



**SLOVENSKI STANDARD**  
**oSIST prEN 16917-1:2015**  
**01-november-2015**

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**Očesna optika - Instrumenti in preskusne metode za ocenjevanje vida voznikov - 1.**  
**del: Ostrina vida**

Ophthalmic optics - Instruments and test methods for assessing drivers' vision - Part 1:  
Visual acuity

Augenoptik - Geräte und Prüfverfahren zur Beurteilung des Sehvermögens von  
Kraftfahrern - Teil 1: Sehschärfe

Optique ophtalmique - Instruments et méthodes d'essai pour évaluer la vision des  
conducteurs - Partie 1: Acuité visuelle

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**Ta slovenski standard je istoveten z: prEN 16917-1**

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**ICS:**

11.040.70      Oftalmološka oprema      Ophthalmic equipment

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**DRAFT**  
**prEN 16917-1**

September 2015

ICS 11.040.70

English Version

## Ophthalmic optics - Instruments and test methods for assessing drivers' vision - Part 1: Visual acuity

Optique ophtalmique - Instruments et méthodes  
d'essai pour évaluer la vision des conducteurs - Partie  
1: Acuité visuelle

Augenoptik - Geräte und Prüfverfahren zur Beurteilung  
des Sehvermögens von Kraftfahrern - Teil 1:  
Sehschärfe

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 170.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

<b>Contents</b>	<b>Page</b>
European foreword.....	3
Introduction .....	4
1 Scope.....	5
2 Normative references.....	5
3 Terms and definitions .....	5
4 Visual acuity test requirements.....	5
4.1 General.....	5
4.2 Sub-set of letter size to be used for screening purpose.....	6
4.3 Number of sets .....	6
4.4 Number of optotype .....	6
4.5 Test field and distance .....	6
5 Test methods .....	6
6 Information to be supplied by the manufacturer.....	6
7 Marking.....	7
Annex A (normative) Pass/fail criteria.....	8
Annex B (informative) Recommendation for conducting the test.....	9
Bibliography.....	10

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## European foreword

This document (prEN 16917-1:2015) has been prepared by Technical Committee CEN/TC 170 “Ophthalmic optics”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

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## Introduction

Driver safety is an important concern, and one of the priority of the European community is to reduce the number of fatal accident and more generally, to improve safety for drivers. Recently published new European Directives about driving licence have proposed new requirements and particularly new visual requirements for drivers to help improve safety. This European Standard will help the application of these Directives, and more particularly proposes standard specification and test methods to control that visual acuity of the driver reaches the minimum requirement of the Directives.

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## 1 Scope

This European Standard applies to the minimum requirements and test methods for instruments used for assessing driver's visual acuity in the context of the European driving licence requirements.

This European Standard does not apply to decision or recommendation to grant a driving licence according to the vision test results, that shall be the responsibility of a medical authority.

## 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.

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

EN ISO 10938, *Ophthalmic instruments — Chart projectors (ISO 10938)*

EN 60601-1, all parts, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1, all parts)*

## 3 Terms and definitions

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

### 3.1

#### group 1 driving licence applicant

applicant for a driving licence of category A, A1, A2, AM, B, B1, BE

Note 1 to entry: The categories are defined in the European driving Directive (see Bibliography [1], [2] and [3]).

### 3.2

#### group 2 driving licence applicant

applicant for a driving licence of category C, CE, C1, D, DE, D1, D1E

Note 1 to entry: The categories are defined in the European driving Directive (see Bibliography [1], [2] and [3]).

### 3.3

#### visual acuity

refers to the ability of the visual system to resolve details

Note 1 to entry: The visual acuity score of an individual expresses the reciprocal of the angular size of the critical detail within the smallest optotype that can be correctly recognized. The Landolt ring is the standard optotype, and the gap of the Landolt ring is taken as the critical detail. See Bibliography [4].

## 4 Visual acuity test requirements

### 4.1 General

The instruments used for assessing visual acuity shall comply with the requirements of EN ISO 8596 and EN ISO 10938 as appropriate when this standard does not provide specifications.

**prEN 16917-1:2015 (E)**

The instrument used to present the visual acuity test can be in the form of a printed chart, a chart projector, an electronic display, an enclosed device or any other device that is compliant with the specifications of this standard.

**4.2 Sub-set of letter size to be used for screening purpose**

Optotypes of 0,1 to 0,8 for monocular testing and 0,5 for binocular testing shall be provided.

Other visual acuity grades are discretionary.

NOTE A Landolt ring is a recommended optotype as being a gold standard. Others optotypes may be used provided scientific equivalence has been proved.

**4.3 Number of sets**

A minimum of 2 different sets of optotypes of each acuity grade shall be provided.

**4.4 Number of optotype**

A minimum number of optotype per grade shall be provided as specified in Table 1 in order that the criteria for assigning visual acuity grades according to EN ISO 8596 can be met. The minimum number may be presented all in one line, or in succession, or on multiple lines.

**Table 1 — Visual acuity grades**

Acuity grade	Minimum number of presentations
0,1	2
0,125 to 0,2	
≥0,25	5

**4.5 Test field and distance**

The test field shall be a rectangular, square, or round in shape.

The size of the test field shall be not less than 2°, and the test field shall extend at least 0,5° in all direction from the contour of the optotype as specified in EN ISO 8596.

The minimum real or virtual distance of use shall be 4 m, as specified in EN ISO 8596.

**5 Test methods**

Testing of the instrument shall comply with EN ISO 8596 and EN ISO 10938.

**6 Information to be supplied by the manufacturer**

The instrument shall be accompanied by documents which shall contain the following information:

- name and address of the manufacturer or supplier;
- instructions for use and setup of the equipment;
- maintenance required for continued compliance with the requirements of this standard;
- safety requirements and any other necessary precautions;
- reference to this European Standard, i.e. EN 16917-1, if the manufacturer claims compliance;



f) specify the pass/fail criteria (see normative Annex A).

## 7 Marking

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

- a) name and address of the manufacturer or supplier;
- b) for electrically-powered devices, additional marking as required by EN 60601-1;
- c) reference to this European Standard, i.e. EN 16917-1, if the manufacturer or supplier claims compliance with it.

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**Annex A**  
(normative)

**Pass/fail criteria**

The number of correctly called optotypes to pass the criteria shall be at least 80 % of the total number of optotypes.

For test having less than 5 optotypes, 80 % means all optotypes shall be correctly called.

Other results lead to fail the criteria.

NOTE This pass/fail criteria is stricter than EN ISO 8596, 6.4 criteria as it relates to a screening device.

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