भारतीय मानक Indian Standard

> नेत्र संबंधी प्रकाशिकी और उपकरण — निकटवर्ती पठन चार्ट

> > (ISO 7921 : 2024, संशोधित)

Ophthalmic Optics and Instruments — Near Reading Charts

(ISO 7921 : 2024, MOD)

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भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002 MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG NEW DELHI - 110002 www.bis.gov.in www.standardsbis.in

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NATIONAL FOREWORD

This Indian Standard which is modified adoption of ISO 7921 : 2024 'Ophthalmic optics and instruments — Near reading charts' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Ophthalmic Instruments and Appliances Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	Corresponding Indian Standard	Degree of Equivalence	
ISO 3 : 1973 Preferred numbers — Series of preferred numbers	IS 1076 (Part 1) : 1985/ISO 3 Preferred numbers: Part 1 Series of preferred numbers (<i>second revision</i>)	Identical	
ISO 15004-1 Ophthalmic — instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments	IS 18638 (Part 1) : 2024 Ophthalmic instruments — Fundamental requirements and test methods: Part 1 General requirements applicable to all ophthalmic instruments (ISO 15004-1 : 2020, MOD)	Modified	
IEC 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2024 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (IEC 60601-1 : 2020, MOD) (<i>third revision</i>)	Modified	

In this Standard, reference to IEC 60601-1 has been modified to IS 13450 (Part 1) : 2024 which is a modified adoption of IEC 60601-1 : 2020.

In this Standard, reference to ISO 15004-1 has been modified to IS 18638 (Part 1) : 2024 which is a modified adoption of ISO 15004-1 : 2020.

This standard also makes a reference to the BIS certification marking of the product, details of which is given in <u>National Annex B</u>.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*). The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

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Introduction

This document provides the terms, definitions, and requirements for standardized charts for the assessment of near reading acuity. Reading is a complex visual task that involves more than the mere identification or recognition of individual letters, symbols, or other optotypes. The charts used to assess near reading acuity are intended for the practical purpose of demonstrating whether or not a patient can read sentences or paragraphs of text of a particular size. This document is not meant to replace or supplant standards for visual acuity charts for research or for basic clinical assessments, such as visual acuity measurements before and after cataract surgery.

A patient's reading ability can be labelled using terms such as "difficult" or "easy", or "with errors" or "fluent" or "error-free". Proper assessment of reading ability requires the use of text that is appropriate for the patient, for example, based on the patient's age or educational level. However, the actual determination of a patient's near reading acuity based on these and possibly other factors involves clinical evaluation that is beyond the scope of this document.

This document bases the nominal near reading acuity grade on values given as the logarithm of reading acuity determination (logRAD). LogRAD is similar to the logarithm of minimum angle of resolution (logMAR), used in standard visual acuity testing, in that both are based on the angular size of the test target at a particular viewing distance. However, logRAD specifically depends on the height of lowercase letters, which occur more frequently than uppercase letters, numbers, and symbols in typical text. On the other hand, logMAR is determined by the width of an individual line or the size of a gap. For ease of clinical application, equivalent near reading acuity grades are provided for several common recording notations, including decimal reading acuity, M size, N size, and reduced Snellen fractions.

This document allows for the use of any typeface that is similar in appearance to either of two common typefaces: Times New Roman, a typeface with serifs, which is widely used for printed text; and Helvetica, a sans serif typeface, which is commonly used for both printed charts and electronic displays, such as computer monitors, laptops, and smartphones.

This document applies to the Latin alphabet. It can also apply to similar alphabets, such as Greek and Cyrillic, that can be expressed with typefaces similar to Times New Roman or Helvetica. For other writing systems, such as Arabic, Chinese, Hebrew, Japanese, and Korean, this document can be used as a reference, especially for researchers who wish to demonstrate equivalence of near reading charts using those writing systems with charts using the Latin alphabet.

Indian Standard

OPHTHALMIC OPTICS AND INSTRUMENTS — NEAR READING CHARTS (ISO 7921 : 2024, MOD)

1 Scope

This document applies to printed, projected, and electronic displays of high-contrast text that are designed for assessment and measurement of near reading acuity under photopic conditions.

The definitions and requirements of this document apply to the Latin alphabet.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3:1973, Preferred numbers — Series of preferred numbers

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

IEC 60601-1, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <u>https://www.iso.org/obp</u>
- IEC Electropedia: available at <u>https://www.electropedia.org/</u>

3.1

near reading acuity grade

number assigned to a *font* (3.2.1) or text size at a specified reading distance

Note 1 to entry: Five different scaling systems are used to describe near reading acuity grade: logRAD (3.1.2), decimal reading acuity, *M size* (3.1.3), *N size* (3.1.4), and reduced Snellen fraction. See <u>Table 1</u>.

3.1.1

reading acuity angle

inverse tangent of one-fifth of *x*-height (3.3) for reading text at the standardized distance of 40 cm (400 mm)

Note 1 to entry: Reading acuity angle is measured in minutes of arc.

EXAMPLE Given an *x*-height of 0,582 mm, the reading acuity angle is calculated using Formula (1):

$$60 \cdot \tan^{-1} \left(\frac{0,582/5}{400} \right) = 1,00 \operatorname{arc} \cdot \min$$
 (1)

3.1.2 logarithm of reading acuity determination logRAD

logarithm (base 10) of reading acuity angle (3.1.1)

3.1.3 M size M notation distance, in metres, at which *x*-height (3.3) subtends 5 min of arc

Note 1 to entry: M size is commonly written as the value followed by the capital letter, "M", such as 2M and 0,4M.

3.1.4

N size

body height of a *font* (3.2.1) expressed in typographical points, based on the height of a flat capital letter, such as "E" or "H", and space for diacritical marks above and below the letters

Note 1 to entry: See <u>Figure 1</u>.

Note 2 to entry: In PostScript, 1 point is 1/72 in or approximately 0,353 mm.

Note 3 to entry: N size is commonly written as the capital letter, "N", followed by the size in points, such as N12.

3.2

typeface

complete set of characters forming a family in a particular design

3.2.1

font

complete set of characters for one *typeface* (3.2) at one particular style and type size

EXAMPLE Times New Roman, bold, 9 point.

3.2.2

serif

small line, projection, or stroke attached to the end of a larger stroke in a character of a particular *typeface* (3.2)

3.2.3

sans serif

typeface (3.2) whose characters do not include *serifs* (3.2.2)

3.3

x-height

height of a flat lowercase letter excluding *ascenders* (3.4) and *descenders* (3.5), such as x or z

Note 1 to entry: See Figure 1.

Note 2 to entry: *x*-height is measured in millimetres.

Note 3 to entry: Desired *x*-height at 40 cm is calculated from the given *logRAD* (3.1.2) value using Formula (2)

 $x - \text{height} = 0,582 \cdot 10^{\log \text{RAD}}$

(2)



Key

- 1 *x*-height
- 2 ascender
- 3 descender
- 4 N size



3.4 ascender if present, the part of a letter that extends above the upper limit of the *x*-height (3.3)

Note 1 to entry: See Figure 1.

Note 2 to entry: Diacritical marks and symbols that are not connected to a letter are not considered to be ascenders. Examples include accent marks, tilde, umlaut, and the dot on letters such as "i" and "j".

Note 3 to entry: The upper edge of a letter with rounded lines, such as "o" or "s", can extend above the upper limit of the *x-height* (3.3) but is not considered to be an ascender.

3.5

descender

if present, the part of a letter that extends below the lower limit of the *x*-height (3.3)

Note 1 to entry: See Figure 1.

Note 2 to entry: The lower edge of a letter with a rounded line, such as "o" or "s", can extend below the lower limit of the *x*-height (3.3) but is not considered to be a descender.

4 Requirements

The following requirements are based on a standardized reading distance of 40 cm.

4.1 A typeface that is similar in appearance to either of two common typefaces, "Times New Roman", a typeface with serifs, or "Helvetica", a sans serif typeface, shall be used, with standard font and letter spacing, without italics or other emphasis, as specified by the font.

4.2 Spacing between lines of text of a given text size shall be not larger than one-and-a-half line spacing.

NOTE Single line spacing typically is 120 % to 145 % of the N size.

4.3 Spacing between text of different sizes shall be not less than double the line spacing of the smaller text size.

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4.4 Different excerpts of linguistically simple literature, formatted as continuous text, shall be used for each text size. Use of capital (uppercase) letters, numbers, and symbols shall be kept to a minimum.

A manufacturer may choose the nature of the reading material, based on factors beyond the scope of this document, such as the age or educational level of the patient being assessed.

A manufacturer may provide a few additional, isolated words consisting only of lowercase letters without ascenders or descenders, e.g. "river", "move", in each font or text size.

4.5 Text sizes shall progress geometrically (logarithmically) according to ISO 3:1973, R'10.

EXAMPLE At the standardized reading distance of 40 cm, a text size with a logRAD value of 0,00 (decimal acuity of 1,00) subtends 5 min of arc and has an *x*-height of 0,582 mm.

4.6 Charts shall include a text size with a logRAD value of 0,00 and a manufacturer may provide one or more smaller text sizes. Manufacturers shall specify the largest text size provided in the chart. All step sizes shown in <u>Table 1</u> shall be provided within the range of text sizes provided in the chart. Determination of the logRAD value when using a chart at a test distance other than 40 cm shall be in accordance with <u>Annex A</u>.

Table 1 — Reading acuity angle, *x*-height, and near reading acuity grades for various notations at the standardized reading distance of 40 cm

Reading acuity	y-hoight	Near reading acuity grades					
angle min of arc	mm	logRAD ^a	Decimal read- ing acuity ^{a,b}	M size ^a	N size ^c	Reduced fract	Snellen tion
20,0	11,61	+1,30	0,05	8,00	60	20/400	6/120
15,8	9,22	+1,20	0,063 (0,06)	6,30	48	20/320	6/95
12,6	7,33	+1,10	0,08	5,00	36	20/250	6/75
10,0	5,82	+1,00	0,10	4,00	30	20/200	6/60
7,94	4,62	+0,90	0,125	3,20	24	20/160	6/48
6,31	3,67	+0,80	0,16	2,50	18	20/126	6/38
5,01	2,92	+0,70	0,20	2,00	14	20/100	6/30
3,98	2,32	+0,60	0,25	1,60	12	20/80	6/24
3,16	1,84	+0,50	0,32 (0,3)	1,30	10	20/63	6/19
2,51	1,46	+0,40	0,40	1,00	8	20/50	6/15
2,00	1,16	+0,30	0,50	0,80	6	20/40	6/12
1,58	0,922	+0,20	0,63 (0,6)	0,63	5	20/32	6/9,5
1,26	0,733	+0,10	0,80	0,50	4	20/25	6/7,5
1,00	0,582	0,00	1,00	0,40	3	20/20	6/6,0
0,79	0,462	-0,10	1,25	0,32	2	20/16	6/4,8
0,63	0,367	-0,20	1,60	0,25	1,8	20/12,5	6/3,8
0,50	0,292	-0,30	2,00	0,20	1,5	20/10	6/3,0

^a Values that end in zero may be truncated to delete the last zero only for the purpose of identifying the near reading acuity grade.

^b Values in parentheses shall be used only for the purpose of identifying the near reading acuity grade.

^c Values are approximations for Helvetica and rounded to the nearest common size for the purpose of identifying the near reading acuity grade.

4.7 The text size shall be determined by the *x*-height, as given in <u>Table 1</u>. The permissible deviation in *x*-height is ± 5 % for logRAD values to -0,10 and ± 10 % for logRAD values of -0,20 and smaller.

4.8 For electronically generated charts, the pixel size shall be sufficiently small so that there is no performance difference between the electronically displayed text and printed text that meets the

requirements of <u>4.7</u>. For example, the full vertical pixel size (red, green and blue components together) should not be larger than about 0,08 mm in order to properly display text with a logRAD value of 0,00, or not larger than about 0,04 mm in order to properly display text with a logRAD value of -0,30, at the standardized test distance of 40 cm.

4.9 The luminance of the background surrounding the text shall be within the range of 80 cd/m² to 200 cd/m², with a recommended luminance of 80 cd/m² to 120 cd/m², and shall apply to all methods of presentation. The background shall be white and, for printed charts, it shall be a matt surface.

4.10 The luminance of the text shall be no more than 15 % of the background, which results in a contrast of no less than 85 %. Contrast, *C*, in percent, can be calculated according to the Weber formula, see Formula (3):

$$C(\%) = \frac{L_S - L_T}{L_S} \cdot 100$$
(3)

where

- $L_{\rm S}$ is the luminance of the surrounding field;
- $L_{\rm T}$ is the luminance of the text.

5 Test methods

5.1 Type tests

All tests described in this document 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 of *x*-height is 0,01 mm or less.

6 Accompanying documents

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

- a) name and full address of the manufacturer or supplier;
- b) instructions for setup and use of the chart, and for verifying that the ambient illumination restrictions specified in f) are met;
- c) maintenance required for continued conformity with the requirements of this document;
- d) safety requirements and any other necessary precautions;
- e) luminances of the text and surrounding field or calculated contrast of the chart;
- f) specifications, including the ranges of near reading acuity and luminance conditions within which the chart complies with this document;

Ambient illumination conditions needed to ensure conformity with contrast and background luminance specifications for the chart shall include:

1) light sources not intended to illuminate the chart, including specular reflections and illuminated objects, may not increase the chart background luminance from the viewpoint of the subject;

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- 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 text contrast or is visible to the subject.
- g) reference to this document, i.e. ISO 7921:2024, if the manufacturer claims conformity with it;
- h) a copy of <u>Table 1</u> of this document;
- i) additional information as specified in ISO 15004-1 and/or IEC 60601-1, as applicable.

7 Marking

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

- a) name or trade name of the manufacturer or supplier;
- b) name and model of the chart, where appropriate;
- c) additional marking as required by ISO 15004-1 and/or IEC 60601-1, as applicable;
- d) reference to this document, i.e. ISO 7921:2024, if the manufacturer or supplier claims conformity with it.

Annex A

(normative)

Clinical application of near reading acuity notations

This document sets the recommended test distance for reading at 40 cm and bases all calculations on that distance. However, a clinician might need to measure a patient's reading acuity at a different distance, for example, when viewing a computer monitor at 60 cm or when using near addition power of greater than +2,50 D. For some notations, many clinicians are already in the habit of recording the nominal acuity grade along with the measurement distance, such as 1,6M at 60 cm or 6/7,5 at 33 cm. Unfortunately, this does not always allow the clinician to easily compare reading acuities at different distances for a given patient and it makes statistical analyses across patients very difficult if not impossible.

For proper comparisons at different measurement distances and for statistical analyses, such as average reading acuity for a given patient population, the logarithm of the reading acuity angle (logRAD) should be used. Near reading acuity grade notations can be determined by reference to <u>Table 1</u>.

For example, an *x*-height of 0,922 mm; decimal value of 0,63; M size of 0,64; N size of 5; and Snellen fractions of 20/32 and 6/9,5 all represent a reading acuity angle of 1,58 min of arc, and thus a logRAD value +0,20. If these acuity grades were measured at a distance other than 40 cm, then the predicted logRAD values at 40 cm would be given by the approximations in Table A.1.

measurement distance (applicable near addition power)	predicted logRAD at 40 cm
25 cm (+4,00 D)	measured logRAD plus 0,2
33 cm (+3,00 D)	measured logRAD plus 0,1
50 cm (+2,00 D)	measured logRAD minus 0,1
63 cm	measured logRAD minus 0,2

Table A.1 — Predicted logRAD value at 40 cm when measurement distance is other than 40 cm

Therefore, if the reading acuity was assessed as +0,2 logRAD using a computer monitor at 63 cm, the clinician would expect the patient to achieve 0,00 logRAD (decimal acuity of 1,00) when reading text at 40 cm. Similarly, if a patient exhibits a reading acuity of +0,2 logRAD when viewing at 25 cm, either with a +4,00 D near addition lens or with about 4 D of accommodation, then the expected reading acuity at 40 cm would be +0,4 logRAD. Of course, the clinician should actually measure the patient's acuity at any distance at which the patient intends to read. For statistical analyses and research purposes, precise calculations of logRAD are necessary.

Bibliography

- [1] ISO 8596, Ophthalmic optics Visual acuity testing Standard and clinical optotypes and their presentation
- [2] ISO 10938, Ophthalmic optics Chart displays for visual acuity measurement Printed, projected and electronic
- [3] Consilium Ophthalmologicum Universal, Visual Functions Committee, Visual acuity measurement standard, 1984.
- [4] RADNER W., Reading charts in ophthalmology. Graefes Arch Clin Exp Ophthalmol. 2017; **255**:1465-82.
- [5] RADNER W., Standardization of Reading Charts: A Review of Recent Developments. Optom Vis Sci. 2019; **96**:768-79.

NATIONAL ANNEX B

(National Foreword)

B-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product may be marked with the Standard Mark.

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in.

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Amendments Issued Since Publication

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