BS EN 16280:2012

BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of EN 16280:2012.

BSI, as a member of CEN, is obliged to publish EN 16280:2012 as a British Standard. However, attention is drawn to the fact that during the development of this European Standard, the UK committee voted against its approval as a European Standard.

It should be noted that in the UK, use of breath test devices by members of the public to determine whether or not they might be over the drink drive limit is not encouraged. There is a risk that improper use of such non-professional devices could mistakenly lead individuals to think they were not impaired or above the limit, thereby threatening road safety.

The UK committee would like to point out that devices used by the police have to meet stringent type approval standards. Public confidence in these could be diminished by the use of other devices which might conform to other standards but are not type approved. Other devices might not operate with the same accuracy and could in any particular case give a different reading; these scenarios could have legal implications.

In the UK, a device will not be type approved unless it meets all the requirements set out in the Guide to Type Approval for Electronic Breath Screening Devices (ESDs) used for law enforcement in Great Britain, published by the Home Office and is available here: http://www.homeoffice.gov.uk/publications/police/road-traffic-documents/breathalcoholscreening.pdf?view=Binary

The UK participation in its preparation was entrusted to Technical Committee PTI/15, Natural Gas and Gas Analysis.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Atemalkoholtestgeräte für den allgemeinen Gebrauch

This European Standard was approved by CEN on 18 August 2012.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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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.

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 organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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.

6.13 Power supply duration

Devices shall have an internal power supply.

With batteries fully charged at the beginning of the test, the breath alcohol test device shall be able to perform 75 consecutive measurements from switch on to result displayed at + 10 °C with a concentration of 0,10 mg/L.

The external power supply, if available for the device under test, shall be disconnected during this test.

7 Metrological characteristics for testing

7.1 General conditions

Immediately prior to testing and if appropriate (see example), the device may undergo adjustment to an alcohol standard.

For example, in case of lot by lot testing, the manufacturer shall perform the adjustment.

Tests shall be performed at the highest frequency allowed by the device and in test mode unless otherwise specified.

The tests shall be suitable to check that the devices comply with the provisions of this document in the different submitted power supply configurations.

The effect of each factor shall be determined in turn with all other factors being at their reference level. The effects shall not be combined unless otherwise specified. In performing the tests in this scheme a complete breath test using the alcohol standard shall be carried out. Wherever possible, the test shall allow all aspects of the normal operation of the device to be verified. Tests shall be run at the reference point and the extreme points of each condition listed.

The power supply used shall be of the type supplied by the manufacturer.

The following tests shall be carried out on a device representative of the devices to be used and without any additional protective means.

The uncertainties of the results of test equipments for providing volume-, flow-, time-, back pressure measurements should be included in compliance considerations.

7.2 Test gas characteristics

The gas used shall be wet gas unless otherwise stated for a particular test.

Wet gas shall have a gas temperature of (34,0 ± 1,0) °C with a relative humidity of at least 90 % at the entrance of the mouthpiece.

The carrier gas shall have 5 % of CO_2 (volumetric fractions). If the influence of 5 % of CO_2 is no more than 0,01 mg/L for a concentration of 0,4 mg/L of ethanol then the carrier gas may be air. If changes of the O_2 concentration in the carrier gas are relevant, the constitution of the carrier gas shall reflect the O_2 concentration of human breath which may vary between 12 vol % and 21 vol %.

The uncertainty of test gas concentration listed in Table 1 shall be ≤ 7µg/L.

The concentration of ethanol in the wet gas is calculated on the basis of the formula detailed in Annex C.

7.3 Reference conditions

The reference conditions defined for the tests are as follows:

— temperature: ambient temperature: (18 to 26) °C;

— humidity: ambient air humidity: (20 to 80) % RH;

— atmospheric pressure: ambient atmospheric pressure;

— test gas flow: (0,20 ± 0,05) L/s;

— volume: (1,5 ± 0,1) L;

If required by the test device, the test gas flow rate shall be reduced to allow the device to take a sample of the test gas for analysis.

Regardless of the selected mode (normal or test mode), the device shall be tested the way it is normally used.

7.4 Accuracy tests

7.4.1 General

The device shall be tested in test mode with the number and nominal alcohol concentration of test gases listed in Table 1 in 7.4.2. The individual results shall be within the error limits indicated for each test gas.

7.4.2 Accuracy testing

For accuracy testing, the following concentrations and number of measurements shall be used:

Table 1

Nominal alcohol concentration (mg/L)	Number of measurements
0,00	10
0,10	10
0,20	10
0,40	10

Acceptance criteria:

— for a nominal alcohol concentration of 0,00 mg/L, the device shall indicate a 0,00 mg/L reading;

— for a sample containing alcohol, each analytical result shall comply with the MPE defined in 6.2.

Two tests in normal mode shall be performed at the nominal alcohol concentrations 0,60 mg/L and 2,00 mg/L and the appropriate message shall be displayed by the device.

The requirements for frequency of measurements (6.12) shall be confirmed during this test.

The manufacturer shall provide information at which reported results the device shall display an appropriate message instead of a numerical value. This shall be confirmed by testing the device.

7.4.3 Drift testing

Before the drift testing, the device may be adjusted if appropriate.

For drift testing, the following values shall be used:

— 10 measurements at nominal alcohol concentration 0,20 mg/L, once a month for at least six months; if the manufacturer stipulates a longer period of validity, the period of testing shall be prolonged accordingly;

Acceptance criteria: each individual result shall comply with the MPE defined in 6.2.

For devices with a limitation for the number of tests to be conducted without calibration, these tests shall be conducted according to this limitation in half of the time of the calibration period. These tests shall be uniformly distributed over this period.

Acceptance criteria: each individual result shall comply with the MPE defined in 6.2.

7.5 Memory effect

7.5.1 Effect of high alcohol concentration

Subject the device 3 times to the following cycle:

— perform a measurement with a nominal alcohol concentration of 1,00 mg/L;

— perform a measurement with a nominal alcohol concentration of 0,20 mg/L.

Acceptance criteria:

— each obtained value for a nominal alcohol concentration of 0,20 mg/L shall comply with the MPE defined in 6.2;

— the recovery time for each test shall comply with the requirements of 6.12.

7.5.2 Effect of humidity in sample gas (condensation)

Perform the following tests at temperature (+ 10 ± 1) °C:

— ten measurements at nominal alcohol concentration 0,00 mg/L at the highest frequency permitted by the device;

— five measurements at nominal alcohol concentration 0,20 mg/L;

Acceptance criteria: each obtained value shall comply with the MPE defined in 6.2.

7.6 Influence factors

7.6.1 General

Regarding influence factors, the following procedure shall be applied unless otherwise specified in this chapter:

Test: ten measurements at nominal alcohol concentration 0,20 mg/L.

Acceptance criteria: each obtained value shall comply with the MPE defined in 6.2.

If the manufacturer specifies extended operating conditions different to those stated the device shall be tested to those conditions.

7.6.2 Operating temperature

The following test procedure shall be applied:

— a first test is done at the reference conditions;

— then a test is done at (+ 10 ± 1)°C;

— then a test is done at (+ 40 ± 1)°C;

— then a test is done at the reference conditions.

The device under test shall be placed in the test chamber at the reference temperature and a test shall be carried out. The temperature shall then be reduced to the minimum specified and the device under test allowed to stabilise for at least 3 h. A test shall be carried out. The temperature shall then be raised to the maximum level in not less than 1 h to minimise the risk of condensation occurring and the device under test allowed to stabilise for at least 3 h. A test shall then be carried out.

7.6.3 Acceptance of breath samples

7.6.3.1 Minimum volume

Use ambient reference conditions.

The laboratory shall check the minimum volume, that is 1,2 L:

— Test volume: (1,10 ± 0,05) L; exhalation time: (5,5 ± 0,5) s.

The device shall not accept the specimen.

7.6.3.2 Minimum time of exhalation

Use ambient reference conditions.

The laboratory shall check the minimum time:

— Time: (2,9 ± 0,1) s; flowrate: (0,60 ± 0,05) L/s.

The device shall not accept the specimen.

— Time: (4,9 ± 0,1) s; flowrate: (0,60 ± 0,05) L/s.

The device shall accept the specimen.

7.6.3.3 Continuity of the breath exhalation

Use ambient reference conditions.

— Volume: (1,6 ± 0,1) L

— Flowrate: (0,20 ± 0,05) L/s

After 4 s, stop the flow for a period of (0,2 ± 0,1) s and then continue with the same flowrate.

The device shall not accept the specimen.

7.6.3.4 Back pressure

Use ambient reference conditions.

Apply for the test a gas with a flowrate at (0,20 ± 0,01) L/s to the device equipped in its normal sampling configuration.

The maximum back pressure shall be 30 hPa.

7.6.4 Influence factors exhalation parameters

In this test the influence factors cannot be examined separately. The laboratory shall check the influence of the following exhalation parameters:

— volume: (1,6 ± 0,1) L; exhalation time: (8,0 ± 0,5) s;

— volume: (4,5 ± 0,3) L; exhalation time: (15,0 ± 0,5) s;

— time: 5 s; flowrate 0,6 L/s;

— time: 5 s; volume: 1,5 L;

— time: 3,5 s, 4,0 s, 4,5 s ; flowrate: 0,6 L/s;

— time: 3,5 s, 4,0 s, 4,5 s; volume: 1,5 L.

For times from (3,5 to 4,5) s, it is possible for the device not to accept the sample according to the minimum time in 6.6.

For all occasions where the device does accept the sample, each obtained value shall comply with the MPE defined in 6.2.

7.6.5 Voltage variation

The following test procedure shall be applied.

Each test consists of 10 measurements at a nominal alcohol concentration of 0,20 mg/L. Each obtained value shall comply with the MPE defined in 6.2:

— reduce the power voltage until the device clearly ceases to function; increase the voltage just above and perform a test.

If an alternative power source (standard power supply with sufficient current capacity) is used in bench testing to simulate the battery, it is important that the internal impedance of the battery is also simulated. The maximum internal impedance of the battery is to be specified by the manufacturer of the device.

The device shall have an easy means for the testing laboratories to perform the test.

7.7 Mechanical and climatic disturbances

7.7.1 General

For all these tests, submit the switched off device to the relevant test. On completion of each test, either immediately, or after a defined waiting time, conduct 10 measurements at a nominal alcohol concentration of 0,20 mg/L, unless otherwise specified.

The difference between the mean values of the 10 tests before and after disturbance shall be less than 0,040 mg/L.

7.7.2 Free fall

This test is to be carried out in accordance with EN 60068-2-32 (Test Ed: Free Fall) with the following conditions:

— test surface concrete;

— height of fall shall be: 500 mm;

— number of falls: 6. Three devices are needed to test for each of the three mutually perpendicular axes. Each device falls twice.

Attitude the device under test in the first fall shall be in a different chosen dimensional axis with the second fall in the same axis but the opposite side.

This test shall be carried out on a device without any additional protective means.

At the end of the test the device shall be inspected for obvious damage. The device shall fail the test if the damage impairs the functionality or safety of the device (cf. Clause 5).

If there is no damage on the device, the test shall fulfil the requirements in 7.7.1.

7.7.3 Climatic environment

7.7.3.1 Cold

This test is to be carried out in accordance with EN 60068-2-1 (Test A: Cold) with the following conditions:

— temperature: - 20 °C;

— duration: 6 h.

The devices shall be tested with the device power OFF. The chamber conditions should be such as to inhibit condensation at all times. After each separate test the device shall be allowed to stabilise at 20 °C for a minimum of 1 h after which a test shall be carried out.

7.7.3.2 Dry Heat

This test is to be carried out in accordance with EN 60068-2-2 (Test B: Dry Heat) with the following conditions:

— temperature: + 70 °C;

— duration: 6 h.

The devices shall be tested with the device power OFF. The chamber conditions should be such as to inhibit condensation at all times. After each separate test the device shall be allowed to stabilise at 20 °C for a minimum of 1 h after which a test shall be carried out.

7.7.3.3 Damp Heat (Cyclic)

This test is to be carried out in accordance with EN 60068-2-30 (Test Db and guidance - Damp Heat, cyclic) with the following conditions:

The test consists of exposure to cyclic temperature variation between 25 °C and 55 °C, maintaining the relative humidity above 95 % during the temperature change and low temperature phases, and at 93 % at the upper temperature phases.

Condensation should occur on the device under test during the temperature rise.

The devices shall be tested with the device power OFF.

The 24 h cycle consists of:

1) temperature rise during 3 h;

2) temperature maintained at upper value until 12 h from the start of the cycle;

3) temperature lowered to lower value within 3 h to 6 h, the rate of fall during the first hour and a half being such that the lower value would be reached in 3 h;

4) temperature maintained at lower value until the 24 h cycle is completed.

The stabilising period before and recovery after the cyclic exposure shall be such that the device under test is within 3 °C of their final temperature.

8 Marking

A breath alcohol test device compliant with this document shall bear a visible and indelible marking in the official language(s) of the country where the device is sold comprising:

— the reference of this standard;

— the identification of the manufacturer and the supplier (if different);

— the name of the device and model type;

— the serial number;

— if the device uses format 1 (6.7.4), the specified limit shall be indicated;

— the wording: “Be aware of the applicable law on drink driving”;

— the operating temperature range.

The date of the next calibration shall be noted either on the display in digital format once the device is switched on or on a durable label (day/month/year).

The device shall be provided with an individual package with information that includes the above marking requirements, the calibration period, the next date of calibration and the maximum number of tests (if applicable) between two calibrations and, if a specific limit is used, the countries where this legal limit are applicable.

9 Operating instructions

Each device shall be supplied with operating instructions in the official language(s) of the country where the device is sold. They shall specify at least:

a) the reference of this standard;

b) the identification of the manufacturer and the supplier (if different);

c) the name of the device and model type;

d) if the device uses Format 1) (6.7.4), the specified limit shall be indicated;

e) information on the current drink driving limits in the European countries, to allow a indication of the country where this legal limit is applicable;

f) the relationship between different units;

EXAMPLE 0,35 mg/L = 35 µg/100 ml;

g) the technical characteristics: range of concentration, range of temperature, operating conditions, storage conditions, time and maximum number of tests (if applicable) between two calibrations, etc;

h) a recommendation to use a new mouthpiece for each test;

i) the types of battery or accumulator to be used;

j) the recommended frequency of the calibration and adjustment operations, as well as the procedures, including environmental conditions, and means required for these operations; these calibration and adjustment operations shall only be conducted by competent persons;

k) the risk of obtaining erroneous results in the event of exceeding the number of measurements or the duration of use;

l) the use-related restrictions, if any, of the device;

m) the maximum value for which the device indicates a zero value;

n) the procedures for recharging batteries;

o) the possible use-related restrictions of the breath tester to include:

1) wait at least 20 min following the last ingestion of alcohol prior to conducting a measurement;

2) certain substances can interfere with the result;

3) wait at least 5 min after smoking;

p) breath test procedure;

q) environmental and safety information; for example: handling of mouthpieces;

r) if the device has a memory function, then there should be a description of what the device does when the memory reaches its capacity limit.

Annex A
(informative)

Example of type testing requirements

A.1 Additional information for compliance testing

Applicants (manufacturers or authorised agents) should supply to a testing laboratory breath alcohol test devices of the type intended for sale, for testing purposes.

The number of devices required for evaluation should be 10.

On completion of the type approval testing the applicants should supply free of charge to certification authority two devices identical to the final type approved device. These devices will be held as exemplar devices, and may be used to test any modifications to the type-approved device, before recommending the proposed change for certification.

The applicants should provide the following at the time of testing:

1) a handbook or a set of written instructions for the use of the device operator;

2) a written technical description of the device's operation;

3) details of the internal analytical unit used by the device.

The manufacturer and any third party carrying out technical operations should have a quality system certified to EN ISO 9001.

The testing laboratory should be certified for conducting the tests required according to EN ISO/IEC 17025 or equivalent.

The certification authority or its agents should accept no liability for breakage or damage.

A.2 Certification procedure

Reports on devices that successfully completed the testing procedure in the main document can be submitted by the applicant to the certification authority who issues certification. As a condition of certification the applicant should agree:

1) to ensure that the type and serial number of each device is clearly identified by an indelible marking;

2) to ensure that the serial number is unique to each device;

3) to ensure that any repair and calibration facility relating to the device is certified to the EN ISO 9001 and open to inspection by the certification authority or accrediting body;

4) to ensure that any update of the operating instructions should be sent to the certification authorities;

5) to indicate the version number of any software or firmware.

The certification authority undertakes to keep all information provided confidential in so far as that undertaking does not conflict with any other overriding legal duty.

Annex B
(informative)

Figures for format 1 and format 2 - 6.7.4 Display (in normal mode)

Format 1		**Format 2**
Reported result is expressed as a numerical value. Above the national limits (C), a message is displayed such as "Don't drive".		Reported result expressed as a numerical value
Example for C = 0,25 mg/L Indicate message = "Don't drive"		(mg/L)
Numerical value		**Numerical value**
0,00 to 0,04		0,00
0,05		0,05
0,06		0,06
0,07		0,07
0,08		0,08
0,09		0,09
0,10		0,10
0,11		0,11
0,12		0,12
0,13		0,13
0,14		0,14
0,15		0,15
0,16		0,16
0,17		0,17
0,18		0,18
0,19		0,19
0,20		0,20
0,21		0,21
0,22		0,22
0,23		0,23
0,24		0,24
Message "Don't drive"		0,25
		0,26
		0,27
		0,28
		0,29
		0,30
		0,31
		0,32
		0,33
		0,34
		0,35
		0,36
		0,37
		0,38

		0,39
		0,40
		0,41
		0,42
		0,43
		0,44
		0,45
		0,46
		0,47
		0,48
		0,49
		0,50
		Over range message

Annex C
(informative)

Formula for wet gas alcohol concentration

The concentration of ethanol in the air is calculated from formula of OIML R 126:1998:

C_{aqua} = mass concentration of ethanol of an aqueous solution of ethanol.

When air is bubbled through such a solution, the mass concentration C_{air} of ethanol in the air is given by Dubowski's formula:

$$C_{air} = 0{,}041\,45 \times 10^{-3} \times C_{aqua} \times \exp(0{,}065\,83t)$$

where

t is the temperature in °C.

For t = 34 °C:

$$C_{air} = 0{,}38866 \times 10^{-3}\ C_{aqua}$$

Bibliography

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[2] EN 60068-1, *Environmental testing — Part 1: General and guidance (IEC 60068-1)*

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[4] EN ISO 9001, *Quality management systems — Requirements (ISO 9001)*

[5] EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025)*

[6] OIML Recommendation R 126:1998, *Evidential breath analysers*

[7] OIML International Document D 11, *General requirements for electronic measuring instruments* (Edition 2004)

[8] Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC

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