus range

For projector charts, the minimum focus range shall be 2.9 m to 6.1 m.

4.2.2 Projector screens

If the **projector** requires the use of specific screens, the specification of such screens shall be provided by the manufacturer.

4.3 Requirements specific to printed charts

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

4.4 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 and if optotype is graduated logarithmically or not.

It is recommended to include a minimum range of 0.1 to 1.25 decimal visual acuity.

4.5 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 International Standard shall be verified using measuring devices for which the measuring error is less than 10 % of the smallest value to be determined.

5.3 Resolution

The resolution requirements for optical projectors can be tested by using a Ronchi ruling having a spatial frequency (lines/millimetre) that is four times the spatial frequency of a grating having an element size of the 1,0 decimal acuity optotype. The grating is placed in the plane of the optotype in the optical projector or generated on the electronic screen. The image is viewed from a distance less than 1/4 of the specified test distance by an observer with a decimal visual acuity of at least 1,0 to determine if the detail can be resolved.

Test results shall be evaluated using generally accepted rules of statistics.

6 Accompanying documents

The chart display for visual acuity measurement shall be accompanied by documents which shall contain the following information:

- a) name and address of the manufacturer or supplier;
- b) instructions for setup and use of the equipment, and for verifying that the ambient illumination restrictions specified in e) are met;
- c) maintenance required for continued compliance with the requirements of this International Standard;
- d) safety requirements and any other necessary precautions;
- e) specifications, including the ranges of visual acuity and luminance conditions within which the chart complies with this International Standard;

Ambient illumination conditions needed to ensure compliance with chart contrast and background luminance specifications include:

- Light sources not intended to illuminate the chart display, including specular reflections and illuminated objects, may not increase the chart background luminance from the viewpoint of the subject.
- 2) Light sources visible to the subject (outside the chart itself) may not exceed the chart background in luminance.
- 3) No light source shall illuminate the chart in such a way that a specular reflection from the chart surface reduces optotype contrast or is visible to the subject.
- f) reference to this International Standard, i.e. ISO 10938:2016, if the manufacturer claims compliance;

for electrically powered devices, additional documents as specified in ISO 15004-1.

Marking, labelling and packaging 7

The chart display for visual acuity measurement shall be permanently marked with at least the following information:

- name and address of the manufacturer or supplier;
- b) name, model, and serial number of the device, where appropriate;
- c) for electrically-powered devices, additional marking as required by ISO 15004-1;
- 51ANDARDSISO.COM. Click to view the full policy of the Control of d) reference to this International Standard, i.e. ISO 10938:2016, if the manufacturer or supplier claims

5