



COMMITTEE DRAFT OIML CD4

Date: 20 may 2008

Reference number: .....

Supersedes document: OIML R 126- CD3

Circulated to P- and O-members and liaison international bodies and external organisations for:

discussion planned at a meeting to be held on June2008 .....

comments by:.....

vote (P-members only) and comments by

OIML TC17 / SC7 /

Title: OIML R 126 Breath alcohol analyzers

Secretariat:

TC17/SC7: France

TITLE OF THE CD (English):

Revision OIML R 126

Breath alcohol analyzers

Part 1: Metrological and technical requirements

Part 2: Metrological controls and performance tests".

Part 3: Report Format for Type Evaluation

TITLE OF THE CD (French):

Ethylomètres

Original version in: English

**TC 17 / SC 7 SECRETARIAT: FRANCE**

**P-Members:**

AUSTRALIA  
AUSTRIA  
BELGIUM  
BRAZIL  
FRANCE  
GERMANY  
NETHERLANDS  
NORWAY  
POLAND  
ROMANIA  
RUSSIAN FEDERATION  
UNITED KINGDOM  
UNITED STATES

**O-Members:**

BULGARIA  
CANADA  
CZECH REPUBLIC  
DENMARK  
FINLAND  
HUNGARY  
IRELAND  
JAPAN  
SERBIA AND MONTENEGRO  
SLOVAKIA  
SLOVENIA  
SWEDEN  
SWITZERLAND

**Liaisons:**

IEC, International Electrotechnical Commission  
ISO, International Organization for Standardization

**CONTENT**

Part 1 Metrological and technical requirements .....	78
Part 1 Metrological and technical requirements .....	78
1 Scope .....	78
2 Terminology.....	79
2.1 Breath alcohol analyzer.....	79
2.2 Stationary breath alcohol analyzer.....	79
2.3 Mobile breath alcohol analyzer .....	89
2.4 Portable breath alcohol analyzer .....	89
2.5 Alveolar air.....	89
2.6 End expiratory breath.....	89
2.7 dead anatomical volume.....	89
2.8 Measuring mode .....	89
2.9 Maintenance mode.....	89
2.10 Stand by mode .....	810
2.11 Adjustment device .....	810
2.12 Disturbances .....	910
2.13 Built-in automatic checking facility.....	910
2.14 Drift.....	910
2.15 Memory residual effect .....	910
2.16 Abbreviations .....	911
3 Description of the instrument.....	911
4 Units of measurement and decimal sign .....	911
5 Metrological requirements.....	1011
5.1 Measuring range .....	1011
5.2 Breath measuring conditions .....	1012
5.3 Maximum permissible errors (MPE) .....	1012
5.3.1 Maximum permissible errors for type approval and initial verification.....	1012
5.3.2 Maximum permissible errors for breath alcohol analyzers in service (for the subsequent verifications) .....	1012
5.4 Scale intervals.....	1112
5.5 Repeatability.....	1112
5.5.1 Experimental standard-deviation .....	1112
5.5.2.....	1113
5.6 Drift.....	1113

<b>5.6.1</b>	Zero drift.....	<del>11</del> <b>13</b>
<b>5.6.2</b>	Drift at 0.40 mg/L .....	<del>11</del> <b>13</b>
<b>5.7</b>	Memory and residual effect.....	<del>11</del> <b>13</b>
<b>5.7.1</b>	Memory effect.....	<del>11</del> <b>13</b>
<b>5.7.2</b>	Small changes in mass concentration .....	<del>11</del> <b>13</b>
<b>5.8</b>	Multiple indicating devices .....	<del>12</del> <b>13</b>
<b>5.9</b>	Rated operating conditions .....	<del>12</del> <b>13</b>
<b>5.9.1</b>	Physical influence factors .....	<del>12</del> <b>14</b>
<b>5.9.2</b>	Conditions of exhalation.....	<del>12</del> <b>15</b>
<b>5.10</b>	Significant fault .....	<del>13</del> <b>15</b>
<b>5.11</b>	Disturbances and other influence quantities .....	<del>13</del> <b>16</b>
<b>5.11.1</b>	Disturbances .....	<del>13</del> <b>16</b>
<b>5.11.2</b>	Physiological influence quantities.....	<del>14</del> <b>17</b>
<b>5.12</b>	Durability .....	<del>14</del> <b>18</b>
<b>5.13</b>	Presumption of compliance .....	<del>15</del> <b>18</b>
	Durability.....	<del>Erreur ! Signet non défini.</del> <b>19</b>
<b>6</b>	Technical requirements.....	<del>15</del> <b>19</b>
<b>6.1</b>	Construction .....	<del>15</del> <b>19</b>
	Presentation and storage of the measuring result .....	<del>15</del> <b>20</b>
<b>6.2.1</b>	Reading of the results (on display as well as in print) shall be reliable, easy and unambiguous under conditions of normal use. ....	<del>15</del> <b>20</b>
<b>6.2.2</b>	If the instrument is connected to an external data printing device or data storage, the data transmission from the instrument to the printing device shall be designed so that the results can not be falsified. ....	<del>16</del> <b>20</b>
<b>6.2.3</b>	Availability of measurement results.....	<del>16</del> <b>20</b>
<b>6.3</b>	Adjustment .....	<del>16</del> <b>20</b>
<b>6.4</b>	Protection against fraud.....	<del>16</del> <b>21</b>
<b>6.4.1</b>	Except in the maintenance mode (with a restricted access) , it shall be impossible to make any adjustments without breaking the seals .....	<del>16</del> <b>21</b>
<b>6.4.2</b>	The possibility to change the software shall comply with the requirement in 6.8. <del>16</del> <b>21</b>	
<b>6.4.3</b>	The risk of calculated (deliberate) influence by digital telephones or static magnets shall be minimized. (For disturbances by radiated, radio frequency electromagnetic fields see also 5.12.1.1). ....	<del>16</del> <b>21</b>
<b>6.4.4</b>	Data transmission shall comply with 6.10.....	<del>16</del> <b>21</b>
<b>6.5</b>	Checking operations.....	<del>16</del> <b>21</b>
<b>6.6</b>	Software .....	<del>17</del> <b>22</b>
<b>6.7</b>	Durable recording of the measuring results.....	<del>17</del> <b>22</b>

<b>6.7.1</b>	Printing device .....	<u>1722</u>
<b>6.7.2</b>	Storage of measuring results .....	<u>1823</u>
<b>6.8</b>	Data transmission.....	<u>1923</u>
<b>7</b>	Inscriptions.....	<u>1923</u>
<b>8</b>	Operating instructions.....	<u>1924</u>
<b>9</b>	Sealing .....	<u>2025</u>
<b>Part 2</b>	<b>METROLOGICAL CONTROLS AND PERFORMANCE TESTS</b> .....	<u>2129</u>
<b>10</b>	Metrological controls .....	<u>2129</u>
<b>10.1</b>	General .....	<u>2129</u>
<b>10.2</b>	Responsibility for compliance with the requirements .....	<u>2229</u>
<b>11</b>	Type evaluation .....	<u>2229</u>
<b>11.1</b>	Units submitted to type test .....	<u>2229</u>
<b>11.2</b>	Documentation .....	<u>2230</u>
<b>11.3</b>	Examinations and tests .....	<u>2330</u>
<b>11.3.1</b>	The instrument and the documentation shall be given a visual inspection to obtain a general appraisal of its design and construction and the documentation shall be studied. <u>2330</u>	
<b>11.3.2</b>	The instrument shall be submitted to performance tests specified in 11.4 to determine its correct functioning under various conditions. ....	<u>2331</u>
<b>11.4</b>	Performance tests.....	<u>2431</u>
<b>11.4.1</b>	Reference conditions .....	<u>2431</u>
<b>11.4.2</b>	Breath Profile.....	<u>2431</u>
<b>11.4.3</b>	Test apparatus .....	<u>2432</u>
<b>11.4.4</b>	Errors under rated operating conditions .....	<u>2633</u>
<b>11.4.5</b>	Disturbances tests.....	<u>3752</u>
<b>11.4.6</b>	Physiological influence quantities.....	<u>4765</u>

Annexe A Examples of detection of alcohol in upper respiratory tracts	<a href="#">4866</a>
A.1 Peak method	<a href="#">4866</a>
A.2 Two-measurement cycle	<a href="#">4967</a>
A.3 Delay before measurement	<a href="#">5068</a>
Annex B General information and breath profile (informative)	<a href="#">5169</a>
MEASUREMENT FLOW RATE DURING EXHALATION	<a href="#">5170</a>
MEASUREMENT ALCOHOL DURING EXHALATION / DETERMINATION OF THE ALCOHOL PLATEAU	<a href="#">5372</a>
Annex C	<a href="#">5777</a>
Annexe D Test Report Format	<a href="#">5878</a>

# Part 1 Metrological and technical requirements

## 1 Scope

This International Recommendation applies to quantitative breath alcohol analyzers that measure the mass concentration of alcohol in exhaled human breath.

For the purpose of this Recommendation, only ethanol is considered as alcohol.

This Recommendation does not apply to devices designated to ascertain only the presence of alcohol in the exhaled breath, and which do not display numerical results above the permitted limits.

The purpose of this Recommendation is to specify, the minimum metrological specifications and tests applicable to type approval, initial verification and in service verification of breath alcohol analyzers, owing to national differences in legal systems.

In addition to the minimum requirements, National Authorities may require that breath alcohol analyzers are equipped with special devices according to their policies for measuring alcohol in human breath samples.. For example:

- Device(s) that detects the presence of alcohol in the upper respiratory tracts,
- prohibition of display or printing of results which do not represent the final measurement result,
- making mandatory a printing device,
- making the measurement impossible if no paper is detected in the printing device,
- requiring additional printed information.

National Authorities may require that the breath alcohol analyzers display measurement results obtained in terms of ethanol content in the exhaled human breath, either into physiological conditions or in terms of other quantities. This Recommendation does not cover the metrological performance of such devices.<sup>1</sup>

## 2 Terminology

### 2.1 Breath alcohol analyzer

instrument that measures within specified error limits and displays the breath alcohol mass concentration by analysing exhaled human breath representative of the level of the alcohol intoxication of the subject.

### 2.2 Stationary breath alcohol analyzer

breath alcohol analyzer intended only for use in a fixed location within buildings or places providing stable environmental operating conditions.

---

1 However it is advisable that national penal law defines offences in terms of alcohol in breath so that these instruments are more appropriately used

**2.3 Mobile breath alcohol analyzer**

breath alcohol analyzer intended for use in mobile applications (e.g. in cars).

**2.4 Portable breath alcohol analyzer**

breath alcohol analyzer intended for used inside or outside buildings and in mobile applications (e. g. handheld devices generally powered by an autonomous battery, however, this is not required).

**2.5 Alveolar air**

Air contained in the pulmonary alveoli where the gaseous exchange takes place between the arterial blood and the gas contained within the alveoli.

**2.6 End expiratory breath**

Air considered sufficiently representative of alveolar air (in opposition to Dead anatomical volume).

**2.7 dead anatomical volume**

Conducting area of gas flow known as area of conduction without exchange of a defined volume. This volume is variable between individuals. It is approximately equal to 2.2 mL (milliliters) times the body mass in kilograms. We can consider an average volume of 150 mL.

**2.8 Measuring mode**

Clearly indicated mode in which the breath alcohol analyzer can make measurements at the rate normally expected in service and in which it shall meet the performance requirements of this Recommendation.

**2.9 Maintenance mode**

Mode in which the breath alcohol analyzer can be adjusted and is subject to metrological control.

**2.10 Stand by mode**

Mode of the breath alcohol analyzer which only certain circuits are energized in order to conserve power and/or prolong component life, and to attain the measuring mode more rapidly than would be possible if starting from the un-powered state

**2.11 Adjustment device**

device for adjusting the breath alcohol analyzer when it is in maintenance mode.

**2.12 Intrinsic error [VIM 5.24]**

The error of a measuring instrument, determined under reference conditions.

### 2.13 Disturbances [OIML D11, 3.13.2]

influence quantity having a value within the limits specified in this Recommendation, but outside the specified rated operating conditions of the measuring instrument. Note : An influence quantity is a disturbance if the rated operating conditions for that influence quantity are not specified.

### 2.14 Built-in automatic checking facility

Internal device or process which checks that the breath alcohol analyzer is suitably adjusted. Such a device may include internal checking elements (for example signal stability, temperature stability) or additional external elements to be connected to the instrument such as optical or electrical filters or cylinder with a known concentration test gas.

### 2.15 Drift

Change in the instrument indication of the same alcohol concentration which occurs during a stated period of time at a given mass concentration of alcohol in air.

### 2.16 Memory residual effect

Difference between the results of measurement of the same alcohol concentration when delivered samples are interposed with a sample containing a specified higher alcohol concentration.

### 2.17 Abbreviations

MPE	Maximum permissible error
BBA	Breath alcohol analyzer
OIML	International Organisation of Legal Metrology
EUT	Equipment Under Tests

## 3 Description of the instrument

The breath alcohol analyzer shall be designed such that a measurement result is representative of the alcohol concentration present in the end expiratory breath.

Conformity to this requirement is supposed to be demonstrated when the breath alcohol analyzer fulfils the requirements in 5.9.2.

## 4 Units of measurement and decimal sign

The breath alcohol analyzer shall display and/or print measurement results in term of mass concentration of alcohol in a specified volume of exhaled air.

The mass concentration shall be indicated in milligram per litre of exhaled breath (mg/L).

The national authorities may require the use of an equivalent unit of measurement if the indication is in conformity with the legal international units and if it represents the mass concentration of alcohol in a specified volume of exhaled air.

The decimal marker on the display or print by the measuring instrument shall be either a comma on the line or a dot on the line. Admissibly of the comma and/or the dot is left to national legislation.

Note : In accordance with OIML policy, the dot is used in the English version of this Recommendation and a comma in the French version.

## 5 Metrological requirements

### 5.1 Measuring range

The breath alcohol analyzer shall be capable of measuring all mass concentrations in the range 0.00 mg/L to at least 2.00 mg/L. However, in the measuring mode, the breath alcohol analyzer may indicate 0.00 mg/L for mass concentrations equal to or smaller than a given value defined under the responsibility of national authorities. Such a masking function shall be able to be cancelled in maintenance mode.

The greatest permissible value for the upper limit of the measuring range is 3.00 mg/L.

The breath alcohol analyzer shall indicate when its upper limit of measurement is exceeded.

### 5.2 Breath measuring conditions

The breath measuring conditions for all measurements of alcohol concentration including calibration are :

Temperature : 34.0 °C,

Pressure :  $P_{atm}$  during the tests (hPa)

Humidity : 95 % RH (in the pressure condition during the breath) ,

Presence of CO<sub>2</sub> : 5 %.

### 5.3 Maximum permissible errors (MPE)

The following MPE shall apply within the rated operating conditions (specified in 3.2).

#### 5.3.1 Maximum permissible errors for type approval and initial verification

The maximum permissible errors, positive or negative, on each individual indication are :

$\pm 0.020$  mg/L or  $\pm 5$  % of the true value of mass concentration, whichever the greater, for all mass concentrations over the measuring range;

#### 5.3.2 Maximum permissible errors for breath alcohol analyzers in service (for the subsequent verifications)

$\pm 8$  % of the true value of mass concentration or  $\pm x$  mg/L, whichever the greater, for all mass concentrations over the measuring range.

$x$  is a fixed value which is defined by National Authorities and which shall not be less than 0.02 mg/L

## 5.4 Scale intervals

The scale interval is at least 0.01 mg/L in the measuring mode. However, in the maintenance mode, it shall be possible to display a scale interval equal to 0.001 mg/L.

## 5.5 Repeatability

### 5.5.1 Experimental standard-deviation

The experimental standard-deviation is given by the formula :

$$s = \sqrt{\frac{\sum_{i=1}^n (Y_i - \bar{Y})^2}{n - 1}}$$

where :

n = the number of measurements made at a given mass concentration ;

Y<sub>i</sub> = the i<sup>th</sup> measurement (out of n) for the given mass concentration ;

$\bar{Y}$  = the arithmetic mean of the n values.

### 5.5.2

The experimental standard deviation for all mass concentrations shall be less than or equal to one third of the maximum permissible error.

## 5.6 Drift

### 5.6.1 Zero drift

The drift from 0.00 mg/L shall be less than 0.010 mg/L in 4 hours under reference conditions as defined in 5.9.

### 5.6.2 Drift at 0.40 mg/L

5.6.2.1 Short-term drift: the drift at 0.40 mg/L shall be less than 0.010 mg/L in 4 hours under reference conditions as defined in 5.9.

5.6.2.2 Long-term drift: the drift at 0.40 mg/L shall be less than 0.020 mg/L in two months under reference conditions as defined in 5.9.

## 5.7 Memory and residual effect

### 5.7.1 Memory effect

The memory effect shall be less than 0.010 mg/L when the test is conducted according to [A.4.3.1](#).

### 5.7.2 Small changes in mass concentration

The error in the result obtained with a gas having a mass concentration which is 0.10 mg/L less than that of another gas previously injected shall be less than or equal to the MPE for the lower mass concentration.

## 5.8 Multiple indicating devices

For a given value of the mesurand, the difference between the indications of multiple indicating or printing devices shall be not greater than the absolute value of the MPE, but shall be zero between digital indicating and/or printing devices.

## 5.9 Rated operating conditions

### 5.9.1 Physical influence factors

Breath alcohol analyzers shall be designed and manufactured such that their errors do not exceed the MPEs specified in 5.3 under the following rated operating conditions:

a	Ambient temperature	low	+5 °C for stationary breath alcohol analyzers -10 °C for mobile breath alcohol analyzers -10 °C or -25 °C for portable breath alcohol analyzers <sup>(1)</sup>	
		high	+30 °C for stationary breath alcohol analyzers +40 °C for mobile breath alcohol analyzers +40 °C or +50 °C for portable breath alcohol analyzers <sup>(1)</sup>	
b	Relative humidity	up to 85 %, during 2 days for mobile breath alcohol analyzers up to 93 %, during 4 days for portable breath alcohol analyzers		
c	Atmospheric pressure	860 hPa - 1060 hPa		
d	Vibration	Negligible for stationary breath alcohol analyzer 10 Hz - 150 Hz, 7 m.s <sup>-2</sup> , 1 m <sup>2</sup> .s <sup>-3</sup> , -3 dB/octave for mobile and portable breath alcohol analyzers only		
e	DC mains voltage	As specified by the manufacturer		
f	AC mains voltage	$U_{nom} - 15 \%$ to $U_{nom} + 10 \%$		
g	AC mains frequency	$f_{nom} - 2 \%$ to $f_{nom} + 2 \%$		
h	Voltage of internal battery	All voltages between a new or freshly charged battery, down to the lowest voltage at which the instrument functions properly within MPE, according to the specifications given by the manufacturer.		
i	Voltage of a road vehicle battery	12 V battery	9 V - 16 V	
		24 V battery	16 V - 32 V	
j	Total fraction by volume of hydrocarbons (as methane equivalent) in the environment	5 ppm		
k	Mass concentration of carbon dioxide	10 %		
<sup>(1)</sup> These values are to be decided by the National Authority.				

### 5.9.2 Conditions of exhalation

The breath alcohol analyzer shall give an error message if the conditions of exhalation specified by the manufacturer (e.g.: continuity and flow) in order to ensure a representative measurement are not fulfilled..

These conditions, specified by the manufacturer, shall comply with the following values:

- Exhaled volume : greater than or equal to 1.2 L,
- Pressure : greater than or equal to 10 hPa (new proposition 20 hPa, to be discussed),
- Flow rate : greater than or equal to 0.10 L/s.

## 5.10 Significant fault

A fault greater than the magnitude of the MPE defined in 5.3.1

## 5.11 Disturbances and other influence quantities

### 5.11.1 Disturbances

Breath alcohol analyzer shall be designed and manufactured such that when they are exposed to the disturbances indicated below,

(a) either significant faults do not occur,

(b) or significant faults are detected and acted upon by means of a checking facility:

#### 5.11.1.1 During the following disturbances:

a	Radiated radiofrequency, electromagnetic fields	From 80 MHz to 2000 MHz, 10 V/m						
b	Conducted radiofrequency fields	From 0.15 MHz to 80 MHz, 10 V/m						
c	Electrostatic discharges	6 kV contact discharge 8 kV air discharge						
d	Bursts on supply lines	Amplitude 1 kV Repetition rate 5 kHz						
e	Bursts on signal, data and control lines	Amplitude 1 kV Repetition rate 5 kHz						
f	Surges on signal, data and control lines	Unbalanced lines		Line to line		1 kV		
				Line to earth		2 kV		
g	AC mains voltage dips short interruptions and voltage variation	Balanced lines		Line to earth		2 kV		
g	AC mains voltage dips short interruptions and voltage variation	Reduction	100 %	100 %	30 %	> 95 %		
		Duration	0.5 cycle	1 cycle	25 cycles	250 cycles		
h	Electrical transient conduction for external batteries of a vehicle		Pulse 1	Pulse 2		Pulse 3		Pulse 4
		level	-100 V	2a	2b	3a	3b	- 7 V
		Minimum number of pulses or test time	5000 pulses	5000 pulses		1 hour		1 pulse

#### 5.11.1.2 And after the following disturbances

a	Damp heat, cyclic (condensing)		mobile	portable
		temperature	55 °C	55 °C

		duration	2 cycles		4 cycles
b	Mechanical shocks		stationary	mobile	portable
		Height of fall	25 mm	50 mm	1 m
		Number of fall	1	1	3
g	Shakes	10 g, 6 ms, 2 Hz, in 3 axes, 1000 shakes for each axes			
h	Storage test	- 25 °C, 6 hours + 70 °C, 6 hours			

#### 5.11.1.3 Application

The provisions in 5.10.1 (a) and 5.10.1 (b) may be applied separately to :

- (a) each individual cause of significant fault; and/or
- (b) each part of the measuring instrument.

The choice of whether 5.10.1 (a) or 5.10.1 (b) is applied, is left to the manufacturer

#### 5.11.2 Physiological influence quantities

Breath alcohol analyzer shall be designed and manufactured such that when they are exposed to the physiological influence quantities indicated below, the variation of indication do not exceed 0.1 mg/L

Interfering substance	Nominal value for vapour mass concentration mg/L ( $\pm 5\%$ )
Acetone	0.5
Acetaldehyde	0.15
Methanol	0.1
Isopropanol	0.1
Carbon monoxide	0.2
Toluene	0.2

#### 5.12 Durability

The provisions in 5.10 and 5.12 shall be met durably.

Measuring instruments according to this Recommendation shall be designed and manufactured such that either :

- (a) either significant faults do not occurs,
- (b) or significant faults are detected and acted upon by means of a checking facility.

Provisions in (a) and (b) may be applied separately to each part of the measuring instrument.

The choice of whether (a) or (b) is applied, is left to the manufacturer.

The breath alcohol analyzer shall be designed to maintain an adequate stability of its metrological characteristics over a period of time to be specified by the manufacturer.

### **5.13 Presumption of compliance**

The type of a measuring instrument according to this Recommendation is presumed to comply with the provisions in 5.1 to 5.12 if it passes the examination and tests specified in Part 2 of this recommendation.

## **6 Technical requirements**

### **6.1 Construction**

The BAA shall be designed such that it is robust enough to operate in the intended conditions of use.

### **6.2 Presentation and storage of the measuring result**

#### **6.2.1** Reading of the results (on display as well as in print) shall be reliable, easy and unambiguous under conditions of normal use.

The result of the measurement shall be displayed digitally by means of aligned figures.

In measuring mode, the minimum BBA display shall be to indicate at least two digits (e.g. a measured value of 0.427 mg/L shall be reported as 0.42 mg/L in measuring mode), that is rounded down.

In maintenance mode, it shall be possible to display at least three digits (e.g. a measured value of 0.427 mg/L shall be reported as 0.427 mg/L in maintenance mode).

The height of the figures on the display shall be equal to at least :

5 mm for illuminated displays,

10 mm in all other cases.

The name of the unit of measurement or its symbol shall appear in close proximity to the measurement indication. The characters used shall be at least 3 mm high.

If the characters are not illuminated, the display shall have an illumination device.

When a measurement result is nil, it shall not be possible to confuse such a result with the zero indication prior to measurement.

- 6.2.2** If the instrument is connected to an external data printing device or data storage, the data transmission from the instrument to the printing device shall be designed so that the results can not be falsified.

It shall not be possible to print a document or store the measuring data in the external device for legal purposes if the instrument checking facilities detect a significant fault or a malfunction.

- 6.2.3** Availability of measurement results

It shall be possible to retain the results in a readable or accessible form for at least 15 minutes.

If other measurements can be performed during this period, the previous result shall be accessible without ambiguity.

If this requirement can be met only by printing the results, the absence of paper in the printer shall prevent further measurement being made.

### **6.3 Adjustment**

At least before each measurement, the instrument shall verify a zero with a tolerance  $\pm 0.005$  mg/L, using an appropriate purge, and shall adjust if needed.

At least, once during each measurement cycle the instrument shall automatically adjust or check its adjustment implementing the built-in check facility.

When the adjustment routine is not possible or the check fails, the instrument shall give an error message and shall not allow any further measurement.

The user shall not have access to the maintenance mode nor to the adjustment device

### **6.4 Protection against fraud**

A BBA shall have no characteristics likely to facilitate its fraudulent use; neither by accidental nor by deliberate means when using the instrument in the normal manner; whereas possibilities for unintentional misuse shall be minimal. The general essential requirement dealing with fraudulent use shall be fulfilled in such a way that the interest of all parties involved in the transaction are protected.

In particular, the following aspects shall be taken into account :

- 6.4.1** Except in the maintenance mode (with a restricted access) , it shall be impossible to make any adjustments without breaking the seals
- 6.4.2** The possibility to change the software shall comply with the requirement in 6.8.
- 6.4.3** The risk of calculated (deliberate) influence by digital telephones or static magnets shall be minimized. (For disturbances by radiated, radio frequency electromagnetic fields see also 5.12.1.1).
- 6.4.4** Data transmission shall comply with 6.10

### **6.5 Checking operations**

When powered on, the instruments shall automatically check their correct operation (e.g.: checksums, watchdogs, etc.). When any defect or an error signal is detected, the instrument shall give an error message and shall not allow any further measurement.

Breath alcohol Analyzers shall check correct operation automatically both before each measurement and after any measurement which gives a result greater than a predetermined value of the mass concentration (this value may be zero).

#### Warm-up time

Under reference conditions (3.2.4), the breath alcohol analyzer shall be capable of attaining the measuring mode :

- In less than 15 minutes after being switched on,
- In less than 5 minutes after switching from stand-by mode to measuring mode.

After successful checking operation (including automatic checking of adjustment), using the built-in automatic checking facility, from the moment the breath alcohol analyzer indicates that it is ready to receive an exhalation, the breath alcohol analyzer shall be available at least one minute.

After a defined period of time not using the instrument, it is no longer ready to perform a measurement and it shall indicate this status

The breath alcohol analyzer shall indicate its readiness to start a measurement and shall not perform measurements until it is ready to do so. When after a specified period of time the instrument is no longer ready to perform measurements, it shall indicate this status.

The breath alcohol analyzer shall monitor the continuity of exhalation and shall give an indication if the flow of exhaled air is interrupted between the beginning and the end of the sampling. A signal (preferably audible) shall indicate the continuity of the exhalation.

The breath alcohol analyzer may be equipped with a function which automatically detects whether the measuring result is affected by the presence of alcohol in the upper respiratory tracts. Examples of compliance are given in Annex A.

## 6.6 Software

The software that is critical for metrological characteristics shall contain a routine generating an identification code that is automatically changed in case of any modification in the software. This software shall be designed such that changes in software are not possible without breaking a seal.

A fixed version number shall be assigned by the manufacturer to all software which, together with the identification code generated by the software itself, forms the full identification of the software. This version number shall be updated by the manufacturer in the case of a software change that may affect the functions and accuracy of the measuring device.

The instrument shall be provided with a facility to display the actual version of the identification code.

## 6.7 Durable recording of the measuring results

### 6.7.1 Printing device

The breath alcohol analyzer may be equipped with a printing device which print at least :

- the result of the measurement,
- the symbol of the unit in which the result is expressed.

If the printing device is in the scope of the type approval, then the printing device shall operate correctly during the influence factors and disturbances testing.

The printed result shall not differ from the result displayed by the BAA.

Printed figures shall be at least 2 mm high.

If the symbol of the unit is pre-printed, the paper shall be especially prepared for the printing device.

Printouts shall remain readable for at least thirty days, even when exposed to daylight or equivalent lighting.

The manufacturer shall recommend a paper type in the instruction manual and supply the paper necessary for use during type approval.

In case the printer fails (for instance being switched off, out of paper or ink, or in case of disturbed communication), a warning shall be given or the measurement shall be prohibited.

The data transmission between the BBA and the printer shall comply with 6.8.

It shall not be possible to print out a measuring result if the instrument checking facilities detect a significant fault or a malfunction.

#### **6.7.2** Storage of measuring results

For electronic storage of the measuring results, the following requirements apply :

Measuring systems may be fitted with a memory device to store measurement results, providing proof in case of a dispute.

The storage of data shall have sufficient permanency to ensure that the data are not corrupted under normal storage conditions. There shall be sufficient memory storage for any particular application. It shall be assured that means are available for future recovery of the stored data.

When the storage is full, it is permitted to delete memorized data provided that :

- Data are deleted in the same order as the recording order and the established rules are respected, and
- Deletion can be carried out only after a special manual operation.

Memorization shall be such that it is impossible in normal use to modify stored values.

Memory devices shall be fitted with checking facilities according to 6.5.

The aim of the checking facilities is to ensure that stored data correspond to the date provided by the calculator and that restored data correspond to stored data.

## 6.8 Data transmission

The BBA may be equipped with an interface permitting coupling to any peripheral devices or other instruments. An interface shall not allow the metrological functions of the instruments or their measurement data to be inadmissibly influenced by the peripheral devices, by other interconnected instruments, or by disturbances acting on the interface.

If the instrument is connected to a data printer or an external data storage, the design of the data transmission shall ensure that the measuring results can not be falsified.

## 7 Inscriptions

The breath alcohol analyzer shall be marked with a tamper evident label on a visible part of the instrument with the following information:

- a) Manufacturer's trade mark/corporate name;
- b) Year of manufacture;
- c) Type designation / model number;
- d) Type approval mark according to national regulations;
- e) Serial number of the instrument ;
- f) Measuring range;
- g) Details of the electrical power:
  - in the case of mains power: the nominal mains voltage, frequency and power required;
  - in the case of power by a road vehicle battery: the nominal battery voltage and power required;
  - in the case of an internal removable battery: the type and nominal voltage of the battery;
- h) Ambient temperature range.

Software identification may be either marked on the breath alcohol analyzer or displayed on demand through the indicating device.

If the size of the instrument is not sufficient, the items f, g and h could be removed in the instructions manual.

## 8 Operating instructions

Each individual instrument shall be accompanied by an instruction manual for the users.

The instruction manual shall be in the official language(s) of the country (or an other accepted language according to national legislation) and easily understandable.

It shall include :

- a) Operating instructions,
- b) Maximum and minimum storage temperatures,
- c) Rated operating conditions,
- d) Warm-up time after switching on the electrical power,

- e) All other relevant mechanical and electromagnetic environmental conditions,
- f) Mechanical and electromechanical environment classes,
- g) Safety and security conditions :

The BAA shall be capable of being used under satisfactory hygienic conditions. It shall be equipped to use a disposable mouthpiece for each measurement and mouthpieces shall be individually packaged.

The BAAs shall conform to relevant national regulations and standards for electrical safety and, where appropriate, for compressed gases. Verification of compliance with these regulations and standards is not within the scope of this Recommendation.

The BAA breath sampling system including the mouthpiece shall be designed so that to prevent the subject of the measurement from inhaling contaminated air from previous usages And it shall prevent the deposition of droplets from entering in theBAA.

Regardless of whether the BAA has an automatic function detects whether the measuring result is affected by the presence of alcohol in the upper respiratory tracts or not, manufacturers may stipulate in their operating procedures that a subject shall not have consumed or placed alcohol (or any other substance that may interfere with this test) in the upper respiratory tracts for at least 15 minutes prior to the collection of a breath sample.

## 9 Sealing

Effective sealing devices shall be provided by the manufacturer on all parts of the breath alcohol analyzer that are not materially protected in another way against operations liable to affect its accuracy or integrity.

This applies in particular to:

- a) Adjustments means;
- b) Replacement of specific parts if this replacement is expected to change the metrological characteristics;
- c) Software integrity.

If the BAA equipped with air filters, the manufacturer shall design the device so that it is possible to change the filters without breaking a security seal.

if the air filter is not installed, the BAA shall deliver an error message, and no measurement shall be possible.

All other types of filters shall be in a sealed part of the BAA.

## **Part 2 METROLOGICAL CONTROLS AND PERFORMANCE TESTS**

### **10 Metrological controls**

#### **10.1 General**

In general, legal metrological control can consist of type approval, initial and subsequent verification, and metrological supervision.

This chapter gives general guidelines for each of these steps.

## 10.2 Responsibility for compliance with the requirements

Notwithstanding the kind of legal metrological control in a country, the manufacturer (or his formal representative) has the full responsibility that the instrument comply with the requirements in Part 1 at the moment they are delivered to the user.

After assignment, the owner of the instrument has the responsibility that the instrument is well maintained and complies with the requirements in Part 1 as long as the instrument is in use. The operational presence of the instrument in his premises is considered as “in use”.

## 11 Type evaluation

### 11.1 Units submitted to type test

Type evaluation shall be carried out on at least one unit, which represents the definitive type. The evaluation shall consist of the examination and tests specified in 13.3 and 13.4.

The applicant shall supply at least 1 production sample of the instrument for type testing.

In order to accelerate the test procedure, the test procedure, the testing laboratory can carry out different tests simultaneously on two units. In this case, the testing laboratory shall assure that all submitted instruments are in conformance to type.

All accuracy and influence tests shall be performed on the same unit, but disturbance tests may be carried out on one more additional instrument. This additional instrument will be also submitted before to the accuracy tests.

If a specimen does not pass a specific test and as a result and it has to be modified or repaired, the applicant shall carry out this modification to all instruments supplied for test. If the testing laboratory has sound reasons to fear that the modification has negative influence on tests that already had a positive result, these tests shall be repeated.

### 11.2 Documentation

The documentation submitted with the application for type approval shall include :

- (a) description of its general principle of measurement,
- (b) list of the essential sub assemblies, components with their essential characteristics,
- (c) mechanical drawings,
- (d) electric/electronic diagrams,
- (e) installation requirements,
- (f) security sealing plan,
- (g) panel layout,
- (h) general information on the software (in particular the requirements 6.5 shall be covered,
- (i) test outputs, their use, and their relationships to the parameters being measured,

- (j) operating instructions that shall be provided to the user,
- (k) documents or other evidence that supports the assumption that the design and characteristics of the measuring instrument comply with the requirements of this Recommendation.

If the breath alcohol analyzer is equipped with a printing device, the manufacturer shall provide information about the quality of the printing paper to fulfil the requirements of readability defined in 6.9.1.

If the testing laboratory deems this necessary, it can require more detailed documentation, either to be able to study the quality of the instrument, or to be able to lay down the approved type, or both.

### 11.3 Examinations and tests

Examination and testing of instrumentations are intended to verify compliance with the requirements of Part 1 of this International Recommendation.

- 11.3.1** The instrument and the documentation shall be given a visual inspection to obtain a general appraisal of its design and construction and the documentation shall be studied.

In particular, the following aspects shall be examined:

- a) units and decimal sign,
- b) measuring ranges,
- c) scale intervals,
- d) Presentation of the result,
- e) Adjustment facilities,
- f) Protection against fraud,
- g) Checking facilities,
- h) Durability protection,
- i) Software,
- j) Durable recording of measuring results,
- k) Printing device
- l) Storage of measuring results,
- m) Data transmission,
- n) Inscriptions,
- o) Operating instructions,
- p) Sealing,
- q) Suitability for testing

- 11.3.2** The instrument shall be submitted to performance tests specified in 11.4 to determine its correct functioning under various conditions.

The tests specified in this Recommendation constitute minimum test procedures. Further tests may be undertaken, if necessary, in order to clarify issues of compliance of the breath alcohol analyzer with the requirements of this document.

## 11.4 Performance tests

### 11.4.1 Reference conditions

- Ambient temperature :  $23\text{ °C} \pm 5\text{ °C}$ ,
- Relative humidity :  $50\% \pm 30\%$ ,
- Atmospheric pressure :  $1013 \pm 20\text{ hPa}$ ,
- Total fraction by volume of hydrocarbons (as methane equivalent) in the environment :  $= 2\text{ ppm}$

During each test, the temperature, the relative humidity and the atmospheric pressure shall not vary by more than  $5\text{ °C}$ ,  $10\%$  and  $10\text{ hPa}$  respectively within the reference range

### 11.4.2 Breath Profile

The human breath containing alcohol may be considered corresponding to the following characteristics :

- Evolution of the alcohol concentration during the breath exhalation

The evolution of the breath of a human being is characterized by a plateau in the curve of mass concentration against time during the last part of the exhalation. The mass concentration at this plateau represents the mass concentration in the end-expiratory breath.

Annex B2 shows the general form of this breath profile.

Annex C gives an example of a reference principle which could be used for the implementation of the tests

- Evolution of the flow rate curve during the breath exhalation

Annex B1 shows the general form of this breath profile

### 11.4.3 Test apparatus

The apparatus shall be able to determine the true value of the mass concentration with an uncertainty less than or equal to one third of the maximum permissible error (for example expressed at a level of confidence of about  $95\%$  calculated with  $k = 2$ ).

Taking into account the duty cycle of the testing apparatus, the tests shall be conducted with the maximum frequency permitted by the breath alcohol analyzer.

In order to minimize the measurement intrinsic error, the breath alcohol analyzer may be adjusted, if necessary, before type approval testing begins. Thereafter no adjustment shall be carried out until all type approval testing is complete.

#### 11.4.3.1 Characteristic reference values of the test gas

Unless otherwise specified, the test gas injected continuously into the breath alcohol analyzer shall be characterised by the following parametric values :

- Delivered volume :  $2\text{ L} \pm 0.3\text{ L}$ ,

- Total duration of injection (into breath analyzer) :  $5 \text{ s} \pm 0.5 \text{ s}$ ,
- Type of profile : constant flow rate,
- Relative humidity of the gas : at least 90 % at the exit way pressure of the instrument
- Gas temperature :  $34 \text{ }^\circ\text{C} \pm 0.5 \text{ }^\circ\text{C}$ ,
- carrier gas : air containing insignificant concentrations of relevant impurities with volumetric fraction of  $\text{CO}_2$  :  $5 \% \pm 1 \%$ .

The completed test reports shall indicate what kind of test means has been used for each test.

Test reports shall indicate when other gases were used and how their equivalence with the reference gases was established.

#### Simplified means

This Recommendation permits the use of calibration gases produced by simplified means for some tests. Such means may consist in the use of dry gases or wet gases generated by simple test means (e.g. the absence of  $\text{CO}_2$  in test gases, constant mass concentration during injection). The completed test reports shall indicate when such alternative tests have been implemented.

For tests other than those for accuracy and to demonstrate the capability of the breath alcohol analyzer to make measurements on the end expiratory air, the following simplified means could be used :

- Dry gases, which can be used for tests defined in 11.4.3.7 to 11.4.3.12, 11.4.4
- Gases without  $\text{CO}_2$ , which can be used for tests defined in 11.4.3 and 11.4.4.

In all cases, the evolution of the concentration and the flow rate during injection may be constant.

For cases involving dry gases in cylinders:

- variations of atmospheric pressure and variation of the compressibility factor between filling and usage conditions must be taken into account,
- the quality of the gas regulators and the manner by which the gas is delivered to the breath alcohol analyzer, should be taken into account to minimize contamination and a change in the composition of ethanol throughout its use cycle,
- test facilities must be taken into account in calculations of the uncertainties of the measurement.

#### 11.4.3.2 capability of the test apparatus

In order to demonstrate the capability of the breath alcohol analyzer to make measurements on the end expiratory breath , the apparatus used by the laboratory shall be capable of performing tests defined in 11.4.3.2, corresponding to the breath profile described in 11.4.2.

#### 11.4.3.3 type of test facility

The apparatus shall be of one of the two following types :

Type 1 : the apparatus delivers constant test gases with constant volume concentrations of alcohol ;

Type 2 : the apparatus is similar to the one corresponding to 11.4.2.1. During tests, the plateau shall be reached when half of the test volume has been injected (  $\pm 10$  % of total volume).

#### 11.4.4 Errors under rated operating conditions

The type of measuring instrument is presumed to comply with the provisions specified in 5.3 to 5.10 of this Recommendation, if it passes the tests (11.4.2.1-11.4.2.13), confirming that the error of the measuring instrument does not exceed the MPE on initial verification specified in 5.4 under the reference conditions in 11.4.1.

Precondition : normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.

Adjust the EUT as close to zero indication as practicable prior to the test.

Condition of the EUT : Power is to be “on” for the duration of the test.

The EUT shall not be readjusted at any time during the test.

During the test, the following information shall be recorded :

- a) date and time,
- b) temperature,
- c) relative humidity
- d) measurands,
- e) indications,
- f) errors,
- g) functional performance.

##### 11.4.4.1 Accuracy tests

###### a) Maximum permissible errors and repeatability

Compliance with the requirements of 5.4 and 5.7 for maximum permissible errors and repeatability shall be verified at least at the following nominal values:

Test gas No	Mass concentration (mg/L)
1	0.00 to 0.05
2	0.10
3	0.25
4	0.40
5	0.70
6	0.95

Test gas No	Mass concentration (mg/L)
7	1.50
8	2.00 mg/L or the upper value specified by the manufacturer into the limits of the measuring range in 5.2

At least 20 measurements shall be made consecutively at each gas concentration.

For each test gas, each of the 20 measurement results shall comply with the MPE defined in 5.4.1

#### b) Drift

The compliance with the drift requirements shall be tested at certain gas concentrations.

Zero drift: Test gas No 1,

Drift at 0,4 mg/L: test gas No 4,

Test procedure for each test gas:

- 10 subsequent measurements
- after the time intervals specified under 3.6 again 10 subsequent measurements

For each drift test, the deviation between the mean value of the two series of measurements shall fulfil the requirements for drift (5.7.)

Other tests for type approval may be performed during the drift tests.

#### c) Memory and residual effect

- Memory effect

The breath alcohol analyzer shall be subjected to an initial test that includes 10 measurements using test gas n° 2. The mean value of these 10 measurements is calculated.

Then, the breath alcohol analyzer shall be subjected 10 times to the following cycle :

- one measurement using test gas No. 7 or No. 8 ,
- one measurement using test gas No. 2.

The mean value of these 10 measurements with test gas n° 2 during the cycle is calculated.

For the mass concentration at 0.10 mg/L, the difference between the two calculated mean values shall be less than the limit specified in 5.8.1.

- Small changes in mass concentration

The breath alcohol analyzer shall be subjected to 10 measurements using test gas No 4. The mean value of these 10 measurements is calculated.

Then the breath alcohol analyzer is subjected to 10 measurements using test gas No 3. The mean value of these 10 measurements is calculated.

The difference between these two mean values shall comply with the requirement specified in 5.8.2.

#### 11.4.4.2 Influence factors in the parameters which characterise the test gases

These tests shall be carried out under a breath profile as defined in A.2.

For these tests, the values of the parameters that are not specified shall be those defined in the introduction of 11.4.2. The values of the parameters to be varied are specified below.

For each test, 10 measurements using test gas n° 4 shall be performed. Each of these 10 measurements shall fulfil the maximum permissible error requirement defined in 5.1.1.

To be representative of the human exhalation variation, it is necessary to vary two parameters in the same time (volume, duration and flow rate are correlated)

##### a) Influence of delivered volume (in conjunction with exhalation time)

- First test :
  - delivered volume :  $1.2 \text{ L} \pm 0.1 \text{ L}$ ,
  - duration of injection:  $5 \text{ s} \pm 0.5 \text{ s}$ .
  
- Second test :
  - delivered volume :  $4.5 \text{ L} \pm 0.3 \text{ L}$ ,
  - duration of injection:  $18 \text{ s} \pm 0.5 \text{ s}$ .

##### b) Influence of the duration of exhalation (in conjunction with flow)

- First test:
  - delivered volume:  $2.5 \text{ L} \pm 0.2 \text{ L}$ ,
  - duration of injection:  $5 \text{ s} \pm 0.5 \text{ s}$ .
- Second test:
  - delivered volume:  $2.5 \text{ L} \pm 0.2 \text{ L}$ ,
  - duration of injection:  $15 \text{ s} \pm 0.5 \text{ s}$ .

##### c) Influence of the breath profile

- First test:
  - delivered volume:  $3 \text{ L} \pm 0.2 \text{ L}$ ,
  - duration of injection:  $5 \text{ s} \pm 0.5 \text{ s}$ ,
  - type of profile : constant flow rate.
  
- Second test:
  - delivered volume:  $3 \text{ L} \pm 0.2 \text{ L}$ ,
  - duration of injection:  $5 \text{ s} \pm 0.5 \text{ s}$ ,

- type of profile : forceful expiration (according to annex C1).
- d) Influence of the flow rate (in conjunction with volume)
- First test :
    - Delivered volume :  $1.5 \text{ L} \pm 0.1 \text{ L}$ ,
    - Duration of injection :  $5 \text{ s} \pm 0.5 \text{ s}$ .
  - Second test :
    - Delivered volume :  $4 \text{ L} \pm 0.2 \text{ L}$ ,
    - Duration of injection :  $5 \text{ s} \pm 0.5 \text{ s}$ .
- e) Influence of interruption in the breath flow
- First test : the injection of gas normally required for the reference conditions specified in 11.4.3 shall be stopped  $1 \pm 0.5 \text{ s}$  after the start of injection.
  - Second test : the injection of gas normally required for at least 15 s (seeb)) shall be stopped at  $6 \pm 1 \text{ s}$  after the start of injection.
  - Third test : verification of the end of the detection of exhalation. The injection of gas supplied at a flowrate equal to 0.15 L/s is decreased at a flow rate equal to 0.03 L/s.
  - Fourth test : short flow interruption. The injection of a gas with a flow specified in 11.4.2.1 shall be interrupted for a short period (e.g.:0.5 s) and then continued.

For these 4 tests, the instrument shall not give a result.

#### 11.4.4.3 Dry heat

This test is applied to verify compliance with the provisions in 5.10.1 a) under condition of dry heat (high ambient temperature).

The test is carried out according to IEC 60068-2-2, and IEC 60068-3-1.

In addition to the information to the IEC test procedures, the following test procedure in brief shall be applied:

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test
stabilization	2 hours at each temperature under “free air” conditions
Temperature	High temperature as specified in 5.10.1 a)
Temperature sequence	Reference temperature, Specified temperature
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at the relevant temperature, perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and

	record: <ol style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) relative humidity</li> <li>d) measurands,</li> <li>e) indications,</li> <li>f) errors,</li> <li>g) functional performance.</li> </ol>
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.4.4 Cold

This test is applied to verify compliance with the provisions in 5.10.1 a) under condition of cold (low ambient temperature).

The test is carried out according to IEC 60068-2-1, and IEC 60068-3-1.

In addition to the information to the IEC test procedures, the following test procedure in brief shall be applied:

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test
stabilization	2 hours at each temperature under “free air” conditions
Temperature	Low temperature as specified in 5.10.1 a)
Temperature sequence	Reference temperature, Specified temperature
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at the relevant temperature, perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record: <ol style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) relative humidity</li> <li>d) measurands,</li> <li>e) indications,</li> <li>f) errors,</li> <li>g) functional performance.</li> </ol>
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.4.5 Damp heat, steady-state (non condensing)

This test is applied to verify compliance with the provisions in 5.10.1 b) under condition of ambient humidity without condensation.

The test is carried out according to IEC 60068-2-78.

In addition to the information to the IEC test procedures, the following test procedure in brief shall be applied:

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test The EUT shall be handled such that no condensation of water occurs on it.
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. The EUT is kept under the conditions defined in 5.10.1 b) At the end of this period and still under this condition, perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record: a) date and time, b) temperature, c) relative humidity d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	The error of the breath alcohol analyzer is determined one time per day and at the end of the test after a recovery period of one hour. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.4.6 Atmospheric pressure

This test is applied to verify compliance with the provisions in 5.10.1 c) under condition of changes in atmospheric pressure.

The following test procedure shall be applied

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test
stabilization	10 minutes at each pressure
Pressure sequence	Reference pressure (ambient pressure, see 11.4.1), 860 hPa $\pm$ 10 hPa 1060 hPa $\pm$ 10 hPa Reference pressure (ambient pressure, see 11.4.1)
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at the relevant pressure, perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record: a) date and time, b) temperature, c) relative humidity d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.4.7 Random vibration

This test is applied to verify compliance with the provisions in 5.10.1 d) under condition of moderate vibrations.

The test is carried out according to IEC 60068-2-1 IEC 60068-2-64, and IEC 60068-3-8.

In addition to the information to the IEC test procedures, the following test procedure in brief shall be applied:

Precondition	Before the vibrations, the MPE shall be determined
Condition of the EUT	Power is to be "off" for the duration of the test
Test	<p>Adjust the EUT as close to zero indication as practicable prior to the test.</p> <p>The EUT shall not be readjusted at any time during the test.</p> <p>After having been switched off, the following vibration level shall be applied on 3 mutually perpendicular axis during at least 2 minutes per axis, the EUT being mounted on a rigid fixture by its normal mounting means so that the gravitational force acts in the same direction as it would be in normal use.</p> <ul style="list-style-type: none"> <li>- Total frequency range : 10 Hz to 150 Hz</li> <li>- Total RMS level : <math>7 \text{ m.s}^{-2}</math></li> <li>- ASD level 10 Hz- 20 Hz : <math>1 \text{ m}^2.\text{s}^{-3}</math></li> <li>- ASD level 20 Hz- 150 Hz : - 3 dB/octave</li> </ul> <p>After the vibrations, the EUT shall be switched on and, after a stabilization time, perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record:</p> <ol style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) relative humidity</li> <li>d) measurands,</li> <li>e) indications,</li> <li>f) errors,</li> <li>g) functional performance.</li> </ol>
Maximum allowable variations	The error of the BAA is determined after the whole test has been carried out. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.4.8 DC mains voltage variations

This test is applicable only for stationary BAA.

This test is applied to verify compliance with the provisions in 5.10.1 e) under condition of variations in a DC mains network.

The test is carried out according to IEC 60645-2.

In addition to the information to the IEC test procedures, the following test procedure in brief shall be applied:

Precondition	Normal electric power supplied and "on" for a time period equal
--------------	---

	to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test
Voltage sequence	Reference voltage (nominal voltage specified by the manufacturer) High voltage: the upper limit being the DC level at which the EUT has been manufactured to automatically detect high level conditions. Low voltage : the DC level at which the EUT has been manufactured to automatically detect low level condition, Reference voltage (nominal voltage specified by the manufacturer)
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at the relevant voltage perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record: <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) reference voltage at beginning and end, high voltage and low voltage,</li> <li>d) measurands,</li> <li>e) indications,</li> <li>f) errors,</li> <li>g) functional performance.</li> </ul>
Maximum allowable variations	The errors shall be determined when the BAA is powered on at the upper limit of the voltage and when the BAA is powered on at the lower limit of the voltage. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.4.9 AC mains voltage variations

This test is applicable only for stationary BAA.

This test is applied to verify compliance with the provisions in 5.10.1 f) under condition of variations in the mains power voltage.

The test is carried out according to IEC 61000-2-1 and IEC 61000-4-1

In addition to the information to the IEC test procedures, the following test procedure in brief shall be applied:

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test
Voltage sequence	Nominal (reference) voltage High voltage: $U_{nom} + 10\%$ Low voltage : $U_{nom} - 15\%$ Nominal (reference) voltage
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at the relevant voltage perform 5 measurements

	using test gas n°4 defined in 11.4.2.1 a) and record: <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) reference voltage at beginning and end, high voltage and low voltage,</li> <li>d) measurands,</li> <li>e) indications,</li> <li>f) errors,</li> <li>g) functional performance</li> </ul>
Maximum allowable variations	The errors shall be determined when the BAA is powered on at the upper limit of the voltage and when the BAA is powered on at the lower limit of the voltage. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4
Notes	The values of $U_{nom}$ are those marked on the measuring instrument. In case a range is specified, the “-“ relates to the lowest value and the “+” to the highest value of the range

#### 11.4.4.10 Low voltage of internal battery

This test is applied to verify compliance with the provisions in 5.10.1 h) under condition of running out internal battery.

There is no reference to standards for this test.

Precondition	Before the test, the instrument shall be switched “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test
Lower limit of the test voltage	The lowest voltage at which the EUT functions properly according to the specifications given by the manufacturer
Test procedure	<p>The test consists of exposure to the specified condition of the battery(s) for a period sufficient for achieving temperature stability and for performing the required measurements.</p> <p>Test sequence: Stabilize the power supply at the voltage within the defined limits and apply the measurement and/or loading condition. After stabilization at the relevant voltage perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record:</p> <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) power supply voltage,</li> <li>d) functional mode</li> <li>e) measurements and/or loading condition,</li> <li>f) indications,</li> <li>g) errors,</li> <li>h) functional performance</li> </ul> <p>Reduce the power voltage to the EUT until the equipment clearly ceases to function properly according to the specifications and metrological requirements, and note the following data:</p> <ul style="list-style-type: none"> <li>i) power supply voltage</li> <li>j) indications</li> </ul>

	k) errors l) other relevant responses of the instrument
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4
Notes	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 specified type of battery also be simulated.

#### 11.4.4.11 Voltage variations of a road vehicle battery

This test is applied to verify compliance with the provisions in 5.10.1 i) under condition of high (under charge) and low battery voltage.

The test is carried out according to ISO 16750-2

In addition to the information to the ISO test procedures, the following test procedure in brief shall be applied:

The test consists of two separate tests. In between, the power shall be switched off.

Precondition	Before each test, the EUT is switched off for a period of time long enough to be thermally stable at the environmental temperature. For each test (low voltage and high voltage respectively), the power is switched on at that test voltage.
stabilization	The EUT is powered at the test voltage for a time period equal to or greater than the warm-up time specified by the manufacturer.
Test voltages	Voltages as specified in 5.10.1 i)
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at the relevant voltage perform 5 measurements using test gas n <sup>o</sup> 4 defined in 11.4.2.1 a) and record: <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) voltage,</li> <li>d) measurands,</li> <li>e) indications,</li> <li>f) errors,</li> <li>g) functional performance</li> </ul>
Maximum allowable variations	The errors shall be determined when the BAA is powered on at the upper limit of the voltage and when the BAA is powered on at the lower limit of the voltage. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.4.12 AC mains frequency variations

This test is applicable only for stationary BAA powered by AC mains voltage (direct or through a generator).

This test is applied to verify compliance with the provisions in 5.10.1 g) under condition of varying AC mains power frequency.

The test is carried out according to IEC/TR 61000-2-1, IEC 61000-2-2 and IEC 61000-4-1

In addition to the information to the IEC test procedures, the following test procedure in brief shall be applied:

Precondition	Normal electric power of the nominal voltage and frequency supplied and “on” for a time period equal to or greater then the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test, the voltage kept at the nominal voltage.
Voltage sequence	Nominal (reference) frequency High voltage: $f_{nom} + 2\%$ Low voltage : $f_{nom} - 2\%$ Nominal (reference) frequency
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at the relevant frequency perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record: <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) voltage,</li> <li>d) reference frequency at beginning and end, high frequency and low frequency,</li> <li>e) measurands,</li> <li>f) indications,</li> <li>g) errors,</li> <li>h) functional performance</li> </ul>
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4
Notes	The values of $f_{nom}$ are those marked on the measuring instrument. In case a range is specified, the “-“ relates to the lowest value and the “+” to the highest value of the range

#### 11.4.4.13 Total fraction by volume of hydrocarbons (as methane equivalent) in the environment

This test is applied to verify compliance with the provisions in 5.10.1 j) under condition of hydrocarbons in the environment.

The following test procedure shall be applied

Precondition	Normal electric power supplied and “on” for a time period equal to or greater then the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at 5 ppm of hydrocarbons , perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record: <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) relative humidity</li> </ul>

	d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.4.14 Influence of volume fraction of CO<sub>2</sub>

This test is applied to verify compliance with the provisions in 5.10.1 k) under condition of CO<sub>2</sub> in the environment.

The following test procedure shall be applied

Precondition	Normal electric power supplied and “on” for a time period equal to or greater then the warm-up time specified by the manufacturer.
Condition of the EUT stabilization	Power is to be “on” for the duration of the test
Test	Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test. After stabilization at 10 % of CO <sub>2</sub> , perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record: a) date and time, b) temperature, c) relative humidity d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.4

#### 11.4.5 Disturbances tests

The tests shall be carried out using test gas n° 4. .

The application of each test shall be long enough to apply during a complete cycle of measurement of the breath alcohol analyzer.

The type of measuring instrument is presumed to comply with the provisions specified in 5.12 if it passes the following tests :

##### 11.4.5.1 Radiated, radio frequency, electromagnetic fields (See OIML D 11-12.1.1)

This test is applied to verify compliance with the provisions in 5.12.1.1a) under conditions of radiated electromagnetic fields.

This test is carried out according to IEC 61000-4-3.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	Before the test, the instrument shall be switched “on” for a time period equal to or greater then the warm-up time specified by the manufacturer. Adjust the EUT as close to zero indication as practicable prior to the test.
Condition of the EUT :	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
EM Field	Radiated 10 V/m, modulated 80 % AM, sine wave
Frequency range:	from 80 MHz to 2000 MHz
Performance test:	Stabilize all factors at nominal reference conditions. Record the following with and without radiated electromagnetic fields: <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) relative humidity,</li> <li>d) value of the measurand,</li> <li>e) indications and errors,</li> <li>f) functional performance</li> </ul> conventionally 3 cycles of tests are performed starting each test at a different moment of the measuring cycle.
Performance of the instrument	Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing

In the event that the breath alcohol analyzer has no mains or input ports, the applicable frequency range is from 26 MHz to 2000 MHz.

The frequencies are stepped across incrementally with the step size not exceeding 1% of the previous frequency.

#### 11.4.5.2 Conducted radio-frequency fields (See OIML D 11-12.1.2)

This test doesn't apply if the breath alcohol analyzer has no mains or other input ports. Otherwise it shall be conducted on supply lines and on all connection cables if the instrument is composed of several elements connected together. For connection cables, the test shall be performed at each extremity of the cables if both of the elements are part of the instrument.

This test is applied to verify compliance with the provisions in 5.12.1.1b) under conditions of conducted electromagnetic fields.

This test is carried out according to IEC 61000-4-6.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	Before the test, the instrument shall be switched “on” for a time period equal to or greater then the warm-up time specified by the manufacturer. Adjust the EUT as close to zero indication as practicable prior
----------------	--

	to the test.
Condition of the EUT :	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
EM Field	Radiated 10 V/m, modulated 80 % AM, sine wave
Frequency range:	from 0,15 MHz to 26 MHz
Performance test:	<p>Stabilize all factors at nominal reference conditions. Record the following with and without radiated electromagnetic fields:</p> <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) relative humidity,</li> <li>d) value of the measurand,</li> <li>e) field strength,</li> <li>f) indications and errors,</li> <li>g) functional performance</li> </ul> <p>conventionally 3 cycles of tests are performed starting each test at a different moment of the measuring cycle.</p>
Performance of the instrument	<p>Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing</p>

#### 11.4.5.3 Electrostatic discharges (See OIML D 11-12.2)

This test is applied to verify compliance with the provisions in 5.12.1.1c) under conditions of electrostatic discharges.

This test is carried out according to IEC 61000-4-2.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	<p>Before the test, the instrument shall be switched “on” for a time period equal to or greater then the warm-up time specified by the manufacturer. Adjust the EUT as close to zero indication as practicable prior to the test.</p>
Condition of the EUT :	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
Discharges	<p>Contact mode : 6 kV Air mode : 8 kV</p>
Performance test:	<p>The test consist in exposing the EUT to both direct and indirect, electrostatic discharges. Contact discharges are the preferred test method. Nevertheless, air discharges shall be used where contact discharges cannot be applied (e.g. non conductive surfaces). At least ten successive discharges shall be applied with a time interval between discharges of at least ten seconds on each point of application. The number of points of application on each surface will depend on the size of the instrument and shall be specified in the test report. The discharges shall be applied on each surface accessible in normal</p>

	<p>operation. 5 measurements shall be performed in each surface.</p> <p>Record the following with and without discharges:</p> <ol style="list-style-type: none"> <li>date and time,</li> <li>temperature,</li> <li>relative humidity,</li> <li>value of the measurand,</li> <li>discharges,</li> <li>indications and errors,</li> <li>functional performance</li> </ol> <p>conventionally 3 cycles of tests are performed starting each test at a different moment of the measuring cycle.</p>
Performance of the instrument	<p>Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility.</p> <p>It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing</p>

#### 11.4.5.4 Bursts on supply lines (See OIML D 11-13.5)

This test is only applicable to breath alcohol analyzer powered from AC mains or DC mains.

This test is applied to verify compliance with the provisions in 5.12.1.1d) under conditions of bursts on supply lines.

This test is carried out according to IEC 61000-4-1 and IEC 61000-4-4.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	<p>Before the test, the instrument shall be switched “on” for a time period equal to or greater then the warm-up time specified by the manufacturer.</p> <p>Adjust the EUT as close to zero indication as practicable prior to the test.</p>
Condition of the EUT :	<p>The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.</p>
Performance test:	<p>The test consist in exposing the EUT to bursts of voltage spikes of 1kV, with a repetition rate of 5kHz.</p> <p>At least 10 positive and 10 negative bursts randomly phased shall be applied.</p> <p>Record the following:</p> <ol style="list-style-type: none"> <li>date and time,</li> <li>temperature,</li> <li>relative humidity,</li> <li>value of the measurand,</li> <li>indications and errors,</li> <li>functional performance</li> </ol>
Performance of the instrument	<p>Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility.</p>

	It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing
--	--

#### 11.4.5.5 Bursts on signal, data and control lines (See OIML D 11-12.4)

This test is applied to verify compliance with the provisions in 5.12.1.1e) under conditions of bursts on signal, data and control lines.

This test is carried out according to IEC 61000-4-1 and IEC 61000-4-4.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	Before the test, the instrument shall be switched “on” for a time period equal to or greater than the warm-up time specified by the manufacturer. Adjust the EUT as close to zero indication as practicable prior to the test.
Condition of the EUT :	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
Performance test:	The test consist in exposing the EUT to bursts of voltage spikes of 1kV, with a repetition rate of 5kHz. At least 10 positive and 10 negative bursts randomly phased shall be applied.  Record the following: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) indications and errors, f) functional performance
Performance of the instrument	Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing

#### 11.4.5.6 Surges on signal, data and control lines (See OIML D 11-12.5)

This test is applied to verify compliance with the provisions in 5.12.1.1f) under conditions of surges on signal, data and control lines.

This test is carried out according to IEC 61000-4-5.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	Before the test, the instrument shall be switched “on” for a time period
----------------	--

	<p>equal to or greater than the warm-up time specified by the manufacturer. Adjust the EUT as close to zero indication as practicable prior to the test.</p>								
Condition of the EUT :	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.								
Performance test:	<p>The test consist in exposing the EUT to surges as follow :</p> <table border="1" style="margin-left: 40px;"> <tr> <td rowspan="2">Unbalanced lines</td> <td>Line to line</td> <td>1 kV</td> </tr> <tr> <td>Line to earth</td> <td>2 kV</td> </tr> <tr> <td>Balanced lines</td> <td>Line to earth</td> <td>2 kV</td> </tr> </table> <p>At least 3 positive and 3 negative surges shall be applied.</p> <p>Record the following:</p> <ol style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) relative humidity,</li> <li>d) value of the measurand,</li> <li>e) line,</li> <li>f) indications and errors,</li> <li>g) functional performance</li> </ol>	Unbalanced lines	Line to line	1 kV	Line to earth	2 kV	Balanced lines	Line to earth	2 kV
Unbalanced lines	Line to line		1 kV						
	Line to earth	2 kV							
Balanced lines	Line to earth	2 kV							
Performance of the instrument	<p>Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing</p>								

11.4.5.7 AC mains voltage dips, short interruptions and voltage variations (See OIML D 11, 13.4)

This test is applied to verify compliance with the provisions in 5.12.1.1g) under conditions of AC mains voltage dips, short interruptions and voltage variations.

This test is carried out according to IEC 61000-4-11, IEC 61000-6-1 and IEC 61000-6-2.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	<p>Before the test, the instrument shall be switched “on” for a time period equal to or greater than the warm-up time specified by the manufacturer. Adjust the EUT as close to zero indication as practicable prior to the test.</p>										
Condition of the EUT :	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.										
Performance test:	<p>The test consist in exposing the EUT to mains voltage reductions as follow</p> <table border="1" style="margin-left: 40px;"> <tr> <td>Reduction</td> <td>100 %</td> <td>100 %</td> <td>30 %</td> <td>&gt; 95 %</td> </tr> <tr> <td>Duration</td> <td>0.5 cycle</td> <td>1 cycle</td> <td>25 cycles</td> <td>250 cycles</td> </tr> </table> <p>The mains voltage reductions shall be repeated 10 times with an interval of at least 10 seconds. The error of the BAA is determined for each configuration of testing.</p>	Reduction	100 %	100 %	30 %	> 95 %	Duration	0.5 cycle	1 cycle	25 cycles	250 cycles
Reduction	100 %	100 %	30 %	> 95 %							
Duration	0.5 cycle	1 cycle	25 cycles	250 cycles							

	Record the following: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) voltage reduction, f) indications and errors, g) functional performance
Performance of the instrument	Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing

11.4.5.8 Electrical transient conduction for external batteries of a vehicle (See OIML D 11, 14.2.2)

This test shall be applied to breath alcohol analyzer powered from external 12 V or 24 V road vehicle batteries.

This test is applied to verify compliance with the provisions in 5.12.1.1h) under conditions of Electrical transient conduction for external batteries of a vehicle.

This test is carried out according to ISO 7637-2.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	Before the test, the instrument shall be switched “on” for a time period equal to or greater then the warm-up time specified by the manufacturer. Adjust the EUT as close to zero indication as practicable prior to the test.						
Condition of the EUT :	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.						
Performance test:	The test consist in exposing the EUT to disturbances on the power voltage by direct coupling on supply lines as follow: $U_{nom} = 12V$						
		Pulse 1	Pulse 2		Pulse 3		Pulse 4
level	-100 V	2a + 50 V	2b + 10 V	3a - 150 V	3b + 100 V	- 7 V	
Minimum number of pulses or test time	5000 pulses	5000 pulses		1 hour		1 pulse	
	$U_{nom} = 24 V$						
		Pulse 1	Pulse 2		Pulse 3		Pulse 4
level	-100 V	2a + 50 V	2b + 20 V	3a - 200 V	3b + 200 V	- 16 V	
Minimum number of pulses or test time	5000 pulses	5000 pulses		1 hour		1 pulse	
	Record the following: a) date and time,						

	<ul style="list-style-type: none"> <li>b) temperature,</li> <li>c) relative humidity,</li> <li>d) value of the measurand,</li> <li>e) voltage,</li> <li>f) indications and errors,</li> <li>g) functional performance</li> </ul>
Performance of the instrument	<p>Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility.</p> <p>It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing</p>

11.4.5.9 Mechanical shocks (See OIML D 11-11.2)

This test is applied to verify compliance with the provisions in 5.12.1.2 b) after conditions of mechanical shocks.

This test is carried out according to IEC 60068-2-31.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	<p>Before the test, the instrument shall be switched “on” for a time period equal to or greater then the warm-up time specified by the manufacturer.</p> <p>Adjust the EUT as close to zero indication as practicable prior to the test.</p>												
Condition of the EUT :	<p>The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.</p>												
Performance test:	<p>The test consist in exposing the EUT to mechanical shocks as follow:</p> <ul style="list-style-type: none"> <li>- For stationary or/and mobile breath alcohol analyzer The breath alcohol analyzer is placed on a rigid surface in the position in which it is normally used, is tilted on one bottom edge and is then allowed to fall freely onto the test surface. This test shall be repeated for each edge in turn (subject to a maximum inclination of 30 °).</li> <li>- For portable breath alcohol analyzer : 3 arbitrary positions are chosen.</li> </ul> <p>The height of fall given below is that of the opposite edge</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>stationary</th> <th>mobile</th> <th>portable</th> </tr> </thead> <tbody> <tr> <td>Height of fall</td> <td>25 mm</td> <td>50 mm</td> <td>1 m</td> </tr> <tr> <td>Number of fall</td> <td>1</td> <td>1</td> <td>3</td> </tr> </tbody> </table> <p>Record the following:</p> <ul style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> <li>c) relative humidity,</li> <li>d) value of the measurand,</li> <li>e) height of fall,,</li> <li>f) indications and errors,</li> <li>g) functional performance</li> </ul>		stationary	mobile	portable	Height of fall	25 mm	50 mm	1 m	Number of fall	1	1	3
	stationary	mobile	portable										
Height of fall	25 mm	50 mm	1 m										
Number of fall	1	1	3										
Performance of the instrument	<p>Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility.</p>												

:

## 11.4.5.10 Shakes

This test is applied to verify compliance with the provisions in 5.12.1.2 b) after conditions of shakes. This test simulates shocks in a car trunk.

The following test procedure shall be applied:

Precondition	
Condition of the EUT	Power is to be "off" for the duration of the test Adjust the EUT as close to zero indication as practicable prior to the test. The EUT shall not be readjusted at any time during the test.
Test	After having been switched off, the EUT is placed in its reference position on a table which can generate shakes in the following conditions: wave shape: half-sinusoid amplitude: 10 g ( $g = 9.81 \text{ m/s}^2$ ) duration: 6 ms frequency: 2 Hz number of axes: 3 perpendicular axes number of shakes: 1000 for each axes  After shakes, the EUT shall be switched on and, after a stabilization time, perform 5 measurements using test gas n <sup>o</sup> 4 defined in 11.4.2.1 a) and record: a) date and time, b) temperature, c) relative humidity d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility.

## 11.4.5.11 Damp heat cyclic (condensing) (OIML D 11, 10.2.2)

This test is applied to verify compliance with the provisions in 5.12.1.2 c) after conditions of Damp heat cyclic (condensing).

This test is carried out according to IEC 60068-2-30 and IEC 60068-3-4.

In addition to the information to the IEC test procedures, the following test procedures in brief shall be applied :

Precondition :	Before the test, the instrument shall be switched "on" for a time period equal to or greater then the warm-up time specified by the manufacturer.
----------------	---

	Adjust the EUT as close to zero indication as practicable prior to the test.									
Condition of the EUT :	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.									
Performance test:	<p>The breath alcohol analyzer shall be exposed to cyclic variation between 25 °C and the temperature specified below. The relative humidity shall be above 95 % during the temperature change and low temperature phases and at 93 % at the upper temperature phases. Condensation should occur on the breath alcohol analyzer during the temperature rise.</p> <p>The 24 cycle consists of :</p> <ol style="list-style-type: none"> <li>1) Temperature rise during 3 h,</li> <li>2) Temperature maintained at the upper value during 9 h,</li> <li>3) Temperature lowered to the lower value during 3 h,</li> <li>4) Temperature maintained at the lower value during 9 h.</li> </ol> <table border="1" data-bbox="683 734 1286 884"> <tr> <td></td> <td>Mobile</td> <td>Portable</td> </tr> <tr> <td>Temperature</td> <td>55 °C</td> <td>55 °C</td> </tr> <tr> <td>Duration</td> <td>2 cycles</td> <td>4 cycles</td> </tr> </table> <p>Record the following:</p> <ol style="list-style-type: none"> <li>b) date and time,</li> <li>c) temperature,</li> <li>d) relative humidity,</li> <li>e) value of the measurand,</li> <li>f) indications and errors,</li> <li>g) functional performance</li> </ol>		Mobile	Portable	Temperature	55 °C	55 °C	Duration	2 cycles	4 cycles
	Mobile	Portable								
Temperature	55 °C	55 °C								
Duration	2 cycles	4 cycles								
Performance of the instrument	Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility.									

#### 11.4.5.12 Storage test

This test is applied to verify compliance with the provisions in 5.12.1.2 d) after conditions of storage.

The following test procedures shall be applied :

Precondition :	Power is to be “off” for the duration of the test Adjust the EUT as close to zero indication as practicable prior to the test.
Condition of the EUT :	The EUT shall not be readjusted at any time during the test
Performance test:	<p>After having been “off”, the EUT is exposed to a low temperature of -25 °C during six hours and to a high temperature of 70 °C during six hours.</p> <p>The change of temperature shall not exceed 1 °C/min during cooling down and heating up.</p> <p>Then the EUT shall be switched on and, after a recovery period of one hour at the reference conditions, perform 5 measurements using test gas n°4 defined in 11.4.2.1 a) and record:</p> <ol style="list-style-type: none"> <li>a) date and time,</li> <li>b) temperature,</li> </ol>

	c) relative humidity, d) value of the measurand, e) indications and errors, f) functional performance
Performance of the instrument	Either significant faults as defined in 5.11.1 do not occur, or significant fault are detected and acted upon by means of a checking facility.

#### 11.4.5.13 Durability

The requirement defined in 5.13 is met if the instrument submitted to the accuracy tests and disturbances tests passes each single test.

#### 11.4.6 Physiological influence quantities

The breath alcohol analyzer shall be tested according to the following procedure :

- determination of the indication for a dry test gas having an ethanol content of 0.4 mg/L  $\pm$  5 % without any interfering substance.
- determination of the indication for the same test gas with one and only one of the interfering substances listed in the following table at the indicated mass concentration :

Interfering substance	Nominal value for vapour mass concentration mg/L ( $\pm$ 5 %)
Acetone	0.5
Acetaldehyde	0.15
Methanol	0.1
Isopropanol	0.1
Carbon monoxide	0.2
Toluene	0.2

If the variation of the indication is not more than the maximum value defined in 5.12.2(0.1 mg/L for the current interfering substances in the above table) the breath alcohol analyzer has passed the test for the interfering substance concerned. If the variation is more than the value defined in 5.12.2 and if no error message is given, the breath alcohol analyzer has failed. If an error message is given, another test shall be performed with the same interfering substance at a mass concentration 5 times smaller. In that case the variation shall not be more than a fifth of the maximum value defined in 5.12.2

This test shall be performed at least 5 times for each of the interfering substance. Each time, the requirement shall be fulfilled.

National Authorities may decide to test the influence of other compounds.

## Annexe A

### Examples of detection of alcohol in upper respiratory tracts

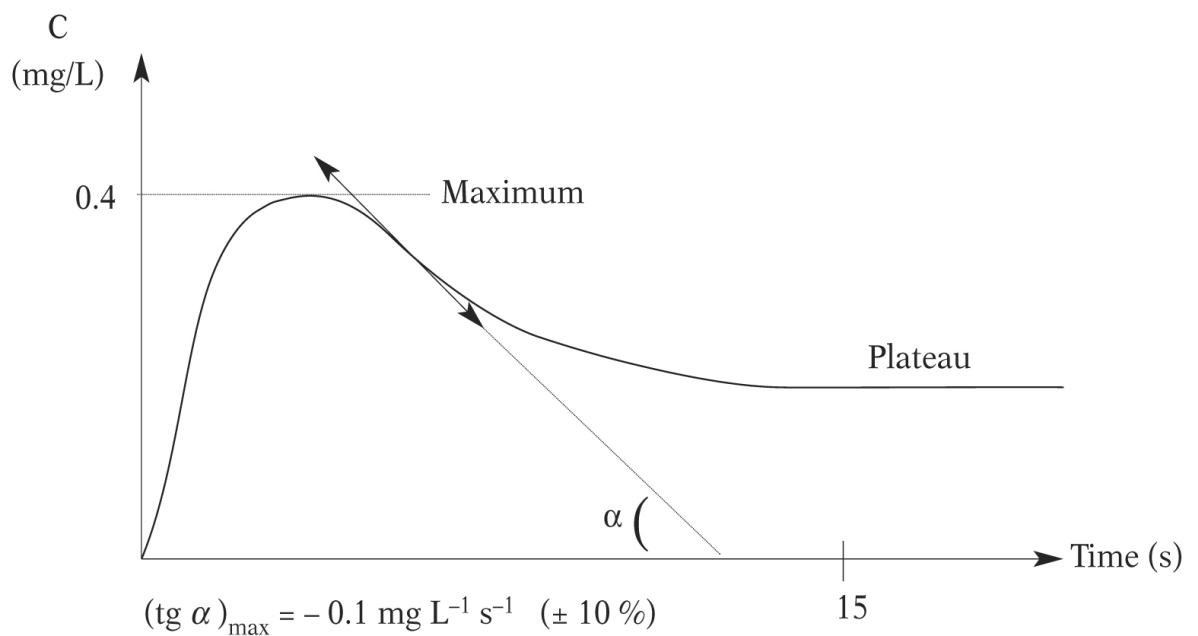
(informative)

The member State may choose one, two or all the following solutions for detection of alcohol in the upper respiratory tracts (A1 A2 or A3) and/or avoiding the corresponding influence (A3).

#### A.1 Peak method

In the event that the breath alcohol analyzer mouth alcohol detection operates by the detection of a peak in the IR signal, the following test demonstrates that the instrument is able to detect alcohol in upper respiratory tracts.

The test consists in injecting a test gas providing an evolution of the mass concentration as indicated below:



The characteristics of the gas injected are the following:

- delivered volume:  $3 \text{ L} \pm 0.2 \text{ L}$ ,
- duration:  $15 \text{ s} \pm 0.5 \text{ s}$
- mass concentration at maximum of the curve:  $0.4 \text{ mg/L} \pm 0.020 \text{ mg/L}$

Ten measurements shall be performed and the instrument shall detect the presence of alcohol in the upper respiratory tracts and shall deliver no measurement result.

## A.2 Two-measurement cycle

### A.2.1 First method

The measuring cycle shall include two measurements. These two measurements shall be performed within a delay no smaller than 2 min.

The breath alcohol analyzer shall be able to memorize what value constitutes the offence of driving or working under influence of alcohol hereafter called “the legal value”.

The measuring cycle can be stopped after the first measurement if the concentration value is less than the legal value. In that case, the result of measurement shall be displayed and printed, if applicable.

If one of the two measurements is less than the legal value and the other one more than or equal to the legal value, the smallest result shall be displayed and printed (if applicable). There is no need of a comparison between the two results.

If both of the two measurements are more than or equal to the legal value, it is necessary to calculate the ratio :

$R = \left| 1 - \frac{C_2}{C_1} \right| / t$ , where t is the time difference between the end of the first breath and the end of the second breath.

If R is less than  $0.03 \text{ min}^{-1}$ , the member State may choose one of the two following solutions:

- the smallest value of C1 and C2 is displayed and printed (if applicable).
- the two values C1 and C2 are displayed and printed (if applicable).

In any case, when the second measurement is not performed, it is possible to indicate the unique available result as an indicative one for instance indicating “measuring cycle not completed”.

If R is more than or equal to  $0.03 \text{ min}^{-1}$ , the measuring cycle shall be cancelled and the breath alcohol analyzer shall display a warning message to specify that the cycle is not valid and that a new one shall start.

### A.2.2 Second method

The breath analyzer shall use a measuring cycle involving two subject sample measurements, each measurement corresponding to an exhalation. The two subject sample measurements are separated by at least 2 minutes. The resultant displayed or recorded measurement in a subject test is to be specified by the legal authority (e.g. lower value, mean of the two values or both values).

If the difference between the two subject sample measurements exceeds the greater of the following two values:

- 0.10 mg/L, or;
- 20% relative of the smallest of the two measurements;

Note: the national authority may elect to test to breath differences that are tighter than those listed above. The national authority may also elect to not perform a comparison of samples in the event that either of the sample measurements are below the alcohol level that constitutes the offence of driving or working under influence of alcohol.

Then the analyzer shall automatically invalidate the measurement cycle because of breath difference, based on national requirements.

The test procedure for this function consists of measuring two samples of test gases differing by 12.5%, in a measurement cycle consisting of two measurements separated by at least two minutes, but no longer than 5 minutes. The characteristics of the test gases are:

- First test gas: Test gas No. 4
- Second test gas: Test gas No. 3
- Duration of injection: 5 s
- Duration of plateau: 3 s
- Volume: 3 L

The mass concentration at maximum of an injection curve is 0.40 and .25 mg/L, respectively, with the second gas being lower than the first test gas. The results of the sequential test shall be that the instrument will either invalidate the measurement cycle and/or display a warning as required by the National Authority

### **A.3 Delay before measurement**

Good measurement practice regardless of technical solutions (A1, A2) is an observation period prior to subject tests of at least 15 min.

During this period of time, the subject shall not introduce anything in his mouth to ensure that alcohol has been cleared from the upper respiratory tract.

## **Annex B**

### **General information and breath profile ( informative)**

As defined in the scope of this Recommendation, the purpose of this document is to evaluate the suitability of breath alcohol analyzer for measuring the mass concentration of alcohol in exhaled human breath. This can not be reproducibly due to wide human variation and the variability of breath samples themselves.

For example, characteristics of a sample will depend on the willingness or physical ability of the subject to deliver the optimal sample. A subject may deliver the sample with a long steady breath , or he may deliver the sample with a short forceful breath.

In these two cases, the evolution of the flow of exhalation is very different. In the first case, the flow is constant with a possible light decrease, following the regularity of the breath, in the second case, there is a peak of the flow at the beginning of the breath and a fast decrease at the end of the breath.

The aims of this annex are to characterize the breath profiles and define the acceptance criteria.

(explanatory Note)

Knowing that the instruments can be influenced by variations of pressure at the time of a breath; it is important to consider this new factor of influence.

Same manner, the taking into account of different the volume died from the physiological point of view from the individuals highlight a dilution of the alcohol concentration contained in the air cells (representative of the alcohol concentration contained in blood) and the volume of the high respiratory tracts (free from alcohol or more precisely if one considers a presence of alcohol on the mucous membranes that Ci no representative of alcohol is contained in the air cells)

Present the appendix aims at:

to present using theoretical curves the physical phenomena allowing to characterize the influence factors–

to prepare the next ones discussed in order to rule on the types of profiles and the criteria of acceptances

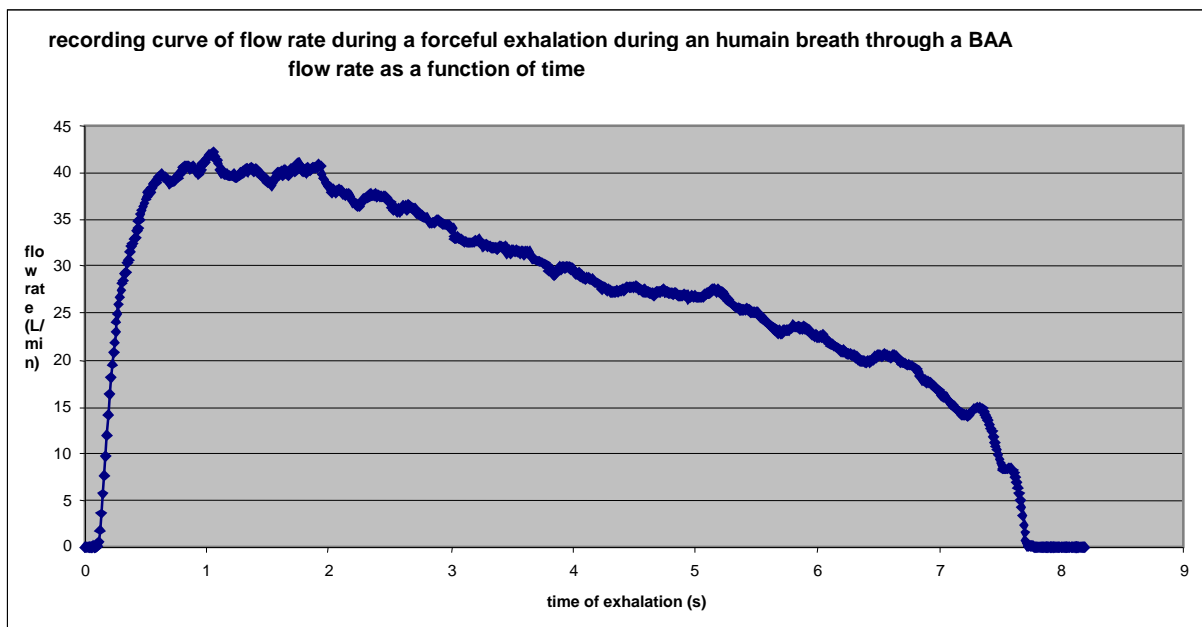
#### **B.1 MEASUREMENT FLOW RATE DURING EXHALATION**

the aim of this section is to define a method to fix to characterize the variation of the air flow as a function of time during an exhalation .

### Conventional curve of forced exhalation:

The curve is divided into two distinct areas: ·

- the first part of the curve (located in the first  $\frac{1}{4}$  of the time of exhalation) represents the peak of flow at the time of the exhalation
- the second part represents a regular decrease of the flow of breath



Standard to be respected: ·

- during the first  $\frac{1}{4}$  of the time of exhalation, the maximum flow rate is reached.
- at the  $\frac{2}{3}$  of the time of exhalation, the flow rate of breath must be lower than the  $\frac{2}{3}$  of the maximum flow rate.
- starting from the maximum flow rate, the flow rate shall significantly decrease without interruption of breath.

note: this standard is sufficiently flexible to allow an easy simulation of a forced exhalation

## B.2 MEASUREMENT ALCOHOL DURING EXHALATION / DETERMINATION OF THE ALCOHOL PLATEAU

The duration of the plateau of the alcohol concentration in a human breath shows very variable characteristics according to the morphology of the subjects.

It is an important influence factor for the determination of the alcohol concentration

The aim of this section is to define a method to determine the duration of the alcohol plateau at the time of an exhalation taking into account the diversity of the subjects.

### Curves of the alcohol concentration as a function of time obtained from a human exhalation

#### Theoretical curves:

By considering an average dead anatomical volume of 150 ml, a theoretical curve of the alcohol concentration (expressed in %) according to time and volume of the breath can be calculated starting from the following formula:

$$C_i = C_{(i-1)} + \left[ \frac{D * (100 - C_{(i-1)}) * (t_i - t_{(i-1)})}{V_m} \right]$$

$(C_0 = 0)$  ;  $i = \text{incremental indice}$

where C = alcohol concentration (expressed in %)

D = flow rate (L/s)

t = time of exhalation (s)

$V_m$  = dead anatomical volume (L)

note : this is a reference to the volume of air from the upper respiratory tract

In theory, the alcohol concentration representative of alveolar air is obtained in the last third of the time of exhalation (concentration superior to 99 % of the maximum value).

This value (99 % of the waiting concentration) is a proposition based on the statistic rules about response time. Another value can be proposed for example 99.5 %.

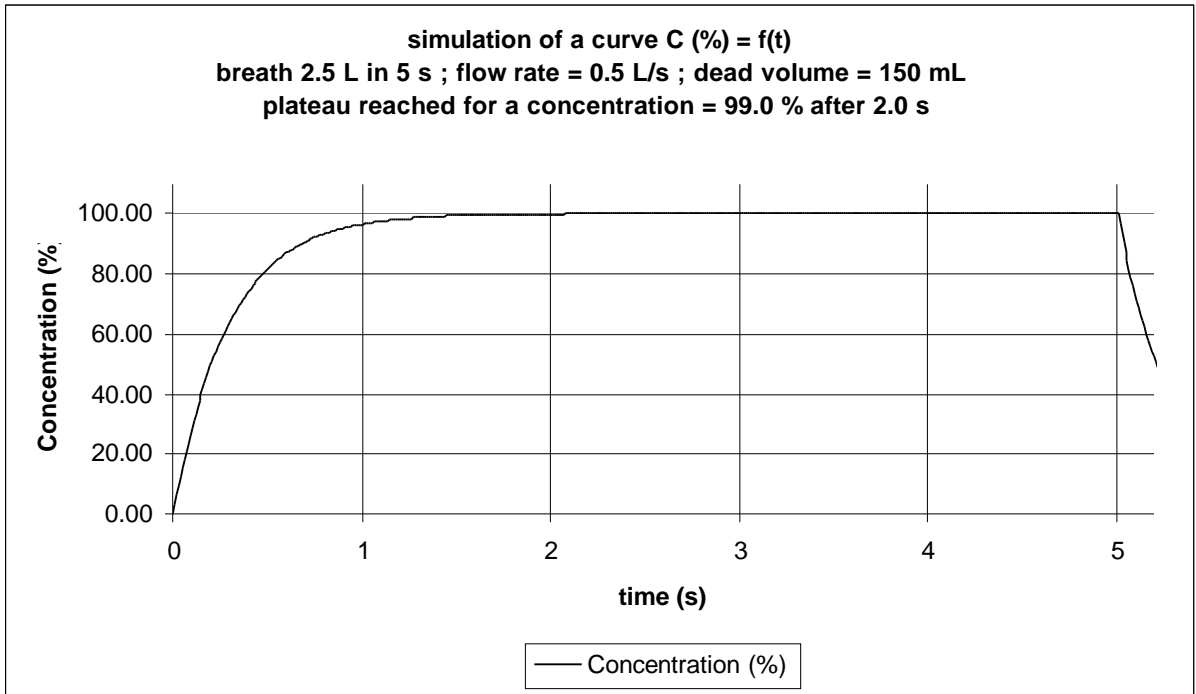
This value and its variations must be taken into account in the global calculation of the overall uncertainty of the test facility in accordance with the requirement of chapter A.3. (Note: 1/3 EMT)

Example by considering an average dead anatomical volume of 150 ml

Example / curve A

breath Profile : 2.5 L in 5 s , constant breath

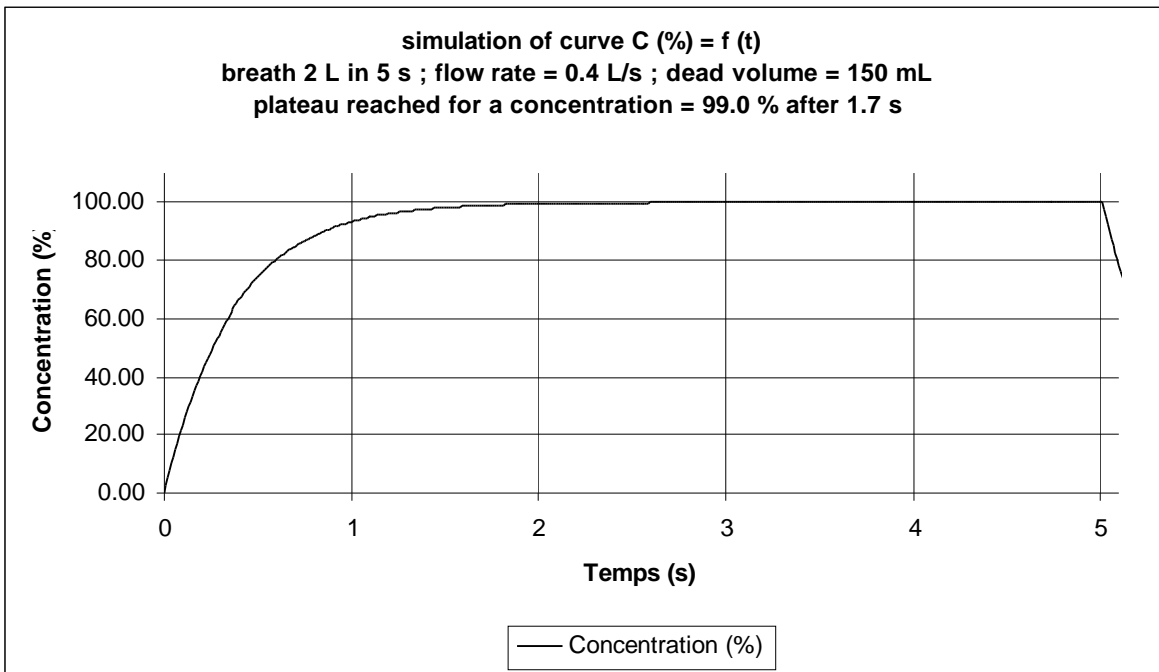
Dead volume = 150 mL



Example / curve B

breath Profile : 2.0 L in 5 s , constant breath

Dead volume = 150 mL

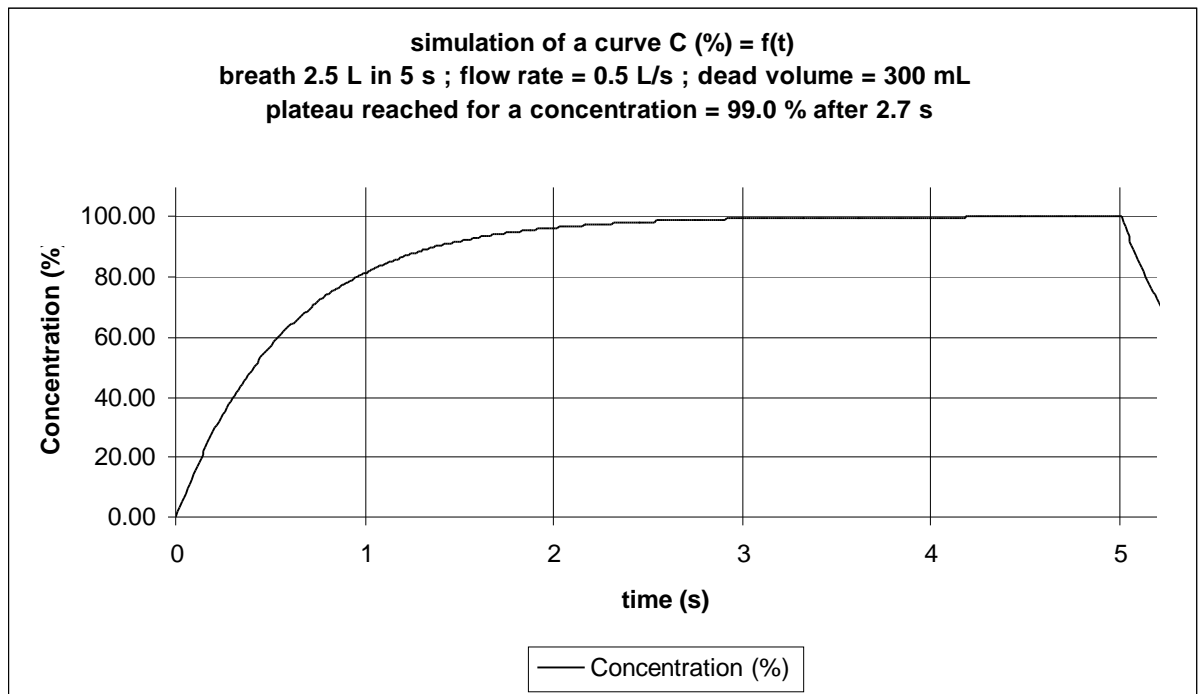


Example by considering an average dead anatomical volume of 300 ml

Example / curves C

breath : Profile 2.5 L in 5 s , constant breath

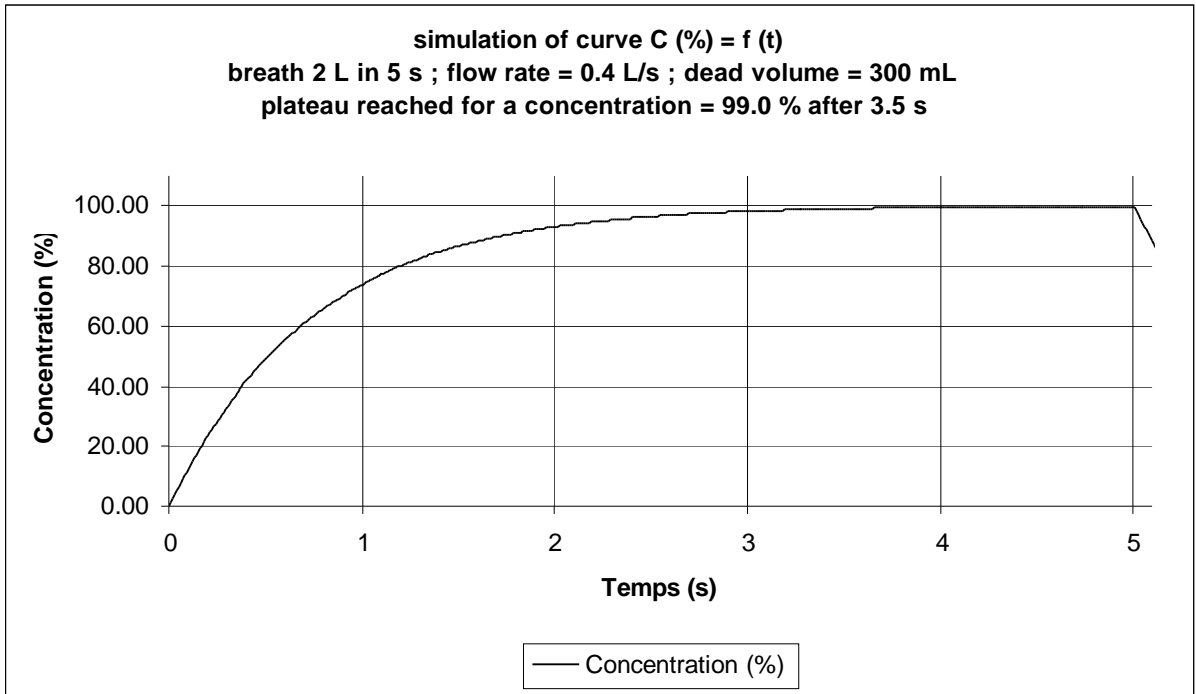
Dead volume = 300 mL



Example / curves D

breath Profile : 2.0 L in 5 s , constant breath

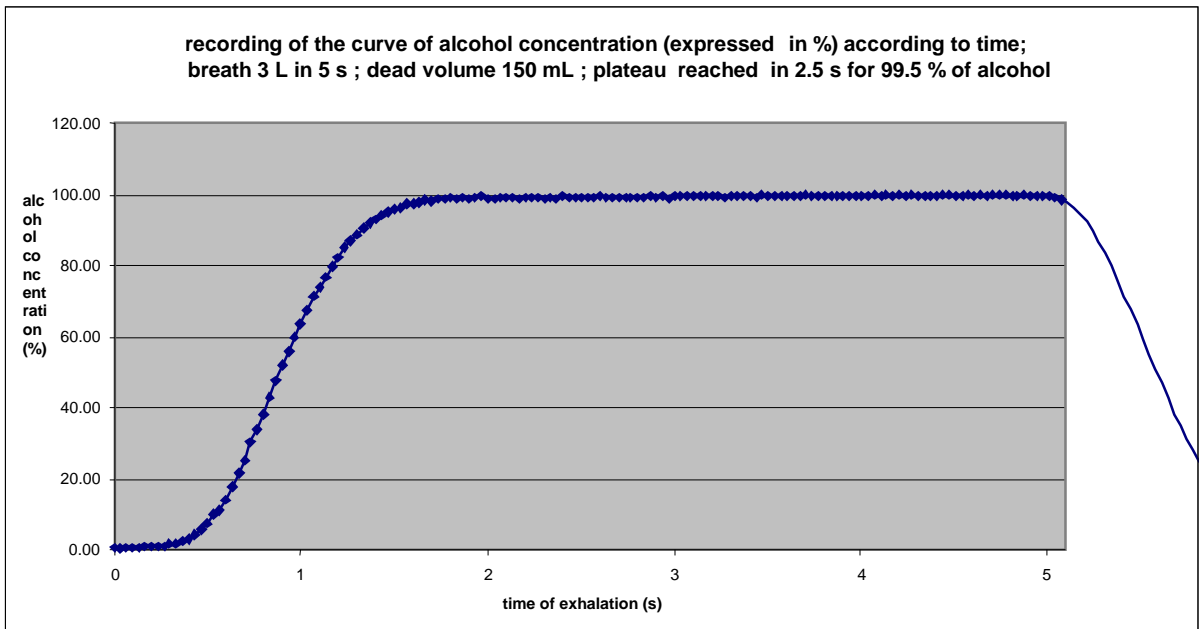
Dead volume = 300 mL



Proposal for the next draft :

Confirmation of the mathematical model and qualitative information on the determination of the plateau.

Example of a curve of alcohol concentration as a function of time obtained on simulation test bench.



## Annex C Reference principle for the implementation of the tests

Dubowski's formula

Let  $C_{H_2O}$  be the 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 the following formula :

$$C_{air} = 0.04145 \times 10^{-3} C_{H_2O} \times \text{Exp}(0.06583t)$$

Where  $t$  is the temperature in °C

For  $t = 34$  °C,  $C_{air} = 0.38866 \times 10^{-3} C_{H_2O}$

## **Annexe D**

### **Test Report Format**

To be developed when the list of test is finalised.