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INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

~~Fifth Working~~ Second 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

OIML TC 17/SC 7 Secretariats: France, Germany

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Foreword

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

International Documents (OIML D), which are informative in nature and which are intended to harmonize and improve work in the field of legal metrology;

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

This publication - reference OIML R 126, edition 2012 (E) - was developed by the OIML Technical Subcommittee TC 17/SC 7 Breath testers. It was approved for final publication by the International Committee of Legal Metrology at its 47th meeting in Bucharest, Romania, in October 2012 and supersedes the previous edition dated 1998. It was sanctioned by the Fourteenth International Conference on Legal Metrology in 2012.

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Part 2 ~~1~~-Metrological controls and performance tests

1 ~~10~~Metrological controls

Legal metrological control consists of the whole of legal metrology activities including type evaluation, initial and subsequent verification.

The Part 1 of this Recommendation provides the required minimum performance criteria for EBA during operation.

This Part 2 of this Recommendation concerns the examinations and ~~test~~tests for (type)-evaluation, verification and during supervision in order to verify the conformity of the instrument to the requirements ~~in~~as specified in Part 1

Every test is subject to uncertainty. The uncertainty of the test method shall be taken into account in the decision on the applicability of the test method.

~~Relevant literature will be cited in the bibliography.~~ For more information, please refer to relevant literature, e.g. OIML G 1-100 [6], OIML G 1-104 [7], OIML G 19[37].

Commented [DL1]: Text amended according to 2019 Meeting (see minutes point (8))

2 ~~11~~Type evaluation

2.1 ~~11.1~~Instruments submitted for type evaluation

Type evaluation shall be carried out on at least one instrument, which represents the definitive type. The evaluation shall consist of the examination and tests specified in the clause ~~R 126-2, 244-3~~.

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 instruments. In this case, the testing laboratory shall ensure that all submitted instruments are in conformance to type.

All accuracy (§11.5.2) and influence tests (§11.5.3, 11.5.4 and 11.5.6) shall be performed on the same instrument, but disturbance tests (§11.5.5) may be carried out on one or two additional instruments. These additional instruments shall also be submitted beforehand to the accuracy tests.

If a unit 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 may have a negative influence on tests that already had a positive result, these tests shall be repeated.

2.2 ~~11.2~~ 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 [R 126-1, 7.1.9.8](#)),
- 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 applicable.

If the EBA is equipped with a printing device, the manufacturer shall provide information about the quality of the printing paper to fulfil the requirements of readability.

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.

2.3 ~~11.3~~ Examination and tests

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

The examination and tests shall cover all applicable requirements of the clauses 4 ~~4~~to 9 of Part 1.

The instrument shall be submitted to the performance tests specified in [R 126-2, 2.5](#)~~11.5~~ to determine its correct functioning under various conditions.

2.3.1 ~~11.3.1~~ Visual examination

The instrument 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 ([R 126-1, 5](#));
- b) measuring ranges ([R 126-1, 6.1](#));
- c) scale intervals ([R 126-1, 6.3](#));
- d) presentation of the result ([R 126-1, 7.1.1](#));
- e) protection against fraud ([R 126-1, 7.1.2](#) and [7.1.9.43](#));
- f) checking operations ([R 126-1, R 126-1, 7.1.3](#));
- g) durability ([R 126-1, 6.5](#));
- h) software ([R 126-1, 7.1.9](#));
- i) inscriptions and sealing ([R 126-1, 9](#));
- j) operating instructions ([R 126-1, 8](#));
- k) suitability for testing.

and if applicable:

- l) printing device ([R 126-1, 7.2.1.1](#));
- m) storage of measurement results ([R 126-1, 7.2.1.2](#));
- n) data transmission;

2.3.2 11.3.2 Software validation

The validation procedure of the software related functionalities of EBAs is given in the following table:- 71.
National regulations may require higher levels for the validation and examination steps.

Table 17

Commented [RK2]: amended according to CT4 and decisions taken in the Paris-meeting (see minutes point (6))

Chapter	Validation Procedure	Examination Level	Comments
Software Identification	AD + VFTSw	A	Select B if high conformity (level B) is required, perform also CIWT
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. If high conformity (level B) is required, perform also CIWT/ SMT
Prevention of misuse	AD + VFTSw	A	Only a low risk of misuse is assumed
Fraud Protection	AD + VFTSw	A	Only a low risk of fraud is assumed
Defect Detection	AD + VFTSw	A	
Interfaces	AD + VFTSw	A	
Maintenance and Verification of Software	AD + VFTSw + VFTM	A	Added in VFTSw and VFTM For verified update procedures
Software Documentation			Parked until main document is completed
Storage of Data	AD + VFTSw	A	Storage For storage of data only with the EBA
	AD + VFTSw + CIWT/SMT	B	Transmission into open system If required by national authorities, for storage in unsecure storages
Automatic storing	AD + VFTSw	A	If high conformity (level B) is required, perform also SMT
Transmission of data	AD + VFTSw + CIWT/SMT	B	Transmission into open systems if required by national authorities

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.

With:

Table 2Table 8

Abbreviation	Description	Application	used for examination level:
AD	Analysis of the documentation and validation of the design	Always	A
VFTM	Validation by functional testing of metrological functions	Correctness of the algorithms, uncertainty, compensating and correcting algorithms, rules for price calculation	
VFTSw	Validation by functional testing of software functions	Correct functioning of communication, indication, fraud protection, protection against operating errors, protection of parameters, fault detection	
DFA	Metrological data flow analysis	Software separation, evaluation of the impact of commands on the instrument's functions	B
CIWT	Code inspection and walkthrough	All purposes	
SMT	Software module testing	All purposes when input and output can clearly be defined	

2.4 ~~11.4~~ Test conditions and test gas generator

2.4.1 ~~11.4.1~~ Reference ambient conditions

Unless otherwise specified in the test conditions, the following table outlines the ambient conditions that shall be maintained during the testing.

Table 389

condition	Range of nominal value	Maximum variation during each test
Ambient temperature:	23 °C ± 5 °C	5 °C in total with a drift of less than 3 °C per hour
Ambient relative humidity:	50 % ± 30 %	10 %
Ambient pressure:	860 hPa to 1060 hPa	20 hPa (not applicable to long term drift tests)
concentration of hydrocarbons in the environment	≤ 2 ppm Total fraction by volume (as methane equivalent)	
AC mains voltage and frequency (if appropriate)	nominal values specified in R 126-1 , 6.10.1, table 2	values specified in R 126-1 , 6.10.1, table 2

2.4.2 ~~11.4.2~~ Relevant characteristics of human breath

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

- Evolution of the flowrate curve during the breath exhalation: increasing and decreasing flow rates during exhalation, (Annex ~~C.1A.4~~ of ~~R 126-2~~ provides explanatory information).
- Evolution of the alcohol concentration during the breath exhalation: Increasing alcohol concentration during forced exhalation in an EBA to a characteristic plateau which represents the mass concentration in the end-expiratory breath. (Annex ~~C.2A.4~~ of ~~R 126-2~~ provides explanatory information).
- Breath temperature of 34 °C.
- Relative humidity of 95 %.

2.4.3 ~~11.4.3~~ Test gas generator

The test gas generator shall be able to deliver a test gas with the target value of the mass concentration with an uncertainty less than or equal to one third of the maximum permissible error.

Taking into account the duty cycle of the test gas generator, the tests shall be conducted with the maximum frequency permitted by the EBA

2.4.3.1 ~~11.4.3.1~~ Characteristics of the test gas

Unless otherwise specified, the test gas injected without interruption into the EBA shall be characterized by the ~~following parametric values: parametric values given in table 4. Regarding the content of humidity and CO₂, the exceptions defined in table 6 may be considered at the respective tests.~~

Table 4910

Parameter	nominal value with allowed variation
delivered volume	2 L ± 0.3 L
total duration of the injection (into the breath analyzer)	greater than or equal to 5 s
type of profile	constant flowrate
Ethanol concentration	according to the respective test (0.4 mg/L if not otherwise specified)
gas temperature	34 °C ± 0.5 °C
relative humidity of the gas	95 % ± 5 % (without condensation)
carrier gas	air containing insignificant concentrations of relevant impurities with a volume fraction of CO ₂ of: 5 % ± 0.5 % vol

Commented [RK3]: Proposal of the Secretariat to solve inconsistencies with table 6

2.4.3.2 11.4.3.2 Capabilities of the test gas generator

For the different tests, the test gas generator shall be of one of the two following types.

For the complete test program, both types are needed:

- type 1: the test gas generator delivers test gases with constant mass concentrations of alcohol;
- type 2: the test gas generator delivers a test gas which fulfills the breath profile defined in ~~R 126-2, 2.4.2~~11.4.2.

The following table classifies the features of the different test gas generators and simplified means stated in this recommendation.

Please note that in the following clauses, ~~compressed dry gases from cylinders~~ will also be covered by the term “test gas generator”.

Please also note that this table 5 is not meant to exclude the enhancement of advanced generator types with more features than currently marked or shown.

Test reports shall indicate which generator and, if applicable the applied enhancements for this generator, was used for each test.

Table 5
Table 51011

feature	type 2 generator	type 1 generator	simplified means- type 1 without CO2	simplified means – dry gas	
				with CO2	without CO2
capability to generate profiles defined in 11.4.2	X				
gas temperature: 34 °C ± 0.5 °C	X	X	X		
relative humidity range: 95 % ± 5 %	X	X	X		
CO2 concentration volume fraction: 5 % ± 0.5 % vol	X	X		X	
realization of different flow rates	X	X	X	X	X

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

Annex ~~D-A~~ of R 126-2 provides ~~explanatory information and about the~~ reference principles to be used ~~as well as~~ ~~examples for test gas generators, for implementing tests and establishing test gas generator performance.~~

To test the capability of the EBA to make measurements on the end expiratory breath, the test gas generator used by the laboratory shall be capable of delivering test samples with the specification of 11.4.3.1, but with flowrate and alcohol profiles described in 11.4.2, described here as a type 2 gas generator. The type 2 test gas generator is the only one capable of delivering a test sample close to human physiology.

So, for the complete test program the type 2 generator will be sufficient, but for certain tests it is allowed to use test gases deriving from a type 1 generator (constant ethanol concentration) or even more simplified means (dry gases in cylinders). 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 ~~following~~ table ~~126~~ shows an overview which simplified test gases are allowed to be used for each test.

The test report shall indicate for each test what kind of test means have been used as well as the test gas parameters applied. Test reports shall indicate when other gases were used and how their equivalence with the reference gases was established.

Commented [RK4]: amended according to decisions taken in the Paris-meeting (see minutes point (12))

Commented [RK5]: Proposal of the Secretariat to clarify that the provision of various flow rates is a basic function of all generator types.

Table 6112

test clause of part 2	dry gases allowed	gases without CO2 allowed	remarks
§ 11.5.22.5.5.1	MPE and repeatability accuracy tests		
2.5.5.2	drift		
2.5.5.3	memory effects		
§ 11.5.32.5.6	influence factors of the condition of injection	X	X
§ 11.5.4.12.5.7.1	Temperature test Physical influence factors		X
§ 11.5.4.22.5.7.2	Damp heat, steady-state		X
§ 11.5.4.32.5.7.3	Static atmospheric pressure	X	X
§ 11.5.4.42.5.7.4	Random vibration	X	X
§ 11.5.4.52.5.7.5	DC mains voltage variations	X	X
§ 11.5.4.62.5.7.6	AC mains voltage variation	X	X
§ 11.5.4.72.5.7.7	AC mains frequency variation	X	X
§ 11.5.4.82.5.7.8	Low voltage of internal battery	X	X
§ 11.5.4.92.5.7.9	Voltage variations of a vehicle battery	X	X
§ 11.5.4.102.5.7.10	Hydrocarbons in the environment	X	X
§ 11.5.4.11	CO2 in the test gas	X	
§ 11.5.5.12.5.8.1	Conducted currents by RF EM fields disturbance tests	X	X
§ 11.5.5.22.5.8.2	Radiated RF electromagnetic fields	X	X
§ 11.5.5.32.5.8.3	Electrostatic discharges	X	X
§ 11.5.5.42.5.8.4	Bursts on AC and DC mains	X	X
§ 11.5.5.52.5.8.5	Surges on AC + DC mains power lines	X	X
§ 11.5.5.62.5.8.6	Bursts on signal, data and control lines	X	X
§ 11.5.5.72.5.8.7	Ripple on DC mains power	X	X
§ 11.5.5.82.5.8.8	DC mains voltage dips, short interruptions and variations	X	X
§ 11.5.5.92.5.8.9	AC mains voltage dips, short interruptions and reductions	X	X
§ 11.5.5.102.5.8.10	Surges on signal, data and control lines	X	X
§ 11.5.5.112.5.8.11	Electrical transients conduction along supply lines	X	X
§ 11.5.5.122.5.8.12	Electrical transient conduction via lines other than supply lines	X	X
§ 11.5.5.132.5.8.13	Mechanical shocks	X	X
§ 11.5.5.142.5.8.14	Shakes	X	X
§ 11.5.5.152.5.8.15	Damp heat cyclic (condensing)		X
§ 11.5.5.162.5.8.16	Storage test		X
§ 11.5.5.172.5.8.17	Vibration (as disturbance)	X	X
§ 11.5.5.182.5.9	physiological influence quantities	X	X
§ 11.5.62.6.1	sand and dust		X
2.6.2	salt mist		X
2.6.3	water		X

Commented [RK6]: Secretariat propose to add the name of the test to facilitate reading

Commented [DL7]: amended according to decisions taken in the Paris-meeting (see minutes point (11))

Commented [RK8]: Secretariat proposal:
Since a surface film of salt or sand +dust on the EBA could interact with a moist breath sample, these tests should not be done with dry gases!

Some of the tests defined in 11.5.3 require a generator with the ability to vary the flowrate or alcohol concentration during breath exhalation. The actual performance details of the test gas evolution for each test are described in 11.5.3. For all other tests, the flowrate and alcohol concentration may be constant during injection.

2.4.3.3 ~~11.4.3.3~~ Guidelines for the use of **compressed** dry gases ~~in cylinders~~:

- variations in atmospheric pressure, as well as the temperature of the gas shall be taken into account,
- the quality of the gas pressure regulators and the manner in which the gas is delivered to the EBA should be taken into account to minimize contamination and a change in the composition of ethanol throughout its use cycle,
- the measurement uncertainties of the test gas generator shall be taken into account in calculations of the uncertainties of the measurement.
- The main component of the gas shall be dry air. If other gas e.g. N₂ is used as main component, the equivalence to air shall be established.
- When working with dry test gas the atmospheric pressure has to be monitored and reported in the test protocol.

Commented [DL9]: amended according to decisions taken in the Paris-meeting (see minutes point (12))

2.4.4 ~~Presumption of compliance~~

~~The type of measuring instrument is presumed to comply with the provisions specified in 6.6 to 6.11 of this Recommendation, if it passes the tests (11.5.2 to 11.5.6), confirming that the error of the measuring instrument does not exceed the MPE on initial verification specified in 6.6.1 under the reference conditions in 11.4.1.~~

Commented [RK10]: Deleted according to the Paris-meeting (see minutes point (13))

2.5 ~~11.5~~ Performance tests

2.5.1 ~~11.5.1~~ General instructions

The tests specified in Part 2 of this Recommendation are designed to prove compliance of the instrument with the requirements specified in Part 1. For special situations, additional performance criteria and their associated tests may be required in order to prove compliance.

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

Before starting the process of type evaluation tests the EBA may be adjusted, if necessary in order to minimize the initial intrinsic error and if permitted by national authorities.

Thereafter no adjustment shall be carried out until all tests for the type evaluation are completed

2.5.2 Preconditions for the tests:

Unless otherwise specified, the following preconditions apply for all tests:

- Normal electric power supplied and “on” for a time period equal to or greater than the warm-up time specified by the manufacturer.
- Power supply of the EUT is to be “on” for the duration of the test and the EUT shall not be switched off.
- The EUT shall not be readjusted at any time during the test.
- The EUT shall be used in metrological test mode
- the EUT shall performed standard measurement cycles. The use of special or shorted test cycles is only allowed if specified at the respective test.
- ~~if the EUT is equipped with an internal printer, its correct function and correct printout shall be tested with each test of 2.5.7 to-2.6.3.~~

Commented [RK11]: Secretariat proposal: instead of adding in every table in “EUT performance” an additional text for the printer

2.5.3 Parameters at least to be recorded

Unless otherwise specified, the following parameters shall be recorded for all tests:

- a) ~~date and time;~~
- b) ~~ambient temperature;~~
- c) ~~ambient relative humidity;~~
- d) ~~ambient pressure;~~
- e) ~~values of the measurand;~~
- f) ~~indications and errors of the EUT;~~
- g) ~~functional performances;~~
- h) ~~if applicable: correct printout of the internal printer.~~

~~Note: with “functional performances” all laboratory-specific and/ or test-specific issues shall be covered, e.g. settings of the test gas generator or parameters of specific test equipment.~~

Commented [RK12]: to shorten the tables, the standard parameters at least to recorded are listed here now, as agreed in the Paris-meeting (see minutes point (14))

Commented [RK13]: added as agreed in the Paris meeting (see minutes point (7))

Commented [RK14]: Secretariat proposal for clarification

2.5.4 Determination of errors and faults

To rate the effect of an influence factor a disturbance on the EBA, the fault has to be determined in the following way:

- ~~The intrinsic indication is determined as the average of the prescribed number of measurements under reference conditions without disturbance. The intrinsic error will be the deviation between the intrinsic indication and the reference value.~~
- ~~The indication is determined as the average of the prescribed number of measurements during or after the impact of the influence factor or the disturbance. The error of indication will be the deviation between the indication and the reference value.~~

~~The fault is determined as the difference between indication and intrinsic indication.~~

Commented [RK15]: to shorten the tables, the standard procedure for calculation of error and faults is now given her, as agreed in the Paris-meeting

~~2.5.3.2.5.5~~ ~~11.5.2~~ Accuracy tests~~2.5.3.2.5.5.1~~ ~~11.5.2.1~~ Maximum permissible errors and repeatabilityTable ~~71213~~

Maximum permissible errors and repeatability	
Test method	repeated measurements over the complete measuring range.
Applicability	Applicable to all EBA.
Object of the test	Verification of compliance of the complete measurement range with the provisions in R 126-1 , 6.6.1 and R 126-1 , 6.7 under ambient reference conditions.
Precondition	As defined in 11.5.1
Condition of the EUT	Power is to be "on" for the duration of the test.
Test procedure in brief	The test comprises of at least 20 measurements made consecutively at each test gas concentration.
Test gases Mass concentration of ethanol	Test gas n°No.: 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) 1.90 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.
measurement conditions	ethanol concentrations: see above test gas conditions: within reference conditions as defined in R 126-2 , 2.4.3.1, table 4 and 2.4.3.2, table 6 . 11.4.3.1 ambient conditions: within reference conditions as defined in R 126-2 , 2.4.1 11.4.1 .
EUT performance	<ul style="list-style-type: none"> - number of measurements per concentration: at least 20 - time schedule: to be performed consecutively for each concentration —parameters at least to be recorded: as defined in R 126-2, 2.5.3. <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances. -
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - Each of the 20 measurement results for every test gas concentration shall comply with the requirements for the MPE specifieddefined in R 126-1, 6.6.1 - Each set of measurements shall comply with repeatability defined in R 126-1, 6.7.

Commented [RK16]: superfluous, since there is the general statement in 2.5.1 and 2.5.2, which is valid for all tests (in the following tables as well)

~~2.5.3.22.5.5.2~~ **11.5.2.2 Drift**~~Table 81314~~

Drift	
Test method	measurements with the same test gas after certain time intervals.
Applicability	Applicable to all EBA.
Object of the test	Verification of compliance with the requirements for drift (R 126-1 , 6.8).
Precondition	As defined in 11.5.1. Other tests for type approval may be performed during the time interval between the drift tests.
Condition of the EUT	Power is to be "on" for the duration of the test.
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-term drift: 4 hours after the start For long-term drift: every 2 weeks until the 6 months testing time are completed.
Measurement conditions	ethanol concentrations: for zero drift: 0.00 mg/L to 0.05 mg/L for short-term drift: 0.40 mg/L for long-term drift: 0.40 mg/L test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.4.4.3.4 ambient conditions: within reference conditions as defined in R 126-2, 2.4.14.4.4.
EUT performance	<ul style="list-style-type: none"> - number of measurements per point in time: 10 - time schedule: <ul style="list-style-type: none"> - at start - as defined in "test procedure in brief" - parameters at least to be recorded: <u>as defined in R 126-2, 2.5.3</u> a) date and time; b) ambient temperature; c) ambient relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances.
Acceptance criteria	<ul style="list-style-type: none"> - For the zero drift and the short-term drift test: the difference between the mean measurement errors of the two series of measurements shall fulfil the requirements for drift (R 126-1, 6.8.1 and 6.8.2). - 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 fulfil the requirements for long-term drift (R 126-1, 6.8.3).

~~2.5.3.3~~ ~~2.5.5.3~~ ~~11.5.2.3~~ Memory effectsTable ~~914~~15

Memory effects	
Test method	measurement of different mass concentrations of ethanol in succession.
Applicability	Applicable to all EBA.
Object of the test	Verification of compliance with the requirements for memory effects (R 126-1 , 6.9) with large differences in mass concentration as well as with small differences in mass concentration.
Precondition	As defined in 11.5.1
Condition of the EUT	Power is to be “on” for the duration of the test.
Test procedure in brief	<p>The tests comprise of:</p> <ul style="list-style-type: none"> - 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 of measurements with alternating concentrations: <ul style="list-style-type: none"> - one measurement using the higher concentration - followed immediately with one measurement using the lower gas concentration <p>This alternating test sequence will be repeated 10 times.</p> <p>For large differences in mass concentration:</p> <ul style="list-style-type: none"> - test gas No 7 is used in the event the maximum concentration of the measuring range of the EBA is 2 mg/L. - test gas n° No-8 shall be used when it is greater than 2 mg/L
Measurement conditions	<p>ethanol concentrations:</p> <p>case 1: large differences: high gas concentration: 1.50 mg/L (test gas n° No-7) or 1.90 mg/L (Test gas n° No-8)</p> <p>low gas concentration: 0.10 mg/L (test gas n° No-2)</p> <p>case 2: small differences: high gas concentration: 0.40 mg/L (test gas n° No-4)</p> <p>low gas concentration: 0.25 mg/L (test gas n° No-3)</p> <p>test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 611.4.3.1.</p> <p>ambient conditions: within reference conditions as defined in R 126-2, 2.4.111.4.1.</p>
EUT performance	<ul style="list-style-type: none"> - number of alternating test sequences: 10 - time schedule: consecutively at each test condition - parameters at least to be recorded: as defined in R 126-2, 2.5.3. <ul style="list-style-type: none"> a) date and time; b) ambient temperature; c) ambient relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances. -
Acceptance criteria	<ul style="list-style-type: none"> - Each individual measurement shall comply with the MPE as defined R 126-1, 6.6.1. - The average of the initial test series results and the average of the results for the lower concentration of the alternating cycle shall be calculated. The difference between these averagesaverage values shall fulfill the requirements for memory effects.

~~2.5.42.5.6~~ ~~11.5.3~~ **Influence factors of the conditions of injection**

For each test condition, 2 or more tests with different conditions are defined.

Table 10~~1516~~

Test method	variations of the test gas parameters.
Applicability	Applicable to all EBA.
Object of the test	Verification of compliance with the requirements for conditions of exhalation (R 126-1, 6.10.2 and 7.1.6), defined by the parameters: delivered volume; duration of the injection; variation of the flowrate as a function of time; variation of the alcohol concentration as a function of time.
Precondition	As defined in 11.5.1
Condition of the EUT	Power is to be "on" for the duration of the test.
Basic test procedure	For each test condition, 2 or more tests with different conditions are defined. For each test, 10 subsequent tests sequences shall be performed.
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: as defined at the respective tests; all other parameters within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6. 11.4.3.1 ambient conditions: within reference conditions as defined in R 126-2, 2.4. 11.4.1.
Tests	<p>a) Influence of delivered volume and injection duration</p> <p>test gas generator: type 1 or type 2</p> <p>First test:</p> <ul style="list-style-type: none"> delivered volume: 1.5 L ± 0.1 L; duration of the injection: 5 s ± 0.5 s; - variation of the flowrate as a function of time: no variation - variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o plateau duration equal to 3 s (type 2 test gas generator). <p>First test:</p> <ul style="list-style-type: none"> - delivered volume: 1.5 L ± 0.1 L; - duration of the injection: 5 s ± 0.5 s. <p>Second test:</p> <ul style="list-style-type: none"> - delivered volume: 4.5 L ± 0.3 L; - duration of the injection: 15 s ± 0.5 s; variation of the flowrate as a function of time: no variation variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or - plateau duration equal to 3 s (type 2 test gas generator).
	<p>b) Influence of flowrate and of duration of injection duration</p> <p>test gas generator: type 1 or type 2</p> <ul style="list-style-type: none"> - variation of the flowrate as a function of time: no variation <p>First test:</p> <ul style="list-style-type: none"> - delivered volume: 1.5 L ± 0.1 L; - duration of the injection: 10 s ± 0.5 s; variation of the flowrate as a function of time: no variation - variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o plateau duration equal to 4.5 s (type 2 test gas generator). <p>Second test:</p> <ul style="list-style-type: none"> - delivered volume: 3.0 L ± 0.2 L; - duration of the injection: 15 s ± 0.5 s; variation of the flowrate as a function of time: no variation - variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or

		<ul style="list-style-type: none"> o plateau duration equal to 6 s (type 2 test gas generator). <p>Third test:</p> <ul style="list-style-type: none"> - delivered volume: 4.5 L \pm 0.3 L; - duration of the injection: 7.5 s \pm 0.5 s; variation of the flowrate as a function of time: no variation - variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o plateau duration equal to 3.5 s (type 2 test gas generator).
c)	Influence of variations in the flowrate during exhalation	<p>test gas generator: type 1 or type 2</p> <ul style="list-style-type: none"> - variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o the same plateau duration in the both tests (type 2 test gas generator). <p>First test:</p> <ul style="list-style-type: none"> - delivered volume: 3.0 L \pm 0.2L; - flowrate: 0.6 L/s \pm 0.08 L/s - variation of flowrate as a function of time: no variation variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o the same plateau duration in the first and second test (type 2 test gas generator); <p>Second test:</p> <ul style="list-style-type: none"> - delivered volume: 3.0 L \pm 0.2 L; - variation in the flowrate as a function of time: <ul style="list-style-type: none"> o Initial flowrate: 0.6 L/s during 1.5 s, o between 1.5 s and 5 s the flowrate decreases to 0.2 L/s; o after 5 s, the flowrate remains equal to 0.2 L/s until the end of injection; variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o the same plateau duration in the first and second test (type 2 test gas generator);
d)	Influence of duration of the plateau during injection	<p>test gas generator: type 2</p> <ul style="list-style-type: none"> - variation of the flowrate as a function of time: no variation <p>First test:</p> <ul style="list-style-type: none"> - delivered volume: 3.0 L \pm 0.2 L; - duration of the injection: 5 s \pm 0.5 s; variation of the flowrate as a function of time: no variation - duration of the plateau: 3 s (type 1 2 test gas generator) <p>Second test:</p> <ul style="list-style-type: none"> - delivered volume: 3.0 L \pm 0.2 L; - duration of the injection: 5 s \pm 0.5 s; variation of the flowrate as a function of time: no variation - duration of the plateau: 1.5 s (type 1 2 test gas generator)
e)	Influence of an interruption in the breath flow	<p>test gas generator: type 1 or type 2</p> <ul style="list-style-type: none"> variation of the flowrate as a function of time: no variation - variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o plateau duration equal to 3 s (type 2 test gas generator) <p>First test:</p> <ul style="list-style-type: none"> - delivered volume: 2.0 L \pm 0.2 L;

	<ul style="list-style-type: none"> - duration of the injection: $5 \text{ s} \pm 0.5 \text{ s}$; - flowrate: $0.4 \text{ L/s} \pm 0.08 \text{ L/s}$ - variation of the flowrate as a function of time: no variation - The injection shall be stopped $1 \text{ s} \pm 0.5 \text{ s}$ after the start of the injection. <p>Second test:</p> <ul style="list-style-type: none"> - flowrate: $0.2 \text{ L/s} \pm 0.02 \text{ L/s}$ - duration of the injection: $15 \text{ s} \pm 0.5 \text{ s}$; - variation of the flowrate as a function of time: no variation - The injection shall be stopped at $6 \text{ s} \pm 1 \text{ s}$ after the start of the injection. (Delivered volume $\geq 1.2 \text{ L}$) <p>Third test: Verification of the detection of the end of exhalation.</p> <ul style="list-style-type: none"> - flowrate: $0.15 \text{ L/s} \pm 0.02 \text{ L/s}$ - The injection of a gas shall be supplied at a flowrate of 0.15 L/s is for $6 \text{ s} \pm 1 \text{ s}$, and then decreased to a flowrate of 0.03 L/s. to determine the “end of exhalation” of the EUT. <p>Fourth test: Short flow interruption.</p> <ul style="list-style-type: none"> - flowrate $0.4 \text{ L/s} \pm 0.08 \text{ L/s}$ - The injection shall be interrupted for a short period (e.g. 0.5 s) and then continued.
EUT performance	<ul style="list-style-type: none"> - number of test sequences per test condition: 10 - time schedule: consecutively at each test condition - parameters at least to be recorded: as defined in R 126-2, 2.5.3. <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; - functional performances.
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - For test condition a) to d): Each measurement result shall comply with the MPE defined specified in R 126-1, 6.6.1. - For test condition e) The EBA shall not provide a measurement result. No significant Faultfault shall occur.

Commented [RK17]: added for clarification

Commented [RK18]: added for clarification

~~2.5.5.2.5.7~~ **11.5.4 Tests for operating conditions and physical influence factors**~~2.5.5.4.2.5.7.1~~ **11.5.4.1 Temperature Test (dry heat and cold)**~~Table 11.4.17~~

Temperature test (dry heat and cold)				
Applicable standards	IEC 60068-2-1; [8] , IEC 60068-2-2; [9] 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 R 126-1 , 6.6.1 under conditions of high and low temperature specified in R 126-1 , 6.10, table 2, clause a.			
Precondition	As defined in 11.5.1			
Condition of the EUT	Power is to be “on” for the duration of the test.			
Test procedure in brief	<p>The test comprises of gradual exposure to high and low temperatures not allowing condensation to occur.</p> <ul style="list-style-type: none"> - Climatic condition: “free air” (= sufficient air circulation to keep the temperature at a stable level) - Change of temperature: $\leq 1^\circ\text{C}/\text{min}$ during heating up and cooling down - Stabilizing time at each temperature: at least 2 hours - Time of exposure: at least 2 hours after the EUT has reached temperature stability <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Reference temperature of T_R 2. Specified high temperature T_H 3. Specified low temperature T_L 4. Reference temperature T_R 			
Test levels	Low ($T_{\text{amb-low}}$)	stationary EBA	Temperature 0 °C	relative humidity $\leq 50\%$
		transportable EBA	-5 °C	$\leq 50\%$
		portable EBA	-10 °C	$\leq 50\%$
	High ($T_{\text{amb-high}}$)	stationary EBA	40 °C	$\leq 39\%$
		transportable EBA	45 °C	$\leq 30\%$
		portable EBA	45 °C	$\leq 30\%$
Notes	By default: Reference temperature: $T_R = 20^\circ\text{C}$			
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: delivered volume: 1.5 L \pm 0.1 L</p> <p>duration of injection: 5 s \pm 0.5 s</p> <p>all other parameters as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.4.4.3.1</p> <p>ambient conditions: <u>temperature and humidity at the respective test level, all other parameters within reference conditions as defined in R 126-2, 2.4.1.</u></p>			
EUT performance	<ul style="list-style-type: none"> - number of measurementmeasurements per temperature: 5 - time schedule: after stabilization, towards the end of exposure time at each temperature —parameters at least to be recorded: <u>as defined in R 126-2, 2.5.3.</u> a) —date and time; b) —ambient testing temperature; c) —ambient testing relative humidity; d) —ambient pressure; e) —values of the measurand; f) —indications and errors of the EUT; - functional performances. 			
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - All errors shall be within the maximum permissible errorsMPE specified in R 126-1, 6.6.1 			

~~2.5.5.22.5.7.2~~ **11.5.4.2 Damp heat, steady state (non-condensing)****Table 12-17**

Damp heat, steady-state (non-condensing)				
Applicable standards	IEC 60068-2-78, <u>[16]</u> , <u>IEC 60068-3-4</u>			
Test method	Exposure to damp heat in steady-state ₂			
Applicability	Applicable to all EBA, but 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 MPE in <u>R 126-1</u> , 6.6.1 under conditions of high humidity and constant temperature, specified in <u>R 126-1</u> , 6.10, table 2, clause b ₂			
Precondition	As defined in 11.5.1			
Condition of the EUT	Power is to be “on” for the duration of the test.			
Test procedure in brief	The test comprises exposure to the specified high-level-temperature and the specified constant relative humidity for 48h (2x24h). The EUT shall be handled such that condensation of water on the EUT does not occur. Test sequence: 1. Specified temperature and relative humidity 2. reference conditions			
		stationary EBA	transportable EBA	portable EBA
	Ambient temperature	40 °C	45 °C	45 °C
	Relative humidity	85 %		
	Duration	2 periods of 24 hours after the EUT has reached temperature stability		
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas <u>n° No. 4</u>) test gas conditions: within reference conditions as defined in <u>R 126-2</u> , 2.4.3.1, <u>table 4 and 2.4.3.2, table 6.4.1-4.3.1</u> ambient conditions: <u>temperature and humidity at the respective test level, all other parameters within the reference conditions as defined for this test in 6.10, table 2, clause b</u> <u>R 126-2</u> , 2.4.1			
EUT performance	<div>- Number of measurements and time schedule:<div>- during exposure: 5 measurements every 24 hours at test conditions</div><div>- after exposure: after a recovery period of one hour 5 measurements at reference conditions</div></div> <div>- Parameters at least to be recorded: <u>as defined in R 126-2, 2.5.3.41-5.3:</u><div><u>a) — date and time;</u></div><div><u>b) — ambient testing temperature;</u></div><div><u>c) — ambient testing relative humidity;</u></div><div><u>d) — ambient pressure;</u></div><div><u>e) — values of the measurand;</u></div><div><u>f) — indications and errors of the EUT;</u></div><div><u>g) — functional performances.</u></div></div>			
Acceptance criteria	<div>- All functions shall operate as designed.</div> <div>- The error of the EUT is determined for each set of measurements. All errors shall be within the <u>MPE maximum permissible errors</u> specified in <u>R 126-1</u>, 6.6.1.</div>			

~~2.5.5.3~~2.5.7.3 ~~11.5.4.3~~ Static atmospheric pressure

Table 1318

Static atmospheric pressure	
Applicable standard	No applicable standards is available.
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 MPE in R 126-1, 6.6.1 under conditions of static atmospheric pressure changes to upper and lower limit specified in R 126-1, 6.10, table 2, clause c).
Precondition	As defined in 11.5.1.
Condition of the EUT	Power is to be "on" for the duration of the test.
Test procedure in brief	<p>The test comprises the exposure of the EUT to the specified upper and lower atmospheric pressures limits. Exposure is to be established for at least 10 minutes at each pressure.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Specified lower pressure limit 2. Specified upper pressure limit 3. reference conditions
Test level	Atmospheric pressure
	Lower limit 86 (± 1) kPa
	Upper limit 106 (± 1) kPa
	Uncertainty of the pressure sensor 0.15 kPa
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: delivered volume: 1.5 L ± 0.1 L duration of injection: 5 s ± 0.5 s all other parameters within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.11.4.3.1</p> <p>ambient conditions: ambient pressure as at respective test level, temperature and humidity at all other parameters within reference conditions as defined in R 126-2, 2.4.11.4.3.1.</p>
EUT performance	<ul style="list-style-type: none"> - number of measurements at each pressure level: 5 - time schedule: after stabilization at the respective pressure - parameters at least to be recorded: as defined in R 126-2, 2.5.3.11.5.3. <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances. -
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - All errors shall be within the MPE maximum permissible errors specified in R 126-1, 6.6.1.

Commented [RK19]: Secretariat propose to change the test gas conditions to the reference conditions, since we see no reason why the volume should be different from the reference condition for this test.

~~2.5.5.4.2.5.7.4~~ **11.5.4.4 Random vibration****Table 1419**

Vibration (random)		
Applicable standard	IEC 60068-2-47 [14], IEC 60068-2-64 [15], IEC 60068-3-8 [...]	
Test method	Exposure to random vibration.	
Applicability	Applicable for portable and transportable EBA.	
Object of the test	Verification of compliance with the provisions for reference conditions in 11.4.1 MPE in R 126-1, 6.6.1 under conditions of random vibration specified in R 126-1, 6.10, table 2, clause d).	
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	Power is to be "off" for the duration of the exposure. The EUT shall be switched on immediately after the exposure. The EUT shall not be readjusted at any time during the test.	
Test procedure in brief	The test comprises exposure to the vibration for at least 2 minutes per axis. 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 sequence: 1. Measurements before application of influence (at reference conditions) 2. The influence quantity shall be applied 4.3. Measurements after application of influence (at reference conditions)	
Test level	Test level	
	Total frequency range	10 – 150 Hz
	Total RMS level (mean value of acceleration)	7 m·s ⁻²
	ASD level 10-20 Hz	1 m ² ·s ⁻³
	ASD level 20-150 Hz	-3 dB/octave
Measurement conditions	Duration per axis	For each of the orthogonal directions the vibration exposure time shall be 2 minutes in each functional mode
	ethanol concentration:	0.40 mg/L (test gas n° No. 4)
	test gas conditions:	within reference conditions as defined in 11.4.3.1, R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.
EUT performance	ambient conditions:	within reference conditions as defined in R 126-2, 2.4.11.4.1
	- number of measurements before and after application:	5
	- time schedule:	before and after application of the influence quantity, the EUT shall be switched on and the measurements shall be performed consecutively after stabilization
Acceptance criteria	- parameters at least to be recorded:	as defined in R 126-2, 2.5.3.11.5.3.
	- a) —date and time;	
	- b) —ambient testing temperature;	
	- c) —ambient testing relative humidity;	
	- d) —ambient pressure;	
	- e) —values of the measurand;	
	- f) —indications and errors of the EUT;	
	- g) —functional performances.	
	- — as defined in 11.5.3.	
	- The error of the EBA 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 MPE specified in R 126-1, 6.6.1.	

Commented [RK20]: editorial correction of a logic flaw, proposed by Australia

Commented [RK21]: already stated in the lines below

Commented [RK22]: already stated in 2.5.2, not necessary to repeat here

Commented [RK23]: the actual test sequence was missing

~~2.5.5.5.7.5~~ ~~11.5.4.5~~ DC mains voltage variations

Table 1520

DC mains voltage variation		
Applicable standard	IEC 60654-2 [19]	
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 MPE in 4.4 R 126-1, 6.6.1 under conditions of DC mains power voltage changes between upper and lower limit specified in R 126-1 , 6.10, table 2, clause e.	
Precondition	As defined in 11.5.1	
Condition of the EUT	Power is to be “on” for the duration of the test.	
Test procedure in brief	<p>The test comprises exposure to the specified power supply condition for a period of time sufficient for achieving stability -at the relevant voltage level and subsequently performing the required measurements.</p> <p>Test Sequence:</p> <ol style="list-style-type: none"> 1. Reference voltage level 2. Upper voltage level 3. Lower voltage level 4. Reference voltage level 	
Test lev level	Applied DC operating range	As specified by the manufacturer, but not less than $U_{nom} - 15 \% \leq U_{nom} \leq U_{nom} + 10 \%$
	Reference voltage level	Nominal DC voltage specified by the manufacturer.
	Upper voltage limit	DC level at which the EUT has been designed to automatically detect high-level conditions.
	Lower voltage limit	DC level at which the EUT has been designed to automatically detect low-level conditions.
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.11.4.3.1</p> <p>ambient conditions: within reference conditions as defined in R 126-2, 2.4.111.4.1</p>	
EUT performance	<ul style="list-style-type: none"> - number of measurements at each voltage level: 5 - time schedule: after stabilization at the relevant voltage level - parameters at least to be recorded: _____ <ul style="list-style-type: none"> a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure; e) — values of the measurand; f) — indications and errors of the EUT; g) a) functional performances; as defined in R 126-2, 2.5.3, plus h) b) reference voltage at beginning and end, high voltage and low voltage 	
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - The errors of the EUT shall be determined for the reference voltage, the upper voltage and the lower voltage. - All errors shall be within the maximum permissible errorsMPE specified in R 126-1, 6.6.1. 	

~~2.5.5.6~~2.5.7.6 ~~11.5.4.6~~ AC mains voltage variations

Table 1621

AC mains voltage variation		
Applicable standards	IEC/TR3 61000-2-1 [...] IEC TR 61000-4-1 [...] [21]	
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 transportable 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 MPE in 11.4 R 126-1, 6.6.1 under conditions of AC mains network voltage changes between upper and lower limit specified in R 126-1, 6.10, table 2, clause f₂ .	
Precondition	As defined in 11.5.1	
Condition of the EUT	The power is to be “on” for the duration of 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 stability at the relevant voltage level and subsequently performing the required measurements. Test Sequence: <ol style="list-style-type: none"> 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.	
Test Levels	U _{nom}	Nominal AC voltage specified by the manufacturer
	If a range is specified by the manufacturer:	U _{nom1} concerns the highest U _{nom2} concerns the lowest value
	If only one nominal mains voltage value (U _{nom}) is specified by the manufacturer:	then U _{nom1} = U _{nom2} = U _{nom}
	reference voltage level	to (U _{nom1} + U _{nom2}) / 2
	Upper level	U _{nom1} + 10 %
Measurement conditions	ethanol concentration:	0.40 mg/L (test gas n° No. 4)
	test gas conditions:	within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.11.4.3.1
	ambient conditions:	within reference conditions as defined in R 126-2, 2.4.11.4.1
EUT performance	<ul style="list-style-type: none"> - number of measurements per voltage level: 5 - time schedule: after stabilization at the relevant voltage level - parameters at least to be recorded: <ol style="list-style-type: none"> a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure; e) — values of the measurand; f) — indications and errors of the EUT; g) — functional performances; a) as defined in R 126-2, 2.5.3, plus h) b) reference voltage at beginning and end, high voltage and low voltage. 	
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - The errors of the EUT shall be determined for the reference voltage, the upper voltage and the lower voltage. All errors shall be within the maximum permissible errors MPE specified in R 126-1, 6.6.1 .	

~~2.5.5.7.2.5.7.7~~ 11.5.4.7 AC mains frequency variations

Table 1722

AC mains frequency variation	
Applicable standards	IEC/TR3 61000-2-1 [...], IEC 61000-2-2 [...], IEC TR 61000-4-1 [...] [21]
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 MPE in 4.4 R 126-1, 6.6.1- under conditions of AC mains network power frequency changes between upper and lower limit specified in R 126-1, 6.10, table 2, clause g.
Precondition	As defined in 11.5.1
Condition of the EUT	The power is to be “on” for the duration of the test.
Test procedure in brief	The test comprises the exposure of the EUT to a variation in AC mains power frequency for a period of time sufficient for achieving stability at the relevant frequency level and for performing the required measurements. Test Sequence: <ol style="list-style-type: none"> 1. Reference frequency 2. Upper frequency 3. Lower frequency 4. Reference frequency
Test levels	f_{nom} nominal mains frequency value as specified by the manufacturer
	If a range is specified by the manufacturer: f_{nom1} concerns the highest and f_{nom2} concerns the lowest value
	If only one nominal mains frequency value (f_{nom}) is specified by the manufacturer: $f_{nom1} = f_{nom2} = f_{nom}$
	Reference frequency $(f_{nom1} + f_{nom2}) / 2$
	Upper level $f_{nom1} + 2\%$
	Lower level $f_{nom2} - 2\%$
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6 4.4.3.1, ambient conditions: within reference conditions as defined in R 126-2, 2.4.14.4.4
EUT performance	<ul style="list-style-type: none"> - number of measurements per frequency level: 5 - time schedule: after stabilization at the relevant frequency level - parameters at least to be recorded: <ol style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances. a) as defined in R 126-2, 2.5.3, plus h)b) reference voltage at beginning and end, high voltage and low voltage
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - The errors of the EUT shall be determined for the reference frequency, the upper frequency and the lower frequency. All errors shall be within the maximum permissible errors MPE specified in R 126-1, 6.6.1.

~~2.5.5.8, 2.5.7.8~~ **11.5.4.8 Low voltage of internal battery****Table 1823**

Low voltage of internal battery (not connected to the mains power)		
Applicable standards	No applicable 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 MPE in 4.4 R 126-1, 6.6.1 during low battery voltage specified in R 126-1, 6.10 , table 2, clause h.	
Precondition	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 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.	
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 stability at the relevant voltage level and for performing the required measurements. The test sequence is as follows: 5. Reference Voltage level 6. Lower voltage level 7. 0.9 *lower voltage level 8. Reference voltage level	
Test level:	U_{bmin} Lower limit of the voltage	The lowest voltage at which the EUT functions properly according to the specifications (U_{bmin})
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No -4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6 4.4.3.1 ambient conditions: within reference conditions as defined in R 126-2, 2.4.1 4.4.4	
EUT performance	<ul style="list-style-type: none"> - number of measurements at each voltage level: 5 - time schedule: after stabilization at the relevant voltage level - parameters at least to be recorded: as defined in R 126-2, 2.5.3. <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances. 	
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - at 0.9 U_{bmin}: the EUT shall either: <ul style="list-style-type: none"> o cease to function (turn itself off), o not allow any measurements and give an appropriate error message or o shall measure correctly - The errors of the EUT shall be determined for the lower voltage level(s) and the reference voltage level. All errors shall be within the maximum permissible errorsMPE specified in R 126-1, 6.6.1. 	

~~2.5.5.9~~2.5.7.9 ~~11.5.4.9~~ Voltage variations of a road vehicle battery

Table 1924

Voltage variations of a road vehicle battery					
Applicable standard	ISO 16750-2 [...] <u>[35]</u>				
Test method	Variation in supply voltage.				
Applicability	Applicable to all transportable 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 <u>MPE</u> in 4.4 R 126-1, 6.6.1 under conditions of high (while charging) and low battery voltage specified in <u>R 126-1, 6.10.1, table 2, clause i</u> .				
Precondition	As defined in 11.5.1				
Condition of the EUT	Power is to be "on" for the duration of 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 stability at the relevant voltage level and performing the required measurements at these conditions. Test sequence: 1. Upper voltage level 2. Lower voltage level 3. Reference voltage level				
Test level	Nominal battery voltage	$U_{nom} = 12\text{ V}$		$U_{nom} = 24\text{ V}$	
		Lower limit	Upper limit	Lower limit	Upper limit
		9V	16V	16V	32V
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: within reference conditions as defined in <u>R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6</u> 4.4.3.1 . ambient conditions: within reference conditions as defined in <u>R 126-2, 2.4.1</u> 4.4.1 .				
EUT performance	<ul style="list-style-type: none"> - number of measurements per voltage level: 5 - time schedule: after stabilization at the relevant voltage level - parameters at least to be recorded: <u>as defined in R 126-2, 2.5.3.1</u>5.3. a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure; e) — values of the measurand; f) — indications and errors of the EUT; g) — functional performances. 				
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - The errors of the EUT shall be determined for the upper voltage level, for the lower voltage level and for the reference voltage level. All errors shall be within the maximum permissible errors <u>MPE</u> specified in <u>R 126-1, 6.6.1</u> .				

~~2.5.5.102.5.7.10~~ ~~11.5.4.10~~ Hydrocarbons in the environment

Table 2025

Total fraction by volume of hydrocarbons in the environment		
Applicable standard	Currently no No applicable standard is available.	
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 MPE in 4.4 R 126-1, 6.6.1 under conditions of being exposed to the level of hydrocarbons in the environment specified in R 126-1, 6.10 1, table 2 clause j.	
Precondition	As defined in 11.5.1	
Condition of the EUT	Power is to be "on" for the duration of the test.	
Test procedure in brief	The test comprises exposure to a simulated environment containing a specific fraction of hydrocarbons. Test sequence: 1. Measurements at influence conditions 2. Measurements at reference condition	
Test level	Total fraction of hydrocarbons (as methane equivalent)	5 ppm ± 1 ppm (by volume)
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No -4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6 ambient conditions: within reference conditions as defined in R 126-2, 2.4.1+4.4.	
EUT performance	<ul style="list-style-type: none"> - number of measurements per condition: 5 - time schedule: consecutively at each test condition after stabilization at the relevant condition - parameters at least to be recorded: <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances; a) as defined in R 126-2, 2.5.3, plus h) type and volume concentration of applied hydrocarbons. 	
Acceptance criteria	<ul style="list-style-type: none"> - All functions shall operate as designed. - The errors of the EUT shall be determined for the influence condition and for the reference condition. All errors shall be within the maximum permissible errors MPE specified in R 126-1, 6.6.1.	

Table 2126

Influence of the volume fraction of CO ₂ in the test gas	
Test method	measurements with raised CO ₂ -content in the test gas.
Applicability	Applicable for all EBA.
Object of the test	Verification of compliance with the provisions for MPE in R 126-1, 6.10.46.6.1, table 2, clause k , under conditions of raised CO ₂ in the test gas as specified in R 126-1, 6.10.1, table 2, clause k.
Precondition	As defined in 11.5.1
Condition of the EUT	Power is to be "on" for the duration of the test.
Test procedure in brief	The test comprises of 5 measurements with a test gas with raised CO ₂ -content and 5 measurements with a standard test gas, both of the same ethanol concentration Test sequence: 1. measurements with test gas with raised CO ₂ -content; 2. measurements with standard test gas
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) plus 108 % vol of CO₂ 0.40 mg/L (test gas n° No. 4) test gas conditions: CO₂-concentration as specified, all other parameters within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6 11.4.3.1 ambient conditions: within reference conditions as defined in R 126-2, 2.4.1 11.4.1
EUT performance	- number of measurements per test gas: 5 - time schedule: consecutively with each test gas - parameters at least to be recorded: as defined in R 126-2, 2.5.311.5.3. a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances.
Maximum allowable variations	- All functions shall operate as designed. - The errors of the EUT shall be determined for the influence condition and the reference condition. All errors shall be within the MPE specified in R 126-1, 6.6.1.

Commented [RK24]: amended according the decision taken in the Paris-meeting(see minutes point (21))

~~2.5.6.2.5.8~~ ~~11.5.5~~ Disturbances tests~~2.5.6.4.2.5.8.1~~ ~~11.5.5.1~~ Conducted (common mode) currents generated by RF EM fieldsTable ~~227~~28

Conducted (common mode) currents generated by RF EM fields				
Applicable standard	IEC 61000-4-6 [...] 26]			
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 R 126-1, 6.11.1 while exposed to electromagnetic fields specified in R 126-1, 6.11.1, table 3, clause ab .			
Precondition	As defined in 11.5.1			
Condition of the EUT	Power is to be "on" for the duration of the test.			
Test procedure in brief	<p>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.</p> <p>The characteristics of the test equipment consisting of an RF generator, (de-) coupling devices, attenuators, etc. shall be verified before connecting the EUT.</p> <p>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.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance 			
Test level	Frequency range	RF amplitude	AM, sine wave modulation	
	0.15 – 80 MHz	10 V (e.m.f.)	80 %	1 kHz
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 64.4.3.1.</p> <p>ambient conditions: within reference conditions as defined in R 126-2, 2.4.1.4.1</p>			
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5 - number of measurements during disturbance: 5 - parameters at least to be recorded: <ul style="list-style-type: none"> a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure; e) — values of the measurand; f) — indications and errors of the EUT; g) — functional performances; a) as defined in R 126-2, 2.5.3, plus h) applied RF (e.m.f.), voltage level. 			
Acceptance criteria	<ul style="list-style-type: none"> — The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation). — The error of indication is determined as the average of the errors of five measurements (determined during the disturbance). <p>The fault is determined (difference between error of indication and intrinsic error).</p> <p>The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4</p> <ul style="list-style-type: none"> - Either significant faults (see 3.1.13) 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. 			

~~2.5.6.22.5.8.2~~ **11.5.5.2 Radiated RF electromagnetic fields**

This test in metrological test mode require a substantial amount of test time.

The following test schemes A or B shall be applied:

- **Test scheme A:**

The manufacturer may implement a test mode to reduce test time. This test mode shall cover all possible influences caused by disturbances.

All output signals of the relevant sensors are monitored after determining what the influence on the measurement result will be. All these signals will have their own MPE.

For this special test mode, the testing procedure applied by the testing laboratory shall be discussed with the manufacturer and approved by the OIML issuing Authority. The manufacturer shall provide the means (monitoring system) and determine which sensors are relevant (with the MPE).

If a deviation is detected for one output signals at one frequency, 5 measurements (of ethanol concentration) shall be performed at this frequency.

If no deviation is detected, at least 5 measurements of ethanol concentration shall be conducted during the frequency range (see test level) with the maximum frequency permitted by the EBA to perform the maximum standard measurement cycles (if necessary several frequency ranges shall be applied).

- **Test scheme B**

The instrument performs the measurements repeatedly until stopped. Measuring ambient air for zero-setting is considered as part of the measurements. The time between each measurement is taken into account during the relevant disturbance test.

The method applied by the testing laboratory to cover the frequency range shall be reported in detail in the Evaluation Report.

Table 2328

Radiated RF electromagnetic fields				
Applicable standard	IEC 61000-4-3; [23]; IEC 61000-4-20 [29]			
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 R 126-1, 6.11.1 under conditions of exposure to electromagnetic fields specified in R 126-1, 6.11.1, table 3, clause a.			
Precondition	As defined in 11.5.1			
Condition of the EUT	Power is to be "on" for the duration of the test. <u>The electrical power supplied to the EUT shall not be switched off except for a reset when a significant fault has been indicated.</u>			
Test procedure in brief	<p>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.</p> <p>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.</p> <p>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. <u>0.5 s.</u></p> <p>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.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance 			
Test level	Frequency range	RF amplitude	AM, sine wave modulation	
	26 - 80 ¹⁾ MHz	10 V/m	80 %	1 kHz
	80 - 3000 <u>6000</u> MHz	10 V/m	80 %	1 kHz
Note	1) Only where the instrument is not employing any cable or cable connection.			

Commented [RK25]: Proposal of the Secretariat to allow special test mode for the RF electromagnetic fields (see minutes note (15))

Commented [RK26]: amended according to the proposal and with a confirmation of accredited test houses that this test range could be realized within the normal scope of the accreditation for these tests.

Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No- 4) test gas conditions: within reference conditions as defined in <u>R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6</u> 4.4.3.1 ambient conditions: within reference conditions as defined in <u>R 126-2, 2.4.1.4.4</u> 4.4
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5 - number of measurements during disturbance: <u>5</u>Depending on the actual test set-up - parameters at least to be recorded: <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances; a) as defined in R 126-2, 2.5.3, plus h) field strength level.
Acceptance criteria	<ul style="list-style-type: none"> The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation). The error of indication is determined as the average of the errors of five measurements (determined during the disturbance). The fault is determined (difference between error of indication and intrinsic error). <u>Test scheme A:</u> <ul style="list-style-type: none"> o All output signals shall be within their own MPE o For the measurement of ethanol concentration-, the Test scheme B acceptance criteria shall be applied. <u>Test scheme B:</u> <ul style="list-style-type: none"> o <u>The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4.</u> o Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. o It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result.

~~2.5.6.3, 2.5.8.3~~ ~~11.5.5.3~~ Electrostatic discharges

Table 2429

Electrostatic discharges			
Applicable standard	IEC 61000-4-2 [...] [22]		
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 R 126-1 , 6.11.1 in case of direct exposure to electrostatic discharges or such discharges in the neighborhood of the EUT specified in R 126-1 , 6.11.1, table 3, clause b.		
Precondition	As defined in 11.5.1		
Condition of the EUT	Power is to be "on" for the duration of the test.		
Test procedure in brief	<p>The test comprises exposure of the EUT to electrical discharges.</p> <p>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.</p> <p>An EUT not equipped with a safety ground connection shall first be fully discharged before exposure to a next discharge.</p> <p>At least 10 discharges per preselected discharge location shall be applied.</p> <p>The number of points of application on each surface will depend on the size of the instrument and shall be defined according to IEC 61000-4-2. The tested points shall be described in the test report.</p> <p>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.</p> <p><i>Direct application:</i> 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.</p> <p>On insulated surfaces only the air discharge mode can be applied. The EUT is approached by the charged electrode until a spark discharge occurs.</p> <p><i>Indirect application:</i> The discharges are applied in the contact mode only on coupling planes mounted in the vicinity of the EUT.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance 		
Test level	Charge voltage	-Contact discharge	6 kV
		Air discharge	8 kV
	time interval between successive discharges		At least 1 s
	number of discharges per preselected discharge location		At least 10
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6, 11.4.3.1 ambient conditions: within reference conditions as defined in R 126-2, 2.4.11.4.1		
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5; - number of measurements during disturbance: 5 - parameters at least to be recorded: <ol style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure e) values of the measurand; f) indications and errors of the EUT; g) functional performances; a) as defined in R 126-2, 2.5.3, plus h) b) discharge type, level and surface 		
Acceptance criteria	The intrinsic error is errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4 the average errors of five measurements (under reference conditions without perturbation);		

	<ul style="list-style-type: none">—The error of indication is determined as the average of the errors of five measurements (determined during the disturbance.)—The fault is determined (difference between error of indication and intrinsic error):<ul style="list-style-type: none">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.
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~~2.5.6.4, 2.5.8.4~~ **11.5.5.4 Bursts (transients) on AC and DC mains****Table 2530**

Bursts (transients) on AC and DC mains	
Applicable standards	IEC 61000-4-4 [...] [24]
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 transportable EBA powered by a road vehicle battery.
Object of the test	Verification of compliance with the provisions for disturbances in <u>R 126-1</u> , 6.11.1 during conditions where electrical bursts are superimposed on the mains voltage specified in <u>R 126-1</u> , 6.11.1, table 3, clause c.
Precondition	As defined in 11.5.1
Condition of the EUT	Power is to be "on" for the duration of the test.
Test procedure in brief	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. A burst generator as defined in the referred standard shall be used. The characteristics of the generator shall be verified before connecting the EUT. Both positive and negative polarity of the bursts shall be applied. 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. Test sequence: 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance
Test level	Amplitude (peak value) 1kV
	Repetition rate 5 kHz
	duration of the test for each amplitude and polarity ≥ 1 min
	number of bursts (each for positive and negative polarity) 10
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: within reference conditions as defined in <u>R 126-2</u> , 2.4.3.1, table 4 and 2.4.3.2, table 6 11.4.3.1 ambient conditions: within reference conditions as defined in <u>R 126-2</u> , 2.4.1 11.4.1
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5. - number of measurements (during disturbance): 5 - time schedule: consecutively at each test condition - parameters at least to be recorded: <u>as defined in R 126-2</u>, 2.5.3. a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure e) — values of the measurand; f) indications and errors of the EUT;
Acceptance criteria	The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) The error of indication is determined as the average of the errors of five measurements (determined during the disturbance). The fault is determined (difference between error of indication and intrinsic error) The errors and fault of the EUT shall be determined as prescribed in R 126-2 , 2.5.4. <ul style="list-style-type: none"> - 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.

~~2.5.6.5.2.5.8.5~~ ~~11.5.5.5~~ Surges on AC and DC mains power lines

Table 2634

Surges on AC and DC mains power lines				
Applicable standard	IEC 61000-4-5 4.25.1			
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 (transportable EBA).			
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 during conditions where electrical surges are superimposed on the mains voltage specified in R 126-1, 6.11.1, table 3, clause d.			
Precondition	As defined in 11.5.1			
Condition of the EUT	Power is to be "on" for the duration of the test.			
Test procedure in brief	<p>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.</p> <p>A surge generator as defined in the referred standard shall be used. The characteristics of the generator shall be verified before connecting the EUT.</p> <p>The injection network circuit depends on the applicable conductor and is defined in the referred standard. At least 3 positive and 3 negative surges shall be applied.</p> <p>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.</p> <p>The surges are applied during all the time necessary to perform the test; to that purpose more surges than indicated above may be necessary.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance 			
Test level	Mains mode	AC		DC
		Line to line	Line to ground	Line to line Line to ground
		1.0 kV	2.0 kV	1.0 kV 2.0 kV
	Number of surges	3 positive 3 negative	3 positive 3 negative	3 positive 3 negative
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° 4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.11.4.3.1 ambient conditions: within reference conditions as defined in R 126-2, 2.4.11.4.1			
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5 - number of measurements (during disturbance): 5 - time schedule: consecutively at each test condition - parameters at least to be recorded: as defined in R 126-2, 2.5.3. <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure 			
Acceptance criteria	<ul style="list-style-type: none"> The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation). The error of indication is determined as the average of the errors of five measurements (determined during the disturbance.) The fault is determined (difference between error of indication and intrinsic error). The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4. - 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. 			

~~2.5.6.6~~ ~~2.5.8.6~~ ~~11.5.5.6~~ Bursts on signal, data and control linesTable 27~~32~~

Bursts (transients) on signal, data and control lines		
Applicable standards	IEC 61000-4-4 [...] [24]	
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 R 126-1 , 6.11.1 during conditions where electrical bursts are superimposed on I/O and communication ports specified in R 126-1 , 6.11.1, table 3, clause e.	
Precondition	As defined in 11.5.1	
Condition of the EUT	Power is to be "on" for the duration of the test.	
Test procedure in brief	<p>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.</p> <p>A burst generator as defined in the referred standard shall be used. The characteristics of the generator shall be verified before connecting the EUT.</p> <p>Both positive and negative polarity of the bursts shall be applied.</p> <p>Test sequence:-</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance 	
Test level	Amplitude (peak value)	1 kV
	Repetition rate	5 kHz
	duration of the test	≥ 1 min for each amplitude and polarity
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° N0-4)</p> <p>test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 611.4.3.1</p> <p>ambient conditions: within reference conditions as defined in R 126-2, 2.4.111.4.1.</p>	
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5. - number of measurements (during disturbance): 5 - time schedule: consecutively at each test condition - parameters at least to be recorded: <ul style="list-style-type: none"> a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure e) — values of the measurand; f) — indications and errors of the EUT; g) — functional performances. a) as defined in R 126-2, 2.5.3, plus h) b) exposed conductors 	
Acceptance criteria	<p>The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation). The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4.</p> <p>— The error of indication is determined as the average of the errors of five measurements (determined during the disturbance.</p> <p>— The fault is determined (difference between error of indication and intrinsic error).</p> <p>Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.</p> <ul style="list-style-type: none"> - It is acceptable when during the disturbance test the breath analyzer is not providing a measurement result. 	

~~2.5.6.7, 2.5.8.7~~ **11.5.5.7 Ripple on DC mains power****Table 2833**

Ripple on DC mains power		
Applicable standard	IEC 61000-4-17 [...] [28]	
Test method	Introducing a ripple voltage on the DC input power port.	
Applicability	<p>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</p> <p>Not applicable to:</p> <ul style="list-style-type: none"> - transportable EBA powered by a road vehicle battery and - transportable EBA connected to battery charger systems with incorporated switch mode converters) 	
Object of the test	Verification of compliance with the provisions for disturbances in <u>R 126-1</u> , 6.11.1 under conditions of a ripple on the DC mains voltage specified in <u>R 126-1</u> , 6.11.1, table 3, clause f.	
Precondition	As defined in 11.5.1	
Condition of the EUT	Power is to be “on” for the duration of the test.	
Test procedure in brief	<p>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.</p> <p>A test generator as defined in the referred standard shall be used. Before starting the tests, the performance of the generator shall be verified.</p> <p>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.</p> <p>The waveform of the ripple, at the output of the test generator, has a sinusoid-linear character.</p> <p>The test level is a peak-to-peak voltage expressed as a percentage of the nominal DC voltage, U_{DC}.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance 	
Test level	Percentage of the nominal DC voltage U_{DC}	2%
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: within reference conditions as defined in <u>R 126-2</u>, 2.4.3.1, table 4 and 2.4.3.2, table 6 4.4.3.1</p> <p>ambient conditions: within reference conditions as defined in <u>R 126-2</u>, 2.4.1 4.4.1</p>	
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5 - number of measurements (during disturbance): 5 - time schedule: consecutively at each test condition - parameters at least to be recorded: as defined in R 126-2, 2.5.3. <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; - functional performances: _____ 	
Acceptance criteria	<ul style="list-style-type: none"> - The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) - The error of indication is determined as the average of the errors of five measurements (determined during the disturbance) - The fault is determined (difference between error of indication and intrinsic error). - The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4 - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. 	

Table 293435

DC mains voltage dips, short interruptions and (short term) variations					
Applicable standard	IEC 61000-4-29 [30]				
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: transportable EBA powered by a road vehicle battery and EBA requiring a DC to AC conversion.				
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 under conditions of disturbances on the DC mains voltage specified in R 126-1, 6.11.1, table 3, clause g.				
Precondition	As defined in 11.5.1				
Condition of the EUT	Power is to be “on” for the duration of the test.				
Test procedure in brief	<p>A test generator as defined in the referred standard shall be used. Before starting the tests, the performance of the generator shall be verified.</p> <p>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 EUT shall be tested for each of the specified voltage variations.</p> <p>The disturbances are applied during all the time necessary to perform the test; to that purpose more disturbances than indicated above may be necessary.</p> <p>Test sequence:</p> <ol style="list-style-type: none">Measurements before disturbance (at reference conditions)Measurements during disturbance				
Test level	Voltage dips	40 and 70	%Amplitude of the rated voltage	Duration	Test condition Unit
		test a	Amplitude40 %	0.01 s; 0.03; 0.1; 0.3; 1 s	slow impedance % of the rated voltage
		test b		1 s	
		test c	70 %	0.01s	
		test d	1 s		
	Short interruptions	test e	0 % Test condition Amplitude	0.001 s	High impedance and/or low high impedance % of the rated voltage
		test f		0.001; 0.003; 0.01; 0.03; 0.1; 0.3; 1 s	
	Voltage variations	test g	85 and 120 %	0.1 s; 10 s	low impedance % of the rated voltage
		test h		10 s	
		test i	120 %	0.1 s; 0.1; 0.3; 1; 3; 10 s	
test j		10 s			
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6</p> <p>ambient conditions: within reference conditions as defined in R 126-2, 2.4.14.4.1</p>				
EUT performance	<ul style="list-style-type: none">number of measurements at reference conditions (before disturbance): 5number of measurements (during disturbance): 5 for each test condition of the different dips and reductiontime schedule: consecutively at each test conditionparameters at least to be recorded:<ul style="list-style-type: none">a) date and time;b) ambient testing temperature;c) ambient testing relative humidity;				

Commented [RK27]: amended according to the revised table

	<p>d) — ambient pressure; e) — values of the measurand; f) — indications and errors of the EUT; g) — functional performances; a) — as defined in R 126-2, 2.5.3, plus h) percentage of voltage reduction and duration.</p>
Acceptance criteria	<p>The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4 for each test condition.</p> <p>— The intrinsic error is errors and fault of the EUT shall be determined as the average of the errors of five measurements (under reference conditions without perturbation);</p> <p>— The error of indication is determined as the average of the errors of five measurements (determined during the disturbance);</p> <p>The fault is determined (difference between error of indication and intrinsic error) for each of the different dips and reductions.</p> <ul style="list-style-type: none"> - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.

~~2.5.6.9~~2.5.8.9 ~~11.5.5.9~~ AC mains voltage dips, short interruptions and voltage variationsTable 30~~35~~36

AC mains voltage dips, short interruptions and reductions					
Applicable standards	IEC 61000-4-11 [...] <u>[27]</u> , IEC 61000-6-1 [...] <u>[31]</u> , IEC 61000-6-2 [...] <u>[32]</u>				
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 transportable EBA powered by a road vehicle battery.				
Object of the test	Verification of compliance with the provisions for disturbances in <u>R 126-1</u> , 6.11.1 under conditions of short time mains voltage reductions specified in <u>R 126-1</u> , 6.11.1, table 3, clause g.				
Precondition	As defined in 11.5.1				
Condition of the EUT	Power is to be "on" for the duration of the test.				
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 sequence: 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance				
Test Level	Voltage dips-Short interruptions	Test a	100 %	0.5 cycles	<u>low impedance</u>
		Test b	100 %	1 cycle	
		Test c	30 %	25 cycles	
	<u>Voltage dips</u>	100-%Test d	> 95 %	250 cycles	<u>high impedance</u>
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No-4) test gas conditions: within reference conditions as defined in <u>R 126-2</u> , 2.4.3.1, table 4 and 2.4.3.2, table 6 <u>4.4.3.1</u> ambient conditions: within reference conditions as defined in <u>R 126-2</u> , 2.4.1 <u>4.4.1</u>				
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5; - number of measurements (during disturbance): _____ 5 for each of the different dips and reduction<u>test condition</u> - time schedule: consecutively at each test condition - parameters at least to be recorded <ul style="list-style-type: none"> a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure; e) — values of the measurand; f) — indications and errors of the EUT; g) — functional performances; a) as defined in R 126-2, 2.5.3, plus h)b) percentage of voltage reduction and duration. 				
Acceptance criteria	— The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation). — The error of indication is determined as the average of the errors of five measurements (determined during the disturbance). The fault is determined (difference between error of indication and intrinsic error) for each of the different dips and reductions.				

Commented [RK28]: amended according to the revised table 3

	<p>The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4 for each test condition.</p> <ul style="list-style-type: none">- 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.
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~~2.5.6.102.5.8.10~~ 11.5.5.10 Surges on signal, data and control lines

Table 313637

Surges on signal, data and control lines				
Applicable standard	IEC 61000-4-5 [...] 25]			
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 EBA connected to a local power source through an indoor network.			
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 during conditions where electrical surges are superimposed on I/O and communication ports specified in R 126-1, 6.11.1, table 3, clause h.			
Precondition	As defined in 11.5.1			
Condition of the EUT	Power is to be "on" for the duration of the test.			
Test procedure in brief	<p>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.</p> <p>A surge generator as defined in the referred standard shall be used. The characteristics of the generator shall be verified before connecting the EUT. 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.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. Measurements during disturbance 			
Test Level	Unsymmetrical lines		Symmetrical lines	Shielded I/O and communication lines
	Line to line	Line(s) to ground	Line(s) to ground	Shield to ground
	1.0 kV	2.0 kV	2.0 kV	2.0 kV
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 641-4.3.1</p> <p>ambient conditions: within reference conditions as defined in R 126-2, 2.4.11-4.1.</p>			
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5; - number of measurements (during disturbance): 5 - time schedule: consecutively at each test condition - parameters at least to be recorded: <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; g) functional performances; a) as defined in R 126-2, 2.5.3, plus h) b) exposed conductors. 			
Acceptance criteria	<ul style="list-style-type: none"> The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation). The error of indication is determined as the average of the errors of five measurements (determined during the disturbance). <p>The fault is determined (difference between error of indication and intrinsic error)</p> <p>The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4:</p> <ul style="list-style-type: none"> - 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. 			

~~2.5.6.112.5.8.11~~ ~~11.5.5.11~~ Electrical transients conduction along supply lines

Table 3237

Electrical transients conduction along supply lines			
Applicable standard	ISO 7637-2 [...] [33]		
Test method	Electrical transient conduction along supply lines.		
Applicability	Applicable to portable and transportable EBAs which may be in operation while being powered while in operation are supplied by an in-vehicle battery that is being charged by a combustion engine driven generator.		
Object of the test	<p>This test is applied to verify compliance of the EUT with the requirements in R 126-1, 6.11.1 when exposed to electrical transients conducted along the power lines from an external DC power source where this power source concerns the on-board batteries of a vehicle (R 126-1, 6.11.2, table 3, clause i).</p> <p>Verification of compliance with the provisions for disturbances in 6.11.1 under the following conditions:-</p> <ul style="list-style-type: none"> - 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); - transients on the supply lines which occur as a result of the switching processes (pulses 3a and 3b) specified in R 126-1, 6.11.1, table 3, clause i). 		
Precondition	As defined in 11.5.1		
Condition of the EUT	Power is to be "on" for the duration of the test.		
Test procedure in brief	<p>The test comprises exposure to disturbances on the power voltage by direct coupling into the supply lines.</p> <p>Test sequence: <u>1.</u> Measurements before disturbance (at reference conditions) <u>2.</u> Measurements during disturbance</p>		
Test level	Test pulse	Pulse Voltage U_s	
		$U_{nom} = 12\text{ V}$	$U_{nom} = 24\text{ V}$
	2a	+ 50 V	+ 50 V
	2b	+ 10 V	+ 20 V
	3a	- 150 V	- 200 V
	3b	+ 100 V	+ 200 V
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6 4.4.3.1</p> <p>ambient conditions: within reference conditions as defined in R 126-2, 2.4.1 4.4.1</p>		
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5 - number of measurements (during disturbance): 5 - time schedule: consecutively at each test condition - parameters at least to be recorded: as defined in R 126-2, 2.5.3 4.5.3 a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; - functional performances. 		
Acceptance criteria	<ul style="list-style-type: none"> - The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) - The error of indication is determined as the average of the errors of five measurements (determined during the disturbance) - The fault is determined (difference between error of indication and intrinsic error). - The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4: - 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. 		

~~2.5.6.122.5.8.12~~ ~~11.5.5.12~~ Electrical transient conduction via lines other than supply lines

Table 3338

Electrical transient conduction via lines other than supply lines				
Applicable standard	ISO 7637-3 [...], [34], § 3.5.1: fast transient test pulses a and b			
Test method	Electrical transient conduction along lines other than supply lines.			
Applicability	Applicable to I/O lines of transportable EBA installed in vehicles.			
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 under conditions of transients which occur on other lines as a result of the switching processes (pulses a and b) (R 126-1, 6.11.2, table 3, clause j).			
Precondition	As defined in 11.5.1			
Condition of the EUT	Power is to be "on" for the duration of the test.			
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, using only the Capacitive Coupling Clamp method shall be applied.			
Test level	Test sequence:			
	1. Measurements before disturbance (at reference conditions)			
	2. Measurements during disturbance			
		U_{nom}	12 V	24 V
pulse a		U_s	-60 V	-80 V
	pulse b	U_s	40 V	80 V
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6 ambient conditions: within reference conditions as defined in R 126-2, 2.4.1+4.1			
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): 5 - number of measurements (during disturbance): 5 - time schedule: consecutively at each test condition - parameters at least to be recorded: <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure e) values of the measurand; f) indications and errors of the EUT; g) functional performances. a) as defined in R 126-2, 2.5.3, plus h) exposed conductors 			
Acceptance criteria	<ul style="list-style-type: none"> The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) The error of indication is determined as the average of the errors of five measurements (determined during the disturbance) The fault is determined (difference between error of indication and intrinsic error). The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4: <ul style="list-style-type: none"> - 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. 			

Commented [RK29]: amended according to Paris meeting (see minutes note 16)

11.5.5.13 Battery voltage variations during starting up a vehicle engine

Table 39

Battery voltage variations during starting up a vehicle engine					
Applicable standard	ISO 16750-2 [...]				
Test method	Supply voltage variation due to energizing the starter motor of a vehicle				
Applicability	Applicable to transportable EBA powered by the on-board battery of the vehicle that can 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 table 3, clause k				
Precondition	As defined in 11.5.1				
Condition of the EUT	Power is to be "on" for the duration of the test.				
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				
	Test sequence: 1.—Measurements before disturbance (at reference conditions) 2.—Measurements during disturbance				
	The following test levels are applicable:				
Nominal battery voltage	$U_{nom} = 12\text{ V}$		$U_{nom} = 24\text{ V}$		Unit
Test profile ¹⁾	I	III	I	III	
U_S	8	3	10	6	V
U_A	9,5	5	20	10	V
t_a	1				s
t_r	40	100	40	40	ms
Notes	¹⁾ As specified in ISO 16750-2.				
Measurement conditions	ethanol concentration: — 0.40 mg/L (test gas No. 4) test gas conditions: — within reference conditions as defined in 11.4.3.1 ambient conditions: — within reference conditions as defined in 11.4.1				
EUT performance	— number of measurements at reference conditions (before disturbance): 5; — number of measurements (during disturbance): 5 — time schedule: — consecutively at each test condition — parameters at least to be recorded: a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure; e) — values of the measurand; f) — indications and errors of the EUT; g) — functional performances.				
Acceptance criteria	— The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) — The error of indication is determined as the average of the errors of five measurements (determined during the disturbance) — The fault is determined (difference between error of indication and intrinsic error). 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.				

11.5.5.14 “Load dump” test

Table 40

“Load dump” test					
Applicable standard	ISO 16750-2 [...]				
Test method	Supply voltage variation due to disconnecting a discharged battery				
Applicability	Applicable to transportable EBA powered by the on-board battery of the vehicle that can 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 disconnecting a discharged vehicle battery while the charging alternator is running, specified in 6.11.1 table 3, clause 1.				
Precondition	As defined in 11.5.1				
Condition of the EUT	Power is to be “on” for the duration of the test.				
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. Test sequence: 1. —Measurements before disturbance (at reference conditions) 2. —Measurements during disturbance				
Nominal battery voltage	$U_{nom}=12\text{ V}$		$U_{nom}=24\text{ V}$		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_s	10	10	10	10	ms
t_d	40-400	40-400	100-350	100-350	ms
Notes	¹⁾ As specified in ISO 16750-2				
Measurement conditions	ethanol concentration: — 0.40 mg/L (test gas No. 4) test gas conditions: — within reference conditions as defined in 11.4.3.1 ambient conditions: — within reference conditions as defined in 11.4.1				
EUT performance	— number of measurements at reference conditions (before disturbance): 5 — number of measurements (during disturbance): 5 — time schedule: — consecutively at each test condition — parameters at least to be recorded: a) — date and time; b) — ambient testing temperature; c) — ambient testing relative humidity; d) — ambient pressure; e) — values of the measurand; f) — indications and errors of the EUT; g) — functional performances.				
Acceptance criteria	— The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) — The error of indication is determined as the average of the errors of five measurements (determined during the disturbance) — The fault is determined (difference between error of indication and intrinsic error) — 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.				

~~2.5.6.132.5.8.13~~ ~~11.5.5.15~~ Mechanical shocks

Table 3441

Mechanical shock				
Applicable standard	IEC 60068-2-31 [...] [13]			
Test method	Dropping the EUT onto a rigid surface after tilting.			
Applicability	Applicable for all EBA s .			
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1 , 6.11.1 under conditions of mechanical shocks specified in R 126-1 , 6.11.1, table 4, clause a.			
Precondition	As defined in 11.5.1			
Condition of the EUT	Power is to be "on" for the duration of the test.			
Test procedure in brief	<p>For stationary or transportable EBAs:</p> <ul style="list-style-type: none"> - 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°. <p>For portable EBAs:</p> <ul style="list-style-type: none"> - The test surface shall be smooth, hard, rigid, horizontal, and made of concrete or steel; - the specimen shall be allowed to fall freely in its normal attitudes of use, taking into account all 3 spatial axes; - the height shall be measured from the part of the specimen nearest to the test surface, when the specimen is suspended prior to letting it fall. <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. The disturbance shall be applied 3. Measurements after disturbance (at reference conditions) 			
Test level		stationary EBA	transportable EBA	portable EBA
	Height of fall	25 mm	50 mm	1000 mm
	Number of falls (on each bottom edge)	1	1	6
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: reference conditions as defined in R 126-2 , 2.4.3.1, table 4 and 2.4.3.2, table 6 4.4.3.1 , ambient conditions: reference conditions as defined in R 126-2 , 2.4.14.4.1.1.			
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): <u>5</u> - number of measurements at reference conditions (after disturbance): <u>5</u> - time schedule: consecutively at each test condition - parameters at least to be recorded: <u>as defined in R 126-2, 2.5.34.5.3.</u> <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; e) values of the measurand; f) indications and errors of the EUT; - functional performances. 			
Acceptance criteria	<ul style="list-style-type: none"> - The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) - The error of indication is determined as the average of the errors of five measurements (determined after the disturbance) - The fault is determined (difference between error of indication and intrinsic error). - The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4.: - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. 			

Commented [RK31]: amendment of the Secretariat: test procedure for portable EBAs was missing

~~2.5.6.142.5.8.14~~ 11.5.5.16 Shakes

Table 3542

Shakes (shocks)	
Applicable standard	none
Test method	Exposure to shocks while not being in operation.
Applicability	Applicable for portable and transportable EBA.
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 after being exposed to shocks likely to be experienced in a car trunk thus specified in R 126-1, 6.11.1, table 4, clause 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	Power is to be "off" for the duration of the test. 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 sequence: 1. Measurements before disturbance (at reference conditions) 2. The disturbance shall be applied 3. Measurements after disturbance (at reference conditions)
Test level	Shock specifications: wave shape: half-period of a sinusoid amplitude: 10 g (g = 9.81 m/s ²) duration: 6 ms frequency: 2 Hz number of axes: 3 perpendicular axes number of shakes: 1 000 for each axis
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6. 11.4.3.1 ambient conditions: within reference conditions as defined in R 126-2, 2.4.1 11.4.1 .
EUT performance	- number of measurements at reference conditions (before disturbance): <u>5</u> - number of measurements at reference conditions (after disturbance): <u>5</u> - time schedule: consecutively at each test condition —parameters at least to be recorded: <u>as defined in R 126-2, 2.5.3.</u> a) —date and time; b) —ambient testing temperature; c) —ambient testing relative humidity; d) —ambient pressure; e) —values of the measurand; f) —indications and errors of the EUT; g) —functional performances.
Acceptance criteria	The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) The error of indication is determined as the average of the errors of five measurements (determined after the disturbance) The fault is determined (difference between error of indication and intrinsic error). The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4. - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.

Commented [RK32]: already stated below

Commented [RK33]: already stated in 11.5.2, not necessary to repeat here

Commented [DL34]: Secretariat proposes to delete the "repetition rate" as is not defined, instead the number of shakes is defined

~~2.5.6.152.5.8.15~~ 11.5.5.17 Damp heat cyclic (condensing)

Table 3643

Damp heat, cyclic (condensing)			
Applicable standard	IEC 60068-2-30 [...], [12] IEC 60068-3-4 [...]		
Test method	Exposure to damp heat with cyclic temperature variation.		
Applicability	Applicable for transportable and portable EBA.		
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 under conditions of high humidity combined with cyclic temperature changes specified in R 126-1, 6.11.1, table 4, clause c).		
Precondition	Before and after the disturbance, 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 "off" for the duration of the test. The EUT shall not be readjusted at any time during the test. Before and after the disturbance, 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		
Test procedure in brief	<p>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.</p> <p>Condensation is expected to occur on the EUT during the temperature rise.</p> <p>The 24 h cycle comprises of:</p> <ul style="list-style-type: none"> - temperature rise for 3 hours, - temperature maintained at upper value until 12 hours from the start of the cycle, - 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, - temperature maintained at the lower level until the 24 h period is completed. <p>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.</p> <p>Special electrical conditions and recovery conditions may need to be specified.</p> <p>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.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. The disturbance shall be applied 3. Measurements after disturbance (at reference conditions) 		
Test level	Upper temperature	55 °C	
	relative humidity at upper temperature	≥ 93 %	
		transportable EBA	portable EBA
	Duration (number of 24-hour cycle)	2	4
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No-4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6 and 4.4.3.4, ambient conditions: temperature and humidity at the respective test level, all other parameters within reference conditions as defined in R 126-2, 2.4.1 11.4.1		
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): <u>5</u> - number of measurements at reference conditions (after disturbance): <u>5</u> - time schedule: consecutively at each test condition - parameters at least to be recorded: <u>as defined in R 126-2, 2.5.341.5.3,</u> <ul style="list-style-type: none"> a) date and time; b) ambient testing temperature; c) ambient testing relative humidity; d) ambient pressure; 		

Commented [RK35]: moved to the line below

Commented [RK36]: already stated in 11.5.2, not necessary to repeat here

	e) — values of the measurand; f) — indications and errors of the EUT; - functional performances.
Acceptance criteria	— The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) — The error of indication is determined as the average of the errors of five measurements (determined after the disturbance) The fault is determined (difference between error of indication and intrinsic error). The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4. - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.

~~2.5.6.162.5.8.16~~ 11.5.5.18 Storage test

Table 3744

Storage test	
Applicable standard	none
Test method	Exposure to changing temperatures while not being in operation.
Applicability	Applicable all EBA ₂
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 after being exposed to the extreme situations which may occur during storage of the instrument thus specified in R 126-1, 6.11.1, table 4, clause d.
Precondition	The EUT is set in its switched off mode and no external electric power shall be connected.
Condition of the EUT	Power is to be "off" for the duration of the test. The EUT 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 EUT is exposed to low temperatures 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 sequence: <ol style="list-style-type: none"> 1. Measurements before disturbance (at reference conditions) 2. The disturbance shall be applied 3. Measurements after disturbance (at reference conditions)
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.
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 641.4.3.1. ambient conditions: within reference conditions as defined in R 126-2, 2.4.11.4.1
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before disturbance): <u>5</u> - number of measurements at reference conditions (after disturbance): <u>5</u> - time schedule: consecutively before and after exposure, after switching on the EUT and after a one-hour recovery period at reference condition. - parameters at least to be recorded: <u>as defined in R 126-2, 2.5.3.</u> <ul style="list-style-type: none"> — date and time; — ambient testing temperature; — ambient testing relative humidity; — ambient pressure; — values of the measurand; — indications and errors of the EUT; — functional performances.
Acceptance criteria	<ul style="list-style-type: none"> — The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) — The error of indication is determined as the average of the errors of five measurements (determined after the disturbance) - The fault is determined (difference between error of indication and intrinsic error). The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4. - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.

Commented [RK37]: already stated in 11.5.2, not necessary to repeat here

~~2.5.6.172.5.8.17~~ 11.5.5.19 **Vibration (as disturbance)**

Table 3845

Random Vibration		
Applicable standard	IEC 60068-2-47, <u>[14]</u> , IEC 60068-2-64, <u>[15]</u> IEC 60068-3-8	
Test method	Exposure to random vibration.	
Applicability	Applicable to stationary EBA.	
Object of the test	Verification of compliance with the provisions for disturbances in <u>R 126-1, 6.11.1</u> after being exposed to the extreme situations which may occur during transport of the instrument thus specified in <u>R 126-1, 6.11.1, table 4, clause e</u> .	
Precondition	The EUT is set in its switched-off mode and no external electric power shall be connected.	
Condition of the EUT	Power is to be “off” for the duration of the test. The EUT 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 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. After the exposure, the external electrical power (where applicable) shall be connected and the EUT shall be switched on., the EUT performance is tested. Test sequence: 1. Measurements before disturbance (at reference conditions) 2. The disturbance shall be applied 3. Measurements after disturbance (at reference conditions)	
Test level	Total frequency range	10 – 150 Hz
	Total RMS level	7 m·s ⁻²
	ASD level 10-20 Hz	1 m ² ·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 at least 2 minutes
Measurement conditions	ethanol concentration:	0.40 mg/L (test gas <u>n° No. 4</u>)
	test gas conditions:	within reference conditions as defined in <u>R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.4.4.3.4</u>
	ambient conditions:	within reference conditions as defined in <u>R 126-2, 2.4.1+4.4.1</u>
EUT performance	<ul style="list-style-type: none">- number of measurements at reference conditions (before disturbance): <u>5</u>- number of measurements at reference conditions (after disturbance): <u>5</u>- time schedule: After switching on the EUT and after a one-hour recovery period at reference condition, consecutively at each test condition—parameters at least to be recorded: <u>as defined in R 126-2, 2.5.3+5.3.</u><ul style="list-style-type: none">a) date and time;b) ambient testing temperature;c) ambient testing relative humidity;d) ambient pressure;e) values of the measurand;f) indications and errors of the EUT;- functional performances.	
Acceptance criteria	<ul style="list-style-type: none">— The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation)— The error of indication is determined as the average of the errors of five measurements (determined after the disturbance)The fault is determined (difference between error of indication and intrinsic error)The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4.- Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.	

Commented [RK38]: already stated in 11.5.2, not necessary to repeat here

~~2.5.6.182.5.8.18~~ ~~11.5.5.20~~ **Durability**

The instrument is presumed to comply with the requirement defined in 6.5 if the instrument submitted to the accuracy tests and disturbance tests passes each of the tests.

~~2.5.72.5.9~~ **11.5.6 Physiological influence quantities**

The EBA shall be tested according to the following procedure:

1. ~~determination of the indication for a dry or wet test gas having an ethanol content of 0.4 mg/L \pm 5 % without any interfering substance;~~
 2. ~~determination of the indication for the same test gas with one and only one of the interfering substances listed in the table in 6.11.2 table 5 at the indicated mass concentration.~~
- a) ~~If the variation of the indication is not more than the maximum value defined in 6.11.2 (0.1 mg/L for the interfering substances listed in the table 5) the EBA has passed the test for the interfering substance concerned,~~
b) ~~If the variation is more than the value defined in 6.11.2 and no error message is given, the EBA has failed, or~~
c) ~~If an error message is given another test shall be performed with the same interfering substance at a mass concentration 5 times lower. In that case the variation of the indication shall not be more than the maximum value defined in 6.11.2.~~

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

Table 3946

physiological influence quantities	
Applicable standard	none
Test method	test gases with additionally one interfering substance at a time.
Applicability	Applicable to all EBA.
Objective of the test	Verification of compliance with the provisions in R 126-1 , 6.11.2.
Condition of the EUT	The EUT electrical power shall be switched on during the test.
Test procedure in brief	The test comprises of at least 5 measurements per test gas. Test sequence: 1. Measurements with test gas n° 4 2. Measurements with one of the test gases with the additional substance For each substance, this test sequence has to be repeated.
Test gases mass concentration of substances	a) ethanol concentration: 0.40 mg/L (test gas n°, 4) b) 0.40 mg/L ethanol plus acetone 0.5 mg/L c) 0.40 mg/L ethanol plus methanol 0.1 mg/L d) 0.40 mg/L ethanol plus isopropanol 0.1 mg/L e) 0.40 mg/L ethanol plus carbon monoxide 0.2 mg/L Depending on the results, additionally test gases with more diluted interfering substances might be needed (see acceptance criteria)
Measurement conditions	test gas characteristics: test gas composition as defined for this test, other parameters within reference conditions as defined in R 126-2 , 2.4.3.1, table 4 and 2.4.3.2, table 6. ambient conditions: within reference conditions as defined in R 126-2 , 2.4.1
EUT performance	- number of measurements with each test gas and concentration: 5 - at least the following parameters shall be recorded: as defined in R 126-2 , 2.5.3.
calculation of results	- calculation of deviation - The average of the five measurements with ethanol test gas is calculated - For each interfering substance, the average of the five measurements with the respective substance is calculated - the deviation $\Delta_{ts[1...5]}$ between the average results ethanol test gas and each result of the 5 measurements with the respective interfering substance is calculated - Calculation of sensitivity $sensitivity_{ts} = \frac{\Delta_{ts[1...5]}}{\text{mass concentration of interfering substance}}$
Acceptance criteria	a) If the sensitivity is not more that the value defined in R 126-1 , 6.11.2 the EBA has passed the test for the interference substance concerned, b) if the sensitivity measured is more than the value defined in R 126-1 , 6.11.2 and no error message is given, the EBA has failed, or

Commented [RK39]: amended test procedure as agreed in the Paris meeting

	<p>c) if an error message is given another test shall be performed with the same interfering substance at a mass concentration 5 times lower. In that case the sensitivity shall not be more than the value defined in <u>R 126-1, 6.11.2.</u></p> <p>d) if still an error message is given, the mass concentration of the added interfering substance has to be reduced repeatedly by a factor of 2. If the error message is not given any longer and the sensitivity is not more than the value defined in <u>R 126-1, 6.11.2</u> the EBA has passed the test for the interference substance concerned.</p> <p><u>The requirement shall be fulfilled for each result of each measurement with each interfering substance.</u></p>
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~~11.5.7 stress tests~~

2.6 ~~11.6~~ Tests for optional disturbances and requirements

2.6.1 ~~11.6.1~~ Sand and dust

Table 4046

Sand and dust	
Applicable standard	IEC 60512-11-8; [17] , IEC 60529; [18] , IEC 60721-2-5 [20]
Test method	Exposure to sand and dust.
Applicability	Applicable to EBA expected to be used in a dusty or sandy environment.
Objective of the test	Verification of compliance with the provisions in R 126-1 , 6.11.3 under a sand or dust-laden atmosphere.
Condition of the EUT	The EUT electrical power shall be switched off during the test.
Test procedure in brief	The test comprises of exposure to cyclic temperature variation between 30 °C and 65 °C, maintaining the following conditions: <ul style="list-style-type: none"> - relative humidity: less than 25 %, - air velocity: 3 m/s, - particle concentration: 5 g/m³, - composition of the particles: as specified in 3.2.1 of IEC 60512-11-8 [...].
Number of test cycles	1 <u>one</u>
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas characteristics: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6, 4.4.3.1 ambient conditions: within reference conditions as defined in R 126-2, 2.4.14.4.1
EUT performance before and after exposure	<ul style="list-style-type: none"> - number of measurements at reference conditions before exposure: <u>5</u> - number of measurements at reference conditions after exposure: <u>5</u> at least the following parameters shall be recorded: as defined in R 126-2, 2.5.34.5.3 . <ul style="list-style-type: none"> a) date and time; b) ambient conditions during the test; c) characteristics of the test gas; d) value of the measurand; e) indications and errors of the EUT; - functional performance.
Acceptance criteria	<ul style="list-style-type: none"> The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) The error of indication is determined as the average of the errors of five measurements (determined during the disturbance) The fault is determined (difference between the error of indication and the intrinsic error) <u>The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4.</u> <ul style="list-style-type: none"> - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.

2.6.2 ~~11.6.2~~ Salt mist

Table 4147

Salt mist	
Applicable standard	IEC 60068-2-11; [10] , IEC 60721-2-5 [20]
Test method	Exposure to salt mist.
Applicability	Applicable when the measuring instrument is expected to be used in a humid salty environment
Objective of the test	Verification of compliance with the provisions in R 126-1 , 6.11.3 under salt mist atmosphere.
Condition of the EUT	The EUT electrical power shall be switched off during the test.
Test procedure in brief	The test comprises of exposure to salt mist atmosphere at 35 °C.
Duration of the test	24 hours
Measurement conditions	ethanol concentration: 0.40 mg/L (test gas n° No. 4) test gas characteristics: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6, 4.4.3.1 ambient conditions: within reference conditions as defined in R 126-2, 2.4.14.4.1
EUT performance before and after exposure	<ul style="list-style-type: none"> - number of measurements at reference conditions before exposure: 5 - number of measurements at reference conditions after exposure: 5 at least the following parameters shall be recorded: as defined in R 126-2, 2.5.3. <ul style="list-style-type: none"> — date and time; — ambient conditions during the test; — characteristics of the test gas; — values of the measurand; — indications and errors of the EUT; - functional performance.
Acceptance criteria	<ul style="list-style-type: none"> — The intrinsic error is determined as the average of the errors of five measurements (under reference conditions without perturbation) — The error of indication is determined as the average of the errors of five measurements (determined during the disturbance) — The fault is determined (difference between the error of indication and the intrinsic error) The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4. <ul style="list-style-type: none"> - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur.

2.6.3 11.6.3 water

Commented [DL40]: Added according to Paris meeting (see minutes note 19)

Table 4248

water		
Applicable standard	IEC 60529 [18]; IEC 60068-2-18 [11]	
Test method	Exposure to water droplets.	
Applicability	Applicable to portable EBA expected to be used in outdoor conditions or on boats.	
Object of the test	Verification of compliance with the provisions in R 126-1, 6.11.3. under wet weather conditions.	
Condition of the EUT	Power is to be "on" for the duration of the test. The test shall be performed with the mouthpiece mounted on the EBA The measurements shall be performed before and after exposure.	
Test procedure in brief	<p>The test comprises exposure of the EBA to water droplets in defined angles</p> <ul style="list-style-type: none"> - temperature of the water: temperature of the EUT $\pm 5^{\circ}\text{C}$ - water quality: potable water <p>During the test, the moisture contained inside the enclosure may partly condense. The dew which may thus deposit shall not be mistaken for an ingress of water.</p> <p>The EUT is placed in its normal operating position under the drip box or spray nozzle. Except for EUT designed for wall mounting, the support for the EUT should be smaller than the base of the enclosure.</p>	
test level	test level index	2 (corresponds to IP X4 for degree of protection by enclosures)
	test condition	spraying water within an angle up to 180° from vertical
	test equipment	oscillating tube spray nozzles
	position of EUT	EUT at the centre of the oscillating tube EUT on turntable
	water flow rate	0,07 L/ min $\pm 5\%$ per hole 10 L/min $\pm 5\%$
	Duration	5 min per position 1 min/m ² of EUT
Measurement conditions	<p>ethanol concentration: 0.40 mg/L (test gas n° No. 4)</p> <p>test gas conditions: within reference conditions as defined in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.</p> <p>ambient conditions: within reference conditions as defined in R 126-2, 2.4.1.</p>	
EUT performance	<ul style="list-style-type: none"> - number of measurements at reference conditions (before exposure): 5 - number of measurements at reference conditions (after exposure): 5 - time schedule: After drying externally the EUT by wiping or by applying low-velocity forced air at room temperature, consecutively at each test condition - parameters at least to be recorded: as defined in R 126-2, 2.5.3. 	
Acceptance criteria	<ul style="list-style-type: none"> - water shall have no harmful effects <p>The errors and fault of the EUT shall be determined as prescribed in R 126-2, 2.5.4.</p> <ul style="list-style-type: none"> - Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults to occur. 	

3 ~~12~~ Initial and subsequent verifications

3.1 ~~12.1~~ General considerations

3.1.1 ~~12.1.1~~ Initial verification

According to national laws and regulations, individual EBAs within the scope of this Recommendation may require initial verification when newly produced according to the approved type and/or may require subsequent verification when in service.

The initial verification of each individual instrument is intended to verify that the EBA is correctly adjusted and conforms to the approved type.

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 tests for initial verifications shall be carried out on the complete instrument.

Initial verification and its requirements are the responsibility of the ~~National~~national authorities.

3.1.2 ~~12.1.2 subsequent~~ Subsequent verification

According to D9 §2.13, subsequent verification is defined as verification of a measuring instrument after a previous verification and including mandatory periodic verification and verification after repair.

Subsequent verification and its requirements are the responsibility of the national authorities.

3.2 ~~12.2~~ Legal status of the instrument submitted for verification

All EBAs produced and ready for initial verification shall conform to the approved type.

Initial verification of an EBA includes a procedure to ensure that the individual measuring instrument conforms to the approved type. But, notwithstanding this initial verification carried out either by the appropriate legal authority or designated body, or under the manufacturer responsibility (if quality assurance by the manufacturer is legally possible), the manufacturer has the full responsibility that the instrument complies with all the applicable requirements according to this Recommendation and other relevant requirements.

3.3 ~~12.3~~ Visual Examination

Before starting the practical tests, the following examinations are recommended to be performed, ~~to be checked or to be confirmed~~ (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 compliance with the approved type
- compliance of the software with the approved type
- completeness and correctness of the inscriptions and markings;
- presence, completeness and language of the documentation intended for the user;
- type of paper and ink (if applicable)
- information for the positioning of sealing and/or stamping.

Note: It is assumed that with a specific software version (which has to be mentioned 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 the measuring range, the unit of the result, or the presentation of the result are not predetermined in the software, it shall be stated in the type approval certificate and the setting of this parameter has to be inspected as well.

Commented [RK41]: editorial correction

3.4 ~~12.4~~ Metrological examination

3.4.1 ~~12.4.1~~ Metrological precondition for performing tests

The performance tests shall be executed under reference ambient conditions (~~R 126-2, 2.4.1+1.4.1~~).
Before starting the tests, it shall be verified that the EBA is switched on for the time period necessary for warm-up.

3.4.2 ~~12.4.2~~ Test gases used for verification

National regulations may dictate whether dry or wet gases have to be used.

If the use of wet test gases is prescribed, the test gas generator shall comply with the requirements of ~~R 126-2, 2.4.3+1.4.3~~.
If the use of dry gases is prescribed, the requirements of ~~R 126-2, 2.4.3.1 +1.4.3.1~~ for dry gases have to be taken into account.

3.4.3 ~~12.4.3~~ Tests for initial or subsequent verifications

The following minimum test program applies to the verification of all EBAs.

The verification shall include:

- a visual examination for conformity of the EBA (see ~~R 126-2, 3.3+2.3~~), and
- a metrological examination of the EBA.

3.4.3.1 ~~12.4.3.1~~ Metrological examination

The following metrological examination tests are recommended to be done on each single EBA due for verification:

- **Accuracy tests:** at least 3 different concentrations shall be tested, with at least 3 repetitions at each concentration.
Different approaches can be used, such as for example:
 - o The complete measuring range shall be tested for accuracy; at least 3 different test gas concentrations are recommended.
 - o Only part of the measuring range close to the legal limit(s) shall be tested for accuracy.

National regulations shall determine which approach has to be prescribed.

Each measurement result shall fulfill the MPEs of ~~R 126-1, 6.6.1~~ or 6.6.2 accordingly.

Additional tests can be made with different volumes (e.g. 1.5 L, 4.5 L), exhalation time (e.g. 15 s), flow rates. Results from these tests shall also comply with the MPE's.

3.4.3.2 ~~12.4.3.2~~ Verification marks, seals and documentation

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

PART 3 Test Report Format

Annex A — Examples for Test gas generator set-ups.

Here, the original pages are shown:

OIML R 126: 1998 (E)

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.

5-2. Committee Working Draft TC17/SC 7-/-p3/p 3: revision of R126 – Part 2 December 2018October 2019

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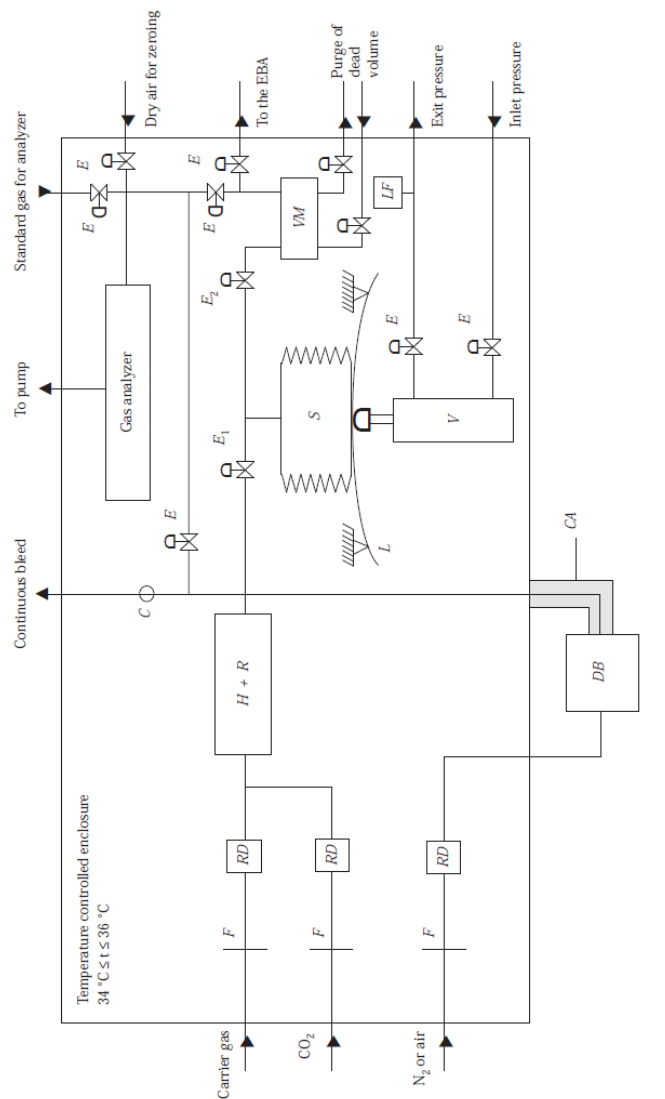
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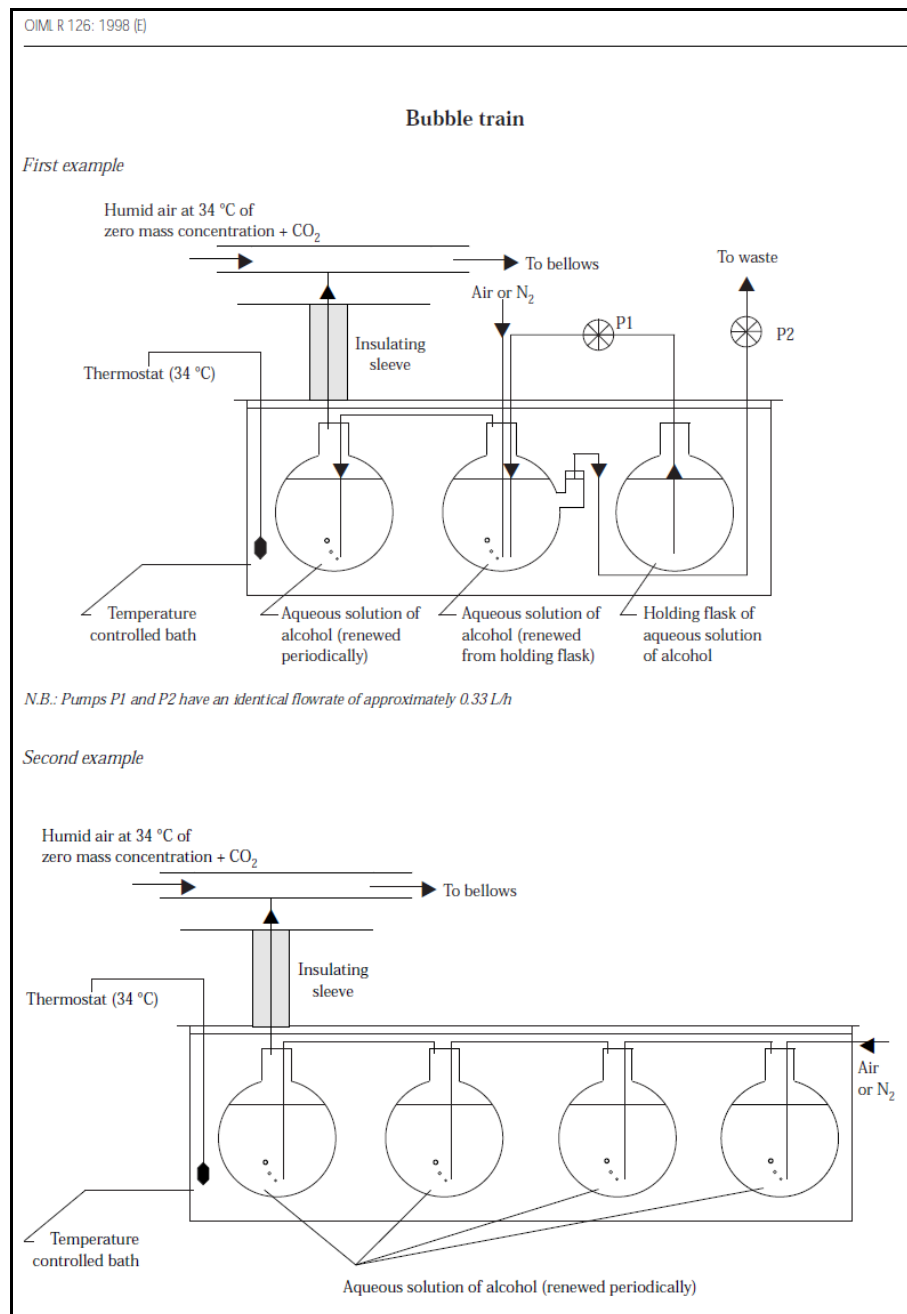
OIML R 126: 1998 (E)

Legend for the diagrammatic sketch on page 35

C non-return valve
CA thermal insulator
DB bubble train (see sketches)
E solenoid valve
E₁ solenoid valve for filling bellows (closed during exhalation)
E₂ 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





Annex A

GENERAL EXAMPLES FOR TEST GAS GENERATORS

(Informative)

A.1 Reference principle for the implementation of the test

For the production of wet test gases based on the principles of Henry's law, the ethanol concentration in the gas phase can be calculated with one of the following equations:

Dubowski's formula

Let γ_{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 β_{air} of ethanol in the air is given by the following formula:

$$\beta_{gas(t)} = 0.04145 * 10^{-3} * \gamma_{H_2O(t)} * e^{(0.06583 * t)}$$

with: $\beta_{gas(t)}$ mass concentration of ethanol in the test gas at a given temperature in mg/L

0.04145 * 10⁻³ and 0.06583 conventional Dubowski coefficients

$\gamma_{H_2O(t)}$ mass concentration of ethanol in the aqueous solution at a given temperature in mg/L

t temperature of solution and test gas in °C

For $t = 34$ °C the equation can be simplified to:

$$\beta_{gas(34)} = 0.38866 * 10^{-3} * \gamma_{H_2O(34)}$$

Upon requirements by national Authorities, other formulas such as Harger's formula might be prescribed to use:

Harger's formula

The conventional partition ratio for the concentration of ethanol in gas to the concentration of ethanol in aqueous solution at a temperature of 34 °C is given by:

$$K_{g/w} = 0.000393$$

This leads to: $\beta_{gas(34)} = 0.393 * 10^{-3} * \gamma_{H_2O(34)}$ at a temperature of $t = 34$ °C

A.2 Example of a type 1 test gas generator

The saturation of pressurized air with water and ethanol using the principles of Henry's law is a well-established set-up for a wet test gas generator for EBAs. They are commonly used all over the world in various designs.

~~Independent from the actual design, they are based on the principle of Henry's law, applied on dissolved substances in aqueous solutions:~~

~~In equilibrium conditions, the partition ratio of the concentration of a species in the liquid phase and in the gas phase will be constant. For dilute aqueous solutions, this partition ratio can be assumed as only temperature dependent.~~

~~For the partition ratio for ethanol at several temperatures various empiric data can be found in the literature.~~

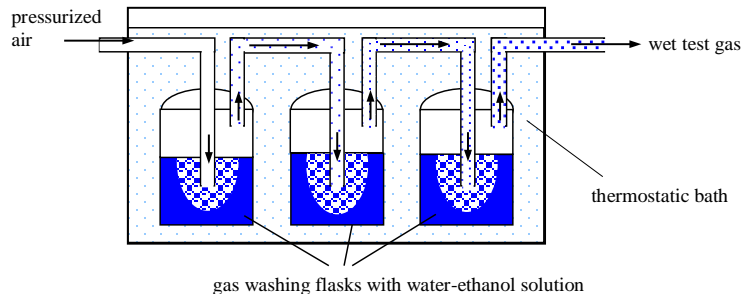
~~For breath alcohol analysis, the equations given in A.1 are the most commonly used for the calculation of the gas concentration of ethanol for a given temperature.~~

~~An example of a type 1 test generator is the so-called bubble train.~~

~~In principle, the bubble train consists of a number of gas washing flasks connected in series, within a temperature-controlled environment e.g. a thermostatic bath. The flasks will be filled with the water-ethanol solution of a known concentration and pressurized air/ gas passing the solution in small bubbles will be heated up as well as enriched with ethanol and water to a dynamic equilibrium.~~

~~The diagram-figure A.1 shows a basic design principle for a 3-flasks-bubble train:~~

Diagram Figure A.1: sketch of 3-flask-bubble train as a type 1 test gas generator



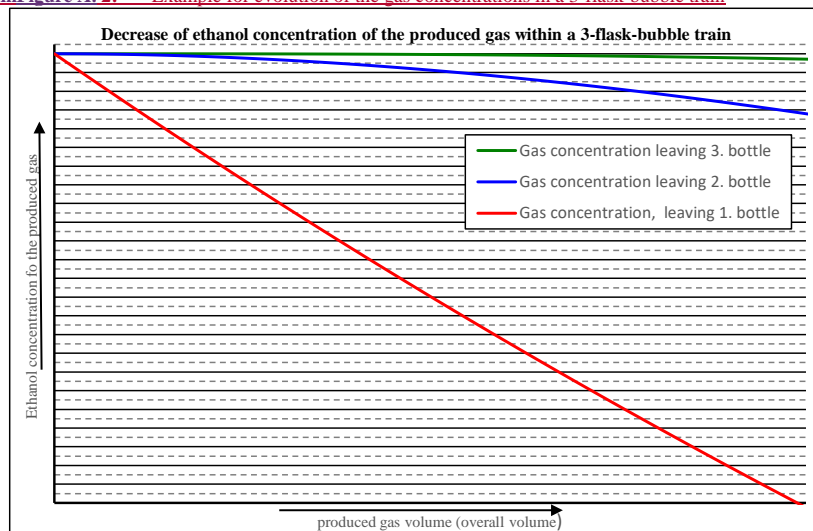
Field Code Changed

During the process of bubbling gas through the solution, a fraction of the ethanol amount in the solution is washed out by the gas flow. This means that the ethanol concentration in the solution, and hence in the test gas, will decrease constantly.

To minimize this effect, a number of gas-washing flasks should be connected in series. The subsequent flasks are working as a kind of buffer and the ethanol concentration can be kept stable for a certain test gas volume.

As a model, diagram-figure A.2 shows the qualitative evolution of the concentration in the solution as a function of the produced gas volume:

DiagramFigure A.-2: Example for evolution of the gas concentrations in a 3-flask-bubble train



By using at least two bubble flasks in series, a stable value of mass concentration at exit is achieved for a certain volume of test gas, allowing a fairly large number of measurements to be made.

Since the achieved partition equilibrium is temperature-dependent, the temperature of the bath shall be held stable. Temperature corrections may be applied.

Following Henry's law, the produced concentration of the test gas can be varied in the bubble train by:

- Either changing the concentration of the solution within the flasks,
- or varying the temperature of the water-ethanol solution

Note: For test gases with different ethanol concentrations but identical temperature (i.e. 34±0 °C), the use of the different corresponding water-ethanol solutions is required. The operation of two or even mores bubble trains might be helpful to realize effective test schemes.

A.3 Example of a type 2 test gas generator

The test gas generator shall generate a stable gas mixture at different concentrations of ethanol. This gas mixture is expelled into breathalyzers simulating human breath and shall correspond to the specifications of clause 11.5.

The generation of gas mixtures is provided by gas and liquid mass flow controllers system managed by a gas analyzer. The characteristics of the mixture are manageable

The dynamics of the different types of human breath is simulated (volumes and durations of expiration are parameterized, simulation of dead anatomical volume). The volume and time exhalation is regulated by the movement of the actuator

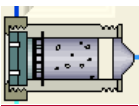

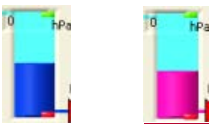

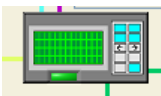

The determination of the ethanol concentration of each breath is done through an analysis system (Flame Ionization Detector). The system is totally independes from the technologies used in EBA.

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, the shapes of the curves may be changed.

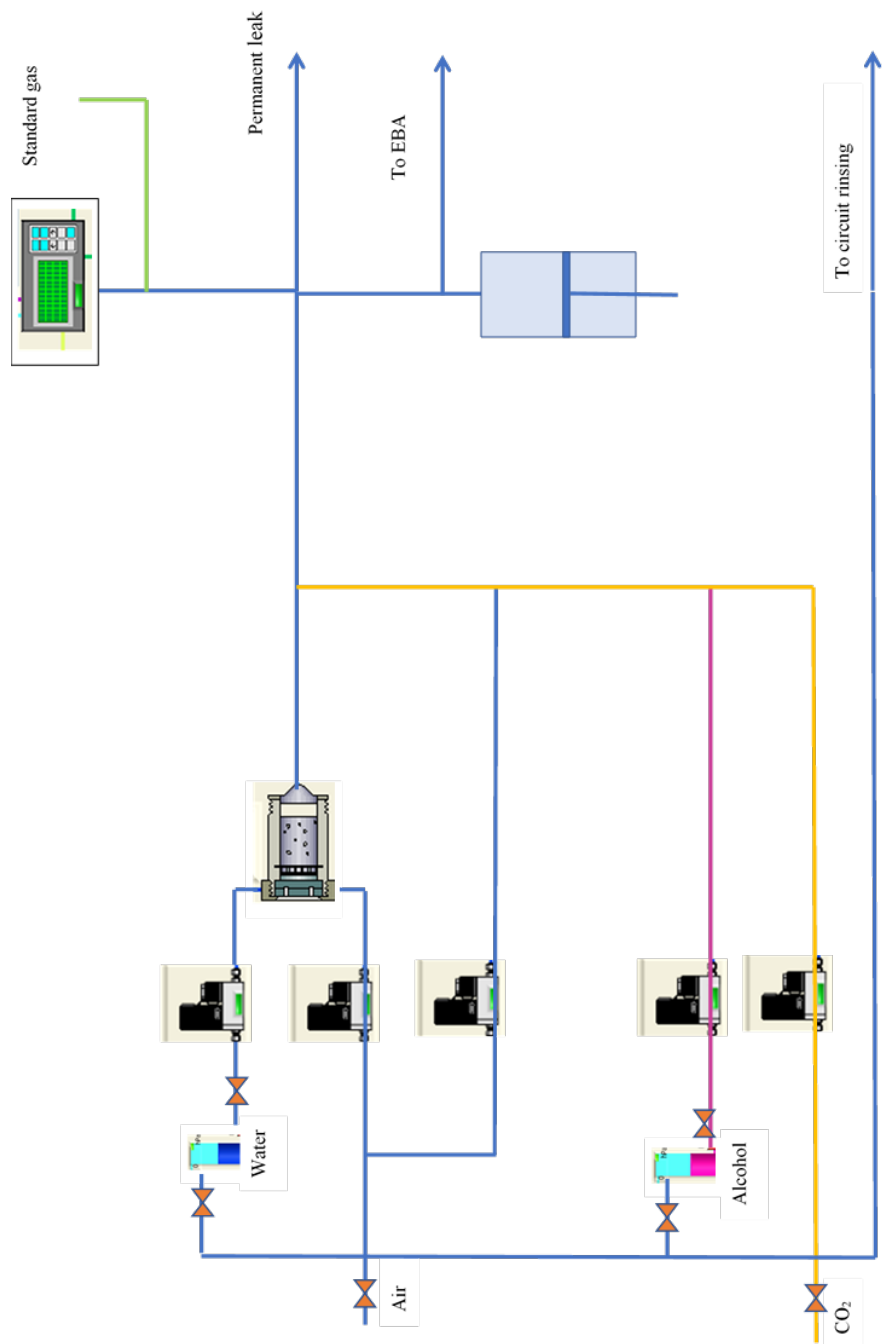
According to the technical solutions adopted, particularly those associated with the devices to regulate the flow rate, the gas analyzer that is included can be considered as a means of checking the apparatus or as providing a standard if it is calibrated periodically.

The diagram 3 on the following page gives example of a type 2 test gas generator.

Legend for diagramFigure A-3:

	<u>Controlled Evaporator Mixer (CEM)</u>
	<u>Valve</u>
	<u>Water and Alcohol tanks</u>
	<u>Mass flow regulators (RDMs)</u>
	<u>FID analyser</u>
	<u>Actuator</u>

~~Diagram~~Figure A.3: example for a type 2 test gas generator



A.4 General Information about breath profiles (Informative)

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 paragraph is to characterize the breath profiles and define the acceptance criteria.

A.4.1 Example of human breath profiles

The forced exhalation of a human being is characterized by the flow of breath and the change of the concentration of the alcohol during exhalation.

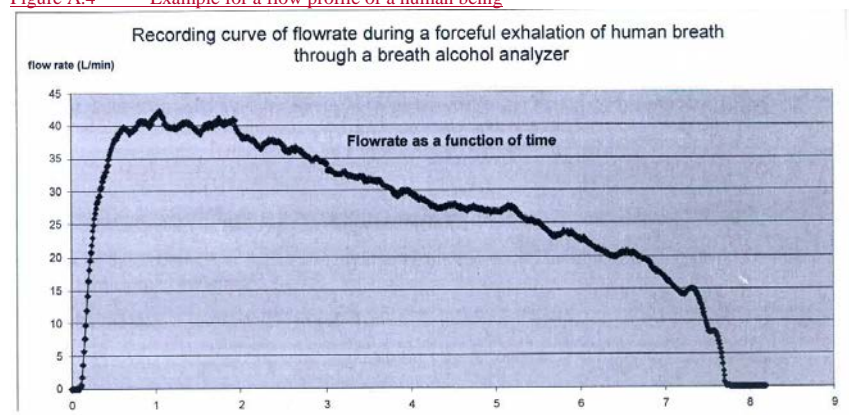
A.4.1.1 flow profile

The flow profile of a forced exhalation is divided into three distinct areas:

- the first part (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 is either a stable or a decreasing flow of breath, depending on the subject
- the third part is a fast decrease of the flow when the subject terminates the exhalation.

The absolute flow rate achieved during an exhalation is varying depending on the subject and the flow resistance of the EBA.

Figure A.4 Example for a flow profile of a human being



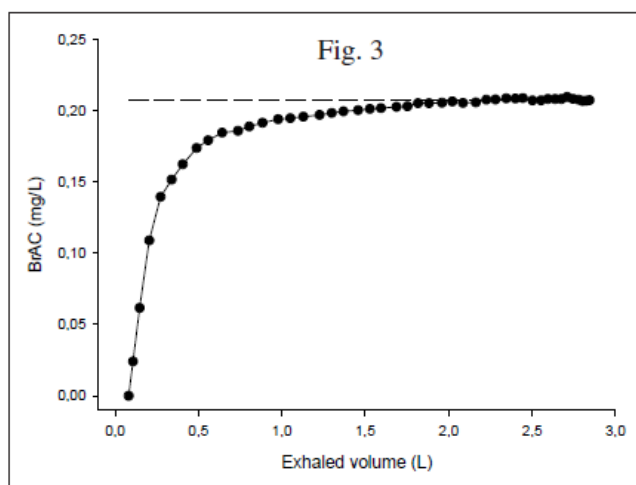
A.4.1.2 alcohol concentration profile

The alcohol concentration profile of a forced exhalation is characterized by a short delay in rise with a steep increase. Then the rise in concentration starts to become smaller until it is nearly flat at the end of the exhalation ('plateau' of alcohol').

The duration of the plateau of the alcohol concentration in human breath shows various characteristics according to the morphology of the subject's respiratory system. It is an important influence factor for the determination of the alcohol concentration.

Since the evolution of the alcohol concentration of a forced exhalation depends on the exhaled volume, figure A.5 shows a volumetric expirogram of breath alcohol concentration (taken out of [38] with courtesy of the author).

Figure A.5: Example of a volumetric expirogram of breath alcohol concentration



A.4.2 Simulation of breath profiles with test gas generators

The variability of the breath profiles needed for the tests in Part 2 of this Recommendation is based on the variability of human breath profiles possible in real life.

A test gas generator shall be able to perform the following simulations:

a) Simulation curves of forced exhalation (exhalation profiles)

The simulated curves shall cover the characteristic variation of the air flow as a function of time during an exhalation of a human being.

b) Simulation curves of alcohol concentration as a function of time (alcohol profiles)

The simulated curves shall cover the characteristic evolution of the alcohol plateau during an exhalation, taking into account the variations deriving from the diversity of the human beings.

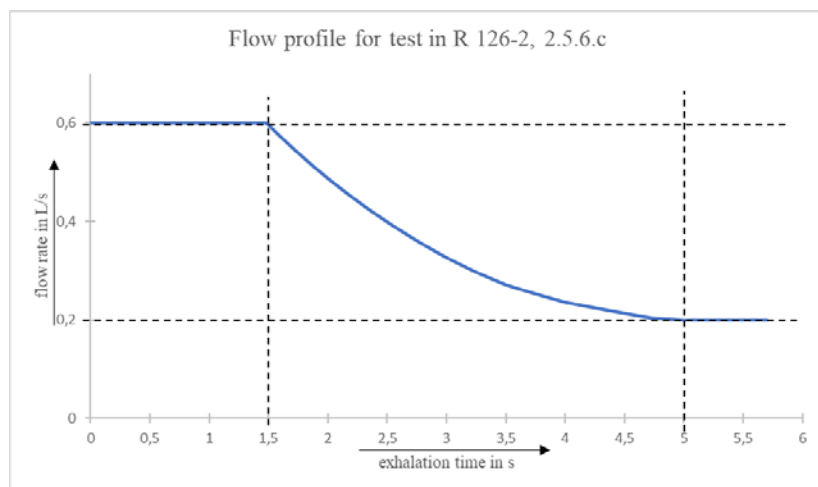
The generated alcohol profiles shall have a steep increase and a real plateau of alcohol at the end of the injection of test gas. This plateau shall have very small variations to avoid unnecessary uncertainties in the test gas concentrations applied to the instrument under test.

A.4.2.1 Simulated exhalation profiles

For the tests defined in R 126-2, §2.5.6.c, the flow profile shall have the following characteristics:

- 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.

Figure A.6 simulated flow profile



Commented [RK42]: The former Annex C is revised and implemented here as part of Annex A

A.4.2.2 Simulated alcohol profiles

Theoretical calculations, which are taken into account the reduced exchange in the upper respiratory system of a human being (dead volume), can be used to generate simplified, ideal exhalation profiles.

The plateau is defined as the time at which the alcohol concentration is stabilized to at least 99 % of the reference value.

For the calculation of simulated progression of an alcohol profile, the following equation can be used:

The dead anatomical volume can be assumed as approximately 2.2 mL per kg of body mass, which leads to an average volume of 150 mL (68 kg * 2.2 mL ≈ 150 ml for an average person).

With this assumed value of 150 mL, an ideal curve of the alcohol concentration (expressed in %) according to time and volume of the breath can be calculated:

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

where C=alcohol concentration (expressed in %),

$C_0=0$;

i=incremental indice

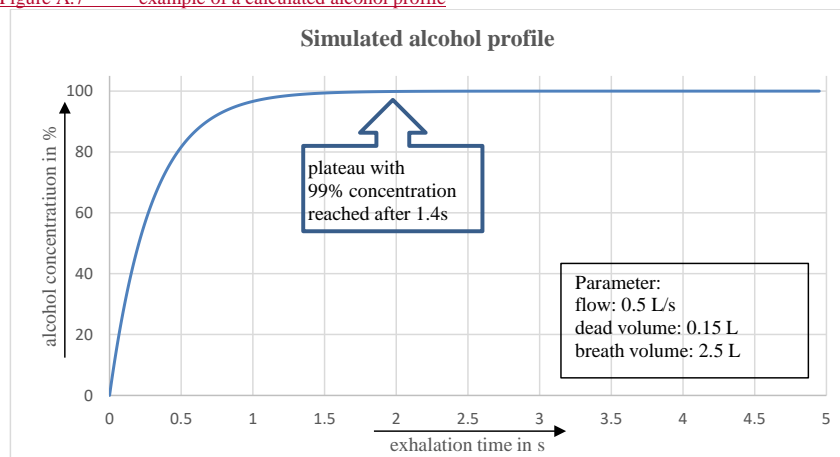
D=flowrate in L/s,

t = time of exhalation in s,

V_m = dead anatomical volume in L.

An Example of a curve of alcohol concentration, calculated with this equation, is shown in figure A.7: as a function of time obtained on a simulation test bench:

Figure A.7 example of a calculated alcohol profile



In practice, the alcohol profile generated by the test gas generators should look similar to the simulated exhalation profile in figure A.7.

The variability of the breath profiles possible is base for the variability of experimental profiles applied in R 126-2, §2.5.6 for testing EBAs.

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

→ Complete Annex to be revised,
The phenomenon of raised alcohol concentration in the upper respiratory tracts (also called residual mouth alcohol) will occur shortly after a person has just consumed something containing alcohol. This could be not only alcoholic beverages but also food containing alcohol, medicines or mouthwashes.
This is only a short-time phenomenon, in normal circumstances alcohol in the upper respiratory tracts is not detectable any more after a short time period.
When taking a breath sample under these circumstances, the evolution of the ethanol concentration during sampling will show a peak of high concentration at the beginning and then decay.
National Authorities may choose one, two or all the following solutions to detect alcohol in the upper respiratory tracts (A.1B.1, A.2B.2 or A.3B.3).

B.1 Peak method

B.1.1 Principle of the peak method

When an EBA is constantly monitoring the ethanol concentration during the injection of the breath sample, e.g. by examining the signal of an IR-sensor and analyzing the profile, this can be used for the detection of 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.
For testing this kind of detection method for alcohol in the upper respiratory tracts, The test consists in injecting a test gas is needed which providing provides a profile an evolution of the mass ethanol concentration as indicated in Figure B.1 below:

Figure B.1: needed profile of the ethanol concentration in the test gas

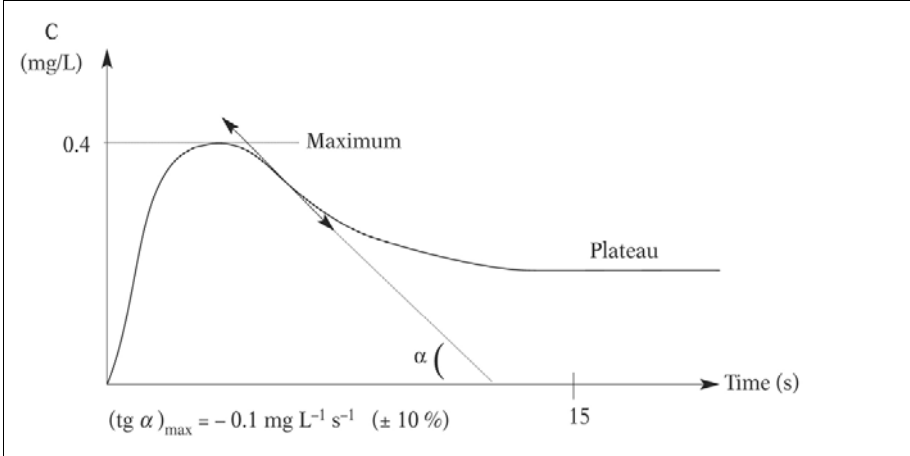


Figure A.1-1

The characteristics of the gas injected are the following:

- Delivered volume: $3 \text{ L} \pm 0.2 \text{ L}$,
- Duration: $15 \text{ s} \pm 0.5 \text{ s}$,
- Mass concentration at maximum of the curve: $0.4 \text{ mg/L} \pm 0.020 \text{ mg/L}$.

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

Commented [RK43]: moved to table B.1

Such a test gas can be generated for example by leading clean air through a balloon flask with a volume of approx. 500 ml. The balloon contains 250 ml of a water-ethanol solution with an ethanol concentration of 1.8 g/L, tempered to 34 °C. The clean air led through the balloon does not enter the water phase but will purge away the cloud of ethanol and water vapor, creating a peak of ethanol as required in figure B.1.

Figure B.2: Example of a test balloon for creating concentration peaksExample with a balloon

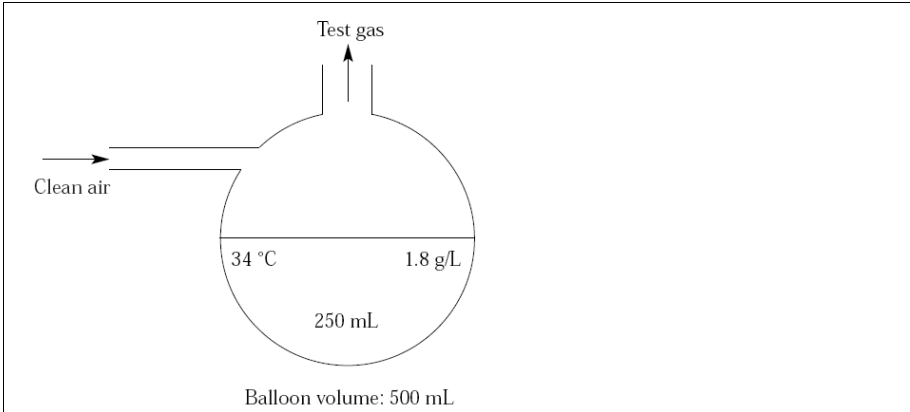


Figure A.1-2

B.1.2 test of the peak method

Table B.1

peak method	
Test method	measurements with a test gas with a peak in the ethanol concentration profile
Applicability	Applicable to all EBAs with an ethanol sensor able to monitor the evolution of ethanol concentration during the complete sampling period
Object of the test	Verification of compliance with the provisions in 7.1.7 under ambient reference conditions.
Precondition	As defined in 11.5.1.
Condition of the EUT	Power is to be “on” for the duration of the test.
Test procedure in brief	The test comprises of 5 measurements with the special test gas
measurement conditions	test gas conditions: delivered volume: 3 L ± 0.1 L duration of injection: 15 s ± 0.5 s variation of the alcohol concentration as a function of time: o according to the evolution shown in figure B.1 o ethanol concentration with a concentration profile as described in B.1.1 all other parameters as defined in in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6. ambient conditions: within reference conditions as defined in 11.4.1.

EUT performance	number of measurements per test scheme: at least 5 time schedule: to be performed consecutively for each test scheme parameters at least to be recorded: as defined in 11.5.3.
Acceptance criteria	<ul style="list-style-type: none">- The EUT shall detect the presence of alcohol in the upper respiratory tracts and shall cancel the measurement cycle.- It shall not deliver any measurement result and shall display an appropriate error message.

B.2 Two-measurement cycle

Since the alcohol in the upper respiratory tracts is only a short-time phenomenon, the results of two independent measurements, performed shortly one after another will differ noticeably if tested within this time frame.

To ensure an appropriate sensitivity for the comparison of the results of the two-measurement cycle, the EBA shall proceed the results internally with a scale interval of 3 digits.

For the indication of the final result the scale interval shall be 0.01 mg/L in the measuring mode, in accordance to R 126-1, 6.3.

There are different approaches how this could be applied for the detection of alcohol in the upper respiratory tracts for evidential breath analysis.

B.2.1 First method

B.2.1.1 Principle of the first method

The measurement cycle of the EBA shall include two measurements of separate breath samples. The time delay between these two measurements shall be performed within a delay not less than at least 2 minutes. The EBA shall be able to memorize the applicable legal limit, i.e. the what-value that constitutes a violation of the law. the offence of driving or working under the influence of alcohol, hereafter called "the legal value".

During a measurement cycle, the following incidents may occur:

- a) result of the First-first measurement value is less than the legal value-limit:
National authorities may define for this case that The the measurement cycle may shall then be stopped automatically after the first measurement if the concentration value is less than the legal value. In this case, and the result of the measurement shall be displayed and printed (if applicable).
In any case, when the second measurement is not performed, national authorities may require it is possible to indicate the unique available result as an indicative result, for instance indicating "measurement cycle not completed".
- b) result of the Second-second measurement value is less than the legal value-limit:
If one of the two measurements results is less than the legal value-limit and the other is greater than or equal to the legal value-limit, national authorities may define that the smallest result shall be displayed and printed (if applicable). In that case, There is no need for a comparison between the two results is not necessary.
- c) The results of First and secondboth measurements values are greater than or equal to the legal value-limit:
If both of the two measurements results are greater than or equal to the legal value-limit, then it is necessary to calculate the ratio:
$$R = \frac{|1 - \frac{C_{m2}}{C_{m1}}|}{t}$$

WhereWith:

R Ratio to judge the changing between first and second result
t is the time delay difference in minutes, between the end of the first breath sample and the end of the second breath sample,

Commented [RK44]: Proposal of the Secretariat as a requirement for the internal calculation and rating of the differences of the results.

Cm₁ ~~is the value~~result of the measurement of the first ~~test~~breath sample,
 Cm₂ ~~is the value~~result of the measurement of the second ~~test~~breath sample.

Depending on the Ratio R:

- o If R is less than 0.03 min⁻¹, alcohol in the upper respiratory tracts is considered as not occurred or neglectable. National Authorities may choose ~~either one~~ of the two following solutions:
 - 1) the smallest value of and is displayed and printed (if applicable);
 - 2) the two values and are displayed and printed (if applicable).

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

- o If R is greater than or equal to 0.03 min⁻¹, the results are considered as afflicted by alcohol in the upper respiratory tracts and the measurement cycle shall be cancelled, and the EBA shall display an appropriate error warning message to specify that the measurement cycle is not valid, and that a new one shall start.

B.2.1.2 Test procedure of the first method

Note:—The test gases described in ~~the this current~~ procedure are chosen for a legal ~~value limit~~ of 0.25 mg/L. For another legal ~~value limits~~, Tables 1, 2 and 3 ~~the needed test gas concentrations must be modified according adapted accordingly.~~

Table B.2

<u>First method - Two-measurements cycle</u>			
Test method	measurements with defined differences of ethanol concentration		
Applicability	Applicable to all EBAs with a two-measurements-cycle for detecting alcohol in the upper respiratory tract		
Object of the test	Verification of compliance with the provisions in 7.1.7 under ambient reference conditions.		
Precondition	As defined in 11.5.1.		
Condition of the EUT	Power is to be "on" for the duration of the test.		
Test procedure in brief	The test comprises of 5 measurements with a two-measurements cycle for each incident and case		
Test gases Mass concentration of ethanol	Incident a) Test gas n° 10: 0.22 mg/L (= legal limit minus 0.03 mg/L)		
	Incident b) Test gas n° 11: 0.28 mg/L (= legal limit plus 0.03 mg/L) and Test gas n° 10: 0.22 mg/L (legal limit minus 0.03 mg/L)		
	Incident c) First test gas: Test gas n° 11: 0.28 mg/L (= legal limit plus 0.03 mg/L) second test gas:		
	case 1:	Test gas n° 12:	
	one of the following test gas concentration shall be chosen as second test gas (n° 12), depending on the time delay:	time delay (min)	Second test gas (mg/L) Theoretical ratio R (min-1)
		2	0.29 0.017
		2.5	0.29 0.014
		3	0.30 0.022
		3.5	0.30 0.019
		4	0.30 0.017
		4.5	0.31 0.022
		5	0.31 0.019
	case 2:	Test gas n° 13	
	one of the following test gas concentration shall be chosen as second test gas (n° 13),	time delay (min)	Second test gas (mg/L) Theoretical ratio R (min-1)
		2	0.30 0.033
		2.5	0.31 0.039

	depending on the time delay:	<u>3</u> <u>3.5</u> <u>4</u> <u>4.5</u> <u>5</u>	<u>0.31</u> <u>0.32</u> <u>0.32</u> <u>0.33</u> <u>0.34</u>	<u>0.032</u> <u>0.036</u> <u>0.031</u> <u>0.034</u> <u>0.035</u>
measurement conditions	<p>ethanol concentrations: see above</p> <p>test gas conditions: delivered volume: <u>3 L ± 0.1 L</u></p> <p>duration of injection: <u>5 s ± 0.5 s</u></p> <p>variation of the alcohol concentration as a function of time:</p> <ul style="list-style-type: none"> ○ no variation (type 1 test gas generator) or ○ plateau duration equal to 3 s (type 2 test gas generator). <p>all other parameters as defined in in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.</p> <p>ambient conditions: within reference conditions as defined in 11.4.1.</p>			
Test schemes	<p>test scheme for incident a)</p> <ul style="list-style-type: none"> - test gas concentration for the first measurement: 0.22 mg/L (Test gas n° 10) - the second measurement shall not be performed (EBA shall terminate measurement cycle after the first test automatically, no 2nd test shall be possible). <p>test scheme for incident b)</p> <ul style="list-style-type: none"> - test gas concentration for the first measurement: <u>0.28 mg/L (test gas n° 11)</u> - test gas concentration for the second measurement: <u>0.22 mg/L (test gas n° 10)</u> <p>test scheme for incident c)</p> <p>Case 1: R is less than 0.03 min⁻¹:</p> <ul style="list-style-type: none"> - test gas concentration for the first measurement: <u>0.28 mg/L (test gas n° 11)</u> - test gas concentration for the second measurement: one of the test gases listed as n° 12 depending on the time between the end of the first injection and the end of the second injection to obtain a theoretical ratio of less than 0.03 <p>Case 2: R is more than or equal to 0.03 min⁻¹:</p> <ul style="list-style-type: none"> - test gas concentration for the first measurement: <u>0.28 mg/L (test gas n° 11)</u> - test gas concentration for the second measurement: one of the test gases listed as n° 13 depending on the time between the end of the first injection and the end of the second injection to obtain a theoretical ratio of more than or equal to 0.03 			
EUT performance	<ul style="list-style-type: none"> - number of measurements per test scheme: <u>at least 5</u> - time schedule: <u>to be performed consecutively for each test scheme</u> - parameters at least to be recorded: <u>as defined in 11.5.3.</u> 			
Acceptance criteria	<p>for incident a)</p> <ul style="list-style-type: none"> - The EUT shall verify that the result C_{m1} of the first measurement is below the legal limit ($C_{m1} < 0.25$ mg/L), and shall display and print (if applicable) the result. <p>for incident b)</p> <ul style="list-style-type: none"> - The EUT shall verify that the result of the second measurement C_{m2} is below the legal limit ($C_{m2} < 0.25$ mg/L), and shall display and print (if applicable) the smallest result. <p>for incident c), case 1:</p> <ul style="list-style-type: none"> - The EUT shall verify that the ratio R obtained from both results C_{m1} and C_{m2} is smaller than 0.03 min⁻¹ and shall, according to national regulations either display and print (if applicable) the smallest result of C_{m1} and C_{m2} as final result of a valid measurement cycle, or display and print (if applicable) both results C_{m1} and C_{m2} <p>for incident c), case 2:</p> <ul style="list-style-type: none"> - The EUT shall verify that the ratio R obtained from both results C_{m1} and C_{m2} is greater or equal to 0.03 min⁻¹ and shall cancel the measurement cycle and display an appropriate error message. 			

to B.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 11.5.2.1

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

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 C_{m1} and $C_{m2} < 0.03 \text{ min}^{-1}$, National, national Authorities may choose either of the two following solutions:
the smallest value of C_{m1} and C_{m2} is displayed and printed (if applicable);
the two values C_{m1} and C_{m2} 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

Table 3

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

After verifying that the ratio R obtained from C_{m1} and $C_{m2} \geq 0.03 \text{ min}^{-1}$, 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

B.2.2.1 Principle of the second method

The breath analyzer shall use a measurement cycle of the EBA shall consist of involving two subject measurements of separate breath samples measurements, each measurement corresponding to an exhalation. The time delay between the measurements of the two subject breath samples measurements are separated by at least shall be between 2 min and 5 min. The resulting displayed or recorded measurement in a subject test shall be specified by the National Authority Authorities shall specify how the final result of both measurements shall be obtained (e.g. lower value result, mean of the two values both results, or both values results).

If the difference between the two subject sample measurements results is more than: exceeds the greater of the following values

0.10 mg/L, or

20 % relative to of the smallest smaller of the two measurements results, depending on whichever is the greater

then the analyzer EBA shall automatically invalidate cancel the measurement cycle as invalid and shall display an appropriate error message because of the breath difference, based on national requirements.

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Note: ~~The National Authority may use specify tighter smaller breath differences than those listed above required here.~~
It may also choose specify not to perform a comparison of samples results when at least one in the event that
either of the sample measurements result is below the legal limit alcohol level that constitutes the offence of
driving or working under the influence of alcohol.

B.2.2.2 Test procedure of the second method

Table B.3

second method - Two-measurements cycle									
Test method	measurements with a difference of 12,5 % of the ethanol concentration between the two measurements of a measurement cycle								
Applicability	Applicable to all EBAs with a two-measurements-cycle for detecting alcohol in the upper respiratory tract								
Object of the test	Verification of compliance with the provisions in 7.1.7 under ambient reference conditions.								
Precondition	As defined in 11.5.1.								
Condition of the EUT	Power is to be "on" for the duration of the test.								
Test procedure in brief	The test comprises of 5 measurements with the special test gas								
measurement conditions	ethanol concentrations: <ul style="list-style-type: none"> - test gas concentration for the first measurement: 0.40 mg/L (test gas n° 4) - test gas concentration for the second measurement: 0.25 mg/L (test gas n° 3) test gas conditions: <table border="0"> <tr> <td>delivered volume:</td><td>3 L ± 0.1 L</td></tr> <tr> <td>duration of injection:</td><td>5 s ± 0.5 s</td></tr> <tr> <td>variation of the alcohol concentration as a function of time:</td><td> <ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o plateau duration equal to 3 s (type 2 test gas generator). </td></tr> <tr> <td>all other parameters as defined in in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.</td><td></td></tr> </table> ambient conditions: within reference conditions as defined in 11.4.1.	delivered volume:	3 L ± 0.1 L	duration of injection:	5 s ± 0.5 s	variation of the alcohol concentration as a function of time:	<ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o plateau duration equal to 3 s (type 2 test gas generator). 	all other parameters as defined in in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.	
delivered volume:	3 L ± 0.1 L								
duration of injection:	5 s ± 0.5 s								
variation of the alcohol concentration as a function of time:	<ul style="list-style-type: none"> o no variation (type 1 test gas generator) or o plateau duration equal to 3 s (type 2 test gas generator). 								
all other parameters as defined in in R 126-2, 2.4.3.1, table 4 and 2.4.3.2, table 6.									
EUT performance	number of measurements per test scheme: at least 5 time schedule: to be performed consecutively for each test scheme parameters at least to be recorded: as defined in R 126-2, 2.4.1								
Acceptance criteria	<ul style="list-style-type: none"> - The EUT shall calculate the difference in the ethanol concentration between the two measurements and shall not calculate/display a final result, if the difference between the 2 measurement results is >0.10 mg/L, or 20 % of the smaller of the two measurements results, depending on whichever is the greater. - It shall not deliver any measurement result and shall display an appropriate error message if applicable. 								

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~~national~~ Authority.

B.3 Delay before measurement

Good measurement practice, regardless of technical solutions (B.1, B.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.

National regulations may demand a mandatory observation period before each measurement in the field.

Annex C—General information and breath profile (Informative)

As defined in the Scope in R 126-1, 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.

C.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.

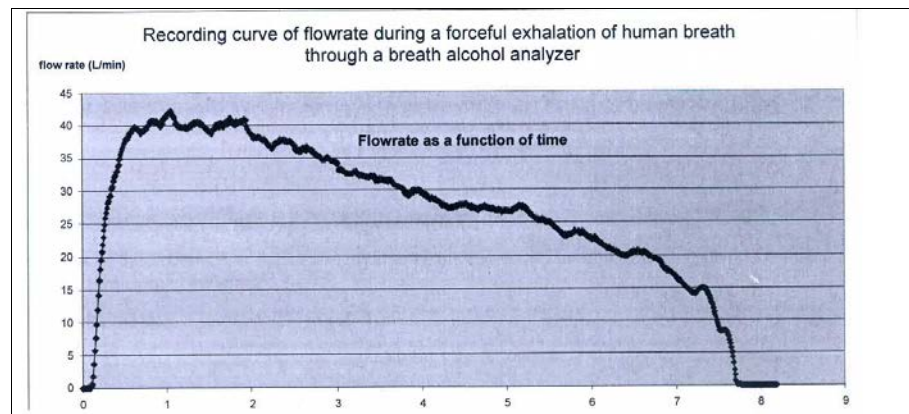


Figure C.1.1

C.1.2—Simulation curve of forced exhalation

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

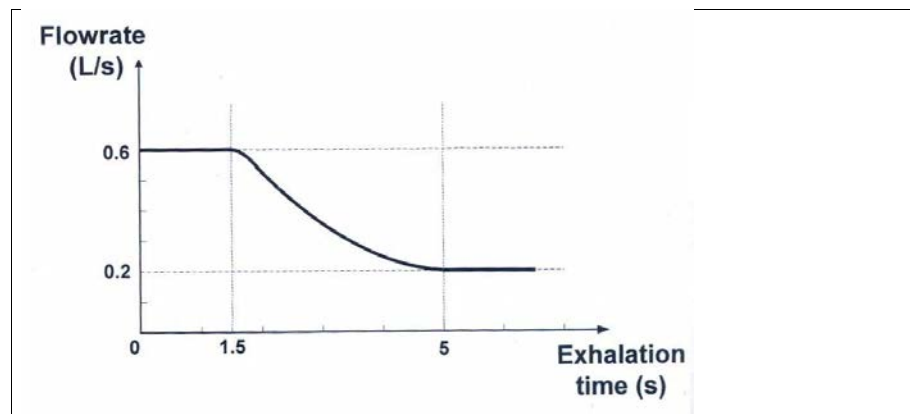


Figure B.1.2

- 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 of 150 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 indices

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

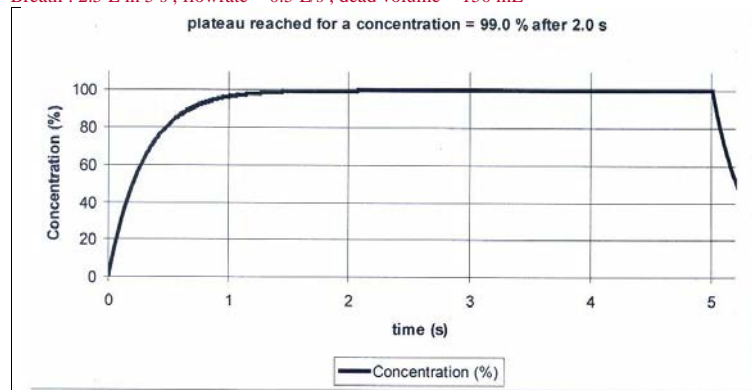


Figure C.2.1

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:

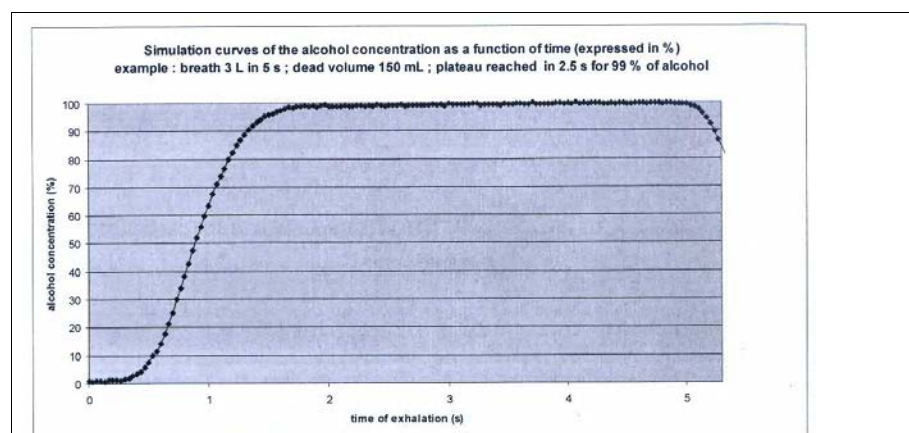


Figure C.2.2

~~Annex D~~ Reference principle for the implementation of the tests

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

Dubowski's formula

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

$$C_{air} = 0.04145 * C_{H_2O} * e^{(0.06583 * t)}$$

Where t is the temperature in °C

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

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 $t = 34\text{ °C}$, $C_{air} = 0.393 * 10^{-3} * C_{H_2O}$

Annex C

Comparison table of R126 CD 2 to Edition 2012

(Informative)

Table D.1: Part 2 of R 126

<u>OIML R 126 Edition 2012 (E)</u>		<u>R126-CD2 (2019)</u>		<u>Remarks</u>
<u>Ref.</u>	<u>Description</u>	<u>Ref.</u>	<u>Description</u>	
Part 2			Part 2 Metrological controls and performance tests	
10	Metrological controls	1	Metrological controls	clause extended with a general statement concerning provisions for measurement uncertainty
11	Type evaluation approval	2	Type evaluation	
11.1	Units submitted to type test	2.1	Instruments submitted for type evaluation	clause regarding adjustment before type approval moved to 2.5.1
11.2	Documentation	2.2	Documentation	documents concerning software are now listed as one point
11.3	Examinations and tests	2.3	Examination and tests	reference added to clarify the tests to be performed
11.3.1	Visual inspection	2.3.1	Visual examination	“adjustment facilities and “checking facilities” are now called “checking operations”
11.3.3	Software validation procedure	2.3.2	Software validation	Revised table with explanatory comments Examination level for storage (in insecure storage) and transmission of data is now raised to level “B” New requirements New table for the description of validation procedures
11.4	Performance tests	2.4	Test conditions and test gas generator	new clause/ head line
11.4.1	Reference conditions	2.4.1	Reference ambient conditions	Conditions now written as a table, new condition for the drift per hour for ambient temperature
11.4.2	Breath profile	2.4.2	Relevant characteristics of human breath	the list of characteristics is extended to breath temperature and relative humidity
11.4.3	Test sample delivery apparatus	2.4.3	Test gas generator	=
11.4.3.1	Characteristic reference values of the test gas	2.4.3.1	Characteristics of the test gas	test gas parameters now written as a table Rest of the clause is moved to the following clauses: 2.4.3.2 and 2.4.3.3
11.4.3.2	Capability of the testing apparatus	2.4.3.2	Capabilities of the test gas generator	More information about different types of test gas generators added, table with main features of the types introduced. New table showing an overview which simplified means are allowed for which test
11.4.3.3	Type of testing apparatus			
		2.4.3.3	Guidelines for the use of compressed dry gases	new clause concerning the use of compressed dry gases
		2.5	Performance tests	New clause/ head line
11.3.2	Test of instrumentation	2.5.1	General instructions	New text, combining parts from 11.1, 11.3. and 11.3.2
11.4.4	Errors under rated operating conditions	2.5.2	Preconditions for the tests	New clause, stating the preconditions valid for all tests
		2.5.3	parameters at least to be recorded	New clause, stating the parameters to be recorded for all tests
		2.5.4	Determination of errors and faults	New clause, description of the error calculation
11.4.4.1	Accuracy tests	2.5.5	Accuracy tests	=
a)	Maximum permissible errors and repeatability	2.5.5.1	Maximum permissible errors and repeatability	Layout changed to a standardized table
b)	Drift	2.5.5.2	Drift	Layout changed to a standardized table New specification of the test for long term drift
c)	Memory effects	2.5.5.3	Memory effects	Layout changed to a standardized table

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<u>11.4.4.2</u> Influence factors of the conditions of injection	<u>2.5.6</u> Influence factors of the conditions of injection	Layout changed to a standardized table, clarification of some test details
	<u>2.5.7</u> Tests for operating conditions	New clause/ head line
<u>11.4.4.3</u> Dry heat	<u>2.5.7.1</u>	Layout changed to a standardized table, definition of specific temperature for the different use-cases of EBA
<u>11.4.4.4</u> Cold		Temperature Test (dry heat and cold) Temperature modified New test sequence
<u>11.4.4.5</u> Damp heat, steady state (non-condensing)	<u>2.5.7.2</u> Damp heat, steady state (non-condensing)	Layout changed to a standardized table, definition of specific temperature for the different use-cases of EBA
<u>11.4.4.6</u> Atmospheric pressure	<u>2.5.7.3</u> Static atmospheric pressure	Layout changed to a standardized table, clarification of some test details Uncertainty of the pressure sensor is added here
<u>11.4.4.7</u> Random vibration	<u>2.5.7.4</u> Random vibration	Layout changed to a standardized table
<u>11.4.4.8</u> DC mains voltage variations	<u>2.5.7.5</u> DC mains voltage variations	Layout changed to a standardized table
<u>11.4.4.9</u> AC mains voltage variations	<u>2.5.7.6</u> AC mains voltage variations	Layout changed to a standardized table
<u>11.4.4.10</u> AC mains frequency variations	<u>2.5.7.7</u> AC mains frequency variations	Layout changed to a standardized table
<u>11.4.4.11</u> Low voltage of internal battery	<u>2.5.7.8</u> Low voltage of internal battery	Layout changed to a standardized table New procedure (0.9 lower voltage level)
<u>11.4.4.12</u> Voltage variations of a road vehicle battery	<u>2.5.7.9</u> Voltage variations of a road vehicle battery	Layout changed to a standardized table, clarification of some test details
<u>11.4.4.13</u> Total fraction by volume of hydrocarbons (as methane equivalent) in the environment	<u>2.5.7.10</u> Hydrocarbons in the environment	Layout changed to a standardized table, clarification of some test details
<u>11.4.4.14</u> Influence of the volume fraction of CO ₂	<u>2.5.7.11</u> Influence of a raised concentration of CO ₂ in the test gas	Layout changed to a standardized table correction of the test gas procedure according the Erratum 2 of the 2012-edition CO ₂ concentration of the test gas decreased
<u>11.4.5</u> Disturbance tests	<u>2.5.8</u> Disturbances tests	Deleted text of the clause, since it is already implemented in 2.5.1 to 2.5.4
<u>11.4.5.2</u> Conducted radio-frequency fields	<u>2.5.8.1</u> Conducted (common mode) currents generated by RF EM fields	Layout changed to a standardized table, clarification of some test details
<u>11.4.5.1</u> Radiated, radio frequency, electromagnetic fields	<u>2.5.8.2</u> Radiated RF electromagnetic fields	New approach introducing test schemes A or B which allows special test modes. Layout changed to a standardized table, clarification of some test details Extended frequency range up to 6000 MHz
<u>11.4.5.3</u> Electrostatic discharges	<u>2.5.8.3</u> Electrostatic discharges	Layout changed to a standardized table, clarification of some test details
<u>11.4.5.4</u> Bursts on supply lines	<u>2.5.8.4</u> Bursts (transients) on AC and DC mains	Layout changed to a standardized table, clarification of some test details
	<u>2.5.8.5</u> Surges on AC and DC mains power lines	New test
<u>11.4.5.5</u> Bursts on signal, data and control lines	<u>2.5.8.6</u> Bursts on signal, data and control lines	Layout changed to a standardized table, clarification of some test details
	<u>2.5.8.7</u> Ripple on DC mains power	New test
	<u>2.5.8.8</u> DC mains voltage dips, short interruptions and (short term) variations	New test
<u>11.4.5.7</u> AC mains voltage dips, short interruptions and voltage variations	<u>2.5.8.9</u> AC mains voltage dips, short interruptions and voltage variations	Layout changed to a standardized table, clarification of some test details
<u>11.4.5.6</u> Surges on signal, data and control lines	<u>2.5.8.10</u> Surges on signal, data and control lines	Layout changed to a standardized table, clarification of some test details
<u>11.4.5.8</u> Electrical transient conduction for external batteries of a vehicle	<u>2.5.8.11</u> Electrical transients conduction along supply lines	Layout changed to a standardized table, clarification of some test details
	<u>2.5.8.12</u> Electrical transient conduction via lines other than supply lines	New test

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<u>11.4.5.9</u> Mechanical shocks	<u>2.5.8.13</u> Mechanical shocks	Layout changed to a standardized table, clarification of some test details Number of falls doubled for portable EBAs
<u>11.4.5.10</u> Shakes	<u>2.5.8.14</u> Shakes	Layout changed to a standardized table, clarification of some test details
<u>11.4.5.11</u> Damp heat cyclic (condensing)	<u>2.5.8.15</u> Damp heat cyclic (condensing)	Layout changed to a standardized table, clarification of some test details
<u>11.4.5.12</u> Storage test	<u>2.5.8.16</u> Storage test	Layout changed to a standardized table, clarification of some test details
	<u>2.5.8.17</u> Vibration (as disturbance)	new test (for stationary EBA only)
<u>11.4.5.13</u> Durability	<u>2.5.8.18</u> Durability	-
<u>11.4.6</u> Physiological influence quantities	<u>2.5.9</u> Physiological influence quantities	Layout changed to a standardized table, clarification of some test details New approach for the acceptance criteria "sensitivity"
	<u>2.6</u> Tests for optional disturbances and requirements	new clause/ headline
	<u>2.6.1</u> Sand and dust	New test
	<u>2.6.2</u> Salt mist	New test
	<u>2.6.3</u> water	New test
	<u>3</u> Initial and subsequent verifications	New clause
	<u>3.1</u> General considerations	New clause
	<u>3.1.1</u> Initial verification	New clause
	<u>3.1.2</u> subsequent verification	New clause
	<u>3.2</u> Legal status of the instrument submitted for verification	New clause
	<u>3.3</u> Visual Examination	New clause
	<u>3.4</u> Metrological examination	New clause
	<u>3.4.1</u> Metrological precondition for performing tests	New clause
	<u>3.4.2</u> Test gases used for verification	New clause
	<u>3.4.3</u> Tests for initial or subsequent verifications	New clause
	<u>3.4.3.1</u> Metrological examination	New clause
	<u>3.4.3.2</u> Verification marks, seals and documentation	New clause
	<u>Annex A</u> General Examples for Test Gas Generators	New clause (clause re-introduced from edition 1998)
<u>Annex C</u> Reference principle for the implementation of the tests (Informative)	<u>A.1</u> Reference principle for the implementation of the test	revised text, revised symbols of the equations
	<u>A.2</u> Example of a type 1 test gas generator	New clause with new diagrams
	<u>A.3</u> Example of a type 2 test gas generator	New clause with new diagrams
<u>Annex B</u> General information and breath profile (Informative)	<u>A.4</u> General Information about breath profiles (Informative)	
<u>B.1</u> Measurement flowrate during exhalation	<u>A.4.1</u> Example of human breath profiles	revised clause, new example of a volumetric diagram
<u>B.2</u> Measurement of the alcohol concentration during exhalation / determination of the alcohol plateau	<u>A.4.2</u> Simulation of breath profiles with test gas generators	revised clause clarification of some details
<u>Annex A</u> Examples of detection of alcohol in upper respiratory tracts (Informative)	<u>Annex B</u> Examples of detection of alcohol in upper respiratory tracts (Informative)	
<u>A.1</u> Peak method	<u>B.1</u> Peak method	
<u>A.2</u> Two-measurement cycle	<u>B.2</u> Two-measurement cycle	
<u>A.3</u> Delay before measurement	<u>B.3</u> Delay before measurement	
	<u>Annex C</u> Comparison table of R126 CD 2 to Edition 2012, part 2	new clause
<u>Annex D</u> Bibliography	<u>Annex D</u> Bibliography	Updated

~~Annex CD~~ — **Bibliography**

Bibliography **(Informative)**

~~When proceeding to the CD stage, this is to be updated to recent documents~~

At the time of publication, the editions indicated were valid. All referred documents are subject to revision, and the users of this Document are encouraged to investigate the possibility of applying the most recent editions of the referred documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

The actual status of the Standards referred to can also be found on the Internet:

IEC Publications:	http://www.iec.ch/searchpub/cur_fut.htm
ISO Publications:	http://www.iso.org
OIML Publications:	https://www.oiml.org/en/publications/ (with free download of PDF files).

In order to avoid any misunderstanding, it is highly recommended that all references to Standards in International Recommendations and International Documents be followed by the version referred to (generally the year or date).

Ref.	Standards and reference documents	Description
[1]	OIML V 1:2013 International vocabulary of terms in legal metrology (VIML)	The VIML includes only the concepts used in the field of legal metrology. These concepts concern the activities of the legal metrology service, the relevant documents, as well as other problems linked with this activity. Also included in this Vocabulary are certain concepts of a general character which have been drawn from the VIM.
[2]	OIML V 2-200:2012 International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM), 3rd Edition	Vocabulary, developed by the Joint Committee for Guides in Metrology (JCGM).
[3]	OIML D 9:2004 Principles of metrological supervision	
[4]	OIML D 11:2013 General requirements for measuring instruments – Environmental conditions	Guidance for establishing appropriate metrological performance testing requirements for influence quantities that may affect the measuring instruments.
[5]	revised OIML D 31: 2008 – 2 CD:Nov 2018	General requirements for software controlled measuring instruments
[6]	OIML G 1-100:2008 Guide to the expression of Uncertainty in Measurement (GUM)	Evaluation of measurement data - Guide to the expression of uncertainty in measurement
[7]	OIML G 1-104:2009 Evaluation of measurement data – An introduction to the „Guide to the expression of Uncertainty” and related documents	
[8]	IEC 60068-2-1:2007 Environmental testing - Part 2-1: Tests - Test A: Cold	Deals with cold tests applicable to both non heat-dissipating and heat-dissipating specimens. The object of the cold test is limited to the determination of the ability of components, equipment or other articles to be used, transported or stored at low temperature.
[9]	IEC 60068-2-2:2007 Environmental testing - Part 2-2: Tests - Test B: Dry heat	Deals with dry heat tests applicable both to heat-dissipating and non heat-dissipating specimens. The object of the dry heat test is limited to the determination of the ability of components, equipment or other articles to be used, transported or stored at high temperature.
[10]	IEC 60068-2-11:1981 Basic environmental testing procedures - Part 2-11: Tests - Test Ka: Salt mist	Compares resistance to deterioration from salt mist between specimens of similar construction. May be used to evaluate the quality and the uniformity of protective coatings.
[11]	IEC 60068-2-18:2017 Environmental testing - Part 2-18: Tests - Test R and guidance: Water	Provides methods of test applicable to products which, during transportation, storage or in service, can be subjected to falling water drops, impacting water, immersion or high pressure water impact.

Commented [RK45]: this will be updated as soon as the new version will be published (to be expected in 2019)

[12]	IEC 60068-2-30:2005 Environmental testing - Part 2-30: Tests - Test Db: Damp heat, cyclic (12 h + 12 h cycle)	Determines the suitability of components, equipment or other articles for use, transportation and storage under conditions of high humidity - combined with cyclic temperature changes and producing condensation on the surface of the specimen.
[13]	IEC 60068-2-31:2008 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	Deals with a test procedure for simulating the effects of rough handling shocks, which may be received during repair work or rough handling in operational use.
[14]	IEC 60068-2-47:2005 Environmental testing - Part 2-47: Test - Mounting of specimens for vibration, impact and similar dynamic tests	Provides methods for mounting products as well as mounting requirements for equipment and other articles, for the series of dynamic tests
[15]	IEC 60068-2-64:2008 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	Demonstrates the adequacy of specimens to resist dynamic loads without unacceptable degradation of its functional and/or structural integrity when subjected to the specified random vibration test requirements.
[16]	IEC 60068-2-78:2012 Environmental testing - Part 2-78: Tests - Test Cab: Damp heat, steady state	Establishes a test method for determining the ability of components or equipment to withstand transportation, storage and use under conditions of high humidity.
[17]	IEC 60512-11-8:1995 Electromechanical components for electronic equipment - Basic testing procedures and measuring methods - Part 11: Climatic tests - Section 8: Test 11h - Sand and dust	Defines a standard test method to assess the ability of a connector to withstand driving fine sand and dust.
[18]	IEC 60529:1989+AMD1:1999+AMD2:2013 Degrees of protection provided by enclosures (IP Code)	Applies to the classification of degrees of protection provided by enclosures for electrical equipment with a rated voltage not exceeding 72,5 kV.
[19]	IEC 60654-2:1979 +AMD1:1992 Operating conditions for industrial-process measurement and control equipment. Part 2: Power	Gives the limiting values for power received by land-based and offshore industrial process measurement and control systems or parts of systems during operation.
[20]	IEC 60721-2-5:1991 Classification of environmental conditions - Part 2: Environmental conditions appearing in nature - Section 5: Dust, sand, salt mist	Presents characteristics of dust, sand and salt mist appearing in nature, and describes the influences from these environmental factors to which products are liable to be exposed during storage, transportation and use.
[21]	IEC TR 61000-4-1:2016 Electromagnetic compatibility (EMC) - Part 4-1: Testing and measurement techniques - Overview of IEC 61000-4 series	IEC TR 61000-4-1:2016(E) gives information and guidance on the EMC basic standards and other basic EMC documents published in the IEC 61000-4 series.
[22]	IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	Relates to the immunity requirements and test methods for electrical and electronic equipment subjected to static electricity discharges, from operators directly, and from personnel to adjacent objects.
[23]	IEC 61000-4-3:2006 +AMD1:2007+AMD2:2010 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	Is applicable to the immunity requirements of electrical and electronic equipment to radiated electromagnetic energy. It establishes test levels and the required test procedures.
[24]	IEC 61000-4-4:2012 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test	Relates to the immunity of electrical and electronic equipment to repetitive electrical fast transients. It gives immunity requirements and test procedures related to electrical fast transients/bursts.
[25]	IEC 61000-4-5:2014+AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	Relates to the immunity requirements, test methods, and range of recommended test levels for equipment with regard to unidirectional surges caused by over-voltages from switching and lightning transients.
[26]	IEC 61000-4-6:2013 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	Relates to the conducted immunity requirements of electrical and electronic equipment to electromagnetic disturbances coming from intended radio-frequency (RF) transmitters in the frequency range 150 kHz up to 80 MHz

[27]	IEC 61000-4-11:2004+AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	Defines the immunity test methods and range of preferred test levels for electrical and electronic equipment connected to low-voltage power supply networks for voltage dips, short interruptions, and voltage variations.
[28]	IEC 61000-4-17:1999 +AMD1:2001+AMD2:2008 Electromagnetic compatibility (EMC) - Part 4-17: Testing and measurement techniques - Ripple on d.c. input power port immunity test	Defines test methods for immunity to ripple at the d.c. input power port of electrical or electronic equipment. Applies to low-voltage d.c. power ports of equipment supplied by external rectifier systems, or batteries which are being charged.
[29]	IEC 61000-4-20:2010 Electromagnetic compatibility (EMC) - Part 4-20: Testing and measurement techniques - Emission and immunity testing in transverse electromagnetic (TEM) waveguides	Relates to emission and immunity test methods for electrical and electronic equipment using various types of transverse electromagnetic (TEM) waveguides.
[30]	IEC 61000-4-29:2000 Electromagnetic compatibility (EMC) - Part 4-29: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations on d.c. input power port immunity tests	Establishes a common and reproducible basis for testing electrical and electronic equipment when subjected to voltage dips, short interruptions or voltage variations on d.c. power ports.
[31]	IEC 61000-6-1:2016 Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments	Applies to electrical and electronic equipment intended for use in residential, commercial, public and light-industrial locations. Immunity requirements in the frequency range 0 Hz to 400 GHz are covered.
[32]	IEC 61000-6-2:2016 Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments	Applies to electrical and electronic equipment intended for use in industrial locations, as described below. Immunity requirements in the frequency range 0 Hz to 400 GHz are covered.
[33]	ISO 7637-2:2011 Road vehicles — Electrical disturbances from conduction and coupling — Part 2: Electrical transient conduction along supply lines only	Specifies test methods and procedures to ensure the compatibility to conducted electrical transients of equipment installed on passenger cars and commercial vehicles fitted with 12 V or 24 V electrical systems.
[34]	ISO 7637-3:2016 Road vehicles — Electrical disturbances from conduction and coupling — Part 3: Electrical transient transmission by capacitive and inductive coupling via lines other than supply lines	Defines bench test methods to evaluate the immunity of devices under test (DUTs) to transient pulses coupled to lines other than supply lines.
[35]	ISO 16750-2:2012 Road vehicles — Environmental conditions and testing for electrical and electronic equipment — Part 2: Electrical loads	Applies to electric and electronic systems/components for road vehicles. It describes the potential environmental stresses and specifies tests and requirements recommended for the specific mounting location on/in the road vehicle
[36]	ISO/IEC 9594-8:2017 Information technology - Open Systems Interconnection - The Directory - Part 8: Public-key and attribute certificate frameworks	addresses some of the security requirements in the areas of authentication and other security services through the provision of a set of frameworks upon which full services can be based
[37]	OIML G 19:2017 The role of measurement uncertainty in conformity assessment decisions in legal metrology	
[38]	David Grubb, Lars Lindberg: "Exhalation profile and elimination kinetics of mouth alcohol", Blutalkohol Vol 48/2011, p. 57 - 66	