SLOVENSKI STANDARD
SIST EN 16280:2014

01-marec-2014

Naprave za preskušanje alkoholiziranosti za splošno uporabo - Zahteve in preskusne metode

Breath alcohol test devices for general public - Requirements and test methods

Atemalkoholtestgeräte für den allgemeinen Gebrauch - Anforderungen und Prüfungen

Ethylotests pour le grand public - Exigences et méthodes d'essais

Ta slovenski standard je istoveten z: **EN 16280:2012**

ICS:

13.200	Preprečevanje nesreč in katastrof	Accident and disaster control
71.040.10	Kemijski laboratoriji. Laboratorijska oprema	Chemical laboratories. Laboratory equipment

SIST EN 16280:2014 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 16280

October 2012

ICS 13.320; 71.040.40

English Version

Breath alcohol test devices for general public - Requirements and test methods

Ethylotests pour le grand public - Exigences et méthodes d'essais

Atemalkoholtestgeräte für den allgemeinen Gebrauch

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Ref. No. EN 16280:2012: E

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Foreword

This document (EN 16280:2012) has been prepared by Technical Committee CEN/TC 367 “Breath-alcohol testers”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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Introduction

The two main objectives of breath testers, the specifications of which are defined in this document, consist, on the one hand, in contributing to the prevention of accidents related to the consumption of alcohol, in particular road accidents, and on the other hand, in educating and making consumers aware of their responsibilities by enabling them to measure their breath alcohol level.

The purpose of this standard is to define requirements for a device which is capable of producing measurements that will deter a person who has consumed alcohol from driving or carrying out other risk-related activities.

Any appropriate technology capable of providing the functionality required in this document may be used.

The intention of the standard is to define specifications for a breath alcohol tester which will benefit to the general public at an affordable level.

The requirements in this standard apply for electronic devices only.

1 Scope

This European Standard applies to breath alcohol test devices which measure the concentration of alcohol contained in an exhaled breath sample, designed and intended to be used as a self tester for the general public and to provide a reliable indication of the breath alcohol concentration at the time of the test.

This European Standard specifies requirements for basic safety and performance, test methods and requirements for marking, labelling and operating instructions.

This European Standard gives guidelines for compliance testing procedures consisting of a number of technical performance tests.

It is not intended that the results of these devices should be used to rebut the results of evidential breath alcohol analysers covered by OIML R 126:1998, or breath alcohol test devices used in professional applications covered by EN 15964 or similar national regulations.

Therefore, the results of measurements need to be displayed so as to protect, as far as it is practicable, the user from underestimating his alcohol concentration based on measurement uncertainties, intrinsic in every measurement.

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 60068-2-1, *Environmental testing — Part 2-1: Tests — Test A: Cold (IEC 60068-2-1)*

EN 60068-2-2, *Environmental testing — Part 2-2: Tests — Test B: Dry heat (IEC 60068-2-2)*

EN 60068-2-30, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle) (IEC 60068-2-30)*

EN 60068-2-32, *Basic environmental testing procedures — Part 2: Tests — Test Ed: Free fall (IEC 60068-2-32)*

EN 60335-2-29, *Household and similar electrical appliances — Safety — Part 2-29: Particular requirements for battery chargers (IEC 60335-2-29)*

3 Terms and definitions

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

3.1
alcohol
considered to be ethanol

3.2
breath alcohol test device
device which accepts a breath specimen, measures the concentration and indicates the level of alcohol in that breath specimen

3.3
operating state
state of the device in which it is able to take a breath specimen and determine the alcohol level in that breath specimen

3.4
normal mode
mode in which the device is ready to measure and display the level of alcohol in the breath specimen of the subject under test, either quantitatively or by preset level indication

3.5
test mode
mode in which the device displays the result of a test specified in this standard expressed in numerical format

3.6
unit of measurement
concentration of ethanol expressed in milligrams of ethanol per litre of exhaled volume (mg/L)

Note 1 to entry: Concentration in ethanol may be expressed in any other equivalent units, e.g. µg/L or µg/100 ml.

3.7
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.8
Maximum Permissible Error
MPE
extreme allowed value of measurement with respect to a test gas concentration defined in this standard

3.9
adjustment
process required to correct the measurement value of the breath alcohol test device when it is found to be outside of the defined MPE

3.10
calibration
process required to establish a relation between the measurement value of the breath alcohol test device and a reference gas

3.11
mouthpiece
disposable hygienically wrapped part that is fitted to the breath alcohol test device through which the subject under test provides the breath specimen, and that is used to prevent the breath sample being mixed with ambient air and diluting the alcohol concentration

4 Type-testing

An example of type-testing requirements is described in Annex A (informative).

5 Safety

5.1 General comments

The device shall be designed as far as possible to ensure the safety of the user of the device. Particular attention shall be made to the design and use of electrical connections as well as the materials chosen for mouthpiece construction and packaging.

5.2 Hygiene

The device shall be capable of use under hygienic conditions. It shall preclude the possibility of inhaling contaminated air from previous usages. It shall be possible to insert and remove these mouthpieces without touching the part which will be in contact with the lips of the user. The mouthpieces shall be supplied in individual, easily opened sealed packaging.

5.3 Electrical safety

The device shall be capable of operating within the requirements of relevant electrical safety regulations and standards. A battery charger or an external power supply provided as an accessory to the device shall be compliant with EN 60335-2-29.

6 General specifications

6.1 General requirements

It shall be clearly apparent when the device is ready to accept a breath specimen.

The device may have provision for manual acceptance of the test gas presented to it when conducting adjustment or calibration operations as well as metrological tests.

Devices shall be provided with an indication when the internal power supply is becoming exhausted.

If this low power indication is given, either the device stops operating or the device shall be capable of running further measurements according to the MPEs. The battery warning indicator shall not lead to confusion with any other displayed function.

Devices that also use external power supply shall be provided with an indicator that displays that power is on. This indicator shall not lead to confusion with any other displayed function.

The means by which the device is calibrated or adjusted shall only be accessible to authorised persons.

General device functions shall be verified to ensure that the device performs in accordance with the manufacturer's information.

6.2 Maximum permissible error (MPE)

The maximum permissible error is 0,04 mg/L for nominal alcohol concentration up to and including 0,20 mg/L.

The maximum permissible error is 20 % of nominal alcohol concentration above 0,20 mg/L.

6.3 Measurement range

Devices shall be capable of measuring alcohol concentrations according to the MPE in the range going from 0,00 to 0,50 mg/L.

6.4 Operating environmental conditions

— **Temperature:**

The devices shall be capable of use between + 10 °C and + 40 °C.

If the manufacturer specifies that the device may be operated outside this range, then it shall fulfil the requirements of this standard for these conditions.

If the device is operated outside the temperature range, then this shall be indicated.

6.5 Ease of use

The device shall be simple to use. Any influence by user errors on the result shall be eliminated.

6.6 Breath sampling method

The device shall monitor the continuity of exhalation and the volume given in the time (duration) in order to identify an acceptable breath specimen for analysis. The device shall give a signal if the acceptable volume is not achieved and shall terminate the test procedure at that point, after which the device may reset automatically and indicate readiness to accept a further attempt.

For a device, in its normal sampling configuration, the back pressure, volume, flow rate and duration required to collect a satisfactory breath specimen shall comply with the following:

— minimum volume = 1,2 L;

— minimum flowrate = 0,15 L/s;

— maximum back pressure = 30 hPa at a flowrate of 0,2 L/s;

— minimum duration = 3 to 5 s.

6.7 Expression of results

6.7.1 Units of measurement

The units of measurement shall be mg/L or equivalent unit (cf.3.6).

6.7.2 Rounding in test mode

In test mode, the device shall display the analytical result of each test rounded to the nearest 0,01 mg/L or equivalent unit.

6.7.3 Rounding in normal mode

In normal mode, the reported result shall be rounded to the nearest 0,01 mg/L or equivalent unit analytical result, increased by the MPEs at the level of the analytical result.

6.7.4 Display

For all devices, the reported results shall be limited to a maximum value according to the measurement range (0,50 mg/L).

In normal mode, it shall not be possible to read out the numerical value of a particular result that is either over a national limit or over range.

The reported result of the measurement of the alcohol content of the breath specimen shall be displayed in one of the following ways:

— **Format 1):** the alcohol concentration is expressed as a numerical value (numerical format) up to a national limit, in particular a drink driving limit. For any reported results above the national limit, the display shall indicate an appropriate message (not a numerical result) which should not be confused with any other message. Additionally, besides displaying the appropriate message, the device may have a red light only indicating the “over limit” message which should not be confused with any other light. For reported results less than or equal to the MPEs, the display shall indicate 0,00 mg/L.

— **Format 2):** the alcohol concentration is expressed as a numerical value (numerical format). Above the measurement range, the display shall indicate an over range message (not a numerical result) which

should not be confused with any other message. For reported results less than or equal to the MPEs, the display shall indicate 0,00 mg/L.

An example for both formats is given in Annex B.

The display shall permit easy reading of the reported result in all levels of ambient light (for example, indirect bright sunlight and in the dark). The reported result shall be displayed for at least 10 s.

The device shall have an easy means for the testing laboratories to show the conversion from the analytical result to the reported result (see 6.7.3) and from numerical values to message displayed (Format 1)).

The units of measurement shall be displayed in the vicinity of the result.

6.8 Adjustment

The device shall have the means for adjusting the results of measurement of the device to an alcohol standard. The procedure and equipment shall be specified by the manufacturer.

6.9 Calibration period

The result of the measurement shall be stable for at least 6 months (cf. 7.4.3).

The manufacturer may stipulate a longer period of stability but no more than one (1) year.

If a maximum number of measurements within this period is given additionally by the manufacturer, the breath tester shall have:

— either a visible counter;

— or a masked counter which is supplemented by a feature indicating clearly that the maximum number of measurements is reached.

If this number of tests is reached before the period of stability has expired, then the device shall prevent further measurements until it has been calibrated.

The expiration of calibration period shall be noted (cf. Clause 8).

6.10 Start-up time

The device shall be ready to carry out a measurement within 3 min after switching on, over the operating temperature range not including recovery time (time between 2 measurements) according to 6.12.

6.11 Time for accepting a specimen

When the device is ready to accept a breath specimen a period of not less than 3 min shall be allowed for a satisfactory specimen to be provided after which time the device shall automatically switch off. This time shall not be greater than 10 min.

6.12 Frequency of measurement

The maximum allowed recovery time shall be:

— ≤ 1 min for a nominal alcohol concentration ≤ 0,05 mg/L;

— ≤ 3 min for a nominal alcohol concentration > 0,05 mg/L and ≤ 0,50 mg/L;

— ≤ 10 min for a nominal alcohol concentration > 0,50 mg/L and ≤ 2,00 mg/L.