

FINAL DRAFT
RECOMMENDATION

56th CIML Meeting

2021

SUBMITTED
FOR CIML
APPROVAL

Revision of R 126:

Evidential breath analyzers

Part 2: Metrological controls and performance tests

(Clean version)



ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

Contents

Foreword	4
1 Metrological controls	5
2 Type evaluation	5
2.1 Instruments submitted for type evaluation	5
2.2 Documentation	6
2.3 Examination and tests	6
2.4 Test conditions and test gas generator	8
2.5 Performance tests	13
2.6 Tests for optional disturbances and requirements	58
3 Initial and subsequent verifications	62
3.1 General considerations	62
3.2 Legal status of the instrument submitted for verification	62
3.3 Visual examination	62
3.4 Metrological examination	63
Annex A General examples for test gas generators	64
A.1 Reference principle for the implementation of the test	64
A.1.1 Dubowski's formula	64
A.1.2 Harger's formula	64
A.2 Example of a type 1 test gas generator	65
A.3 Example of a type 2 test gas generator	67
A.4 General information about breath profiles	70
A.4.1 Example of human breath profiles	70
A.4.2 Simulation of breath profiles with test gas generators	71
Annex B Examples of detection of alcohol in upper respiratory tracts	74
B.1 Peak method	74
B.1.1 Principle of the peak method	74
B.1.2 Test procedure for the peak method	75
B.2 Two-measurement cycle – first and second methods	76
B.2.1 Principle of the two-measurements cycle - first method	76
B.2.2 Test procedure of the two-measurements cycle - first method	77
B.2.3 Principle of the two-measurements cycle - second method	79
B.2.4 Test procedure of the two-measurements cycle second method	79
B.3 Delay before measurement	80
Annex C Comparison table between R 126:2012 and R 126:2021	81
Annex D Bibliography	87

Foreword

The International Organisation of Legal Metrology (OIML) is a worldwide, intergovernmental organisation whose primary aim is to harmonise the regulations and metrological controls applied by the national metrological services, or related organisations, of its Member States.

The main categories of OIML publications are:

- **International Recommendations (OIML R)**, which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. 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 harmonise and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.

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

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

Additionally, the OIML participates in Joint Committees with other Institutions for the development of **Vocabularies (OIML V)** and **Joint Guides (G)** 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 126-2, edition 2021 (E) - was developed by OIML Technical Subcommittee TC 17/SC 7 *Breath testers*. It was approved for final publication by the International Committee of Legal Metrology at its 56th meeting in 2021 and supersedes OIML R 126:2012. It was sanctioned by the International Conference on Legal Metrology in 2021.

OIML Publications may be downloaded from the OIML website in the form of PDF files. Additional information on OIML Publications may be obtained from the Organisation's headquarters:

Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris – France
Telephone: 33 (0)1 48 78 12 82
Fax: 33 (0)1 42 82 17 27
E-mail: biml@oiml.org
Internet: www.oiml.org

Part 2 Metrological controls and performance tests

1 Metrological controls

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

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

Part 2 of this Recommendation concerns the examinations and tests for (type-)evaluation, verification and during supervision in order to verify the conformity of the instrument to the requirements 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.

For more information, refer to relevant literature, e.g. OIML G 1-100 [6], OIML G 1-104 [7], OIML G 19[36].

2 Type evaluation

2.1 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 2.2 to 2.5 and if applicable, the tests specified in 2.6

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 (2.5.5) and influence tests (2.5.6, 2.5.7 and 2.5.9) shall be performed on the same instrument, but disturbance tests (2.5.8) 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 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, 7.1.10),
- 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 it necessary, it can require more detailed documentation, either to be able to study the quality of the instrument, or to be able to document in sufficient detail the approved type, or both.

2.3 Examination and tests

Examination and testing of instruments are intended to verify their compliance with the requirements of R 126-1.

The examination and tests shall cover all the applicable requirements of R 126-1, 4 to 9.

2.3.1 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 7.1.10.3);
- f) checking operations (R 126-1, 7.1.3);
- g) software (R 126-1, 7.1.10);
- h) inscriptions and sealing (R 126-1, 9);
- i) operating instructions (R 126-1, 8);
- j) suitability for testing.

and if applicable:

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

2.3.2 Software validation

The validation procedure of the software related functionalities of EBAs is given in Table 1.

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

Table 1 - Software validation procedures

Chapter	Validation procedure	Examination level	Comments
Software identification	AD + VFTSw	A	If high conformity (level B) is required, also perform CIWT.
Correctness of algorithms and functions	AD + VFTSw	A	If high conformity (level B) is required, also perform 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 of software	AD + VFTSw + VFTM	A	For verified update procedures.
Storage of data	AD + VFTSw	A	For storage of data only with the EBA.
	AD + VFTSw + CIWT/SMT ⁽¹⁾	B	If required by national authorities, for storage in unsecure storages.
Automatic storing	AD + VFTSw	A	If high conformity (level B) is required, also perform SMT.
Transmission of data	AD + VFTSw + CIWT/SMT ⁽¹⁾	B	Transmission into open systems, if required by national authorities.

- ⁽¹⁾: The SMT validation procedure will be applied only in exceptional cases when the functions of a software module cannot be examined exclusively on the basis of written information (validation procedure CIWT). It is appropriate and effective in the verification of dynamic measurement algorithms.

Table 2 - Abbreviations for software validation

Abbreviation	Description	Application	Used for examination level:
AD	Analysis of the documentation and validation of the design	Always	A (normal level) ⁽²⁾
VFTM	Validation by functional testing of metrological functions	Correctness of the algorithms, uncertainty, compensating and correcting algorithms.	
VFTSw	Validation by functional testing of software functions	Correct functioning of communication, indication, fraud protection, protection against operating errors, protection of parameters, fault detection	
CIWT	Code inspection and walkthrough	All purposes	B (raised level) ⁽²⁾
SMT	Software module testing	All purposes when input and output can clearly be defined	

⁽²⁾: For detailed information about validation procedures and examination levels, refer to OIML D 31 [5].

2.3.3 Operational tests

The instrument shall be submitted to the performance tests specified in 2.5 to determine its correct functioning under various conditions and influence factors.

2.4 Test conditions and test gas generator

2.4.1 Reference conditions

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

Table 3 - Reference conditions

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	0 µmol/mol to 5 µmol/mol total mol fraction (as methane equivalent)	
AC mains voltage and frequency (if appropriate)	Nominal values specified in R 126-1, 6.10.1, Table 2	Within the nominal values specified in R 126-1, 6.10.1, Table 2

Note: Throughout OIML R 126, “reference conditions” refers to ambient conditions.

2.4.2 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 A.4 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 A.4 provides explanatory information);
- breath temperature of 34 °C;
- relative humidity of 95 %;
- mol fraction of CO₂: up to 50 mmol/mol

2.4.3 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 Characteristics of the test gas

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

Table 4 - Reference gas conditions

Parameter	Nominal value with allowed deviation
Delivered volume	2 L \pm 0.3 L
Total duration of the injection (into the EBA)	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) with a deviation from the target value of \pm ($\frac{2}{3}$ MPE)
Gas temperature	34 °C \pm 0.5 °C
Relative humidity of the gas	95 % \pm 5 % (without condensation)
Carrier gas	Air containing insignificant concentrations of relevant impurities with a mol fraction of CO ₂ of: (50 \pm 5) mmol/mol

2.4.3.2 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 fulfils the breath profile defined in A.4.2.

Table 5 classifies the features of the different test gas generators and simplified means stated in this Recommendation.

Note that in the following clauses, compressed dry gases will also be covered by the term “test gas generator”.

Also note that Table 5 is not intended to exclude the enhancement of advanced generator types with more features than currently marked or shown. The development of new combinations of features shall not be hampered with this table.

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

Table 5 - Generator types and features

Feature	Type 2 generator	Type 1 generator	Simplified means-type 1 without CO ₂	Simplified means – dry gas	
				with CO ₂	without CO ₂
Capability to generate profiles defined in A.4.2	X				
Gas temperature: 34 °C ± 0.5 °C	X	X	X		
Relative humidity range: 95 % ± 5 %	X	X	X		
Mol fraction CO ₂ : (50 ± 5) mmol/mol	X	X		X	
Realisation 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 A provides information about the reference principles to be used as well as examples for test gas generators.

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 2.4.3.1, but with flowrate and alcohol profiles described in A.4.2. Test gas generators with the feature of generating flow and alcohol profiles are described here as a type 2 gas generator.

So, for the complete test program the type 2 generator will be sufficient, but for certain tests the use of test gases deriving from a type 1 generator (constant alcohol concentration) is allowed, 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). Table 6 shows an overview in 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.

Table 6 – Overview: use of simplified means

Test clause of R 126-2		Dry gases allowed	Gases without CO ₂ allowed	Remarks
2.5.5.1	MPE and repeatability			
2.5.5.2	Drift			The humidity in breath might also cause a drift. Therefore, it is essential to use only wet test gases here
2.5.5.3	Memory effects			
2.5.5.4	Effect of water vapour (condensation)		X	
2.5.6.1	Influence factors of the condition of injection	X	X	Dry gases are allowed provided that the parameters of the test gas (flow, alcohol concentration profiles) can be modified accordingly
2.5.6.2	Alcohol in the upper respiratory tract		X	
2.5.7.1	Temperature test		X	
2.5.7.2	Damp heat, steady-state		X	
2.5.7.3	Static atmospheric pressure	X	X	Dry gases or gases without CO ₂ are allowed in combination with a
2.5.7.4	Random vibration	X	X	

Test clause of R 126-2		Dry gases allowed	Gases without CO ₂ allowed	Remarks
2.5.7.5	DC mains voltage variations	X	X	preliminary repeatability test performed with wet gases. This may consist of the repeatability test defined in 2.5.5.1
2.5.7.6	AC mains voltage variation	X	X	
2.5.7.7	AC mains frequency variation	X	X	
2.5.7.8	Low voltage of internal battery	X	X	
2.5.7.9	Power supply duration test	X	X	
2.5.7.10	Voltage variations of a vehicle battery	X	X	
2.5.7.11	Hydrocarbons in the environment	X	X	
2.5.7.12	Raised fraction of CO ₂ in the test gas	X		
2.5.8.1	Conducted currents by RF EM fields	X	X	Dry gases or gases without CO ₂ are allowed in combination with a preliminary repeatability test performed with wet gases. This may consist of the repeatability test defined in 2.5.5.1
2.5.8.2	Radiated RF electromagnetic fields	X	X	
2.5.8.3	Electrostatic discharges	X	X	
2.5.8.4	Bursts on AC and DC mains	X	X	
2.5.8.5	Surges on AC + DC mains power lines	X	X	
2.5.8.6	Bursts on signal, data and control lines	X	X	
2.5.8.7	Ripple on DC mains power	X	X	
2.5.8.8	DC mains voltage dips, short interruptions and variations	X	X	
2.5.8.9	AC mains voltage dips, short interruptions and reductions	X	X	
2.5.8.10	Surges on signal, data and control lines	X	X	
2.5.8.11	Electrical transient conduction along supply lines	X	X	
2.5.8.12	Electrical transient conduction via lines other than supply lines	X	X	
2.5.8.13	Mechanical shock	X	X	
2.5.8.14	Shakes	X	X	
2.5.8.15	Damp heat cyclic (condensing)		X	
2.5.8.16	Storage test		X	
2.5.8.17	Vibration (as disturbance)	X	X	
2.5.9	Physiological influence quantities	X	X	Dry gases or gases without CO ₂ are allowed in combination with a preliminary repeatability test performed with wet gases. This may consist of the repeatability test defined in 2.5.5.1
2.6.1	Sand and dust		X	
2.6.2	Salt mist		X	
2.6.3	Water		X	

Some of the tests defined in 2.5.6 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 2.5.6.1. For all other tests, the flowrate and alcohol concentration may be constant during injection.

2.4.3.3 Guidelines for the use of compressed dry gases

When compressed gases are used within the context of this Recommendation, the following guidelines shall be followed:

- a) Variations in atmospheric pressure, as well as the temperature of the gas shall be taken into account.
- b) 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 minimise contamination and a change in the composition of alcohol throughout its use cycle.
- c) The measurement uncertainties of the test gas generator shall be taken into account in calculations of the uncertainties of the measurement.
- d) The main component of the gas shall be dry air. If other gas, e.g. N₂, is used as the main component, the equivalence to air shall be established.
- e) When working with dry test gas the atmospheric pressure has to be monitored and reported in the test protocol.

2.5 Performance tests

2.5.1 General instructions

The tests specified in R 126-2 are designed to prove compliance of the instrument with the requirements specified in R 126-1. 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.

If permitted by national authorities, before starting the process of type evaluation the EBA may be adjusted, if necessary, in order to minimise the initial intrinsic error.

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 of the EUT;
- power supply for the duration of the test:
 - a) mains power-operated EUTs: to be “on” for the duration of the test and not be switched off. It is acceptable when the EUT enters standby mode after a specified idle time within the duration of the test;
 - b) battery-operated EUTs: according to the instruction manual. It is acceptable when the EUT enters standby mode or “off” after a specified idle time within the duration of the test.
- the EUT shall not be readjusted at any time during the test;
- the EUT shall be used in metrological test mode;
- the EUT shall perform 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.

2.5.3 Parameters at least to be recorded

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

- date and time;
- ambient temperature;
- ambient relative humidity;
- ambient pressure;
- values of the measurand;
- indications and errors of the EUT;
- functional performances;
- 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.

2.5.4 Determination of errors and faults

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

- The intrinsic indication is determined as the arithmetic mean 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 arithmetic mean of the prescribed number of measurements during or after the impact of the influence factor or the disturbance. The measurement error will be the deviation between the indication and the reference value.
- The fault is determined as the difference between the measurement error and the intrinsic error.

2.5.5 Accuracy tests

2.5.5.1 Maximum permissible errors and repeatability

Table 7 - 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.
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 no.: 1) 0 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 gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1.
EUT performance	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 2.5.3.
Acceptance criteria	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 specified in R 126-1, 6.6.1. Each set of measurements shall comply with repeatability defined in R 126-1, 6.7.

2.5.5.2 Drift

Table 8 - 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	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 at least during each set of measurements. ⁽¹⁾
Test procedure in brief	The tests comprise 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 is completed.
Measurement conditions	Ethanol concentrations: for zero drift: 0.00 mg/L to 0.05 mg/L (test gas no. 1) for short-term drift: 0.40 mg/L (test gas no. 4) for long-term drift: 0.40 mg/L (test gas no. 4) Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1.
EUT performance	Number of measurements per point in time: 10 Time schedule: - at start - as defined in “test procedure in brief” Parameters at least to be recorded: as defined in 2.5.3.
Acceptance criteria	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).

- (1): It is strongly recommended to follow the EBA instruction manual. The test situation shall correspond to the normal use of the respective EBA in the field. The testing laboratory shall note how any power-down or standby mode functions were operated between drift tests.

2.5.5.3 Memory effects

Table 9 - Memory effects

Test method	Measurement of different mass concentrations of ethanol in succession.
Applicability	Applicable to all EBAs.
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.
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 subjected to a series of measurements with alternating concentrations: <ul style="list-style-type: none"> o one measurement using the higher concentration, o followed immediately by one measurement using the lower gas concentration. <p>This alternating test sequence shall 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 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 no. 7) or 1.90 mg/L (test gas no. 8)</p> <p>low gas concentration: 0.10 mg/L (test gas no. 2)</p> <p>Case 2: small differences: high gas concentration: 0.40 mg/L (test gas no. 4)</p> <p>low gas concentration: 0.25 mg/L (test gas no. 3)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>
EUT performance	<p>Number of alternating test sequences: 10</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>
Acceptance criteria	<p>Each individual measurement shall comply with the MPE as defined in R 126-1, 6.6.1.</p> <p>The arithmetic mean of the initial test series results and the arithmetic mean of the results for the lower concentration of the alternating cycle shall be calculated. The difference between these mean values shall fulfil the requirements for memory effects (R 126-1, 6.9).</p>

2.5.5.4 Effect of water vapour (condensation)

Table 10 - Effect of water vapour (condensation)

Test method	Measurement of different mass concentrations of ethanol in succession under specific temperature conditions.														
Applicability	Applicable to all EBAs.														
Object of the test	Verification of compliance with the requirements for memory effects - effect of water vapour (R 126-1, 6.9.3).														
Condition of the EUT	Power is to be “on” for the duration of the test.														
Test procedure in brief	The tests comprise of measurements with two different wet test gases at the specified low ambient temperature for the use-case type of EBAs. Stabilising time at the low ambient temperature: at least 2 hours. Test sequence: 1) Ten measurements at 0.00 mg/L at the maximum rate permitted by the EBA; 2) Five measurements at 0.40 mg/L.														
Measurement conditions	Ethanol concentrations: a) 0.00 mg/L (test gas no. 1); b) 0.40 mg/L (test gas no. 4) Test gas conditions: within reference conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: <table><tr><td>Use-case</td><td>Temperature</td><td>Relative humidity</td></tr><tr><td>stationary</td><td>0 °C</td><td>≤ 85 %</td></tr><tr><td>transportable</td><td>−5 °C</td><td>≤ 85 %</td></tr><tr><td>portable</td><td>−10 °C</td><td>≤ 85 %</td></tr></table> All other parameters within reference conditions as defined in 2.4.1.			Use-case	Temperature	Relative humidity	stationary	0 °C	≤ 85 %	transportable	−5 °C	≤ 85 %	portable	−10 °C	≤ 85 %
Use-case	Temperature	Relative humidity													
stationary	0 °C	≤ 85 %													
transportable	−5 °C	≤ 85 %													
portable	−10 °C	≤ 85 %													
EUT performance	Number of measurements: for (1): 10 measurements for (2): 5 measurements Time schedule: (1) and (2) to be performed consecutively, both at the maximum rate permitted by the EBA. Parameters at least to be recorded: as defined in 2.5.3.														
Acceptance criteria	Each individual measurement shall comply with the MPE as defined in R 126-1, 6.6.1.														

2.5.6 Influence factors of the conditions of injection

2.5.6.1 Variations of the test gas parameters

Table 11 - Variations of the test gas parameters

Test method		Variations of the test gas parameters
Applicability		Applicable to all EBAs. Test f) is applicable only to EBAs for which the minimum exhalation time (t_{\min}) < 5 s ⁽¹⁾
Object of the test		Verification of compliance with the analysis of end expiry breath (R126-1, 4.3) and the requirements for conditions of exhalation (R 126-1, 6.10.2 and 7.1.7), 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.
Condition of the EUT		Power is to be “on” for the duration of the test.
Basic test procedure		For each influence to be tested, 2 or more tests with different conditions are defined. For each test, at least 5 subsequent test sequences shall be performed.
Measurement conditions		Ethanol concentration: 0.40 mg/L (test gas no. 4) Test gas conditions: as defined at the respective tests; all other parameters within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1.
Influence	a) Influence of delivered volume and duration of injection	Test gas generator: type 1 or type 2 <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"> • no variation (type 1 test gas generator) or • plateau duration equal to 3 s (type 2 test gas generator). First test: <ul style="list-style-type: none"> - Delivered volume: 1.5 L ± 0.1 L; - Duration of the injection: 5 s ± 0.5 s. Second test: <ul style="list-style-type: none"> - Delivered volume: 4.5 L ± 0.3 L; - Duration of the injection: 15 s ± 0.5 s
	b) Influence of flowrate and of duration of injection	Test gas generator: type 1 or type 2 <ul style="list-style-type: none"> - Variation of the flowrate as a function of time: no variation First test: <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 alcohol concentration as a function of time: no variation (type 1 test gas generator) or plateau duration equal to 4.5 s (type 2 test gas generator). Second test: <ul style="list-style-type: none"> - Delivered volume: 3.0 L ± 0.2L; - Duration of the injection: 15 s ± 0.5 s; - Variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> • no variation (type 1 test gas generator);or • plateau duration equal to 6 s (type 2 test gas generator). Third test: <ul style="list-style-type: none"> - Delivered volume: 4.5 L ± 0.3 L; - Duration of the injection: 7.5 s ± 0.5 s; - Variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> • no variation (type 1 test gas generator); or • plateau duration equal to 3.5 s (type 2 test gas generator).
	c) Influence of flowrate during exhalation	Test gas generator: type 1 or type 2 <ul style="list-style-type: none"> - Variation of the alcohol concentration as a function of time: <ul style="list-style-type: none"> • no variation (type 1 test gas generator) or • the same plateau duration in both tests (type 2 test gas generator).

Test method	Variations of the test gas parameters
	<p>First test:</p> <ul style="list-style-type: none"> - Delivered volume: $3.0 \text{ L} \pm 0.2 \text{ L}$; - Flowrate: $0.6 \text{ L/s} \pm 0.08 \text{ L/s}$ - Variation of flowrate as a function of time: no variation <p>Second test:</p> <ul style="list-style-type: none"> - Delivered volume: $3.0 \text{ L} \pm 0.2 \text{ L}$; - Variation in the flowrate as a function of time: <ul style="list-style-type: none"> • Initial flowrate: 0.6 L/s during 1.5 s, • between 1.5 s and 5 s the flowrate decreases to 0.2 L/s; • after 5 s, the flowrate remains equal to 0.2 L/s until the end of the injection.
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: $3.0 \text{ L} \pm 0.2 \text{ L}$; Duration of the injection: $5 \text{ s} \pm 0.5 \text{ s}$; Duration of the plateau: 3 s <p>Second test:</p> <ul style="list-style-type: none"> Delivered volume: $3.0 \text{ L} \pm 0.2 \text{ L}$; Duration of the injection: $5 \text{ s} \pm 0.5 \text{ s}$; Duration of the plateau: 1.5 s
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 alcohol concentration as a function of time: <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>First test: Abruption at the beginning of the exhalation</p> <ul style="list-style-type: none"> - Delivered volume: $2.0 \text{ L} \pm 0.2 \text{ L}$; - 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: verification of the minimum exhaled volume</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 (delivered volume $< 1.2 \text{ L}$) <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 for $6 \text{ s} \pm 1 \text{ s}$, and then decreased fast (within 1 s to 2 s) 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 after 1 to 2 s for a short period (e.g. 0.5 s) and then continued.
f) Operation at the minimum exhaled volume and minimum exhalation time (t_{\min}) ⁽¹⁾	<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: no variation - Flowrate: $0.4 \text{ L/s} \pm 0.08 \text{ L/s}$ - Delivered volume: 1.2 L to 1.3 L - First test: Duration of the injection: $(t_{\min} - 0.5 \text{ s}) \pm 0.4 \text{ s}$ - Second test: Duration of the injection: t_{\min}⁽²⁾
EUT performance	<p>Number of test sequences per test condition: at least 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>

Test method	Variations of the test gas parameters
Acceptance criteria	<p>All functions shall operate as designed.</p> <p>For test conditions a) to d):</p> <p style="padding-left: 40px;">Each measurement result shall comply with the MPE specified in R 126-1, 6.6.1.</p> <p>For test condition e)</p> <p style="padding-left: 40px;">The EBA shall not provide a measurement result. No significant fault shall occur.</p> <p>For test condition f):</p> <ul style="list-style-type: none"> - First test: The EBA shall not accept a measurement with a duration of injection shorter than t_{\min}. - Second test: Each measurement result shall comply with the MPE specified in R 126-1, 6.6.1.

- ⁽¹⁾: t_{\min} shall be 3 s as defined in R 126-1, 6.10.2, or a value between 3 s and 5 s according to the manufacturer and to national regulations.
- ⁽²⁾: It has to be ensured that the delivered volume shall be ≥ 1.2 L, taking into account the uncertainties of measuring flowrate and duration of injection.

2.5.6.2 Alcohol in the upper respiratory tract

Depending on which solution is prescribed by national authorities for the detection of alcohol in the upper respiratory tracts, a suitable test procedure has to be performed.

Examples for possible methods of detection and the corresponding test procedures can be found in Annex B. The choice of detection method is within the responsibility of the manufacturer, who has to fit the detection method to the technical details of the EBA to be tested.

It is acceptable to use a different method of detection as well as a different test procedure, provided that validity can be demonstrated and the test procedure will be documented in detail. The national authority shall approve the chosen test procedure. All test procedures shall follow the basic requirements for test performance as given in Table 12.

The test procedure applied by the testing laboratory shall be reported in detail in the Evaluation Report.

Note: Within the framework of OIML-CS, it is mandatory to use one of the test procedures indicated in Annex B which has to be suitable for the EBA to be tested, taking into account the specific sensor and measuring cycle.

Table 12 - Basics of a test procedure for alcohol in the upper respiratory tract

Test method	Measurements to detect ethanol in the upper respiratory tract
Applicability	Applicable to all EBAs.
Object of the test	Verification of compliance with the provisions in R 126-1, 7.1.8 under ambient reference conditions.
Condition of the EUT	Power is to be “on” for the duration of the test.
Test procedure in brief	Depending on the test procedure chosen.
Measurement conditions	As described in Annex B
EUT performance	Number of measurements per test scheme: depending on the test procedure Time schedule: depending on the test procedure Parameters at least to be recorded: as defined in 2.5.3.
Acceptance criteria	The EUT shall detect the presence of alcohol in the upper respiratory tract. It shall not deliver any measurement result and shall display an appropriate error message.

2.5.7 Tests for operating conditions and physical influence factors

2.5.7.1 Temperature test (dry heat and cold)

Table 13 - Temperature test (dry heat and cold)

Test method	Gradual exposure to high and low temperatures not allowing condensation to occur.			
Applicable standards	IEC 60068-2-1 [8], IEC 60068-2-2 [9]			
Applicability	Applicable to all EBAs.			
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.			
Condition of the EUT	Power is to be “on” for the duration of the test.			
Test procedure in brief	<p>The test comprises 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 maintain the temperature at a stable level) - Change of temperature: $\leq 1^\circ\text{C}/\text{min}$ during heating up and cooling down - Stabilising 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 $T_R^{(1)}$ 2) Specified high temperature $T_{\text{amb-high}}$ 3) Specified low temperature $T_{\text{amb-low}}$ 4) Reference temperature $T_R^{(1)}$ 			
Test levels			Temperature	relative humidity
	Low ($T_{\text{amb-low}}$)	stationary EBA	0 °C	$\leq 50\%$
		transportable EBA	-5 °C	$\leq 50\%$
		portable EBA	-10 °C	$\leq 50\%$
	High ($T_{\text{amb-high}}$)	stationary EBA	40 °C	$\leq 30\%$
		transportable EBA	45 °C	$\leq 30\%$
		portable EBA	45 °C	$\leq 30\%$
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: delivered volume: 1.5 L \pm 0.1 L duration of injection: 5 s \pm 0.5 s all other parameters as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: temperature and humidity at the respective test level, all other parameters within reference conditions as defined in 2.4.1.</p>			
EUT performance	<p>Number of measurements per temperature: 5</p> <p>Time schedule: after stabilisation, towards the end of exposure time at each temperature</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>			
Acceptance criteria	<p>All functions shall operate as designed.</p> <p>All errors shall be within the MPE specified in R 126-1, 6.6.1.</p>			

⁽¹⁾ Default reference temperature: $T_R = 20^\circ\text{C}$

2.5.7.2 Damp heat, steady state (non-condensing)

Table 14 - Damp heat, steady-state (non-condensing)

Test method	Exposure to damp heat in steady-state.			
Applicable standard	IEC 60068-2-78 [16]			
Applicability	Applicable to all EBAs, but not applicable to those stationary EBAs 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 R 126-1, 6.6.1 under conditions of high humidity and constant temperature, specified in R 126-1, 6.10, Table 2, clause a “High” and clause b.			
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 (2 × 24 h). 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 EBAs	Transportable EBAs	Portable EBAs
	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: Test gas conditions: Ambient conditions:	0.40 mg/L (test gas no. 4) within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. temperature and humidity at the respective test level, all other parameters within reference conditions as defined in 2.4.1.		
EUT performance	Number of measurements and time schedule: <ul style="list-style-type: none">during exposure: 5 measurements every 24 hours at test conditionsafter exposure: after a recovery period of one hour 5 measurements at reference conditions Parameters at least to be recorded: as defined in 2.5.3.			
Acceptance criteria	All functions shall operate as designed. The error of the EUT is determined for each set of measurements. All errors shall be within the MPE specified in R 126-1, 6.6.1.			

2.5.7.3 Static atmospheric pressure

Table 15 - Static atmospheric pressure

Test method	Exposure to low and high atmospheric pressure.	
Applicable standard	No applicable standard is available.	
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.	
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 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	(860 ± 10) hPa
	Upper limit	(1060 ± 10) hPa
	Uncertainty of the pressure sensor	1.50 hPa
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: ambient pressure at respective test level, all other parameters within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements at each pressure level: 5</p> <p>Time schedule: after stabilisation at the respective pressure</p> <p>Parameters at least to be recorded: as defined in 2.5.3</p>	
Acceptance criteria	<p>All functions shall operate as designed.</p> <p>All errors shall be within the MPE specified in R 126-1, 6.6.1.</p>	

2.5.7.4 Random vibration

Table 16 - Random vibration

Test method	Exposure to random vibration.	
Applicable standards	IEC 60068-2-47 [14], IEC 60068-2-64 [15]	
Applicability	Applicable for portable and transportable EBAs.	
Object of the test	Verification of compliance with the provisions for MPE in R 126-1, 6.6.1 under conditions of random vibration specified in R 126-1, 6.10, Table 2, clause d.	
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.	
Test procedure in brief	<p>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.</p> <p>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.</p> <p>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.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1) Measurements before application of influence (at reference conditions); 2) The influence quantity shall be applied; 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
	Duration per axis	For each of the orthogonal directions the vibration exposure time shall be 2 minutes.
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements (before and after application): 5</p> <p>Time schedule: before and after application of the influence quantity, the EUT shall be switched on and the measurements shall be performed consecutively after stabilisation</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>	
Acceptance criteria	<p>The error of the EBA is determined at the reference conditions before and after the influence is applied. All functions shall operate as designed.</p> <p>All errors shall be within the MPE specified in R 126-1, 6.6.1.</p>	

2.5.7.5 DC mains voltage variations

Table 17 - DC mains voltage variations

Test method	Applying low and high level DC mains power voltage.	
Applicable standard	IEC 60654-2 [19]	
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 equipment powered by a road vehicle battery.	
Object of the test	Verification of compliance with the provisions for MPE in R 126-1, 6.6.1 under conditions of DC mains power voltage changes between the upper and lower limits specified in R 126-1, 6.10, Table 2, clause e.	
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 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 no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in, 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements at each voltage level: 5</p> <p>Time schedule: after stabilisation at the relevant voltage level</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) reference voltage at beginning and end, high voltage and low voltage. 	
Acceptance criteria	<p>All functions shall operate as designed.</p> <p>The errors of the EUT shall be determined for the reference voltage, the upper voltage and the lower voltage.</p> <p>All errors shall be within the MPE specified in R 126-1, 6.6.1.</p>	

2.5.7.6 AC mains voltage variations

Table 18 - AC mains voltage variations

Test method	Applying low and high level AC mains power voltage (on a single phase).	
Applicable standard	IEC TR 61000-4-1 [21]	
Applicability	Applicable for those EBAs which are designed to be temporarily or permanently connected to an AC mains power network while in operation. Not applicable to transportable EBAs 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 MPE in R 126-1, 6.6.1 under conditions of AC mains network voltage changes between the upper and lower limits specified in R 126-1, 6.10, Table 2, clause f.	
Condition of the EUT	The power is to be “on” for the duration of the test.	
Test procedure in brief	<p>The test comprises exposure of the EUT to the lower and upper limit power supply conditions 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 <p>In the case of three-phase power supply, the voltage variation shall apply for each phase successively.</p>	
Test Levels	U_{nom}	Nominal AC voltage specified by the manufacturer
	If a range is specified by the manufacturer:	U_{nom1} concerns the highest value 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	$(U_{nom1} + U_{nom2}) / 2$
	Upper level	$U_{nom1} + 10 \%$
	Lower level	$U_{nom2} - 15 \%$
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements per voltage level: 5</p> <p>Time schedule: after stabilisation at the relevant voltage level</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) reference voltage at beginning and end, high voltage and low voltage. 	
Acceptance criteria	<p>All functions shall operate as designed.</p> <p>The errors of the EUT shall be determined for the reference voltage, the upper voltage and the lower voltage.</p> <p>All errors shall be within the MPE specified in R 126-1, 6.6.1.</p>	

2.5.7.7 AC mains frequency variations

Table 19 - AC mains frequency variations

Test method	Variation in AC mains power frequency.	
Applicable standard	IEC TR 61000-4-1 [21]	
Applicability	Only applicable for those EBAs 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 MPE in 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.	
Condition of the EUT	The power is to be “on” for the duration of the test.	
Test procedure in brief	<p>The test comprises 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.</p> <p>Test sequence:</p> <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	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements per frequency level: 5</p> <p>Time schedule: after stabilisation at the relevant frequency level</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) reference frequency at beginning and end, high frequency and low frequency. 	
Acceptance criteria	<p>All functions shall operate as designed.</p> <p>The errors of the EUT shall be determined for the reference frequency, the upper frequency and the lower frequency.</p> <p>All errors shall be within the MPE specified in R 126-1, 6.6.1.</p>	

2.5.7.8 Low voltage of internal battery

Table 20 - Low voltage of internal battery (not connected to the mains power)

Test method	Applying minimum supply voltage.	
Applicable standard	No applicable standard is available.	
Applicability	Applicable to all EBAs supplied by an internal battery while in operation.	
Object of the test	Verification of compliance with the provisions for MPE in R 126-1, 6.6.1 during low battery voltage specified in R 126-1, 6.10, Table 2, clause h.	
Precondition	<p>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.</p> <p>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.</p> <p>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.</p>	
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 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.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1) Reference voltage level 2) Lower voltage level 3) $0.9 \times$ lower voltage level 4) 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	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements at each voltage level: 5</p> <p>Time schedule: after stabilisation at the relevant voltage level</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>	
Acceptance criteria	<p>All functions shall operate as designed.</p> <p>At $0.9 \times U_{bmin}$: the EUT shall either:</p> <ol style="list-style-type: none"> a) cease to function (turn itself off); b) not allow any measurements and give an appropriate error message; or c) shall measure correctly. <p>In case c the voltage shall be reduced until case a or b does occur.</p> <p>The errors of the EUT shall be determined for the lower voltage level(s) and the reference voltage level.</p> <p>All errors shall be within the MPE specified in R 126-1, 6.6.1.</p>	

2.5.7.9 Power supply duration test

Table 21 - Power supply duration test

Test method	Consecutive measurements of mass concentrations of ethanol under specific temperature conditions.
Applicability	Applicable to portable EBAs powered by internal batteries.
Object of the test	Verification of compliance with the requirements for power supply duration (battery) (R 126-1, 7.1.6).
Condition of the EUT	Power is to be “on” for the duration of the test.
Test procedure in brief	<p>The tests comprise of repeated measurements at different ambient conditions starting with a fully charged internal battery.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1) Complete charging of rechargeable batteries, or replacement of non-rechargeable batteries to a new set. 2) 50 individual measurements at reference ambient conditions with a test gas concentration of 0.40 mg/L. 3) Exposure to -10°C, with a stabilising time of at least 2 hours 4) 20 individual measurements at an ambient temperature of -10°C, (R 126-1, 6.10.1 Table 2 a) with a test gas concentration of 0.40 mg/L.
Measurement conditions	<p>Ethanol concentrations: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: for (2): reference conditions as defined in 2.4.1 for (3): ambient temperature: -10°C, all other parameters within reference conditions as defined in 2.4.1.</p>
EUT performance	<p>Number of measurements: for test sequence no. 2): 50 for test sequence no. 4): 20</p> <p>Time schedule: consecutively</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>
Acceptance criteria	<p>Each individual measurement shall comply with the MPE as defined R 126-1, 6.6.1.</p> <p>The EBA shall be capable of performing all the tests on one set of batteries, or a single charge of batteries.</p>

2.5.7.10 Voltage variations of a road vehicle battery

Table 22 - Voltage variations of a road vehicle battery

Test method	Variation in supply voltage.				
Applicable standard	ISO 16750-2 [35]				
Applicability	Applicable to all transportable or portable EBAs 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 MPE in R 126-1, 6.6.1 under conditions of high (while charging) and low battery voltage specified in R 126-1, 6.10.1, Table 2, clause i.				
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 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.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1) Upper voltage level 2) Lower voltage level 3) Reference voltage level 				
Test level	Nominal battery voltage	$U_{\text{nom}} = 12 \text{ V}$		$U_{\text{nom}} = 24 \text{ V}$	
		Lower limit	Upper limit	Lower limit	Upper limit
		9 V	16 V	16 V	32 V
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in, 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>				
EUT performance	<p>Number of measurements per voltage level: 5</p> <p>Time schedule: after stabilisation at the relevant voltage level</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>				
Acceptance criteria	<p>All functions shall operate as designed.</p> <p>The errors of the EUT shall be determined for the upper voltage level, for the lower voltage level and for the reference voltage level.</p> <p>All errors shall be within the MPE specified in R 126-1, 6.6.1.</p>				

2.5.7.11 Hydrocarbons in the environment

Table 23 - Hydrocarbons in the environment

Test method	Exposure to an environment containing hydrocarbons.	
Applicable standard	No applicable standard is available.	
Applicability	Applicable for all EBAs.	
Object of the test	Verification of compliance with the provisions for MPE in R 126-1, 6.6.1 under conditions of exposure to the level of hydrocarbons in the environment specified in R 126-1, 6.10 1, Table 2, clause j.	
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: <ol style="list-style-type: none"> 1) Measurements at influence conditions 2) Measurements at reference conditions 	
Test level	Mol fraction of hydrocarbons (as methane equivalent)	5 µmol/mol ± 1 µmol/mol
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4) Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1.	
EUT performance	Number of measurements per condition: 5 Time schedule: consecutively at each test condition after stabilisation at the relevant condition Parameters at least to be recorded: <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) type and mol fraction of applied hydrocarbons. 	
Acceptance criteria	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 MPE specified in R 126-1, 6.6.1.	

2.5.7.12 Raised fraction of CO₂ in the test gasTable 24 - Raised fraction of CO₂ in the test gas

Test method	Measurements with raised CO ₂ -content in the test gas.
Applicability	Applicable for all EBAs.
Object of the test	Verification of compliance with the provisions for MPE in R 126-1, 6.6.1 under conditions of raised CO ₂ in the test gas as specified in R 126-1, 6.10.1, Table 2, clause k.
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 concentrations: 0.40 mg/L (test gas no. 4) with 80 mmol/mol CO ₂ 0.40 mg/L (test gas no. 4) with 50 mmol/molCO ₂ (standard test gas) Test gas conditions: CO ₂ -concentration as specified, all other parameters within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1.
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 2.5.3.
Acceptance criteria	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.

2.5.8 Disturbances tests

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

This test in metrological test mode requires a substantial amount of test time. To keep the expenditure of test time within a reasonable timeframe, one of the following test schemes A or B shall be applied:

The procedure provided by the manufacturer must be approved by the national authority and the manufacturer shall provide the documentation to justify its procedure. The method applied by the testing laboratory to cover the frequency range shall be reported in detail in the Evaluation Report.

2.5.8.1.1 Test scheme A

Apart from the metrological test mode, the manufacturer may implement a special test mode to reduce the test time. This special test mode shall cover all possible influences caused by disturbances.

All output signals of the relevant sensors shall be monitored after determining what the influence on the measurement result will be. All these signals will have their own MPE (to be determined accordingly). The manufacturer shall provide all the necessary information.

Alternatively, the algorithm used in normal operation to calculate the measurement result can be used for combining the signals of the sensors to indicate a measurement result in units of alcohol mass concentration.

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

If a deviation is detected on any output signal at one frequency, 5 measurements (of ethanol concentration) in metrological test mode shall be performed at this frequency.

If no deviation is detected, at least 5 measurements (of ethanol concentration) in metrological test mode shall be conducted during the frequency range (see test level) with the maximum test frequency permitted by the EBA.

2.5.8.1.2 Test scheme B

The instrument performs measurements in metrological test mode consecutively until stopped while it is exposed to the disturbance. Measuring ambient air for zero-setting is considered as part of the measurements. The time between each measurement has to be taken into account during the relevant disturbance test.

Table 25 - Conducted (common mode) currents generated by RF EM fields

Test method	Injection of RF currents representing exposure to RF electromagnetic fields.			
Applicable standard	IEC 61000-4-6 [26]			
Applicability	Applicable for all those EBAs 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 a.			
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 MHz – 80 MHz	10 V (e.m.f.)	80 %	1 kHz
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1</p>			
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): Depending on the actual test setup</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) applied RF (e.m.f). voltage level. 			
Acceptance criteria	<p>Test scheme A: All output signals shall be within their own MPE For the measurement of ethanol concentration, the Test scheme B acceptance criteria shall be applied.</p> <p>Test scheme B: The errors and faults of the EUT shall be determined as prescribed in 2.5.4. Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not display a measurement result.</p>			

2.5.8.2 Radiated RF electromagnetic fields

This test in metrological test mode requires a substantial amount of test time. To keep the expenditure of test time within a reasonable limit, one of the following test schemes A or B shall be applied.

The procedure provided by the manufacturer must be approved by the national authority, and the manufacturer shall provide the documentation to justify its procedure. The method applied by the testing laboratory to cover the frequency range shall be reported in detail in the Evaluation Report.

2.5.8.2.1 Test scheme A

Apart from the metrological test mode, the manufacturer may implement a special test mode to reduce the test time. This special test mode shall cover all the possible influences caused by disturbances.

All output signals of the relevant sensors shall be monitored after determining what the influence on the measurement result will be. All these signals will have their own MPE (to be determined accordingly). The manufacturer shall provide all the necessary information.

Alternatively, the algorithm used in normal operation to calculate the measurement result can be used for combining the signals of the sensors to indicate a measurement result in units of alcohol mass concentration.

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

If a deviation is detected on any output signals at one frequency, 5 measurements (of ethanol concentration) in metrological test mode shall be performed at this frequency.

If no deviation is detected, at least 5 measurements (of ethanol concentration) in metrological test mode shall be conducted during the frequency range (see test level) with the maximum test frequency permitted by the EBA.

2.5.8.2.2 Test scheme B

The instrument performs the measurements in metrological test mode consecutively until stopped while it is exposed to the disturbance. Measuring ambient air for zero-setting is considered as part of the measurements. The time between each measurement has to be taken into account during the relevant disturbance test.

Table 26 - Radiated RF electromagnetic fields

Test method	Exposure to radiated radio frequency electromagnetic fields.			
Applicable standards	IEC 61000-4-3 [23]; IEC 61000-4-20 [29]			
Applicability	Applicable to all EBAs.			
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.			
Condition of the EUT	Power is to be “on” for the duration of the test. The electrical power supplied to the EUT shall not be switched off except for a reset when a significant fault has been indicated.			
Test procedure in brief	<p>The EUT is exposed to electromagnetic fields with the required field strength and the field uniformity as 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 respond, but shall in no case be less than 0.5 s.</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 MHz – 80 ⁽¹⁾ MHz	10 V/m	80 %	1 kHz
	80 MHz – 6 000 MHz	10 V/m	80 %	1 kHz
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>			
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): Depending on the actual test setup</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) field strength level. 			
Acceptance criteria	<p>Test scheme A: All output signals shall be within their own MPE For the measurement of ethanol concentration, the Test scheme B acceptance criteria shall be applied.</p> <p>Test scheme B: The errors and faults of the EUT shall be determined as prescribed in 2.5.4. Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not provide a measurement result.</p>			

⁽¹⁾: Only applicable where the instrument does not employ any cable or cable connection.

2.5.8.3 Electrostatic discharges

Table 27 - Electrostatic discharges

Test method	Exposure to electrostatic discharges (ESD).		
Applicable standard	IEC 61000-4-2 [22]		
Applicability	Applicable to all EBAs.		
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 in the case of direct exposure to electrostatic discharges or such discharges in the neighbourhood of the EUT specified in R 126-1, 6.11.1, Table 3, clause b.		
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 the following 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 [22]. 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> <ul style="list-style-type: none"> - Direct application: In the contact discharge mode to be carried out on conductive surfaces, the electrode shall be in contact with the EUT before activation of the discharge. In such cases the discharge spark occurs in the vacuum relays of the contact discharge tip. On insulated surfaces only the air discharge mode can be applied. The EUT is approached by the charged electrode until a spark discharge occurs. - Indirect application: The discharges are applied in the contact mode only on coupling planes mounted in the vicinity of the EUT. <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	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>		
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): 5</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) discharge type, level and surface 		

Test method	Exposure to electrostatic discharges (ESD).
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in 2.5.4. Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring. It is acceptable that during the disturbance test the EUT does not provide a measurement result.

2.5.8.4 Bursts (transients) on AC and DC mains

Table 28 - Bursts (transients) on AC and DC mains

Test method	Introducing transients on the mains power lines.	
Applicable standard	IEC 61000-4-4 [24]	
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 EBAs powered by a road vehicle battery.	
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 the mains voltage specified in R 126-1, 6.11.1, Table 3, clause c.	
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 Ω and 1000 Ω load are defined in the referred standard.</p> <p>A burst generator as defined in the referred standard shall be used.</p> <p>The characteristics of the generator shall be verified before connecting the EUT. Both positive and negative polarity of the bursts shall be applied.</p> <p>The injection network on the mains shall contain blocking filters to prevent the burst energy from being dissipated in the mains.</p> <p>At least 10 positive and negative randomly phased bursts shall be applied.</p> <p>The bursts are applied during all the time necessary to perform the test; therefore, more bursts 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	Amplitude (peak value)	1 kV
	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	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5.</p> <p>Number of measurements (during disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>	
Acceptance criteria	<p>The errors and fault of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not provide a measurement result.</p>	

2.5.8.5 Surges on AC and DC mains power lines

Table 29 - Surges on AC and DC mains power lines

Test method	Introducing electrical surges on the mains power lines.				
Applicable standard	IEC 61000-4-5 [25]				
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 EBAs that are only designed to be connected to a local power source through an indoor network or a road vehicle battery (transportable EBAs).				
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.				
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 synchronised 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; therefore, 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	3 positive 3 negative
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1</p>				
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>				
Acceptance criteria	<p>The errors and faults of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not provide a measurement result.</p>				

2.5.8.6 Bursts on signal, data and control lines

Table 30 - Bursts (transients) on signal, data and control lines

Test method	Introducing transients on signal, data and control lines.	
Applicable standard	IEC 61000-4-4 [24]	
Applicability	Applicable for EBAs 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.	
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 Ω and 1000 Ω loads 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 polarities 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 no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) exposed conductors 	
Acceptance criteria	<p>The errors and faults of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not provide a measurement result.</p>	

2.5.8.7 Ripple on DC mains power

Table 31 - Ripple on DC mains power

Test method	Introducing a ripple voltage on the DC input power port.	
Applicable standard	IEC 61000-4-17 [28]	
Applicability	<p>Applicable for those EBAs 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 EBAs powered by a road vehicle battery, and • transportable EBAs connected to battery charger systems with incorporated switch mode converters. 	
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 under conditions of a ripple on the DC mains voltage specified in R 126-1, 6.11.1, Table 3, clause f.	
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 sinusoidal-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 no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>	
Acceptance criteria	<p>The errors and fault of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not provide a measurement result.</p>	

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

Table 32 - DC mains voltage dips, short interruptions and (short term) variations

Test method	Introducing voltage dips, short interruptions and voltage variations on DC mains power lines using the test setup defined in the applicable standard.			
Applicable standard	IEC 61000-4-29 [30]			
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 EBAs powered by a road vehicle battery and EBAs 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.			
Condition of the EUT	Power is to be “on” for the duration of the test.			
Test procedure in brief	A test generator as defined in the referred standard shall be used. Before starting the tests, the performance of the generator shall be verified. The 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. The disturbances are applied during all the time necessary to perform the test; therefore, more disturbances than indicated above may be necessary. Test sequence: 1) Measurements before disturbance (at reference conditions) 2) Measurements during disturbance			
Test level			Amplitude of the rated voltage	Duration
	Voltage dips	Test a	40 %	0.01 s
		Test b		1 s
		Test c	70 %	0.01 s
		Test d		1 s
	Short interruptions	Test e	0 %	0.001 s
		Test f		1 s
	Voltage variations	Test g	85 %	0.1 s
		Test h		10 s
		Test i	120 %	0.1 s
		Test j		10 s
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4) Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1.			

EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): 5 for each test condition</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) percentage of voltage reduction and duration.
-----------------	--

Test method	Introducing voltage dips, short interruptions and voltage variations on DC mains power lines using the test setup defined in the applicable standard.
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in 2.5.4 for each test condition. Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring. It is acceptable that during the disturbance test the EUT does not provide a measurement result.

2.5.8.9 AC mains voltage dips, short interruptions and voltage variations

Table 33 - AC mains voltage dips, short interruptions and voltage variations

Test method	Introducing short-time reductions of mains voltage using the test setup defined in the applicable standard.			
Applicable standards	IEC 61000-4-11 [27], IEC 61000-6-1 [31], IEC 61000-6-2 [32]			
Applicability	Applicable for those EBAs having a rated input current of less than 16 A per phase and that are designed to be temporarily or permanently connected to an AC mains power network while in operation. Not applicable to transportable EBAs powered by a road vehicle battery.			
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 under conditions of short time mains voltage reductions specified in R 126-1, 6.11.1, Table 3, clause g.			
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			Amplitude	Duration
	Voltage dips	Test a	0 %	0.5 cycles
		Test b	0 %	1 cycle
		Test c	70 %	25 cycles
	Short interruptions	Test d	0 %	250 cycles
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4) Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6 Ambient conditions: within reference conditions as defined in 2.4.1.			
EUT performance	Number of measurements at reference conditions (before disturbance): 5 Number of measurements (during disturbance): 5 for each test condition Time schedule: consecutively at each test condition Parameters at least to be recorded a) as defined in 2.5.3, plus b) percentage of voltage reduction and duration.			
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in 2.5.4 for each test condition. Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring. It is acceptable that during the disturbance test the EUT does not provide a measurement result.			

2.5.8.10 Surges on signal, data and control lines

Table 34 - Surges on signal, data and control lines

Test method	Introducing electrical surges on signal, data and control lines.			
Applicable standard	IEC 61000-4-5 [25]			
Applicability	Only applicable for those EBAs which are designed to, during operation, be temporarily or permanently connected to electrical signal, data and/or control lines that may exceed a length of 10 m. Not applicable to EBAs connected to a local power source through an indoor network.			
Object of the test	Verification of compliance with the provisions for disturbances in 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.			
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 no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>			
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) exposed conductors. 			
Acceptance criteria	<p>The errors and faults of the EUT shall be determined as prescribed in 2.5.4:</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not provide a measurement result.</p>			

2.5.8.11 Electrical transient conduction along supply lines

Table 35 - Electrical transient conduction along supply lines

Test method	Electrical transient conduction along supply lines.		
Applicable standard	ISO 7637-2 [33]		
Applicability	Applicable to portable and transportable EBAs which may be in operation while being powered 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, 6.11.1, 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). 		
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:</p> <ol style="list-style-type: none"> 1) Measurements before disturbance (at reference conditions) 2) Measurements during disturbance 		
Test level	Test pulse	Pulse Voltage U_s	
		$U_{nom} = 12 \text{ V}$	$U_{nom} = 24 \text{ V}$
	2a	112 V	112 V
	2b	10 V	20 V
	3a	- 220 V	- 300 V
	3b	150 V	300 V
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>		
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>		
Acceptance criteria	<p>The errors and faults of the EUT shall be determined as prescribed in 2.5.4:</p> <p>Either significant faults do not occur or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not provide a measurement result.</p>		

2.5.8.12 Electrical transient conduction via lines other than supply lines

Table 36 - Electrical transient conduction via lines other than supply lines

Test method	Electrical transient conduction along lines other than supply lines.			
Applicable standard	ISO 7637-3 [34]			
Applicability	Applicable to I/O lines of transportable EBAs 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, 6.11.1, Table 3, clause j).			
Condition of the EUT	Power is to be “on” for the duration of the test.			
Test procedure in brief	<p>The test consists of exposure to bursts of voltage spikes by capacitive coupling via lines other than supply lines, using only the Capacitive Coupling Clamp method.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1) Measurements before disturbance (at reference conditions) 2) Measurements during disturbance 			
Test level		U_{nom}	12 V	24 V
	Pulse a	U_s	–60 V	–80 V
	Pulse b	U_s	40 V	80 V
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>			
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements (during disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded:</p> <ol style="list-style-type: none"> a) as defined in 2.5.3, plus b) exposed conductors 			
Acceptance criteria	<p>The errors and faults of the EUT shall be determined as prescribed in 2.5.4:</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p> <p>It is acceptable that during the disturbance test the EUT does not provide a measurement result.</p>			

2.5.8.13 Mechanical shock

Table 37 - Mechanical shock

Test method	Dropping the EUT onto a rigid surface.			
Applicable standard	IEC 60068-2-31 [13]			
Applicability	Applicable for all EBAs.			
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.			
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. <p>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> <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 EBAs	Transportable EBAs	Portable EBAs
	Height of fall	25 mm	50 mm	1 000 mm
	Number of falls (on each bottom edge)	1	1	6
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>			
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements at reference conditions (after disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>			
Acceptance criteria	<p>The errors and fault of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p>			

2.5.8.14 Shakes

Table 38 - Shakes

Test method	Exposure to shakes while not in operation.
Applicable standard	None
Applicability	Applicable for portable and transportable EBAs.
Object of the test	Verification of compliance with the provisions for disturbances in R 126-1, 6.11.1 after being exposed to shakes likely to be experienced in a car boot and specified in R 126-1, 6.11.1, Table 4, clause b.
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 the influence quantity; it shall be switched on immediately after this exposure.
Test procedure in brief	The test comprises exposure to simulated shakes fulfilling the specified test level. After the exposure, the external electrical power (where applicable) shall be connected and the EUT shall be switched on, following which 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	Shakes specifications: wave shape: half-period of a sinusoid amplitude: 10 g ($g = 9.81 \text{ m/s}^2$) duration: 6 ms frequency: 2 Hz number of axes: 3 perpendicular axes number of shakes: 1 000 for each axis
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4) Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1.
EUT performance	Number of measurements at reference conditions (before disturbance): 5 Number of measurements at reference conditions (after disturbance): 5 Time schedule: consecutively at each test condition Parameters at least to be recorded: as defined in 2.5.3.
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in 2.5.4. Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.

2.5.8.15 Damp heat cyclic (condensing)

Table 39 - Damp heat, cyclic (condensing)

Test method	Exposure to damp heat with cyclic temperature variation.		
Applicable standard	IEC 60068-2-30 [12]		
Applicability	Applicable for transportable and portable EBAs.		
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.		
Condition of the EUT	Power is to be “off” for the duration of 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 variations 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 the upper value until 12 hours from the start of the cycle; - Temperature lowered to the 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-hour period; - Temperature maintained at the lower level until the 24 h period is completed. <p>The stabilising period before and the 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>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 EBAs	Portable EBAs
	Duration (number of 24-hour cycles)	2	4
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: temperature and humidity at the respective test level, all other parameters within reference conditions as defined in 2.4.1.</p>		
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements at reference conditions (after disturbance): 5</p> <p>Time schedule: consecutively at each test condition</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>		
Acceptance criteria	<p>The errors and faults of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p>		

2.5.8.16 Storage test

Table 40 - Storage test

Test method	Exposure to changing temperatures while not in operation.
Applicable standard	None
Applicability	Applicable to all EBAs.
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 as specified in R 126-1, 6.11.1, Table 4, clause d.
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.
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 6 hours and a temperature of + 70 °C for 6 hours.
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4) Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: temperatures at the respective test levels, all other parameters within reference conditions as defined in 2.4.1.
EUT performance	Number of measurements at reference conditions (before disturbance): 5 Number of measurements at reference conditions (after disturbance): 5 Time schedule: consecutively before and after exposure, after switching on the EUT and after a one-hour recovery period at reference conditions. Parameters at least to be recorded: as defined in 2.5.3.
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in 2.5.4. Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.

2.5.8.17 Vibration (as disturbance)

Table 41 - Vibration (as disturbance)

Test method	Exposure to random vibration.	
Applicable standards	IEC 60068-2-47 [14], IEC 60068-2-64 [15]	
Applicability	Applicable to stationary EBAs.	
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 transport of the instrument as specified in R 126-1, 6.11.1, Table 4, clause e.	
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.	
Test procedure in brief	<p>The EUT shall subsequently be tested in three, mutually perpendicular axes mounted on a rigid fixture by its normal mounting means.</p> <p>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.</p> <p>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.</p> <p>After the exposure, the external electrical power (where applicable) shall be connected and the EUT shall be switched on. Then, the EUT performance is tested.</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	Total frequency range	10 Hz – 150 Hz
	Total RMS level	1.6 m·s ⁻²
	ASD level 10 Hz - 20 Hz	0.05 m ² ·s ⁻³
	ASD level 20 Hz - 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	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements at reference conditions (before disturbance): 5</p> <p>Number of measurements at reference conditions (after disturbance): 5</p> <p>Time schedule: Test consecutively after switching on the EUT and after the warm-up period of the EUT at reference condition.</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>	
Acceptance criteria	<p>The errors and fault of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p>	

2.5.8.18 Durability

The instrument is presumed to comply with the requirement defined in R 126-1, 6.5 if the instrument submitted to the accuracy tests and disturbance tests passes each of the tests.

2.5.9 Physiological influence quantities

Table 42 - Physiological influence quantities

Test method	Test gases with additionally one interfering substance at a time.
Applicable standard	None.
Applicability	Applicable to all EBAs.
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	<p>The test comprises of at least 5 measurements per test gas.</p> <p>Test sequence:</p> <ol style="list-style-type: none"> 1) Measurement with test gas no. 4 2) Measurement with test gas no. 4 with one additional substance <p>For each substance, this test sequence shall be repeated 4 times.</p>
Test gases mass concentration of substances	<ol style="list-style-type: none"> a) Ethanol concentration: 0.40 mg/L (test gas no.. 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 <p>Depending on the results, additionally test gases with reduced concentrations of the interfering substances may be needed (see acceptance criteria).</p>
Measurement conditions	<p>Test gas conditions: test gas composition as defined for this test, other parameters within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1</p>
EUT performance	<p>Number of measurements with each test gas and concentration: 5</p> <p>At least the following parameters shall be recorded: as defined in 2.5.3.</p>
Calculation of results	<ul style="list-style-type: none"> - Calculation of deviation the deviation $\Delta_{is[1...5]}$ between each result of the 5 measurements with the respective interfering substance (b to e) and the appendant result for ethanol test gas a) is calculated - Calculation of sensitivity: $sensitivity_{is} = \frac{\Delta_{is[1...5]}}{\text{mass concentration of interfering substance}}$
Acceptance criteria	<ol style="list-style-type: none"> a) if none of the calculated values for sensitivity is equal or below the value defined in R 126-1, 6.11.2 the EBA has passed the test for the interference substance concerned; b) if a calculated value for sensitivity exceeds the value defined in R 126-1, 6.11.2 and no error message is given, the EBA has failed; c) if an error message is displayed, another sequence of 5 test shall be performed with the same interfering substance at a mass concentration 5 times lower. In this case the sensitivity shall not be more than the value defined in R 126-1, 6.11.2; d) if an error message continues to be displayed, the mass concentration of the added interfering substance shall be reduced repeatedly by a factor of 2 and again, another sequence of 5 tests shall be performed. If the error message is no longer displayed and the sensitivity is not more than the value defined in R 126-1, 6.11.2, the EBA has passed the test for the interference substance concerned. <p>This requirement shall be fulfilled for each measurement with each interfering substance.</p>

2.6 Tests for optional disturbances and requirements

2.6.1 Sand and dust

Table 43 - Sand and dust

Test method	Exposure to sand and dust.	
Applicable standards	IEC 60512-11-8 [17], IEC 60529 [18], IEC 60721-2-5 [20]	
Applicability	Applicable to EBAs 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	<p>The test comprises of exposure to cyclic temperature variation between 30 °C and 65 °C, maintaining the following conditions:</p> <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 [17]. <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	Number of test cycles	One (cycle specified in 3.2.3 of IEC 60512-11-8 [17])
	Cycle duration	2 hours as specified in 3.2.3 of IEC 60512-11-8 [17]
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>	
EUT performance	<p>Number of measurements at reference conditions before exposure: 5</p> <p>Number of measurements at reference conditions after exposure: 5</p> <p>At least the following parameters shall be recorded: as defined in 2.5.3.</p>	
Acceptance criteria	<p>The errors and faults of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p>	

2.6.2 Salt mist

Table 44 - Salt mist

Test method	Exposure to salt mist.
Applicable standards	IEC 60068-2-11 [10], IEC 60721-2-5 [20]
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	<p>The test comprises exposure to salt mist atmosphere at the following conditions:</p> <ul style="list-style-type: none"> - Temperature of environment and salt solution: 35 °C - Mass fraction of NaCl of the salt solution: $(5 \pm 1) \%$ - Relative humidity of the test atmosphere: $> 85 \%$ - Salt solution to be nebulised in such an amount that it will condense with a rate of (1 to 2) ml/ hour per surface of 80 cm² <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).
Duration of the test	24 hours.
Measurement conditions	<p>Ethanol concentration: 0.40 mg/L (test gas no. 4)</p> <p>Test gas conditions: within reference conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>
EUT performance	<p>Number of measurements at reference conditions before exposure: 5</p> <p>Number of measurements at reference conditions after exposure: 5</p> <p>At least the following parameters shall be recorded: as defined in 2.5.3..</p>
Acceptance criteria	<p>The errors and faults of the EUT shall be determined as prescribed in 2.5.4.</p> <p>Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</p>

2.6.3 Water

Table 45 – Water

Test method	Exposure to water droplets.		
Applicable standards	IEC 60529 [18]; IEC 60068-2-18 [11]		
Applicability	Applicable to portable EBAs 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 according to the manufacturer’s prescriptions (with the mouthpiece mounted on the EBA, with a protective cover,...) The measurements shall be performed before and after exposure. The mouthpiece shall be changed before the measurement.		
Test procedure in brief	The test comprises exposure of the EBA to water droplets in defined angles <ul style="list-style-type: none">- Temperature of the water shall be equal to the temperature of the EUT within ± 5 °C- Water quality: potable water 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. The EUT is placed in its normal operating position under the drip box or spray nozzle. Except for EUTs designed for wall mounting, the support for the EUT should be smaller than the base of the enclosure. Test sequence: <ul style="list-style-type: none">1) Measurements before disturbance (at reference conditions)2) The disturbance shall be applied3) Measurements after disturbance (at reference conditions).		
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 ± 0.0035) L/min per hole	(10 ± 0.5) L/min
	Test duration	10 min per position	1 min/m² of EUT
	Angel of inclination	180 °	
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4) Test gas conditions: within reference gas conditions as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1.		
EUT performance	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 2.5.3.		
Acceptance criteria	Water shall have no harmful effects. The errors and faults of the EUT shall be determined as prescribed in 2.5.4. Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.		

3 Initial and subsequent verifications

3.1 General considerations

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.

3.1.1 Initial verification

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 authorities.

3.1.2 Subsequent verification

According to OIML D 9, 2.13 [3], 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 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's 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 Visual examination

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

- a visual inspection to determine the conformity with the approved type and to obtain a general appraisal of its design and construction;
- completeness of essential accessories and subsidiary devices (e.g. mouthpieces, durable storage/printing device) and their compliancy with the approved type;
- compliance of the software with the approved type;
- completeness and correctness of the inscriptions and markings;
- presence, 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;
- correct date and time settings, within allowed tolerance specified by national regulations.

Note: It is assumed that with a specific software version (which shall be mentioned in the type approval) all measuring conditions such as 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 shall also be inspected.

3.4 Metrological examination

3.4.1 Metrological precondition for performing tests

The performance tests shall be executed under reference conditions (2.4.1) unless specified otherwise within the test.

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 Test gases used for verification

The gas used for verification shall comply with the requirements of 2.4.3.1 (Table 4). National regulations may dictate whether simplified means (as those defined in 2.4.3.2) have to be used.

If the use of simplified means is prescribed, the requirements of 2.4.3.2 and 2.4.3.3 shall be taken into account. Verification reports shall indicate when other gases were used and how their equivalence with the reference gases was established.

3.4.3 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 3.3); and
- a metrological examination of the EBA.

3.4.3.1 Metrological examination

The following metrological examination tests are recommended to be carried out 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:
 - The complete measuring range shall be tested for accuracy; at least 3 different test gas concentrations are recommended;
 - Only part of the measuring range close to the legal limit(s) shall be tested for accuracy.

National regulations may determine which approach has to be used and may decide that additional tests as described below are mandatory.

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

- **Additional tests** can be carried out with different volumes (e.g. 1.5 L, 4.5 L), exhalation times (e.g. 15 s), flow rates and/ or with a greater number of repetitions. Results from these tests shall also comply with the MPEs.

In general, metrological examinations shall assure that all parameters of the EBA which can have influence on the result are set correctly. Depending on the actual configuration of the EBA, additional tests for checking internal sensors such as pressure or temperature sensors may be considered necessary by national authorities.

3.4.3.2 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.

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:

A.1.1 Dubowski's formula

Let $\gamma_{(t)}$ be the mass concentration of ethanol of an aqueous solution of ethanol. When air is bubbled through such a solution, the mass concentration $\beta_{(t)}$ of ethanol in the produced test gas is given by the following formula:

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

with: $\beta_{(t)}$ mass concentration of ethanol in the test gas at a given temperature t in mg/L
 0.04145×10^{-3} and 0.06583 conventional Dubowski coefficients
 $\gamma_{(t)}$ 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:

$$\beta_{(34)} = 0.38866 \times 10^{-3} \times \gamma_{(34)}$$

A.1.2 Harger's formula

If required by national legislation, national authorities may be required to use other formulas such as 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:

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

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

A.2 Example of a type 1 test gas generator

The saturation of air with water vapour and ethanol vapour when lead through a water-ethanol solution is a well-established setup 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 those most commonly used for the calculation of the gas concentration of ethanol for a given temperature.

An example of a type 1 test gas 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 temperature controlled bath. The flasks will be filled with the water-ethanol solution of a known concentration and pressurised air/ gas passing through the solution in small bubbles will be heated up as well as enriched with ethanol and water in a dynamic equilibrium.

Figure A.1 shows a basic design principle for a 3-flasks-bubble train.

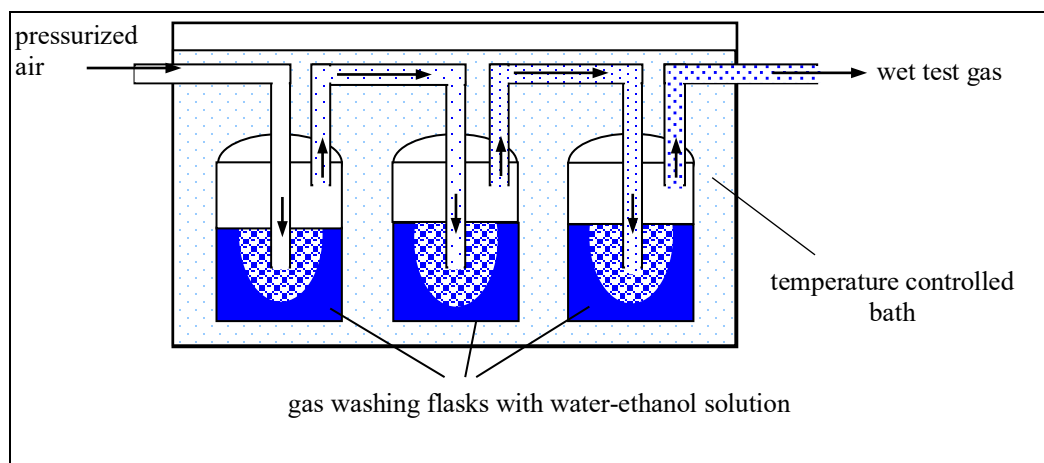


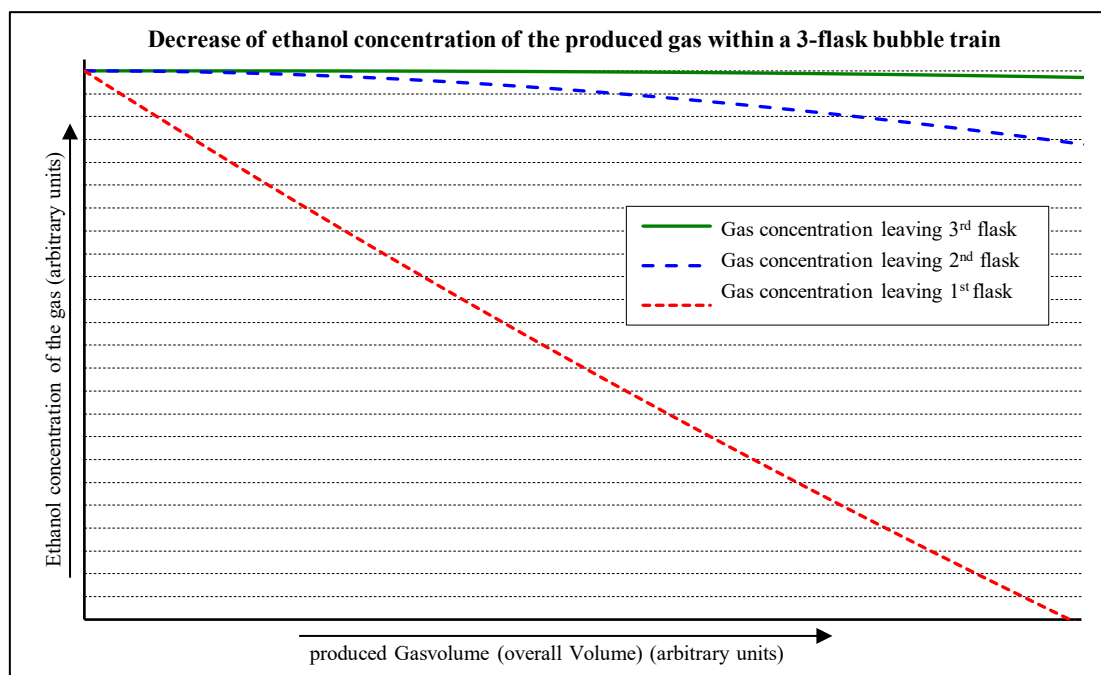
Figure A.1 – Diagram of 3-flask-bubble train as a type 1 test gas generator

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 with the throughput of gas.

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

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

Figure A.2 – Example of the 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 the exit is achieved for a certain volume of test gas, allowing a fairly large number of measurements to be made. The use of two or even more bubble trains in a laboratory might be helpful to realise effective test schemes.

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 1: For test gases with different ethanol concentrations but identical temperatures (i.e. 34.0 °C), the use of the different corresponding water-ethanol solutions is required.

Note 2: It has to be avoided that the wet test gas leaving the bubble train is compressed by flow restrictions (e.g. diameter of the outlet) before entering the EBA under test.

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 breath analysers simulating human breath profiles and shall correspond to the specifications of 2.4.3.

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

The dynamics of the different types of human breath profiles are simulated (volumes and durations of expiration are parameterised along with a simulation of dead anatomical volume). The volume and duration of injection (= simulated exhalation) are regulated by the movement of an actuator.

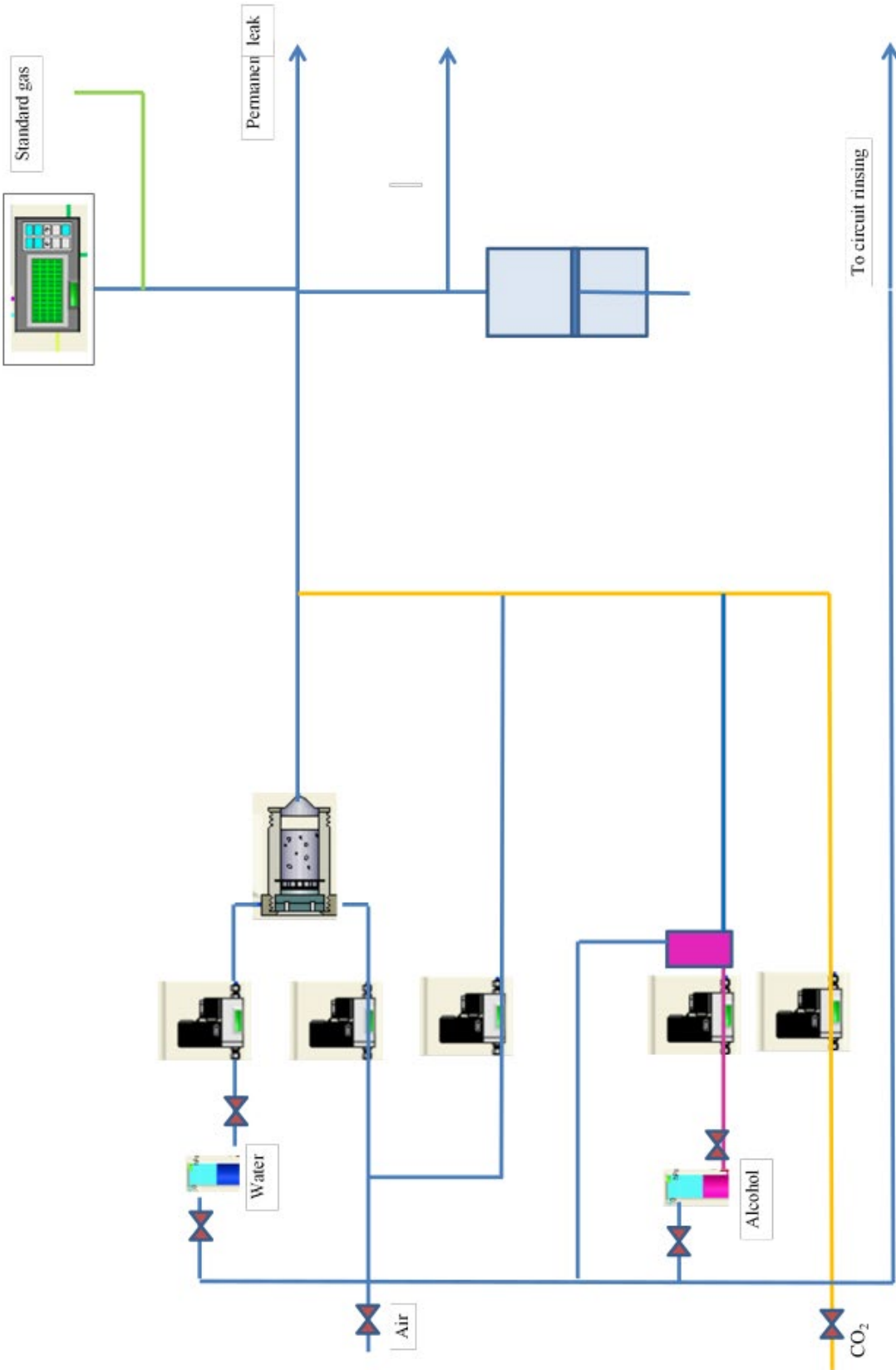
The determination of the ethanol concentration of each breath is carried out through an analysis system (Flame Ionisation Detector). The system is totally independent from the technologies used in an EBA.

The presence of a variable volume compartment in the pathway of the gas after being mixed (acting as a mechanical 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.

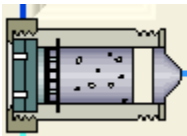

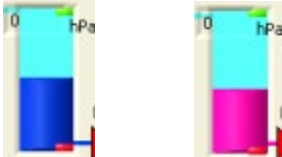

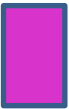


According to the technical solutions adopted, particularly those associated with the devices to regulate the flow rate, the gas analyser that is included can be considered as a means of checking the apparatus or as providing a standard if it is calibrated periodically.

Figure A.3 on the following page gives an example of a type 2 test gas generator.

Figure A.3 - Example of a type 2 test gas generator



Legend for Figure A.3:

	Controlled evaporator mixer (CEM)
	Valve
	Water and alcohol tanks
	Mass flow controllers (MFCs) (RDMs)
	Mixing valve
	FID analyser
	Actuator

A.4 General information about breath profiles

As defined in the Scope, the purpose of this Recommendation is to evaluate the suitability of EBAs 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 and/ 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 A.4 is to characterise the breath profile and define possible means to simulate it.

A.4.1 Example of human breath profiles

The forced exhalation of a human being is characterised 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 $\frac{1}{4}$ 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 varies depending on the subject and the flow resistance of the EBA.

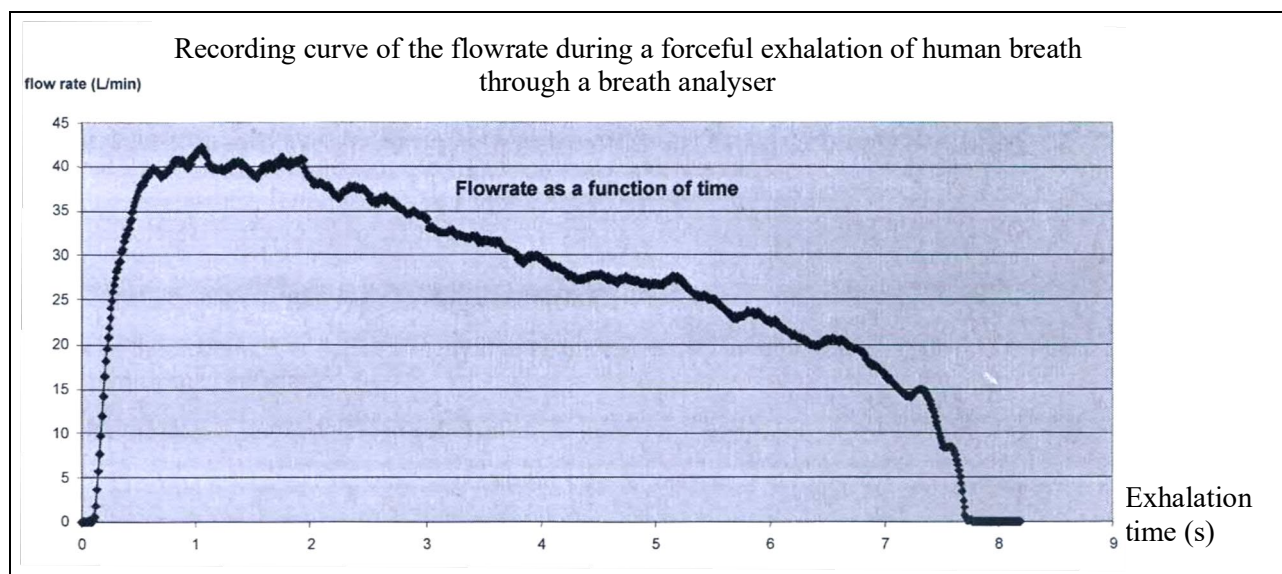


Figure A.4 - Example of a flow profile of a human being

A.4.1.2 Alcohol concentration profile

The alcohol concentration profile of a forced exhalation is characterised by a short delay in rise followed by 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 concentration).

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 from [37] by courtesy of the author).

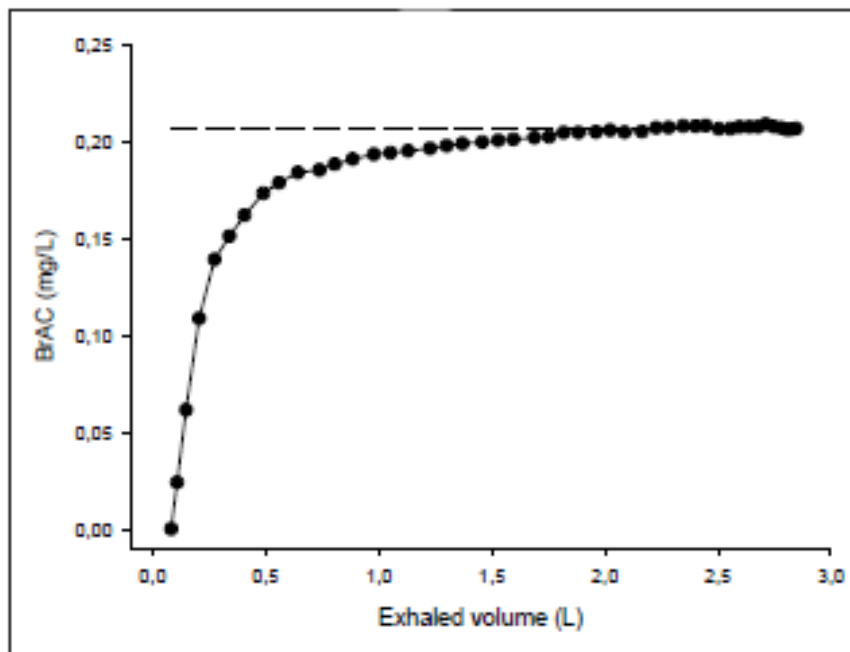


Figure A.5 – Example of a volumetric expirogram of breath alcohol concentration

A.4.2 Simulation of breath profiles with test gas generators

The characteristics of the breath profiles needed for the tests in Part 2 of this Recommendation are selected to correspond with the variability of real human breath profiles.

A type 2 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 human beings. The generated alcohol profiles shall have a steep increase and a real plateau of alcohol at the end of the injection of the 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

Figure A.6 shows the flow profile as needed for the tests defined in 2.5.6.1.c

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

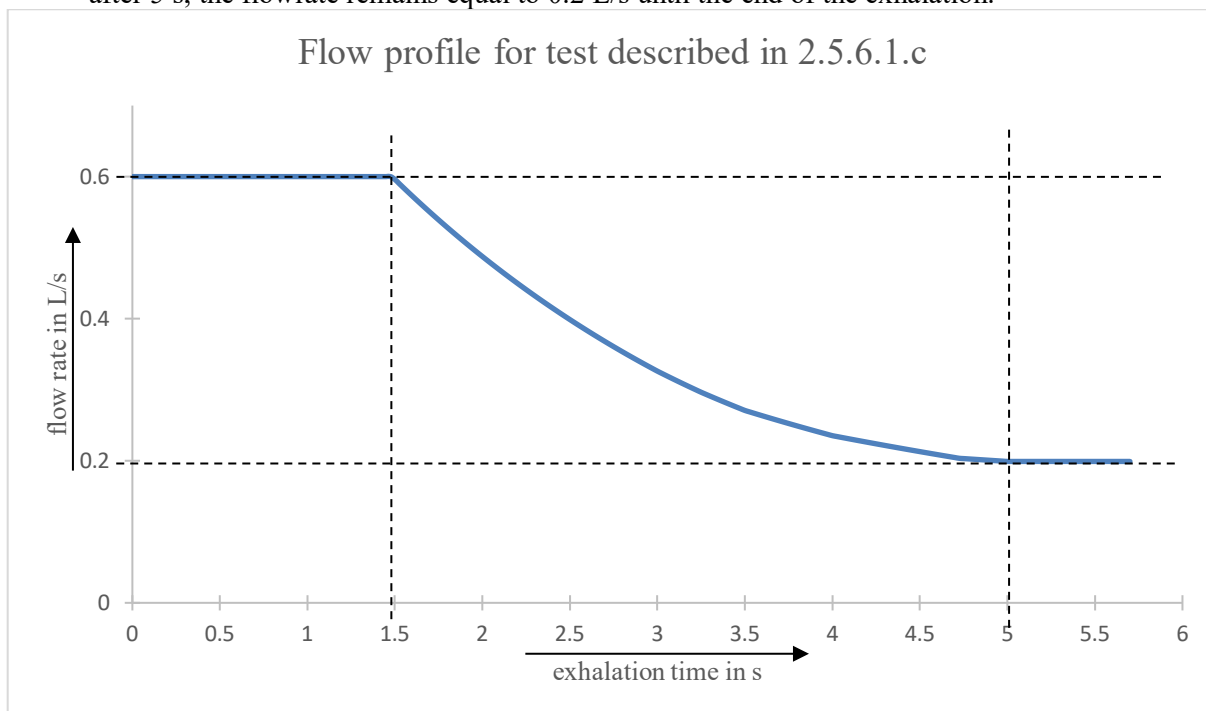


Figure A.6 – Simulated flow profile

A.4.2.2 Simulated alcohol concentration profiles

Theoretical calculations taking 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 stabilised to at least 99 % of the reference value.

For the calculation of the simulated progression of an alcohol concentration profile, the equation below 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 \times 2.2 mL \approx 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:

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

where β = alcohol concentration (expressed in % of the reference value);

$\beta_0 = 0$;

I = incremental index;

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.

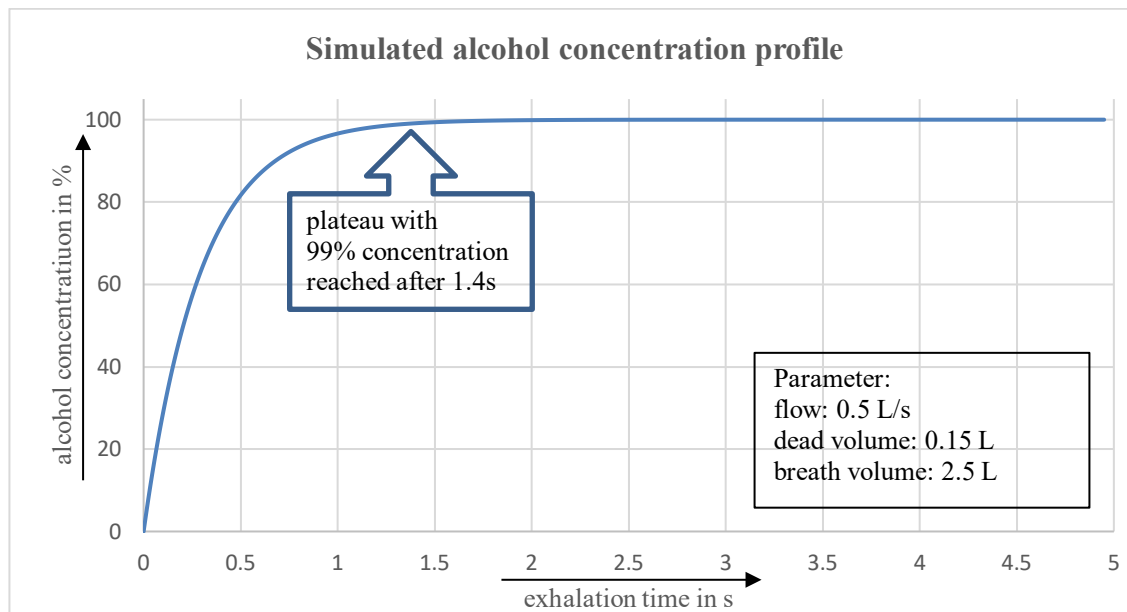


Figure A.7— Example of a calculated alcohol concentration profile

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

Annex B

Examples of detection of alcohol in upper respiratory tracts

(Informative)

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, medicines or mouthwash containing alcohol.

This is only a short-time phenomenon, as in normal circumstances alcohol in the upper respiratory tracts is no longer detectable 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 a decay.

National authorities may choose one, two or all of the following solutions to detect and/or exclude alcohol in the upper respiratory tracts. The corresponding tests are also described in the following clauses.

B.1 Peak method

B.1.1. Principle of the peak method

The peak method is applicable only to EBAs which are constantly monitoring the ethanol concentration during the injection of the breath sample. The resulting ethanol profile can be used for the detection of alcohol in the upper respiratory tracts.

For testing this kind of detection method for alcohol in the upper respiratory tracts, a test gas is needed which provides a profile of the ethanol concentration as indicated in Figure B.1.

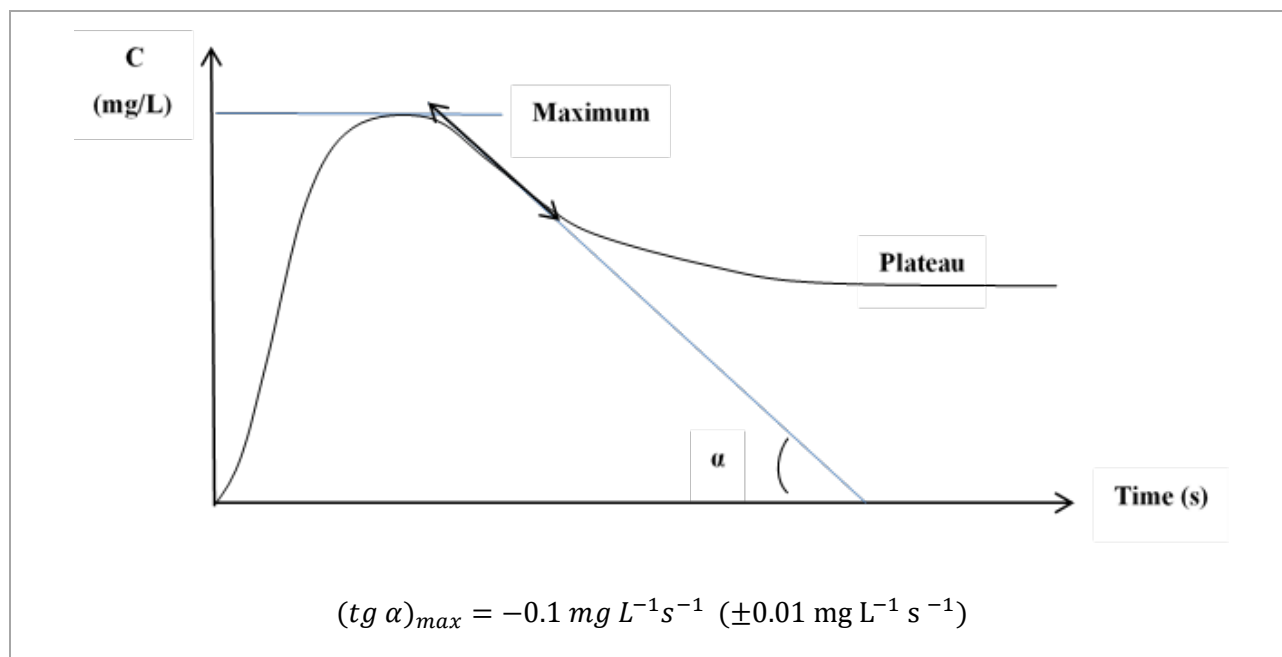
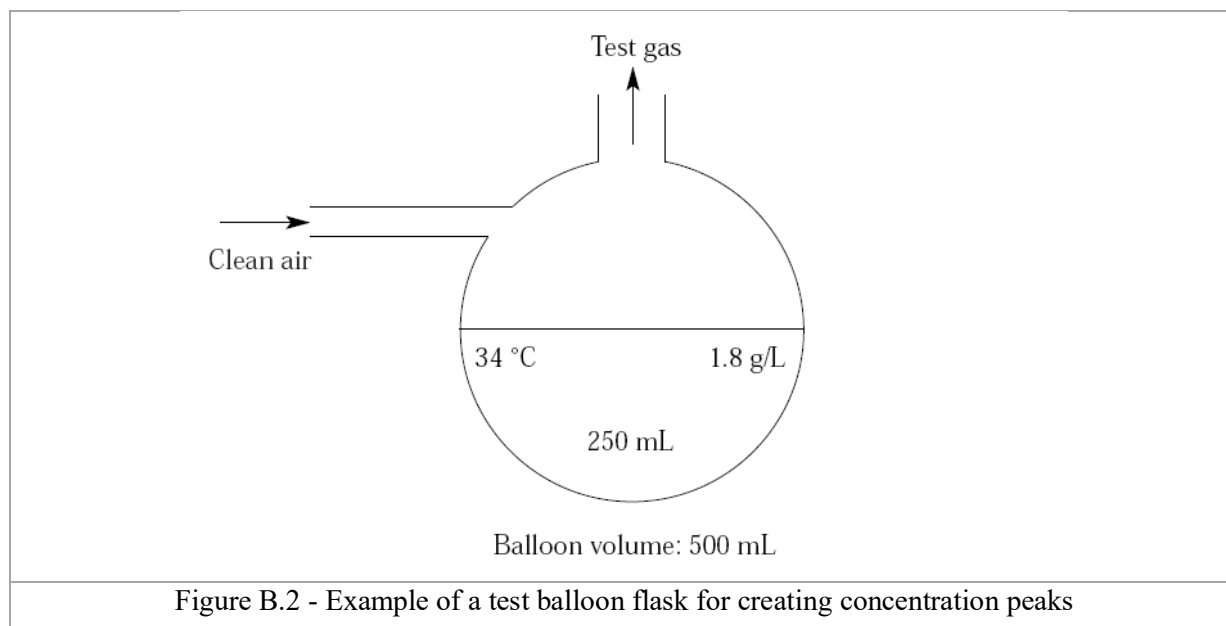


Figure B.1 - Example of a simulated alcohol concentration profile with residual mouth alcohol

Such a test gas can be generated for example by leading clean air through a balloon (two-neck round bottom flask) with a volume of approximately 500 ml. The balloon flask contains 250 ml of a water-ethanol solution with an ethanol concentration of 1.8 g/L, kept at a temperature of 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 vapour, creating a peak of ethanol as required (see Figure B.1).



B.1.2. Test procedure for 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 sampling period.
Object of the test	Verification of compliance with the provisions in R 126-1, 7.1.8 under ambient reference conditions.
Precondition	As defined in 2.5.2.
Condition of the EUT	Power is to be “on” for the duration of the test.
Test procedure in brief	The test comprises 5 measurements with the special test gas.
Measurement conditions	<p>Test gas generator: type 2 (enhanced) or example given in figure B.2</p> <p>Variation of the alcohol concentration as a function of time according to the evolution shown in Figure B.1</p> <p>Ethanol concentration: concentration profile as described in B.1.1</p> <p>Test gas conditions: delivered volume: $3 \text{ L} \pm 0.1 \text{ L}$ duration of injection: $15 \text{ s} \pm 0.5 \text{ s}$ all other parameters as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: within reference conditions as defined in 2.4.1.</p>
EUT performance	<p>Number of measurements per test scheme: at least 5</p> <p>Time schedule: to be performed consecutively for each test scheme</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>
Acceptance criteria	<p>The EUT shall detect the presence of alcohol in the upper respiratory tracts and shall cancel the measurement cycle.</p> <p>It shall not deliver any measurement result and shall display an appropriate error message.</p>

B.2 Two-measurement cycle – first and second methods

Since the alcohol in the upper respiratory tracts is only a short-time phenomenon, the results of two independent measurements, performed shortly one after the other 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 process the results internally with a scale interval of 0.001 mg/L.

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

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

B.2.1. Principle of the two-measurements cycle - 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 at least 2 minutes.

The EBA shall be able to memorise an applicable legal limit, i.e. the value that constitutes a violation of the law.

During a measurement cycle, the following incidents may occur:

a) result of the first measurement is less than a legal limit:

National authorities may define for this case that the measurement cycle shall then be stopped automatically after the first measurement 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 the unique available result to be indicated as an indicative result, for instance indicating “measurement cycle not completed”.

b) result of the second measurement is less than a legal limit:

If one of the two measurement results is less than the legal limit and the other is greater than or equal to the legal limit, national authorities may define that the smallest result shall be displayed and printed (if applicable). In this case, a comparison between the two results is not necessary.

c) The results of both measurements are greater than or equal to a legal limit:

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

$$R = \frac{\left| 1 - \frac{\beta_2}{\beta_1} \right|}{t}$$

With:

R Ratio to judge the change between first and second results

t Time delay, in minutes, between the end of the first breath sample and the end of the second breath sample,

β_1 Result of the measurement of the first breath sample,

β_2 Result of the measurement of the second breath sample.

Consequences to be taken after the measurement are depending on the ratio R :

- **Case 1:** if R is less than 0.03 min^{-1} , alcohol in the upper respiratory tracts is considered as not being present or negligible. National Authorities may choose one of the two following solutions:
 - 1) the smallest value of the measurement results is displayed and printed (if applicable);
 - 2) the two values are displayed and printed (if applicable).

- **Case 2:** if R is greater than or equal to 0.03 min^{-1} , the results are considered as being affected by alcohol in the upper respiratory tracts and the measurement cycle shall be cancelled. The EBA shall display an appropriate error message to specify that the measurement cycle is not valid.

Note: National authorities may then determine whether the two-measurements cycle is to be repeated, or whether another course of action is to be taken.

B.2.2. Test procedure of the two-measurements cycle - first method

Note that the test gases described in this procedure are chosen for a legal limit of 0.25 mg/L .

For other legal limits, the required test gas concentrations must be adapted accordingly.

Table B.2 - Two-measurements cycle - first method

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 R126-1,7.1.8 under ambient reference conditions.		
Precondition	As defined in 2.5.2.		
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	<u>Incident a)</u>	Test gas A:	legal limit minus $0.03 \text{ mg/L} = 0.22 \text{ mg/L}$
	<u>Incident b)</u>	Test gas B:	legal limit plus $0.03 \text{ mg/L} = 0.28 \text{ mg/L}$ and
		Test gas A:	legal limit minus $0.03 \text{ mg/L} = 0.22 \text{ mg/L}$
	<u>Incident c)</u>	First test gas:	test gas B: legal limit plus $0.03 \text{ mg/L} = 0.28 \text{ mg/L}$
		Second test gas:	
	Case 1:	Test gas C:	
	One of these test gas concentrations shall be chosen as second test gas C, depending on the time delay:	Time delay (min)	Theoretical ratio $R \text{ (min}^{-1}\text{)}$
		2	0.017
		2.5	0.014
		3	0.022
		3.5	0.019
		4	0.017
		4.5	0.022
		5	0.019
	Case 2:	Test gas D	
	One of these test gas concentrations shall be chosen as second test gas D, depending on the time delay:	Time delay (min)	Theoretical ratio $R \text{ (min}^{-1}\text{)}$
		2	0.033
		2.5	0.039
		3	0.032
		3.5	0.036
		4	0.031
		4.5	0.034
		5	0.035

Measurement conditions	<p>Test gas generator: Type 1 or type 2</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>Ethanol concentrations: See above</p> <p>Test gas conditions: Delivered volume: 3 L \pm 0.1 L</p> <p>Duration of injection: 5 s \pm 0.5 s</p> <p>All other parameters as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6.</p> <p>Ambient conditions: Within reference conditions as defined in 2.4.1.</p>
Test schemes	<p>Test scheme for incident a)</p> <ul style="list-style-type: none"> test gas concentration for the first measurement: test gas A the second measurement shall not be performed (the EBA shall terminate the measurement cycle automatically after the first test). <p>Test scheme for incident b)</p> <ul style="list-style-type: none"> test gas concentration for the first measurement: test gas B test gas concentration for the second measurement: test gas A <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: test gas B test gas concentration for the second measurement: one of the test gases listed as C, 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 greater than or equal to 0.03 min⁻¹:</p> <ul style="list-style-type: none"> test gas concentration for the first measurement: test gas B test gas concentration for the second measurement: one of the test gases listed as D, depending on the time between the end of the first injection and the end of the second injection to obtain a theoretical ratio of greater than or equal to 0.03.
EUT performance	<p>Number of measurements per test scheme: at least 5</p> <p>Time schedule: to be performed consecutively for each test scheme</p> <p>Parameters at least to be recorded: as defined in 2.5.3.</p>
Acceptance criteria	<p>For incident a)</p> <ul style="list-style-type: none"> The EUT shall verify that the result β_1 of the first measurement is below the legal limit ($\beta_1 < 0.25$ 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 β_2 is below the legal limit ($\beta_2 < 0.25$ 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 β_1 and β_2 is smaller than 0.03 min⁻¹ and shall, according to national regulations, either display and print (if applicable) the smallest result of β_1 and β_2 as the final result of a valid measurement cycle, or display and print (if applicable) both results β_1 and β_2. <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 β_1 and β_2 is greater than or equal to 0.03 min⁻¹ and shall cancel the measurement cycle and display an appropriate error message.

B.2.3. Principle of the two-measurements cycle - second method

The cycle of the EBA shall consist of two measurements of separate breath samples. The time delay between the measurements of the two breath samples measurements shall be between 2 min and 5 min. National authorities shall specify how the final result of both measurements shall be obtained (e.g. lower result, mean of both results, or both results).

If the difference between the two measurement results is more than 0.10 mg/L, or 20 % of the smaller of the two measurement results, depending on whichever is the greater, the EBA shall automatically cancel the measurement cycle as invalid and shall display an appropriate error message.

Note: National authorities may specify smaller differences than required here. They may also specify not to perform a comparison of results when at least one measurement result is below the legal limit.

B.2.4. Test procedure of the two-measurements cycle second method

Table B.3 – Two-measurements cycle – second method

Test method	Measurements with different ethanol concentrations for 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 R 126-1, 7.1.8 under ambient reference conditions.
Precondition	As defined in 2.5.2.
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 generator: type 1 or type 2 Variation of the alcohol concentration as a function of time: <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). Ethanol concentrations: Test gas concentration for the first measurement: 0.40 mg/L (test gas no. 4) Test gas concentration for the second measurement: 0.25 mg/L (test gas no. 3) Test gas conditions: delivered volume: 3 L ± 0.1 L duration of injection: 5 s ± 0.5 s all other parameters as defined in 2.4.3.1, Table 4 and 2.4.3.2, Table 6. Ambient conditions: within reference conditions as defined in 2.4.1
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 2.5.3.
Acceptance criteria	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 measurement results, depending on whichever is the greater. It shall not deliver any measurement result and shall display an appropriate error message if applicable.

B.3 Delay before measurement

Good measurement practice, regardless of technical solutions, 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

Comparison table between R 126:2012 and R 126:2021

(Informative)

The items in the following table are ordered according to the numbering in the present edition (2021)

Table D.1 - R 126-2

R 126:2012		R 126:2021		
Ref.	Description	Ref.	Description	Remarks
Part 2			Part 2 <i>Metrological controls and performance tests</i>	
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.
		2.3.3	Operational tests	New clause, part of “2.3 Examination and tests” is moved here for a more logical order.
11.4	Performance tests	2.4	Test conditions and test gas generator	New clause/title.
11.4.1	Reference conditions	2.4.1	Reference 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	List of characteristics 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 presented as a table. Remainder of the clause moved to the 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	

R 126:2012		R 126:2021		
Ref.	Description	Ref.	Description	Remarks
11.4.3.3	Type of testing apparatus			More information about different types of test gas generators added, Table with main features of the types introduced. New table showing an overview of which simplified means are allowed for which test.
		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/title.
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	Minimum parameters 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 standardised table.
b)	Drift	2.5.5.2	Drift	Layout changed to a standardised table. New specification of the test for long term drift.
c)	Memory effects	2.5.5.3	Memory effects	Layout changed to a standardised table.
		2.5.4	Effect of water vapour (condensation)	New test.
		2.5.6	Influence factors of the conditions of injection	New clause/title
11.4.4.2	Influence factors of the conditions of injection	2.5.6.1	Variations of the test gas parameters	Layout changed to a standardised table, clarification of some test details.
		2.5.6.2	Alcohol in the upper respiratory tract	New mandatory obligation for testing.
		2.5.7	Tests for operating conditions and physical influence factors	New clause/title.
11.4.4.3	Dry heat	2.5.7.1	Temperature test (dry heat and cold)	Layout changed to a standardised table, definition of specific temperature for the different use-cases of EBAs. Temperature modified. New test sequence.
11.4.4.4	Cold			
11.4.4.5	Damp heat, steady state (non-condensing)	2.5.7.2	Damp heat, steady state (non-condensing)	Layout changed to a standardised table, definition of specific temperature for the different use-cases of EBAs.
11.4.4.6	Atmospheric pressure	2.5.7.3	Static atmospheric pressure	Layout changed to a standardised table, clarification of some test details. Uncertainty of the pressure sensor is added here.
11.4.4.7	Random vibration	2.5.7.4	Random vibration	Layout changed to a standardised table.

R 126:2012		R 126:2021		
Ref.	Description	Ref.	Description	Remarks
11.4.4.8	DC mains voltage variations	2.5.7.5	DC mains voltage variations	Layout changed to a standardised table.
11.4.4.9	AC mains voltage variations	2.5.7.6	AC mains voltage variations	Layout changed to a standardised table.
11.4.4.10	AC mains frequency variations	2.5.7.7	AC mains frequency variations	Layout changed to a standardised table.
11.4.4.11	Low voltage of internal battery	2.5.7.8	Low voltage of internal battery	Layout changed to a standardised table. New procedure (0.9 × lower voltage level).
		2.5.7.9	Power supply duration test	New test.
11.4.4.12	Voltage variations of a road vehicle battery	2.5.7.10	Voltage variations of a road vehicle battery	Layout changed to a standardised table, clarification of some test details.
11.4.4.13	Total fraction by volume of hydrocarbons (as methane equivalent) in the environment	2.5.7.11	Hydrocarbons in the environment	Layout changed to a standardised table, clarification of some test details.
11.4.4.14	Influence of the volume fraction of CO ₂	2.5.7.12	Raised fraction of CO ₂ in the test gas	Layout changed to a standardised table. Correction of the test gas procedure according to Erratum 2 of R 126:2012. CO ₂ concentration of the test gas decreased.
11.4.5	Disturbance tests	2.5.8	Disturbances tests	Deleted text of the clause, since it is already implemented in 2.5.1 to 2.5.4.
11.4.5.2	Conducted radio-frequency fields	2.5.8.1	Conducted (common mode) currents generated by RF EM fields	Layout changed to a standardised table, clarification of some test details.
11.4.5.1	Radiated, radio frequency, electromagnetic fields	2.5.8.2	Radiated RF electromagnetic fields	New approach introducing test schemes A or B which allow special test modes. Layout changed to a standardised table, clarification of some test details. Extended frequency range up to 6000 MHz.
11.4.5.3	Electrostatic discharges	2.5.8.3	Electrostatic discharges	Layout changed to a standardised table, clarification of some test details.
11.4.5.4	Bursts on supply lines	2.5.8.4	Bursts (transients) on AC and DC mains	Layout changed to a standardised table, clarification of some test details.
		2.5.8.5	Surges on AC and DC mains power lines	New test.
11.4.5.5	Bursts on signal, data and control lines	2.5.8.6	Bursts on signal, data and control lines	Layout changed to a standardised table, clarification of some test details.
		2.5.8.7	Ripple on DC mains power	New test.
		2.5.8.8	DC mains voltage dips, short interruptions and (short term) variations	New test.
11.4.5.7	AC mains voltage dips, short interruptions and voltage variations	2.5.8.9	AC mains voltage dips, short interruptions and voltage variations	Layout changed to a standardised table, clarification of some test details.
11.4.5.6	Surges on signal, data and control lines	2.5.8.10	Surges on signal, data and control lines	Layout changed to a standardised table, clarification of some test details.

R 126:2012		R 126:2021		
Ref.	Description	Ref.	Description	Remarks
11.4.5.8	Electrical transient conduction for external batteries of a vehicle	2.5.8.11	Electrical transient conduction along supply lines	Layout changed to a standardised table, clarification of some test details.
		2.5.8.12	Electrical transient conduction via lines other than supply lines	New test.
11.4.5.9	Mechanical shocks	2.5.8.13	Mechanical shock	Layout changed to a standardised table, clarification of some test details. Number of falls doubled for portable EBAs.
11.4.5.10	Shakes	2.5.8.14	Shakes	Layout changed to a standardised table, clarification of some test details.
11.4.5.11	Damp heat cyclic (condensing)	2.5.8.15	Damp heat cyclic (condensing)	Layout changed to a standardised table, clarification of some test details.
11.4.5.12	Storage test	2.5.8.16	Storage test	Layout changed to a standardised table, clarification of some test details.
		2.5.8.17	Vibration (as disturbance)	New test (for stationary EBA only).
11.4.5.13	Durability	2.5.8.18	Durability	-
11.4.6	Physiological influence quantities	2.5.9	Physiological influence quantities	Layout changed to a standardised table, clarification of some test details. New approach for the acceptance “sensitivity” criteria.
		2.6	Tests for optional disturbances and requirements	New clause/ headline.
		2.6.1	Sand and dust	New test.
		2.6.2	Salt mist	New test.
		2.6.3	Water	New test.
		3	Initial and subsequent verifications	New clause.
		3.1	General considerations	New clause.
		3.1.1	Initial verification	New clause.
		3.1.2	Subsequent verification	New clause.
		3.2	Legal status of the instrument submitted for verification	New clause.
		3.3	Visual examination	New clause.
		3.4	Metrological examination	New clause.
		3.4.1	Metrological precondition for performing tests	New clause.
		3.4.2	Test gases used for verification	New clause.
		3.4.3	Tests for initial or subsequent verifications	New clause.

R 126:2012		R 126:2021		
Ref.	Description	Ref.	Description	Remarks
		3.4.3.1	Metrological examination	New clause.
		3.4.3.2	Verification marks, seals and documentation	New clause.
		Annex A	General examples for test gas generators	New clause (clause re-introduced from edition 1998).
Annex C	Reference principle for the implementation of the tests (Informative)	A.1	Reference principle for the implementation of the test	Revised text, revised symbols of the equations.
		A.2	Example of a type 1 test gas generator	New clause with new diagrams.
		A.3	Example of a type 2 test gas generator	New clause with new diagrams.
Annex B	General information and breath profile (Informative)	A.4	General information about breath profiles	
B.1	Measurement flowrate during exhalation	A.4.1	Example of human breath profiles	Revised clause.
		A.4.1.1	Flow profile	Revised clause.
		A.4.1.2	Alcohol concentration profile	New example of a volumetric diagram.
B.2	Measurement of the alcohol concentration during exhalation / determination of the alcohol plateau	A.4.2	Simulation of breath profiles with test gas generators	Revised clause. Clarification of some details.
		A.4.2.1	Simulated exhalation profiles	Revised clause.
		A.4.2.2	Simulated alcohol profiles	Revised clause.
Annex A	Examples of detection of alcohol in upper respiratory tracts (Informative)	Annex B	Examples of detection of alcohol in upper respiratory tracts	
A.1	Peak method	B.1	Peak method	
		B.1.1	Principle of the peak method	Revised clause, new diagrams.
		B.1.2	Test procedure for the peak method	Revised clause.
A.2	Two-measurement cycle	B.2	Two-measurements cycle – first and second methods	Revised clause.
		B.2.1	Principle of the two-measurements cycle – first method	Revised clause.
		B.2.2	Test procedure of the two-measurements cycle - first method	Revised clause.
		B.2.3	Principle of the two-measurements cycle - second method	Revised clause.
		B.2.4	Test procedure of the two-measurements cycle - second method	Revised clause.

R 126:2012		R 126:2021		
Ref.	Description	Ref.	Description	Remarks
A.3	Delay before measurement	B.3	Delay before measurement	-
		Annex C	Comparison table of R 126-2:202x to R 126-2:2012	New clause.
Annex D	Bibliography	Annex D	Bibliography	Updated.

Annex D Bibliography

(Informative)

At the time of publication, the editions indicated were valid. All referred documents are subject to revision, and the users of this Recommendation are encouraged to investigate the possibility of applying the most recent editions of the referred documents indicated below. Members of the 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 <i>International vocabulary of terms in legal metrology</i> (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 <i>International Vocabulary of Metrology - Basic and General Concepts and Associated Terms</i> (VIM), 3rd Edition	Vocabulary, developed by the Joint Committee for Guides in Metrology (JCGM).
[3]	OIML D 9:2004 <i>Principles of metrological supervision</i>	
[4]	OIML D 11:2013 <i>General requirements for measuring instruments – Environmental conditions</i>	Guidance for establishing appropriate metrological performance. Testing requirements for influence quantities that may affect measuring instruments.
[5]	OIML D 31:2019 <i>General requirements for software-controlled measuring instruments</i>	
[6]	OIML G 1-100:2008 <i>Guide to the expression of uncertainty in Measurement</i> (GUM)	Evaluation of measurement data - Guide to the Expression of uncertainty in measurement
[7]	OIML G 1-104:2009 <i>Evaluation of measurement data – An introduction to the “Guide to the expression of Uncertainty” and related documents</i>	This document introduces measurement uncertainty, the GUM, and the GUM Supplements and other documents
[8]	IEC 60068-2-1:2007 <i>Environmental testing - Part 2-1: Tests - Test A: Cold</i>	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.

Ref.	Standards and reference documents	Description
[9]	IEC 60068-2-2:2007 <i>Environmental testing - Part 2-2: Tests - Test B: Dry heat</i>	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 <i>Basic environmental testing procedures - Part 2-11: Tests - Test Ka: Salt mist</i>	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 <i>Environmental testing - Part 2-18: Tests - Test R and guidance: Water</i>	Provides test methods 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.
[12]	IEC 60068-2-30:2005 <i>Environmental testing - Part 2-30: Tests - Test Db: Damp heat, cyclic (12 h + 12 h cycle)</i>	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 <i>Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens</i>	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 <i>Environmental testing - Part 2-47: Test - Mounting of specimens for vibration, impact and similar dynamic tests</i>	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 <i>Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance</i>	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 <i>Environmental testing - Part 2-78: Tests - Test Cab: Damp heat, steady state</i>	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 <i>Electromechanical components for electronic equipment - Basic testing procedures and measuring methods - Part 11: Climatic tests - Section 8: Test 11h - Sand and dust</i>	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 <i>Degrees of protection provided by enclosures (IP Code)</i>	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 <i>Operating conditions for industrial-process measurement and control equipment. Part 2: Power</i>	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 <i>Classification of environmental conditions - Part 2: Environmental conditions appearing in nature - Section 5: Dust, sand, salt mist</i>	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 <i>Electromagnetic compatibility (EMC) - Part 4-1: Testing and measurement techniques - Overview of IEC 61000-4 series</i>	Gives information and guidance on the EMC basic standards and other basic EMC documents published in the IEC 61000-4 series.

Ref.	Standards and reference documents	Description
[22]	IEC 61000-4-2:2008 <i>Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test</i>	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 <i>Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test</i>	Applicable to the immunity requirements of electrical and electronic equipment to radiated electromagnetic energy. Establishes test levels and the required test procedures.
[24]	IEC 61000-4-4:2012 <i>Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test</i>	Relates to the immunity of electrical and electronic equipment to repetitive electrical fast transients. Gives immunity requirements and test procedures related to electrical fast transients/bursts.
[25]	IEC 61000-4-5:2014+AMD1:2017 <i>Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test</i>	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 <i>Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields</i>	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 <i>Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests</i>	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 <i>Electromagnetic compatibility (EMC) - Part 4-17: Testing and measurement techniques - Ripple on d.c. input power port immunity test</i>	Defines test methods for immunity to ripple at the DC input power port of electrical or electronic equipment. Applies to low-voltage DC power ports of equipment supplied by external rectifier systems, or batteries which are being charged.
[29]	IEC 61000-4-20:2010 <i>Electromagnetic compatibility (EMC) - Part 4-20: Testing and measurement techniques - Emission and immunity testing in transverse electromagnetic (TEM) waveguides</i>	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 <i>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</i>	Establishes a common and reproducible basis for testing electrical and electronic equipment when subjected to voltage dips, short interruptions or voltage variations on DC power ports.
[31]	IEC 61000-6-1:2016 <i>Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments</i>	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 <i>Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments</i>	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.

Ref.	Standards and reference documents	Description
[33]	ISO 7637-2:2011 <i>Road vehicles — Electrical disturbances from conduction and coupling — Part 2: Electrical transient conduction along supply lines only</i>	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 <i>Road vehicles — Electrical disturbances from conduction and coupling — Part 3: Electrical transient transmission by capacitive and inductive coupling via lines other than supply lines</i>	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 <i>Road vehicles — Environmental conditions and testing for electrical and electronic equipment — Part 2: Electrical loads</i>	Applies to electric and electronic systems/components for road vehicles. Describes the potential environmental stresses and specifies tests and requirements recommended for the specific mounting location on/in the road vehicle.
[36]	OIML G 19:2017 <i>The role of measurement uncertainty in conformity assessment decisions in legal metrology</i>	
[37]	David Grubb, Lars Lindberg: <i>Exhalation profile and elimination kinetics of mouth alcohol</i> , Blutalkohol Vol 48/2011, p. 57 - 66	