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First Committee Draft Revision International Recommendation 126

"Evidential Breath alcohol analyzers"

Part 1: Metrological and technical requirements
Part 2: Metrological controls and performance tests
Part 3: Test report format

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OIML R 126

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Part 1: Metrological and technical requirements
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Foreword

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1 Introduction

Evidential Breath alcohol analyzers (EBA) are used worldwide in professional applications like law enforcement, promotion of traffic safety and work safety. Test results may lead to severe consequences for everybody involved. Therefore, the test results shall be reliable and acceptable.

This document contains a description of the minimum technical requirements to be met for compliance testing for EBAs. It contains also details concerning the compliance testing and performance requirements as a prerequisite for approval.

Any appropriate technology capable of providing the functionality required in this document may be used.

EBAs considered in this standard use mouthpieces for sampling the breath specimens.

2 Scope

This Recommendation applies to quantitative EBAs 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 EBAs are referred to by some national authorities as “evidential” EBAs 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 EBAs 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 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 of quantitative EBAs, recognizing national differences in legal systems. It also gives guidance for establishing metrological specifications for initial and in-service verifications.

3 Terms and definitions

3.1 General metrology and legal metrology terms

The basic terminology used in this document is consistent with the definitions in OIML V2 International Vocabulary Metrology – Basic and General Concepts and Associated Terms (VIM) and OIML V1 International Vocabulary of Terms in Legal Metrology (VILM).
For convenience, the most important definitions concerning this recommendation are presented here again.
Remark of the Secretariat: ***Delft, June 30 - July 1, 2015:*** *It was agreed on to postpone the assessment of the chapter terms and definitions until the rest of the document is completed.*

3.1.1 measurement error (VIM 2.16)

measured quantity value minus a reference quantity value

3.1.2 adjustment of a measuring system (VIM 3.11)

set of operations carried out on a **measuring system** so that it provides prescribed **indications** corresponding to given **values** of a **quantity** to be measured

3.1.3 calibration (VIM 2.39)

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

3.1.4 verification of a measuring instrument (VIML 2.09)

conformity assessment procedure (other than type evaluation) which results in the affixing of a verification mark and/or issuing of a verification certificate.
Note See also OIML V2-200:2012, 2.44.

3.1.5 software terminology

Terms will be defined/ inserted later, when the documented is completed.

3.1.6 disturbance (OIML D 11, 3.13.2)

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

3.1.7 significant fault (OIML D 11, 3.10)

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.

3.1.8 2.20 intrinsic error (OIML D 11, 3.7)

error of a measuring instrument, determined under reference conditions .

3.1.9 Experimental standard deviation (GUM G001-100, 4.22)

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,
Yi = the ith measurement (out of n) for the given mass concentration,
Ŷ= 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.

3.1.10 Measurement precision (VIM 2.15)

closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions.

3.1.11 Measurement repeatability (VIM 2.21)

measurement precision under a set of repeat-ability conditions of measurement.

3.1.12 repeatability condition of measurement (VIM 2.20)

condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time.

3.1.13 measurement reproducibility (VIM 2.25)

measurement precision under reproducibility conditions of measurement.

3.1.14 reproducibility condition of measurement (VIM 2.24)

condition of measurement, out of a set of conditions that includes different locations, operators, measuring systems, and replicate measurements on the same or similar objects .

3.1.15 stability of a measuring instrument (VIM 3.19)

property of a measuring instrument, whereby its metrological properties remain constant in time

3.2 Specific terms

3.2.1 evidential breath alcohol analyzer (EBA)

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

3.2.2 stationary breath alcohol analyzer (stationary EBA)

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

3.2.3 mobile breath alcohol analyzer (mobile EBA)

evidential breath alcohol analyzer intended for use in mobile applications (e.g. in vehicles) and easily transportable, but depending on an external power source.

3.2.4 portable breath alcohol analyzer (portable EBA)

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

3.2.5 alveolar air

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

3.2.6 end expiratory breath

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

3.2.7 anatomical dead volume

conducting area of gas flow known as the area of conduction without significant exchange of a defined volume. This volume varies between individuals *remark: to be clarified*

3.2.8 measuring mode

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

3.2.9 metrological test mode

mode in which the EBA is subject to metrological control like verification or adjustment. More information is available in comparison to the measuring mode (e.g. higher resolution, intermediate results, etc.), and access to maintenance and adjustment means is possible.

3.2.10 standby mode

mode of the EBA 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 unpowered state.

3.2.11 automatic checking facility (D11, 3.19.1)

internal device or process that checks whether the EBA 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

Question : it this definition used within the document?

3.2.12 checking facility (D11, 3.19)

facility incorporated in a measuring instrument which enables significant faults to be detected and acted upon

3.2.13 standard measurement cycle

the measurement cycle of an EBA consists of all steps necessary to obtain a valid result , from starting the measurement, sampling, analyzing, internal control procedures, calculation and displaying the result. Since National authorities may define specific measurement cycles for their country, “standard” refers to the respective country.

3.2.14 instrumental drift (VIM 4.21)

continuous or incremental change over time in indication, due to changes in metrological proper-ties of a measuring instrument

3.2.15 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

3.2.16 plateau of alcohol

the plateau 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 Annex B.2)

3.2.17 EBA in service

An EBA that is sold to the market and gets used (?)
An EBA which undergoes a service procedure (e.g. maintenance and periodic verification (?)

Remark: to be clarified!

3.3 abbreviations and symbols

MPE	Maximum Permissible Error
EUT	Equipment Under Test
EBA	Evidential breath analyzer

T_{al}	low ambient temperature
T_{ah}	high ambient temperature

Part 1 Metrological and technical requirements

4 Description of the instrument

4.1 Schematic description

Generally, an EBA provides a means for sampling and then measuring the ethanol content of a sample of endexpiratory breath of a human being. The means for conveying the breath sample through the gas handling system depends on the kind of alcohol sensor used in the specific EBA. Incorporated into the gas handling system is an alcohol sensor, which analyze the breath sample and provides signals related to the concentration of ethanol. The sensor signals are then electrically processed to display the results of a measurement in mg/ L or another nationally prescribed unit of SI. Additionally, the EBA has means to check if the boundary conditions for the acceptance of a breath sample are fulfilled.

Typically, the major components of an EBA are as follows:

- Disposable mouth pieces to collect the breath sample
- A hose to convey the breath sample through the gas handling system or a sampling probe with a kind of pump to convey a sub-sample through the gas handling system
- a mean to control either flowrate, time or volume
- sensor to measure the ethanol content of the breath sample
- A data system to process the measurement signal including an indicating device to display the results and communication messages
- A control facility to initiate and check instrument operations
- An adjustment facility to set instrument operating parameters within prescribed limits.

4.2 Sampling and mouthpiece

For evidential breath analysis, a representative sample consists of analyzing a breath specimen from alveolar air (endexpiratory breath). The breath specimen shall not be influenced by breathing techniques (holding the breath..).

The EBA shall be capable of being used under satisfactory hygienic conditions. This means in detail:

- To sample the breath specimen, the use of disposable mouthpieces for each measurement shall be indispensable
- -the mouthpieces shall be individually packaged.
- It shall not be possible to inhale air from previous usages of the EBA
- The mouthpiece shall be able to prevent that droplets and crumbs enter the gas handling system of the EBA
- Condensation during sampling and analysis shall be prevented to avoid dilution of the sample.

Remark: to be discussed as testing procedures have to be added if specifications are listed

4.3 Analysis

The ethanol concentration of a breath sample might vary during the process of expiration, since the air of the anatomical dead volume might not contain the same ethanol content as the deep-lung air.

The EBA shall be able to detect a minimum volume, to determine the ethanol concentration of the end-expiratory breath from pulmonary alveoli and also the continuity of exhalation.

4.4 Presentation and storage of the result

The measured ethanol concentration shall be presented on a display. Additionally it may be printed and/or stored in the instrument's memory.

4.5 Measurement cycle

In general, a measurement cycle of an EBA consists of the following steps:

- Preparation of the measurement/ getting ready for sampling
- Sampling;
- Analysis of the sample including internal checking operations
- Presentation and storage of the result.

Depending on national regulations, the sampling may consist of one or more breath specimens.

4.6 Principle design requirements

- The breath specimen shall be delivered through a mouthpiece and the EBA shall have means to control for taking a representative breath sample.
- The analysis shall be done by be sensors specific to alcohol and shall be traceable to national standards.
- The display and storage of the results shall be independent from external sources.
- The complete measurement process shall be reliable, adjustable and verifiable.

5 Units of measurement and decimal sign

The EBA 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, the dot is used in the English version of this Recommendation and *a comma in the French version.*

6 Metrological requirements

6.1 Measuring range

The measuring range of the EBA shall be from 0.00 mg/ to at least 2.00 mg/ L
A greater upper limit of the measuring range may be defined by the manufacturer. The EBA shall indicate when its upper limit of measurement is exceeded, with the mention of the value of the upper limit e.g., "result > 2mg/ L".
The instrument shall fulfil the requirements of this Recommendation for the complete specified measuring range.

6.2 Masking of results

National authorities may require a masking function which indicates 0.00 mg/ L for measured mass concentrations equal or smaller than a given value.
National authorities may also require a masking function for results greater than a given limit.
This masking function shall be deactivated in the maintenance mode.

6.3 Scale interval

For the indication of the result, the scale interval shall be at least 0.01 mg/L in the measuring mode.
A measured value to three decimal places shall be truncated to two decimal places (e.g. a measured value of 0.427 mg/L is rounded down to 0.42 mg/L).

In the metrological test mode, it shall be possible to display a scale interval equal to 0.001 mg/L. This interval scale shall be used for metrological tests.

6.4 Multiple indicating devices

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

6.5 Durability of the EBA

The provisions in 6.6, 7.7, 6.8, 6.9, 6.10 and 6.11 shall be met durably.
The EBA shall be designed to maintain stability of its metrological characteristics over a period of time (to be specified by the manufacturer) which shall be at least as long as the verification period.
The verification period is defined under the responsibility of the National Authorities (subsequent verifications).

6.6 Maximum permissible errors (MPEs)

The following MPEs shall apply within the rated operating conditions (specified in 6.10).

6.6.1 Maximum permissible errors for type approval and initial verification

For type approval, 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. mg/L

6.6.2 Maximum permissible errors for EBAs in service

Remark of the secretariat: How is "service" defined? It seems the interpretation of this term varies between countries. To be discussed, if this shall cover also the periodic verification
For EBAs in service, the maximum permissible error (MPE), 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 maximum permissible error shall be:

$\frac{reference\ value*3}{4} - 1.35\ mg/l$ for all mass concentrations greater than 2 mg/L.

Table 6-1 MPEs for EBAs

Ethanol concentration $c_{Ethanol}$	MPEs for type approval and initial verification	MPEs in service	Comment
0.000 mg/ L – 0.400 mg/L	0,020 mg/L	0,030 mg/L	
> 0.400 mg/ L – 2.000 mg/L	5 % of $c_{Ethanol}$	7,5 % of $c_{Ethanol}$	
> 2.000 mg/L	$\frac{c_{Ethanol}}{2} - 0{,}9\ mg/L$	$\frac{c_{Ethanol} * 3}{4} - 1{,}35\ mg/L$	Only applicable for enlarged measuring range

6.7 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:

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

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

6.8 Drift

6.8.1 Zero drift

The drift measured under reference conditions at 0.00 mg/L shall be less than 0.010 mg/L in 4 hours.
Remark: In Delft, June 30,2015: Paul Kok, Tom Ciuksza and Hubert Berry volunteered to write a proposal for this subclause

6.8.2 Short-term drift

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

6.8.3 Long-term drift

The drift measured under reference conditions at 0.40 mg/L shall be less than 0.020 mg/L in six months.
When tested with a frequency of every 2 weeks within these 6 months, each result has to fulfill the requirements for long-term drift.

6.9 Memory effects

6.9.1 Memory effect with large differences in mass concentration

Under reference conditions the memory effect shall be less than 0.010 mg/L.

6.9.2 Memory effect with small differences in mass concentration

Under reference conditions The memory effect shall be less than 0.010 mg/.
Question of the secretariat: What is the difference to the tests of 6.9.1? Assuming that large differences in mass concentrations have no influence, why should then do similar question should have an effect? If this test shall be kept, maybe an explanation would be helpful to understand.
→ to be discussed

6.10 Minimum requirements for rated operating conditions

EBAs shall be designed and manufactured such that their errors do not exceed the MPEs specified in 6.6 under the following rated operating conditions:

Table 6-2 minimum rated operating conditions

a	Ambient temperature	Low (T_{al})	0 °C for stationary EBA –5 °C for mobile EBA –10 °C for portable EBA
		High (T_{ah})	40 °C for stationary EBA 45 °C for mobile EBA 45 °C for portable EBA
b	Relative humidity	Up to 85 % at T_{ah} The decision if a lower level is necessary is postponed.	
c	Atmospheric pressure	860 hPa – 1 060 hPa	
d	Random vibration	Negligible for stationary EBA For mobile and portable EBA: 10 Hz – 150 Hz, 7 $m \cdot s^{-2}$, 1 $m^2 \cdot s^{-3}$, –3 dB/octave	
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 in the test gas	10 %	

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

*Note: methane equivalent:
The content of hydrocarbons shall be expressed in ppm_{vol} methane (CH_4) equivalent. For the actual test, other hydrocarbons can be used and their concentration has to be recalculated accordingly to their number of Carbon-atoms.

6.11 Disturbances and physiological influence quantities

6.11.1 Disturbances

EBAs shall be designed and manufactured such that when they are exposed to the disturbances indicated below

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

These provisions in (a) and (b) may be applied separately to

- each individual cause of disturbance, and/or
- each part of the measuring instrument.

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

6.11.1.1 During the following disturbances

Table 6-3

a	Radiated radiofrequency, electromagnetic fields	In the frequency range 0,15 MHz up to 3000 MHz, 10 V/m *Note to the Project Group(to be deleted later):* Part of the statements in (a) and (b) do not concern requirements, but concern the manner of testing or simulating. In fact b only concerns a practical solution for simulation of the effect caused by exposure to EM fields in the frequency range of 0,15 up to 80 MHz up to a level of 10 V/m by making use of the attached cabling for easy simulation. This I consider the test method, which is described in Part 2 of the Recommendation						
	Mains power frequency electromagnetic field							
c	Electrostatic discharges	Up to 6 kV contact discharge or 8 kV air discharge						
d	Bursts on AC or DC mains supply lines	Amplitude 1 kV Repetition rate 5 kHz						
e	Surges on AC or DC mains supply lines	AC or DC mains	Line to line	1 kV				
			Line to ground	2 kV				
f	Bursts on signal, data and control lines	Amplitude 1 kV Repetition rate 5 kHz						
g	Ripple on DC mains [1)] electrical power port	Ripple	Sinusoidal harmonics					
		Harmonic frequency	2,3 or 6 times rectified origin frequency					
		Amplitude ($U_{peak-peak}$ / U_{DC})	2%					
h	Mains supply [(1)] voltage dips, short interruptions and voltage variation	DC	Short interruption (100 % Reduction)	Reduction			Rise	
				30 %	60 %	15 %	20 %	
			Duration 1 to 1000 ms	0.01 to 1 s		0.1 to 1 s	0.1 to 1 s	
		AC	Short interruption (100% reduction)	Reduction				
				30 %		> 95 %		
			duration 0.5 and 1 cycle	25 cycles		250 cycles		
i	Surges on signal, data and control lines	Unsymmetrical lines	Line to line	1 kV				
			Line to ground	2 kV				
		Symmetrical lines	Line to ground	2 kV				
		shielded I/O lines	Line to earth	2 kV				
j	Electrical transient conduction for external batteries of a vehicle	Pulse		2a	2b	3a	3b	
		12 V system	Level U_{nom}	+50 V	+10 V	-150 V	+100 V	
		24 V system		+50 V	+20 V	–200 V	+200 V	
k	Electrical transient conduction via lines other than supply lines	Pulse		a	b			
		12V system	Level (U_s)	-60 V	40 V			
		24 V system		-80 V	80 V			
l	Vehicle battery voltage variations during starting up a vehicle engine	Exposure to the international (ISO) normalized typical power supply voltage distortion caused by cranking the engine using a DC electrical starter motor. *Note to the Project Group (to be deleted later)*: This concerns the former defined ISO 7637-2 pulse 4 which is no longer part of ISO 7637-2 but is made part of ISO						
m	Vehicle electrical power source voltage variations	Exposure to the international (ISO) normalized typical power supply voltage distortion caused by disconnecting a discharged vehicle battery						

Comment [TG(,M1]: part 2 table 27

Comment [TG(,M2]: part 2 table 28

Comment [TG(,M3]: part 2 table 29

[1)] Mains supply only concerns electrical power supply directly from a mains (non-local) network. Thus implying that using the electrical power from transportable or mobile sources like vehicle batteries or generators is not considered supplying from a mains source. It also implies that DC mains does not concern the DC provided by the output port of the AC to DC adapter applied for supplying the electrical power to the EBA. In this case the adapter is considered part of the instrument and thus the requirements on AC mains apply.

6.11.1.2 And after the following disturbances

Table 6-4

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

6.11.2 Physiological influence quantities

Remark of the Secretariat: chapter is under construction by subgroup SG3. Here, the original text of 2012 is shown.

EBA 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

Table 6-5

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.

7 Basic Technical requirements

The technical requirements for EBAs are split into 2 parts, into basic requirements and optional requirements. The basic requirements cover the prerequisites that all EBAs have to fulfil.
The optional requirements only apply when national authorizes require them and an instrument is equipped with these extra functions/ functionalities, e.g. a printer. Only then, the EBA has to fulfil the optional requirements for these functionalities.

7.1 Presentation of the measurement result

7.1.1 Display

Reading of the results (on the 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.
The height of the figures on the display shall be equal to at least

- 5 mm for illuminated displays, and
- 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.

7.1.2 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.

7.2 Protection against fraud

A breath alcohol analyzer EBA shall have no characteristics likely to facilitate its fraudulent use, either by accidental or by deliberate means when using the instrument in the normal manner. The possibilities for unintentional misuse shall be considered in the construction (hardware and software) to reduce them to a minimum.
In particular, the following aspects shall be taken into account:

- access to the metrological test mode shall be restricted;
- it shall be impossible to make any adjustments without breaking the sealing;
- only in the metrological test mode it shall be possible to make any adjustments via the software.

Remark: see also "*7.9. software → 7.9.3 prevention of misuse*"
Do we need both chapters (7.2 and 7.9.3)?

7.3 Checking operations

When powered on, the EBA 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 EBA 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).
Note of the secretariat: *No better or detailed examples cold be found, also D 11 is rather unspecific about checking operations.*
We propose to leave it as it is unless someone has a better proposal.

7.4 Warm-up time

Under reference conditions (11.4.1), the EBA shall be capable of attaining the measuring mode after a warm-up period specified by the manufacturer (without being greater than 15 minutes) after being switched on, or in less than 5 minutes after switching from stand-by mode to measuring mode.
Remark: Delft, June 30,2015: Jürgen Sohège volunteered to write a proposal.

7.5 Availability for measurement

From the moment the EBA indicates that it is ready to receive an exhalation, it shall be available for at least one minute.
The EBA 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.

7.6 Conditions of exhalation

For a representative measurement, certain conditions of exhalation (e.g. continuity and flow), have to be fulfilled.
The EBA shall give an error message if these conditions are not fulfilled.
The conditions, specified by the manufacturer for the respective EBA, 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 flowrate of 12 L/min);
- flowrate: greater than or equal to 6 L/min;
- exhalation time: greater than or equal to 5 s.

Remark: Delft, June 30,2015: Jürgen Sohège volunteered to write a proposal.

7.7 Continuity of the exhalation

The EBA 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 that declared in 5.8.2.
Remark: Delft, June 30 - July 1, 2015:Since this subclause is related to the previous one, this issue was postponed.

7.8 Alcohol in the upper respiratory tract

The EBA shall be equipped with a function which automatically detects whether the measurement result is affected by the presence of alcohol in the upper respiratory tracts (so-called mouth alcohol). Examples of compliance are given in Annex B.
Remark: Delft, June 30 - July 1, 2015:*It was agreed on, that a test procedure for this issue is missing. The secretariat will check the corresponding Annex B to see if a revision or additional information is needed.*

7.9 Software

In general the requirements of OIML D31 have to be fulfilled. The severity of testing shall be selected independently for each requirement.
The whole software of the EBA should be considered as legally relevant.
However, if the software of the evidential breath analyzer is separated into parts, each part shall separately conform to 7.9.1.

7.9.1 Software identification (D 31:2008; 5.1.1)

The software of the EBA shall be unambiguously identified with version number and by a hash function [D 31:2008; 3.1.2.5].
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 software identification and all its parts shall be stated in the type approval certificate/ certificate of conformity.

7.9.2 ~~6.4.2~~ Correctness of algorithms and functions

The measuring algorithms and operations of an evidential breath analyzer shall be functionally correct. The measurement result and any accompanying information shall be displayed, recorded and/or printed correctly.
It shall be possible to examine algorithms and functions by means of an appropriate validation method (i.e. metrological tests, software tests or software examination as described in OIML D31).

7.9.3 ~~6.4.3~~ Prevention of misuse

An evidential breath analyzer and especially the software shall be designed and constructed in such a way that the risk of unintentional, accidental, or intentional misuse is minimized.

7.9.4 Fraud protection (D 31:2008; 5.1.3.2)

For protection against fraudulent use, the following requirements shall be fulfilled:

a) 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 EBAs 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.

b) 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. The manufacturer shall state the completeness of the documentation of these functions. No hidden functions shall exist.

c) Parameters that fix the legally relevant characteristics of the EBA shall be secured against unauthorized modification. If necessary for the purpose of verification, the current parameter settings should be able to be displayed or printed.

7.9.5 ~~6.4.5~~ Support of Fault Detection

For fault detection, checking facilities [D11:2013 3.19] shall be implemented into the EBA.

The software shall be checked at least at instrument start-up/boot-up. If a change in software occurs it shall be detected by the EBA. The EBA shall abort the current measurement and prevent the use of the EBA for further measurements. A detected fault should be registered in an error log.

7.9.6 ~~6.4.6~~ Interfaces

If the EBA is equipped with interfaces the following requirement has to be fulfilled:

The functions, parameters and measurement results shall not be inadmissibly influenced by commands received via an interface. There shall be an unambiguous assignment of each command to all initiated functions or data changes in the software. Only allowed and documented commands are permitted to activate functions through the interfaces.

Comment [d4]: Need an interface to update the software on the EBA.

Comment [d5]: 6.4.10 has reference to documentation of commands

7.9.7 ~~6.4.8~~ Maintenance and verification of EBA software

Installation of software in an EBA in use shall be considered as:

- A modification of the EBA, when exchanging the software with another updated and approved version;
- A repair of the EBA when re-installing the same version.

The software of an EBA shall not be modified or installed via any interface or by other means without breaking the sealing (D31 3.1.38).
After installation of the software of the EBA, the instrument shall not be used for legal purposes until a verification of the EBA has been performed and the sealing has been renewed.

7.9.8 ~~6.4.10~~ Software documentation

In addition to the general documentation required in 11.2, the manufacturer shall submit the following documentation:

1. Description of the legally relevant software and how the requirements are met;
2. Description of system configuration and minimal required resources;
3. Description of security means of the operating system (password, etc. if applicable.
4. Description of the (software)sealing method(s);
5. Overview of the system hardware, e.g. topology block diagram, type of computer (s),
6. Type of network etc. Where a hardware component is deemed legally relevant or where it performs legally relevant functions, this should also be identified;
7. Description of accuracy of the algorithms (e.g. filtering of A/D conversion results, calculation of the result, rounding algorithms, etc.);
8. Description of the user interface, menus. Commands that communicate through the interfaces shall be documented.
9. Description of the software identification which has to be clearly assigned to the legally relevant functions including the description of all encryption means (if any);
10. Clear instructions on how to check the actual software identification against the reference number at listed in the type approval certificate. This reference may be additionally marked on or displayed by the instrument.
11. List of commands of each hardware interfaces

Remark, Delft, June 30,2015: It was agreed that this would be deferred until R126 is completed.

Comment [d6]: Linked back to second bullet in interfaces section 6.4.6.

8 Optional requirements

EBA may be fitted with one or more of the following options. These options could be either prescribed by certain national authorities or it could be a feature of construction chosen by the manufacturer.

The optional requirements only apply when national authorizes require them and an instrument is equipped with these extra functions/ functionalities, e.g. a printer. Only then, the EBA has to fulfil the optional requirements for these functionalities.

8.1 Durable recording of measurement results

8.1.1 Printing device

The EBA **may** be fitted with a printing device under legal metrological control. In such a case, the requirements defined below apply. Printing devices that are 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.

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

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

The printout shall at least contain the following information:

- Instrument reference
- Date and time of measurement
- Measuring results
- Identification of the tested person according to national regulations

The printing device shall be fitted with checking facilities to ensure the correct functioning of the printout. 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).

The printing device, either external or internal and shall fulfill the requirements for disturbances as defined in 6.11.1.

Here, the end of the Delft-meeting was reached.

8.1.2 Storage of data

The EBA **may** store measurement data for further applications under legal metrological control. In such a case, the requirements defined below apply

- The measurement result stored shall be accompanied by the additional information that is necessary for future legally relevant use.
- These data shall be protected by hardware/ software means to guarantee the authenticity and integrity of the data.
- The software that displays or further processes these data shall check the authenticity and integrity of the data. If an irregularity is detected, the data shall be marked unusable.

If data is transmitted from the EBA (secure environment) to an external environment, a high protection level of the transmitted data may be required. For this high protection level the application of cryptographic methods is necessary. National authorities may decide on the level of protection for the transmission and storage of data. The software that displays or further processes the transmitted data for legal purposes shall be secured and shall check the authenticity and integrity of the data.

Comment [d7]: Definition of data – is this just the measurement result and/or time driver etc...

8.1.3 Automatic storing

(Preliminary text, to be agreed at the next SG2-meeting in Berlin, 22nd Feb 2016)

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

The EBA shall have sufficient permanency to store the data until no longer legally required, according to national regulations. Storage capacity shall be at least 1000 measurements. It is permitted to delete stored data, however it shall not be possible in normal use to delete stored data.

Data may be deleted in one of the following ways:

- When the memory capacity is reached, data is deleted in the same order as the recording order (FIFO).
- Deletion is carried out after a special manual operation that may require specific access rights.
- A warning should be given before data is deleted.

Note: General national regulations may contain strict limitations for the deletion of stored measurement data.

8.1.4 Other….?

➔ **To be discussed if there are additional optional functionalities for which it would be sensible to have a standardized requirement/ testing procedure.**

For example:

- issues to consider for instruments with multiple sensors,
- issues to consider for 2 or more breath samples for a valid measurement
- issues to consider for breath temperature measurement

… ***➔to be discussed, please send proposals together with your comments!***

9 Operating instructions

9.1 Instruction manual

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, including instructions for the mouthpiece (e.g. hygienic aspects of use)
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, and
g) safety and security conditions.

9.2 Additional instructions

The EBA 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.
Additionally to the automatic function that detects the presence of alcohol in the upper respiratory tracts, 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.

10 Inscriptions and Sealing

10.1 Inscriptions

The EBA 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.

The items (f), and (h) may be moved to the instruction manual if the size of the instrument does not allow to put all information on the label.

10.2 Sealing

Effective sealing devices shall be provided by the manufacturer on all parts of the EBA 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 EBA 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. When air filters are not installed, the EBA 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.
Remark of the secretariat: is this paragraph still needed/ sensible? Are there any EBAs using air filters?

Part 2 Metrological controls and performance tests

11 Metrological controls

In general (depending on national or regional legislation), legal metrological control can consist of type approval, initial and metrological supervision.
The part 2 of this recommendation gives general gives guidelines for each of these steps.

11.1 Responsibility for compliance with the requirements

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

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

11.2 Uncertainty of test results

Every test is subject to uncertainty. The uncertainty (of a measurement) is defined as:
"non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used” (VIM 2.26)
The uncertainty of the test method shall be taken into account in the decision on the applicability of the test method.

Cited from the template for recommendations*: More detailed text to be drafted. This shall be based on the work in OIML TC3/SC5, project* p2 *Expression of uncertainty in measurement in legal metrology applications.*

This means that each of the tests in XX shall be completed with requirements regarding the acceptable uncertainty.

Remark of the secretariat: Chapter is still under construction

12 Type evaluation

12.1 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 XX.

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 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 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.

12.2 Documentation

The documentation submitted with the application for type approval shall include

a) a description of its general principle of measurement,

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

c) mechanical drawings,

d) electric/electronic diagrams,

e) installation requirements,

f) security sealing plan,

g) panel layout,

h) information on the software (covering in particular the requirements in 6.5),

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

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

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

l) a print sample.

If the breath alcohol analyzer is equipped with a printing device, the manufacturer shall provide information about the quality of the printing paper to fulfil the requirements of readability defined in 6.5.1.
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.

12.3 Examination and software validation

12.3.1 examination

The instrument and the documentation shall be given a visual inspection to obtain a general appraisal of its design and construction, and the documentation shall be studied.
In particular, the following aspects shall be examined:

a) units and decimal sign (5);

b) measuring ranges (6.1);

c) scale intervals (6.3);

d) presentation of the result (7.1);

e) protection against fraud (7.2 and 7.9.4);

f) checking facilities (7.3);

g) durability protection (6.5);

h) software (7.9);

i) inscriptions and sealing (10);

j) operating instructions (9);

k) suitability for testing (??).

and if applicable:

l) printing device (8.1.1);

m) storage of measurement results (8.1.2);

n) data transmission (8.1.3);

12.3.2 Software validation

preliminary text, to be agreed on at the next meeting in Berlin Feb. 2016)

The validation procedure of the software related functionalities of EBAs is given in the following table:

Table 12-1

Chapter	Validation Procedure	Examination Level	Comments
Software Identification	AD + VFTSw	A	Select B if high conformity is required Fr – to high US – Previous document allowed for examination level of A with option to go higher DE – we require in the new wording higher requirements on the equipment there should be higher testing. CAN – what tests are conducted when DE look at the software? Agree that Validation Level A is sufficient
Correctness of algorithms and functions	AD + VFTSw	A (with B can be implemented based on the national requirements)	There is generally agreement with level B however the US would rather see level A only. There is discussion for the need for vote to establish a proposal for the PG. For the correctness of algorithms and function do we recommend examination of A with option of B or B mandatory? Each national delegate to make a submission on this point.
Prevention of misuse	AD + VFTSw	A	Only a low risk of misuse Agreed
Fraud Protection	AD + VFTSw	A	Only a low risk is assumed Agreed
Fault Detection	AD + VFTSw	A	Agreed
Interfaces	AD + VFTSw	A	Agreed
Conformity to the approved type			Removed from the software section
Maintenance and Verification of Software	AD + VFTSw + VFTM	A	Added in VFTSw and VFTM Agreed
Software Documentation			Parked until main document is completed
Storage of Data	AD + VFTSw	A	Storage of data By default
	AD + VFTSw + CIWT/SMT	B	Transmission into open system If required by national authorities with footnotes.
Automatic storing	AD + VFTSw	A	Agreed
Transmission of data			

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)

National regulations may require higher levels for the validation and examination steps.

12.4 Test methods

12.4.1 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.

→remark: to be discussed if a maximum variation rate would be sensible, e.g. "no more than "2°C per hour"

12.4.2 Breath profile

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

- Evolution of the flowrate curve during the breath exhalation
  Annex B.1 provides explanatory information and general accepted flowrate curves to be used for establishing testing 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 apparatus performance.

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

12.4.3 Test sample delivery apparatus

12.4.3.1 Characteristic reference values of the test gas

Unless otherwise specified, the test gas EBA shall be characterized by the following parametric values:

- delivered volume: 2 L ± 0.3 L; → *to be checked if this range and the value is correct*
- total duration of the injection (into the breath analyzer): 5 s ± 0.5 s;
  resulting flowrate: *0,4 L/s ± 0.1 L/s*
- type of profile: constant flowrate; → *what about ethanol concentration? profile or constant?*
- gas temperature: 34 °C ± 0.5 °C;
- relative humidity of the gas 95 % rH± 5 % rH (without condensation);
- carrier gas: air containing insignificant concentrations of relevant impurities with a volume fraction of CO2 of: 5 % ± 0.5 $\%_{vol}$,

The test reports shall indicate what kind of test means have 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 CO2 in test gases, constant mass concentration during injection). The completed test reports shall indicate when such alternative tests have been implemented.

This simplified means (a gas or gases without CO2,) could be used for the following tests and to demonstrate the capability of the EBA to make measurements on the end expiratory air:

dry gases for tests defined in 11.4.4.2, 11.4.4.6 through 11.4.4.14, 11.4.5 (except 11.4.5.11 and 11.4.5.12) and 11.4.6 with a preliminary repeatability test performed with wet gases; (→ *to be discussed and updated)*

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

gases without CO2, which can be used for tests defined in 11.4.4.2 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 flowrate during injection may be constant.

Dry gases

Dry gases purchased from gas cylinders can be used as source for test gas samples. 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, and the measurement uncertainties of the testing apparatus must be taken into account in calculations of the uncertainties of the measurement.

12.4.3.2 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 delivering a test sample according to 12.4.3.1.1and a breath profile described in 12.4.2.

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

- type 1: the apparatus delivers constant test gases with constant mass concentrations of alcohol;
- type 2: the apparatus delivers a test gas which is capable of fulfilling the breath profile defined in 11.4.2.For the complete test program, both types are needed. **(→ references to be updated at the end)**

Note: For certain tests, the testing procedures may specify the use of one of the specific types indicated above.
→ *remark: To be discussed if more detailed information is needed*

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.

Example of testing apparatus

"saturation-type" wet test gas generators

The saturation of air with water and ethanol is a well-established set-up for a wet test gas generator for EBAs. Saturation-type wet test gas generators are commonly used all over the world in various designs.

Independent from the actual design, they are based on following functional principle:
When pressurized gas or air is led as carrier gas through a water-ethanol-solution, the gas will be enriched with water and ethanol until an equilibrium is reached. According to Henry's law, for a particular substance the partition equilibrium between the gaseous and the liquid phase only depends on the actual temperature and the concentration of the liquid.

For the partition ratio for ethanol various empiric data can be found in the literature. The equation for the calculation of the gas concentration and the most common used partition coefficients (Dubowski equation) can be found in Annex XX

For the saturation-type wet test gas generator a number of gas washing bottles will be filled with a water-ethanol-solution of a known concentration, warmed up/ thermostated to the target temperature and pressurized air will be send trough the solution in small bubbles, where the building-up of the equilibrium takes place.

With the progressing flow of gas, the ethanol will be washed out of the solution. To encounter this dilution and to produce a tests gas with a stable ethanol concentration, a number of gas-washing bottles have to be connected in series, so that the concentration of the produced gas can be kept stable for a certain time. As an example, picture XX shows the evolution of the ethanol concentration in each bottle when 3 bottles are connected in series.

The saturation-type wet test gas generator can be designed in various ways, from basic to sophisticate.
In picture XX of Annex A, a schematic sketch of a basic 3-flask-bubble train can be found.

To achieve a wet test gas with the prescribed CO2-content, there are various ways:

- CO2 can be added and mixed into a wet test gas. First, a wet test gas will be produced using “normal” compressed air. Then, the produced test gas will be mixed with pure CO2-gas to generate the prescribed concentration of CO2 in the resulting gas mixture. When using this method, the change of gas volume has to be taken into account for the correction of the generated ethanol concentration. Also, when using this method it has to be ensured if the remaining relative humidity will be still within the specifications.
- Compressed air with the required CO2-content can be used as carrier gas for a saturation-type wet gas generator: CO2 has a very poor solubility in water. When bubbling gas or air containing a certain concentration of CO2 through the saturation-type test gas generator, the water in the flasks will be saturated with CO2 with very short time, and with progressing flow, the amount of CO2 in the gaseous phase remains on the same level. Nevertheless, the concentration has to be corrected due to the change of volume which is caused by the raising temperature and the addition of water and ethanol vapour to the volume.

12.5 Performance tests

12.5.1 General instructions

The instrument shall be submitted to the performance tests 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 EBA with the requirements of this Recommendation.

If not otherwise stated, the tests shall be carried out using the standard measurement cycle of the respective country. The test report shall state which measurement cycle was used and, if necessary, describe it shortly.

When a test description calls for repetitive measurements, they shall be performed consecutively one after the other, with the maximum frequency the EBA allows for. If a break in between the test series is unavoidable, it shall not take more time than 10 min.

12.5.2 Accuracy tests

12.5.2.1 Maximum permissible errors and repeatability

Table 12-2

Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least 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 not be readjusted at any time during the test. The EUT shall be used in metrological test mode and shall perform standard measurement cycles.
Test procedure in brief	The test comprises of 20 measurements at different test gas concentrations. At each measuring point, the 20 measurements shall be performed consecutively one after the other, with the maximum frequency the EBA allows for. If a break in between the test series is unavoidable, it shall not take more time than 10 min. The break between two different concentrations shall not take more time than one working day.
Test gases Mass concentration of ethanol	1) 0.00 mg/ L to 0.05 mg/ L 2) 0.10 mg/ L 3) 0.25 mg/ L 4) 0.40 mg/ L 5) 0.70 mg/ L 6) 0.95 mg/ L 7) 1.50 mg/ L 8) 1.95 mg/ L 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.
EUT performance	With each test gas concentration, 20 measurements shall be performed and record: a) date and time,(Start and end of each test series) b) ambient temperature, c) ambient relative humidity, d) measured values, e) indications and errors of the EUT f) operating conditions of the test gas generator(flow, gas temperature, concentration,…)
Permitted maximum deviation	All functions shall operate as designed. Each of the 20 measurement results for every test gas concentration shall comply with the MPEs defined in 6.6.1.

12.5.2.2 Drift

This test is applied to verify compliance with the requirements for drift (6.8).
Other tests for type approval may be performed during the time interval between the drift tests.

Table 12-3

Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT	The EUT shall not be readjusted at any time during the test. The EUT shall be used in metrological test mode and shall perform standard measurement cycles.
Test procedure in brief	The tests comprise of 10 subsequent measurements at the start and 10 subsequent measurements after the following time intervals: For zero drift: 4 hours after the start For short time drift: 4 hours after the start For long time drift: every 2 weeks until the 6 months test time are completed.
Test gases Mass concentration of ethanol	For zero drift: 0.00 mg/ L to 0.05 mg/L For short time drift: 0.40 mg/ L For long time drift: 0.40 mg/ L
EUT performance	At each defined point in time, 10 measurements shall be performed and record: a) date and time,(Start and end of each test series) b) ambient temperature, c) ambient relative humidity, d) measured values, e) indications and errors of the EUT f) operating conditions of the test gas generator(flow, gas temperature, concentration, …)
Permitted maximum deviation	For the zero drift and the short term drift test, the difference between the mean measurement errors of the two series of measurements shall fulfill the requirements for drift (6.8.1 and 6.8.2.1). For the long term drift, the difference between the mean measurement error of the start series and each mean measurement error of all intermediate series and the final series shall fulfill the requirements for long term drift (6.8.2.2)

12.5.2.3 Memory effects

This test is applied to verify compliance with the requirements for memory effects (6.9) with large differences in mass concentration as well as with small differences in mass concentration.

Table 12-4

Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT	The EUT shall not be readjusted at any time during the test. The EUT shall be used in metrological test mode and shall perform standard measurement cycles.
Test procedure in brief	The tests comprise of an initial test series with 10 subsequent measurements with the test gas with the lower concentrations to determine the mean start value. Then the EUT is subject to a series measurements with alternating concentrations: - one measurement using the higher concentration - followed immediately with one measurement using the lower gas concentration This alternating cycle will be repeated 10 times.
Test gases Mass concentration of ethanol	For large differences: low gas concentration: 0.10 mg/ L (test gas No. 2) High gas concentration: 1,50 mg/ L (test gas No. 7) For small differences: low gas concentration: 0.25 mg/ L (test gas No. 3) High gas concentration: 0,40 mg/ L (test gas No. 4)
EUT performance	At each point in time, 10 measurements shall be performed and record: a) date and time,(Start and end of each test series) b) ambient temperature, c) ambient relative humidity, d) measured values, e) indications and errors of the EUT f) operating conditions of the test gas generator(flow, gas temperature, concentration, …)
Permitted maximum deviation	The mean of initial test series and the mean of the results for the lower concentration of the alternating cycle are calculated. The difference between these mean values shall fulfill the requirements for memory effects (6.9) For the long term drift, the difference between the mean measurement error of the start series and each mean measurement error of all intermediate series and the final series shall fulfill the requirements for long term drift (6.8.2.2)

12.5.3 Influence factors of the conditions of injection

These tests are applied to verify

- the capability of the EUT to cope with the varying conditions of flow, volume and exhalation time of a human breath sample and
- compliance with the minimum requirements for the conditions and continuity of exhalation (7.6 and 7.7)

For each test condition, 2 or more tests with different conditions are defined.
Each test is characterized by 4 parameters:

- delivered volume;
- duration of the injection;
- variation of the flow (and therefore pressure) as a function of time;
- variation of the alcohol concentration as a function of time.

Table 12-5

Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT	The EUT shall not be readjusted at any time during the test. The EUT shall be used in metrological test mode and shall perform standard measurement cycles.
Basic test procedure in brief	For each test condition, 2 or more tests with different conditions are defined. For each of these tests 10 subsequent measurements shall be performed. If not otherwise stated, the following conditions for the dynamic properties of the test gas apply: Variation as a function of time for: - Flowrate: no variation (constant) - Ethanol concentration: constant or evolution to a plateau duration equal to 3 s

Test gases Mass concentration of ethanol	0,40 mg/ L (test gas No. 4)	
EUT performance	For each test condition,10 measurements shall be performed and record: a) date and time,(Start and end of each test series) b) ambient temperature, c) ambient relative humidity, d) measured values, e) indications and errors of the EUT f) operating conditions of the test gas generator(flow, gas temperature, concentration, …)	
Test conditions	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; - *resulting flowrate:* *0.3 L/s ± 0.05 L/s* Second test: - delivered volume: 4.5 L±0.3 L; - duration of the injection: 15s±0.5 s; - *resulting flowrate* *0.3 L/s ± 0.03 L/s*
	b) Influence of flowrate and injection duration	First test: - delivered volume: 1.5 L ±0.1 L; - duration of the injection: 10s ± 0.5 s; - *resulting flowrate:* *0.15 L/s ± 0.02 L/s* Second test: - delivered volume: 3 L±0.2L: - duration of the injection: 15 s±0.5 s: - *resulting flowrate:* *0.2 L/s ± 0.02 L/s* Third test: - delivered volume: 4.5 L ±0.3 L: - duration of the injection: 7.5 s± 0.5 s: - *resulting flowrate:* *0.6 L/s ± 0.08 L/s*
	c) Influence of variations in the flow rate during exhalation	First test: - delivered volume: 3 L ±0.2L; - flowrate: 0.6 L/s ± 0,08 L/s - *resulting duration of injection:* *5 s ± 0.5 s* Second test: - delivered volume: 3 L ± 0.2 L; - variation in the flowrate as a function of time: Initial flowrate: 0.6 L/s during 1.5 s, between 1.5 s and 5 s the flowrate decreases to 0.2 L/s; after 5 s, the flowrate remains equal to 0.2 L/s until the end of injection; - resulting duration of injection:
	d) Influence of duration of the plateau during injection	First test: - delivered volume: 3 L ± 0.2 L; - duration of the injection: 5 s ± 0.5 s; - duration of the plateau: 3 s - *resulting flowrate:* *0.6 L/s ± 0,08 L/s* Second test: - delivered volume: 3 L ± 0.2 L; - duration of the injection: 5 s ± 0.5 s; - duration of the plateau: 1.5 s - *resulting flow rate* *0.6 L/s ± 0.08 L/s*

	e) Influence of an interruption in the breath flow	First test: The injection of gas with: - flowrate: 0.4 L/s ± 0,08 L/s shall be stopped 1 s ± 0.5 s after the start of the injection. - *resulting delivered volume:* *0.4 L ± 0.3 L;* Second test: The injection of gas with: - flowrate: 0.2 L/s ± 0.02 L/s shall be stopped at 6 s ± 1 s after the start of the injection. - *resulting delivered volume:* *1.2 L ± 0.3 L;-* Third test: Verification of the end of the detection of exhalation. The injection of a gas supplied at a - flowrate of: 0.15 L/s is decreased to a - - flowrate of: 0.03 L/s. - *Duration of injection before decreasing?* Fourth test: Short flow interruption. The injection of a gas with a - flowrate 0.4 L/s ± 0.08 L/s shall be interrupted for a short period (e.g. 0.5 s) and then continued. For these tests, the minimum requirements of 7.6 and 7.7 shall not be fulfilled.
Permitted maximum deviation	All functions shall operate as designed. For test condition a) to d): Each measurement result shall comply with the MPEs defined in 6.6.1. For test condition e) For these tests the EBA shall give no valid result.	

12.5.4 Tests for operating conditions

For breath alcohol analyzers which have more than one option for power supply, the tests in 12.5.5.1 through 12.5.15 shall be performed with every option.

12.5.4.1 Temperature Test (dry heat and cold)

This test is applied to verify compliance with the minimum requirements for operating conditions for ambient temperature (6.10 a)

Table 12-6

Table 0 Temperature test (dry heat and cold)					
Applicable standards	IEC 60068-2-1 [...], IEC 60068-2-2 [...], IEC 60068-3-1 [...]				
Test method	Gradual exposure to high and low temperatures not allowing condensation to occur				
Applicability	Applicable to all EBA				
Object of the test	Verification of compliance with the provisions in 6.6.1 under conditions of high and low temperature specified in 6.10 a				
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least a 16 hours' time period while taking into account the warm-up time specified by the manufacturer.				
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.				
Test procedure in brief	The test comprises exposure to the specified high temperature under "free air" conditions during the period of at least 2 hours (the period specified is the period following the moment at which the EUT has reached temperature stability). "Free air" conditions meaning sufficient air circulation to keep the temperature at a stable level. The change in temperature shall not exceed 1 °C/min during heating up and cooling down. The stabilizing time at each temperature is at least 2 hours. The absolute humidity of the test atmosphere shall not exceed 20 g/m3. When tests are performed at temperatures below 35 °C, the relative humidity shall not exceed 50 %. Sequence: 1. Reference temperature of T_R 2. Specified high temperature T_H 3. Specified low temperature T_L 4. Intermediate temperature T_I 5. Reference temperature T_R				
Test levels	The following high temperature test levels may be specified:				
Level index high (I_H)	1	**2**[1)]	**2**[2)]	3	Unit
Temperature (T_H)	30	**40**	**45**	55	°C
	The following low temperature test levels may be specified:				
Level index low (I_L)	-1[1)]	-1[2)]	**1**[3)]	-3	
Temperature (T_L)	0	-5	**-10**	-25	°C
Notes	Note: [1)] Applicable for stationary EBA only [2)] Applicable for mobile EBA [3)] Applicable for transportable EBA I_H concerns the index for T_H; I_R concerns the index for T_R; I_I concerns the index for T_I; I_L concerns the index for T_L. By default: T_R = 20 °C and I_R = 0, I_H = 2, I_I = 1 and I_L = -2 I_R = (I_H + I_L)/2 (rounded to an integer by deleting the mantissa) and I_I = (I_R -1)				
EUT performance	After stabilization at the relevant temperature five measurements shall be performed using a test gas with 0.400 mg/ L ethanol (test gas No. 4) and under the reference parameters for test gases as defined in 12.1.5 (2012-version:0.3 L/min) and record a) date and time, b) temperature, c) relative humidity, d) measurand value, e) indicated values, f) error values, g) functional performance				
Permitted maximum deviation	All functions shall operate as designed. All errors shall be within the maximum permissible errors specified in 6.6.1				

12.5.4.2 Damp heat, steady state (non-condensing)

This test is applied to verify compliance with the minimum requirements for operating conditions for relative humidity (6.10 b)

Table 12-7

Table 3 Damp heat, steady-state (non-condensing) 11.4.4.5		
Applicable standards	IEC 60068-2-78 [...], IEC 60068-3-4 [...]	
Test method	Exposure to damp heat in steady-state	
Applicability	Not applicable for those stationary EBA which are expected to be used only in a climate controlled environment.	
Object of the test	Verification of compliance with the provisions for MPEs in 6.6.1 under conditions of high humidity and constant temperature, specified in 6.10.b	
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.	
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.	
Test procedure in brief	The test comprises exposure to the specified high level temperature and the specified constant relative humidity for a certain fixed period of time as defined by the test level chosen. The EUT shall be handled such that condensation of water on the EUT does not occur.	
	Test level	unit
Relative humidity (RH)	**85**	%
Duration	**2**	24-hours period
EUT performance	The EUT is kept under the conditions defined in 6.10. b. At the end of this period and still under this condition, five measurements shall be performed, using a test gas with 0.400 mg/ L ethanol (test gas No. 4) and record: a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.	
Permitted maximum deviation	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 maximum permissible errors specified in 6.6.1	

12.5.4.3 Static atmospheric pressure

This test is applied to verify compliance with the minimum requirements for operating conditions for static atmospheric pressure (6.10 c)

Table 12-8

Table 6 Static atmospheric pressure 11.4.4.6			
Applicable standard	No applicable standards exist		
Test method	Exposure to low and high atmospheric pressure		
Applicability	Applicable for all EBA		
Object of the test	Verification of compliance with the provisions for MPEs in 6.6.1 under conditions of static atmospheric pressure changes to upper and lower limit specified in 6.10.c)		
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.		
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.		
Test procedure in brief	The test comprises the installing an EUT such that it can be exposed to the applicable higher and lower atmospheric pressures limits. Exposure is to be established for at least 10 minutes at each pressure.		
Atmospheric pressure		**Test level**	unit
	Lower limit	**86 (± 1)**	kPa
	Upper limit	**106 (± 1)**	kPa
	Uncertainty of the recorded pressure	**0.15**	kPa
EUT performance	After stabilization at the relevant pressure five measurements shall be performed using a test gas with 0.400 mg/ L ethanol (test gas No. 4) and under the reference parameters for test gases as defined in 12.1.5 *(2012-version:0.3 L/min)* and record: a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.		
Permitted maximum deviation	All functions shall operate as designed. All errors shall be within the maximum permissible errors specified in 6.6.1		

12.5.4.4 Random vibration

This test is applied to verify compliance with the minimum requirements for operating conditions random vibration (6.10 d)

Table 12-9

Table 8 Vibration (random) 11.4.4.7		
Applicable standard	IEC 60068-2-47 [...], IEC 60068-2-64 [...], (IEC 60068-3-8 [...])	
Test method	Exposure to random vibration	
Applicability	Applicable for all EBA	
Object of the test	Verification of compliance with the provisions for reference conditions in 12.5.2 under conditions of random vibration specified in 6.10 d)	
Precondition	Prior to the test the MPE shall be determined	
Condition of the EUT	The electrical power supply to the EUT is switched off during the test and the EUT shall not be readjusted at any time during the test.	
Test procedure in brief	The test comprises exposure to the vibration for a time sufficient for testing the various functions of the EUT during the exposure. The EUT shall subsequently be tested in three, mutually perpendicular axes mounted on a rigid fixture by its normal mounting means. The EUT shall normally be mounted in such a way that the gravity vector points in the same direction as it would in normal use. If the measurement principle is such that the effect of the direction of the gravity vector can be considered negligible the EUT may be mounted in any position.	
	Test level	unit
Total frequency range	**10 – 150**	Hz
Total RMS level	**7**	$m \cdot s^{-2}$
ASD level 10-20 Hz	**1**	$m^2 \cdot s^{-3}$
ASD level 20-150 Hz	**-3**	dB/octave
Duration per axis	For each of the orthogonal directions the vibration exposure time shall be 2 minutes in each functional mode.	
EUT performance	After the application of the influence quantity, the EUT shall be switched on and after stabilization time five measurements shall be performed, using a test gas with 0.400 mg/ L ethanol (test gas No. 4) and record: a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.	
Permitted maximum deviation	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 maximum permissible errors specified in 6.6.1	

12.5.4.5 DC mains voltage variations

This test is applied to verify compliance with the minimum requirements for operating conditions DC mains voltage (6.10 e)

Table 12-10

Table 10 DC mains voltage variation 11.4.4.8	
Applicable standard	IEC 60654-2 [...]
Test method	Applying low and high level DC mains power voltage
Applicability	Applicable for those EBA which are designed to be temporarily or permanently connected to a DC mains power network while in operation. Not applicable to equipment powered by a road vehicle battery.
Object of the test	Verification of compliance with the provisions for reference conditions in 12.5.2 under conditions of DC mains power voltage changes between upper and lower limit specified in 6.10 e
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.
Test procedure in brief	The test comprises exposure to the specified power supply condition for a period of time sufficient for achieving temperature stability and subsequently performing the required measurements. Test Sequence: 1. Reference voltage level 2. Upper voltage level 3. Lower voltage level 4. Reference voltage level The DC operating range applied as specified by the manufacturer, but not less than $U_{nom} - 15\ \% \leq U_{nom} \leq U_{nom} + 10\ \%$
Test level	The reference voltage level is the nominal DC voltage specified by the manufacturer.
	The upper voltage limit is the DC level at which the EUT has been designed to automatically detect high-level conditions.
	The lower limit will be the DC level at which the EUT has been designed to automatically detect low-level conditions.
EUT performance	After stabilization at the relevant voltage five measurements shall be performed, using a test gas with 0.400 mg/ L ethanol (test gas No. 4) and record: a) date and time, b) temperature, c) reference voltage at beginning and end, high voltage and low voltage, d) measurand values, e) indications, f) errors, g) functional performance.
Permitted maximum deviation	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 maximum permissible errors specified in 6.6.1

12.5.4.6 AC mains voltage variations

This test is applied to verify compliance with the minimum requirements for operating conditions for AC mains voltage (6.10 f)

Table 12-11

Table 12 AC mains voltage variation 11.4.4.9		
Applicable standards		IEC/TR3 61000-2-1 [...], IEC 61000-4-1 [...]
Test method		Applying low and high level AC mains power voltage (on a single phase)
Applicability		Applicable for those EBA which are designed to be temporarily or permanently connected to an AC mains power network while in operation. Not applicable to mobile EBA which are powered by a road vehicle battery unless an external DC to AC conversion device is required while in operation.
Object of the test		Verification of compliance with the provisions for reference conditions in 12.5.2 under conditions of AC mains network voltage changes between upper and lower limit specified in 6.10 f
Precondition		The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT		The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.
Test procedure in brief		The test comprises exposure of the EUT to the lower and upper limit power supply condition for a period of time sufficient for achieving temperature stability and subsequently performing the required measurements. Test Sequence: 1. Reference Voltage level 2. Upper voltage level 3. Lower voltage level 4. Reference voltage level In the case of three phase power supply, the voltage variation shall apply for each phase successively. The values of U 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.
		Test Levels
Mains voltage	Upper limit	$\boldsymbol{U_{nom1}}$ **+ 10 %**
	Lower limit	$\boldsymbol{U_{nom2}}$ **- 15 %**
Notes		The values of U_{nom} are those marked on the measuring instrument. If a range is specified, U_{nom1} concerns the highest and U_{nom2} concerns the lowest value. If only one nominal mains voltage value (U_{nom}) is specified then $U_{nom1} = U_{nom2} = U_{nom}$. The reference voltage level is equal to $(U_{nom1} + U_{nom2}) / 2$.
Permitted maximum deviation		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 maximum permissible errors specified in 6.6.1

12.5.4.7 AC mains frequency variations

This test is applied to verify compliance with the minimum requirements for operating conditions for AC mains frequency (6.10 g)

Table 12-12

Table 13 AC mains frequency variation 11.4.4.10		
Applicable standards		IEC/TR3 61000-2-1 [...], IEC 61000-2-2 [...], IEC 61000-4-1 [...]
Test method		Variation in AC mains power frequency
Applicability		Only applicable for those EBA which are designed to be temporarily or permanently connected to an AC power network while in operation.
Object of the test		Verification of compliance with the provisions for reference conditions in 12.5.2 under conditions of AC mains network power frequency changes between upper and lower limit specified in 6.10 g
Precondition		The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT		The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.
Test procedure in brief		The test comprises the exposure of the EUT to the specified power condition for a period of time sufficient for achieving temperature stability and for performing the required measurements. Test Sequence: 1. Reference frequency 2. Upper frequency 3. Lower frequency 4. Reference frequency
		The following test levels are preferred for OIML Recommendations
		Test level
Mains frequency	Upper limit	f_{nom1} + 2 %
	Lower limit	f_{nom2} – 2 %
Notes		1) The values of fnom are those marked on the measuring instrument. If a range is specified f_{nom1} concerns the highest and f_{nom2} concerns the lowest value . If only one nominal mains frequency value (f_{nom}) is specified then $f_{nom1} = f_{nom2} = f_{nom}$. 2) The reference frequency is equal to ($f_{nom1} + f_{nom2}$) / 2.
Permitted maximum deviation		All functions shall operate as designed. All errors shall be within the maximum permissible errors specified in 6.6.1

12.5.4.8 Low voltage of internal battery

This test is applied to verify compliance with the minimum requirements for operating conditions for voltage variations of internal batteries (6.10 h)

Table 12-13

Table 24 Low voltage of internal battery (not connected to the mains power) 11.4.4.11	
Applicable standards	No standard is available
Test method	Applying minimum supply voltage
Applicability	Applicable to all EBA supplied by an internal battery while in operation
Object of the test	Verification of compliance with the provisions for reference conditions in 12.5.2 during low battery voltage specified in 6.10 h
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.
Test procedure in brief	The test comprises exposure of the EUT to the specific low battery level condition during a period of time sufficient for achieving temperature stability and for performing the required measurements. The maximum internal impedance of the battery and the minimum battery supply voltage level (U_{bmin}) are to be specified by the manufacturer of the instrument. If an alternative power supply source is applied instead of the internal battery the internal impedance of the specified type of battery shall also be simulated. The alternative power supply shall be capable of delivering sufficient power at the required supply voltage. The test sequence is as follows: • Let the power supply stabilize at a voltage as defined within the rated operating conditions and apply the measurement and/or loading condition. • Record: – the data defining the actual measurement conditions including date, time and environmental conditions, – the actual power supply voltage. • Perform measurements and record the error (-s) and other relevant performance parameters. • Verify compliance with MPEs in 6.6.1 • Repeat the above procedure with actual supply voltage at U_{bmin} and again at 0,9 U_{bmin} • Verify compliance with MPEs in 6.6.15.2
Test level: Lower limit of the voltage	The lowest voltage at which the EUT functions properly according to the specifications (U_{bmin})
Number of test cycles	At least one test cycle for each functional mode
EUT performance	After stabilization at the relevant voltage five measurements shall be performed, using a test gas with 0.400 mg/ L ethanol (test gas No. 4) and record: a) date and time, b) temperature, c) voltage d) measurand values, e) indications, f) errors, g) functional performance.
Permitted maximum deviation	All functions shall operate as designed. All errors shall be within the maximum permissible errors specified in 6.6.1

12.5.4.9 Voltage variations of a road vehicle battery

This test is applied to verify compliance with the minimum requirements for operating conditions for the voltage of road vehicle batteries (6.10 i)

Table 12-14

Table 25 Voltage variations 11.4.4.12					
Applicable standard	ISO 16750-2 [...]				
Test method	Variation in supply voltage				
Applicability	Applicable to all mobile or portable EBA supplied by the on board battery of a vehicle which may at the same time be charged by use of a combustion engine driven generator				
Object of the test	Verification of compliance with the provisions for reference conditions in 12.5.2 under conditions of high (while charging) and low battery voltage specified in 6.10 i				
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.				
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.				
Test procedure in brief	The test comprises exposure to the specified maximum and minimum power supply voltage conditions for a period of time sufficient for achieving temperature stability and performing the required measurements at these conditions.				
Nominal battery voltage	U_{nom} = 12 V		U_{nom} = 24 V		
	Lower limit	Upper limit	Lower limit	Upper limit	Unit
Test Level	**9**	**16**	**16**	**32**	V
EUT performance	After stabilization at the relevant voltage record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurands, e) indications, f) errors, g) functional performance.				
Permitted maximum deviation	All functions shall operate as designed. All errors shall be within the maximum permissible errors specified in 6.6.1				

12.5.4.10 Hydrocarbons in the environment

This test is applied to verify compliance with the minimum requirements for operating conditions for hydrocarbons in the environment (6.10 g)

Table 12-15

Table 30 "Total fraction by volume of hydrocarbons in ten environment" test new 11.4.4.13	
Applicable standard	none
Test method	Exposure to an environment containing hydrocarbons
Applicability	Applicable for all EBA
Object of the test	Verification of compliance with the provisions for reference conditions in 12.5.2 under conditions of being exposed to the level of hydrocarbons in the environment specified in 6.10 g
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.
Test procedure in brief	The test comprises exposure to a simulated environment containing a specific fraction of hydrocarbons
Test level	Total fraction of 5ppm (by volume) of hydrocarbons (as methane equivalent)
EUT performance	After stabilization at the test level five measurements are performed using a test gas with 0.400 mg/ L ethanol (test gas No. 4) The error of the breath alcohol analyzer is determined and the following parameters are recorded: a) date and time, b) temperature, c) relative humidity d) measurand values, e) indications, f) errors, g) functional performance.
Permitted maximum deviation	All functions shall operate as designed. All errors shall be within the maximum permissible errors specified in 6.6.1

12.5.4.11 Influence of raised CO2-content in the test gas

This test is applied to verify compliance with the provisions in xx under conditions of CO2 in the test gas
The following shortened test procedure shall be applied:

Table 12-16

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	After stabilization at the test level five measurements are performed using a test gas with 0.400 mg/ L ethanol **plus** 10 %vol of CO_2. The error of the breath alcohol analyzer is determined and the following parameters are recorded: a) date and time, b) temperature, c) relative humidity d) measurand values, 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.

12.5.5 Tests during the impact disturbances

12.5.5.1 Conducted (common mode) currents generated by RF EM fields

This test is applied to verify compliance with the requirements for disturbances when exposed to conducted currents generated by radiofrequency electromagnetic fields (6.11.1.1 ?)

Table 12-17

Table 21 Conducted (common mode) currents generated by RF EM fields 11.4.5.2				
Applicable standard	IEC 61000-4-6 [...]			
Test method	Injection of RF currents representing exposure to RF electromagnetic fields			
Applicability	Applicable for all those EBA that are or can be equipped with external electrical wiring (mains power, signal, data and control lines)			
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 while exposed to electromagnetic fields specified in 6.11.1.1 ?			
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.			
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.			
Test procedure in brief	A RF EM current, simulating the influence of EM fields shall be coupled or injected into the power ports and I/O ports of the EUT using coupling/decoupling devices as defined in the referred standard. The characteristics of the test equipment consisting of an RF generator, (de-) coupling devices, attenuators, etc. shall be verified before connecting the EUT. If the EUT comprises several devices the tests shall be performed at each extremity of the cable if both of the elements are part of the EUT.			
	Frequency range	RF amplitude	AM, sine wave modulation	
Test level	0.15 – 80	**10**	80	1
Unit	MHz	V (e.m.f.)	%	kHz
EUT performance	Sequentially during and after the exposure to the RF current record the following parameters: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) applied RF (e.m.f). voltage level , f) indications and errors, g) functional performance.			
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result .			

12.5.5.2 Radiated RF electromagnetic fields

This test is applied to verify compliance with the requirements for disturbances when exposed to radiated radiofrequency electromagnetic fields (6.11.1.1 a)

Table 12-18

Table 22 Radiated RF electromagnetic fields 11.4.5.1				
Applicable standard	IEC 61000-4-3 [...]; IEC 61000-4-20 [...]			
Test method	Exposure to radiated radio frequency electromagnetic fields			
Applicability	Applicable to all EBA			
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of exposure to electromagnetic fields specified in 6.11.1.1 a			
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.			
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.			
Test procedure in brief	The EUT is exposed to electromagnetic fields with the required field strength and the field uniformity like defined in the referred standard. The level of field strength specified refers to the field generated by the unmodulated carrier wave. The EUT shall be exposed to the modulated wave field. The frequency sweep shall be made only pausing to adjust the RF signal level or to switch RF-generators, amplifiers and antennas if necessary. Where the frequency range is swept incrementally, the step size shall not exceed 1 % of the preceding frequency value. The dwell time of the amplitude modulated carrier at each frequency shall not be less than the time necessary for the EUT to be exercised and to respond, but shall in no case be less than 0.5 s. Adequate EM fields can be generated in facilities of different type and setup, the use of which is limited by the dimensions of the EUT and the frequency range of the facility.			
	Frequency range	RF amplitude	AM, sine wave modulation	
Test level	26 - 80[1)]	**10**	80	1
	80 – 3000	**10**	80	1
Unit	MHz	V/m	%	kHz
Note	1) Only where the instrument is not employing any cable or cable connection.			
EUT performance	Sequentially during and after the exposure to the EM Field record the following parameters: a) date and time, b) temperature, c) relative humidity, d) value of the measurand, e) field strength level, f) indications and errors, g) functional performance.			
Permitted maximum deviation	either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.			

12.5.5.3 Mains power frequency electromagnetic field

This test is applied to verify compliance with the requirements for disturbances when exposed to mains power frequency electromagnetic fields (6.11.1.1 b?)

Table 12-19

Table 20 Mains power frequency electromagnetic field (new)			
Applicable standard	IEC 61000-4-8 [...]		
Test method	Exposure to power frequency electromagnetic fields (50 Hz or 60 Hz)		
Applicability	Applicable to all EBA		
Object of the test	Verification of compliance with the provisions in [1] ..... while exposed to power frequency electromagnetic fields (50 Hz or 60 Hz) specified in		
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.		
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.		
Test procedure in brief	The test comprises the exposure to a power frequency magnetic field. (50 Hz or 60 Hz)		
		Test level	unit
Magnetic field strength	Continuous field	**100**	A/m
	Short duration (1 s to 3 s)	**1000**	A/m
EUT performance	Sequentially during and after the exposure to the surges record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand value, e) applied magnetic field strength and frequency f) indications and errors, g) functional performance.		
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.		

[2] requirement needs to be referred to. Suggest general requirement for immunity to disturbances

[1] requirement needs to be referred to. Suggest general requirement for immunity to disturbances

12.5.5.4 Electrostatic discharges

This test is applied to verify compliance with the requirements for disturbances when exposed electrostatic discharges (6.11.1.1 c)

Table 12-20

Table 23 Electrostatic discharges 11.4.5.3			
Applicable standard	IEC 61000-4-2 [...]		
Test method	Exposure to electrostatic discharges (ESD)		
Applicability	Applicable to all EBA		
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 in case of direct exposure to electrostatic discharges or such discharges in the neighborhood of the EUT specified in 6.11.1.1 c		
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.		
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.		
Test procedure in brief	The test comprises exposure of the EUT to electrical discharges. An ESD generator as defined in the referred standard shall be used and the test setup shall comply with the dimensions, materials used and conditions as specified in the referred standard. Before starting the tests, the performance of the generator shall be verified. At least 10 discharges per preselected discharge location shall be applied. An EUT not equipped with a safety ground connection shall first be fully discharged before exposure to a next discharges. The time interval between successive discharges shall be at least 1 second. Contact discharge is the preferred test method. Air discharge is far less defined and reproducible and therefore shall be used only where contact discharge cannot be applied. *Direct application:* In the contact discharge mode to be carried out on conductive surfaces, the electrode shall be in contact with the EUT before activation of the discharge. In such case the discharge spark occurs in the vacuum relays of the contact discharge tip. On insulated surfaces only the air discharge mode can be applied. The EUT is approached by the charged electrode until a spark discharge occurs. *Indirect application*: The discharges are applied in the contact mode only on coupling planes mounted in the vicinity of the EUT. Conventionally 3 cycles of tests are performed starting each test at a different moment of the measuring cycle.		
		Charge voltage	unit
Test level	Contact discharge	**6**	kV
	Air discharge	**8**	kV
EUT performance	Five measurements shall be performed during exposure of each surface to the disturbance. Sequentially during and after the exposure to the discharges record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand value e) discharge type, level and surface f) indications and errors, g) functional performance.		
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.		

12.5.5.5 Bursts (transients) on AC and DC mains

This test is applied to verify compliance with the requirements for disturbances when exposed bursts on AC or DC mains supply lines (6.11.1.1 d)

Table 12-21

Table 16 Bursts (transients) on AC and DC mains 11.4.5.4			
Applicable standards	IEC 61000-4-4 [...]		
Test method	Introducing transients on the mains power lines		
Applicability	Applicable for those EBAs which are designed to be temporarily or permanently connected to a mains power network while in operation. Not applicable to mobile EBA powered by a road vehicle battery		
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 during conditions where electrical bursts are superimposed on the mains voltage specified in 6.11.1.1 d		
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.		
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.		
Test procedure in brief	A burst generator as defined in the referred standard shall be used. The characteristics of the generator shall be verified before connecting the EUT. The test comprises exposure to bursts of voltage spikes for which the output voltage on 50 Ω and 1000 Ω load are defined in the referred standard. Both positive and negative polarity of the bursts shall be applied. The duration of the test shall not be less than 1 min for each amplitude and polarity. The injection network on the mains shall contain blocking filters to prevent the burst energy being dissipated in the mains. At least 10 positive and negative randomly phased bursts shall be applied. The bursts are applied during all the time necessary to perform the test; therefore, more bursts than indicated above may be necessary.		
	One of the following test levels may be specified:		
Test level index	**2**	**3**	unit
Amplitude (peak value)	**1**	**2**	kV
Repetition rate	**5**		kHz
EUT performance	Sequentially during and after the exposure to the bursts record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.		
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.		

12.5.5.6 Surges on AC and DC mains power lines

This test is applied to verify compliance with the requirements for disturbances when exposed to surges on AC or DC mains supply lines (6.11.1.1 e)

Table 12-22

Table 17 Surges on AC and DC mains power lines					
Applicable standard	IEC 61000-4-5 [...]				
Test method	Introducing electrical surges on the mains power lines				
Applicability	Only applicable for those EBAs which are designed to be temporarily or permanently connected to a mains power network while in operation. Not applicable to EBA only designed to be connected to - a local power source through an indoor network or - a road vehicle battery (mobile EBA)				
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 during conditions where electrical surges are superimposed on the mains voltage specified in 6.11.1.1 e				
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.				
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.				
Test procedure in brief	A surge generator as defined in the referred standard shall be used The characteristics of the generator shall be verified before connecting the EUT. The test comprises exposure to electrical surges for which the rise time, pulse width, peak values of the output voltage/current on high/low impedance load and the minimum time interval between two successive pulses are defined in the referred standard. At least 3 positive and 3 negative surges shall be applied. On AC mains supply lines the surges shall be synchronized with the AC supply frequency and shall be repeated such that the injection of surges on all the 4 phase shifts: 0°, 90°, 180° and 270° with the mains phase is covered. The injection network circuit depends on the applicable conductor and is defined in the referred standard. The surges are applied during all the time necessary to perform the test; to that purpose more surges than indicated above may be necessary.				
Mains mode	AC		DC		
	Line to line	Line to ground	Line to line	Line to ground	unit
Test level	**1.0**	**2.0**	**1.0**	**2.0**	kV
EUT performance	Sequentially during and after the exposure to the surges record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.				
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.				

12.5.5.7 Bursts on signal, data and control lines

This test is applied to verify compliance with the requirements for disturbances when exposed to bursts on signal, data and control lines (6.11.1.1 f)

Table 12-23

Table 18 Bursts (transients) on signal, data and control lines 11.4.5.5		
Applicable standards	IEC 61000-4-4 [...]	
Test method	Introducing transients on signal, data and control lines	
Applicability	Applicable for EBA which while in operation are designed to be permanently or temporarily connected to external electrical signal, data and/or control lines.	
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 during conditions where electrical bursts are superimposed on I/O and communication ports specified in 6.11.1.1 f	
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.	
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.	
Test procedure in brief	A burst generator as defined in the referred standard shall be used The characteristics of the generator shall be verified before connecting the EUT. The test comprises exposure to bursts of voltage spikes for which the output voltage on 50 W and 1000 W load are defined in the referred standard. Both positive and negative polarity of the bursts shall be applied. The duration of the test shall not be less than 1 min for each amplitude and polarity.	
	Test level	unit
Amplitude (peak value)	**1**	kV
Repetition rate	**5**	kHz
EUT performance	Sequentially during and after the exposure to the bursts record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand value, e) exposed conductors, f) indications and errors, g) functional performance.	
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.	

12.5.5.8 Ripple on DC mains power

This test is applied to verify compliance with the requirements for disturbances when exposed to ripple on DC mains electrical power port (6.11.1.1 g)

Table 12-24

Table 11 Ripple on DC mains power (new)		
Applicable standard	IEC 61000-4-17 [...]	
Test method	Introducing a ripple voltage on the DC input power port.	
Applicability	Applicable for those EBA which are designed to be temporarily or permanently connected to a DC power network (distribution system) supplied by external rectifier systems while in operation Not applicable to: - mobile EBA powered by a road vehicle battery and - mobile EBA connected to battery charger systems with incorporated switch mode converters specified in 5.10.1.1 g ?)	
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of a ripple on the DC mains voltage specified in 6.11.1.1 g	
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.	
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.	
Test procedure in brief	A test generator as defined in the referred standard shall be used. Before starting the tests, the performance of the generator shall be verified.	
	The test comprises subjecting the EUT to ripple voltages such as those generated by traditional rectifier systems and/or auxiliary service battery chargers overlaying on DC power supply sources.	
	The frequency of the ripple voltage is the applicable power frequency or a multiple (2, 3 or 6) dependent on the rectifier system used for the mains . The waveform of the ripple, at the output of the test generator, has a sinusoid-linear character. The test level is a peak-to-peak voltage expressed as a percentage of the nominal DC voltage, U_{DC}.	
	Test level	unit
Percentage of the nominal DC voltage	**2**	%
EUT performance	After stabilization at the relevant a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.	
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.	

12.5.5.9 DC mains voltage dips, short interruptions and (short term) variations

This test is applied to verify compliance with the requirements for disturbances when exposed to DC mains voltage dips, short interruptions and short term variations (6.11.1.1 h)

Table 12-25

Table 14 DC mains voltage dips, short interruptions and (short term) variations (new)			
Applicable standard		IEC 61000-4-29 [...]	
Test method		Introducing voltage dips, short interruptions and voltage variations on DC mains power lines using the test setup defined in the applicable standard	
Applicability		Applicable for those EBAs which are designed to be temporarily or permanently connected to a DC mains power network while in operation. Not applicable to: - mobile EBA powered by a road vehicle battery - EBA requiring a DC to AC conversion.	
Object of the test		Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of disturbances on the DC mains voltage.	
Precondition		The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.	
Condition of the EUT		The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.	
Test procedure in brief		A test generator as defined in the referred standard shall be used. Before starting the tests, the performance of the generator shall be verified. The EUT shall be exposed to voltage dips, short interruptions, for each of the selected combinations of amplitude and duration, using a sequence of three dips/interruptions and intervals of at least 10 s between each test event. The most representative operating modes of the EUT shall be tested for each of the specified voltage variations. The disturbances are applied during all the time necessary to perform the test; to that purpose more disturbances than indicated above may be necessary.	
Voltage dips		**Test Levels**	Unit
	Amplitude	**40 and 70**	% of the rated voltage
	Duration	**0.01; 0.03; 0.1; 0.3; 1**	s
Short interruptions	Test condition	High impedance and/or[2] low impedance	
	Amplitude	**0**	% of the rated voltage
	Duration	**0.001; 0.003; 0.01; 0.03; 0.1; 0.3; 1**	s
Voltage variations	Amplitude	**85 and 120**	% of the rated voltage
	Duration	**0.1; 0.3; 1; 3; 10**	s
EUT performance		The fault of the EUT is determined separately for each of the different dips and reductions. Sequentially during and after the exposure to the dips and interruptions the following parameters shall be recorded: a) date and time, b) temperature, c) relative humidity, d) measurand value, e) percentage of voltage reduction and duration, f) indications and errors, g) functional performance.	
Permitted maximum deviation		Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.	

choice to be made

[2] choice to be made

12.5.5.10 AC mains voltage dips, short interruptions and voltage variations

This test is applied to verify compliance with the requirements for disturbances when exposed to AC mains voltage dips, short interruptions and voltage variations (6.11.1.1 h)

Table 12-26

Table 15 AC mains voltage dips, short interruptions and reductions 11.4.5.7				
Applicable standards		IEC 61000-4-11 [...], IEC 61000-6-1 [...], IEC 61000-6-2 [...]		
Test method		Introducing short-time reductions of mains voltage using the test set-up defined in the applicable standard		
Applicability		Applicable for those EBA having a rated input current of less than 16 A per phase and are designed to be temporarily or permanently connected to an AC mains power network while in operation. Not applicable to mobile EBA powered by a road vehicle battery.		
Object of the test		Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of short time mains voltage reductions specified in 6.11.1.1 h		
Precondition		The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.		
Condition of the EUT		The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.		
Test procedure in brief		A test generator is to be used which is suitable to reduce the amplitude of the AC mains voltage for the required period of time. The performance of the test generator shall be verified before connecting the EUT. The mains voltage reduction tests shall be repeated 10 times with intervals of at least 10 s between the tests. The tests shall be applied continuously during the measurement time. The fault of the EUT is determined separately for each of the different dips and reductions The interruptions and reductions are repeated throughout the time necessary to perform the whole test; for this reason, more than ten interruptions and reductions may be necessary.		
		Test Level		unit
Voltage dips	Test a	Reduction	**100**	%
		Duration	**0.5**	cycles
	Test b	Reduction	**100**	%
		Duration	**1**	cycles
	Test c	Reduction	**30**	%
		Duration	**25/30**	cycles
Short interruptions		Reduction	**100**	%
		Duration	**250/300**	cycles
EUT performance		The fault of the EUT is determined separately for each of the different dips and reductions. Sequentially during and after the exposure to the dips and interruptions record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand value, e) percentage of voltage reduction and duration, f) indications and errors, g) functional performance.		
Permitted maximum deviation		Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.		

12.5.5.11 Surges on signal, data and control lines

This test is applied to verify compliance with the requirements for disturbances when exposed to Surges on signal, data and control lines (6.11.1.1 i)

Table 12-27

Table 19 Surges on signal, data and control lines 11.4.5.6					
Applicable standard	IEC 61000-4-5 [...]				
Test method	Introducing electrical surges on signal, data and control lines				
Applicability	Only applicable for those EBA which are designed to, during operation, be temporarily or permanently connected to electrical signal, data and/or control lines that may exceed a length of 10 m. Not applicable to EBAs connected to a local power source through an indoor network				
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 during conditions where electrical surges are superimposed on I/O and communication ports specified in 6.11.1.1 i				
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.				
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.				
Test procedure in brief	A surge generator as defined in the referred standard shall be used. The characteristics of the generator shall be verified before connecting the EUT. The test comprises exposure to electrical surges for which the rise time, pulse width, peak values of the output voltage/current on high/low impedance load and the minimum time interval between two successive pulses are defined in the referred standard. At least 3 positive and 3 negative surges shall be applied. The applicable injection network depends on the kind of wiring the surge is coupled into and is defined in the referred standard.				
	Unsymmetrical lines		Symmetrical lines	Shielded I/O and communication lines	
Test Level	Line to line	Line(s) to ground	Line(s) to ground	Shield to ground	Unit
	1.0	**2.0**	**2.0**	**2.0**	kV
EUT performance	Sequentially during and after the exposure to the surges record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand value, e) exposed conductors, f) indications and errors, g) functional performance.				
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.				

12.5.5.12 Electrical transient conduction for external batteries of a vehicle

This test is applied to verify compliance with the requirements for disturbances when exposed to electrical transient conduction for external batteries of a vehicle (6.11.1.1 j)

Table 12-28

Table 26 Electrical transients conduction along supply lines 11.4.5.8			
Applicable standard	ISO 7637–2 [...]		
Test method	Electrical transient conduction along supply lines.		
Applicability	Applicable to mobile or portable? EBAs while in operation are supplied by the on board battery of a vehicle which at the same time may be charged by use of a combustion engine driven generator.		
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 under the following conditions (4): • transients due to a sudden interruption of currents in a device connected in parallel with the device under test due to the inductance of the wiring harness (pulse 2a); • transients from DC motors acting as generators after the ignition is switched off (pulse 2b)(5); • transients on the supply lines which occur as a result of the switching processes (pulses 3a and 3b).specified in 6.11.1.1 j)		
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.		
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.		
Test procedure in brief	The test comprises exposure to disturbances on the power voltage by direct coupling into the supply lines.		
	Test level		unit
Test pulse	**Pulse voltage *U*s**		
	U_{nom} = 12 V	**U_{nom} = 24 V**	
2a	**+ 50**	**+ 50**	V
2b(5)	**10**	**20**	V
3a	**- 150**	**- 200**	V
3b	**+ 100**	**+ 200**	V
EUT performance	Sequentially during and after the exposure to the transients record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.		
Permitted maximum deviation	either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.		

12.5.5.13 Electrical transient conduction via lines other than supply lines

This test is applied to verify compliance with the requirements for disturbances when exposed to Electrical transient conduction via lines other than supply lines (6.11.1?)

Table 12-29

Table 27 Electrical transient conduction via lines other than supply lines (new)					
Applicable standard	ISO 7637-3 [...], § 3.5.1: fast transient test pulses a and b				
Test method	Electrical transient conduction along lines other than supply lines				
Applicability	Applicable to analogue I/O cabling of modular mobile EBA installed in vehicles.				
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of transients which occur on other lines as a result of the switching processes (pulses a and b) specified in?)				
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.				
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.				
Test procedure in brief	The test consists of exposure to bursts of voltage spikes by capacitive and inductive coupling via lines other than supply lines. Only the Capacitive Coupling Clamp method shall be applied.				
	Test level				unit
		U_{nom}	12	24	V
	pulse a	U_s	-60	-80	V
	pulse b	U_s	40	80	V
EUT performance	Sequentially during and after the exposure to the transient record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand value, e) exposed conductors, f) indications and errors, g) functional performance.				
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.				

12.5.5.14 Battery voltage variations during starting up a vehicle engine

This test is applied to verify compliance with the requirements for disturbances when exposed to Vehicle battery voltage variations during starting up a vehicle engine (6.11.1.1 l)

Comment [TG(,M8]: part 2 table 28

Table 12-30

Table 28 Battery voltage variations during starting up a vehicle engine 11.4.5.8					
Applicable standard	ISO 16750-2 [...]				
Test method	Supply voltage variation due to energizing the starter motor of a vehicle				
Applicability	Applicable to mobile EBAs powered by the on board battery of the vehicle and which EBA may be in operation while the vehicle engine is started				
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of starting the vehicle engine (during and after cranking) specified in 6.11.1.1 l				
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.				
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.				
Test procedure in brief	The test comprises exposure to a typical supply voltage characteristic simulating the voltage variation while cranking the engine using a DC electrical starter motor				
	The following test levels are applicable:				
Nominal battery voltage	U_{nom} = 12 V		U_{nom} = 24 V		Unit
Test profile [1)]	**I**	**III**	**I**	**III**	
U_S	**8**	**3**	**10**	**6**	V
U_A	**9,5**	**5**	**20**	**10**	V
t_8	**1**				s
t_f	**40**	**100**	**40**	**40**	ms
Notes	[1)] As specified in ISO 16750-2.				
EUT performance	Sequentially during and after the exposure to the disturbance Record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurands, e) indications, f) errors, g) functional performance.				
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.				

12.5.5.15 "Load dump" test

This test is applied to verify compliance with the requirements for disturbances when exposed to a load dump test (6.11.1.1 ?)

Table 12-31

Table 29 "Load dump" test (new)					
Applicable standard	ISO 16750-2 [...]				
Test method	Supply voltage variation due to disconnecting a discharged battery				
Applicability	Applicable to mobile EBA powered by the on board battery of the vehicle and which EBA may be in operation while the vehicle engine is running.				
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of disconnecting a discharged vehicle battery while the charging alternator is running specified in 6.11.1.1 ?)				
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.				
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test except for a reset when a significant fault has been indicated.				
Test procedure in brief	The test comprises exposure to a typical pulse on the supply voltage, simulating the voltage peak due to the impedance of connected loads when disconnecting the battery.				
Nominal battery voltage	U_{nom} = 12 V		U_{nom} = 24 V		Unit
Test pulse shape [1)]	**I**	**II**	**I**	**II**	
U_S	**80**	**100**	**150**	**200**	V
R_i	**0,5**	**4**	**1**	**8**	V
t_r	**10**	**10**	**10**	**10**	ms
t_d	**40-400**	**40-400**	**100-350**	**100-350**	ms
Notes	[1)] As specified in ISO 16750-2				
EUT performance	Sequentially during and after the exposure to the disturbance record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.				
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.				

12.5.6 Tests after the impact of disturbances

12.5.6.1 Mechanical shocks

This test is applied to verify compliance with the requirements for disturbances after exposed to mechanical shocks (6.11.1.1 a)

Table 12-32

Table 9 Mechanical shock 11.4.5.9			
Applicable standard	IEC 60068-2-31 [...]		
Test method	Dropping the EUT onto a rigid surface after tilting		
Applicability	Applicable for all EBA		
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of mechanical shocks specified in 6.11.1.2 a		
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.		
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test. If the instrument is operated from a carrying case then this test should be carried out with the instrument in it.		
Test procedure in brief	The EUT, standing in its normal position of use on a rigid surface, is tilted along one bottom edge and subsequently is allowed to fall freely back on to the test surface. The height of fall is the distance between the opposite bottom edge and the test surface. However, the angle between the bottom and the test surface shall not exceed 30°.		
Test level	**stationary**	**mobile/portable**	unit
Height of fall	**25**	**50**	mm
Number of falls (on each bottom edge)	**1**	**1**	-
EUT performance	After the application of the influence quantity record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand value, e) height of fall, f) indications and errors, g) functional performance.		
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.		

12.5.6.2 Shakes

This test is applied to verify compliance with the requirements for disturbances after exposed shakes (6.11.1.2 b)

Table 12-33

Table 31 Shakes (shocks) 11.4.5.10	
Applicable standard	none
Test method	Exposure to shocks while not being in operation
Applicability	Applicable for portable and mobile EBA
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 after being exposed to shocks likely to be experienced in a car trunk thus specified in 6.11.1.2 b
Precondition	The EUT is kept at the reference conditions specified in 11.4.1 in its switched off mode and no external electric power shall be connected.
Condition of the EUT	The EUT is mounted in its reference position on a table which can generate shakes and kept in switched off mode during the exposure to influence quantity and shall be switched on immediately after this exposure. The EUT shall not be readjusted at any time during the test
Test procedure in brief	The test comprises the exposure to simulated shocks fulfilling the specified test level. After the exposure the external electrical power (where applicable) shall be connected and the EUT shall be switched on where after the EUT performance is tested
Test level	Shock specifications: wave shape: half-period of a sinusoid amplitude: 10 g (g = 9.81 m/s2) duration: 6 ms frequency: 2 Hz Repetition rate: number of axes: 3 perpendicular axes number of shakes:1 000 for each axis
EUT performance	After the switching on of the EUT five measurements shall be performed, using a test gas with 0.400 mg/ L ethanol (test gas No. 4). The following parameters shall be recorded: a) date and time, b) temperature, c) relative humidity d) measurand values, e) indications, f) errors, g) functional performance.
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.

12.5.6.3 Damp heat cyclic (condensing)

This test is applied to verify compliance with the requirements for disturbances after exposed to damp heat cyclic (6.11.1.2 c)

Table 12-34

Table 4 Damp heat, cyclic (condensing) 11.4.5.11			
Applicable standards	IEC 60068-2-30 [...], IEC 60068-3-4 [...]		
Test method	Exposure to damp heat with cyclic temperature variation		
Applicability	Applicable for mobile and portable EBA		
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 under conditions of high humidity combined with cyclic temperature changes specified in 6.11.1.2 c)		
Precondition	The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.		
Condition of the EUT	The electrical power supplied to the EUT shall not be switched off and the EUT shall not be readjusted at any time during the test.		
Test procedure in brief	The test comprises exposure to cyclic temperature variation between 25 °C and the appropriate upper temperature while maintaining the relative humidity above 95 % during the temperature change and the low temperature phases and at or above 93 % RH at the upper temperature phases. Condensation is expected to occur on the EUT during the temperature rise. The 24 h cycle comprises: 1) temperature rise during 3 hours, 2) temperature maintained at upper value until 12 hours from the start of the cycle, 3) temperature lowered to lower temperature level within a period of time of 3 to 6 hours, the declination (rate of fall) during the first hour and a half being such that the lower temperature level would be reached in a 3 hours period, 4) temperature maintained at the lower level until the 24 h period is completed. The stabilizing period before and recovery period after the cyclic exposure shall be such that the temperature of all parts of the EUT is within 3 °C of its final value. Special electrical conditions and recovery conditions may need to be specified. The stabilizing period before and recovery after the cyclic exposure shall be such that all parts of the EUT are approximately at their final temperature.		
	Test level		Unit
Upper temperature	**55**		°C
	Mobile	Portable	
Duration	**2**	**4**	24-hour cycle
EUT performance	After the exposure to the damp heat test record the following parameters: a) date and time, b) temperature, c) relative humidity, d) measurand values, e) indications, f) errors, g) functional performance.		
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.		

12.5.6.4 Storage test

This test is applied to verify compliance with the requirements for disturbances after exposed to a storage test (6.11.1.2 d)

Table 12-35

Table ..32 Storage test 11.4.5.12	
Applicable standard	none
Test method	Exposure to shocks while not being in operation
Applicability	Applicable all EBA
Object of the test	Verification of compliance with the provisions for disturbances in 6.11.1 after being exposed to the extreme situations which may occur during storage of the instrument thus specified in 6.11.1.2d
Precondition	The EUT is set in its switched off mode and no external electric power shall be connected.
Condition of the EUT	The EUT kept in switched off mode until the immediate switching on after this exposure. The EUT shall not be readjusted at any time during the test.
Test procedure in brief	The EUT is exposed to a low temperature and high temperatures for a period of 6 hours each. The change of temperature shall not exceed 1 °C/min during cooling down and heating up. After the exposure the external electrical power (where applicable) shall be connected and the EUT shall be switched on. After a one hour recovery period at reference conditions the EUT performance is tested.
Test level	Exposure to: - a temperature of – 25 °C for a time period of 6 hours and - a temperature of + 70 °C for a time period of 6 hours.
EUT performance	After switching on the EUT and after a one hour recovery period at reference conditions five measurements shall be performed, using a test gas with 0.400 mg/ L ethanol (test gas No. 4). The following parameters shall be recorded: a) date and time, b) temperature, c) relative humidity d) measurand values, e) indications, f) errors, g) functional performance.
Permitted maximum deviation	Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.

12.5.6.5 Durability

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

12.5.7 Physiological influence quantities

Remark 1 of the Secretariat: chapter is under construction by subgroup SG3. Here, the original text of 2012 is shown.

The EBA 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 EBA 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 EBA 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.

13 Initial Verification

13.1 General considerations

A new instrument shall undergo initial verification only after type approval. The verification shall be carried out using suitable standards, having adequate accuracy. These standards shall be subjected to a suitable calibration program, assuring their traceability.

The initial verification shall include:
- an inspection for conformity of the EBA including the subsidiary devices (if applicable), and
- a metrological examination of the EBA.

Note: Dismantling the EBA or its components for testing purposes is not what is intended.

13.2 Legal status of the instrument submitted for verification

All EBAs produced and ready for initial verification shall be in conformance with the approved type.
Initial verification of an EBA includes a procedure to ensure that the individual measuring instruments conform to the approved type. But, notwithstanding this initial verification carried out by the appropriate legal authority or under its responsibility, the manufacturer has the full responsibility that the instrument complies with all the applicable requirements according to this Recommendation and other relevant requirements.

13.3 Inspection at initial verification

Before starting the practical tests, the following examinations shall be performed (as far as it is applicable):

- a visual inspection to determine the conformity with the approved type and to obtain a general appraisal of its design and construction;
- completeness of essential accessories and subsidiary devices (e.g. mouthpieces, durable storage/printing device) and their compliancy with the approved type
- compliance of the software with the approved type
- completeness and correctness of the inscriptions and markings;
- presence, the completeness and the language of the documentation intended for the user;
- compliance of the power supply voltage and frequency at the location of use with the specifications on the measuring instrument's label;
- type of paper and ink (if applicable)
- sealing devices;
- provisions for stamping.

Note: It is assumed that with a specific software version (which has to be assigned in the type approval) all measuring conditions like the measuring range, unit, resolution in different modes, presentation of the result, details of the measurement cycle, fraud protection etc. are also predetermined.
If part of this, like the unit of the result, is not predetermined in the software, it has to be inspected as well.

13.4 Metrological examination at initial verification

13.4.1 Metrological preconditions for performing tests

The performance tests shall be executed under rated operating conditions.
Before starting the tests, it shall be verified that the EBA is switched on for the time period necessary for warm-up.

13.4.2 Test gases used for initial verification

According to the respective tests, dry or wet gases have to be used.

For wet gases, the test gas source shall comply with the requirements of ???

For dry gases, the actual atmospheric pressure has to be taken into account

13.4.3 Tests for initial verification

The following metrological examination is recommended to be done with each single EBA due for initial verification:

- Test of accuracy (MPEs)/ linearity for ethanol concentration
  at least at 3 different concentrations shall be tested, with at least 3 repetitions at each concentration.
  If the complete measuring range has to be tested or rather only the range close to the legal limits is an issue of national regulations.
  For each concentration, the standard deviations shall be less than or equal to the requirements of repeatability

- Tests of accuracy for auxiliary quantities
  It is recommended to test the correct detection of the minimum requirements for volume and blowing time. *allowed errors for these parameters?? National regulations?*
- Additional tests, e g. sensitivity to certain interfering substances, correct calibration of the sensors for the auxiliary quantities (volume, pressure, flow, temperature,…), plateau duration may be prescribed by National authorities

  → *To be discussed at the Berlin-meeting*

13.5 Verification marks, seals and document

After successful initial verification, the verification marks and seals shall be attached and/or an accompanying document shall be produced according to national regulations.

14 Metrological supervision - Periodic verification

The obligation of mandatory subsequent or periodic verification and, if applicable, the interval, is subjected to national legislation.

The periodic verification shall be carried out using suitable standards of adequate accuracy. These standards shall be subjected to a suitable calibration program, assuring their traceability.

As a rule, the tests for periodic verification shall be carried out on the complete instrument.

14.1 Examination prior to the periodic verification

A periodic verification shall only be performed provided that an earlier initial verification has been successfully performed and the appropriate verification marks and protective seals are undamaged;

Furthermore, the following points shall be examined:

a. completeness of essential accessories and subsidiary devices (e.g. mouthpieces, durable storage/printing device) and their compliancy with the approved type

b. compliance of the software with the approved type

c. type of paper and ink (if applicable)

Any non-conformities concerning these preconditions shall be reported and, where needed, acted upon according to the national regulations. Non-conform instruments shall undergo a maintenance procedure and then shall undergo the procedure for initial verification.

14.2 Metrological examination for periodic verification

14.2.1 Metrological preconditions for performing tests

The performance tests shall be executed under rated operating conditions.
Before starting the tests, it shall be verified that the EBA is switched on for the time period necessary for warm-up.

14.2.2 Test gases used for periodic verification

According to the respective tests, dry or wet gases have to be used.

For wet gases, the test gas source shall comply with the requirements of ???

For dry gases, the actual atmospheric pressure has to be taken into account

14.2.3 Tests for periodic verification

The following metrological examination is recommended to be done with each single EBA due for periodic verification. Typically, the same tests are performed for initial and for periodic verification:

- Test of accuracy (MPEs)/ linearity for ethanol concentration
  at least at 3 different concentrations shall be tested, with at least 3 repetitions at each concentration.
  If the complete measuring range has to be tested or rather only the range close to the legal limits is an issue of national regulations.

- Tests of accuracy for auxiliary quantities
  It is recommended to test the correct detection of the minimum requirements for volume, flow and blowing time

- Additional tests, e g. sensitivity to certain interfering substances correct calibration of the sensors for the auxiliary quantities(volume, pressure, flow, temperature,…), plateau duration may be prescribed by National authorities

  → *To be discussed at the Berlin-meeting*

Annex A Examples for Test gas generator set-ups

→ To be reintroduced Annex G from 98-version
→ to be /checked/ revised and updated if necessary
Here, the original pages are shown:

ANNEX G

GENERAL EXAMPLE OF AN APPARATUS FOR TESTING EVIDENTIAL BREATH ANALYZERS

(Informative)

G.1 General

G.1.1 The testing apparatus shall deliver injections of gas corresponding to the specifications of clause 9 and of Annex A. An apparatus having components as shown in the diagrams on page 35 should meet the requirement.

G.1.2 The volume delivered is regulated by the movement of the actuator. The elastic diaphragm correctly simulates the effects of the respiratory muscles and allows the rates of exhalation to be simulated.

G.1.3 The presence of the dead volume is fundamental, rendering possible the production of an injection of gas during which the mass concentration develops in the same exponential manner as in an exhalation. By varying the dead volume and the elasticity of the diaphragm, the shapes of the curves may be changed.

G.1.4 According to the technical solutions adopted, particularly those associated with the devices to regulate the flow rate, the gas analyzer that is included can be considered as a means of checking the apparatus or as providing a standard if it is calibrated periodically.

The apparatus may be automated by using any appropriate means.

G.2 Bubble train

G.2.1 Principle

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 Dubowski's formula(*):

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

where t is the temperature in °C.

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

G.2.2 Practical application

The formula of G.2.1 demonstrates that different mass concentrations in the air can be obtained by varying the mass concentration of ethanol in the water, but it is preferable to vary the proportion of air that has passed through the solution in the test gas.

The sketches on page 36 give two examples of bubble trains used in practice. By using at least two bubble flasks in series, a stable value of mass concentration at exit is achieved, allowing a fairly large number of measurements to be made.

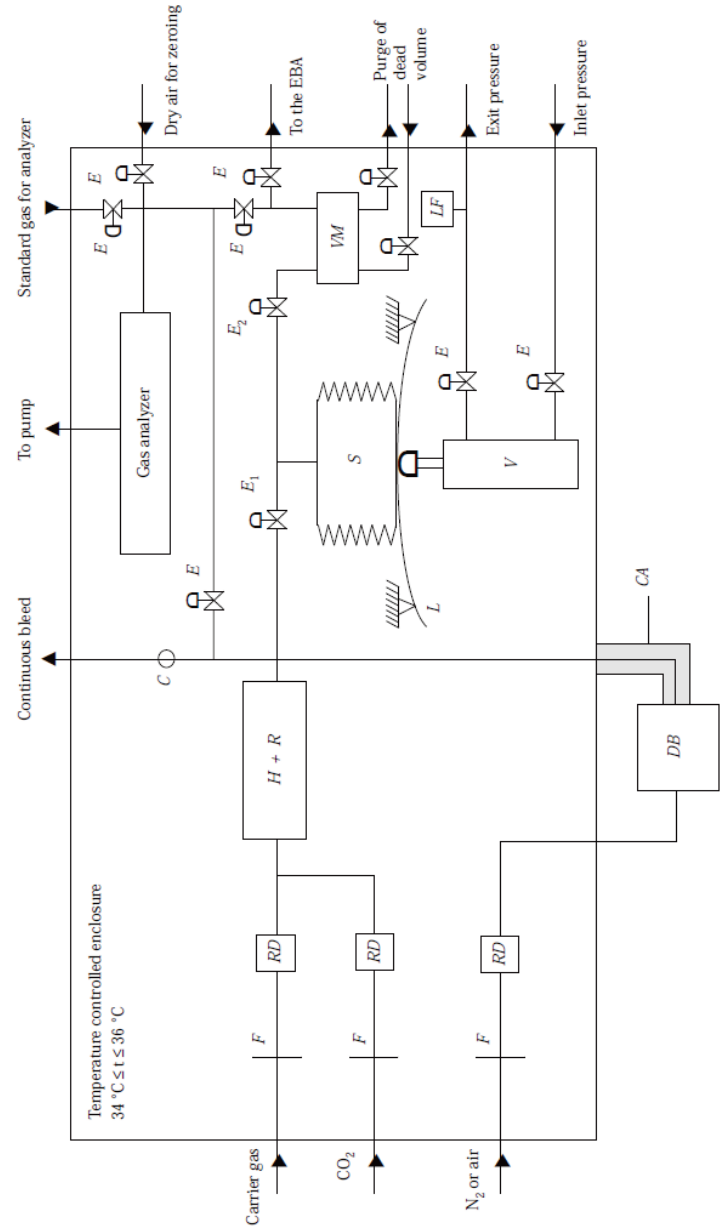
The temperature of the bath shall be held at 34 °C to within ± 0.1 °C. Temperature corrections may be applied.

(*) From "*Breath-ethanol testing: disposable breath tester*" Part 1, National Testing Information Service, USA.

Legend for the diagrammatic sketch on page 35

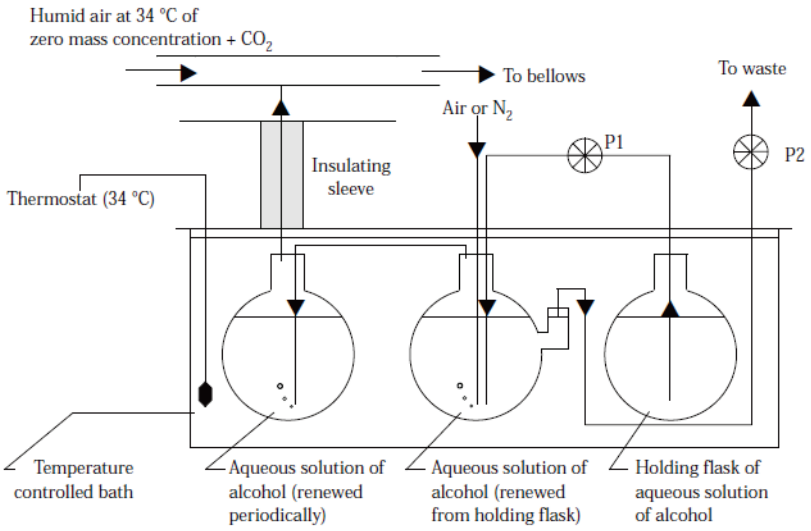
C ..... non-return valve
CA ..... thermal insulator
DB ..... bubble train (see sketches)
E ..... solenoid valve
E_1 ..... solenoid valve for filling bellows (closed during exhalation)
E_2 ..... solenoid valve open during exhalation
F ..... filter
H ..... humidifier
L ..... diaphragm
LF ..... flow controller
R ..... temperature regulator
RD ..... flow regulator
S ..... bellows
V ..... actuator
VM ..... dead volume (to give an exponential evolution of mass concentration during an exhalation)

Diagrammatic sketch of the test rig



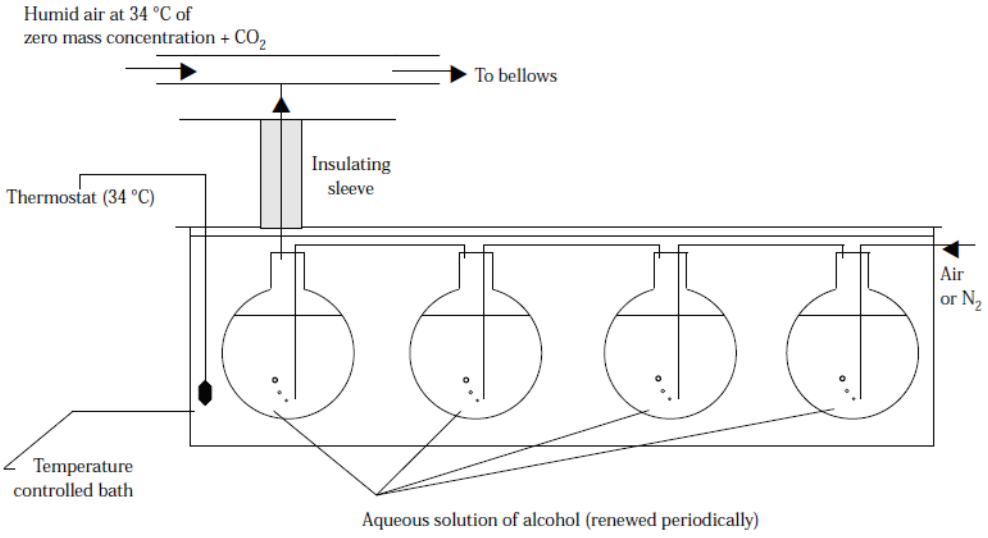
Bubble train

First example



N.B.: Pumps P1 and P2 have an identical flowrate of approximately 0.33 L/h

Second example



Annex B (old A) Examples of detection of alcohol in upper respiratory tracts (Informative)

→ Complete Annex to be revised,
National Authorities may choose one, two or all the following solutions to detect alcohol in the upper respiratory tracts (A.1, A.2 or A.3).

B.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:

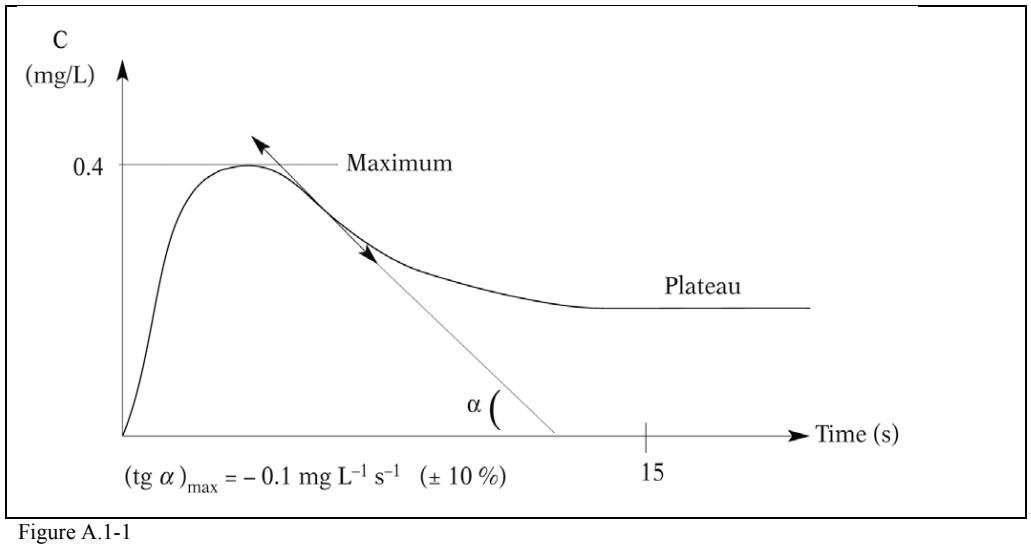


Figure A.1-1

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

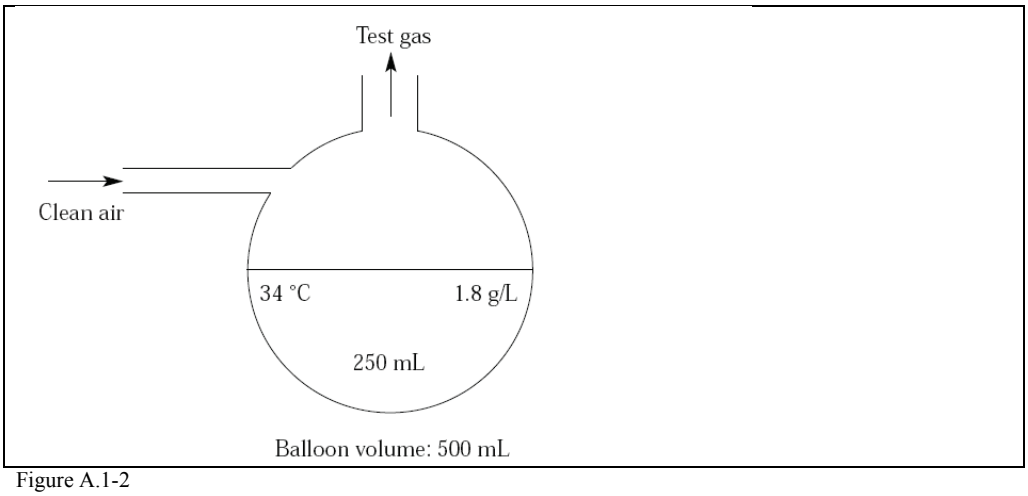


Figure A.1-2

B.2 Two-measurement cycle

B.2.1 First method

B.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 EBA 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 greater 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 values greater than or equal to the legal value

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

$$R = \frac{\left|1-\frac{cm_2}{cm_1}\right|}{t}$$

Where:
t is the time difference between the end of the first breath and the end of the second breath,
Cm1 is the value of the measurement of the first test,
Cm2 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 and is displayed and printed (if applicable); 1Cm 2Cm
the two values and are displayed and printed (if applicable). 1Cm 2Cm

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 greater than or equal to 0.03 min-1, the measurement cycle shall be cancelled and the EBA shall display a warning message to specify that the cycle is not valid and that a new one shall start.

B.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, 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 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 that of the legal value minimum plus 0.3 mg/L,
    the ratio R must be smaller than 0.03 min-1 of Table 2 and greater than or equal to 0.03 min-1 of Table 3.

The test gases described in this paragraph are different from those defined in 11.4.4.1.
Table 1

Test gas No.	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 smaller 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 the plateau: 3 s;
- volume: 3 L.

After 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 smaller 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 the plateau: 3 s;
- volume: 3 L.

After 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 values greater than or equal to the legal value
d)
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 Table 1 according to the time between the end of the first injection and the end of the second injection of the device (see Table 2);
- duration of injection: 5 s;
- duration 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 verifying 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 1 according to the time between the end of the first breath and the end of the second breath of the device (see Table 3);
- duration of injection: 5 s;
- duration of the plateau: 3 s;
- volume: 3 L

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 verifying that the ratio R obtained from Cm_1 and $Cm_2 \geq 0.03$ min-1, the measurement cycle shall be cancelled and the EBA shall display a warning message to specify that the cycle is not valid and that a new one shall start.

B.2.2 Second method

The breath 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 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 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 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.

B.3 Delay before measurement

Good measurement practice, regardless of technical solutions (A.1, A.2), 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 C General information and breath profile (Informative)

→Annex to be discussed if additional information for a better understanding is needed.

As defined in the Scope, the purpose of this Recommendation is to evaluate the suitability of EBA 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.

C.1 Measurement 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.

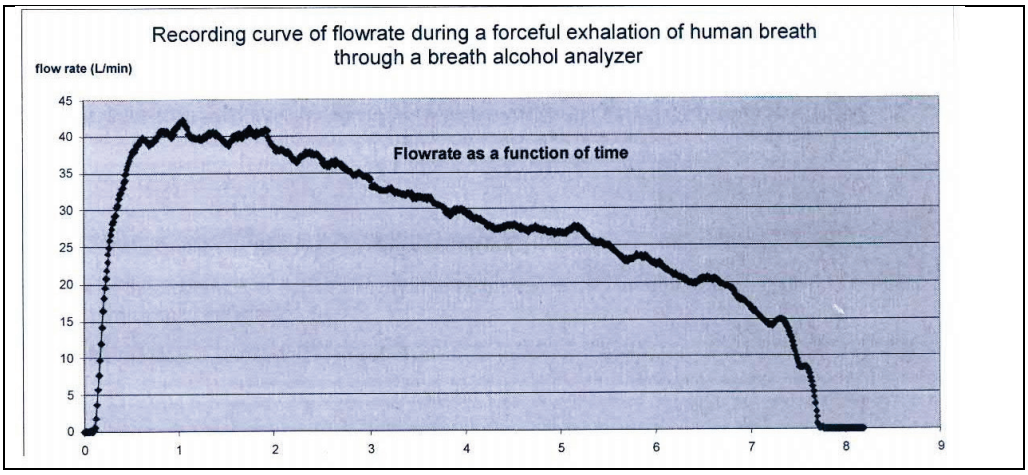


Figure B.1.1

C.1.2 Simulation curve of forced exhalation

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

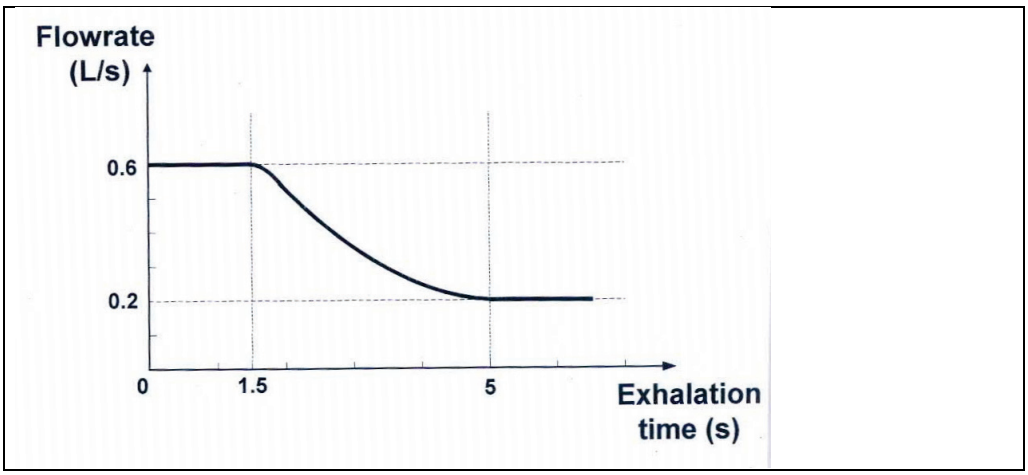


Figure B.1.2

- initial condition: 3 L; exhalation time: 5 s; flowrate: 0.6 L/s,
- after 1.5 s, the flowrate decreases until 0.2 L/s,
- after 5 s, the flowrate remains equal to 0.2 L/s until the end of the exhalation.

C.2 Measurement of 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.

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

The dead anatomical volume is approximately equal to 2.2 mL times the body mass in kilograms and therefore an average volume of150 mL can be chosen.
By considering an average dead anatomical volume of 150 mL, a theoretical curve of the alcohol concentration (expressed in %) according to time and volume of the breath can be calculated using the following formula:

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

C_0=0);*i=incremental indice L/s*

where C=alcohol concentration (expressed in %),
D=flowrate(L/s),t = time of exhalation (s),
V_m = dead anatomical volume (L).

Note: This is a reference to the volume of air from the upper respiratory tract.
In theory, the alcohol concentration representative of alveolar air is obtained in the last third of the time of exhalation (concentration superior to 99 %of the maximum value).
This value (99 % of the expected concentration) is a proposition based on the statistic rules about response time.

Graph: simulation of a curve C (%) = f(t)breath 2.5 L in 5 s ; flowrate = 0.5 L/s ; dead volume = 150 mL

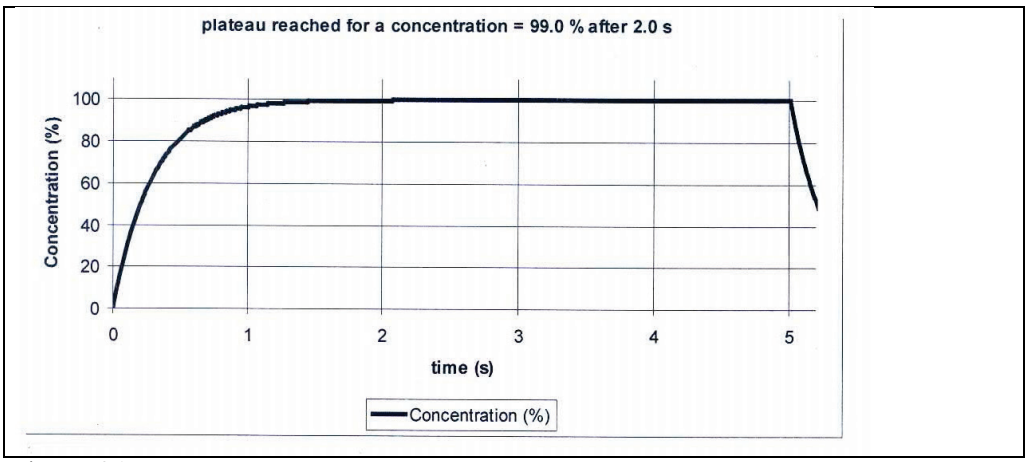


Figure B.2.1

C.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 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:

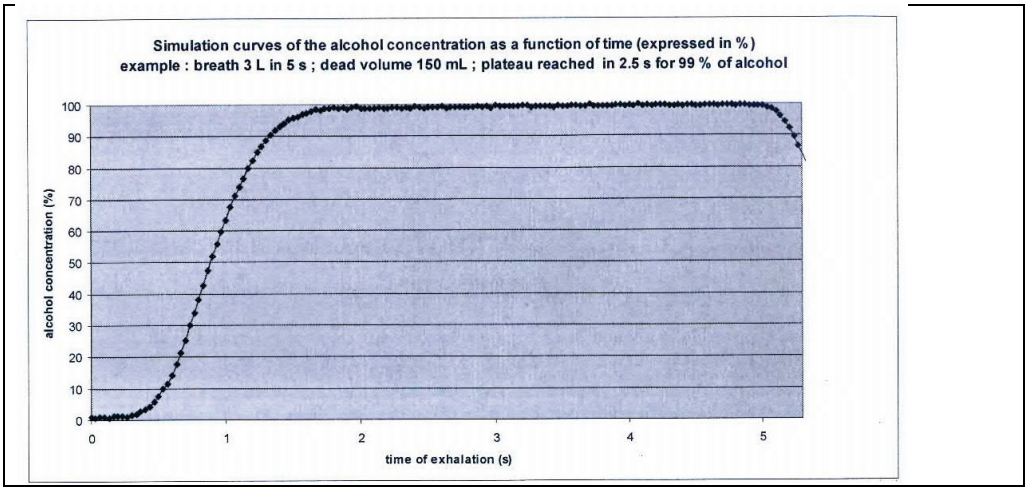


Figure B.2.2

Annex D Reference principle for the implementation of the tests (Informative)

→Annex to be revised (Title to be revised, content checked for additional information

Dubowski's formula
Let C_{H2O} 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:

$$C_{air} = 0.04145 * C_{H2O} * e^{(0.06583* t)}$$

Where t is the temperature in °C

For t = 34 °C, C_{air} = 0.38866 * 10-3 *C_{H2O}

Upon requirements by National Authorities, other formulas can be used such as:

Harger's formula
The partition ratio for concentration of ethanol in headspace to concentration in solution is given by:

$K_{a/w}$ = 0.000393

For t = 34 °C, $C_{air} = 0.393 * 10^{-3} * C_{H2O}$

Annex E Bibliography

To be updated to recent documents