INTERNATIONAL ROAD SAFETY

Test Lab

EVALUATION•DEVELOPMENT•TEST

Test report for tests according to the European standard EN 15964:2011 Breath alcohol test devices other than single use devices – Requirements and test methods

Approved by CEN on 29 January 2011

201:04

Make/Model

Alcoscan ALP-1

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1 Introduction / Background

This document contains the results from the testing of the breath alcohol test device(s) listed below against the European standard EN 15964:2011.

The tests were conducted for the organisation and on the device(s) given in Table 1:1 below.

TABLE 1:1. Device(s) tested

Manufacturer	Type	Make/Model	Serial No.
Sentech Korea Cor	Alcometer	ALP-1	ALP sam2
Sentech Korea Cor	Alcometer	ALP-1	ALPsam4
Sentech Korea Cor	Alcometer	ALP-1	ALPsam6

The document is based on the European standard EN 15964:2011 *Breath alcohol test devices other than single use devices – Requirements and test methods* approved by CEN (the European Committee for Standardization).

This test report contains the following information:
- name, address and accreditation (if any) of the laboratory which performed the tests;
- type of breath alcohol test device tested including make model and serial numbers;
- organisation for which the test is performed (for example manufacturer, importer, dealer);
- test equipment;
- data, results and conclusions for all tests;
- date and time of the tests;
- summary.

The first four chapters of the report summarize basic information on the testing. Chapter 1 outlines the structure of the report. Chapter 2 lists the normative references referred to in some of the elements of testing. Chapter 3 summarizes the definitions used in EN 15964:2011 and gives general information about the lab conditions and the testing procedures. Chapter 4 gives examples of type testing requirements from Annex A of EN 15964:2011.

Chapters 5 through 9 contain the results from the testing. The basis of these chapters and their subsections is the text from the corresponding sections in EN 15964:2011, each giving the original text as a background, and then presenting clearly whether or not the device meets the requirements of the particular element of testing. This is followed by a part of Annex A of EN 15964:2011, viz. part *A2 Certification procedure*; and Annex B, which contains the formula for the concentration of the gas. Finally, there is a bibliography. Annex C (*Simulated tetra immunity test*) and Annex D (*Software validation and verification*) of EN 15964:2011 are not included here, but the reader is referred to EN 15964:2011.

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*

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*

(EN 15964:2011, 2)

3 Terms and definitions

This chapter gives a summary of the terminology used in this test report. It also contains general information about the test methods and the lab conditions (see further EN 15964:2011 and the normative references listed in chapter 2). Table 3:1, below, summarizes section 3 *Terms and definitions* of EN 15964:2011.

TABLE 3:1. Definitions

Alcohol	Considered to be ethanol
Breath alcohol test device	Device which accepts a breath specimen, measures the concentration and indicates the level of alcohol in that breath specimen.
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.
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
Test mode	Mode in which the device displays the result of a test gas specified in this standard in numerical format.
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.
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.
MPE Maximum Permissible Error	Extreme allowed value of measurement with respect to a test gas concentration defined in this standard.
Verification	Testing process to establish that the breath alcohol test device is operating within the limits of the defined MPE and repeatability.
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.
Mouthpiece	Hygienically wrapped part 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.

General test methods

This section summarizes the metrological characteristics for the tests. These are described in their entirety in Chapter 7 of EN 15964:2011.

Table 3:2 lists the general conditions given in section 7.1 of EN 15964:2011.

TABLE 3:2. General conditions

Adjustment	May be conducted to an alcohol standard immediately prior to testing and if appropriate.
Frequency of tests	The tests shall be performed at the maximum rate authorised by the provided features, taking into account the test equipment possibilities.
Design of the tests	The tests are to be designed in such a way that they check that the device complies with the provisions of this document in the different submitted power supply configurations.
Effect of factors	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.
Performance of tests	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.
Conditions	The tests shall be run at the reference point and the extreme points for each condition listed.
Power supply	The power supply used shall be of the type supplied by the manufacturer.
The device	The tests are to be carried out on a device representative of the devices to be used and without any additional protective means.

Table 3:3 below summarizes the test gas characteristics. Detailed information can be found in section 7.2 of EN 15964:2011.

TABLE 3:3. Test gas characteristics

Type of gas	Wet gas unless otherwise stated for a particular test
Temperature of the gas	34,0 ± 0,5 °C
Relative humidity (at the entrance of the mouth piece)	90 %
Carrier gas	5 % CO_2 (volumetric fractions)
Air as the carrier gas	If the influence of 5 % of CO_2 ≤ 0,01 mg/L for a concentration of 0,4 mg/L of ethanol
Changes in the O_2 concentration of the carrier gas	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 the test gas concentration	≤ 1/3 of MPE
The concentration of ethanol in the wet gas	The concentration of ethanol in the wet gas is calculated on the basis of the formula detailed in Annex B of EN 15964:2011

NOTE For consistency, this document follows EN 15964:2011 in using a decimal comma instead of the decimal point.

Reference conditions

Table 3:4 below lists the reference conditions for the tests given in section 7.3 of EN 15964:2011).

TABLE 3:4. Reference conditions

Ambient temperature	22 ±4 °C
Ambient air humidity	50 ± 30 % RH
Atmospheric pressure	Ambient atmospheric pressure
Test gas flow	0,20 ± 0,05 litres/second
Volume	1,5 l ± 0,1 litres

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.

(EN 15964:2011, 7.3)

Maximum permissible error (MPE)

The maximum permissible errors (MPE) for the different alcohol concentrations defined in section 6.2 of EN 15964:2011 are listed in Table 3:5 below.

TABLE 3:5. Maximum permissible error (MPE)

Nominal alcohol concentration	MPE
0 – 0,20 mg/L	±0,02 mg/L
0,21 – mg/L	±10%

4 Type-testing

This chapter contains additional information for compliance testing from the *Example of type testing requirements* in Annex A of EN 15964:2011. For information on the certification procedure, see A.2 of Annex A below.

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. (EN 15964:2011, Annex A)

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. (EN 15964:2011, 5.1)

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. (EN 15964:2011, 5.2)

Test 5.2

It was checked that the mouthpiece of the breath alcohol test device is designed in such a way that the device can be used under hygienic conditions and that it precludes the possibility of inhaling contaminated air from previous users.

Fail	
Pass	X

The mouthpiece must be disposable.

Fail	
Pass	X

It was made sure that the mouthpiece can be inserted and removed without touching the part that is in contact with the lips of the user.

Fail	
Pass	X

It was checked that the mouthpieces are supplied in individual, easily opened sealed packaging.

Fail	
Pass	X

TOTAL RESULT 5.2				Fail		Pass X
References to attachments, reports or other documentation			No:			
Date of test:	2013-10-21	Signature:	MH			
Comments:						

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. (EN 15964:2011, 5.3)

Test 5.3

Is the device equipped with a battery charger or an external power supply provided as an accessory?

No	X
Yes	

If the answer is ***No***, move on to section 6 below.

If there is such an accessory to the device, it shall be tested for compliance with EN 60335-2-29.

This test was conducted by the following laboratory, which is accredited according to ISO/IEC 17025:2005, and which is an accredited subcontractor for tests according to the European standard EN 60335-2-29.

The breath alcohol test device was tested in order to check that it fulfils the requirements of the European standard EN 60335-2-29 as regards electrical safety.

Fail	
Pass	

TOTAL RESULT 5.3			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2013-12-04	Signature:	MH			
Comments:						

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. (EN 15964:2011, 6.1)

Test 6.1

It was checked that the breath alcohol test device shows clearly when it is ready to accept a breath test.

Fail	
Pass	X

It was checked that the time allowed to give a breath sample, from the point in time when the device indicates that it is ready to accept a breath specimen, was within the limit of 3 to 10 minutes.

Fail	
Pass	X

It was also checked that the breath alcohol test device could be turned off at any time.

Fail	
Pass	X

The device was tested in normal mode in order to check that breath samples were taken automatically when the requirements regarding volume, flowrate, and pressure in 6.6 were met.

Fail	
Pass	X

The device was tested in order to see that it indicates when the internal power supply is becoming exhausted.

Fail	
Pass	X

It was made sure that the battery warning indicator cannot be confused with any other displayed function.

Fail	
Pass	X

It was also checked that at least 10 more breath tests could be taken after the low power indication.

Fail	
Pass	X

The means by which the device is calibrated or adjusted were checked in order to see that they are only accessible to authorized persons.

Fail	
Pass	X

Does the breath alcohol test device have an external power supply?

No	X
Yes	

If the answer is ***No***, move on to section 6.2 below.

It was checked that the device indicates that the power is on when the external power supply is being used.

Fail	
Pass	

It was also checked that the indicator cannot be confused with any other displayed function.

Fail	
Pass	

TOTAL RESULT 6.1				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-10-21	Signature:	AW				
Comments:							

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. (EN 15964:2011, 6.2)

6.3 Measurement range

Devices shall be capable of measuring alcohol concentrations in the range 0,00 mg/L to 2,00 mg/L. (EN 15964:2011, 6.3)

Test 6.3

The breath alcohol test device was tested in order to control that it is capable of measuring alcohol concentrations according to the MPE in the range from 0,00 mg/L to 2,00 mg/L.

It was first checked that the device indicated a 0,00 mg/L reading (or 0 – 0,02 mg/L) when tested with a nominal alcohol concentration of 0,00 mg/L.

Fail	
Pass	X

It was then checked that the device displays a result between 1,80 mg/L and 2,20 mg/L when tested with a nominal alcohol concentration of 2,00 mg/L.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	°C		RH		
Reference meter No:	056		056		
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Simulator No:	004
Alcohol concentration 0,00 mg/L Batch No:	Dest Water
Alcohol concentration 2,00 mg/L Batch No:	534

TOTAL RESULT 6.3			Fail		Pass X
References to attachments, reports or other documentation			No:		
Date of test:	2014-01-07	Signature:	MH		
Comments:					

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. (EN 15964:2011, 6.4.1)

Test 6.4.1

The breath alcohol test device was tested in order to see that it is capable of use in the temperature range between -5 °C and +40 °C, or in a wider temperature range given by the manufacturer.

The device was tested for the following temperature range given by the manufacturer: -5°C +40°C °C.

The temperature range given by the manufacturer has to be -5 °C to +40 °C or wider.

Fail	
Pass	X

It was checked that the device reports results according to the MPE when tested in the temperature range given above. (See further 7.6.2 below, where the test is described in detail.)

Fail	
Pass	X

TOTAL RESULT 6.4.1			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2013-10-08	Signature:	MH			
Comments:						

6.4.2 Humidity

The devices shall be capable of use up to 93 % RH. (EN 15964:2011, 6.4.2)

Test 6.4.2

The breath alcohol test device was tested in order to check that it could be used in humidity up to 93 % RH.

Fail	
Pass	X

TOTAL RESULT 6.4.2			Fail		Pass	
References to attachments, reports or other documentation			No:			
Date of test:	2013-12-05	Signature:	AW			
Comments:						

6.5 Ease of use

In normal mode, the device shall not be influenced in its operation by user error. (EN 15964:2011, 6.5)

Test 6.5

The device was tested in various ways in order to make sure that it is easy to use and that the test results cannot be influenced by user errors.

Fail	
Pass	X

TOTAL RESULT 6.5			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2014-02-14	Signature:	MH			
Comments:						

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.

(EN 15964:2011, 6.6)

Test 6.6

The device was tested in order to check that it can identify an acceptable breath specimen on the basis of the pressure, volume, and flowrate.

It was first checked that the normal sampling configuration of the device given by the manufacturer complies with the requirements of this standard (see Table 6.6:1).

TABLE 6.6:1

	Requirements in this standard	Normal sampling configuration given by the manufacturer	Fail	Pass
Minimum volume	1,2 litres	1,2 litres		X
Minimum flowrate	0,15 litres/second	0,15 litres/second		X
Maximum pressure	30 hPa at a flowrate of 0,2 litres/second	30 hPa at a flowrate of 0,2 litres/second		X

The device was then tested in order to see that it works according to these requirements.

It was first checked that the device accepts a test with the given minimum volume and the given minimum flowrate, and that, after the test, it automatically resets and indicates that it is ready to accept a new test.

Fail	
Pass	X

It was then checked that the device does not accept a test with the given minimum flowrate and a volume of 1,1 litres, but that it gives a signal that it failed to take the test, and then automatically resets and indicates that it is ready to accept a new test.

Fail	
Pass	X

It was then checked that the device does not accept a test with the given minimum volume and a flowrate of 0,14 litres/second, but that it gives a signal that it failed to take the test, and then automatically resets and indicates that it is ready to accept a new test.

Fail	
Pass	X

It was also checked that the device, with the mouthpiece attached, accepts a breath sample with a flowrate of 0,2 litres/second and the maximum pressure given, and that it automatically resets after the test and indicates that it is ready to accept a new test.

Fail	
Pass	X

Finally it was checked that the device, with the mouthpiece attached, does not accept a test with a flowrate of 0,2 litres/second and a pressure of 31 hPa, but that it gives a signal that it failed to take the test, and then automatically resets and indicates that it is ready to accept a new test.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	20°C		30%RH		
Reference meter No:	056		056		
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
PLC controlled calibration syringe No:	070
Meter for pressure No:	046
Simulator No:	004
Alcohol concentration 0,00 mg/L Batch No:	Dest water

TOTAL RESULT 6.6			Fail		Pass X
References to attachments, reports or other documentation			No:		
Date of test:	2014-02-14	Signature:	MH		
Comments:					

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. (EN 15964:2011, 6.7.1)

Test 6.7.1

It was checked that the results are displayed in terms of mg/L or an equivalent unit as the unit of measurement.

Fail	
Pass	X

Units of measurement used by the device:
mg/l

TOTAL RESULT 6.7.1			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2013-12-04	Signature:	AW			
Comments:						

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. (EN 15964:2011, 6.7.2)

Test 6.7.2

The device was tested with an alcohol concentration of 0,40 mg/l in order to check that the analytical results of tests made with the device in *test mode* are rounded to the nearest 0,001 mg/L or to an equivalent unit. (See 6.7.1 above for units of measurement used by the device.)

Fail	
Pass	X

The device was also tested with an alcohol concentration of 0,40 mg/l in order to check that the analytical results of tests made with the device in *normal mode* are rounded down to the nearest 0,01 mg/L or to an equivalent unit (see 6.7.1 above for units of measurement used by the device), and to the appropriate band when in indicating format.

Fail	
Pass	X

CLIMATIC CONDITIONS				
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH	
Verified value:	20°C		35%RH	
Reference meter No:	056		056	
Does the laboratory meet the climatic requirements?	Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	086
Simulator No:	004
Alcohol concentration 0,40 mg/L Batch No:	525

TOTAL RESULT 6.7.2				Fail		Pass X
References to attachments, reports or other documentation			No:			
Date of test:	2013-12-04	Signature:	AW			
Comments:						

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. (EN 15964:2011, 6.7.3)

Test 6.7.3

It was checked that the units of measurement are shown in the vicinity of the results.

Fail	
Pass	X

In accordance with this standard, this device presents the measurement results in either or both of the following 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 content is expressed in a quantitative format.

X	

For devices that use both formats, it was checked that the display cannot be converted from indicating format to digital format in normal mode.

Fail	
Pass	X
Not applicable	

It was checked that the measurement results can be easily read in all levels of ambient light.

Fail	
Pass	X

It was also checked that the results are shown in the display for at least 60 seconds, or that it is possible to recall the result of the last test.

Fail	
Pass	X

Finally it was checked that a new test can be initiated while the results of a previous test is being shown.

Fail	
Pass	X

TOTAL RESULT 6.7.3			Fail		Pass X
References to attachments, reports or other documentation			No:		
Date of test:	2013-11-12	Signature:	AW		
Comments:					

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). (EN 15964:2011, 6.8)

Test 6.8

It was checked that the measurement results can be adjusted to an alcohol standard by means of instructions and equipment specified by the manufacturer.

Fail	
Pass	X

The device was tested in order to make sure that the time required between adjustments was not less than three months (see further 7.4.4 below).

Fail	
Pass	X

It was also checked that the results were stable during the time period between adjustments (see further 7.4.4 below).

Fail	
Pass	X

TOTAL RESULT 6.8			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2013-10-29	Signature:	AW			
Comments:						

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. (EN 15964:2011, 6.9)

Test 6.9

The start-up time of the device was tested at the upper and lower temperatures of the operating temperature range.

The device was tested in the following temperature range given by the manufacturer (cf. 6.4 above): -5°C +40°C °C

Low ambient temperature

The device was kept at the lowest ambient temperature given above for at least an hour and then tested in order to see that it accepts a breath sample within 3 minutes from having been switched on.

Fail	
Pass	X

High ambient temperature

The device was kept at the highest ambient temperature given above for at least an hour and then tested in order to see that it accepts a breath sample within 3 minutes from having been switched on.

Fail	
Pass	X

CLIMATIC CONDITIONS				
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH	
Verified value:	23°C		35RH	
Reference meter No:	056		056	
The variation in temperature in the climatic chamber is ±2 °C.				
Does the laboratory meet the climatic requirements?	Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Reference meter time No:	045
Climatic chamber No:	089

TOTAL RESULT 6.9			Fail		Pass X
References to attachments, reports or other documentation			No:		
Date of test:	2013-10-01	Signature:	MH		
Comments:					

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.

(EN 15964:2011, 6.10)

Test 6.10

The device was tested with different alcohol concentrations in order to check that it meets the requirements as regards the maximum recovery time allowed between tests.

The device was first tested with an alcohol concentration of 0,00 mg/L in order to check that the device signalled that it was ready for, and that it was able to receive, a second test within 1 minute from the first test at nominal alcohol concentrations ≤ 0,05 mg/L.

Fail	
Pass	X

The device was then tested with an alcohol concentration above 0,05 mg/L but ≤ 0,40 mg/L in order to check that the device signalled that it was ready for, and that it was able to receive, a second test within 2 minutes from the first test at nominal alcohol concentrations > 0,05 mg/L and ≤ 0,40 mg/L (see the traceability table below for the exact alcohol concentration used here).

Fail	
Pass	X

Finally the device was tested with an alcohol concentration above 0,40 mg/L but ≤ 2,00 mg/L in order to check that the device signalled that it was ready for, and that it was able to receive, a second test within 3 minutes from the first test at nominal alcohol concentrations > 0,40 mg/L and ≤ 2,00 mg/L (see the traceability table below for the exact alcohol concentration used here).

Fail	
Pass	X

CLIMATIC CONDITIONS						
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH			
Verified value:	25°C		30%RH			
Reference meter No:	056		056			
Does the laboratory meet the climatic requirements?			Fail		Pass	X

TRACEABILITY			
The following equipment was used:			
Reference meter time No:			045
PLC controlled calibration syringe No:			070
Simulator No:			004, 0,61
Alcohol concentration 0,00 mg/L Batch No:			Dest Water
Alcohol concentration, mg/L:	0,10	Batch No:	523
Alcohol concentration, mg/L:	0,40	Batch No:	518

TOTAL RESULT 6.10				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-10-08	Signature:	MH				
Comments:							

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. (EN 15964:2011, 6.11)

Test 6.11

The internal power supply of the device was tested at the extreme points of the operating temperature range of the device given by the manufacturer making sure that the device could perform 75 consecutive measurements from switch on to result displayed without recharging the internal battery at these ambient conditions.

The device was first tested with 75 consecutive breath specimens at an alcohol level of 0,10 mg/L at the lowest temperature given by the manufacturer checking that the internal battery did not need recharging (see also 6.4.1 above).

Fail	
Pass	X

Temperature used for this test: -5°C °C

The device was then tested with 75 consecutive breath specimens at an alcohol level of 0,10 mg/L at the highest temperature given by the manufacturer checking that the internal battery did not need recharging (see also 6.4.1 above).

Fail	
Pass	X

Temperature used for this test: 40°C °C

CLIMATIC CONDITIONS				
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH	
Verified value:	23°C		35%RH	
Reference meter No:	056		056	
The variation in temperature in the climatic chamber is ±2 °C.				
Does the laboratory meet the climatic requirements?	Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Climatic chamber No:	089
Simulator No:	059
Alcohol concentration 0,10 mg/L Batch No:	521

TOTAL RESULT 6.11				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-09-26	Signature:	MH				
Comments:							

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). (EN 15964:2011, 6.12)

Test 6.12

Is the device equipped with a data memory?

No	
Yes	X

If the answer is ***No***, move on to 6.13 below.

Devices with a permanent data memory were checked in order to see that the downloaded data included at least the following information:

	Fail	Pass
Serial number of the device		X
Date and time of the test		X
Type of test (e.g. normal mode)		X
Measurement result or an indication that the test was not completed		X
An indication when a test was not completed		X

If applicable, it was also checked that the downloaded data included the unit of measurement.

Fail	
Pass	X
Not applicable	

The device was also tested in order to see that it gives a warning when the memory is approaching the limit of its capacity.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	23°C		35%RH		
Reference meter No:	056		056		
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TOTAL RESULT 6.12			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2014-03-20	Signature:	AW			
Comments:						

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. (EN 15964:2011, 6.13)

Test 6.13

The device was checked as regards its general functions in order to make sure that it performs in accordance with the manufacturer's information.

Fail	
Pass	X

The following deviation(s) from the manufacturer's information was noted:

TOTAL RESULT 6.13				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2014-03-20	Signature:	AW				
Comments:							

7 Metrological characteristics for testing

7.1 General conditions

The general conditions for testing are summarized in Table 3:2 of chapter 3 (see also 7.1 of EN 15964:2011).

7.2 Test gas characteristics

The test gas characteristics are listed in Table 3:3 of chapter 3 (see also 7.2 of EN 15964:2011).

7.3 Reference conditions

The reference conditions for the tests are given in Table 3:4 of chapter 3 (see also 7.3 of EN 15964:2011).

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. (EN 15964:2011, 7.4.1)

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. (EN 15964:2011, 7.4.2)

Test 7.4.2

The device was tested with 10 measurements with the nominal alcohol concentration of 0,00 mg/L; 20 measurements with 0,10 mg/L, 0,25 mg/L, 0,40 mg/L; and 10 measurements with 0,60 mg/L, checking that all results comply with the MPE (cf. 6.2). The tests were conducted at the reference conditions (cf. 3, Table 3:4).

The device was first tested 10 times with a nominal alcohol concentration of 0,00 mg/L checking that the reported results were in the range 0,00 – 0,02 mg/L.

Fail	
Pass	X

The device was then tested 20 times with a nominal alcohol concentration of 0,10 mg/L checking that the results comply with the requirements as regards the MPE (0,08 mg/L – 0,12 mg/L).

Fail	
Pass	X

It was also checked that the average of these results comply with the requirements as regards the MPE.

Fail	
Pass	X

The device was then tested 20 times with a nominal alcohol concentration of 0,25 mg/L checking that the results comply with the requirements as regards the MPE (0,225 mg/L – 0,275 mg/L).

Fail	
Pass	X

It was also checked that the average of these results comply with the requirements as regards the MPE.

Fail	
Pass	X

The device was then tested 20 times with a nominal alcohol concentration of 0,40 mg/L checking that the results comply with the requirements as regards the MPE (0,36 mg/L – 0,44 mg/L).

Fail	
Pass	X

It was also checked that the average of these results comply with the requirements as regards the MPE.

Fail	
Pass	X

The device was then tested 10 times with a nominal alcohol concentration of 0,60 mg/L checking that the results comply with the requirements as regards the MPE (0,54 mg/L – 0,66 mg/L).

Fail	
Pass	X

It was also checked that the average of these results comply with the requirements as regards the MPE.

Fail	
Pass	X

Are digital values required above 0,60 mg/L?

No	
Yes	X

If ***Yes***, go on to **Alternative A** below.
If ***No***, go on to **Alternative B** below.

Alternative A. Digital values required above 0,60 mg/L

Maximum value according to the manufacturer: 2,00 mg/L

The device was tested 10 times with a nominal alcohol concentration corresponding to 90 % of the of maximum value given by the manufacturer checking that the reported results comply with the MPE defined in 6.2 above.

Fail	
Pass	X

It was also checked that the average of these results comply with the requirements as regards the MPE.

Fail	
Pass	X

Alternative B. Digital values not required above 0,60 mg/L

The device was tested 10 times with a nominal alcohol concentration of 2,00 mg/L checking that the device gives an indication at this value.

Fail	
Pass	

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	24°C		30% RH		
Reference meter No:	056		056		
Does the laboratory meet the climatic requirements?		Fail		Pass	

TRACEABILITY			
The following equipment was used:			
Simulator pump No:			083
Reference meter time No:			045
Simulator No:			004, 005, 061,
Alcohol concentration 0,00 mg/L Batch No:			Dest water
Alcohol concentration 0,10 mg/L Batch No:			523
Alcohol concentration 0,25 mg/L Batch No:			522
Alcohol concentration 0,40 mg/L Batch No:			518
Alcohol concentration 0,60 mg/L Batch No:			433
Alcohol concentration 2,00 mg/L Batch No:			476
Alcohol concentration, mg/L:		Batch No:	

TOTAL RESULT 7.4.2				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-10-15		Signature:		MH		
Comments:							

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%.

(EN 15964:2011, 7.4.3)

Test 7.4.3

The device was first tested 20 times at the reference conditions with a nominal alcohol concentration of 0,10 mg/L checking that all reported results comply with the requirements as regards the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

It was then checked that the average of these results comply with the requirements as regards the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

It was also checked that the results comply with the requirements as regards the maximum standard deviation for repeatability of 0,012 mg/L.

Fail	
Pass	X

The device was then tested 20 times at the reference conditions with a nominal alcohol concentration of 0,40 mg/L checking that all reported results comply with the requirements as regards the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

It was then checked that the average of these results comply with the requirements as regards the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

It was also checked that these results comply with the requirements as regards the maximum coefficient of variation for repeatability of 3%.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	°C		RH		
Reference meter No:					
Does the laboratory meet the climatic requirements?	Fail		Pass		

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Simulator No:	005
Alcohol concentration 0,10 mg/L Batch No:	523
Alcohol concentration 0,40 mg/L Batch No:	518

TOTAL RESULT 7.4.3			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2013-10-16	Signature:	MH			
Comments:						

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). (EN 15964:2011, 7.4.4)

Test 7.4.4

The breath alcohol test device was calibrated and adjustments carried out (if needed) at the beginning of this test by the manufacturer or according to the manufacturer's instruction.

Calibrated by:
Sentech

The device was exposed to a set of 5 breath samples with a nominal alcohol concentration of 0,10 mg/L once a week for 3 months, checking that the result from each individual test complies with the MPE (cf. 6.2).

Fail	
Pass	X

The averages of each set were also calculated and compared, and it was checked that the maximum difference between the averages was 0,020 mg/L.

Fail	
Pass	X

It was also checked that the averages of each set comply with the requirements as regards the MPE (i.e. 0,08 mg/L – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

At the same time, the device was also exposed to a set of 5 breath samples with a nominal alcohol concentration of 0,40 mg/L once a week for 3 months, checking that the result from each individual test complies with the MPE (i.e. 0,36 mg/L – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

The averages of each of these sets were also calculated and compared, and it was checked that the maximum difference between these averages was 0,020 mg/L.

Fail	
Pass	X

Finally it was checked that these averages comply with the requirements as regards the MPE (i.e. 0,36 mg/L – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

CLIMATIC CONDITIONS				
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH	
Verified value:	23°C		30% RH	
Reference meter No:	056		056	
Does the laboratory meet the climatic requirements?	Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Simulator No:	061, 004, 059, 074
Alcohol concentration 0,10 mg/L Batch No:	495, 512, 523, 524
Alcohol concentration 0,40 mg/L Batch No:	504, 518, 527

TOTAL RESULT 7.4.4				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-10-29	Signature:	AW				
Comments:							

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. (EN 15964:2011, 7.5.1)

Test 7.5.1

The breath alcohol test device was exposed to a cyclic test with ten sets of alternating high and low alcohol concentrations (1,00 mg/L and 0,10 mg/L) at the reference conditions.

It was checked that the results of the tests with 0,10 mg/L comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

It was also checked that the results of the tests with 1,00 mg/L comply with the MPE (i.e. 0,9 – 1,1 mg/L, cf. 6.2).

Fail	
Pass	X

CLIMATIC CONDITIONS				
Limit values:	Temperature 18-26 °C	Ambient air humidity 20-80 % RH		
Verified value:	22°C	30% RH		
Reference meter No:	056	056		
Does the laboratory meet the climatic requirements?		Fail		Pass X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Simulator No:	005, 004
Alcohol concentration 1,00 mg/L Batch No:	501
Alcohol concentration 0,10 mg/L Batch No:	524

TOTAL RESULT 7.5.1			Fail		Pass X
References to attachments, reports or other documentation			No:		
Date of test:	2013-10-22	Signature:	MH		
Comments:					

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. (EN 15964:2011, 7.5.2)

Test 7.5.2

The breath alcohol test device was kept in an ambient temperature of -5 °C for at least an hour. It was then tested at this ambient temperature with 10 breath samples with a nominal alcohol concentration of 0,00 mg/L at the highest frequency permitted by the device checking that all results comply with the MPE (i.e. 0,00 mg/L – 0,02 mg/L, cf. 6.2).

Fail	
Pass	X

The device was also tested under these ambient conditions with five tests with a nominal alcohol concentration of 0,40 mg/L checking that the results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

CLIMATIC CONDITIONS				
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH	
Verified value:	23°C		35% RH	
Reference meter No:	056		056	
The variation in temperature in the climatic chamber is ±2 °C.				
Does the laboratory meet the climatic requirements?	Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Climatic chamber No:	089
Simulator No:	073, 005
Alcohol concentration 0,00 mg/L Batch No:	Dest Water
Alcohol concentration 0,40 mg/L Batch No:	527

TOTAL RESULT 7.5.2			Fail		Pass X
References to attachments, reports or other documentation			No:		
Date of test:	2013-10-29	Signature:	MH		
Comments:					

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. (EN 15964:2011, 7.6.1)

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. (EN 15964:2011, 7.6.2)

Test 7.6.2

The device was tested in a climatic chamber in a temperature range from -5°C to +40°C, or in a wider temperature range stated by the manufacturer.

This device was tested in the following temperature range given by the manufacturer: -5°C +40°C °C.

The device was first tested with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2) at these ambient conditions.

Fail	
Pass	X

The device was also tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2) at these ambient conditions.

Fail	
Pass	X

The device was then exposed to the lowest ambient temperature for at least three hours and tested under these ambient conditions with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L checking that all test results comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was also tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L at the lowest temperature checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2) at these ambient conditions.

Fail	
Pass	X

The device was then exposed to the highest ambient temperature for at least three hours and tested under these ambient conditions with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L checking that all test results comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was also tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L at the highest temperature checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2) at these ambient conditions.

Fail	
Pass	X

Finally the device was again tested at the reference conditions (cf. 3, Table 3:4) with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L checking that all test results comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2) at these ambient conditions.

Fail	
Pass	X

The device was also tested again with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2) at these ambient conditions.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	25°C		35% RH		
Reference meter No:	056		056		
The variation in temperature in the climatic chamber is ±2 °C.					
Does the laboratory meet the climatic requirements?	Fail		Pass	X	

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Climatic chamber No:	089
Simulator No:	059, 073, 061
Alcohol concentration 0,10 mg/L Batch No:	521, 523
Alcohol concentration 0,40 mg/L Batch No:	504, 518

TOTAL RESULT 7.6.2				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-10-03	Signature:	MH				
Comments:							

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.

(EN 15964:2011, 7.6.3)

Test 7.6.3

The device was tested for ambient relative humidity according to EN 60068-2-78.

The device was first tested with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,08– 0,12 mg/L, cf. 6.2) at these ambient conditions.

Fail	
Pass	X

The device was also tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2) at these ambient conditions.

Fail	
Pass	X

The device was then exposed to an ambient relative humidity of 93 % at 40 °C for at least 24 hours and then tested at these ambient conditions with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L checking that all test results comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was also tested at the high relative humidity with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

After having been exposed to high relative humidity the device was kept at the reference conditions (cf. 3, Table 3:4) for at least three hours and then tested at the reference conditions with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L checking that all test results comply with the MPE (i.e. 0,08– 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was also tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L at the reference conditions checking that the test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

CLIMATIC CONDITIONS				
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH	
Verified value:	22°C		30% RH	
Reference meter No:	056		056	
The variation in temperature in the climatic chamber is ±2 °C.				
Does the laboratory meet the climatic requirements?	Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Climatic chamber No:	089
Simulator No:	059, 004, 005, 074 061
Alcohol concentration 0,10 mg/L Batch No:	529, 535
Alcohol concentration 0,40 mg/L Batch No:	532

TOTAL RESULT 7.6.3			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2013-12-05	Signature:	MH			
Comments:						

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. (EN 15964:2011, 7.6.4)

Test 7.6.4

The device was tested for the influence of interfering substances.

The device was first tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and acetone at a nominal value for vapour mass concentration of 0,50 mg/L checking that either all the test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2), or else that the device does not give a result.

Fail	
Pass	X

The device was then tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and carbon monoxide at a nominal value for vapour mass concentration of 0,20 mg/L checking that either all the test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2), or else that the device does not give a result.

Fail	
Pass	X

Finally the device was tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and methane (hydrocarbon) at a nominal value for vapour mass concentration of 0,30 mg/L checking that either all the test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2), or else that the device does not give a result.

Fail	
Pass	X

CLIMATIC CONDITIONS						
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH			
Verified value:	23°C		40% RH			
Reference meter No:	056		056			
Does the laboratory meet the climatic requirements?		Fail		Pass	X	

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Volume syringe No:	007
Simulator No:	004
Alcohol concentration 0,40 mg/L Batch No:	532

TOTAL RESULT 7.6.4				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-12-10	Signature:	AW				
Comments:							

7.6.5 Influence factors exhalation parameters

7.6.5.1 General

The following test shall be performed under normal operating conditions.

(EN 15964:2011, 7.6.5.1)

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. (EN 15964:2011, 7.6.5.2)

Test 7.6.5.2

The device was tested at the reference conditions (cf. 3, Table 3:4) with a breath test with a volume of 1,10 litres lasting 5 seconds checking that it does not accept breath tests below the minimum volume of 1,2 litres.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C	Ambient air humidity 20-80 % RH			
Verified value:	21°C	28% RH			
Reference meter No:	056	056			
Does the laboratory meet the climatic requirements?			Fail		Pass X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
PLC controlled calibration syringe No:	070

TOTAL RESULT 7.6.5.2				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2014-02-18	Signature:	MH				
Comments:							

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. (EN 15964:2011, 7.6.5.3)

Test 7.6.5.3

The breath alcohol test device was tested in order to check the influence of volume and time during the breath exhalation.

Volume 1,5 litres; Exhalation time 5 seconds:

The device was first tested with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L and a volume of 1,5 litres for 5 seconds at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,08– 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was then tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and a volume of 1,5 litres for 5 seconds at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,36– 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

Volume 4,5 litres; Exhalation time 15 seconds:

The device was first tested with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L and a volume of 4,5 litres for 15 seconds at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,08– 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was then tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and a volume of 4,5 litres for 15 seconds at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,36– 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	21°C		30% RH		
Reference meter No:	056		056		
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Reference meter time No:	045
Simulator pump No:	083
PLC controlled calibration syringe No:	070
Simulator No:	005, 074
Alcohol concentration 0,10 mg/L Batch No:	524, 535
Alcohol concentration 0,40 mg/L Batch No:	527, 547

TOTAL RESULT 7.6.5.3				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2014-02-18	Signature:	MH				
Comments:							

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. (EN 15964:2011, 7.6.5.4)

Test 7.6.5.4

The breath alcohol test device was tested as regards the influence of flowrate and time during the breath exhalation.

Volume 1,5 L; Exhalation time 10 s (flowrate at 0,15 L/s):

The device was first tested with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L and a volume of 1,5 litres for 10 seconds with a flowrate of 0,15 litres per second at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was then tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and a volume of 1,5 litres for 10 seconds with a flowrate of 0,15 litres per second at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

Volume 3 L; Exhalation time 15 s (flowrate at 0,2 L/s):

The device was first tested with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L and a volume of 3 litres for 15 seconds with a flowrate of 0,2 litres per second at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was then tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and a volume of 3 litres for 15 seconds with a flowrate of 0,2 litres per second at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

Volume 4,5 L; Exhalation time 7,5 s (flowrate at 0,6 L/s):

The device was first tested with 10 breath samples with a nominal alcohol concentration of 0,10 mg/L and a volume of 4,5 litres for 7,5 seconds with a flowrate of 0,6 litres per second at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,08 – 0,12 mg/L, cf. 6.2).

Fail	
Pass	X

The device was then tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and a volume of 4,5 litres for 7,5 seconds with a flowrate of 0,6 litres per second at the reference conditions (cf. 3, Table 3:4) checking that all test results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C	Ambient air humidity 20-80 % RH			
Verified value:	22°C	28% RH			
Reference meter No:	056	056			
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Reference meter time No:	045
Simulator pump No:	083
PLC controlled calibration syringe No:	070
Simulator No:	074, 061, 059
Alcohol concentration 0,10 mg/L Batch No:	544, 548
Alcohol concentration 0,40 mg/L Batch No:	547, 549

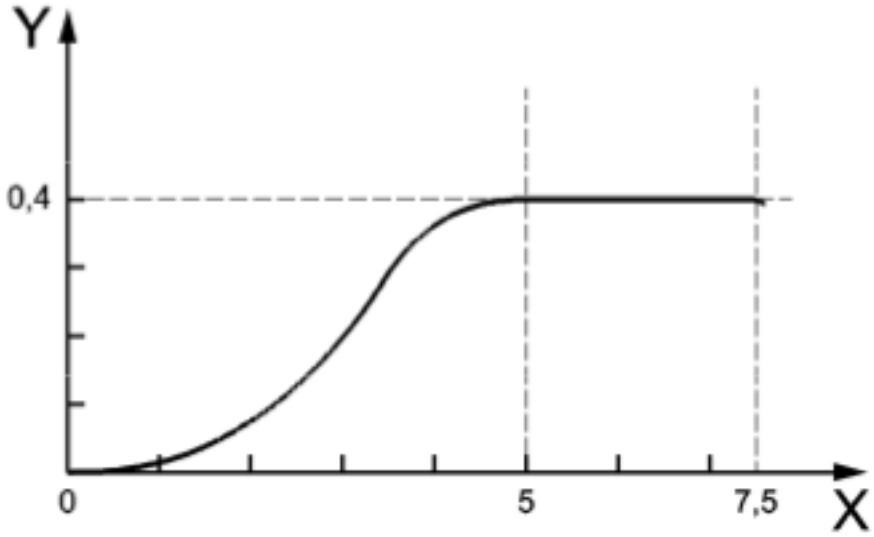
TOTAL RESULT 7.6.5.4			Fail		Pass X
References to attachments, reports or other documentation			No:		
Date of test:	2014-02-25	Signature:	MH		
Comments:					

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. (EN 15964:2011, 7.6.5.5)

Test 7.6.5.5

The device was tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L and a volume of 1,5 litres for 7,5 seconds, each breath sample reaching their plateau level after 5 seconds in order to check that the results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2) also when there is a variation in the alcohol concentration during the breath exhalation.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	21°C		30% RH		
Reference meter No:	056		056		
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Reference meter time No:	045
Simulator pump No:	083
Nanopuls Profiler No:	084
Simulator No:	073
Alcohol concentration 0,40 mg/L Batch No:	527

TOTAL RESULT 7.6.5.5				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-11-05		Signature:	MH			
Comments:							

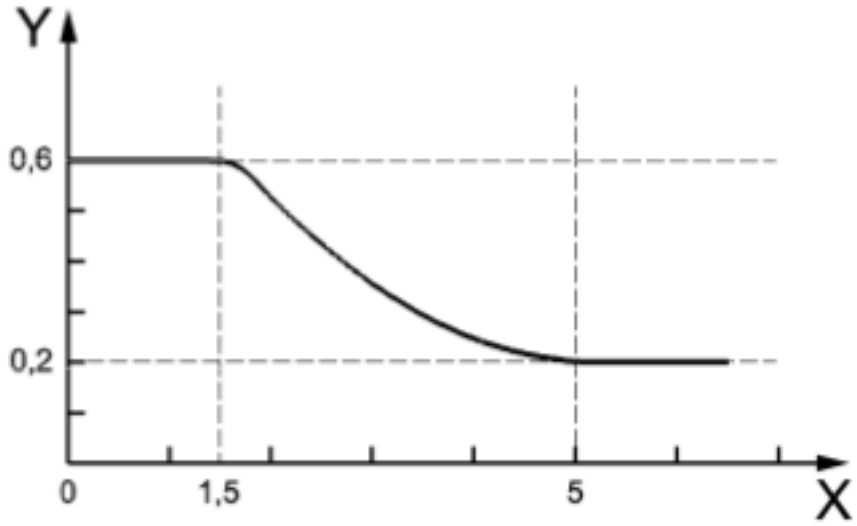
7.6.5.6 Influence of pressure and flowrate during the breath exhalation

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. (EN 15964:2011, 7.6.5.6)

Test 7.6.5.6

The device was tested with 10 breath samples of 3 litres with a nominal alcohol concentration of 0,40 mg/L that start out with a flowrate of 0,6 litres/second and then, after 1,5 seconds, decreases to 0,2 litres/second in order to check that the results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2) also when the flowrate decreases during the breath exhalation.

Fail	
Pass	X

CLIMATIC CONDITIONS						
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH			
Verified value:	21°C		30% RH			
Reference meter No:	056		056			
Does the laboratory meet the climatic requirements?		Fail		Pass	X	

TRACEABILITY	
The following equipment was used:	
Reference meter time No:	045
Simulator pump No:	083
Nanopuls Profiler No:	084
Simulator No:	073
Alcohol concentration 0,40 mg/L Batch No:	527

TOTAL RESULT 7.6.5.6				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-11-25	Signature:	AW				
Comments:							

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. (EN 15964:2011, 7.6.6)

Test 7.6.6

The breath alcohol test device was tested for voltage variation. The device was first tested at its normal voltage with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L checking that all results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

The voltage was then reduced to the level at which the device indicated a power supply warning, and tested, at this level, with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L checking that all results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

Finally the voltage was reduced to a level at which the device ceased to function and then increased just above this level, and tested, at this level, with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L checking that all results comply with the MPE (i.e. 0,36 – 0,44 mg/L, cf. 6.2).

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	20°C		30% RH		
Reference meter No:	056		056		
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Simulator No:	059, 074
Alcohol concentration 0,40 mg/L Batch No:	549

TOTAL RESULT 7.6.6				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2014-02-26	Signature:	MH				
Comments:							

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. (EN 15964:2011, 7.6.7)

Test 7.6.7

At an ambient temperature of -5 °C and with no external power supply connected, the device was tested with 75 consecutive breath specimens at an alcohol level of 0,10 mg/L in order to control that it can perform 75 consecutive measurements from switch on to result displayed without recharging the internal battery, and each measurement fulfilling the MPE (i.e. 0,08 – 0,12 mg/L).

Fail	
Pass	X

CLIMATIC CONDITIONS						
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH			
Verified value:	22°C		35% RH			
Reference meter No:	056		056			
The variation in temperature in the climatic chamber is ±2 °C.						
Does the laboratory meet the climatic requirements?	Fail		Pass	X		

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Climatic chamber No:	089
Simulator No:	059
Alcohol concentration 0,10 mg/L Batch No:	521

TOTAL RESULT 7.6.7				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-09-26	Signature:	MH				
Comments:							

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. (EN 15964:2011, 7.7.1)

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. (EN 15964:2011, 7.7.2.)

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

(EN 15964:2011, 7.7.2.1)

Test 7.7.2.1

The device was subjected to the mechanical disturbance *mechanical shock* in accordance with this standard and the European standard EN 60068-2-27.

The test *mechanical shock* was conducted by the following laboratory, which is accredited according to ISO/IEC 17025:2005 and which is an accredited subcontractor for tests according to the European standard EN 60068-2-27:

Innventia

Before and after the mechanical disturbance *mechanical shock*, the device was tested with a set of 10 breath samples with a nominal alcohol concentration of 0,40 mg/L. The mean values of each set were calculated and compared in order to see that the difference between them was less than 0,040 mg/L, and that the device thus fulfils the requirements of this standard and the European standard EN 60068-2-27 as regards mechanical shock.

Fail	
Pass	X

After the mechanical disturbance *mechanical shock*, the breath alcohol test device was also inspected for any visual damage affecting its functionality.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	24°C		25% RH		
Reference meter No:					
Does the laboratory meet the climatic requirements?	Fail		Pass	X	

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Simulator No:	074
Alcohol concentration 0,40 mg/L Batch No:	527

TOTAL RESULT 7.7.2.1				Fail		Pass	X
References to attachments, reports or other documentation				No:	273905 A		
Date of test:	2013-12-16	Signature:	MH				
Comments:							

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. (EN 15964:2011, 7.7.2.2)

Test 7.7.2.2

The device was subjected to the mechanical disturbance *vibration at fixed frequency* in accordance with this standard and the European standard EN 60068-2-6.

The test *vibration at fixed frequency* was conducted by the following laboratory, which is accredited according to ISO/IEC 17025:2005 and which is an accredited subcontractor for tests according to the European standard EN 60068-2-6:

Innventia

Before and after the mechanical disturbance *vibration at fixed frequency*, the device was tested with a set of 10 breath samples with a nominal alcohol concentration of 0,40 mg/L. The mean values of each set were calculated and compared in order to see that the difference between them was less than 0,040 mg/L, and that the device thus fulfils the requirements of this standard and the European standard EN 60068-2-6 as regards *vibration at fixed frequency*.

Fail	
Pass	X

After the mechanical disturbance *vibration at fixed frequency*, the breath alcohol test device was also inspected for any visual damage affecting its functionality.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	22°C		30% RH		
Reference meter No:	056		056		
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Simulator No:	004, 005
Alcohol concentration 0,40 mg/L Batch No:	532

TOTAL RESULT 7.7.2.2				Fail		Pass	X
References to attachments, reports or other documentation				No:	273905 A		
Date of test:	2013-12-05	Signature:	MH				
Comments:							

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;

(EN 15964:2011, 7.7.2.3)

Test 7.7.2.3

The device was subjected to the mechanical disturbance *random vibrations* in accordance with this standard and the European standard EN 60068-2-64.

The test *random vibrations* was conducted by the following laboratory, which is accredited according to ISO/IEC 17025:2005 and which is an accredited subcontractor for tests according to the European standard EN 60068-2-64:

Innventia

Before and after the mechanical disturbance *random vibrations*, the device was tested with a set of 10 breath samples with a nominal alcohol concentration of 0,40 mg/L. The mean values of each set were calculated and compared in order to see that the difference between them was less than 0,040 mg/L, and that the device thus fulfils the requirements of this standard and the European standard EN 60068-2-64 as regards *random vibrations*.

Fail	
Pass	X

After the mechanical disturbance *random vibrations*, the breath alcohol test device was also inspected for any visual damage affecting its functionality.

Fail	
Pass	X

CLIMATIC CONDITIONS						
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH			
Verified value:	22°C		30% RH			
Reference meter No:	056		056			
Does the laboratory meet the climatic requirements?		Fail		Pass	X	

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Simulator No:	004, 005
Alcohol concentration 0,40 mg/L Batch No:	532

TOTAL RESULT 7.7.2.3				Fail		Pass	X
References to attachments, reports or other documentation				No:	273905 A		
Date of test:	2013-12-05	Signature:	MH				
Comments:							

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. (EN 15964:2011, 7.7.2.4)

Test 7.7.2.4

In accordance with this standard three devices were used in this element of testing. The devices were first tested with 10 breath samples each with an alcohol concentration of 0,40 mg/L and the mean values of the measurement results were calculated.

Check [X]

The breath alcohol test devices were then subjected to the mechanical disturbance *Free fall* in accordance with this standard and the European standard EN 60068-2-32, each device being subjected to two falls from a height of 1 000 mm onto concrete, each device tested for one of three mutually perpendicular axes, the second fall for each device on the opposite side of the first.

Check [X]

The devices were then tested again with 10 breath samples each with an alcohol concentration of 0,40 mg/L and the mean values of the measurement results were calculated and compared with the mean values from the measurements made before the mechanical disturbance in order to see that the difference between them was less than 0,040 mg/L, and that the devices thus fulfil the requirements of this standard and the European standard EN 60068-2-32 as regards *free fall*.

Fail [ ]
Pass [X]

After the mechanical disturbance, the breath alcohol test devices were also inspected for any visual damage affecting their functionality.

Fail [ ]
Pass [X]

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C	Ambient air humidity 20-80 % RH			
Verified value:	22°C	30% RH			
Reference meter No:	056	056			
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter centimetre No:	044
Simulator No:	074
Alcohol concentration 0,40 mg/L Batch No:	527

TOTAL RESULT 7.7.2.4				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-11-07	Signature:	MH				
Comments:							

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. (EN 15964:2011, 7.7.3.1)

Test 7.7.3.1

The breath alcohol test device was tested in accordance with this standard and the European standard EN 60068-2-1 in order to see that it meets the requirements as regards cold.

The device was first tested at the reference conditions with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L, and the mean value of the measurement results was calculated.

Check [X]

The device was then exposed to the climatic disturbance *cold*; with the device power off, the breath alcohol test device was exposed to -20 °C in a climatic chamber for six hours, and then taken out of the climatic chamber and kept at +20 °C for at least one hour.

Check [X]

After the climatic disturbance the device was again tested at the reference conditions with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L, and the mean value of the measurement results was calculated.

Check [X]

The mean values from before and after the climatic disturbance were compared, and it was checked that the difference between them was less than 0,040 mg/L.

Fail [ ]
Pass [X]

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH		
Verified value:	23°C		30% RH		
Reference meter No:	056		056		
The variation in temperature in the climatic chamber is ±2 °C.					
Does the laboratory meet the climatic requirements?	Fail		Pass	X	

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Climatic chamber No:	089
Simulator No:	074
Alcohol concentration 0,40 mg/L Batch No:	527

TOTAL RESULT 7.7.3.1				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2013-11-08	Signature:	MH				
Comments:							

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 hours.

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. (EN 15964:2011, 7.7.3.2)

Test 7.7.3.2

The breath alcohol test device was tested in accordance with this standard and the European standard EN 60068-2-2 in order to see that it meets the requirements as regards dry heat.

The device was first tested at the reference conditions with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L, and the mean value of the measurement results was calculated.

Check [X]

The device was then exposed to the climatic disturbance *dry heat*; with the device power off, the breath alcohol test device was exposed to +70 °C in a climatic chamber for six hours, and then taken out of the climatic chamber and kept at +20 °C for at least one hour.

Check [X]

The device was then tested at the reference conditions with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L, and the mean value of the measurement results was calculated.

Check [X]

The mean values from before and after the climatic disturbance were compared, and it was checked that the difference between them was less than 0,040 mg/L.

Fail [ ]
Pass [X]

CLIMATIC CONDITIONS						
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH			
Verified value:	20°C		25% RH			
Reference meter No:	056		056			
The variation in temperature in the climatic chamber is ±2 °C.						
Does the laboratory meet the climatic requirements?	Fail		Pass	X		

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Climatic chamber No:	089
Simulator No:	074
Alcohol concentration 0,40 mg/L Batch No:	527

TOTAL RESULT 7.7.3.2			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2013-11-22	Signature:	MH			
Comments:						

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. (EN 15964:2011, 7.7.3.3)

Test 7.7.3.3

The breath alcohol test device was tested in accordance with this standard and the European standard EN 60068-2-30 in order to see that it meets the requirements as regards damp heat.

The device was first tested at the reference conditions with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L, and the mean value of the measurement results was calculated.

Check [X]

The device was then exposed to the climatic disturbance *Damp heat (cyclic)*; with the device power off, the breath alcohol test device was placed in a climatic chamber and exposed to a 24-hour cyclic temperature variation between 25 °C and 55 °C, at a relative humidity above 95 % during the temperature change and low temperature phases, and at 93 % at the upper temperature phases, making sure that the device was exposed to condensation at temperature rise (see illustration below).

Check [X]

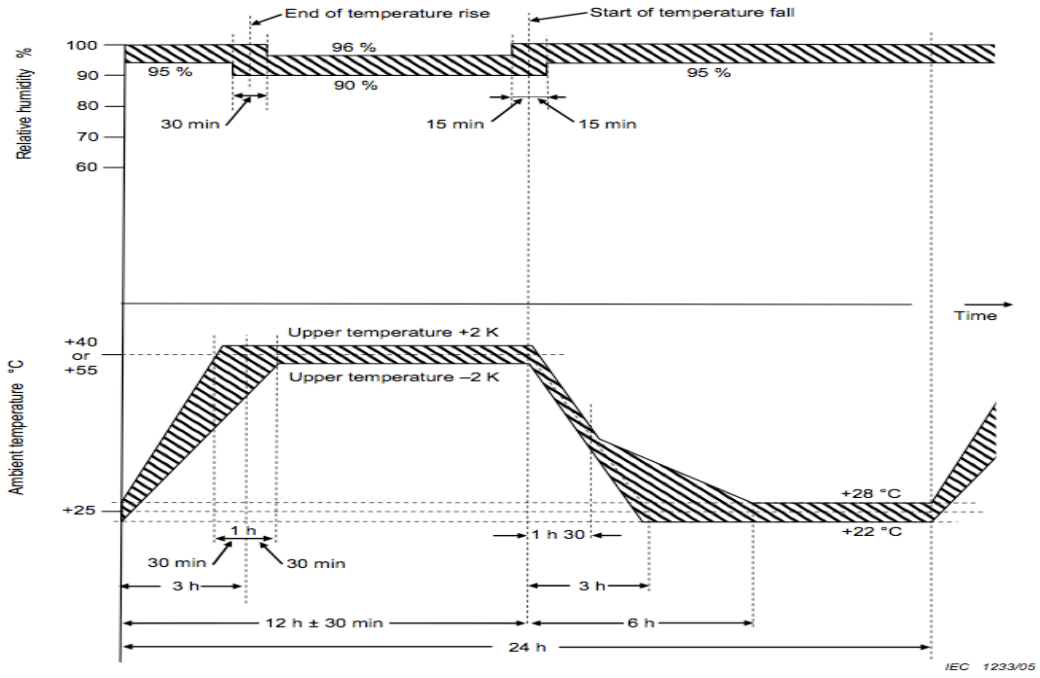


Figure 2a – Test Db – Test cycle – Variant 1

(IEC 60068-2-30)

After the climatic disturbance, the device was taken out of the climatic chamber and kept at the reference conditions until it was certain that all parts of the device under test were within 3 °C of their final temperature.

Check [X]

The device was then tested at the reference conditions with 10 breath samples with a nominal alcohol concentration of 0,40 mg/L, and the mean value of the measurement results was calculated.

Check [X]

The mean values from before and after the climatic disturbance were compared, and it was checked that the difference between them was less than 0,040 mg/L.

Fail [ ]
Pass [X]

CLIMATIC CONDITIONS						
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH			
Verified value:	22°C		35% RH			
Reference meter No:	056		056			
The variation in temperature in the climatic chamber is ±2 °C.						
The variation in humidity in the climatic chamber is ±3% RH.						
Does the laboratory meet the climatic requirements?		Fail		Pass	X	

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Reference meter time No:	045
Climatic chamber No:	089
Simulator No:	074
Alcohol concentration 0,40 mg/L Batch No:	551

TOTAL RESULT 7.7.3.3				Fail		Pass	X
References to attachments, reports or other documentation				No:			
Date of test:	2014-03-17	Signature:	AW				
Comments:							

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. (EN 15964:2011, 7.8.1)

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 discharges 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. (EN 15964:2011, 7.8.2)

Test 7.8.2

The device was subjected to the electrical disturbance *electrostatic discharge* in accordance with this standard and the European standard EN 61000-4-2.

Before the electrical disturbance *electrostatic discharge*, the device was tested with a breath sample with a nominal alcohol concentration of 0,40 mg/L.

Check	X

The test *electrostatic discharge* was conducted by the following laboratory, which is accredited according to ISO/IEC 17025:2005 and which is an accredited subcontractor for tests according to the European standard EN 61000-4-2:

TÛV SÛD

During the electrical disturbance *electrostatic discharge*, the device was tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/l in accordance with this standard.

The result from the test before the electrical disturbance was compared to each one of the results from the tests taken during the disturbance checking that the difference in all cases was less than 0,04 mg/L, and that the device thus fulfils the requirements of this standard and of the European standard EN 61000-4-2 as regards *electrostatic discharge*.

Fail	
Pass	X

CLIMATIC CONDITIONS					
Limit values:	Temperature 18-26 °C	Ambient air humidity 20-80 % RH			
Verified value:	21°C	30% RH			
Reference meter No:	056	056			
Does the laboratory meet the climatic requirements?		Fail		Pass	X

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Simulator No:	059
Alcohol concentration 0,40 mg/L Batch No:	549

TOTAL RESULT 7.8.2			Fail		Pass X
References to attachments, reports or other documentation			No:	CPSC0140682	
Date of test:	2014-03-01	Signature:	AW		
Comments:					

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. (EN 15964:2011, 7.8.3)

Test 7.8.3

The device was subjected to the electrical disturbance *immunity to radiated electric fields* in accordance with this standard and the European standard EN 61000-4-3.

Before the electrical disturbance *immunity to radiated electric fields*, the device was tested with a breath sample with a nominal alcohol concentration of 0,40 mg/L.

Check X

The test *immunity to radiated electric fields* was conducted by the following laboratory, which is accredited according to ISO/IEC 17025:2005 and which is an accredited subcontractor for tests according to the European standard EN 61000-4-3:

TÜV SÜD

During the electrical disturbance *immunity to radiated electric fields*, the device was tested with 10 breath samples with a nominal alcohol concentration of 0,40 mg/l in accordance with this standard.

The result from the test before the electrical disturbance was compared to each one of the results from the tests taken during the disturbance checking that the difference in all cases was less than 0,04 mg/L, and that the device thus fulfils the requirements of this standard and of the European standard EN 61000-4-3 as regards *immunity to radiated electric fields*.

Fail	
Pass	X

CLIMATIC CONDITIONS						
Limit values:	Temperature 18-26 °C		Ambient air humidity 20-80 % RH			
Verified value:	21°C		30% RH			
Reference meter No:	056		056			
Does the laboratory meet the climatic requirements?		Fail		Pass	X	

TRACEABILITY	
The following equipment was used:	
Simulator pump No:	083
Simulator No:	059
Alcohol concentration 0,40 mg/L Batch No:	549

TOTAL RESULT 7.8.3				Fail		Pass	X
References to attachments, reports or other documentation				No:	CPSC0140682		
Date of test:	2013-03-01	Signature:	AW				
Comments:							

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. (EN 15964:2011, 8)

Test 8

It was checked that the date of the next calibration was noted either on the display or on a tamper-evident label.

Fail	
Pass	X

The breath alcohol test device was checked in order to see that it had visible and indelible marking comprising the following information:

	Fail	Pass
Reference to this standard (EN 15964:2011)		X
Identification of the manufacturer and the supplier (if different)		X
Name of the device and model type		X
Serial number		X

If the device does not use a digital format, it was also checked that the marking comprised the specified limits.

Fail	
Pass	
Not applicable	X

It was also checked that the date of the next calibration was noted either on the display or on a tamper-evident label.

Fail	
Pass	X

Is the device provided with an individual package?

No	
Yes	X

If ***No***, move on to section 9 below.

For devices with an individual package, it was checked that this too contained at least the following information:

	Fail	Pass
Reference to this standard (EN 15964:2011)		X
Identification of the manufacturer and the supplier (if different)		X
Name of the device and model type		X
Serial number		X

If the device does not use a digital format, it was also checked that the information on the packaging comprised the specified limits.

Fail	
Pass	
Not applicable	X

TOTAL RESULT 8			Fail		Pass	X
References to attachments, reports or other documentation			No:			
Date of test:	2014-03-05	Signature:	AW			
Comments:						

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. (EN 15964:2011, 9)

Test 9

It was checked that the device is supplied with operating instructions specifying at least:

	Fail	Pass
Reference to this standard (EN 15964:2011)		X
Identification of the manufacturer and the supplier (both of them, if different)		X
Name of the device and model type		X
The types of battery or accumulator to be used		X
The maximum value for which the device indicates a zero value		X
The procedures for recharging batteries		X
The times to be observed following the last ingestion of alcohol and/or after having smoked prior to conducting the measurement		X
Breath test procedure		X
Environmental and safety information, e.g. handling of mouthpieces		X
Description of what the device does when the memory reaches its capacity limit		X

It was also checked that the operating instructions contain information as regards the following technical characteristics:

	Fail	Pass
Range of alcohol concentration		X
Range of temperature		X
Operating conditions		X
Storage conditions		X
Time between two calibrations		X

The operating instructions were also checked in order to see that they give the recommended frequency of the verification and adjustment operations, as well as the procedures, including environmental conditions, and means required for these operations, and instructions as regards the fact that these operations shall be conducted by competent persons.

Fail	
Pass	X

If the device does not use a digital format, it was also checked that the operating instructions contain information as regards the specified limits.

Fail	
Pass	
Not applicable	X

If there are any use-related restrictions of the device, it was checked that these are included in the operating instructions.

Fail	
Pass	X
Not applicable	

It was also checked that it is possible to verify for maintenance and legal metrological control that the device is correctly adjusted.

Fail	
Pass	X

TOTAL RESULT 9			Fail		Pass X
References to attachments, reports or other documentation			No:		
Date of test:	2013-03-10	Signature:	AW		
Comments:					

Annex A of EN 15964:2011

(informative)

Example of type testing requirements

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.

(EN 15964:2011, Annex A, A.2)

Annex B of EN 15964:2011

(informative)

Formula

The concentration of the gas is calculated from the 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:

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

where

t is the temperature in °C.

For t = 34 °C:

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

(EN 15964:2011, Annex B)

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