



COMMITTEE DRAFT OIML CD3

Date: 20 April 2007

Reference number: .....

Supersedes document: OIML R 126- CD2



OIML TC 17 / SC 7

Title: OIML R 126 Breath alcohol analysers

Secretariat:  
TC 17/SC 7: France

Circulated to P- and O-members and liaison international bodies and external organisations for: discussion planned at a meeting to be held on April 2008 (to be confirmed)..... comments by:

vote (P-members only) and comments by

TITLE OF THE CD (English):  
Revision OIML R 126  
Breath alcohol analysers

TITLE OF THE CD (French):  
Ethylomètres

Original version in: English

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

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# Requirements

## 1 Scope

This International Recommendation applies to quantitative breath alcohol analysers which are instruments that automatically measure the mass concentration of alcohol in exhaled human breath representative of the level of alcohol intoxication of the subject.

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

This Recommendation does not apply to instruments which do not quantitatively indicate the result of measurement, but which only indicate whether the mass concentration of alcohol exceeds the allowed limits.

Additionally, national authorities may require that breath alcohol analysers are equipped with special devices according to the national policy for fighting against alcohol abuse. 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 in case of no paper is detected in the printing device,
- requiring additional printed information.

National authorities may require that the breath alcohol analysers convert and display measurement result 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>

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 analysers, owing to national differences in legal systems.

## 2 Terminology

### 2.1 Breath alcohol analyser

An 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 analyser

A breath alcohol analyser intended only for use within buildings or places providing stable environmental conditions.

### 2.3 Mobile breath alcohol analyser

A portable breath alcohol analyser intended for use in mobile applications (e.g. in cars).

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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

**2.4 Portable breath alcohol analyser**

A breath alcohol analyser which operates with an autonomous battery. It may be used in or outside buildings or mobile applications.

**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 an average volume of 150 ml.

**2.8 Measuring mode**

The clearly indicated mode in which the breath alcohol analyser 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**

The mode in which the breath alcohol analyser can be adjusted and subject to metrological testing and control.

**2.10 Stand by mode**

The 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**

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

**2.12 Fault (OIML D11-3.9)**

Difference between the error of indication and the intrinsic error of a measuring instrument.

**2.13 Significant fault (OIML D11-3.10)**

Fault greater than value specified in this Recommendation.

**2.14 Disturbances**

An influence quantity having a value outside the specified rated operating conditions of the measuring system. If the rated operating conditions are not specified for an influence quantity, it is a disturbance.

### **2.15 Built-in automatic checking facility**

A device which allows verifying, by involving all relevant internal elements, that the breath alcohol analyser is suitably adjusted. Such a device may include internal checking elements (for example signal stability, temperature stability) or additional checking external elements to be connected to the instrument such as optical or electrical filters or cylinder with a known concentration test gas.

### **2.16 Drift**

The change in the result of a measurement of the same alcohol concentration which occurs during a stated period of time at a given mass concentration of ethanol in air.

### **2.17 Memory residual effect**

The 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.

## **3 Metrological requirements**

### **3.1 Reliability of the measurement**

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

In order to demonstrate the conformity to this requirement the breath alcohol analyser shall fulfil the requirements in 3.2.3 and the tests in A.5.

### **3.2 Rated operating conditions**

#### **3.2.1 Measuring range**

The breath alcohol analyser 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 analyser 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 cancelled in maintenance mode.

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

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

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

#### **3.2.2 Physical influence factors**

The rated operating conditions corresponding to the physical influence factors are specified in A.6 for the following performance tests :

- Dry heat (A.6.1),



- Cold (A.6.2),
- Damp heat, steady-state (A.6.3),
- Random vibrations (A.6.4),
- Power voltage vibrations (A.6.5),
- Frequency vibrations (A.6.6),
- Influence of atmospheric pressure (A.6.7)

### 3.2.3 Conditions of exhalation

The breath alcohol analyser shall indicate whether the conditions of exhalation (e.g.: continuity and flow) complied with the conditions specified by the manufacturer in order to ensure a representative measurement.

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.

### 3.2.4 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 :  $\leq 2 \times 10^{-6}\text{ mol/mol}$ .

During each test, the temperature and the relative humidity shall not vary by more than 5 °C and 10 % respectively within the reference range.

## 3.3 Maximal permissible errors (MPE)

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

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

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

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

### 3.3.2 Maximum permissible errors for breath alcohol analysers in service (for the subsequent verifications)

$\pm 8\%$  of the true value of mass concentration or  $\pm x\text{ mg/L}$ , 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

### 3.4 Disturbances and other influence quantities

#### 3.4.1 Disturbances

In the presence of a disturbance, the breath alcohol analyser shall display no significant fault.

The significant fault is equal to the magnitude of the maximum permissible error applicable to type evaluation for the following disturbances :

- Radiated radiofrequency, electromagnetic fields (A.8.1),
- Conducted radiofrequency fields (A.8.2),
- Electrostatic discharges (A.8.3),
- Bursts on supply lines (A.8.4),
- Bursts on signal, data and control lines (A.8.5),
- Surges on signal, data and control lines (A.8.6),
- AC mains voltage dips short interruptions and voltage variation (A.8.7),
- Electrical transient conduction for external batteries of a vehicle (A.8.8),
- Mechanical shocks (A.8.9),
- Shakes (A.8.10),
- Damp heat cyclic (A.8.11),
- Storage (A.8.12).

The corresponding tests are described in the Annex A.8

#### 3.4.2 Other influence quantities

##### 3.4.2.1 Physiological influence quantities

The corresponding test and acceptance criteria are specified in A.9 (interfering substances) and A.7 (volumetric fraction of CO<sub>2</sub>)

##### 3.4.2.2 Influence of substance in ambient air

The instrument shall not exceed the MPEs in the presence of hydrocarbons in the ambient air corresponding to a total fraction by volume of hydrocarbons (as methane equivalent) equal to 5 ppm.

### 3.5 Estimation of the repeatability

#### 3.5.1 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 ;

$Y_i$  = the  $i$ th measurement (out of  $n$ ) for the given mass concentration ;

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

### 3.5.2 Requirement applicable to the type approval and the initial verification

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

## 3.6 Drift

### 3.6.1 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 Annex A.4.

### 3.6.2 Drift at 0.40 mg/L

3.6.2.1 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 Annex A.4.

3.6.2.2 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 Annex A.4.

## 3.7 Memory and residual effect

### 3.7.1 Memory effect

The memory effect shall be less than 0.010 mg/l when the test is conducted according to A.4.3.1.

### 3.7.2 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 maximum permissible error for the lower mass concentration.

## 3.8 Durability

All the tests specified in this recommendation shall be performed on the same instrument in order to demonstrate the durability of the instrument.

## 4 Technical requirements

### 4.1 Physical quantity and unit of measurement

The breath alcohol analyser shall display 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 to use an equivalent unit of measurement if the indication is in conformity with the legal international units and as long as it represent a

mass concentration of alcohol in a specified volume of exhaled air. The reference conditions for all measurement alcohol concentration including calibration are :

Temperature : 34.0 °C,

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

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

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

#### **4.2 Display**

The result of measurement shall be displayed digitally by means of aligned figures. The display in the measuring mode shall consist of the display in metrological testing mode rounded down to 0.01 mg/L (e.g. a measured value of 0.427 mg/L shall be displayed as 0.42 mg/L).

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.

#### **4.3 Printing device**

The breath alcohol analyser 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, the printing device shall operate during the influence factors and disturbances.

The printed result shall not differ from the indicated one displayed by the indicating device.

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.

The printing device shall be equipped with an automatic checking facility to verify the correct transmission of the data from the breath alcohol analyser to the printing device. At least the following shall be checked :

- presence of paper;
- the electronic control circuits.

When the printing device is not included into the measuring instrument, the National Authorities shall defined the requirements to prevent intentional and accidental modification of the data during their transmission.

#### **4.4 Measuring conditions**

At least before each measurement, the instrument shall automatically adjust or check adjustment implementing the built-in automatic checking facility. The instrument shall indicate a zero with a tolerance  $\pm 0.005$  mg/L, using an appropriate purge. When this adjustment is not possible or this check gives negative results, the instrument shall indicate an alarm and shall not allow any further measurement.

The breath alcohol analyser shall indicate its readiness to start a measurement and shall not perform measurements when it is not ready. When after a period of time the instrument is no longer ready to perform measurements, it shall indicate this.

The breath alcohol analyser 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.

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

The breath alcohol analyser shall 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 B.

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

#### **4.5 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 indicate an alarm and shall not allow any further measurement.

EBA's 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)

#### **4.6 Suitability for use**

##### **4.6.1 Warm-up time**

Under reference conditions (3.2.3), the breath alcohol analyser shall be capable of attaining the measuring mode :

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

However if these requirements are not fulfilled, the corresponding times shall be marked on the breath alcohol analyser and provided in the user manual

##### **4.6.2 Availability for measurement**

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

After a period time not using the instrument, it is no longer ready to perform a measurement and it shall indicate that.

#### **4.6.3** Availability of the measurement result

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 the 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 measurement being made.

#### **4.7** Marking and sealing

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

- type approval mark
- manufacturer's name
- denomination of the instrument
- serial number
- measurement range
- stationary, mobile or portable
- ambient conditions
- power supply range

Appropriate seals shall protect the integrity of the instruments.

#### **4.8** Physical mean to filter the cleaning air

It shall be possible to change this mean without removing any sealing device, if the filter is a particle filter.

For any another type of filter, the manufacturer shall define the periodicity of this replacement. The replacement is considered as repairing operation.

To replace this filter, it shall be necessary to break the sealing device

#### **4.9 Safety and security**

The EBA shall be capable of being used under satisfactory hygienic conditions. It shall be possible to change the mouthpiece for each measurement; mouthpieces shall be individually packaged.

EBA's 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 EBA breath sampling system including the mouthpiece shall not allow the subject of the measurement to inhale contaminated air from previous usages. It shall prevent the deposition of droplets from exhaled breath in the EBA.

### **5 Type approval**

Manufacturers shall provide the technical documentation, a user manual for the breath alcohol analyser and the description of the adjustment procedure. Other information may be provided such as information on performance tests, on calibrations that support a determination whether the design of the breath alcohol analyser meets the requirements of this Recommendation.

The technical documentation shall include:

- a list of the electronic sub-assemblies with their essential characteristics
- a description of the electronic devices with drawings, diagrams
- a description of the software and its characteristics (including identification numbers) and operation including a list of the data variables and the circumstances when they may be changed
- mechanical drawings
- a plan for marking and sealing .

If the breath alcohol analyser 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 4.4.

Type evaluation consists in assessing the compliance of the breath alcohol analyser with each requirement of this Recommendation.

## **Annex A**

# **PERFORMANCE TESTS**

### **Mandatory**

#### **A.1 General**

This annex defines the program of performance tests intended to verify that the breath alcohol analyser operates as intended in a specified environment and under specified conditions. Each test indicates, where appropriate the reference conditions for determining the intrinsic error.

Different kinds of tests apply :

- Test to ensure representative sampling,
- Accuracy tests (including repeatability, drift and memory and residual effect),
- Influence factors,
- Disturbance tests.

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 analyser with the requirements of this document.

#### **A.2 Breath profile**

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

- Evolution of the alcohol concentration during the breath

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 C2 shows the general form of this breath profile.

- Evolution of the flow rate curve during the breath

Annex C1 shows the general form of this breath profile.

#### **A.3 Test facilities**

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  $k = 2$ ). This uncertainty includes the components of uncertainty on the determination of the plateau.

Taking into account of the testing apparatus, the tests shall be conducted with the maximum frequency allowed by the breath alcohol analyser.

The breath alcohol analyser may be completely calibrated, if necessary, by the manufacturer before type approval testing begins. Thereafter no adjustment shall be carried out until all type approval testing is complete.



### A.3.1 Characteristic reference values of the test gas

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

- Delivered volume :  $2 \text{ L} \pm 0.3 \text{ L}$ ,
- Total duration of injection (into breath analyser) :  $5 \text{ s} \pm 0.5 \text{ s}$ ,
- 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 analyser 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 A.6.4, A.6.5, A.6.6, A.8.1 to A.8.10 (included),
- Gases without  $\text{CO}_2$ , which can be used for tests defined in A.6, A.8.

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 it is delivered to the breath alcohol analyser, 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

### A.3.2 Demonstration of the capability of the breath alcohol analyser to make measurements of end expiratory breath

In order to demonstrate the capability of the breath alcohol analyser to make measurements on the end expiratory breath , the apparatus used by the laboratory shall permit be capable of

performing tests defined in Annex A.6, corresponding to the breath profile describe to Annex A.2.

### A.3.3 Accuracy tests

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

Type 1 : the apparatus delivers constant concentration curves ;

Type 2 : the apparatus is similar to the one corresponding to A.3.1. During tests, the plateau shall be reached when half of the test volume has been injected ( $\pm 10\%$  of total volume).

## A.4 Accuracy tests

### A.4.1 Maximum permissible errors and repeatability

Compliance with maximum permissible errors requirement defined in 3.3.1 and repeatability requirement defined in 3.5 shall be verified at least at the following nominal values:

Test gas n°	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
7	1.50
8	2.00 mg/L or the upper value specified by the manufacturer

For type approval, 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 maximum permissible error requirement.

### A.4.2 Drift

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

Zero drift: Test gas n° 1,

Drift at 0,4 mg/ L: test gas n° 4,

Test procedure for each test gas:

- 10 subsequent measurements
- after the time interval 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 (3.6.)

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

### A.4.3 Memory and residual effect

**A.4.3.1 Memory effect**

The breath alcohol analyser 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 analyser shall be subjected 10 times to the following cycle :

- one measurement using test gas n° 7 or n°8, whichever is greater,
- one measurement using test gas n°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 3.7.1.

**A.4.3.2 Small changes in mass concentration**

The breath alcohol analyser shall be subjected to 10 measurements using test gas n° 4. The mean value of these 10 measurements is calculated.

Then the breath alcohol analyser is subjected to 10 measurements using test gas n° 3. The mean value of these 10 measurements is calculated.

The difference between these two mean values shall comply with the requirement specified in 3.7.2.

**A.5 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 A.3. The values of the parameters to be varied are specified in A.5.1 to A.5.4.

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 3.3.1.

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

**A.5.1 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:  $4 \text{ s} \pm 0.5 \text{ s}$ .
- Second test :
  - delivered volume :  $4.5 \text{ L} \pm 0.3 \text{ L}$ ,
  - duration of injection:  $15 \text{ s} \pm 0.5 \text{ s}$ .

**A.5.2 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:  $15 \text{ s} \pm 0.5 \text{ s}$ .

#### **A.5.3** 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 expiry (according to annex C1).

#### **A.5.4** 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 :  $5 \text{ s} \pm 0.5 \text{ s}$ .

#### **A.5.5** Influence of interruption in the breath flow

- First test : the injection of gas normally required for the reference conditions specified in A.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 (see A.5.2) shall be stopped at  $6 \pm 1 \text{ s}$  after the start of injection.
- Third test : short flow interruption. 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.

For these 3 tests, the instrument shall not give a result.

### **A.6 Physical influence factors**

The effect of each influence factor shall be determined separately and influence factors not under investigation shall remain at their reference values as specified in A.4.

The tests shall be carried out using test gas n° 4. At least 5 measurements shall be performed in each test condition.

For each test condition and each measurement, the maximum permissible error requirement specified in 3.3.1 shall be fulfilled. Nevertheless, in the test at the extreme value of hydrocarbons in the environment, it is acceptable that the breath alcohol analyser gives no result.

#### A.6.1 Dry heat (See OIML D 11, 10.1.1)

The tests consists of exposure of the breath analyser to a temperature defined below according to type of breath alcohol analyser under “free air” conditions for a two hours period after the breath alcohol analyser reached temperature stability.

	Stationary	Mobile	Portable
Temperature	30 °C	40 °C	40 °C or 50 °C *
Duration	2 hours		
Number of cycle	1		

\*Specified by the State

#### A.6.2 Cold (See OIML D 11-10.1.2)

The tests consists of exposure of the breath analyser to a temperature defined below according to type of breath alcohol analyser under “free air” conditions for a two hours period after the breath alcohol analyser reached temperature stability.

	Stationary	Mobile	Portable
Temperature	5 °C	- 10 °C	-25 °C or -10 °C *
Duration	2 hours		
Number of cycle	1		

\* Specified by the State

#### A.6.3 Damp heat, steady-state (non condensing) (See OIML D 11-10.2.1)

The tests consists of exposure of the breath alcohol analyser to the specified high level of temperature and the specified constant relative humidity during the time defined below according to the severity level.

The error of the breath alcohol analyser is determined one time per day and at the end of the test after a recovery period of one hour.

	Mobile	Portable
Temperature	30 °C	40 °C
Humidity	85 % rel	93 % rel
Duration	2 days	4 days

#### A.6.4 Random vibrations (See OIML D 11-11.1.1)

This test is applicable to mobile and handheld breath alcohol analysers. During the test, the breath alcohol analyser is powered off. The test consists of exposure to the vibration level hereafter defined:

- Total frequency range : 10 Hz to 150 Hz
- Total RMS level : 7 m.s<sup>-2</sup>
- ASD level 10 Hz- 20 Hz : 1 m<sup>2</sup>.s<sup>-3</sup>
- ASD level 20 Hz- 150 Hz : - 3 dB/octave

The breath alcohol analyser shall, in turn, be tested in three mutually perpendicular axes 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.

The duration of the test shall be a minimum of two minutes per axis.

The error of the breath alcohol analyser is determined after the whole test has been carried out.

#### A.6.5 Power voltage variations (See OIML D 11-13.1, 13.2)

The error of the breath alcohol analyser is determined in the following conditions:

- when the instrument is powered on at the upper limit of the voltage, if applicable,
- when the instrument is powered on at the lower limit of the voltage.

	Stationary (AC mains voltage)	Stationary (DC mains voltage)	Stationary or portable or mobile (internal battery)
Upper limit	Nominal voltage + 10%	Defined by the manufacturer	N/A
Lower limit	Nominal voltage – 15 %	Defined by the manufacturer	Limit where the instrument ceases to operate within the MPE

For breath alcohol analysers powered from external 12 V road vehicle batteries, the upper and lower limits are defined hereafter:

- Upper limit: 16 V
- Lower limit: limit where the instrument ceases to operate within the MPE.

#### A.6.6 AC mains frequency variations (See OIML D 11-11.3)

This test is applicable to stationary breath alcohol analysers powered by AC mains voltage (direct or through a generator).

Upper limit	Nominal frequency + 2 %
Lower limit	Nominal frequency – 2 %

**A.6.7** Influence of atmospheric pressure (see OIML D11-10.4)

- First test:  
Atmospheric pressure: 860 hPa  $\pm$  10 hPa
- Second test:  
Atmospheric pressure: 1060 hPa  $\pm$  10 hPa

**A.7** Influence of volume fraction of CO<sub>2</sub>

- Mass concentration by volume of CO<sub>2</sub>: 10 %  $\pm$  1 %

**A.8** Disturbances tests

The tests shall be carried out using test gas n° 4. At least 5 measurements shall be performed in each test condition except for the chapter A.8.1, A.8.2., A.8.8 in witch, the measurements shall be made during all the disturbances test s.

For each disturbance test unless otherwise specified, the difference between the result of the test and the performance at reference conditions shall not exceed the significant fault value specified in 3.4.1, It is acceptable that the breath alcohol analyser gives no result during the disturbance testing.

The error of the instrument is generally determined during the disturbance except for mechanical shocks (A.8.9.), shakes (A.8.10) and storage test (A.8.12).

When several test configurations are specified for one disturbance test, the fault shall be determined for each of these configurations.

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

For the tests specified in A.8.1 to A.8.3, conventionally 3 cycles of tests are performed starting each test at different moment of the measuring cycle.

**A.8.1** Radiated, radio frequency, electromagnetic fields (See OIML D 11-12.1.1)

The breath alcohol analyser shall be exposed to electromagnetic field strength as specified hereafter:

- Frequency range: from 80 MHz to 2000 MHz
- Modulation: 80 %AM, 1 kHz, sine wave
- Field strength: 10 V/m

This test includes the susceptibility to electromagnetic fields of general origin and to those specifically caused by digital radio telephones.

In the event that the breath alcohol analyser 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.

**A.8.2** Conducted radio-frequency fields (See OIML D 11-12.1.2)

This test doesn't apply if the breath alcohol analyser 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.

The test conditions are the following:

- Frequency range: from 0,15 MHz to 26 MHz
- Modulation: 80 %AM, 1 kHz, sine wave
- RF amplitude (50  $\Omega$ ): 10 V

#### **A.8.3** Electrostatic discharges (See OIML D 11-12.2)

Contact discharges are the preferred test method. Nevertheless, air discharges shall be used where contact discharges cannot be applied (e.g. non conductive surfaces).

Both types of application shall be performed:

- Direct application
- Indirect application

The discharges shall be applied on each surface accessible in normal operation. 5 measurements shall be performed in each surface.

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 test conditions are the following:

- Test voltage for contact discharge: 6 kV,
- Test voltage for air discharge: 8 kV.

#### **A.8.4** Bursts on supply lines (See OIML D 11-13.5)

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

The test consists of exposure to bursts of voltage spikes of 1 kV. Each spike shall have a rise time of 5 ns and a half amplitude duration of 50 ns. The burst length shall be 15 ms and the burst period (repetition time interval) shall be 300 ms.

At least ten positive and ten negative bursts randomly phased shall be applied.

#### **A.8.5** Bursts on signal, data and control lines (See OIML D 11-12.4)

Both positive and negative polarity of the bursts shall be applied.

Amplitude (peak value)	1 kV
Repetition rate	5 kHz

#### **A.8.6** Surges on signal, data and control lines (See OIML D 11-12.5)

At least 3 positive and 3 negative surges shall be applied. The injection network depends on the lines the surge is coupled into:



Unbalanced lines	Line to line	1 kV
	Line to earth	2 kV
Balanced lines	Line to earth	2 kV

**A.8.7** AC mains voltage dips, short interruptions and voltage variations (See OIML D 11, 13.4)

The mains voltage reductions shall be repeated 10 times with an interval of at least 10 seconds.

The test conditions are the following:

	Test a	Test b	Test c
Reduction	100 %	100 %	30 %
Duration	0.5 cycle	1 cycle	25 cycles

The error of the breath alcohol analyser is determined for each configuration of testing.

For voltage interruption, the test conditions are the following:

- Interruption: > 95 %
- Duration: 250 cycles

**A.8.8** Electrical transient conduction for external batteries of a vehicle (See OIML D 11, 14.2.2)

This test shall be applied to breath alcohol analyser powered from external 12 V road vehicle batteries. If the nominal value for the breath alcohol analyser is 24 V, the tests should be done as stated for 24 V in accordance with OIML D11, 14.2.2.

The test conditions are the following:

	Test pulse 1	Test pulse 2		Test pulse 3		Test pulse 4
		2a	2b	3a	3b	
Level	- 100 V	+ 50 V	+ 10 V	- 150 V	+ 100 V	- 7 V
Minimum number of pulses or test time	5000 pulses	5000 pulses		1 hour		1 pulse

**A.8.9** Mechanical shocks (See OIML D 11-11.2)

- For stationary or/and mobile breath alcohol analyser :

The breath alcohol analyser 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 °).

The height of fall given below is that of the opposite edge.

- For handheld breath alcohol analyser :

3 arbitrary positions are chosen.

	Stationary	Mobile	Portable
Height of fall	25 mm	50 mm	1 m
Number of fall	1	1	3

#### A.8.10 Shakes

This test simulates shocks in a car trunk. The breath alcohol analyser 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

#### A.8.11 Damp heat cyclic (condensing) (OIML D 11, 10.2.2)

The breath alcohol analyser 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 analyser during the temperature rise.

The 24 cycle consists of :

- 1) Temperature rise during 3 h,
- 2) Temperature maintained at the upper value during 9 h,
- 3) Temperature lowered to the lower value during 3 h,
- 4) Temperature maintained at the lower value during 9 h.

	Mobile	Portable
Temperature	55 °C	55 °C
Duration	2 cycles	4 cycles

#### A.8.12 Storage test

The error of the breath alcohol Analyser is determined in reference condition prior to the test.

Then, the breath alcohol analyser is powered off and exposed to a low temperature of - 25 °C during six hours and to a high temperature of 70 °C during six hours.

The change of temperature shall not exceed 1 °C/min during cooling down and heating up.

After a recovery period of one hour, the error of the breath alcohol analyser is determined and the default is calculated.

### A.9 Physiological influence quantities

The breath alcohol analyser 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 :

<b>Interfering substance</b>	<b>Nominal value for vapour mass concentration mg/L (+ 5 %)</b>
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 ... (0,1 mg/L for the current interfering substances in the above table) the breath alcohol analyser has passed the test for the interfering substance concerned. If the variation is more than the value defined in ... and if no error message is given, the breath alcohol analyser 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 ....

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

National responsible bodies may decide to test the influence of other compounds.

## Annex B

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

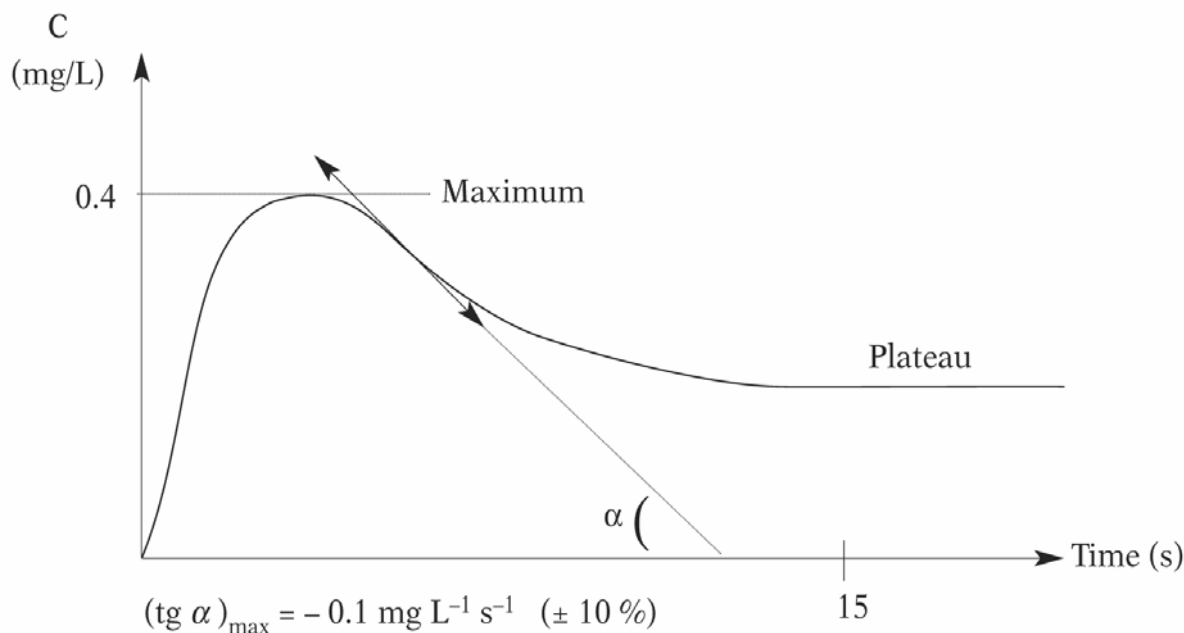
(informative)

The member State may choose one, two or all the following solutions for detection of alcohol in the upper respiratory tracts (B1 or B2) or avoiding the corresponding influence (B3).

#### B.1 Peak method

In the event that the breath alcohol analyser mouth alcohol detection operates by the detection of a peak in the IR signal, the following test, allows demonstrating 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.

#### B.2 Two-measurement cycle

##### B.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 analyser shall be able to memorize that constitute 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 analyser shall display a warning message to specify that the cycle is not valid and that a new one shall start.

### **B.2.2** Second method

The breath analyser 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:

- $0.10 \text{ mg/L}$ , 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 analyser 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

### **B.3 Delay before measurement**

An alternative solution is to ensure that sufficient time has elapsed since the consumption of alcohol to ensure that it has been cleared from the upper respiratory tract. A delay of 15 min is a reasonable limit if combined with an other method (as defined in A1 or A2).

## **Annex C**

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

(explanatory Note)

The study of the human behaviour in front to a control of blood alcohol content and its physiology shows a great diversity on the manner and the capacity of an individual to carry out a breath (voluntarily or not) in a EBA.

If it is easy to take into account and to fix the following factors of influences: volume, time of expiry; it is more complicated to rule on problems of flows and determination of plate of alcohol concentration.

Indeed, it is obvious that the variation of the flow of expiry (of the pressure) at the time of a breath will be very different while realizing:

a long and regular breath (flow at the time of the constant breath or presenting a very light decrease)

a dynamic and short breath (peak of the flow at the beginning of the breath and fast decrease at the end of the breath)

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

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

The object of this chapter is to define a method making it possible to fix characteristics for the determination of the variation of the air flow at the time of an expiry.

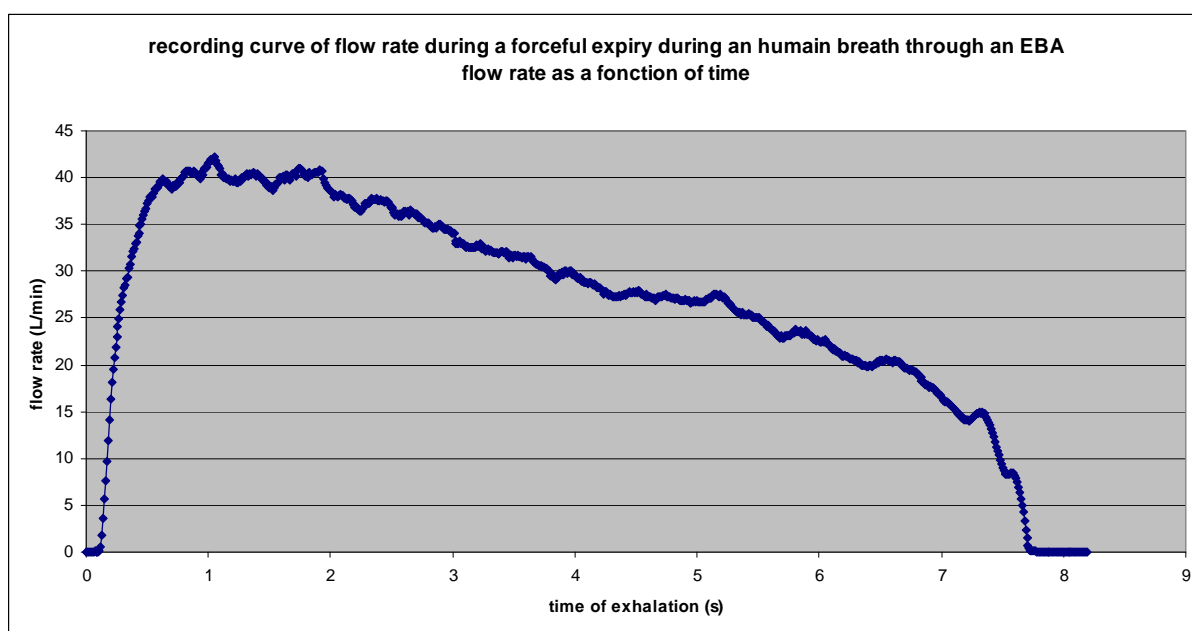
This chapter relates to mainly the test facilities and relates to the definitions of the breaths of tests

#### **Curves of the flow rate as a function of volume obtained from a human 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 to 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



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

The duration of the plate 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 object of this chapter is to define a method making it possible to fix characteristics for the determination of over the duration of the alcohol plate at the time of an expiry.

This chapter relates to mainly the test facilities and relates to the definitions of the breaths of tests

### 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:

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

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

where C = alcohol concentration (expressed in %)

D = flow rate (L/s)

t = time of exhalation (s)

Vm = 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 expiry (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.

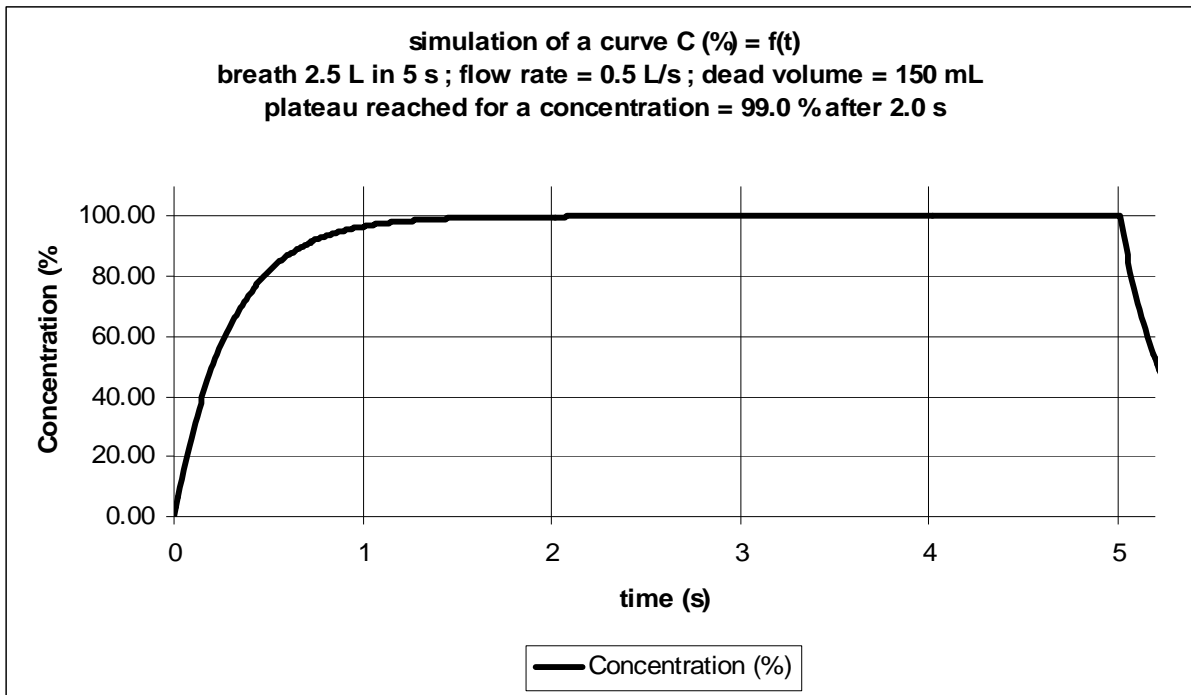
This value and its variations must be taken into account in the global calculation of the overall uncertainty of the test facility in accordance with the requirement of chapter A.3. (Note: 1/3 EMT)

Example by considering an average dead anatomical volume of 150 ml

Example / curve A

breath Profile : 2.5 L in 5 s , constant breath

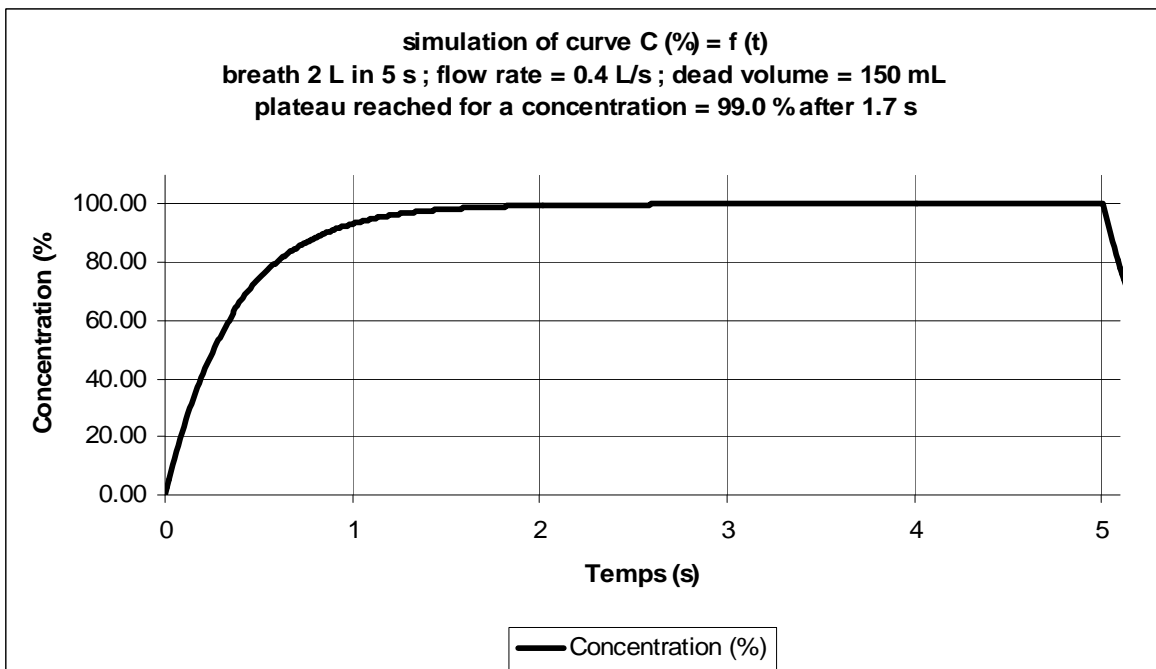
Dead volume = 150 mL



Example / curve B

breath Profile : 2.0 L in 5 s , constant breath

Dead volume = 150 mL

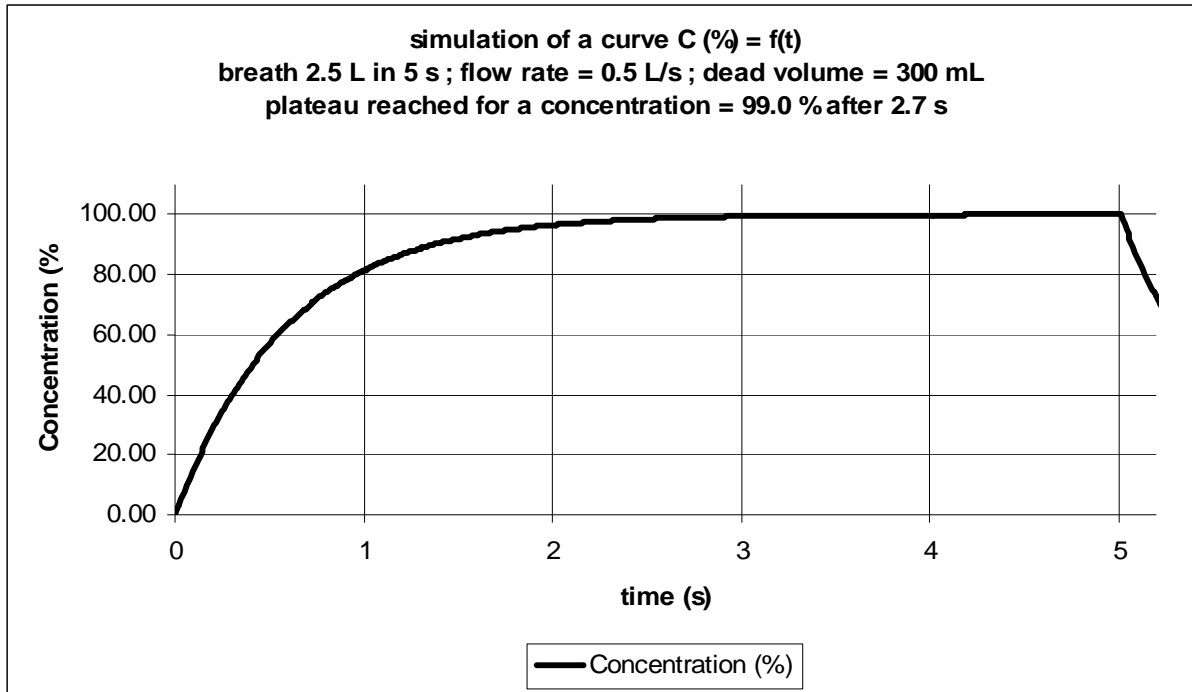


Example by considering an average dead anatomical volume of 300 ml

Example / curves C

breath : Profile 2.5 L in 5 s , constant breath

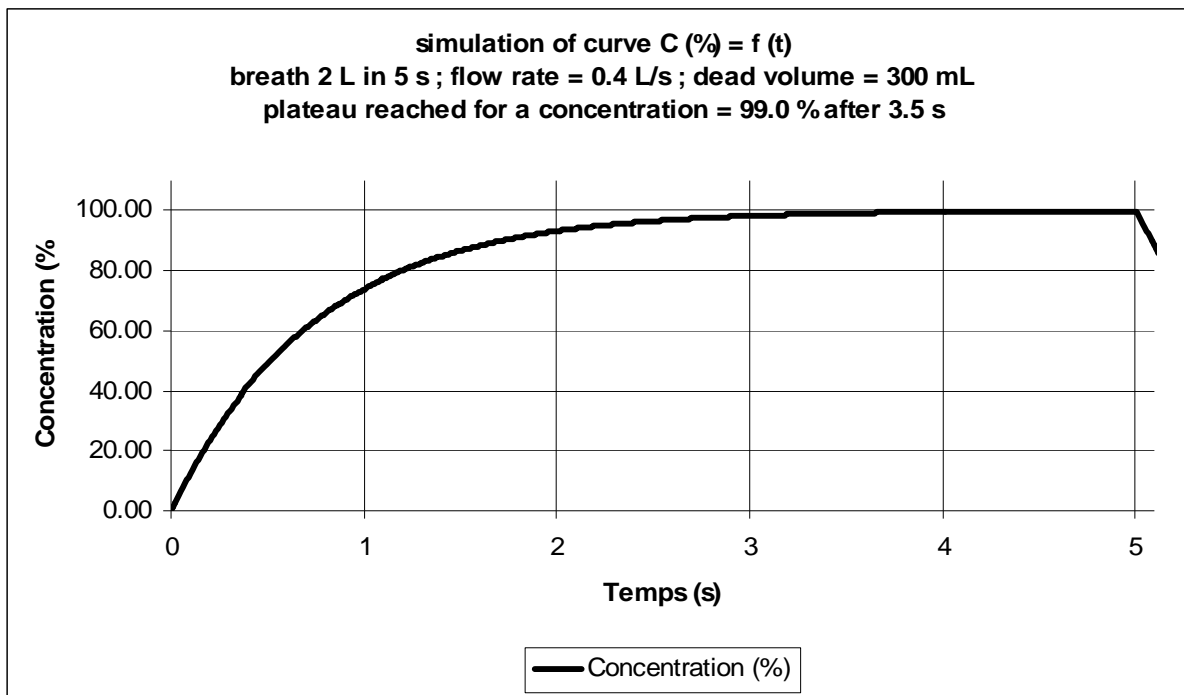
Dead volume = 300 mL



Example / curves D

breath Profile : 2.0 L in 5 s , constant breath

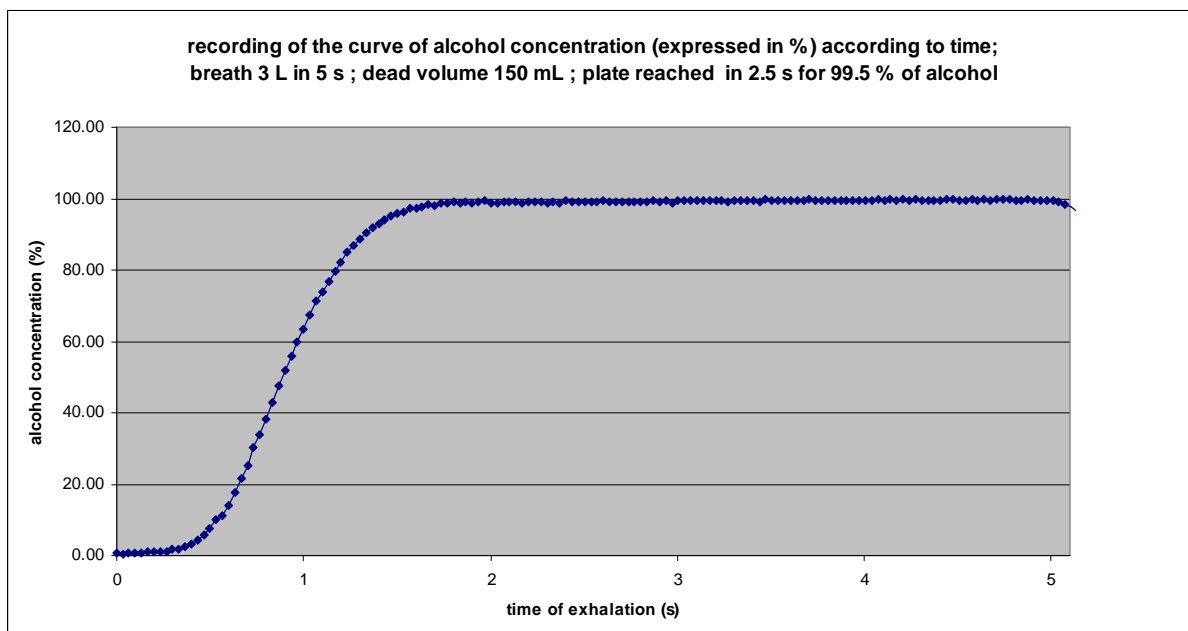
Dead volume = 300 mL



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.



## **Annexe D**

# **Test Report Format**

To be developed when the list of test is finalised.