



COMMITTEE DRAFT OIML CD2

Date: 21 April 2006

Reference number:

Supersedes document: OIML R 126 CD1

OIML TC 17/SC 7

Title: OIML R 126 Breath alcohol analysers

Secretariat: France

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

- discussion planned at a meeting to be held in April 2007 (to be confirmed).....
- comments by: 15 September 2006.....
- 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

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

Requirements.....	6
1 Scope.....	6
2 Terminology.....	6
2.1 Breath alcohol analyser.....	6
2.2 Stationary breath alcohol analyser.....	6
2.3 Mobile breath alcohol analyser.....	7
2.4 Handheld breath alcohol analyser.....	7
2.5 Alveolar air.....	7
2.6 End expiratory air.....	7
2.7 dead anatomical volume.....	7
2.8 Measuring mode.....	7
2.9 Maintenance mode.....	7
2.10 Adjustment device.....	7
2.11 Fault (OIML D11-3.9).....	7
2.12 Significant fault (OIML D11-3.10).....	7
2.13 Checking facility (OIML D 11-3.18).....	7
2.14 Built-in automatic checking facility.....	8
2.15 Drift.....	8
2.16 Memory residual effect.....	8
3 Metrological requirements.....	8
3.1 Representativity of the measurement.....	8
3.2 Rated operating conditions.....	8
3.3 Maximal permissible errors (MPE).....	9
3.4 Disturbances and other influence quantities.....	9
3.5 Repeatability.....	10
3.6 Drift.....	10
3.7 Memory and residual effect.....	11
3.8 Durability.....	11
4 Technical requirements.....	11
4.1 Physical quantity and unit of measurement.....	11
4.2 Scale interval.....	11
4.3 Display.....	11
4.4 Printing device.....	12
4.5 Measuring conditions.....	12

4.6 Checking operations 12

4.7 Suitability for use 13

4.8 Marking and sealing 13

5 Type evaluation 13

Annex A PERFORMANCE TESTS	15
A.1 General	15
A.2 Breath profile	15
A.3 Tests facilities	15
A.4 Reference conditions	17
A.5 Accuracy tests	17
A.6 Influence factors in the parameters which characterise the test gases	18
A.7 Physical influence factors	20
A.8 Disturbances tests	22
A.9 Physiological influence quantities	25
A.10 Influence of volume fraction of CO ₂	26
A.11 Influence of atmospheric pressure	26
Annex B Examples of detection of alcohol in upper respiratory tracks	27
B.1 Pic method	27
B.2 Two-measurement cycle	28
B.3 Delay before measurement	28
Annex C General information and breath profile (mandatory)	29
Annexe D Test Report Format	34

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 alcohol impregnation of the subject.

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

Hereinafter ethanol is alcohol.

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

National authorities may require that breath alcohol analysers are equipped with special devices according to the national policy for fighting against alcoholism such as :

- device 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.¹

The purpose of this Recommendation is to specify, the minimum metrological specifications and tests applicable to type approval and initial 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 alcohol impregnation of the subject.

2.2 Stationary breath alcohol analyser

A breath alcohol analyser intended only for use within buildings or places providing similar environmental 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 analyser

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

2.4 Handheld breath alcohol analyser

A hand-portable breath alcohol analyser that may be used outside buildings or mobile laboratories.

2.5 Alveolar air

Air contained in the pulmonary alveoli where the gaseous exchange takes place.

2.6 End expiratory air

Air considered sufficiently representative of alveolar air (in opposition to air anatomical dead 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 calibrated and subject to metrological testing and control.

2.10 Adjustment device

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

Note : Adjustment using a dry gas is possible provided that the difference of effect between wet and dry gases is known or can be automatically corrected.

2.11 Fault (OIML D11-3.9)

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

2.12 Significant fault (OIML D11-3.10)

Fault greater than value specified in the relevant Recommendation.

2.13 Checking facility (OIML D 11-3.18)

Facility that is incorporated in a measuring instrument and which enables significant faults to be detected and acted upon.

Note : “acted upon” refers to any adequate response by the measuring instrument (luminous signal, acoustic signal, prevention of the measurement process, etc.).

2.14 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 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.

2.15 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.

2.16 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 Representativity of the measurement

The breath alcohol analyser shall be able to guarantee that the measurement result is representative of the alcohol concentration present in the end expiratory air.

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.6.

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 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 to be removed 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.

3.2.2 Physical influence factors

The rated operating conditions corresponding to the physical influence factors are specified in A.7 for the following performance tests :

- Dry heat (A.7.1),
- Cold (A.7.2),
- Damp heat, steady-state (A.7.3),
- Random vibrations (A.7.4),
- Voltage vibrations (A.7.5),
- Frequency vibrations (A.7.6).

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 to equal 0.10 L/s.

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 examination and initial verification

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

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

3.3.2 Recommended maximum permissible errors for breath alcohol analysers in service

$\pm 8\%$ 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

3.4 Disturbances and other influence quantities

3.4.1 Disturbances

In the present of a disturbance, the breath alcohol analyser shall present 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 specify in A.9 (interfering substances) and A.10 (volumic fraction of CO₂)

3.4.2.2 Influence of substance in ambient air

The instrument shall fulfilled 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.

3.4.2.3. Influence of atmospheric pressure

The corresponding test and acceptance criteria are specify in A.11

3.5 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 ith measurement (out of n) for the given mass concentration ;

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

3.5.2 Requirements

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 zero drift shall be less than 0.010 mg/L in 4 hours under reference conditions as defined in Annex A.5.

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.5.

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.5.

3.7 Memory and residual effect

3.7.1 Memory effect

The memory effect shall be less than 0.01 mg/l when the test is conducted according to Annex A 5.3.1.

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 smaller than or equal to the maximum permissible error for the lower mass concentration.

3.8 Durability

All the test 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 reference conditions for all measurement alcohol concentration including calibration are :

Temperature : 34.0 °C,

Pressure : to be discuss (hPa)

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

Presence of CO₂ : 5 %.

4.2 Scale interval

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

4.3 Display

The result of measurement shall be displayed digitally by means of aligned figures. The display in the measuring mode shall consist on 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.

4.4 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.

In the measuring mode, 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 thirty days, even when exposed to daylight or equivalent lighting.

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.

4.5 Measuring conditions

At least before each measurement, the instrument shall automatically adjust or check adjustment implementing the building-in automatic checking facility. The instrument shall indicate a zero with a tolerance ± 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 not anymore ready to perform measurements, it shall indicate it.

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 enable to 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.

Optionally, the breath alcohol analyser 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 B.

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

4.6 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.

4.7 Suitability for use

4.7.1 Warm-up time

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

- 15 minutes after being switched on,
- 5 minutes after a switch 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

4.7.2 Availability for measurement

After successful checking operations, automatic adjustment or checking of adjustment implementing the building-in automatic checking facility and from the moment it indicates that it is ready to receive an exhalation, the breath alcohol analyser shall be available at least one minute.

4.7.3 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 delay the result remains accessible, 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.

4.8 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 temperature range
- power supply range

Instruments shall also bear a label saying that sucking should be avoided instead of blowing.

Appropriate sealing shall protect the integrity of the instruments.

5 Type evaluation

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 related to the representativity of measurement,
- Accuracy tests (including repeatability, drift and memory and residual effect),
- Influence factors,
- Disturbances 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 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 injection. The mass concentration at this plateau represents the mass concentration in the end-expiratory air.

Annex C2 shows the general form is this breath profile.

- Evolution of the flow rate curve during the breath

Annex C1 shows the general form is this breath profile.

A.3 Tests 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 (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.

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 95 %,
- Gas temperature : $34 \text{ }^\circ\text{C} \pm 0.5 \text{ }^\circ\text{C}$,
- carrier gas : pure air with volumetric fraction of 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 reference gases was established.

A.3.1 Demonstration of the capability of the breath alcohol analyser to make measurements end expiratory air

In order to demonstrate the capability of the breath alcohol analyser to make measurements on the end expiratory air, the apparatus used by the laboratory shall permit to perform tests defined in Annex A.6, corresponding to the breath profile describe to Annex A.2

A.3.2 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 is injected ($\pm 10 \%$ of total volume).

A.3.3 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 CO_2 in test gases, constant mass concentration during injection). The completed test reports shall indicate when such alternative tests means have been implemented.

For other tests than accuracy tests and tests 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.7.4, A.7.5, A.7.6, A.8.1 to A.8.10 (included),
- Gases without CO_2 , which can be used for tests defined in A.7, A.8 and A.11.

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

For cases involving dry gases in containers :

- variations of atmospheric pressure and variation of the compressibility factor between filling and usage conditions are taken into account,
- the quality of the containers, 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 uncertainties of the measurement

A.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 : $\leq 2\text{ ppm}$.

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

A.5 Accuracy tests

A.5.1 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 scale 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 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 measurements shall comply with the maximum permissible error requirement.

A.5.2 Drift

At least 10 initial measurements shall be made with each test gases n° 1 and n° 4 to verify the drift specifications defined in 3.6. Then 10 additional measurements are made using the same respective gases at the conclusion of the times intervals specified in 3.6.

For each drift test, the deviation between the mean value of the two series of measurements (initial and additional) shall fulfil the appropriate requirements in 3.6.

Other tests provided for in this recommendation for type approval may be performed during the drift tests.

A.5.3 Memory and residual effect

A.5.3.1 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 the upper use defined test gases limit of the measuring range, whichever the 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 two calculated mean values shall be less than the limit specified in 3.7.1.

A.5.3.2 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 5 measurements using test gas n° 3. The mean value of these 5 measurements is calculated.

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

A.6 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 introduction of A.3. The values of the parameters to be varied are specified in A.6.1 to A.6.7.

For each test, 10 measurements using test gas n° 4 shall be performed. Each of this 10 measurements shall fulfilled the maximum permissible error requirement defined in 3.3.1.

A.6.1 Influence of delivered volume

- 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.6.2 Influence of the duration of exhalation

- 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.6.3 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.6.4 Influence of the flow rate

- 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.6.5 Influence of interruption in the flow breath

- First test : the injection of gas normally required for the reference conditions specified in A.3 shall be stopped 1 second \pm 0.5 s after the start of injection.
- Second test : the injection of gas normally required at least 15 s (see A.6.2) shall be stopped 6 seconds \pm 1 s after the start of injection.

A.7 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.7.1 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	Handheld
Temperature	30 °C	40 °C	40 °C or 50 °C *
Duration	2 hours		
Number of cycle	1		

*Specified by the State

A.7.2 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	Handheld
Temperature	5 °C	- 10 °C	-25 °C or -10 °C *
Duration	2 hours		
Number of cycle	1		

* Specified by the State

A.7.3 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	Handheld
Temperature	30 °C	40 °C
Humidity	85 % rel	93 % rel
Duration	2 days	4 days

A.7.4 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⁻²
- ASD level 10 Hz- 20 Hz : 1 m².s⁻³
- 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 minimum two minutes per axis.

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

A.7.5 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 handheld 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 in 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 in the MPE.

A.7.6 AC mains frequency variations (See OIML D 11-11.1.1)

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.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 if the test method requires otherwise.

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 connexion cables if the instrument is composed of several elements connected together. For that connexion 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 Ω): 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.

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.

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 alcohol breath 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	handheld
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 (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	Handheld
Temperature	30 °C	40 °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 two 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 :

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 ... (0,1 mg/L for the current interfering substance 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 signal is given, the breath alcohol analyser has failed. If a signal 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.

A.10 Influence of volume fraction of CO₂

- Mass concentration by volume of CO₂: 10 % \pm 1 %

A.11 Influence of atmospheric pressure

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

Annex B

Examples of detection of alcohol in upper respiratory tracks

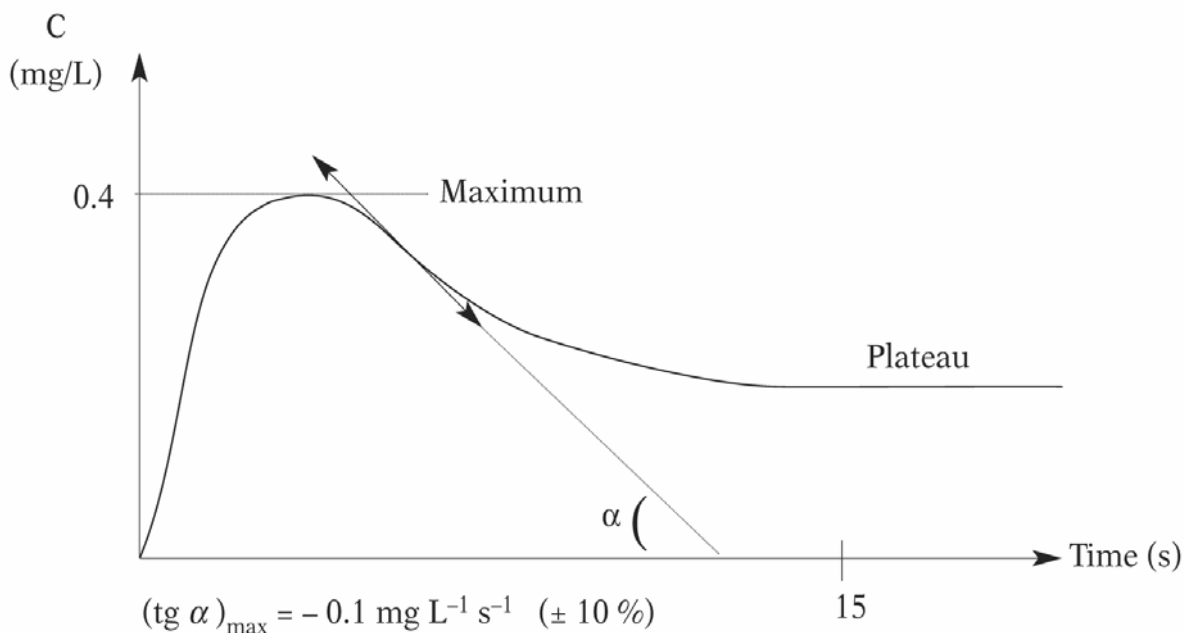
(informative)

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

B.1 Pic method

In the event that the breath alcohol analyser operates with the detection of a pic, the following test, allows demonstrating that the instrument is able to detect alcohol in upper respiratory tracks.

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 L
- duration: 15 s
- mass concentration at maximum of the curve: 0.4 mg/L

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

B.2 Two-measurement cycle

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 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 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.3 Delay before measurement

An other solution to deal with alcohol in the upper respiratory tracks is waiting before performing measurements. A delay of 30 min is considered as a reasonable one.

Annex C

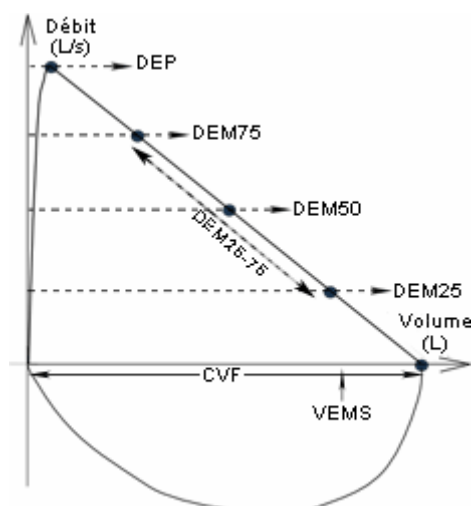
General information and breath profile (mandatory)

C.1 MEASUREMENT FLOW RATE DURING EXHALATION

Curves of the flow rate as a function of volume obtained from a human exhalation

Theoretical curves:

The flow is very strong at the beginning of the exhalation. 75 % of total volumes are expired during the first second of the breath. The flow varies from 5 to 10 L/s.



The curve flow rate -volume starts with zero, at the point of intersection of the axes x and y (flow rate = 0 and volume = 0).

The point where the curve touch axis x is the CVF: the totality of mobilized pulmonary volume is expired.

Immediately after the departure of the breath, the flow increases very quickly to reach its maximum in approximately 100 milliseconds. This point is named the Point of high Expiratory Flow (EPD) (in spirometry). The EPD represents the exhalation of air expired of the anatomic dead volume.

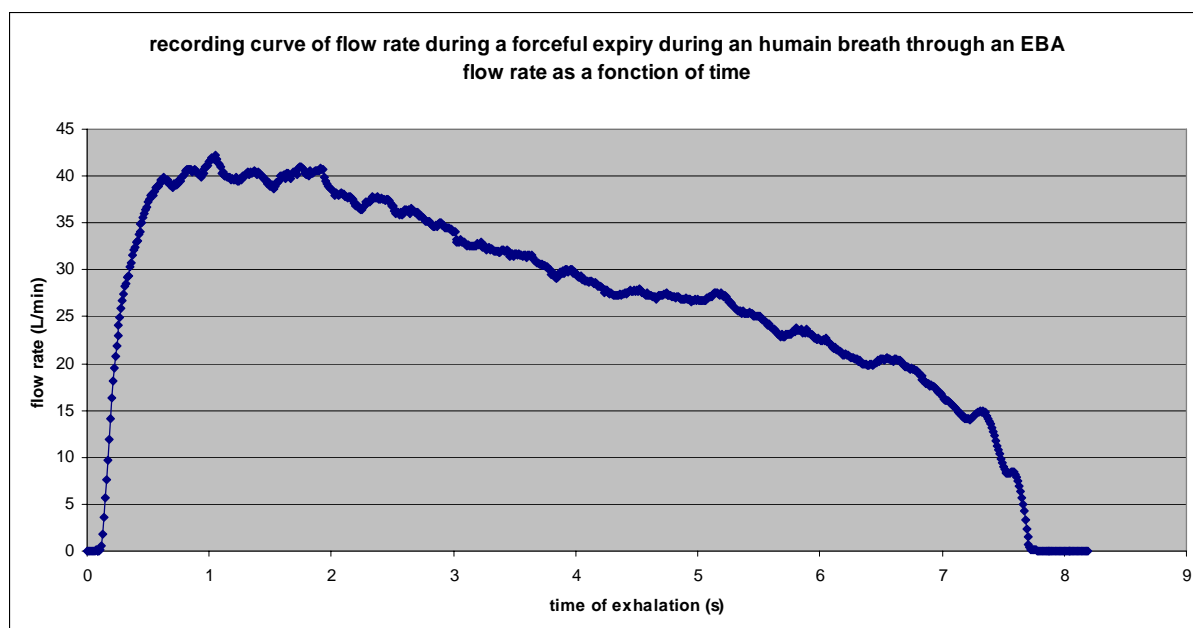
After the EPD, the curve is on line goes down (the flow drops) though there is more expired volume.

The flow continues to decline for finally reaching zero: end of the test.

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

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

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 %)

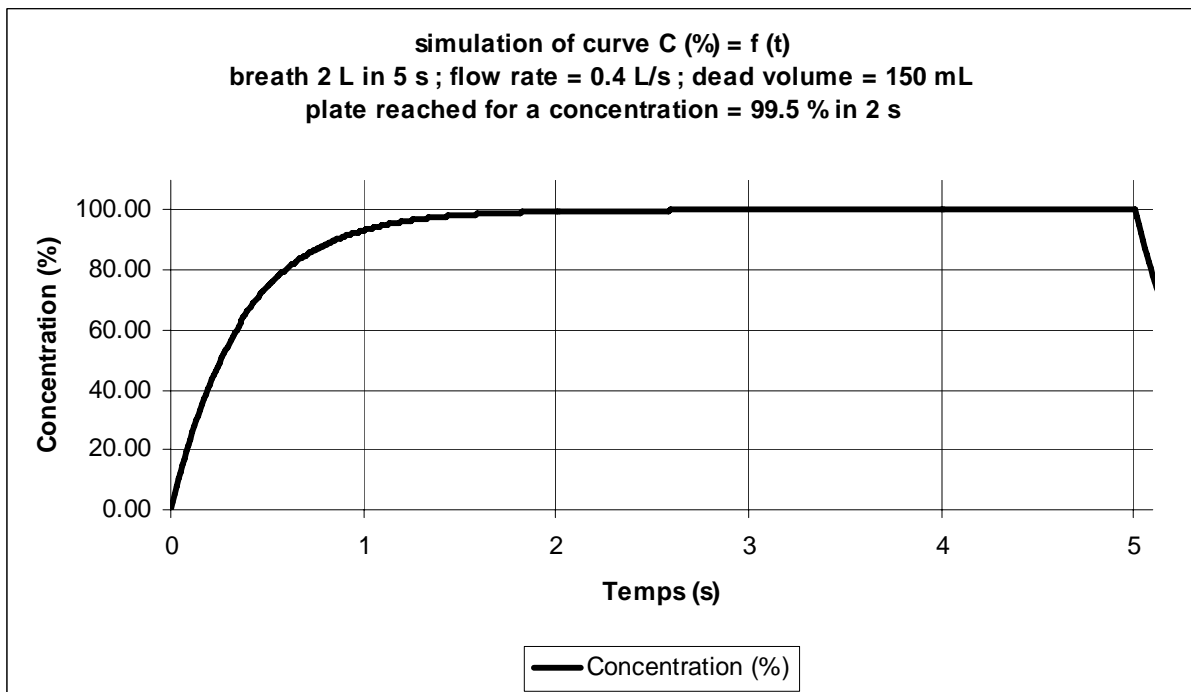
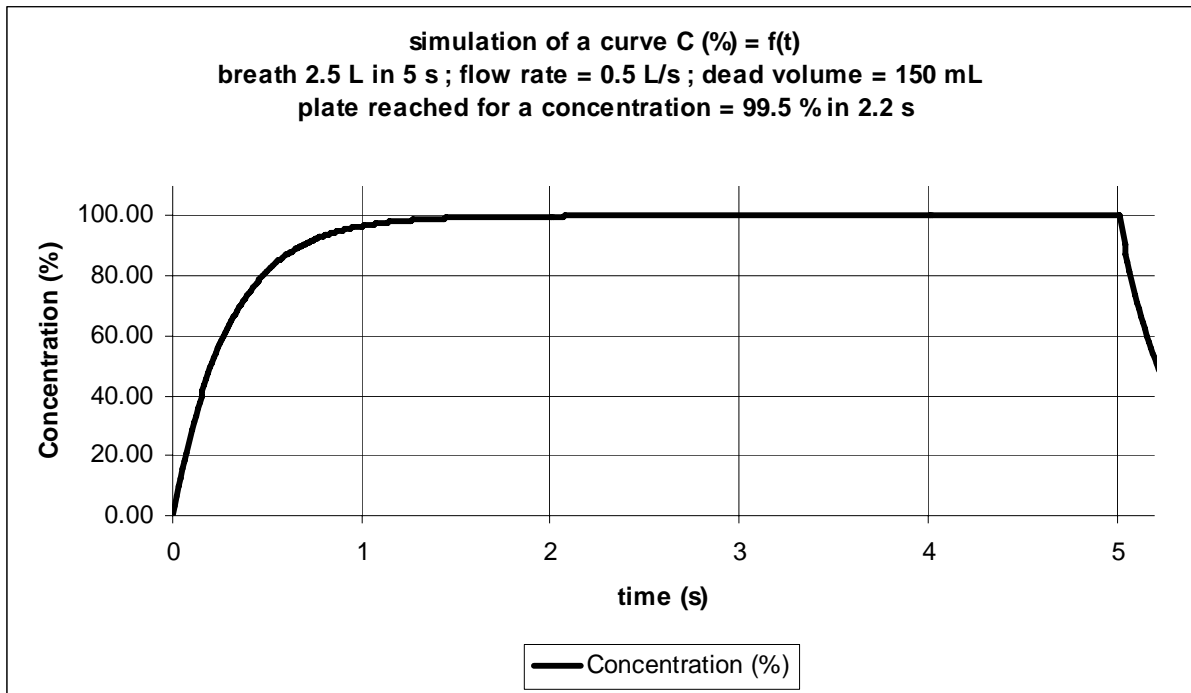
D = flow rate (L/s)

t = time of exhalation (s)

Vm = dead anatomical volume (L)

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)

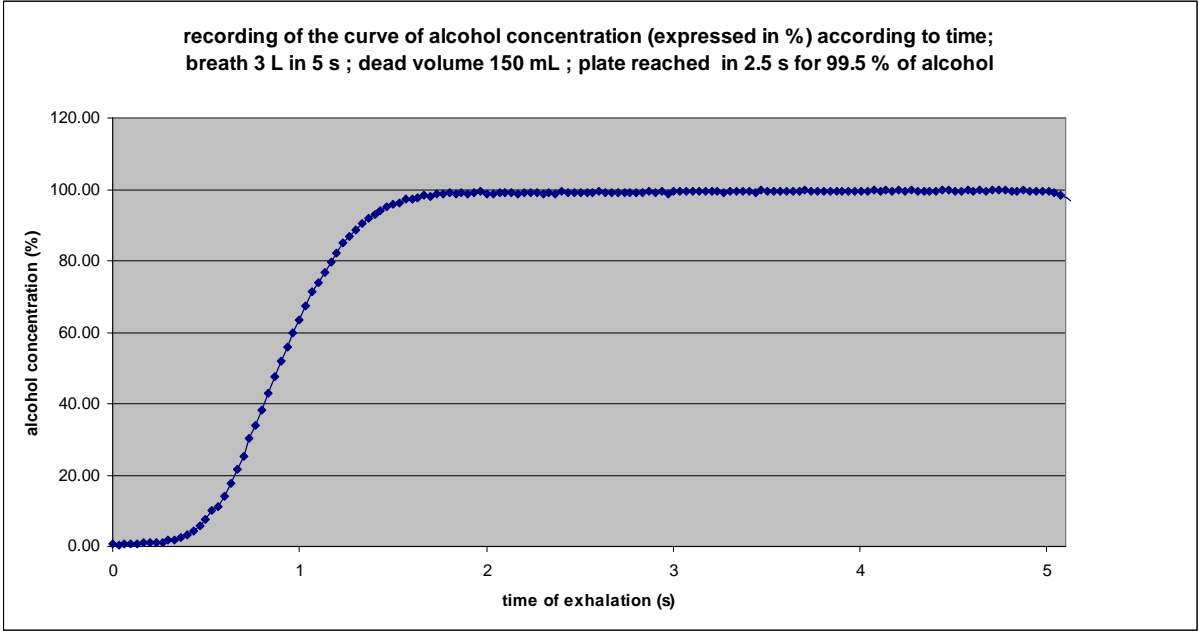
Standard uncertainty on the alcohol concentration determined by a plateau and its variations must be taken into account in the global calculation of the expending uncertainty of the test facilities in accordance with the requirement of chapter A.3. (note : 1/3 EMT)



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.