BS EN 15964:2011

BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of EN 15964:2011.

In particular, compliance with this Standard will not of itself qualify a device for type approval for the conduct of preliminary breath tests under the Road Traffic Act 1988. A device will not be type approved unless it meets all the requirements set out in the Guide to type approval procedures for breath alcohol screening devices used for law enforcement in Great Britain, published by the Home Office and available at http://www.homeoffice.gov.uk/police/powers/road-traffic/road-traffic.html/

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.

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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of an identical text or by endorsement, at the latest by September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.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.

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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.

6.11 Power supply duration

Devices shall have an internal power supply.

With batteries fully charged, the breath alcohol test device shall be able to perform at least 75 individual measurements, each from switch on to result displayed within the operating temperature range.

6.12 Data storage

When a permanent data memory is provided the downloaded data shall include at least:

— serial number of the device;

— date and time of the test;

— type of test (e.g. normal mode);

— measurement result or an indication that the test was not completed;

— unit of measurement if applicable.

The device shall give a warning if the memory is approaching the limit of its capacity (see also requirements in Clause 9).

6.13 General device functions

In addition to the breath alcohol testing requirements, checks shall be made on general device functions to ensure that the device performs in accordance with the manufacturer's information.

7 Metrological characteristics for testing

7.1 General conditions

Immediately prior to testing and if appropriate, the device may undergo adjustment to a reference ethanol vapour test gas.

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

Perform the tests at the maximum rate authorised by the provided features, taking into account the test equipment possibilities.

The tests shall be able 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 standard vapours 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 recommended by the manufacturer.

The following tests shall be carried out on a device representative of devices intended for use and without any additional protective means.

7.2 Test gas characteristics

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

Wet gas shall be generated at a temperature of (34,0 ± 0,5) °C with a relative humidity of at least 90 %.

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 shall be ≤ 1/3 of MPE.

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

7.3 Reference conditions

The reference conditions defined for the tests are as follows:

— Temperature: ambient temperature: (22 ± 4) °C;

— humidity: ambient air humidity (50 ± 30) % 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.

For a breath alcohol test device that is not capable of displaying the measured concentration, the manufacturer shall provide the necessary methods to be able to obtain quantitative readings for the purpose of testing the compliance of the breath alcohol test device with the requirement of this European Standard.

7.4 Accuracy tests

7.4.1 General

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

7.4.2 Accuracy testing

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

Table 1

Concentration (mg/L)	Number of measurements
0,00	10
0,10	20
0,25	20
0,40	20
0,60	10

If digital values are required above 0,60 mg/L, the accuracy has to be tested ten times at 90 % of the maximum value, e.g. at 1,80 mg/L for the maximum range given in 6.3.

If no digital values are required above 0,60 mg/L, the functionality of the device up to the maximum value of the measurement range has to be checked.

If a device displays the result of the test in indicating format above a certain concentration, it shall only be checked whether the device gives the right indication at higher concentrations in normal mode.

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

7.4.3 Repeatability testing

The repeatability shall be determined at 0,10 mg/L and 0,40 mg/L. Twenty consecutive results are required at each level.

Acceptance criteria:

— each obtained value shall comply with the MPE defined in 6.2;

— maximum standard deviation (SD) for repeatability, at 0,10 mg/L alcohol concentration: 0,012 mg/L;

— maximum coefficient of variation (CV) for repeatability, at 0,40 mg/L alcohol concentration: 3 %.

7.4.4 Drift testing

For drift, the following values shall be used:

— two levels of concentration: 0,10 mg/L and 0,40 mg/L;

— five measurements at each of the two levels, once a week for three months.

Acceptance criteria: each measurement result shall comply with the MPE as defined in 6.2. In addition, the average of each set of five measurements shall be calculated. The maximum difference between the averages shall be 0,020 mg/L (per week/3 months).

7.5 Memory effects

7.5.1 Hysteresis

Subject the device ten times to the following cycle:

— perform a measurement with a concentration of 1 mg/L;

— perform a measurement with a concentration of 0,10 mg/L;

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

7.5.2 Effect of water vapour (condensation)

Perform the following tests at – 5 °C:

— ten measurements at 0,00 mg/L at the maximum rate permitted by the device;

— five measurements at 0,40 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 0,10 mg/L and ten measurements at 0,40 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 – 5 °C;

— then a test is done at + 40 °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 Ambient relative humidity

The following test procedure shall be applied according to EN 60068-2-78:

— a first test is done at the reference conditions;

— the temperature and the humidity shall be increased to 93 % relative humidity at 40 °C in not less than 1 h; these conditions shall be maintained for at least 24 h before the test is carried out at these conditions;

— then a test is done at the reference conditions.

7.6.4 Interfering substances

The laboratory shall check the influence of the following interfering substances at the ethanol concentration of 0,40 mg/L.

Table 2

Interfering substances	Nominal value for vapour mass concentration mg/L (± 5 %)
Acetone	0,50
Carbon monoxide	0,20
Methane (Hydrocarbon)	0,30

Acceptance criteria: each obtained value shall comply with the MPE defined in 6.2 or the device shall not give a result.

7.6.5 Influence factors exhalation parameters

7.6.5.1 General

The following tests shall be performed under normal operating conditions.

7.6.5.2 Minimum volume test

The laboratory shall check that no sample is accepted below the minimum volume which is 1,2 L:

— Test volume: 1,1 L; exhalation time: 5 s.

The device shall not accept the specimen.

7.6.5.3 Influence of volume and time during the breath exhalation

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

— volume: 1,5 L; exhalation time: 5 s;

— volume: 4,5 L; exhalation time: 15 s.

Each obtained value shall comply with the MPE defined in 6.2.

7.6.5.4 Influence of flowrate and time during the breath exhalation

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

— volume: 1,5 L; exhalation time: 10 s (flowrate at 0,15 L/s);

— volume: 3 L; exhalation time: 15 s (flowrate at 0,2 L/s);

— volume: 4,5 L; exhalation time: 7,5 s (flowrate at 0,6 L/s);

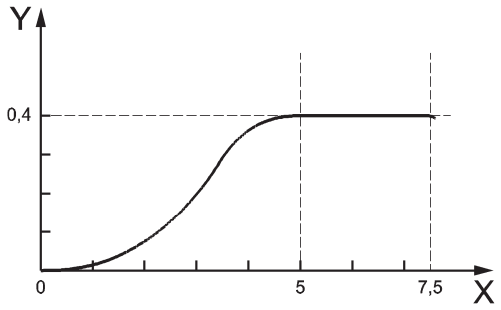
Each obtained value shall comply with the MPE defined in 6.2.

7.6.5.5 Influence of variation of alcohol concentration during the breath exhalation

The laboratory shall check the influence of the following exhalation parameters at 0,40 mg/L:

— volume: 1,5 L; exhalation time: 7,5 s;

— the alcohol concentration shall reach the plateau level at 5 s, for example by injecting quickly the alcohol concentration.



Key
X: Exhalation time (s)
Y: Alcohol concentration (mg/L)

Figure 1 — Influence of variation of alcohol concentration during the breath exhalation

Each obtained value shall comply with the MPE defined in 6.2.

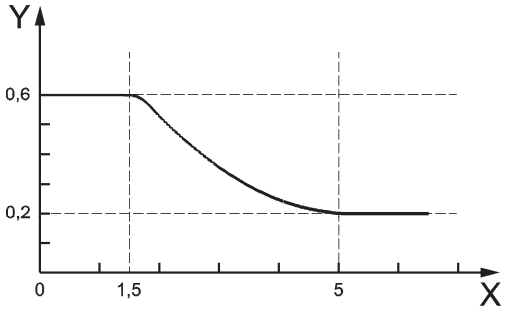
7.6.5.6 Influence of pressure and flowrate during the breath exhalation

In this test the influence factors cannot be examined separately. The test shall simulate the decrease of flowrate during an exhalation.

The laboratory shall check the influence of the following exhalation parameters at 0,40 mg/L:

— Initial condition: exhalation time: 5 s (flowrate at 0,6 L/s);

— The flowrate shall follow this description: between 1,5 s and 5 s exhalation, decrease to 0,2 L/s and continue in order to get 3 L.



Key
X: Exhalation time (s)
Y: Flowrate (L/s)

Figure 2 — Influence of pressure and flowrate during the breath exhalation

Each obtained value shall comply with the MPE defined in 6.2.

7.6.6 Voltage variation (internal battery)

The following test procedure shall be applied.

Each test consists of 10 measurements at a concentration of 0,40 mg/L. Each obtained value shall comply with the MPE defined in 6.2:

— stabilize the power supply at the normal battery voltage within the defined limits and perform a test;

— reduce the power voltage until the device indicates a power supply warning; perform a test;

— reduce the power voltage until the device clearly ceases to function; increase the voltage until the device switches on again and remains on during a test cycle.

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.

7.6.7 Power supply duration tests

With batteries fully charged at the beginning of the test, the breath alcohol test device shall be able to perform 75 individual measurements, each from switch on to result displayed at –5 °C with a concentration of 0,10 mg/L.

Each measurement shall fulfil the MPEs in 6.2.

7.7 Mechanical and climatic disturbances

7.7.1 General

The following test procedure shall be applied:

— 10 measurements at 0,40 mg/L performed before the disturbance;

— Submit the device to the disturbance;

— 10 measurements at 0,40 mg/L performed after the disturbance.

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

7.7.2 Shock & vibration

At the end of each of the following tests, the device shall be inspected for obvious damage. Normal use of the device shall still be possible.

7.7.2.1 Mechanical shock

This test shall be carried out in accordance with EN 60068-2-27 (Test Ea and guidance: shock) with the following conditions:

The device shall be subjected to mechanical shock consisting of three shocks in each direction of three mutually perpendicular axes of the specimen. Each shock shall comprise a 15 g_n severity, 11 milliseconds duration, half sine pulse. This test shall be carried out on a device without its carrying case.

NOTE 1 g_n =10 m/s^2

7.7.2.2 Vibration at fixed frequency

This test shall be carried out in accordance with EN 60068-2-6 (Test Fc - Vibration (sinusoidal)) with the following conditions:

Search for critical frequencies;

— wave form: sinusoidal vibrations;

— frequency range: 5 Hz to 500 Hz;

— constant acceleration: 0,5 g_n;

— sweep mode: logarithmic;

— rate of sweep: 1 octave/min;

— number of directions: 3 orthogonal;

— number of sweeps: 1.

For each critical frequency found, submit the appliance to an endurance test of 30 min with the previously described vibration level.

7.7.2.3 Random vibrations

This test shall be carried out in accordance with EN 60068-2-64 (Test Fh - vibration, broadband random and guidance) with the following conditions:

Frequency range: 10 Hz to 150 Hz.

Acceleration spectral density:

— from 10 Hz to 20 Hz: 0,02 g_n^2/Hz;

— from 20 Hz to 150 Hz: - 3 dB per octave.

Duration: 1 h.

Number of directions: 3 orthogonal.

RMS value of acceleration: 1 g_n;

7.7.2.4 Free fall

This test shall 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: 1 000 mm;

— number of falls: 6; three devices are needed to test for each of the three mutually perpendicular axes.

The position of 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.

At the end of the test the device shall be inspected for obvious damage. Normal use of the device shall still be possible.

7.7.3 Climatic environment

7.7.3.1 Cold

This test shall 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 the test, the device shall be allowed to stabilise at 20 °C for a minimum of 1 hour after which the measurements shall be carried out.

7.7.3.2 Dry heat

This test shall 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 the test the device shall be allowed to stabilise at 20 °C for a minimum of 1 hour after which the measurements shall be carried out.

7.7.3.3 Damp heat (Cyclic)

This test shall 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 reduced 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 stabilizing period before and recovery after the cyclic exposure shall be such that all parts of the device under test are within 3 °C of their final temperature.

7.8 Electrical disturbances

7.8.1 General

For these tests the device shall be switched on and continue to operate normally, a “reset” is acceptable.

The difference between each measurement with the disturbance and the measurement without the disturbance shall be less than 0,04 mg/L for the concentration of 0,40 mg/L.

7.8.2 Electrostatic discharge

An electrostatic discharge generator shall be used with a performance as defined in EN 61000-4-2 (Electrostatic discharge immunity test) with the following test procedure:

— one measurement performed before the disturbance;

— ten measurements performed during the disturbance. During each measurement, a discharge shall be applied to the device for each type of discharge. The time interval between successive discharges shall be at least 10 seconds.

Contact discharge severity level up to and including 6 kV.

Air discharge severity level up to and including 8 kV.

For a device not equipped with a ground terminal, the device shall be fully discharged between discharges. If the device is an integrating instrument, the test pulses shall be continuously applied during the measuring time.

Contact discharges shall be applied on conductive surfaces. Air discharge shall be applied on non-conductive surfaces.

a) Direct application:

In the contact discharge mode to be carried out on conductive surfaces, the electrode shall be in contact with the device under test.

In the air discharge mode on insulated surfaces, the electrode is brought close to the device under test and the discharge occurs by spark.

b) Indirect application:

The discharges shall be applied in the contact mode to coupling planes mounted in the vicinity of the device under test.

7.8.3 Immunity to radiated electric fields

This test shall be carried out in accordance with EN 61000-4-3 (radiated, radio-frequency, electromagnetic field immunity test).

The device under test is irradiated by both horizontal and vertically polarized fields from 4 orthogonal illumination angles.

NOTE The immunity testing against radiations from the digital police communication devices (TETRA) is referred to in Annex C.

Modulation:

All test signals shall be 80 % amplitude modulated with a 1 kHz sine wave.

Test limits and frequencies:

The test limit is in terms of the continuous wave value of the signal; the modulation being applied on top giving peak readings 90 % higher than the continuous wave limit.

For the radiated immunity test, the limit to be used is 10 V/m from 26 MHz to 2 GHz.

The applied radio frequency signal is applied at each test frequency at the test limit for a time long enough to fully operate the device. The frequencies are stepped across incrementally with the step size not exceeding 1 % of the previous frequency:

— new frequency = old frequency x 1,01.

The device shall operate normally throughout the test.

The testing procedure applied by the testing laboratory shall be reported in detail in the report, including defining the measuring cycle and the method used to cover the frequency range.

8 Marking

A breath alcohol test device compliant with this document shall bear a visible and indelible marking comprising:

— reference of this standard;

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

— name of the device and model type;

— serial number;

— if the device does not use a digital format, the specified limits shall be indicated.

If the device is provided with an individual package, then its labelling shall at least include the above marking requirements.

The date of the next calibration shall be noted either on the display or on a tamper-evident label.

9 Operating instructions

Each device shall be supplied with operating instructions. They shall specify at least:

— reference of this standard;

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

— name of the device and model type;

— if the device does not use a digital format, the specified limits shall be indicated;

— technical characteristics: range of concentration, range of temperature, operating conditions, storage conditions, time between two calibrations, etc;

— types of battery or accumulator to be used;

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

— use-related restrictions, if any, of the device.

The manufacturer shall also indicate the maximum value for which the device indicates a zero value:

— the procedures for recharging batteries;

— the times to be observed following the last ingestion of alcohol and/or after having smoked, prior to conducting the measurement;

— breath test procedure;

— environmental and safety information; for example: handling of mouthpieces;

— description of what the device does when the memory reaches its capacity limit.

It shall be possible to verify for maintenance and legal metrological control that the device is correctly adjusted.

Annex A
(informative)

Example of type testing requirements

A.1 Additional information for compliance testing

Manufacturers 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 is as follows:

a) six indicating and ten digital readout devices;

or

b) 12 devices which have both indicating and digital readout systems for display of the result.

NOTE Approved devices should NOT be supplied in a form that allows them to be easily converted from Indicating to Digital format.

On completion of the type approval testing the manufacturers 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 manufacturers should provide the following at the time of testing:

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

d) handbook or a set of written instructions for the use of the device supervisor;

e) written technical description of the device's operation;

f) details of the internal analytical unit used by the device;

g) details of the test and validation programme that the software has undergone; this system should be certified to the EN ISO 9001:2008 standard.

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

A.2 Certification procedure

Reports on devices that successfully complete the testing procedure in the main document can be submitted by the manufacturer to the certification authority who should consider obtaining formal type approval. As a condition of certification the manufacturer should agree:

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

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

c) To ensure that any repair and calibration facility relating to the device is certified to the EN ISO 9001:2008 and open to inspection by the certification authority or accrediting body;

d) To ensure that any update of the operating instructions should be sent to all relevant users including the certification authorities;

e) To label with a version number of any software or firmware.

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

Assistance with training in respect of the device's operation should be made available by the manufacturer or his agent.

Annex B
(informative)

Formula

The concentration of the gas is calculated from the formula of OIML R126:1998:

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:

$$C_{air} = 0{,}04145 \times 10^{-3}\ C_{aqua} \times \exp(0{,}06583t)$$

where

t is the temperature in °C.

For t = 34 °C:

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

Annex C
(informative)

Simulated tetra immunity test

C.1 Test procedure – General

This Annex is intended as a reference source only, and an understanding of the operation of these devices is required before commencing work.

The breath alcohol test device under test is irradiated by both horizontally and vertically polarised fields from four orthogonal illumination angles in turn.

The breath alcohol test device is tested at the eight test frequencies by increasing the field, at each test frequency, from a minimum level of 12 dB down from the appropriate test limit in steps of 3 dB until the test level is achieved. The level at which the threshold of any effect is observed is logged and recorded in the test report.

C.2 Test frequencies

The test frequencies to be used for this test are:

— 380, 385, 390, 395, 400, 405, 410, 415 and 420 MHz.

The tolerance on these frequencies is ± 0,1 MHz.

C.3 Test limits

The test limit is in terms of the peak value of the modulated signal as measured using a peak detector calibrated in terms of the equivalent rms sine wave value that would give the same reading. This is the standard calibration for all peak detector functions on EMC receivers or spectrum analysers.

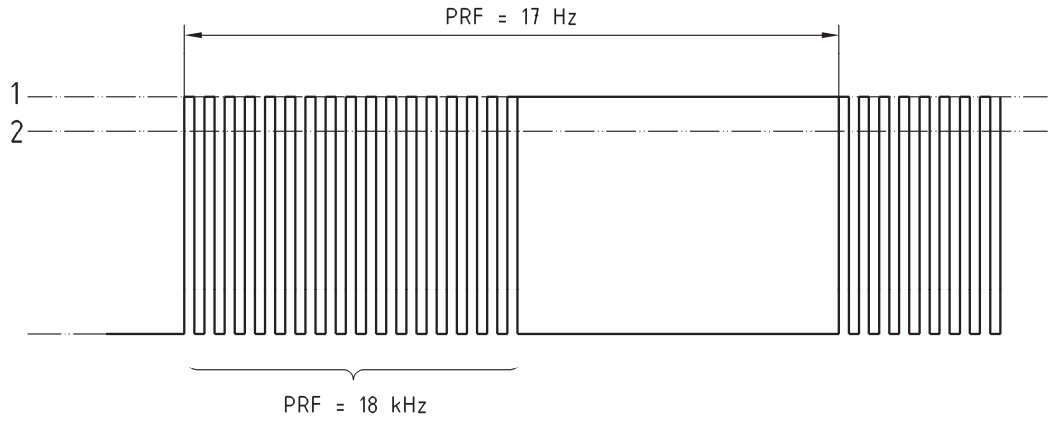
The test limit for devices not operated within vehicles is 65 V/m.

C.4 Modulation

For the test for immunity to TETRA signals:

The modulation to be applied should be:

— an 18 kHz square wave modulation with a depth > 98% additionally gated on and off at 17 Hz. The duty cycle should be 50 %.



Key

1 peak

2 peak RMS = $\frac{\text{Peak}}{\sqrt{2}}$

Figure C.1 — Proposed dual modulation envelope

The test limits are in terms of the peak value of the signal when measured using the peak detector function of the measuring receiver/spectrum analyser. This is calibrated in terms of the equivalent rms value of a sine wave as defined by when measuring a modulated signal, the bandwidth of the measuring receiver should be set wide enough to capture the total energy of the signal. The amplitude reading as measured by the peak detector function is noted. The unknown signal is disconnected and a sine wave signal at the same frequency fed in. Its amplitude is adjusted until the same reading is produced on the measuring receiver. This amplitude is expressed in terms of the rms value of the sine wave e.g. a 1 volt rms sine wave input will give an indicated measurement of 1 volt. This will not change if the signal is switched on and off, the peak reading will still be 1 volt hence the term peak rms. Figure 1 shows the relationship between peak and peak rms.

The characteristics of the equipment to be used to measure the amplitude of the applied susceptibility test are:

— the amplitudes associated with the test limits are based on the peak of the rms envelope over the complete modulation period;

— amplitude measurements should be made in a manner which clearly establishes the peak amplitude of the modulated waveform;

— the measuring instrument must have a fast enough time response to respond to signal amplitude variations; a spectrum analyser may be used;

— the detection, resolution and video bandwidths of the measuring instrument must be wider than the modulating frequency;

— the measurement bandwidth should be increased until the amplitude of the measured signal does not change by more than 1 dB for a factor of three change in bandwidth. This bandwidth setting should then be used for the test. At the proper setting the individual modulation sidebands will not be resolved.

It is important to meet these requirements especially when measuring modulated signals. The use of a spectrum analyser for signal measurement during susceptibility testing does provide advantages over power meters or receivers as it allows a more direct visual check on the quality of the applied signal during the testing. It provides direct indication if the signal source is becoming non-linear, or generating spurious signals. Sometimes, when mismatched, TWT amplifiers have been found to produce parasitic high power oscillations even with no input drive at a frequency which may be well removed from the required test frequency. Regular checks should be made on the quality of the test signal, and presence of spurious signals.

Annex D
(informative)

Software validation and verification

D.1 General

This Annex sets out the requirements for the validation and verification of the software used to control breath alcohol test devices. Testers used by law enforcement agencies must comply with the requirements of the relevant legislation. It is suggested that suppliers of approved equipment separate the software modules that handle the analysis of samples from those that provide the user interface. It is accepted that the analytical software may be generic but the user interface must comply with the need of the relevant national legislation.

D.2 Security

D.2.1 Access levels

D.2.1.1 General

Access to the higher functions of a breath alcohol test device should be security protected, such as by the use of a passcode or electronic hardware key. The level of access that an individual will have should depend on the role played. Three levels of access are required and whilst the precise functions that each level will have access to will be dependant on the design of individual devices, an outline of the basic requirements is:

D.2.1.2 Operator

Run subject tests.

Carry out quality assurance checks.

Print result of last test, if possible.

D.2.1.3 Supervisor

Run subject tests.

Carry out quality assurance checks.

Reset the device after over-due quality assurance test.

Print result of all tests in the memory, if possible.

Download results to an external data system & clear memory.

D.2.1.4 Manufacturer

Run subject tests.

Carry out quality assurance checks.

Open and reseal case.

Reset the device.

Re-calibrate the device.

Print result of all tests in the memory.

Access to any other functions required to maintain the device after repair.

D.2.2 Data protection

All personal data held in a breath alcohol test device should be stored in a way that allows the service to comply with the requirements of any applicable Data Protection laws.

Data stored in a breath alcohol test device may be used to demonstrate to a court or tribunal that the device was operating correctly. It must therefore be held securely and protected against accidental or deliberate alteration. Data should be protected by a check sum or other redundancy check to demonstrate that it has not been altered since it was stored.

If data is transmitted to an external database, there should be a provision in the data transfer protocol to provide assurance that the information received by the external system is identical to that in the breath alcohol test device.

D.2.3 Compliance

A version number should identify the software that controls an approved breath alcohol test device. This version number should appear on all reports generated by the device.

The software installed in breath alcohol test device supplied to users should be identical to that tested as part of the Type Approval process. This will be assured by the use of a digital signature.

The software version may form part of the Approval certificate for a breath alcohol test device. Revision to the software will require a new version number and a new certificate. Software in operational devices should only be changed at the manufacturer' premises, or at a service centre authorised by the manufacturer.

D.2.4 Validation & verification by the manufacturer

Software for breath alcohol test device should be developed by, or on behalf of, the manufacturer using a quality assurance scheme that is accredited to the EN ISO 9001:2008 standard. The manufacturer should provide the testing laboratory with:

a) details of the quality assurance procedures adopted;

b) the results of the validation and verification tests;

c) a list of the data variables classified as:

   1) jurisdiction specific constants;

   2) device specific constants;

   3) occasional adjustments;

   4) calibration factors.

D.2.5 Software testing

Whilst the functional testing described in the main document will provide some assurance that the software performs correctly the test house may carry out additional user-acceptance tests including some or all of the following additional tests:

— repeat of a sub-set of the software developer's validation;

— boundary conditions;

— tests carried out over midnight;

— changes between summer and winter time;

— negative testing to ensure that the device does nothing that it should not do.

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