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IEC, International Electrotechnical Commission
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Contents

Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States. The main categories of OIML publications are:

International Recommendations (OIML R), which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;

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OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements are established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents and Guides are published in French (F) and English (E) and are subject to periodic revision.

Additionally, the OIML participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology Experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice to metrological authorities, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus they do not necessarily represent the views of the OIML.

This publication - reference OIML R 126, edition 20XX (E) - was developed by the OIML Technical Subcommittee TC 17/SC 7 *Breath Testers*. It was approved for final publication by the International Committee of Legal Metrology in 20XX and supersedes the previous edition dated 1998.

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Introduction

OIML Recommendations are considered as International Standards in the sense of the TBT Agreement of the World Trade Organization. They are model regulations to be used by OIML Member States to draw up their national regulations.

Consequently, the main goal of OIML Recommendations is to define technical and metrological requirements in order that they could be harmonized and implemented to avoid barriers to trade.

Even if OIML Recommendations are not international regulations, they can become mandatory through national laws and regulations. In addition, OIML Member States have a moral obligation to implement OIML requirements.

OIML Recommendations mostly define technical and metrological requirements which are evaluated at type approval.

OIML Recommendations may also include information on initial and subsequent verifications. Such information is recommendation only since these issues are under the responsibility of the National Authorities.

1 Scope

This Recommendation applies to quantitative breath alcohol analyzers that render a measurement result of alcohol concentration in exhaled human breath for the purpose of establishing compliance with national policy for fighting against alcohol abuse.

These types of quantitative breath alcohol analyzers are referred to by some national authorities as “evidential” breath alcohol analyzers and serve to provide the principal means by which a definitive alcohol measurement is obtained.

These devices are not to be confused with those that provide a preliminary result, or do not quantitatively indicate a measurement result (i.e. pass/fail devices), or which do not provide a sufficiently accurate result to definitively establish a breath alcohol concentration (often referred to as breath alcohol “screening” devices).

For the purpose of this Recommendation, the term “"alcohol"” shall be used to refer to ethyl alcohol or ethanol.

Additionally, some national authorities may require that breath alcohol analyzers be equipped with special features, for example:

- detecting the presence of alcohol in the upper respiratory tract,
- prohibiting the displaying or reporting of results that do not represent the final measurement result,
- mandating the inclusion of a printing device,
- prohibiting operation of the analyzer in the event that no paper is detected in the printing device,
- requiring ~~additional~~ further printed information in addition to the final measurement result,
- requiring final measurement results to be displayed and reported in terms other than the alcohol content in exhaled human breath (i.e. physiological conditions or in terms of other quantities).

The purpose of this Recommendation is to enumerate the minimum metrological specifications and tests applicable to type approval~~, initial verification, and in-service verification~~ of quantitative breath alcohol analyzers, recognizing national differences in legal systems. It also gives guidance for establishing metrological specifications for initial and in-service verifications.

2 Terminology

2.1 breath alcohol analyzer

instrument that measures and displays the breath alcohol mass concentration of exhaled human breath within specified error limits

2.2 stationary breath alcohol analyzer

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

2.3 mobile breath alcohol analyzer

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

2.4 portable breath alcohol analyzer

breath alcohol analyzer intended for use~~d~~ inside or outside buildings and in mobile applications (e.~~-~~g. handheld devices generally powered by an autonomous battery)

2.5 alveolar air

air contained in the pulmonary alveoli where the gaseous exchange takes place between the blood and the gas contained within the alveoli

2.6 end expiratory breath

air considered sufficiently representative of alveolar air (~~in opposition~~ as opposed to dead anatomical volume)

2.7 dead anatomical volume

conducting area of gas flow known as the area of conduction without significant exchange of a defined volume. This volume is variable between individuals

2.8 measuring mode

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

2.9 maintenance mode

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

2.10 standby mode

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

2.11 adjustment device

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

2.12 measurement error (VIM 2.1~~7~~6 [1])

measured quantity value minus a reference quantity value

2.13 disturbance (OIML D 11, 3.13.2 [6])

influence quantity having a value within the limits specified in this Recommendation, but outside the specified rated operating conditions of the measuring instrument

Note: An influence quantity is a disturbance if the rated operating conditions for that influence quantity are not specified.

2.14 automatic checking facility

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

2.15 drift

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

2.16 memory residual effect

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

2.17 abbreviations

MPE	Maximum Permissible Error
OIML	International Organization of Legal Metrology
EUT	Equipment Under Test

2.18 significant fault (OIML D 11, 3.10 [6])

difference between the error (of indication) and the intrinsic error greater than the value specified in this Recommendation. Significant faults are only relevant to electronic measuring systems

2.19 plateau of alcohol

the plateau ~~is the time in which the alcohol concentration is stabilized within 99 % of the reference value~~ starts when the alcohol concentration (representative of the alveolar air) reaches 99 % of the reference value of the gas used for testing and remains stable (see ~~a~~Annex B.2)

2.20 intrinsic error (OIML D 11, 3.7 [6])

error of a measuring instrument, determined under reference conditions

Part 1

Metrological and technical requirements

3 Description of the instrument

In general, ~~A~~a breath alcohol ~~analyzer~~ analysis consists ~~in general~~ of three stages:

- sampling,
- analysis of the sample,
- determination, presentation and storage of the result.

Each of these three stages represents a measurement step. During each measurement step several quantities can influence the result.

3.1 Sampling

~~Usually a~~ A mouthpiece ~~is~~ should always be used for sampling whenever the subject's lips/mouth have to come into contact with part of the device in order to provide a sample. This allows hygienic handling of the instrument and helps to protect the instruments from particles. Condensation during sampling and analysis shall be prevented, to avoid dilution of the sample.

3.2 Analysis

The ethanol concentration of the breath sample from pulmonary alveoli has to be determined. Influences during the analysis caused by sampling and/or ambient conditions shall be avoided.

3.3 Determination, presentation and storage of the result

The determined ethanol concentration shall be displayed. Additionally it may be printed and / or stored in the ~~instrument's~~instrument's memory.

4 Units of measurement and decimal sign

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

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

The use of an equivalent unit of measurement is possible if the indication is in conformity with the legal international units.

The decimal marker on the display or printout shall be either a comma on the line or a dot on the line. Admissibility of the comma and/or the dot is left to national legislation.

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

5 Metrological requirements

5.1 Measuring range

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

The instrument shall fulfill the requirements of this Recommendation for the complete specified measuring range.

A greater upper limit of the measuring range may be defined by the manufacturer.

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

5.2 Maximum permissible errors (MPEs)

The following MPEs shall apply within the rated operating conditions (specified in 5.8).

5.2.1 Maximum permissible errors for type approval and initial verification and verification after repair

The maximum permissible error, positive or negative, is:

0.020 mg/L or 5 % of the reference value of mass concentration, whichever is the greater.

If the upper limit of the measuring range is greater than 2.00 mg/L, the maximum permissible error shall be:

$\frac{reference\ value}{2} - 0.9$ mg/L for all mass concentrations greater than 2 mg/L.

~~50 % of the reference value minus 0.9 mg/L for all mass concentrations greater than 2 mg/L.~~

5.2.2 Maximum permissible errors for breath alcohol analyzers in service

The maximum permissible error, positive or negative is:

0.030 mg/L or 7.5 % of the reference value of mass concentration, whichever is the greater.

If the upper limit of the measuring range is greater than 2.00 mg/L, the following maximum permissible error shall be:

$reference\ value \times \left(\frac{3}{4}\right) - 1.35$ mg/L for all mass concentrations greater than 2 mg/L.

~~75 % of the reference value minus 1.35 mg/L for all mass concentrations greater than 2 mg/L.~~

5.3 Scale interval

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

A measured value of the three digits has to be rounded down to two digits.

5.4 Repeatability

The repeatability of the instrument is expressed as the experimental standard deviation of a given number of measurement results.

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.

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

5.5 Drift

5.5.1 Zero drift

The drift measured under reference conditions as defined in 11.4.1 ~~from~~ at 0.00 mg/L shall be less than 0.010 mg/L in 4 hours.

5.5.2 Drift at 0.40 mg/L

5.5.2.1 Short-term drift

The drift measured under reference conditions as defined in 11.4.1 at 0.40 mg/L shall be less than 0.010 mg/L in 4 hours.

5.5.2.2 Long-term drift

The drift measured under reference conditions as defined in 11.4.1 at 0.40 mg/L shall be less than 0.020 mg/L in two months.

5.6 Memory effects

5.6.1 Memory effect with large differences in mass concentration

The memory effect shall be less than 0.010 mg/L when the test is conducted according to 11.4.4.1 c).

5.6.2 Memory effect with small differences in mass concentration

The memory effect shall be less than 0.010 mg/L when the test is conducted according to 11.4.4.1 c).

5.7 Multiple indicating devices

All indications (displays, printout, etc.) of the measuring instrument shall show the same result.

5.8 Minimum requirements for rated operating conditions

5.8.1 Physical influence factors

Breath alcohol analyzers shall be designed and manufactured such that their errors do not exceed the MPEs specified in 5.2 under the following rated operating conditions:

a	Ambient temperature	Low	+5 °C for stationary breath alcohol analyzers –10 °C for mobile breath alcohol analyzers –10 °C for portable breath alcohol analyzers
		High	+30 °C for stationary breath alcohol analyzers +40 °C for mobile breath alcohol analyzers +40 °C for portable breath alcohol analyzers
b	Relative humidity	Up to 85 %, during 2 days for mobile and portable breath alcohol analyzers	
c	Atmospheric pressure	860 hPa – 1 060 hPa	
d	Vibration	Negligible for stationary breath alcohol analyzer 10 Hz – 150 Hz, 7 $m.s^{-2}$, 1 $m^2.s^{-3}$, –3 dB/octave for mobile and portable breath alcohol analyzers only	
e	DC mains voltage	As specified by the manufacturer	
f	AC mains voltage	U_{nom} – 15 % to U_{nom} + 10 %	
g	AC mains frequency	f_{nom} – 2 % to f_{nom} + 2 %	
h	Voltage of internal battery	All voltages between a new or freshly charged battery, down to the lowest voltage at which the instrument functions properly within the MPEs, according to the specifications given by the manufacturer.	
i	Voltage of a road vehicle battery	12 V battery	9 V – 16 V
		24 V battery	16 V – 32 V
j	Total fraction by volume of hydrocarbons (as methane equivalent) in the environment	5 ppm	
k	Mass concentration of carbon dioxide	10 %	
~~(1) These values are to be selected by the National Authority.~~			

These provisions apply separately to each influence factor and to each error determination.

5.8.2 Conditions of exhalation

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

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

- exhaled volume: greater than or equal to 1.2 L,
- back pressure: does not exceed 25 hPa (at a ~~flow rate~~flowrate of 12 L/min),
- ~~flow rate~~flowrate: greater than or equal to 0.10 L/s,
- exhalation time: greater than or equal to 5 s.

5.9 Significant fault

Fault greater than the magnitude of the MPE defined in 5.2.1.

5.10 Disturbances and other influence quantities

5.10.1 Disturbances

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

(a) either significant faults do not occur,

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

5.10.1.1 During the following disturbances

a	Radiated radiofrequency, electromagnetic fields	From 80 MHz to 3 000 MHz~~Z~~, 10 V/m In the event that the breath alcohol analyzer has no mains or input ports, the applicable frequency range is from 26 MHz to 3 ~~-~~000 MHz.							
b	Conducted radiofrequency fields	From 0.15 MHz to 80 MHz, 10 V/m							
c	Electrostatic discharges	6 kV contact discharge 8 kV air discharge							
d	Bursts on supply lines	Amplitude 1 kV Repetition rate 5 kHz							
e	Bursts on signal, data and control lines	Amplitude 1 kV Repetition rate 5 kHz							
f	Surges on signal, data and control lines	Unbalanced lines		Line to line			1 kV		
				Line to earth			2 kV		
		Balanced lines		Line to earth			2 kV		
g	AC mains voltage dips, short interruptions and voltage variation	Reduction	100 %	100 %		30 %	> 95 %		
		Duration	0.5 cycle	1 cycle		25 cycles	250 cycles		
h	Electrical transient conduction for external batteries of a vehicle		Pulse 1	Pulse 2		Pulse 3		Pulse 4	
		~~I~~Level		2a	2b	3a	3b		
			–100 V	+50 V	+10 V	–150 V	+100 V	–7 V	
		Minimum number of pulses or test time	5 000 pulses	5 000 pulses		1 hour		1 pulse	

5.10.1.2 And after the following disturbances

a	Damp heat, cyclic (condensing)		Mobile		Portable
		Temperature	55 °C		55 °C
		Duration	2 cycles		4 cycles
b	Mechanical shocks		stationary	mobile	portable
		Height of fall	25 mm	50 mm	1 m
		Number of falls	1	1	3
c	Shakes	10 g, 6 ms, 2 Hz, in 3 axes, 1 000 shakes for each axes			
d	Storage test	–25 °C, 6 hours +70 °C, 6 hours			

5.10.1.3 Application

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

(a) each individual cause of disturbance; and/or

(b) each part of the measuring instrument.

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

5.10.2 Physiological influence quantities

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

Interfering substance	**Nominal value for vapor mass concentration mg/L (± 5 %)**
Acetone	0.5
Methanol	0.1
Isopropanol	0.1
Carbon monoxide	0.2

National regulations may require additional substances to be tested.

5.11 Durability

The provisions in 5.2, 5.4, 5.5, 5.6, 5.8 and 5.10 shall be met durably.

The breath alcohol analyzer shall be designed to maintain ~~an adequate~~ stability of its metrological characteristics over a period of time (to be specified by the manufacturer) which ~~has to~~ shall be at least as long as the verification period.

The verification period is defined under the responsibility of the national Authorities (periodic and subsequent verifications).

5.12 Presumption of compliance

The type of a measuring instrument according to this Recommendation is presumed to comply with the provisions in 5.1 to 5.11 if it passes the examination and tests specified in Part 2 of this Recommendation.

6 Technical requirements

6.1 Presentation of the measurement result

6.1.1 Display

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

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

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

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

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

- 5 mm for illuminated displays,
- 10 mm in all other cases.

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

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

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

6.1.2 Availability of measurement results

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

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

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

6.2 Protection against fraud

A breath alcohol analyzer shall have no characteristics likely to facilitate its fraudulent use,~~;~~ ~~n~~either by accidental ~~n~~or by deliberate means when using the instrument in the normal manner, and~~; whereas~~ possibilities for unintentional misuse shall be minimal. The general essential requirement dealing with fraudulent use shall be fulfilled in such a way that the interests of all parties involved in the transaction are protected.

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

- except in the maintenance mode (with ~~a~~ restricted access), it shall be impossible to make any adjustments without breaking the seals,
- the possibility to change the software shall comply with the requirement in 6.~~5~~4,
- the risk of calculated (deliberate) influence by digital telephones or static magnets shall be minimized. (For disturbances by radiated, radio frequency electromagnetic fields see also 5.10.1.1),
- data transmission shall comply with 6.~~6.3~~5,
- access to the maintenance mode shall be restricted.

6.3 Checking operations

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

The breath alcohol analyzer 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).

6.3.1 Warm-up time

Under reference conditions (11.4.1), the breath alcohol analyzer shall be capable of attaining the measuring mode:

- after a warm-up period specified by the manufacturer (without being ~~in less~~greater than 15 minutes) after being switched on,
- in less than 5 minutes after switching from stand-by mode to measuring mode.

6.3.2 Availability for measurement

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

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

6.3.3 Continuity of the exhalation

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

The exhalation shall be considered interrupted if the flow is below 0.1 L/s.

6.3.4 Alcohol in the upper respiratory tract

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

6.4 Software

The whole software of the breath alcohol analyzer should be considered as legally relevant.

In the event of a software separation as described in 5.2.1.2 of OIML D 31:2008 [7], the whole software is considered as legally relevant.

~~Software separation as described in 5.2.1.2 of OIML D 31:2008 [7] is not allowed.~~

6.4.1 Software identification (D 31:2008; 5.1.1 [7])

The software of the breath alcohol analyzer shall be clearly identified with at least a checksum.

The identification shall be inextricably linked to the software itself and shall be calculated, then presented or printed, on command or displayed during operation or at start up.

The checksum algorithm shall be a normalized algorithm. ~~e.g. the~~ CRC16, MD5, SHA-1 and SHA-2 algorithms ~~is an~~ are acceptable solutions for this calculation.

The software identification and the means of identification shall be stated in the type approval certificate.

6.4.2 Fraud protection (D 31:2008; 5.1.3.2 [7])

6.4.2.1 The software shall be secured against unauthorized modification, loading, or changes by swapping the memory device. In addition to mechanical sealing, technical means may be necessary to secure measuring instruments having an operating system or an option to load software.

Software protection comprises appropriate sealing by mechanical, electronic and/or cryptographic means, making an unauthorized intervention impossible or evident.

6.4.2.2 Only clearly documented functions are allowed to be activated through the user interface, which shall be realized in such a way that it does not facilitate fraudulent use.

For the type approval procedure, the manufacturer of the measuring instrument shall declare and document all program functions that can be activated through the user interface. No hidden functions shall exist. The manufacturer shall state the completeness of the documentation of these functions.

6.4.2.3 Parameters that fix the legally relevant characteristics of the breath alcohol analyzer shall be secured against unauthorized modification. ~~If necessary f~~For the purpose of verification, the current parameter settings should be able to be displayed or printed.

6.5 Durable recording of measurement results

6.5.1 Printing device

The breath alcohol analyzer may be fitted with a printing device under legal metrological control. In such a case, the requirements defined below apply.

Printing devices that are ~~out of the~~ not under legal metrological control shall bear a legend clearly visible to indicate that they are not controlled. Such a legend needs only to be present on printouts.

6.5.1.1 The printed data shall include at least:

- the measurement results and their units;
- the figures of the measurement results when used with pre-printed paper;
- the time and date of the measurement.

When the symbol of the unit of measurement is pre-printed, a specific paper shall be dedicated to the printing device.

6.5.1.2 The minimum height for the figures of the printing device is 2 mm.

6.5.1.3 The printed scale interval shall be at least 0.01 mg/L in the measuring mode. It shall be possible to print a scale interval equal to 0.001 mg/L in the maintenance mode.

6.5.1.4 The printed measurement results shall not differ from the measurement results provided by the indicating device.

6.5.1.5 The printing device shall be fitted with checking facilities and shall comply with the requirement defined in 5.10. “Act upon” means that a warning shall be given or that the instrument shall not provide any printout of the measurement result.

In particular, the checking of a printing device aims at ensuring that the data received and processed by the printing device correspond to those displayed. At least, the following shall be checked:

- presence of paper and ink (if applicable), and
- the electronic control circuits (except the driving circuits of the printing mechanism itself).

6.5.2 Storage of data

6.5.2.1 The breath alcohol analyzer may store measurement data for further applications under legal metrological control. In such a case, the requirements defined below apply (6.5.2.2 to 6.5.3.4).

The measurement value stored shall be accompanied by all the relevant information that is necessary for future legally relevant use.

6.5.2.2 The data shall be protected by software means to guarantee the authenticity, integrity and, if necessary correctness of the information concerning the time of measurement.

6.5.2.3 The software shall check the time of measurement, authenticity, and integrity of the data. If an irregularity is detected, the data shall be discarded or marked unusable.

Confidential keys employed for protecting data shall be kept secret and secured in the breath alcohol analyzer. Means shall be provided whereby these keys can only be input or read if a seal is broken.

6.5.3 Automatic storing

6.5.3.1 When data storage is required, measurement data must be stored automatically when the measurement is completed. When the final value results from a calculation, all data that are necessary for the calculation must be automatically stored with the final result.

6.5.3.2 The storage device must have sufficient permanency to ensure that the data are not corrupted under normal storage conditions. There shall be sufficient memory storage for any particular application.

6.5.3.3 Stored data may be ~~deleted when compliance with national policy for fighting against alcohol abuse is demonstrated~~removed when no longer legally required.

6.5.3.4 ~~After the requirement in 6.5.3.3 is fulfilled~~ If the data are no longer legally required (6.5.3.3) and when the storage is full, it is permitted to delete memorized data when both of the following conditions are met:

- data are deleted in the same order as the recording order and the rules established for the particular application are respected,
- deletion is carried out either automatically or after a special manual operation that may require specific access rights.

7 Inscriptions

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

a) manufacturer's trade mark/corporate name,

b) year of manufacture,

c) type designation / model number,

d) type approval mark according to national regulations,

e) serial number of the instrument,

f) measuring range,

g) details of the electrical power:

- in the case of mains power: the nominal mains voltage, frequency and power required,
- in the case of power by a road vehicle battery: the nominal battery voltage and power required,
- in the case of an internal removable battery: the type and nominal voltage of the battery.

h) Ambient temperature range.

Software identification shall be displayed on demand through the indicating device. If the size of the instrument is not sufficient, items f, g and h may be moved to the instruction manual.

8 Operating instructions

8.1 Instruction manual

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

An instruction manual for users shall be made available for each individual instrument.

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

It shall include:

a) operating instructions,
b) maximum and minimum storage temperatures,
c) rated operating conditions,
d) warm-up time after switching on the electrical power,
e) all other relevant mechanical and electromagnetic environmental conditions,
f) mechanical and electromechanical environment classes,
g) safety and security conditions.

8.2 Additional instructions

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

The breath alcohol analyzer 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 breath alcohol analyzer breath sampling system, including the mouthpiece, shall be designed such that the subject of the measurement is prevented from inhaling contaminated air from previous usages and it shall prevent the deposition of droplets from entering into the breath alcohol analyzer.

Regardless of whether the breath alcohol analyzer has an automatic function that detects whether the measurement result is affected by the presence of alcohol in the upper respiratory tracts or not, manufacturers may stipulate in their operating procedures that the subject shall not introduce anything in the mouth for at least 15 minutes prior to the collection of a breath sample.

9 Sealing

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

This applies in particular to:

a) adjustment means,

b) replacement of specific parts if this replacement is expected to change the metrological characteristics,

c) software integrity.

If the breath alcohol analyzer is equipped with air filters, the manufacturer shall design the device in such a way that it is possible to change the filters without breaking a security seal.

~~If the air filter is~~ When air filters are not installed, the breath alcohol analyzer shall deliver an error message, and no measurement shall be possible.

All other types of filters shall be in a sealed part of the breath alcohol analyzer.

Part 2

Metrological controls and performance tests

10 Metrological controls

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

Part 2 of this Recommendation gives general guidelines for type approval.

11 Type evaluation approval

11.1 Units submitted to type test

Type evaluation shall be carried out on at least one unit, which represents the definitive type. The evaluation shall consist of the examination and tests specified in 11.3 and 11.4.

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

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

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

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

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

11.2 Documentation

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

~~(a)~~a) description of its general principle of measurement,

~~(b)~~b) list of the essential subassemblies, components with their essential characteristics,

~~(c)~~c) mechanical drawings,

~~(d)~~d) electric/electronic diagrams,

~~(e)~~e) installation requirements,

~~(f)~~f) security sealing plan,

~~(g)~~g) panel layout,

~~(h)~~h) general information on the software (in particular the requirements in 6.5 shall be covered),

~~(i)~~i) test outputs, their use, and their relationships to the parameters being measured,

~~(j)~~j) operating instructions that shall be provided to the user,

~~(k)~~k) documents or other evidence that supports the assumption that the design and characteristics of the measuring instrument comply with the requirements of this Recommendation,

~~(l)~~l) the documentation requested in OIML D 31:2008 [7]; ~~clause~~ 6.1.1,

~~(m)~~m) a print sample ~~of print~~.

If the breath alcohol analyzer is equipped with a printing device, the manufacturer shall provide information about the quality of the printing paper to fulfill the requirements of readability defined in 6.~~6~~5.1.

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

11.3 Examinations and tests

Examination and testing of instrument~~ation~~s are intended to verify their compliance with the requirements of Part 1 of this Recommendation.

11.3.1 Visual inspection

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

In particular, the following aspects shall be examined:

a) units and decimal sign (4),
b) measuring ranges (5.1),
c) scale intervals (5.3),
d) presentation of the result (6.1),
e) adjustment facilities (6.2),
f) protection against fraud (6.2),
g) checking facilities (6.3),
h) durability protection (6.2),
i) software (6.4),
j) printing device (6.5.1),
k) storage of measurement results (6.5.2 and 6.5.3),
l) data transmission (5.7 and 6.5),
m) inscriptions (7),
n) operating instructions (8),

o) sealing (9),
p) suitability for testing (11.1 and 11.2).

11.3.2 Testing of instrumentation

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

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

11.3.3 Software validation procedure (6.4 of OIML R 126 and D 31:2008; 6.3 and 8 [7])

The validation procedure of the software related functionalities of breath alcohol analyzer is given by the following table:

Requirement of OIML R 126		**Validation procedure**	**Examination level**
Software identification	6.4.1	AD + VFTSw ~~+ CIWT~~	~~**B**~~**A**
Fraud protection	6.4.2.1; 6.4.2.2; 6.4.2.3	AD+VTFM	**A**
Storage of data	6.5.2.1; 6.5.2.2; 6.5.2.3	AD + VFTSw ~~+ CIWT or SMT~~	~~**B**~~**A**
Automatic storing	6.5.3.1; 6.5.3.2; 6.5.3.3; 6.5.3.4	AD + VFTSw	**A**

Where:

AD: Analysis of the documentation and validation of the design (see D 31:2008; 6.3.2.1)

VFTM: Validation by functional testing of metrological functions (see D 31:2008; 6.3.2.2)

VFTSw: Validation by functional testing of software functions (see D 31:2008; 6.3.2.3)

~~CIWT: Code inspection and walkthrough (see D 31:2008; 6.3.2.5)~~

~~SMT: Software module testing (see D 31:2008; 6.3.2.6)~~

11.4 Performance tests

11.4.1 Reference conditions

- Ambient temperature : 23 °C ± 5 °C
- Relative humidity : 50 % ± 30 %
- Atmospheric pressure : ambient pressure within the rated operating conditions
- Total fraction by volume of hydrocarbons (as methane equivalent) in the environment : ≤ 2 ppm

During each test at reference conditions the temperature, the relative humidity and the atmospheric pressure shall not vary by more than 5 °C, 10 % and 20 hPa respectively within the reference range. AC mains voltage and frequency (if appropriate) shall be maintained at their nominal values.

11.4.2 Breath profile

Human breath containing alcohol may be considered as corresponding to the following characteristics:

- *Evolution of the ~~flow rate~~flowrate curve during the breath exhalation*

  Annex B.1 provides explanatory information and general ~~excepted~~ accepted ~~flow rate~~flowrate curves to be used for establishing testing ~~facility~~ apparatus performance.

- *Evolution of the alcohol concentration during the breath exhalation*

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

  Annex B.2 provides explanatory information and generally accepted breath profiles to be used for establishing testing ~~facility~~ apparatus performance.

  Annex C provides explanatory information and reference principles to be used for implementing tests and establishing testing ~~facility~~ apparatus performance.

11.4.3 Test sample delivery apparatus

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

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

11.4.3.1 Characteristic reference values of the test gas

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

- delivered volume: 2 L ± 0.3 L,
- total duration of the injection (into the breath analyzer): 5 s ± 0.5 s,
- type of profile: constant ~~flow rate~~flowrate,
- relative humidity of the gas: 95 % ± 5 % RH (without condensation),
- gas temperature: 34 °C ± 0.5 °C,
- carrier gas: air containing insignificant concentrations of relevant impurities with volumetric fraction of CO_2: 5 % ± 0.5 % vol.

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.

This Recommendation permits the use of calibration gases produced by simplified means for some tests. Such means may consist in the use of dry 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 have been implemented.

The simplified means (a gas or gases without CO_2,) could be used for the following tests and to demonstrate the capability of the breath alcohol analyzer to make measurements on the end expiratory air:

- dry gases~~, which can be used~~ for tests defined in 11.4.4.2, 11.4.4.6 through 11.4.4.14, ~~and~~ 11.4.5 (except 11.4.5.11 and ~~,~~ 11.4.5.12) and 11.4.6 ~~and 11.4.4.1~~ with ~~a specific test performed prior to this test which will be a~~ a preliminary repeatability test performed with wet gases,

  Note: This preliminary repeatability test may consist of the repeatability test defined in 11.4.4.4.

- gases without CO_2, which can be used for tests defined in 11.4.4.~~1~~2 through 11.4.4.13 and 11.4.5.

In all cases (except in 11.4.4.2), the evolution of the concentration and the ~~flow rate~~flowrate during injection may be constant.

For cases involving dry gases in cylinders:

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

11.4.3.2 Capability of the testing apparatus

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

~~the tests defined in~~ delivering a test sample according to 11.4.3.1~~, corresponding to the~~and a breath profile described in 11.4.2.

11.4.3.3 Type of testing ~~facility~~apparatus

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

- Type 1: the apparatus delivers constant test gases with constant volume concentrations of alcohol.
- ~~-~~Type 2: the apparatus delivers a test gas which is capable of fulfilling the breath profile defined in 11.4.2.~~similar to that described in 11.4.3.1. During tests, the plateau shall be reached when half of the test volume has been injected (± 10 % of the total volume).~~

For the complete test program, both types are needed.

Note: For certain tests, the testing procedures may specify the use of one of the specific types indicated above.

11.4.4 Errors under rated operating conditions

The type of measuring instrument is presumed to comply with the provisions specified in 5.2 to 5.10 of this Recommendation, if it passes the tests (11.4.4.1–11.4.4.13), confirming that the error of the measuring instrument does not exceed the MPE on initial verification specified in 5.2 under the reference conditions in 11.4.1.

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

For breath alcohol analyzers which have more than one option for power supply, the tests in 11.4.4.1 through 11.4.4.14 shall be performed with every option.

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

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

During the test, the following information shall be recorded:

a) date and time,
b) temperature,
c) relative humidity,
d) the values of the measurand~~s~~,
e) indications,
f) errors,
g) functional performance.

11.4.4.1 Accuracy tests

a) Maximum permissible errors and repeatability

Compliance with the requirements of 5.2 and 5.4 for maximum permissible errors and repeatability shall be verified at least at the following nominal values:

Test gas No.	Mass concentration (mg/L)
1	0.00 to 0.05
2	0.10
3	0.25
4	0.40
5	0.70
6	0.95
7	1.50
8	1.95
9	If the upper value specified by the manufacturer is greater than 2 mg/L, the test gas mass concentration shall be equal to 90 % of the upper limit.

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

For each test gas, each of the 20 measurement results shall comply with the MPE defined in 5.2.1.

b) Drift

Compliance with the drift requirements shall be tested at following gas concentrations.

Zero drift: test gas No. 1,

Drift at 0.4 mg/L: test gas No. 4,

Test procedure for each test gas:

- 10 subsequent measurements,
- after the time intervals specified under 5.5 again 10 subsequent measurements.

For each drift test, the difference between the mean measurement errors of the two series of measurements shall fulfill the requirements for drift (5.5).

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

c) Memory effects

- Memory effect with large differences in mass concentration

The breath alcohol analyzer shall be subjected to an initial test that includes 10 measurements using test gas No. 2. The mean value of these 10 measurements is calculated.

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

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

Each individual measurement shall comply with the MPE as defined in 5.2.1.

The mean value of the~~se~~ 10 measurements with test gas No. 2 during the cycle is calculated.

For gas No. 2 ~~For the mass concentration at 0.10 mg/L~~, the difference between the two calculated mean values ~~-~~shall be less than the limit specified in 5.6.1.

~~Each individual measurement shall comply with the MPE.~~

Note: Test gas No. 7 is used in the event that the maximum concentration of the measuring range of the breath analyzer is 2 mg/L. Gas No. 8 is used when it is greater than 2 mg/L.

- Memory effect with small changes in mass concentration

The breath alcohol analyzer shall be subjected to an initial test that includes 10 measurements using test gas No. 3. The mean value of these 10 measurements is calculated.

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

- one measurement using test gas No. 4,
- one measurement using test gas No. 3.

Each individual measurement shall comply with the MPE as defined in 5.2.1.

The mean value of these 10 measurements with test gas No. 3 during the cycle is calculated.

For test gas No. 3, the difference between the two calculated mean values shall be less than the limit specified in 5.6.2.

~~Each individual measurement shall comply with the MPE.~~

11.4.4.2 Influence factors of the conditions of ~~exhalation~~ injection

For each test, 10 measurements using test gas No. 4 shall be performed. Each of these 10 measurements shall fulfill the maximum permissible error requirement defined in 5.2.1.

Each test is characterized by 4 parameters:

- delivered volume,
- duration of the injection,
- variation ~~in the~~ of the pressure as a function of time,
- variation of the ~~in the~~ alcohol concentration as a function of time ~~(plateau)~~.

a) Influence of delivered volume and exhalation duration

- First test:
  - delivered volume: 1.5 L ± 0.1 L,
  - duration of the injection: 5 s ± 0.5 s,
  - variation ~~in~~ of the pressure as a function of time: no variation,
  - variation ~~in~~ of the alcohol concentration as a function of time ~~(plateau)~~: no variation (type 1 testing apparatus) or ~~a~~ plateau ~~duration of plateau~~duration of the plateau~~:~~ equal to 3 s (~~the condition shall be the same in the first and second tests~~type 2 testing apparatus).

- Second test:

- delivered volume: 4.5 L ± ~~+~~ 0.3 L,
- duration of the injection: 15 s ± ~~+~~ 0.5 s,
- variation ~~in~~ of the pressure as a function of time: no variation,
- variation of the alcohol concentration as a function of time: no variation (type 1 testing apparatus) or plateau duration equal to 3 s (type 2 testing apparatus).

~~ovariation in the alcohol concentration as a function of time (plateau): no variation or a duration of (the condition shall be the same in the first and second tests).~~

b) Influence of ~~flow rate~~flowrate and ~~exhalation~~ injection duration

- First test:

- delivered volume: 1.5 L ± ~~+~~ 0.1 L,
- duration of the injection: 10 s ± ~~+~~ 0.5 s,
- variation ~~in~~ of the pressure as a function of time: no variation,
- variation of the alcohol concentration as a function of time: no variation (type 1 testing apparatus) or plateau duration equal to 4.5 s (type 2 testing apparatus).

~~ovariation in the alcohol concentration as a function of time (plateau): no variation or a duration of.5 s (the condition shall be the same in the first, second and third tests).~~

- Second test:

- delivered volume: 3 L ± ~~+~~ 0.2 L,
- duration of the injection: 15 s ± ~~+~~ 0.5 s.
- variation ~~in~~ of the pressure as a function of time: no variation,
- variation of the alcohol concentration as a function of time: no variation (type 1 testing apparatus) or plateau duration equal to 6 s (type 2 testing apparatus).

~~ovariation in the alcohol concentration as a function of time (plateau): no variation or a duration of 6 s (the condition shall be the same in the first, second and third tests).~~

- Third test

- delivered volume: 4.5 L ± ~~+~~ 0.3 L,
- duration of the injection: 7.5 s ± ~~+~~ 0.5 s.
- variation ~~in~~ of the pressure as a function of time: no variation,
- variation of the alcohol concentration as a function of time: no variation (type 1 testing apparatus) or plateau duration equal to 3.5 s (type 2 testing apparatus).

~~ovariation in the alcohol concentration as a function of time (plateau): no variation or a duration of 3.5 s (the condition shall be the same in the first, second and third tests).~~

c) Influence of variations in the ~~flow rate~~flowrate during exhalation

- First test:

- delivered volume: 3 L ± ~~+~~ 0.2 L,
- ~~flow rate~~flowrate: 0.6 L/s,
- variation ~~in~~ of the flowrate as a function of time: no variation,

- variation of the alcohol concentration as a function of time: no variation (type 1 testing apparatus) or the same plateau duration in the first and second test (type 2 testing apparatus).

~~ovariation in the alcohol concentration as a function of time (plateau): no variation or the same duration of the first and second tests.~~

- Second test:

- delivered volume: 3 L ± ~~+~~ 0.2 L,
- variation in the flowrate as a function of time: Initial ~~flow rate~~flowrate: 0.6 L/s during 1.5 s, between 1.5 s and 5 s of exhalation the ~~flow rate~~flowrate decreases until 0.2 L/s. After 5 s, the ~~flow rate~~flowrate remains equal to 0.2 L/s until the end of ~~the exhalation~~injection.~~.~~
- variation of the alcohol concentration as a function of time: no variation (type 1 testing apparatus) or the same plateau duration in the first and second test (type 2 testing apparatus).

~~o variation in the alcohol concentration as a function of time (plateau): no variation or the same duration of in the first and second tests (see annex B.1).~~

d) Influence of ~~duration of plateau~~duration of the plateau during ~~exhalation~~injection

- First test:

- delivered volume: 3 L ± ~~+~~ 0.2 L,
- duration of the injection: 5 s ± ~~+~~ 0.5 s,
- variation ~~in~~ of the pressure as a function of time: no variation,
- ~~duration of plateau~~duration of the plateau: 3 s (type 1 test apparatus).~~.~~

- Second test:

- delivered volume: 3 L ± ~~+~~ 0.2 L,
- duration of the injection: 5 s ± ~~+~~ 0.5 s.
- variation ~~in~~ of the pressure as a function of time: no variation,
- ~~duration of plateau~~duration of the plateau: 1.5 s (type 1 test apparatus).

e) Influence of an interruption in the breath flow

- First test:

The injection of gas normally required for the reference conditions specified in 11.4.1 shall be stopped 1 s ± 0.5 s after the start of the injection. The flowrate is 0.4 L/s.

- Second test:

The injection of gas normally required for at least 15 s shall be stopped at 6 s ± 1 s after the start of the injection. The flowrate is 0.2 L/s.

- Third test:

Verification of the end of the detection of exhalation. The injection of a gas supplied at a ~~flow rate~~flowrate equal to 0.15 L/s is decreased to a ~~flow rate~~flowrate equal to 0.03 L/s.

- Fourth test:

Short flow interruption. The injection of a gas ~~with a flow rate~~flowrate at the flow conditions specified in 11.4.3.1 shall be interrupted for a short period (e.g. 0.5 s) and then continued.

For these four tests, the breath alcohol analyzer shall give no value.

11.4.4.3 Dry heat

This test is applied to verify compliance with the provisions in 5.8.1 a) under conditions of dry heat (high ambient temperature).

The test is carried out according to IEC 60068-2-2 [9] and IEC 60068-3-1 [23].

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

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test.
Stabilization	2 hours at each temperature under “free air” conditions.
Temperature	High temperature as specified in 5.8.1 a).
Temperature sequence	Reference temperature, Specified temperature.
Test	The EUT shall not be readjusted at any time during the test. After stabilization at the relevant temperature, perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and under the conditions defined in 11.4.4.2 a) first test and record: a) date and time, b) temperature, c) relative humidity, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.

11.4.4.4 Cold

This test is applied to verify compliance with the provisions in 5.8.1 a) under conditions of cold (low ambient temperature).

The test is carried out according to IEC 60068-2-1[8] and IEC 60068-3-1 [23].

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

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test.
Stabilization	2 hours at each temperature under “free air” conditions.
Temperature	Low temperature as specified in 5.8.1 a).
Temperature sequence	Reference temperature, Specified temperature.
Test	The EUT shall not be readjusted at any time during the test. After stabilization at the relevant temperature, perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and under the conditions defined in 11.4.4.2 a) first test and record: a) date and time, b) temperature, c) relative humidity, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2

11.4.4.5 Damp heat, steady- state (non condensing)

This test is applied to verify compliance with the provisions in 5.8.1 b) under conditions of ambient humidity without condensation.

The test is carried out according to IEC 60068-2-78 [13].

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

Precondition	Normal electric power supplied and "on" for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be "on" for the duration of the test. The EUT shall be handled such that no condensation of water occurs on it.
Test	The EUT shall not be readjusted at any time during the test. The EUT is kept under the conditions defined in 5.8.1 b). At the end of this period and still under this condition, perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) relative humidity, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	The error of the breath alcohol analyzer is determined once per day under test conditions and at the end of the test after a recovery period of one hour. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.

11.4.4.6 Atmospheric pressure

This test is applied to verify compliance with the provisions in 5.8.1 c) under conditions of changes in atmospheric pressure.

The following shortened test procedure shall be applied:

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test.
Stabilization	10 minutes at each pressure.
Pressure sequence	Reference pressure (ambient pressure, see 11.4.1), 860 hPa ± 10 hPa, 1 -060 hPa ± 10 hPa, Reference pressure (ambient pressure, see 11.4.1).
Test	The EUT shall not be readjusted at any time during the test. After stabilization at the relevant pressure, perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) relative humidity, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.

11.4.4.7 Random vibration

This test is applied to verify compliance with the provisions in 5.8.1 d) under conditions of moderate vibrations.

The test is carried out according to IEC 60068-2-1[8], IEC 60068-2-64 [12] and IEC 60068-3-8 [14].

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

Preliminary test~~condition~~	Before the vibrations, the MPE shall be determined.
Condition of the EUT	Power is to be "off" for the duration of the test.
Test	The EUT shall not be readjusted at any time during the test. After having been switched off, the following vibration level shall be applied on 3 mutually perpendicular axis during at least 2 minutes per axis, the EUT being mounted on a rigid fixture by its normal mounting means so that the gravitational force acts in the same direction as it would be in normal use. - Total frequency range: 10 Hz – 150 Hz - Total RMS level: 7 $m.s^{-2}$ - ASD level 10 Hz – 20 Hz: 1 $m^2.s^{-3}$ - ASD level 20 Hz – 150 Hz: – 3 dB/octave After the vibrations, the EUT shall be switched on and, after a stabilization time, ~~perform~~ 5 measurements shall be performed using test gas No. 4 defined in 11.4.4.1 a). ~~and~~ ~~r~~Record: a) date and time, b) temperature, c) relative humidity, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	The error of the breath alcohol analyzer is determined after the whole test has been carried out. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.

11.4.4.8 DC mains voltage variations

This test is applicable only for EUT which can be powered by DC.

This test is applied to verify compliance with the provisions in 5.8.1 e) under conditions of variations in a DC mains network.

The test is carried out according to IEC 60654-2 [29].

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

Precondition	Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test.
Voltage sequence	Reference voltage (nominal voltage specified by the manufacturer). High voltage: the upper limit ~~being~~ is the DC level at which the EUT has been manufactured to automatically detect high level conditions. Low voltage: the DC level at which the EUT has been manufactured to automatically detect low level conditions. Reference voltage (nominal voltage specified by the manufacturer).
Test	The EUT shall not be readjusted at any time during the test. After stabilization at the relevant voltage perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) reference voltage at beginning and end, high voltage and low voltage, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	The errors shall be determined when the breath alcohol analyzer is powered up at the upper limit of the voltage and when it is powered up at the lower limit of the voltage. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.

11.4.4.9 AC mains voltage variations

This test is applicable only for EUT which can be powered by AC.

This test is applied to verify compliance with the provisions in 5.8.1 f) under conditions of variations in the mains power voltage.

The test is carried out according to IEC/TR 61000-2-1 [26] and IEC 61000-4-1 [28].

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

Precondition	Normal electric power supplied and "on" for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be "on" for the duration of the test.
Voltage sequence	Nominal (reference) voltage, High voltage: U_{nom} + 10 %, Low voltage: U_{nom} – 15 %, Nominal (reference) voltage.
Test	The EUT shall not be readjusted at any time during the test. After stabilization at the relevant voltage perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) reference voltage at beginning and end, high voltage and low voltage, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	The errors shall be determined when the breath alcohol analyzer is powered up at the upper limit of the voltage and when it is powered up at the lower limit of the voltage. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.
Notes	The values of U_{nom} are those marked on the measuring instrument. In case a range is specified, the "-" relates to the lowest value and the "+" to the highest value of the range.

11.4.4.10 Low voltage of internal battery

This test is applied to verify compliance with the provisions in 5.8.1 h) when the breath alcohol analyzer is powered by an internal battery.

There is no reference to standards for this test.

Precondition	Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be “on” for the duration of the test.
Lower limit of the test voltage	The lowest voltage at which the EUT functions properly according to the specifications given by the manufacturer.
Test procedure	The test consists of exposure to the specified condition of the battery(s) for a period sufficient for achieving temperature stability and for performing the required measurements. Test sequence: Stabilize the power supply at the voltage within the defined limits and apply the measurement and/or loading condition. After stabilization at the relevant voltage perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) power supply voltage, d) functional mode, e) measurements and/or loading condition, f) indications, g) errors, h) functional performance. Reduce the power voltage to the EUT until the equipment clearly ceases to function properly according to the specifications and metrological requirements, and note the following data: a) power supply voltage, b) indications, c) errors, d) other relevant responses of the instrument.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.
Notes	If an alternative power source (standard power supply with sufficient current capacity) is used in bench testing to simulate the battery, it is important that the internal impedance of the specified type of battery also be simulated.

11.4.4.11 Voltage variations of a road vehicle battery

This test is applied to verify compliance with the provisions in 5.8.1 i) under conditions of high (under charge) and low battery voltage.

The test is carried out according to ISO 16750-2 [30].

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

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

Precondition	Before each test, the EUT is switched off for a period of time long enough to be thermally stable at the environmental temperature. For each test (low voltage and high voltage respectively), the power is switched on at that test voltage.
Stabilization	The EUT is powered up at the test voltage for a time period equal to or greater than the warm-up time specified by the manufacturer.
Test voltages	Voltages as specified in 5.8.1 i).
Test	The EUT shall not be readjusted at any time during the test. After stabilization at the relevant voltage perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) voltage, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	The errors shall be determined when the breath alcohol analyzer is powered up at the upper limit of the voltage and when it is powered up at the lower limit of the voltage. All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.

11.4.4.12 AC mains frequency variations

This test is applicable only for EUT which can be powered by AC (direct or through a generator).

This test is applied to verify compliance with the provisions in 5.8.1 g) under conditions of varying AC mains power frequency.

The test is carried out according to IEC/TR 61000-2-1 [26], IEC 61000-2-2 [27] and IEC 61000-4-1 [28].

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

Precondition	Normal electric power of the nominal voltage and frequency supplied and "on" for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be "on" for the duration of the test, and the voltage kept at the nominal voltage.
Voltage sequence	Nominal (reference) frequency, High voltage: f_{nom} +2 %, Low voltage: f_{nom} –2 %, Nominal (reference) frequency.
Test	The EUT shall not be readjusted at any time during the test. After stabilization at the relevant frequency perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) voltage, d) reference frequency at beginning and end, high frequency and low frequency, e) measurands, f) indications, g) errors, h) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.
Notes	The values of f_{nom} are those marked on the measuring instrument. In case a range is specified, the "-" relates to the lowest value and the "+" to the highest value of the range.

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

This test is applied to verify compliance with the provisions in 5.8.1 j) under conditions of hydrocarbons in the environment.

The following shortened test procedure shall be applied:

Precondition	Normal electric power supplied and "on" for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be "on" for the duration of the test.
Test	The EUT shall not be readjusted at any time during the test. After stabilization at 5 ppm of hydrocarbons, perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) relative humidity d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.

11.4.4.14 Influence of the volume fraction of CO_2

This test is applied to verify compliance with the provisions in 5.8.1 k) under conditions of CO_2 in the environment.

The following shortened test procedure shall be applied.

Precondition	Normal electric power supplied and "on" for a time period equal to or greater than the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be "on" for the duration of the test.
Test	The EUT shall not be readjusted at any time during the test. After stabilization at 10 % of CO_2, perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) relative humidity, d) measurands, e) indications, f) errors, g) functional performance.
Maximum allowable variations	All functions shall operate as designed. All errors shall be within the MPEs specified in 5.2.

11.4.5 Disturbance~~s~~ tests

The tests shall be carried out using test gas No. 4 defined in 11.4.4.1.

For each disturbance test, the intrinsic error (see 2.20) is determined as the average of the errors of five measurements.

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

The type of measuring instrument is presumed to comply with the provisions specified in 5.10 if it passes the following tests.

11.4.5.1 Radiated, radio frequency, electromagnetic fields (See OIML D 11; 12.1.1 [6])

This test is applied to verify compliance with the provisions in 5.10.1.1 a) under conditions of radiated electromagnetic fields.

This test is carried out according to IEC 61000-4-3 [16]. The testing procedure applied by the testing laboratory shall be reported in detail in the Evaluation Report, including defining the measuring cycle and the method used to cover the frequency range.

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

Precondition	Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer. ~~Adjust the EUT as close to zero indication as practicable prior to the test.~~
Condition of the EUT	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
EM Field	Radiated 10 V/m, modulated 80 % AM, sine wave.
Frequency range	From 80 MHz to 3 000 MHz.
Performance test	~~Stabilize all factors at nominal reference conditions.~~Influence factors shall be fixed at reference conditions as defined in 11.4.1. Record the following with and without radiated electromagnetic fields: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) indications and errors, f) functional performance.
Performance of the instrument	Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing.

11.4.5.2 Conducted radio-frequency fields (See OIML D 11; 12.1.2 [6])

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

This test is applied to verify compliance with the provisions in 5.10.1.1 b) under conditions of conducted electromagnetic fields.

This test is carried out according to IEC 61000-4-6 [19].

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

Precondition	Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer. ~~Adjust the EUT as close to zero indication as practicable prior to the test.~~
Condition of the EUT	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
EM Field	Radiated 10 V/m, modulated 80 % AM, sine wave.
Frequency range	From 0.15 MHz to 26 MHz.
Performance test	Influence factors shall be fixed at reference conditions as defined in 11.4.1. ~~Stabilize all factors at nominal reference conditions.~~ Record the following with and without radiated electromagnetic fields: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) field strength, f) indications and errors, g) functional performance. Conventionally 3 cycles of tests are performed starting each test at a different moment of the measurement cycle.
Performance of the instrument	Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing.

11.4.5.3 Electrostatic discharges (See OIML D 11; 12.2 [6])

This test is applied to verify compliance with the provisions in 5.10.1.1 c) under conditions of electrostatic discharges.

This test is carried out according to IEC 61000-4-2 [15].

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

Precondition	Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer. ~~Adjust the EUT as close to zero indication as practicable prior to the test.~~
Condition of the EUT	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
Discharges	Contact mode: 6 kV, Air mode: 8 kV.
Performance test	Influence factors shall be fixed at reference conditions as defined in 11.4.1. The test consists in exposing the EUT to both direct and indirect, electrostatic discharges. Contact discharges are the preferred test method. Nevertheless, air discharges shall be used where contact discharges cannot be applied (e.g. non conductive surfaces). At least ten successive discharges shall be applied with a time interval between discharges of at least ten seconds on each point of application. The number of points of application on each surface will depend on the size of the instrument and shall be defined according to IEC 61000-4-2.~~and~~ The tested points shall be ~~specified~~ described in the test report. The discharges shall be applied on each surface accessible in normal operation. 5 measurements shall be performed in each surface. Record the following with and without discharges: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) discharges, f) indications and errors, g) functional performance. Conventionally 3 cycles of tests are performed starting each test at a different moment of the measuring cycle.
Performance of the instrument	Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing.

11.4.5.4 Bursts on supply lines (See OIML D 11; 13.5 [6])

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

This test is applied to verify compliance with the provisions in 5.10.1.1 d) under conditions of bursts on supply lines.

This test is carried out according to IEC 61000-4-1 [28] and IEC 61000-4-4 [17].

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

Precondition	Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer. ~~Adjust the EUT as close to zero indication as practicable prior to the test.~~
Condition of the EUT	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
Performance test	Influence factors shall be fixed at reference conditions as defined in 11.4.1. The test consists in exposing the EUT to bursts of voltage spikes of 1 kV, with a repetition rate of 5 kHz. At least 10 positive and 10 negative bursts randomly phased shall be applied. Record the following: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) indications and errors, f) functional performance.
Performance of the instrument	Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing.

11.4.5.5 Bursts on signal, data and control lines (See OIML D 11; 12.4 [6])

This test is applied to verify compliance with the provisions in 5.10.1.1 e) under conditions of bursts on signal, data and control lines.

This test is carried out according to IEC 61000-4-1 [28] and IEC 61000-4-4 [17].

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

Precondition	Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer. ~~Adjust the EUT as close to zero indication as practicable prior to the test.~~
Condition of the EUT	The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
Performance test	Influence factors shall be fixed at reference conditions as defined in 11.4.1. The test consists in exposing the EUT to bursts of voltage spikes of 1 kV, with a repetition rate of 5 kHz. At least 10 positive and 10 negative bursts randomly phased shall be applied. Record the following: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) indications and errors, f) functional performance.
Performance of the instrument	Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility. It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing.

11.4.5.6 Surges on signal, data and control lines (See OIML D 11; 12.5 [6])

This test is applied to verify compliance with the provisions in 5.10.1.1 f) under conditions of surges on signal, data and control lines.

This test is carried out according to IEC 61000-4-5 [18].

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

<table>
<tr><td>Precondition</td><td>Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer.
~~Adjust the EUT as close to zero indication as practicable prior to the test.~~</td></tr>
<tr><td>Condition of the EUT</td><td>The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.</td></tr>
<tr><td>Performance test</td><td>Influence factors shall be fixed at reference conditions as defined in 11.4.1.
The test consists in exposing the EUT to surges as follows:
<table><tr><td rowspan="2">Unbalanced lines</td><td>Line to line</td><td>1 kV</td></tr><tr><td>Line to earth</td><td>2 kV</td></tr><tr><td>Balanced lines</td><td>Line to earth</td><td>2 kV</td></tr></table>
At least 3 positive and 3 negative surges shall be applied.

Record the following:
a) date and time,
b) temperature,
c) relative humidity,
d) value of the measurand,
e) line,
f) indications and errors,
g) functional performance.</td></tr>
<tr><td>Performance of the instrument</td><td>Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility.
It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing.</td></tr>
</table>

11.4.5.7 AC mains voltage dips, short interruptions and voltage variations (See OIML D 11; 13.4 [6])

This test is applied to verify compliance with the provisions in 5.10.1.1 g) under conditions of AC mains voltage dips, short interruptions and voltage variations.

This test is carried out according to IEC 61000-4-11 [20], IEC 61000-6-1 [21] and IEC 61000-6-2 [22].

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

<table>
<tr><td>Precondition</td><td>Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer.
~~Adjust the EUT as close to zero indication as practicable prior to the test.~~</td></tr>
<tr><td>Condition of the EUT</td><td>The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.</td></tr>
<tr><td>Performance test</td><td>Influence factors shall be fixed at reference conditions as defined in 11.4.1.
The test consists in exposing the EUT to mains voltage reductions as follows:
<table><tr><td>Reduction</td><td>100 %</td><td>100 %</td><td>30 %</td><td>> 95 %</td></tr><tr><td>Duration</td><td>0.5 cycle</td><td>1 cycle</td><td>25 cycles</td><td>250 cycles</td></tr></table>
The mains voltage reductions shall be repeated 10 times with an interval of at least 10 seconds.
The error of the breath alcohol analyzer is determined for each configuration of testing.

Record the following:
a) date and time,
b) temperature,
c) relative humidity,
d) value of the measurand,
e) voltage reduction,
f) indications and errors,
g) functional performance.</td></tr>
<tr><td>Performance of the instrument</td><td>Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility.
It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing.</td></tr>
</table>

11.4.5.8 Electrical transient conduction for external batteries of a vehicle (See OIML D 11; 14.2.2 [6])

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

This test is applied to verify compliance with the provisions in 5.10.1.1 h) under conditions of electrical transient conduction for external batteries of a vehicle.

This test is carried out according to ISO 7637-2 [31].

In addition to the information in the ~~IEC~~ ISO test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

<table>
<tr><td>Precondition</td><td>Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer.
~~Adjust the EUT as close to zero indication as practicable prior to the test.~~</td></tr>
<tr><td>Condition of the EUT</td><td>The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.</td></tr>
<tr><td>Performance test</td><td>Influence factors shall be fixed at reference conditions as defined in 11.4.1.
The test consists in exposing the EUT to disturbances on the power voltage by direct coupling on supply lines as follows:
U_{nom} = 12 V
<table>
<tr><td></td><td>Pulse 1</td><td colspan="2">Pulse 2</td><td colspan="2">Pulse 3</td><td>Pulse 4</td></tr>
<tr><td rowspan="2">L~~EVEL~~evel</td><td rowspan="2">–100 V</td><td>2a</td><td>2b</td><td>3a</td><td>3b</td><td rowspan="2">–7 V</td></tr>
<tr><td>+50 V</td><td>+10 V</td><td>–150 V</td><td>+100 V</td></tr>
<tr><td>Minimum number of pulses or test time</td><td>5 000 pulses</td><td colspan="2">5 000 pulses</td><td colspan="2">1 hour</td><td>1 pulse</td></tr>
</table>
U_{nom} = 24 V
<table>
<tr><td></td><td>Pulse 1</td><td colspan="2">Pulse 2</td><td colspan="2">Pulse 3</td><td>Pulse 4</td></tr>
<tr><td rowspan="2">L~~EVEL~~evel</td><td rowspan="2">–100 V</td><td>2a</td><td>2b</td><td>3a</td><td>3b</td><td rowspan="2">–16 V</td></tr>
<tr><td>+50 V</td><td>+20 V</td><td>–200 V</td><td>+200 V</td></tr>
<tr><td>Minimum number of pulses or test time</td><td>5 000 pulses</td><td colspan="2">5 000 pulses</td><td colspan="2">1 hour</td><td>1 pulse</td></tr>
</table>
Record the following:
a) date and time,
b) temperature,
c) relative humidity,
d) value of the measurand,
e) voltage,
f) indications and errors,
g) functional performance.</td></tr>
<tr><td>Performance of the instrument</td><td>Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility.
It is acceptable that the breath alcohol analyzer gives no result during the disturbance testing.</td></tr>
</table>

11.4.5.9 Mechanical shocks (See OIML D 11; 11.2 [6])

This test is applied to verify compliance with the provisions in 5.10.1.2 b) after conditions of mechanical shocks.

This test is carried out according to IEC 60068-2-31 [10].

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

<table>
<tr><td>Precondition</td><td>Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer.
~~Adjust the EUT as close to zero indication as practicable prior to the test.~~</td></tr>
<tr><td>Condition of the EUT</td><td>The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.
If the instrument is operated from a carrying case then this test should be carried out with the instrument in it.</td></tr>
<tr><td>Performance test</td><td>Influence factors shall be fixed at reference conditions as defined in 11.4.1.
The test consists in exposing the EUT to mechanical shocks as follows:
- For stationary or/and mobile breath alcohol analyzers
The breath alcohol analyzer is placed on a rigid surface in the position in which it is normally used, ~~is~~ tilted on one bottom edge and ~~is~~ then allowed to fall freely onto the test surface. This test shall be repeated for each edge in turn (subject to a maximum inclination of 30~~-~~°).
- For portable breath alcohol analyzers:
3 arbitrary positions are chosen.

The height of fall given below is that of the opposite edge
<table><tr><td></td><td>Stationary</td><td>Mobile</td><td>Portable</td></tr><tr><td>Height of fall</td><td>25 mm</td><td>50 mm</td><td>1 m</td></tr><tr><td>Number of falls</td><td>1</td><td>1</td><td>3</td></tr></table>
Record the following:
a) date and time,
b) temperature,
c) relative humidity,
d) value of the measurand,
e) height of fall,
f) indications and errors,
g) functional performance.</td></tr>
<tr><td>Performance of the instrument</td><td>Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility.</td></tr>
</table>

11.4.5.10 Shakes

This test is applied to verify compliance with the provisions in 5.10.1.2 c) after conditions of shakes. This test simulates shocks in a car trunk.

The following shortened test procedure shall be applied:

Precondition	Power is to be "off" for the duration of the test.
~~Condition of the EUT~~	~~Power is to be "off" for the duration of the test.~~ ~~The EUT shall not be readjusted at any time during the test.~~
Test	Influence factors shall be fixed at reference conditions as defined in 11.4.1. After having been switched off, the EUT is placed in its reference position on a table which can generate shakes in the following conditions: wave shape: half-sinusoid amplitude: 10 ~~G~~ g (~~G~~ g = 9.81 m/s^2) duration: 6 ms frequency: 2 Hz number of axes: 3 perpendicular axes number of shakes: 1 000 for each axes After shakes, the EUT shall be switched on and~~,~~ 5 measurements shall be performed using test gas No. 4 defined in 11.4.4.1 a). Record: a) date and time, b) temperature, c) relative humidity, d) value of the measurand~~s~~, e) indications, f) errors, g) functional performance.
Maximum allowable variations	Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility.

11.4.5.11 Damp heat cyclic (condensing) (OIML D 11; 10.2.2 [6])

This test is applied to verify compliance with the provisions in 5.10.1.2 a) after conditions of damp heat cyclic (condensing).

This test is carried out according to IEC 60068-2-30 [25] and IEC 60068-3-4 [24].

In addition to the information in the IEC test procedures, the following shortened test procedures ~~in brief~~ shall be applied.

<table>
<tr><td>Precondition</td><td>Before the test, the breath alcohol analyzer shall be switched on for a time period equal to or greater than the warm-up time specified by the manufacturer.</td></tr>
<tr><td>Condition of the EUT</td><td>The EUT shall not be readjusted at any time during the test except to reset if a significant fault has been indicated.</td></tr>
<tr><td>Performance test</td><td>The breath alcohol analyzer shall be exposed to cyclic variation between 25 °C and the temperature specified below. The relative humidity shall be above 95 % during the temperature change and low temperature phases and at 93 % at the upper temperature phases.
Condensation should occur on the breath alcohol analyzer during the temperature rise.
The 24-hour 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.
<table><tr><td></td><td>Mobile</td><td>Portable</td></tr><tr><td>Temperature</td><td>55 °C</td><td>55 °C</td></tr><tr><td>Duration</td><td>2 cycles</td><td>4 cycles</td></tr></table>
Record the following:
a) date and time,
b) temperature,
c) relative humidity,
d) value of the measurand,
e) indications and errors,
f) functional performance.</td></tr>
<tr><td>Performance of the instrument</td><td>Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility.</td></tr>
</table>

11.4.5.12 Storage test

This test is applied to verify compliance with the provisions in 5.10.1.2 d) after conditions of storage.

The following shortened test procedures shall be applied.

Precondition	Power is to be “off” for the duration of the test.
Condition of the EUT	The EUT shall not be readjusted at any time during the test.
Performance test	After having been switched off, the EUT is exposed to a low temperature of – 25 °C during 6 hours and to a high temperature of 70 °C during ~~six~~ 6 hours. The change of temperature shall not exceed 1 °C/min during cooling down and heating up. Then the EUT shall be switched on. ~~and, a~~After a recovery period of one hour at the reference conditions, perform 5 measurements using test gas No. 4 defined in 11.4.4.1 a) and record: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) indications and errors, f) functional performance.
Performance of the instrument	Either significant faults as defined in 5.9 do not occur, or they are detected and acted upon by means of a checking facility.

11.4.5.13 Durability

The requirement defined in 5.11 is met if the instrument submitted to the accuracy tests and disturbance tests passes each single test.

11.4.6 Physiological influence quantities

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

- determination of the indication for a dry or wet test gas having an ethanol content of 0.4 mg/L ± 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 table in 5.10.2 at the indicated mass concentration.

If the variation of the indication is not more than the maximum value defined in 5.10.2 (0.1 mg/L for the current interfering substances in the above table) the breath alcohol analyzer has passed the test for the interfering substance concerned.

If the variation is more than the value defined in 5.10.2 and if no error message is given, the breath alcohol analyzer has failed. If an error message is given, another test shall be performed with the same interfering substance at a mass concentration 5 times smaller. In that case the variation shall not be more than a fifth of the maximum value defined in 5.10.2.

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

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

Annex A
Examples of detection of alcohol in upper respiratory tracts

(Informative)

National Authorities may choose one, two or all the following solutions for detection of alcohol in the upper respiratory tracts (A.1, A.2 or A.3).

A.1 Peak method

In the event that the detection is accomplished by detecting a peak in the IR signal, the following test demonstrates that the instrument is able to detect alcohol in upper respiratory tracts.

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

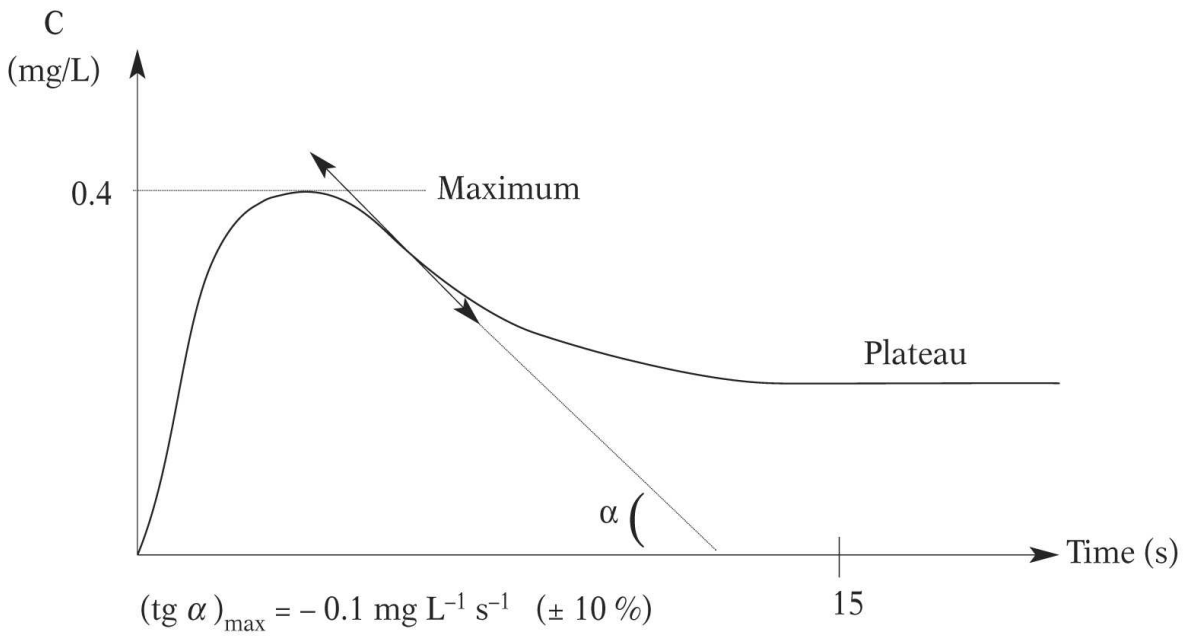

Figure A.1-1

The characteristics of the gas injected are the following:

- Delivered volume: 3 L ± 0.2 L,
- Duration: 15 s ± 0.5 s,
- Mass concentration at maximum of the curve: 0.4 mg/L ± 0.020 mg/L.

Ten measurements shall be performed and the instrument shall detect the presence of alcohol in the upper respiratory tracts and shall not deliver any measurement result.

Example with a balloon

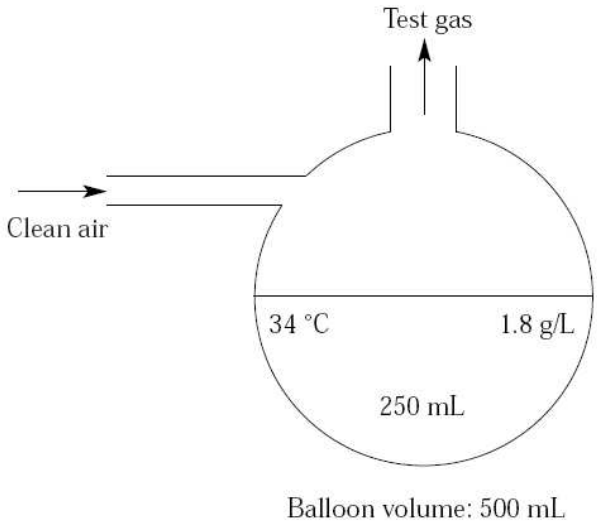

Figure A.1-2

A.2 Two-measurement cycle

A.2.1 First method

A.2.1.1 Principle of the method

The measurement cycle shall include two measurements. These two measurements shall be performed within a delay not less than 2 min.

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

a) First measurement value less than the legal value

The measurement cycle may be stopped after the first measurement if the concentration value is less than the legal value. In this case, the result of the measurement shall be displayed and printed (if applicable).

b) Second measurement value less than the legal value

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

c) First and second measurement~~s~~ values more than or equal to the legal value

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

$$R = \left| 1 - \frac{Cm_2}{Cm_1} \right| / t$$

where:

t is the time difference between the end of the first breath and the end of the second breath,

Cm_1 is the value of the measurement of the first test,

Cm_2 is the value of the measurement of the second test.

If R is less than 0.03 min^{-1}, National Authorities may choose either of the two following solutions:

- the smallest value of Cm_1 and Cm_2 is displayed and printed (if applicable),
- the two values Cm_1 and Cm_2 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 result, for instance indicating “measurement cycle not completed”.

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

A.2.1.2 Test procedure

Note: The test gases described in the current procedure are chosen for a legal value of 0.25 mg/L.

For another legal value, ~~t~~Tables 1, 2 and 3 must be modified according to A.2.1.1:

- Part a)
  - The mass concentration of the first test gas is equal to the mass concentration of the legal value minus 0.3 mg/L,
- Part b)
  - The mass concentration of the first test gas is equal to the mass concentration of the legal value plus 0.3 mg/L,
  - The mass concentration of the second test ~~is~~ gas is equal to the mass concentration of the legal value minus 0.3 mg/L,
- Part c)
  - The mass concentrations of the first and of the second test gases are equal to ~~the mass concentration~~ that of the legal value minimum plus 0.3 mg/L,
  - The ratio R must be less than 0.03 min^{-1} of ~~t~~Table 2 and more than or equal to 0.03 min^{-1} of T~~t~~able 3.

The test gases described in this paragraph are different from those defined in 11.4.4.1.

Table 1

Test gas No. ~~(mg/L)~~	Mass concentration (mg/L)
10	0.22
11	0.28
12	0.29
13	0.30
14	0.31
15	0.32

a) First measurement value less than the legal value

The characteristics of the test gas are:

- First test gas: test gas No. 10,
- Duration of injection: 5 s,
- ~~Duration of plateau~~Duration of the plateau: 3 s,
- Volume: 3 L.

After ~~V~~verifying that the value $Cm_1 < 0.25$ mg/L, the result of measurement shall be displayed and printed (if applicable).

b) Second measurement value less than the legal value

The characteristics of the test gases are:

- First test gas: test gas No. 11,
- Second test gas: test gas No. 10,
- Duration of injection: 5 s,
- ~~Duration of plateau~~Duration of the plateau: 3 s,
- Volume: 3 L.

After ~~V~~verifying that the value $Cm_2 < 0.25$ mg/L, the smallest result shall be displayed and printed (if applicable).

c) First and second measurement~~s~~ values more than or equal to the legal value

Case 1: R is less than 0.03 min^{-1}

The characteristics of the test gases are:

- First test gas: test gas No. 11,

- Second test gas: test gas selected from Ttable 1 according to the time between the end of the first breath and the end of the second breath of the device (see table Table 2),
- Duration of injection: 5 s,
- Duration of plateauDuration of the plateau: 3 s,
- Volume: 3 L.

Table 2

First test gas (mg/L)	Second test gas (mg/L)	t (min)	R = Theoretical ratio
0.28	0.29	2	0.018
0.28	0.29	2.5	0.014
0.28	0.30	3	0.024
0.28	0.30	3.5	0.020
0.28	0.30	4	0.018
0.28	0.31	4.5	0.024
0.28	0.31	5	0.021

After Vverifying that the ratio R obtained from Cm_1 and $Cm_2 < 0.03\ min^{-1}$, National Authorities may choose either of the two following solutions:

- the smallest value of Cm_1 and Cm_2 is displayed and printed (if applicable),
- the two values Cm_1 and Cm_2 are displayed and printed (if applicable).

Case 2: R is more than or equal to $0.03\ min^{-1}$

The characteristics of the test gases are:

- First test gas: test gas No. 11,
- Second test gas: test gas selected from table Table 1 according to the time between the end of the first breath and the end of the second breath of the device (see table Table 3),
- Duration of injection: 5 s,
- Duration of plateauDuration of the plateau: 3 s,
- Volume: 3 L.

Table 3

First test gas (mg/L)	Second test gas (mg/L)	t (min)	R = Theoretical ratio
0.28	0.30	2	0.036
0.28	0.31	2.5	0.043
0.28	0.31	3	0.036
0.28	0.32	3.5	0.041
0.28	0.32	4	0.036
0.28	0.33	4.5	0.040
0.28	0.33	5	0.036

After ~~V~~verifying that the ratio R obtained from Cm_1 and $Cm_2 \geq 0.03\ \text{min}^{-1}$, the measurement cycle shall be cancelled and the breath alcohol analyzer shall display a warning message to specify that the cycle is not valid and that a new one shall start.

A.2.2 Second method

The breath analyzer shall use a measurement cycle involving two subject sample measurements, each measurement corresponding to an exhalation. The two subject sample measurements are separated by at least 2 min. The resulting displayed or recorded measurement in a subject test ~~is to~~ shall be specified by the National 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 values:

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

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

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

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 2 min, but not more than 5 min. 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~~Duration of the plateau: 3 s,
- Volume: 3 L.

The mass concentration at the maximum of an injection curve is 0.40 mg/L and 0.25 mg/L, respectively, with the second test gas being lower than the first. The results of the sequential test shall be such that the instrument will either invalidate the measurement cycle and/or display a warning as required by the National Authority.

A.3 Delay before measurement

Good measurement practice, regardless of technical solutions (A.1, A.2), ~~is~~ involves allowing for an observation period prior to subject tests of at least 15 min to ensure that the alcohol has disappeared from the upper respiratory tract.

Annex B
General information and breath profile

(Informative)

As defined in the Scope, the purpose of this Recommendation is to evaluate the suitability of breath alcohol analyzers for measuring the mass concentration of alcohol in exhaled human breath. The reproducibility is, however, influenced by the wide variability in human breath samples themselves.

The characteristics of a sample will depend on the willingness or physical ability of the subject to deliver an optimal sample. A subject may deliver a sample with a long steady exhalation, or with a short forceful one.

The aim of this Annex is to characterize the breath profiles and define the acceptance criteria.

B.1 Measurement ~~flow rate~~flowrate during exhalation

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

B.1.1 Conventional curve of forced exhalation

The curve is divided into two distinct areas:

- The first part of the curve (located in the first ¼ of the time of exhalation) represents the peak of the flow at the time of the exhalation,
- The second part represents a regular decrease in the flow of breath.

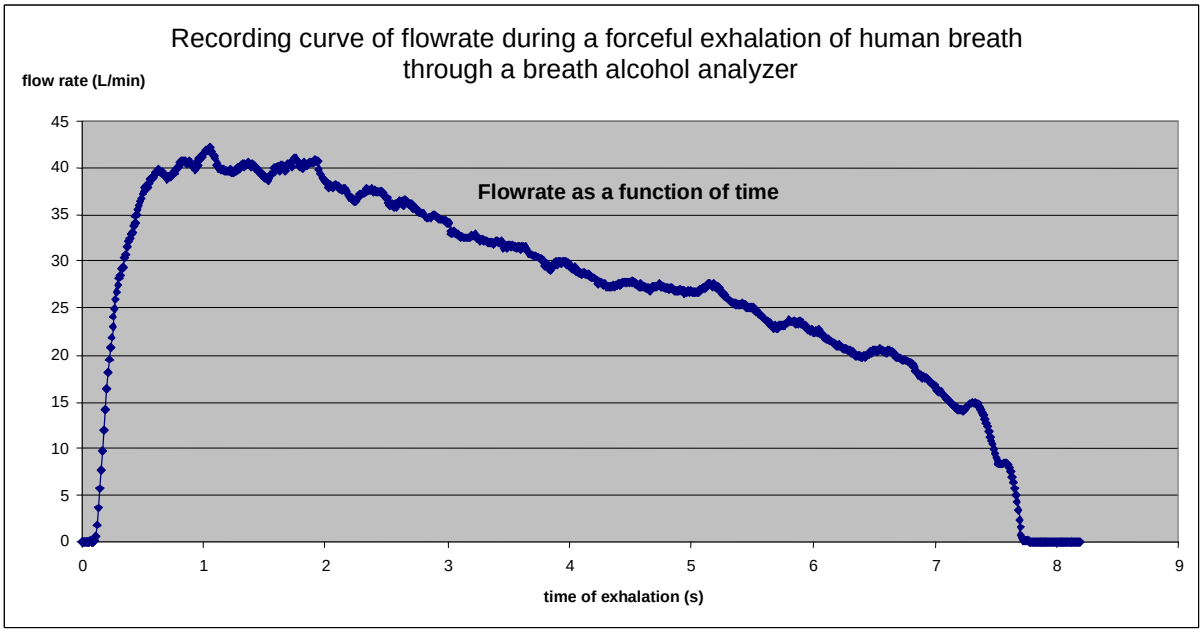

Figure B.1.1

B.1.2 Simulation curve of forced exhalation

(Description of the test in 11.4.4.2 c) - Influence factors of conditions of exhalation**).**

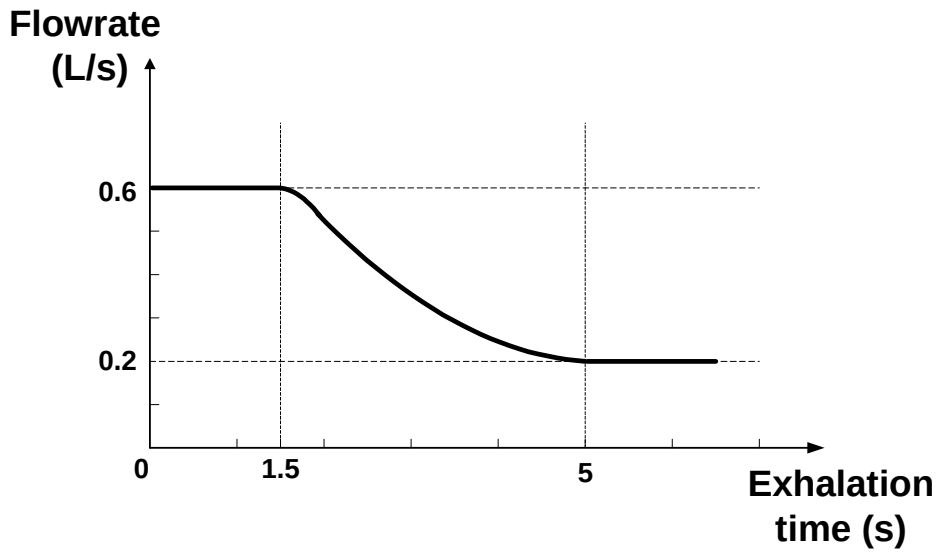

Figure B.1.2

- Initial condition: 3 L; exhalation time: 5 s; ~~flow rate~~flowrate: 0.6 L/s,
- After 1.5 s, the ~~flow rate~~flowrate decreases until 0.2 L/s,
- After 5 s, the ~~flow rate~~flowrate remains equal to 0.2 L/s until the end of the exhalation.

B.2 Measurement of the alcohol concentration during exhalation / determination of the alcohol plateau

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

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

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

B.2.1 Theoretical curves of the alcohol concentration as a function of time obtained from a human exhalation

The dead anatomical volume is approximately equal to 2.2 mL ~~(milliliters)~~ times the body mass in kilograms and therefore an average volume of 150 mL can be chosen.

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

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

$$(C_0 = 0)\,;\, i = incremental\ indice$$

where C = alcohol concentration (expressed in %),

D = ~~flow rate~~flowrate (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 exhalation (concentration superior to 99 % of the maximum value).

This value (99 % of the expected concentration) is a proposition based on the statistic rules about response time.

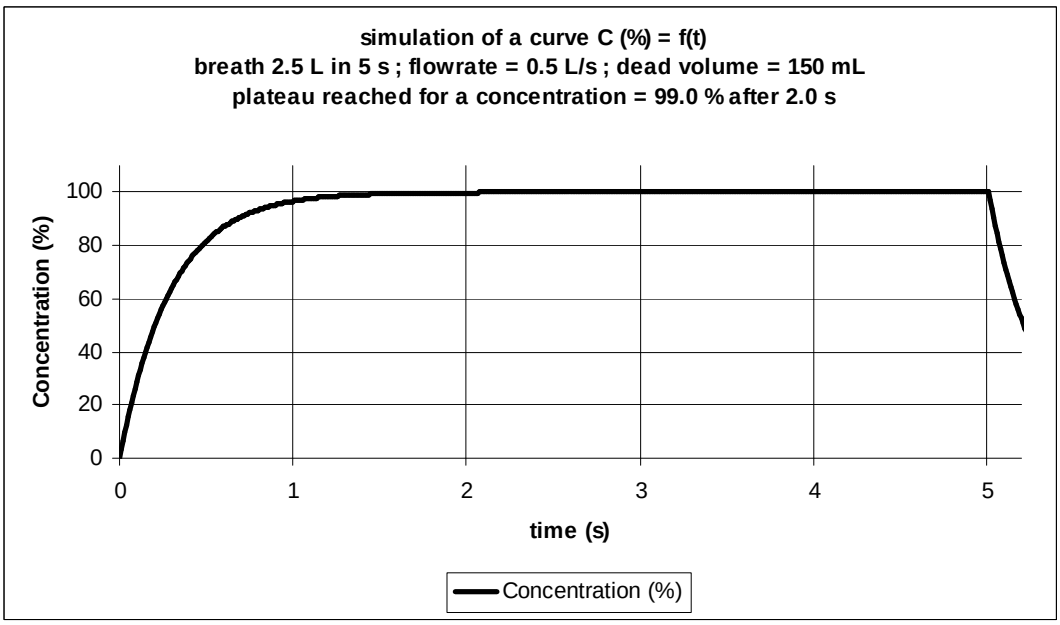

Figure B.2.1

B.2.2 Simulation curves of the alcohol concentration as a function of time

Method to determine the duration of the alcohol plateau at the time of an exhalation: The plateau is the time at which the alcohol concentration is stabilized ~~within~~ to at least 99 % of the reference value.

Example of a curve of alcohol concentration as a function of time obtained on a simulation test bench (description of the test in 11.4.4.2 d) - Influence factors of conditions of exhalation):

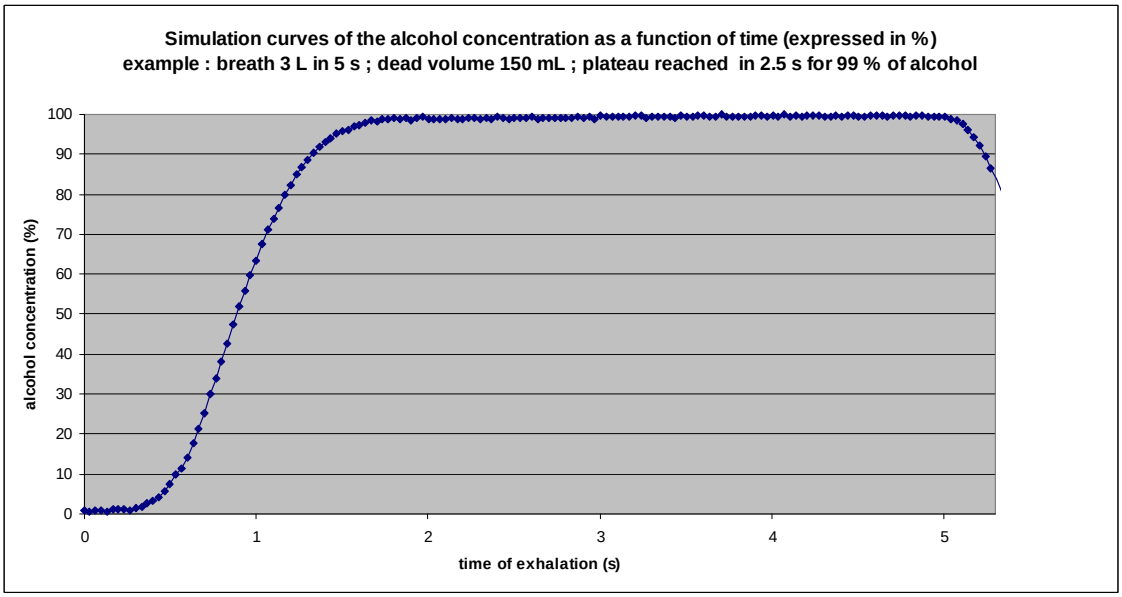

Figure B.2.2

Annex C
Reference principle for the implementation of the tests

(Informative)

Dubowski's formula

Let C_{H_2O} be the mass concentration of ethanol of an aqueous solution of ethanol. When air is bubbled through such a solution, the mass concentration C_{air} of ethanol in the air is given by the following formula:

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

Where t is the temperature in °C

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

Harger's formula

The partition ratio for concentration of ethanol in headspace to concentration in solution is given by :

$$K_{a/w} = 0.000493$$

For t = 34 °C, $C_{air} = 0.493 \times 10^{-3}\, C_{H_2O}$

Annex D
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