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Preskusne naprave za merjenje alkohola v sapi (razen naprave za enkratno uporabo) - Zahteve in preskusne metode

Breath alcohol test devices other than single use devices - Requirements and test methods

Atemalkohol-testgeräte zur Mehrfachverwendung - Anforderungen und Prüfverfahren

Ethylotests autres que les dispositifs à usage unique - Exigences et méthodes d'essais

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Breath alcohol test devices other than single use devices - Requirements and test methods

Ethylotests, autres que les dispositifs à usage unique - Exigences et méthodes d'essais

Atemalkohol-Testgeräte zur Mehrfachverwendung - Anforderungen und Prüfverfahren

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Foreword

This document (EN 15964:2011) 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of an identical text or by endorsement, at the latest by September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Breath alcohol test devices are widely used in Europe in professional applications like law enforcement, promotion of traffic safety and work safety. Test results may lead to severe consequences for everybody involved. Therefore, the test results need to be reliable and acceptable.

This document contains a description of the minimum technical requirements to be met for compliance testing of multi-use breath alcohol test devices. It contains also details concerning the compliance testing and performance requirements of breath alcohol test devices as a prerequisite for approval [1)].

References may also be made to sections of this document for lot-by-lot testing.

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

Breath alcohol test devices considered in this standard use mouthpieces for sampling the breath specimens.

1) European standardization does not cover those subjects that clearly belong to the domain of regulation of the Member States unless this is explicitly supported by the national authority (i.e. regulatory measures remain the competence of the various Member States).

1 Scope

This European Standard applies to breath alcohol test devices which measure the concentration of alcohol contained in an exhaled breath sample intended to be used for screening or preliminary testing. This standard specifies requirements for basic safety and performance, test methods and requirements for marking, labelling and operating instructions.

This standard gives guidelines for type approval procedure consisting of a number of technical performance tests, but excluding in vivo tests, that are carried out on devices supplied by the manufacturers.

In vivo tests, which are designed to test the ability of the device to work with real subjects, may be arranged in compliance with national requirements.

This standard is not applicable to devices covered by OIML R 126:1998 (Evidential breath analyzers) or single use testers.

Devices are designed for law enforcement.

2 Normative references

The following referenced documents are indispensable for the application 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.

EN 60068-2-1, *Environmental testing — Part 2-1: Tests — Test A: Cold*

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

EN 60068-2-6, *Environmental testing — Part 2-6: Tests — Test Fc: Vibration (sinusoidal)*

EN 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

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

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

EN 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

EN 60068-2-78, *Environmental testing — Part 2-78: Tests — Test Cab: Damp heat, steady state*

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

EN 61000-4-2, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

EN 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

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

NOTE e.g. Pass or Fail

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

3.6
unit of measurement
concentration of ethanol expressed in milligrams of ethanol per litre of exhaled volume

NOTE Concentration in ethanol may be expressed in any other equivalent units, e.g. mg/L, 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
MPE
maximum permissible error
extreme allowed value of measurement with respect to a test gas concentration defined in this standard

3.9
verification
testing process to establish that the breath alcohol test device is operating within the limits of the defined MPE and repeatability

3.10
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

3.11
mouthpiece
hygienically wrapped part intended for single use that is fitted to the breath alcohol test device through which the subject under test provides the breath specimen

NOTE A mouthpiece 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 to ensure the safety of the operator and 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 preclude the possibility of inhaling contaminated air from previous users. The mouthpiece is intended for single use only. It shall be possible to handle these mouthpieces without touching the part which will be and which has been in contact with the lips of the person being tested. 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 the EN 60335-2-29 standard.

6 General specifications

6.1 General requirements

It shall be clearly apparent when the device is ready to take and analyse a breath specimen.

When the device is ready to accept a breath specimen a period of not less than 3 minutes or greater than 10 minutes shall be allowed for a satisfactory specimen to be provided after which time the device may automatically switch off. It shall be possible to switch off the device at any time.

In normal mode the specimen of breath shall be taken automatically after the requirements in 6.6 have been met.

The device may have provision for manual acceptance of the vapour presented to it when conducting adjustment or verification 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, the device shall be capable of running at least ten further measurements. 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.

6.2 Maximum permissible error (MPE)

The maximum permissible error is +/-0,02 mg/L for alcohol concentrations up to and including 0,20 mg/L.

The maximum permissible error is ± 10 % of nominal concentration for alcohol concentration above 0,20 mg/L.

6.3 Measurement range

Devices shall be capable of measuring alcohol concentrations in the range 0,00 mg/L to 2,00 mg/L.

6.4 Operating environmental conditions

6.4.1 Temperature

The devices shall be capable of use between – 5 °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 specified range, then it may indicate that it cannot take a sample.

6.4.2 Humidity

The devices shall be capable of use up to 93 % RH.

6.5 Ease of use

In normal mode, the device shall not be influenced in its operation by user error.

6.6 Breath sampling method

The device shall monitor the continuity of exhalation and the volume given 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. Manufacturers may at their discretion set a limit for the number of attempts to provide a breath specimen for analysis from any one subject.

For a device, the pressure, volume and flowrate required to collect a satisfactory breath specimen shall comply with the following absolute values:

— minimum volume = 1,2 L;

— minimum flowrate = 0,15 L/s;

— maximum pressure = 30 hPa at a flowrate of 0,2 L/s, mouthpiece attached.

6.7 Expression of results

6.7.1 Units of measurement

In test mode the units of measurement shall be mg/L or equivalent unit.

6.7.2 Rounding

In test mode, the device shall display the result of each test to the nearest 0,001 mg/L or equivalent unit.

In normal mode, it shall report the result of each test rounded down to the nearest scale interval of 0,01 mg/L or equivalent when in digital format and the appropriate band when in indicating format.

6.7.3 Display

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

The result of measurement of the alcohol content of the breath specimen may be presented in two ways:

— indicating format where the alcohol content of the sample is presented by a system of lights or characters on an alpha-numeric display;

— digital format where the alcohol concentration is expressed in a quantitative format. It shall be permissible for a device to indicate zero for values up to and including 0,03 mg/L;

It shall be permissible for a device to operate in indicating and digital format simultaneously. It shall not be possible for the display to be converted from indicating format to digital format in normal mode.

The display shall permit easy reading of the results in all levels of ambient light. The results and other indications shall be able to be observed for at least one minute or alternatively it shall be possible to recall the result of the last test. However, a new measurement shall be able to be initiated at any time during the display of the result.

6.8 Adjustment

The procedure and equipment for adjusting the breath alcohol test device to a reference alcohol mass concentration shall be supplied by the manufacturer. For this purpose, the gas may be dry or wet, provided it can be shown on the device that the results from each are equivalent.

The required period between two successive adjustments shall be at least three months.

During this period the results shall remain stable (see 7.4.4).

6.9 Start-up time

Within the specified operating temperature range, the device shall be ready to carry out a measurement in less than 3 minutes after switching on.

6.10 Frequency of measurement

The maximum allowed time between two measurements shall be:

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

— ≤ 2 min for a concentration > 0,05 mg/L and ≤ 0,40 mg/L;

— ≤ 3 min for a concentration > 0,40 mg/L and ≤ 2,0 mg/L.