I-9/9/2024-W&M
Government of India
Ministry of Consumer Affairs, Food & Public Distribution
Department of Consumer Affairs
Legal Metrology Division

Krishi Bhawan, New Delhi-01
Dated: 27.6.2024

Subject- Draft Rules on Breath Analyzer for comments from stakeholders – reg.

Undersigned is directed to refer to the above mentioned subject and to state that the Draft Rules on Breath Analyzer, are placed in the website of the Department www.consumeraffairs.nic.in for seeking comments from all stakeholders by 26.7.2024. The comments may be sent to email-ID: dirwm-ca@nic.in/ ashutosh.agarwal13@nic.in/ mk.naik72@gov.in.

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To:

All concerned

[TO BE PUBLISHED IN THE GAZETTE OF INDIA, EXTRA ORDINARY, PART II SECTION 3 SUB-SECTION (i)]

GOVERNMENT OF INDIA

MINISTRY OF CONSUMER AFFAIRS, FOODAND PUBLIC DISTRIBUTION

(DEPARTMENT OF CONSUMER AFFAIRS)

New Delhi, the ……2024

NOTIFICATION

GSR……In exercise of the powers conferred by sub-section (1) read with clauses (c), (f), (h), (i) and (s) of sub-section (1) of section 52 of the Legal Metrology Act 2009, (1 of 2010), the Central Government hereby makes the following rules, namely:-

1. **Short title and commencement**

(1) These rules may be called the Legal Metrology (General) (Amendment) Rules, 2024.

(2) They shall come into force from the date of publication of this notification in the Official Gazette, as follows:

(i) All the **Evidential Breath Analyser** shall be verified and stamped before sale/ putting into use;

(ii) All the **Evidential Breath Analyser** which are already in use at the time of publication of this notification shall be verified and stamped within one year.

2. In the index of the Schedule of the Legal Metrology (General) Rules, 2011 under the Eight Schedule after Part XII, the entries "Part XIII", "**Evidential Breath Analyser**" shall be inserted.

3. In the Legal Metrology (General) Rules, 2011, (herein after referred to as the said rules), under the Eight Schedule the Part XIII and the entries made thereunder, the following shall be inserted, namely. -

EIGHTH SCHEDULE

SPECIFICATIONS FOR MEASURING INSTRUMENTS

PART XIII- EVIDENTIAL BREATH ANALYSER

Part-1

1. Scope

(1) This Specification applies to evidential breath analysers (EBA), which are quantitative instruments that render a measurement result of alcohol concentration in exhaled human breath for the purpose of establishing compliance, for fighting against alcohol abuse and/or for the advancement of public safety.

(2) These types of instruments are referred to as "evidential" and serve to provide the principal means by which a definitive breath alcohol measurement is obtained.

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

(4) For the purpose of this Specification, the term "alcohol" will be used to refer to ethyl alcohol or ethanol in a broader context. However, when dealing with test gas compositions, the exact chemical terminology for each substance will be applied.

(5) Additionally, EBAs may be equipped with special features, for example:

- Prohibiting the displaying or reporting of results that do not represent the final measurement result;
- Mandating the inclusion of a printing device;
- Prohibiting operation of the analyser in the event that no paper is detected in the printing device;
- Requiring further printed information in addition to the final measurement result;
- Requiring final measurement results to be displayed and reported in terms other than the alcohol content in exhaled human breath (i.e. physiological conditions such as ‰ of blood or in terms of other quantities).

(6) The purpose of this Specification is to enumerate the minimum metrological specifications and tests applicable to model approval of quantitative EBAs. It also gives guidance for establishing metrological specifications for initial and re verifications.

(7) The scope of this Specification is limited to the types of EBAs that use mouthpieces for sampling the breath.

2. Terms and definitions

(1) General metrology and legal metrology terms

(i) measurement error:
Measured quantity value minus a reference quantity value

(ii) Adjustment of a measuring system:
Set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured

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

(iv) Verification of a measuring instrument
Conformity assessment procedure which results in the affixing of a verification mark and/or issuing of a verification certificate

(v) Verification

Verification of a measuring instrument which has not been verified previously

(vi) Re verification

Verification of a measuring instrument after a previous verification

(vii) Mandatory periodic verification

Re verification of a measuring instrument, carried out periodically at specified intervals according to the procedure laid down

(viii) Putting into service (use)

Moment of the first use by the end-user of a measuring instrument for the purposes for which it was designed

(ix) Being in service (use)

operational life cycle of a measuring instrument after its putting into service, i.e. a measuring instrument in use, after repair, relocated, or rebuilt that may be resold

(x) Disturbance

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

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

(xi) Fault

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

(xii) Fault limit

Value specified in this Specification delimiting non-significant faults

(xiii) Significant fault

Fault exceeding the applicable fault limit

(xiv) Significant defect

Event that has an impact on the properties or functions of the measuring instrument or a fault

(xv) Intrinsic error

Error of a measuring instrument, determined under reference conditions

(xvi) Initial intrinsic error

Intrinsic error of a measuring instrument as determined prior to performance tests and durability evaluations

(xvii) Experimental standard deviation

For a series of *n* measurements of the same measurand, the quantity *s* (*qk*) characterising the dispersion of the results and given by the formula:

$$s\,(q_k) = \sqrt{\frac{\sum_{j=1}^{n}(q_j - \overline{q})^2}{n-1}}$$

With q_k being the result of the k^{th} measurement and $\overline{q}$ being the arithmetic mean of the n results considered.

(xviii) Measurement precision

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

(xix) Measurement repeatability

Measurement precision under a set of repeatability conditions of measurement

(xx) Repeatability condition of measurement

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

(xxi) Measurement reproducibility

Measurement precision under reproducibility conditions of measurement

(xxii) Reproducibility condition of measurement

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

(xxiii) Stability of a measuring instrument

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

(xxiv) Uncertainty of a measurement

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

(xxv) Sensitivity

Quotient of the change in an indication of a measuring system and the corresponding change in a value of a quantity being measured

Note 1: Sensitivity of a measuring system can depend on the value of the quantity being measured.
Note 2*:* The change considered in a value of a quantity being measured must be large compared with the resolution.
Note 3*:* In the scope of this Specification, sensitivity relates to the added substance which is not identical with the measurand.

(2) **Specific Terms**

(i) Evidential breath alcohol analyser (EBA)

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

(ii) Stationary evidential breath alcohol analyser (stationary EBA)

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

Note: In the scope of this Specification, stationary EBAs are designated as use-case 1.

(iii) Transportable evidential breath alcohol analyser (transportable EBA)

Easily transportable evidential breath alcohol analyser intended for use in mobile applications (e.g. in vehicles)

Note: In the scope of this Specification, transportable EBAs are designated as use-case 2.

(iv) Portable evidential breath alcohol analyser (portable EBA)

Evidential breath alcohol analyser intended for use in outdoor conditions (e.g. handheld devices generally powered by a battery)

Note: In the scope of this Specification, portable EBAs are designated as use-case 3.

(v) Alveolar air

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

(vi) End expiratory breath

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

(vii) Anatomical dead space

Dead space in that portion of the respiratory system which is external to the alveoli and includes the air- conveying ducts from the mouth to the terminal bronchioles

(viii) Measuring mode

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

(ix) Metrological test mode

Mode in which the EBA is subject to metrological control such as verification or adjustment

Note: In this mode, more information will be available compared to the measuring mode (e.g. higher resolution, intermediate results, etc.), and access to maintenance and adjustment means is possible.

(x) Standby mode

mode of the EBA whereby only certain circuits are energised in order to conserve power and/or prolong component life, and to attain the measuring mode more rapidly than would be possible if starting from the switched-off state

(xi) Checking facility

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

(xii) Standard measurement cycle

The measurement cycle of an EBA consists of all steps necessary to obtain a valid result, from starting the measurement, sampling, analysing, internal control procedures, calculation, and displaying the result

(xiii) Drift

Continuous or incremental change over time in indication, due to changes in metrological properties of a measuring instrument

(xiv) Memory effect

Effect on the true alcohol concentration of the sample caused by previous samples

(xv) Plateau of alcohol concentration

Time period during exhalation when the alcohol content is considered to reach a nearly stable value

(3) **Software Terms**

(i) Authenticity

Result of the process of authentication (passed or failed)

(ii) Authentication

Checking of the declared or alleged identity of a user, process, or measuring instrument

Note: This may be necessary when checking that downloaded software originates from the owner of the certificate.

(iii) Cryptographic means

Means such as encryption/ decryption with the purpose of hiding information from unauthorised persons, or hashes and signatures to ensure integrity and authenticity

(iv) Error log

Continuous data file containing an information record of failures or significant defects that have an influence on the metrological characteristics of the measuring instrument

(v) Hash function

(Mathematical) function which maps values from a large (possibly very large) domain into a smaller range

(vi) Integrity (of programs, data, or parameters)

Assurance that the programs, data, or parameters have not been subjected to any unauthorised or unintended changes while in use, transfer, storage, repair, or maintenance

(vii) Interface

Shared boundary between two functional units, defined by various characteristics pertaining to the functions, physical interconnections, signal exchanges, and other characteristics of the units, as appropriate

(viii) legally relevant

Attribute of a part of a measuring instrument, a device or software subject to legal control

(ix) Sealing

Means intended to protect the measuring instrument against any unauthorised modification, readjustment, removal of parts, software, etc.

(x) Software examination

Technical operation that consists of determining one or more characteristics of the software according to the specific procedure (e.g. analysis of technical documentation or running the program under controlled conditions)

(xi) Software identification

Sequence of readable characters (e.g. version number, checksum) that represents the software or software module under consideration

(xii) Transmission of measurement data

Electronic transportation of measurement data via communication lines or other means to a receiver where they are further processed

(xiii) User interface

Interface that enables information to be interchanged between the operator and the measuring instrument or its hardware components or software modules

Note: Examples are switches, keyboard, mouse, display, monitor, printer, touch-screen, software window on a screen including the software that generates it.

(4) **Abbreviations and symbols**

AC	alternating current
AM	amplitude modulation
ASD	acceleration spectral density
DC	direct current
EBA	evidential breath alcohol analyser
EM	electromagnetic
e.m.f.	electromotive force
ESD	electrostatic discharge
EUT	equipment under test
f_{nom}	nominal supply frequency
IEC	International Electrotechnical Committee
MPE	maximum permissible error
RF	radio frequency
RH	relative humidity
RMS	root mean square
T_{amb}-low	low ambient temperature
T_{amb}-high	high ambient temperature
TR	reference temperature
U_{nom}	nominal supply voltage
U_{bmin}	minimum battery supply voltage
U_{DC}	nominal DC voltage
β	ethanol mass concentration in the gaseous phase
γ	ethanol mass concentration in the liquid phase

The abbreviations for software validation procedures are explained in Para 6(3)(ii) of Part II of this specification.

3. Description of the Instrument

(1) Schematic description

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

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

- replaceable mouthpieces to hygienically conduct the breath sample into the EBA for analysis;
- a hose to convey the breath sample through the sampling system or a sampling probe to convey a sub-sample of the breath sample through the sampling system;
- a means to monitor the flowrate, time and volume;
- at least one sensor to measure the alcohol content of the breath sample;
- a data system to process the measurement signal, including an indicating device to display the results and messages;
- an interface to an external data connection;
- a control facility to initiate and check instrument operations; and
- an adjustment facility to set the instrument operating parameters within prescribed limits.

(2) Sampling and mouthpiece

A specimen of an end expiratory breath sample from a continuous and uninterrupted expiration shall be analysed for alcohol concentration. The breath sample shall not be influenced by breathing techniques.

The EBA shall be capable of being used under satisfactory hygienic conditions. This means the use of individually packaged, replaceable mouthpieces for each measurement shall be indispensable.

The mouthpiece shall comply with the requirements of Para2(1)(ix) of Part II

(3) Analysis

The EBA determines the alcohol concentration of the breath sample of end expiratory breath. Influences during the analysis caused by sampling and/or ambient conditions shall be avoided.

(4) Presentation and storage of the result

On a typical EBA, the measurement results will be presented on a display and secured for later access. This could be achieved by either printing or storing the result in the instrument memory, depending on the model as well as the requirements.

(5) **Measurement cycle**

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

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

a complete measurement cycle may consist of one or more breath samples.

4. Units of measurement and decimal sign

The EBA shall display and/or print measurement results in terms of mass concentration of alcohol in a specified volume of exhaled air.
At least in the metrological test mode, the EBA shall be able to indicate the mass concentration in milligram per litre of exhaled breath (mg/L).
The use of an equivalent unit of measurement is possible if the indication is in conformity with SI units.
The decimal marker on the display or printout shall be either a comma or a dot on the line.

Part II

1. Metrological Requirements

(1) **Measuring range**

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

(2) **Masking of low results**

A masking function may be required which indicates 0.00 mg/L for measured mass concentrations equal to or less than a given value.

This masking function shall be deactivated in the metrological test mode.

(3) **Scale interval**

For the indication of the result, the scale interval shall be 0.01 mg/L in the measuring mode.

A measured value with three decimal places shall be truncated to two decimal places (e.g. a measured value of 0.427 mg/L is truncated to 0.42 mg/L).

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

(4) **Multiple indicating devices**

All indications (displays, printout, stored data, transmitted data, etc.) of the measurement results shall show the same value.

(5) **Durability of the EBA**

The provisions in Para 1(6), 1(7), 1(8), 1(9), 1(10) and 1(11) of Part II shall be met durably. The EBA shall be designed to maintain stability of its metrological characteristics over a period of time which shall be at least as long as the verification period.

(6) **Maximum permissible errors (MPE)**

The following MPE shall apply within the rated operating conditions (specified in Para 1(10) of Part II).

(i) **Maximum permissible errors for type approval and initial verification**

The maximum permissible error (MPE), positive or negative, shall be:

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

If the upper limit of the measuring range is greater than 2.000 mg/L, the maximum permissible error shall be:

$\frac{\beta}{2}$ 0.9 mg/L for all mass concentrations of alcohol greater than 2.000 mg/L.

The MPE as specified in the present sub clause also apply to verification after repair or for mandatory periodic verification.

(ii) **Maximum permissible errors for re verification and for EBA in service**

The maximum permissible error (MPE), positive or negative, shall be:

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

If the upper limit of the measuring range is greater than 2.000 mg/L, the maximum permissible error shall be:

$\frac{\beta X3}{4}$ - 1.35 mg/L for all mass concentrations of alcohol greater than 2.000mg/L.

Table 1 - MPE for type approval, initial verification, re-verification and EBAs in service

Reference values for alcohol concentration β	MPE of Para 1(6)(i) of Part II	MPE of Para 1(6)(ii) of Part II	Comment

0.000 mg/L – 0.400 mg/L	0.020 mg/L	0.030 mg/L	
> 0.400 mg/L –2.000 mg/L	5 % of β	7.5 % of β	
> 2.000 mg/L	$\frac{\beta}{2}$ - 0.9 mg/L	$\frac{3X\beta}{4}$ –1.35 mg/L	Only applicable for enlarged measuring range

(iii) Fault limit

The fault limit shall be 0.020 mg/L.

(7) **Repeatability**

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

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

The experimental standard deviation shall be calculated with the formula given in Para 2(1)(xvii) of Part I.

(8) **Drift**

(i) Zero drift

Under reference conditions, the absolute value of zero drift shall not exceed 0.010 mg/L over a period of four hours.

(ii) Short-term drift

Under reference conditions, the absolute value of short-term drift determined at the measurement level of 0.40 mg/L shall not exceed 0.015 mg/L over a period of four hours

(iii) Long-term drift

Under reference conditions, the absolute value of long-term drift determined every two weeks at the measurement level of 0.40 mg/L shall not exceed 0.020 mg/L in six months, using the same EBA

(9) **Memory effects**

(i) Memory effect with large differences in mass concentration

Under reference conditions the memory effect shall not exceed ± 0.010 mg/L.

(ii) Memory effect with small differences in mass concentration

Under reference conditions the memory effect shall not exceed ± 0.010 mg/L

(iii) Effect of water vapor (condensation)

EBAs shall be designed and manufactured such that their errors do not exceed the MPE specified in Para 1(6)(i) of Part II when repeatedly tested with wet test gas at the respective low ambient temperature condition as specified in Para 1(10) (i)of Part II.

(10) **Operating Conditions**

(i) Physical influence factors

EBAs shall be designed and manufactured such that their errors do not exceed the MPE specified in Para 1(6)(i) of Part II under the following rated operating conditions:

Table 2 - Minimum rated operating conditions

a	Ambient temperature	Low ($T_{amb\text{-}low}$)	0 °C for stationary EBAs –5 °C for transportable EBAs –10 °C for portable EBAs
		High ($T_{amb\text{-}high}$)	40 °C for stationary EBAs 45 °C for transportable EBAs 45 °C for portable EBAs
b	Ambient relative humidity	Up to 85 % at $T_{amb\text{-}high}$	
c	Atmospheric pressure	860 hPa – 1060 hPa .	
d	Random vibration	Stationary unit not expected to be subjected to vibration during routine use, therefore treated as a disturbance (see Table 4, clause e) For transportable and portable EBAs: 10 Hz – 150 Hz, 7 m s^{-2}, 1 m^2 s^{-3}, –3 dB/octave	
e	DC mains voltage	As specified by the manufacturer	
f	AC mains voltage	U_{nom} – 15 % to U_{nom} + 10 %	
g	AC mains frequency	f_{nom} – 2 % to f_{nom} + 2 %	
h	Voltage of internal battery	All voltages between a new or freshly charged battery, down to the lowest voltage at which the instrument functions according to the specifications given by the manufacturer	
i	Voltage of a road vehicle battery	12 V battery	9 V – 16 V
		24 V battery	16 V – 32 V

j	Mole fraction of hydrocarbons (as methane equivalent[(1)]) in the environment	0 µmol/mol to 5 µmol/mol
k	Mole concentration of carbon dioxide in the exhaled air	Up to 80 mmol/mol

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

[(1)] Methane equivalent: The content of hydrocarbons shall be expressed in ppm_{vol} methane (CH4) equivalent. For the actual test, other hydrocarbons can be used and the necessary concentration of that hydrocarbon can be recalculated by dividing 5 ppm by the number of carbon atoms in the molecule. Methane equivalent is a value at the minimum rated operating conditions. In practice, various compositions of volatile hydrocarbons can appear in the environment.

(ii) Conditions of exhalation

For a representative measurement, certain conditions of exhalation (e.g. continuity and flow) have to be fulfilled.

The EBA shall provide an error message if one or more of the following conditions are not fulfilled. The conditions, specified by the manufacturer, shall comply with the following values:

exhaled volume: greater than or equal to 1.2 L;
flowrate: greater than or equal to 0.1 L/s;
exhalation time: greater than or equal to 3 s.

(11) **Disturbances and physiological influence substances**

(i) Disturbances

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

- Either significant faults do not occur, or
- significant faults are detected and acted upon by means of a checking facility.

These provisions may be applied separately to
- each individual cause of disturbance, and/or
- each part of the measuring instrument.

The choice of which provision will be applied is left to the manufacturer.

Table 3 specifies disturbing phenomena and their maximum level to which the EBA shall be immune while being exposed during its operation. "Immunity" shall be interpreted such that no significant fault will occur unless this fault is detected and acted upon.

Table 3 - Disturbances to which EBAs shall be immune during exposure and while in operation

a	Radiofrequency (RF), electromagnetic fields	In the frequency range from 0.15 MHz to 6000 MHz (1) Field strength 10 V/m; 80 % AM sinusoidal modulated			
b	Electrostatic discharges	Up to 6 kV contact discharge or 8 kV air discharge			
c	Bursts on AC or DC mains supply(1) lines	Amplitude 1 kV Repetition rate 5 kHz			
d	Surges on AC or DC mains supply(1) lines	AC or DC mains	Line to line	Line to ground	
			1 kV	2 kV	
e	Bursts on signal, data and control lines	Amplitude 1 kV Repetition rate 5 kHz			
f	Ripple on DC mains(1) electrical power port	Ripple	Sinusoidal harmonics		
		Harmonic frequency	2, 3 or 6 times rectified origin frequency		
		Amplitude (U_{peak}-peak/U_{DC})	2 %		
g	Mains supply (1) voltage dips and short inter- ruptions and short variations	DC		Amplitude of the rated voltage	Duration
			Voltage dips	40 % 70 %	0.01 s and 1 s
			Short interruptions	0 %	0.001 s and 1 s
			Voltage variations	85 % 120 %	0.1 s and 10 s
		AC		Amplitude of the rated voltage	Duration
			Voltage dips	0 % 70 %	0.5 and 1 cycle 25 cycles
			Short interruptions	0 %	250 cycles
h	Surges on signal, data and control lines		Line to line	Line to ground	Shield to ground
		Unsymmetrical lines	1 kV	2 kV	
		Symmetrical lines		2 kV	
		Shielded I/O lines			2 kV

i	Electrical transient conduction along supply lines from the on-board battery of a vehicle	Battery voltage supply	U_{nom} = 12 V	U_{nom} = 24 V
		Pulse 2a	112 V	112 V
		Pulse 2b	10 V	+20 V
		Pulse 3a	–220 V	–300 V
		Pulse 3b	150 V	300 V
j	Electrical transient conduction via lines other than supply lines	Battery voltage supply	U_{nom} = 12 V	U_{nom} = 24 V
		Pulse a	–60 V	–80 V
		Pulse b	40 V	80 V

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

Table 4 specifies disturbance phenomena and their maximum level to which the EBA shall be exposed. Testing for immunity shall occur after exposure.

"Immune" shall be interpreted such that no significant fault will occur unless this fault is detected and acted upon.

Table 4 - Disturbances to which EBAs shall be immune after exposure

a	Mechanical shocks		Stationary EBAs	Transportable EBAs	Portable EBAs
		Height of fall	25 mm	50 mm	1 m
		Number of falls (on each bottom edge)	1	1	6
b	Shakes	10 g, 6 ms, 2 Hz, in 3 axes, 1000 shakes for each axis			
c			Stationary EBAs	Transportable EBAs	Portable EBAs
		Temperature		55 °C	55 °C

	Damp heat, cyclic (condensing)	Duration	Not applicable	2 cycles	4 cycles
d	Storage temperature	–25 °C, 6 hours +70 °C, 6 hours			
e	Vibration	For stationary EBAs: 10 Hz – 150 Hz, 1.6 m s^{-2}, 0.05 m^2 s^{-3}, –3 dB/octave			

(ii) Physiological influence substances

EBAs shall be designed and manufactured such that when they are exposed to the physiological influence substances indicated below (quantities are given in Para 6(5)(ix) of Part II, the sensitivity is limited to the values given in the table)

Table 5 - physiological influence substances

Interfering substance	**Sensitivity** (Change (±) of indication in mg/L per vapour mass concentration applied in mg/L)
Acetone	0.2
Methanol	1
Isopropanol	1
Carbon monoxide	0.5

Note: Director (Legal Metrology) may decide additional substances to be tested.

(iii) Optional disturbances expected in specific environmental conditions

For EBAs to be used in specific environmental conditions which are not completely covered by the environmental conditions as specified in Para 1(10) or 1(11) of Part II as additional performance criteria concerning the specific conditions.

The specific environmental conditions may include:

- sandy or dusty environmental conditions similar to the conditions in dusty warehouses, production of concrete and dusty outdoor regions;
- salt misty environmental conditions similar to those on board sea-going vessels;
- water and moist outdoor conditions including light or heavy rain or occasional splashes of water similar to those on board smaller boats; applicable for portable EBAs typically used in these outdoor conditions.

For EBAs expected to typically become exposed to these general more severe circumstances, measures shall have been taken to protect the EBA against becoming influenced or disturbed and to prevent any degradation of performance of the EBA.

EBAs that are claimed to be able to operate as required under these more severe conditions shall be marked as such.

In this case, the EBAs shall be designed and manufactured such that after exposure to one of the disturbances indicated above,

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

Table 6 specifies optional disturbing phenomena and their maximum level which the EBA shall be able to withstand.

Table 6 optional disturbance expected in specific environmental conditions

(As per IS/ISO/ International Standards)

<table>
<tr><td>a</td><td>Sand and dust</td><td colspan="2">Cyclic temperature variation between 30 °C and 65 °C, maintaining thefollowing conditions:
• Relative humidity:
less than 25 %
• Air velocity: 3 m/s
• Particle concentration: 5 g/m^3
• Composition of the particles</td></tr>
<tr><td>b</td><td>Salt mist</td><td colspan="2">Temperature of environment and salt solution: 35 °CMass fraction of NaCl of the salt solution: (5 ± 1) % Relative humidity of the test atmosphere: > 85 %
Salt solution to be nebulised in such an amount that it will condense with arate of (1 to 2) mL/ hour per surface of 80 cm^2</td></tr>
<tr><td rowspan="2">c</td><td rowspan="2">Water</td><td>Test level index</td><td>2</td></tr>
<tr><td>Test condition</td><td>According to the protection class</td></tr>
</table>

2. Technical Requirements

The technical requirements for EBAs are divided into two sections:
2(1) covers the basic technical requirements; and
2(2) covers optional technical requirements.

The basic requirements cover the prerequisites that all EBAs have to fulfil.

The optional requirements will only apply when an EBA is equipped with these extra functions or functionalities (e.g. a printer).

(1) Basic technical requirements

(i) Presentation of the measurement result

(a) Indicating device

Results either displayed or printed shall be reliable, easy to read and unambiguous under normal conditions of use.

All indications (displays, printout, stored data, transmitted data, etc.) of one measurement result shall show the same value.

On displays, the result of the measurement shall be presented in digital format by means of aligned figures. The height of the figures on the display shall be equal or greater than:

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

The unit of measurement or its symbol shall appear in close proximity to the result, with characters at least 3mm high.

The characters shall be easily readable in all ambient light conditions.

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

It shall not be possible to confuse a zero indication prior to the subject sample measurement, and a subject result.

(b) Availability of measurement results

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

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

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

(c) Presentations when in metrological test mode

When the EBA is in metrological test mode, the indications and printed information during this mode shall be clearly and unambiguously distinguishable from those during the measuring mode.

(ii) Protection against fraud

An EBA shall have no characteristics likely to facilitate its fraudulent use, either by accidental or by deliberate means when using the instrument in the normal manner. The possibilities for

unintentional misuse shall be considered in the construction (hardware and software) to reduce them to a minimum. In particular, the following aspects shall be taken into account:

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

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

(iii) Checking operations

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

The EBA shall check correct operation automatically before and after each measurement.

(iv) Warm-up time

Under reference conditions (Para 6(4)(i) of Part II), the EBAs used in different use-cases shall be capable of attaining the measuring mode after being switched on in a time not greater than the warm-up times given in Table 7:

Table 7 - Warm-up times for different use-cases

Reference to definition	Description of evidential breath alcohol analyser	Maximum warm-up time
Para2(2)(ii) of Part I	Use-case 1: stationary EBA	15 min
Para2(2)(iii) of Part I	Use-case 2: transportable EBA	15 min
Para2(2)(iv) of Part I	Use-case 3: portable EBA	5 min

EBAs equipped with a standby mode shall be capable of returning to a measuring mode in 5 min from the standby mode.

(v) Availability for measurement

From the moment the EBA indicates that it is ready to receive an exhalation, it shall be available for at least 1 min.

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

(vi) Power supply duration of internal batteries

If a portable EBA is powered only by internal rechargeable or non-rechargeable batteries, it shall be able to perform at least 50 individual measurements at reference conditions followed by 20 individual measurements at –10 °C without requiring recharge or exchange of the batteries when used within the rated operating conditions.

(vii) Continuity of the exhalation

The EBA shall monitor the continuity of exhalation and shall give an indication if the flow of exhaled air is interrupted between the beginning of the forced exhalation and the end of the sampling. An audible or visual signal shall be given to indicate the continuity of the exhalation.

The exhalation shall be considered interrupted if the flow falls below the minimum value specified in Para 1(10)(ii) of Part II.

(viii) Alcohol in the upper respiratory tract

The EBA shall be equipped with a function which automatically detects whether the measurement result is affected by the presence of alcohol in the upper respiratory tract (also called residual mouth alcohol).

The technical documentation shall clearly describe which method is applied in the respective EBA.

Examples of possible solutions are given in Part II, Annex B, and the basic requirements for a corresponding test performance are described in Para 6(5)(vi)(b) of Part II

(ix) Mouthpieces

The EBA shall be equipped with mouthpieces for sampling. In particular, the following requirements apply for mouthpieces:

- the use of a mouthpiece for sampling shall be mandatory (clear instructions on how to insert and use the mouthpiece shall be given in the manual);
- it shall be possible to replace the mouthpiece easily;
- it shall not be possible to inhale air from previous usages (air from the sampling system) of the EBA;
- the back pressure of the EBA shall not exceed 25 hPa at a flowrate of 0.2 L/s, when measured at the inlet of the mouthpiece with the mouthpiece connected to the EBA;
- the mouthpiece shall prevent droplets and particles from entering the sampling system of the EBA.

(x) Software

The whole software of the EBA should be considered as legally relevant.

However, if the software of the EBA is separated into parts, each part shall separately conform to these requirements

(a) Software identification

The software of the EBA shall be unambiguously identified with its version number and by the result of a hash function or by a checksum.

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

The software identification and all its parts shall be stated in the model approval certificate/certificate of conformity.

(b) Correctness of algorithms and functions

The measurement result and any accompanying information shall be displayed, recorded and/or printed correctly.

The measuring algorithms and operations of an EBA shall be functionally correct. It shall be possible to examine the algorithms and functions by means of an appropriate validation method (i.e. metrological tests, software tests or software examination)

(c) Protection of the software against fraud

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

(ca) the software shall be secured against unauthorised modification, loading, or changes by swapping the memory device. In addition to mechanical sealing, technical means may be necessary to secure EBAs having an operating system or an option to load software. Software protection comprises appropriate sealing by mechanical, electronic and/or cryptographic means, making an unauthorised intervention impossible or evident;

(cb) only clearly documented functions are allowed to be activated through the user interface, which shall be realised in such a way that it does not facilitate fraudulent use. For the type approval procedure, the manufacturer of the measuring instrument shall declare and document all program functions that can be activated through the user interface. The manufacturer shall state the completeness of the documentation of these functions. No hidden functions shall exist;

(cc) parameters that fix the legally relevant characteristics of the EBA shall be protected against modification. If necessary for the purpose of verification, displaying or printing of the current parameter settings shall be possible.

(d) Detection of significant defects

For significant defect detection, checking facilities shall be implemented into the EBA.

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

(e) Interfaces

If the EBA is equipped with interfaces, the following requirements shall be fulfilled:

(ea) the functions, parameters and measurement results shall not be inadmissibly influenced by commands received via an interface;

(eb) there shall be an unambiguous assignment of each command to all initiated functions or data changes in the software;

(ec) only allowed and documented commands are permitted to activate functions through the interfaces

(f) Maintenance and verification of EBA software

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

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

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

(g) Software documentation

In addition to the general documentation required in Para 6(2) of Part II the manufacturer shall submit the following documentation:

(ga) Description of the software and how the requirements are met, with

(gaa) list of software modules that perform legally relevant functions;

(gab) description of the software interfaces that perform legally relevant functions and of the commands and data flows via this interface;

(gac)if a raised risk level (Level B) is required, the source code shall be made available to the laboratory;

(gad) list of parameters to be protected and description of the protection means;

(gb) Description of the system configuration and minimal required resources;

(gc) Description of the security means of the operating system (password, etc. if applicable);

(gd) Description of the (software) sealing method(s);

(ge) Overview of the system hardware, e.g. topology block diagram, type of computer (s), type of network etc. Where a hardware component is deemed legally relevant or where it performs legally relevant functions, this should also be identified;

(gf) Description of the accuracy of the algorithms (e.g. filtering of A/D conversion results, calculation of the result, rounding algorithms, etc.);

(gg) Description of the user interface, menus and dialogues. Commands that communicate through the interfaces shall be documented;

(gh) Description of the software identification including the description of all encryption means (if any), and instructions for obtaining the identification from an instrument in use;

(gi) List of commands of each hardware interface of the EBA;

(gj) List of durability errors that are detected by the software and, if necessary for understanding, a description of the detecting algorithms;

(gk) Description of the datasets stored or transmitted (if applicable);

(gl) If fault detection is realised in the software, a list of faults that are detected and a description of the detecting algorithm;

(gm) If an audit trail is realised in the software, a description on how to access the audit trail.

(2) **Optional Technical Requirements**

The EBA may be fitted with one or more of the following options. These options could be either prescribed or they could be a feature of the construction chosen by the manufacturer.

(i) Durable recording of measurement results

(a) Printing device

The EBA may be fitted with a printing device (internal or external). If this device is considered as legally relevant, the requirements below apply:

(aa) The minimum height for the figures on the printout shall be 2 mm;

(ab) The printout shall at least contain the following information:

(aba) instrument reference;

(abb) date and time of measurement

(abc) measurement results and their units

(abd) identification on the printout of the person subjected to test

(ac) The printed scale interval shall comply with the requirements defined in Para1(3) of Part II "Scale interval".

(ad) The printing device shall be fitted with checking facilities which enable significant defects to be detected and acted upon. "Act upon" means that a warning shall be given or that the instrument shall not provide any printout of the measurement result. At least, the following shall be checked:

(ada) presence of paper and ink (if applicable);

(adb) the status of the printer and its readiness for operation;

(ae) When the internal printing device is exposed to the disturbances of Para 1(11) of Part II, either significant faults do not occur, or significant faults are detected and acted upon by means of a checking facility;

(af) The data transmission to external printing devices considered as legally relevant shall comply with the requirements of Para 2(2)(i)(b) of Part II "Storage and transmission of data".

(b) Storage and transmission of data

The EBA may store measurement data for further legally relevant applications or transmit measurement data before they are used for legal purposes. In such cases, the requirements defined below apply:

(ba) The measurement result stored or transmitted shall be accompanied by all the relevant information that is necessary for future legally relevant use.

(bb) Measurement data must be stored or transmitted automatically when the measurement is completed. When the final measurement result derives from a calculation, the individual measurement results that are necessary for the calculation must be automatically stored or transmitted with the final result.

(bc) The EBA shall have sufficient permanency to store the data until it is no longer legally required. Storage capacity shall be at least 1000 measurements. It is permitted to delete stored data, but this shall not be possible in normal use. Data may be deleted in one of the following ways:

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

Note: Other regulators may contain strict limitations for the deletion of stored measurement data, which shall be applicable.

(bd) The stored or transmitted data shall be protected by hardware/ software means to guarantee the authenticity and integrity of data and, if necessary, also to guarantee the correct information about the time of measurement.

Note: The authenticity and integrity of data can be protected e.g. by generating an electronic signature for each data set

(be) The software that displays or further processes these data shall check the time of measurement, authenticity and integrity of the data. If an irregularity is detected, the data shall be marked as unusable.

(bf) If data is transmitted from the EBA (secure environment) to an external environment, the risk level for the transmission and storage of data may be required. Raised risk levels might require the application of cryptographic methods.

Note: It is appropriate to require a raised risk level when considering an open network.

(bg) The software that displays or further processes the transmitted data for legal purposes shall be secured and shall check the authenticity and integrity of the data.

(bh) The measurement shall not be inadmissibly influenced by a transmission. If in this situation the loss of measurement data can only be avoided by stopping the measurement process, this information shall be easily accessible for the user (e.g. in the manual, or marked on the instrument) and the EBA shall give an appropriate error message

(ii) Redundancy

Director (Legal Metrology) may

- define a measurement cycle with more than one breath sample, or
- demand redundant measuring sensors within an EBA.

In such cases, the requirements defined in the following sub clauses will apply accordingly.

(a) Configuration of the measuring instrument

Director (Legal Metrology) may require

- two independent measuring systems, or
- two or more measurements for a standard measurement cycle, either consisting of repeated breath samples or a check with a test gas as part of the measurement cycle.

In these cases, the measuring instrument may be configured with the following options:

(aa) The EBA may be equipped with two independent measuring systems for ethanol concentration. Depending on the prescribed measurement cycle, they can either be used for measurements of the same breath sample or in combination with a two-measurements cycle.

Each measuring system shall comply with the requirements concerning precision and accuracy. Any disturbance of one measuring system shall not have any effect on the other measuring system larger than the MPE.

(ab) The EBA may require the use of a certified reference gas to verify the good operation of the analytical system within a short period of time.

(ac) The EBA may be configured with a measurement cycle requiring more than one separate breath sample, e.g. a two-measurement cycle.

Note: General information about a two-measurement cycle with separate breath samples can be found in Annex B Part II.

(b) Measurement results

The results generated shall comply with the following requirements:

(ba) As configuration with two independent measuring systems:

(baa) Each measuring system shall fulfill the requirements of Para 1(6)(i) of Part II for MPE independently.

(bab) When applied within a two-measurement cycle with two independent breath samples: the difference between the interim result of the first breath sample and the interim result of the second breath sample shall be smaller than twice the MPE of Para 1(6)(i) of Part II for the lower of both the interim results.

(bb) As configuration with a measurement with certified reference gas:

The difference of the measured result of the reference sample compared to the certified concentration value of the reference gas shall be smaller than the MPE of the device for the certified concentration value of the reference gas.

(bc) As configuration with multiple breath samples for a measurement cycle:

(bca) The EBA shall compare the parameters and results of each breath sample of the measurement cycle. Director (Legal Metrology) shall define the limits for the allowed variation between the breath samples regarding concentration, volume and exhalation time(1)

(bcb) the number of breath samples to be measured and how the final result is determined out of the measurement result for each breath sample shall be as prescribed

(bcc) shall prescribe which details of the multiple measurements shall be given on the printout.

(bcd) If these multiple breath samples are also used for the detection of alcohol in the upper respiratory tracts, either the requirements of Para 2(1) of Annex B or, Para 2(3) of Annex B of Part II shall apply.

(1) When defining the limits of variation between consecutive breath samples, the natural variation of the breath sample from a person shall be taken into account. Differences in alcohol concentration greater than a specified limit might be interpreted as an indicator of invalid measuring conditions. Differences in exhalation time and/or volume greater than a specified limit might be taken as an indicator that the measuring conditions are not comparable.

(2) Different approaches exist to calculate the final result of a measurement cycle. This might be the lowest measured value, the mean value, or another method.

3. Operating Instructions

(1) Instruction manual

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

The instruction manual shall be in the official language(s) and easily understandable. It shall include:

i. operating instructions, including instructions for the mouthpiece (e.g. hygienic aspects of use);

ii. maximum and minimum storage temperatures;

iii. rated operating conditions;

iv. warm-up time after switching on the electrical power;

v. all other relevant mechanical and electromagnetic environmental conditions;

vi. mechanical and electromechanical environment classes; and

vii. safety and security conditions

(2) **Additional instructions**

The EBA shall conform to the relevant acts and national or international standards for electrical safety and, where appropriate, for compressed gases. Verification of compliance with these regulations and standards is not within the scope of this Specification.

Manufacturers may stipulate in their operating procedures that the person subjected to the test shall not introduce anything in their mouth for at least 15 minutes prior to the collection of a breath sample.

4. Inscriptions and Sealing

(1) **Inscriptions**

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

(i) mandatory on the label in all cases:

- manufacturer's trademark/corporate name;
- type designation/model number;
- type/ model approval mark;
- serial number of the instrument;
- year of manufacture;
- details of the electrical power:
  - in the case of mains power: the nominal mains voltage, frequency and power required;
  - in the case of power by a road vehicle battery: the nominal battery voltage and power required;
  - in the case of an internal removable battery: the type and nominal voltage of the battery;

(ii) mandatory either on the tamper-evident label, or in the instruction manual if the size of the EBA is not sufficient:

- measuring range;
- ambient temperature range.

Software identification shall be displayed on demand through the indicating device

(2) **Sealing**

Effective sealing devices shall be provided by the manufacturer on all parts of the EBA that are not materially protected in another way against operations liable to affect its accuracy or integrity. This applies in particular to:

(i) adjustment means;

(ii) replacement of specific parts, if this replacement is expected to change the metrological characteristics;

(iii) software integrity.

5. Metrological Controls

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

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.

6. Pattern evaluation

(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 Para 6(2) to Para 6(5) of Part II and if applicable, the tests specified in Para 6(6) of Part II.

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 and influence tests shall be performed on the same instrument, but disturbance tests 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) **Documentation**

The documentation submitted with the application for type approval shall include

i. a description of its general principle of measurement,
ii. a list of the essential subassemblies, components with their essential characteristics,
iii. mechanical drawings,
iv. electric/electronic diagrams,

v. installation requirements,
vi. security sealing plan,
vii. panel layout,
viii. test outputs, their use, and their relationships to the parameters being measured,
ix. operating instructions that shall be provided to the user,
x. documents or other evidence that support the assumption that the design and characteristics of the measuring instrument comply with the requirements of this Specification,
xi. a print sample, if applicable.

If the EBA is equipped with a printing device, the manufacturer shall provide information about the quality ofthe 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 tostudy the quality of the instrument, or to be able to document in sufficient detail the approved type, or both.

(3) **Examination and tests**

Examination and testing of instruments are intended to verify their compliance with the requirements of Para1 to 4 of Part I and Para 1 to 4 of Part II of this specification.

The examination and tests shall cover all the applicable requirements of Para 3 &4 of Part I and Para 1 to 4 of Part II of this specification.

(i) 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;
b) measuring ranges;
c) scale intervals;
d) presentation of the result;
e) protection against fraud;
f) checking operations;
g) Software;
h) inscriptions and sealing;
i) operating instructions;
j) suitability for testing; and if applicable:
k) printing device;
l) storage of measurement results;
m) Transmission of data.

(ii) Software validation

The validation procedure of the software related functionalities of EBAs is given in Table 1. Director (Legal Metrology) if require may decide 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 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

(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	

VFTM	Validation by functional testing of metrological functions	Correctness of the algorithms, uncertainty, compensating and correcting algorithms	A (normal level)(1)
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) (1)
SMT	Software module testing	All purposes when input and output can clearly be defined	

(1)(For detailed information about validation procedures and examination levels IS/ International / OIML D 31 Standards, revised time to time, may be referred.

(iii) Operational tests

The instrument shall be submitted to the performance tests specified in Para 6(5) of Part II to determine its correct functioning under various conditions and influence factors.

(4) Test conditions and test gas generator

(i) 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 volume fraction (as methane equivalent)	
AC mains voltage and	Nominal values specified in	Within the nominal values specified

frequency (if appropriate)	Para 1(10)(i) of Part II , Table 2	in Para 1(10)(i) of Part II , Table 2

Note: Throughout this specification "reference conditions" refers to ambient conditions.

(ii) 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; (Para 4 of Annex A 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; (Para 4 of Annex A provides explanatory information)
- breath temperature of 34 °C;
- relative humidity of 95 %;
- volume fraction of CO_2: up to 50 mmol/mol.

(iii) 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.

(a) 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 ± 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 ± (2/3 MPE)
Gas temperature	34 °C ± 0.5 °C

Relative humidity of the gas	95 % ± 5 % (without condensation)
Carrier gas	Air containing insignificant concentrations of relevant impurities with a mole fraction of CO_2 of: (50 ± 5) mmol/mol

(b) 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 testprogram, 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 Para 6(4)(ii) of Part II.

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

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, wasused 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		
Mole 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 indicatedabove.

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 Para 6(4)(iii)(a) of Part II, but with flowrate and alcohol profiles described in Para 4(2) of Annex A. 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 CO_2 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 which 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		**Dry gases allowed**	**Gases without CO2 allowed**	**Remarks**
Para 6(5)(v)(a) of Part II	Maximum permissible errors and repeatability			
Para 6(5)(v)(b) of Part II	Drift			The humidity in breath might also cause a drift. Therefore, it is essential to use only wet test gases here
Para 6(5)(v)(c) of Part II	Memory effects			
Para 6(5)(v)(d) of Part II	Effect of water vapour (condensation)		X	
Para 6(5)(vi)(a) of Part II	Variations of the test gas parameters	X	X	Dry gases are allowed provided that the parameters of the test gas (flow, alcohol concentration profiles) can be modified accordingly
Para 6(5)(vi)(b) of Part II	Alcohol in the upper respiratory tract		X	
Para6(5)(vii)(a) of Part II	Temperature test (dry heat and cold)		X	
Para 6(5)(vii)(b) of Part II	Damp heat, steady state (non-condensing)		X	

Para 6(5)(vii)(c) of Part II	Static atmospheric pressure	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 Para 6(4)(iii)(a) of Part II
Para 6(5)(vii)(d) of Part II	Random vibration	X	X	
Para 6(5)(vii)(e) of Part II	DC mains voltage variations	X	X	
Para 6(5)(vii)(f) of Part II	AC mains voltage variations	X	X	
Para 6(5)(vii)(g) of Part II	AC mains frequency variations	X	X	
Para 6(5)(vii)(h) of Part II	Low voltage of internal battery	X	X	
Para 6(5)(vii)(i) of Part II	Power supply duration test	X	X	
Para 6(5)(vii)(j) of Part II	Voltage variations of a road vehicle battery	X	X	
Para 6(5)(vii)(k) of Part II	Hydrocarbons in the environment	X	X	
Para 6(5)(vii)(l) of Part II	Raised fraction of CO_2 in the test gas	X		
Para 6(5)(viii)(a) of Part II	Conducted (common mode) currents generated 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 Para 6(4)(iii)(a) of Part II
Para 6(5)(viii)(b) of Part II	Radiated RF electromagnetic fields	X	X	
Para 6(5)(viii)(c) of Part II	Electrostatic discharges	X	X	
Para 6(5)(viii)(d) of Part II	Bursts (transients) on AC and DC mains	X	X	
Para 6(5)(viii)(e) of Part II	Surges on AC and DC mains power lines	X	X	
Para 6(5)(viii)(f) of Part II	Bursts on signal, data and control lines	X	X	
Para 6(5)(viii)(g) of Part II	Ripple on DC mains power	X	X	
Para 6(5)(viii)(h) of Part II	DC mains voltage dips, short interruptions and (short term) variations	X	X	
Para	AC mains voltage dips, short	X	X	

6(5)(viii)(i) of Part II	interruptions and voltage variations			
Para 6(5)(viii)(j) of Part II	Surges on signal, data and control lines	X	X	
Para 6(5)(viii)(k) of Part II	Electrical transient conduction along supply lines	X	X	
Para 6(5)(viii)(l) of Part II	Electrical transient conduction via lines other than supply lines	X	X	
Para 6(5)(viii)(m) of Part II	Mechanical shock	X	X	
Para 6(5)(viii)(n) of Part II	Shakes	X	X	
Para 6(5)(viii)(o) of Part II	Damp heat cyclic (condensing)		X	
Para 6(5)(viii)(p) of Part II	Storage test		X	
Para 6(5)(viii)(q) of Part II	Vibration (as disturbance)	X	X	
Para 6(5)(ix) of Part II	Physiological influence substances	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 Para 6(4)(iii)(a) of Part II
Para 6(6)(i) of Part II	Sand and dust		X	
Para 6(6)(ii) of Part II	Salt mist		X	
Para 6(6)(iii) of Part II	Water		X	

Some of the tests defined in Para 6(5)(vi) of Part II 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 Para 6(5)(vi)(a) of Part II. For all other tests, the flowrate and alcohol concentration may be constant during injection.

(c) Guidelines for the use of compressed dry gases

When compressed gases are used within the context of this Specification, 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 ofthe uncertainties of the measurement.

d) The main component of the gas shall be dry air. If other gas, e.g. N_2, 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.

(5) **Performance tests**

(i) **General instructions**

The tests specified in Part II of this specification are designed to prove compliance of the instrument with the requirements specified in Para 1 to 4 of Part I and Para 1 to 4 of Part II. For special situations, additional performance criteria and their associated tests may be required in order to prove compliance.

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

before starting the process of type evaluation 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.

(ii) **Preconditions for the tests**

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

(a) normal electric power supplied and "on" for a time period equal to or greater than the warm-uptime of the EUT;

(b) power supply for the duration of the test:

(ba) 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;

(bb) 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.

(c) the EUT shall not be readjusted at any time during the test;

(d) the EUT shall be used in metrological test mode;

(e) the EUT shall perform standard measurement cycles. The use of special or shorted test cycles is only allowed if specified at the respective test;

(f) if the EUT is equipped with an internal printer, its correct function and correct printout shall be tested with each test of Para 6(5)(vii) to Para 6(6)(iii) of Part II of this specification

(iii) **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.

(iv) **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.

(v) **Accuracy tests**

(a) **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 Para 1(6)(i) of Part II and Para 1(7) of Part II 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 Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(b) of Part II, Table 6. Ambient conditions: within reference conditions as defined Para 6(4)(i) of Part II.
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 Para 6(5)(iii) of Part II of this specification.
Acceptance criteria	All functions shall operate as designed. Each of the 20 measurement results for every test gas concentration shall comply with therequirements for the MPE specified in Para 1(6)(i) of Part II of this specification. Each set of measurements shall comply with repeatability defined in Para 1(7) of Part II of this specification.

(b) **Drift**

Table 8 - Drift

Test method	**Measurements with the same test gas after certain time intervals**
Applicability	Applicable to all EBAs.
Object of the test	Verification of compliance with the requirements for drift
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 Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(b) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II of this specification.
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 Para 6(5)(iii) of Part II of this specification
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 fulfill the requirements for drift (Para 1(8)(i) and 1(8)(ii) of Part-II). For the long-term drift: The difference between the mean measurement error of the start series and each mean measurement error of all intermediate series and the final series shall fulfill the requirements for long-term drift (Para 1(8)(iii) of Part-II).

(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.

(c) **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 (Para 1(9) of Part-II) 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	The tests comprise of: • An initial test series with 10 subsequent measurements with the test gas with the lower concentrations to determine the mean start value. • Then the EUT is subjected to a series of measurements with alternating concentrations: o one measurement using the higher concentration, o followed immediately by one measurement using the lower gas concentration. This alternating test sequence shall be repeated 10 times. For large differences in mass concentration: 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	Ethanol concentrations: Case 1: large differences: high gas concentration: 1.50 mg/L (test gas no. 7) or 1.90 mg/L (test gas no. 8) low gas concentration: 0.10 mg/L (test gas no. 2) Case 2: small differences: high gas concentration: 0.40 mg/L (test gas no. 4) low gas concentration: 0.25 mg/L (test gas no. 3) Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II of this specification.
EUT performance	Number of alternating test sequences: 10. Time schedule: consecutively at each test condition Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II of this specification.
Acceptance criteria	Each individual measurement shall comply with the MPE as defined in Para 1(6)(i) of Part II. 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 (Para 1(9) of Part II).

(d) **Effect of water vapour (condensation)**

Table 10 - Effect of water vapour (condensation)

<table>
<tr><th>Test method</th><th>Measurement of different mass concentrations of ethanol in succession under specific temperature conditions</th></tr>
<tr><td>Applicability</td><td>Applicable to all EBAs.</td></tr>
<tr><td>Object of the test</td><td>Verification of compliance with the requirements for memory effects - effect of water vapour (Para 1(9)(iii) of Part II).</td></tr>
<tr><td>Condition of the EUT</td><td>Power is to be "on" for the duration of the test.</td></tr>
<tr><td>Test procedure in brief</td><td>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</td></tr>
<tr><td>Measurement conditions</td><td>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 gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(a) of Part II, Table 6.
Ambient conditions:
<table>
<tr><th>Use-case</th><th>Temperature</th><th>Relative humidity</th></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 Para 6(4)(i) of Part II</td></tr>
<tr><td>EUT performance</td><td>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 Para 6(5)(iii) of Part II</td></tr>
<tr><td>Acceptance criteria</td><td>Each individual measurement shall comply with the MPE as defined in Para 1(6)(i) of Part II.</td></tr>
</table>

(vi) **Influence factors of the conditions of injection**

(a) **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

		(tmin) < 5 s [1]
Object of the test		Verification of compliance with the analysis of end expiry breath [Para 3(3) of Part-I] and the requirements for conditions of exhalation [Para 1(10)(ii) and 2(1)(vii) of Part-II] 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: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(b) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
Influence	a) Influence of delivered volume and duration of injection	**Test gas generator:** type 1 or type 2 Variation of the flowrate as a function of time: no variation. Variation of the alcohol concentration as a function of time: - no variation (type 1 test gas generator); or - plateau duration equal to 3 s (type 2 test gas generator). **First test:** Delivered volume: 1.5 L ± 0.1 L Duration of the injection: 5 s ± 0.5 s **Second test:** 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 Variation of the flowrate as a function of time: no variation. **First test:** 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:** Delivered volume: 3.0 L ± 0.2 L Duration of the injection: 15 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 6 s (type 2 test gas generator).

		Third test: 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: - no variation (type 1 test gas generator); or - plateau duration equal to 3.5 s (type 2 test gas generator).
Test method		**Variations of the test gas parameters**
	c) Influence of flowrate during exhalation	**Test gas generator:** type 1 or type 2 Variation of the alcohol concentration as a function of time: - no variation (type 1 test gas generator); or - the same plateau duration in both tests (type 2 test gas generator). **First test**: Delivered volume: 3.0 L ± 0.2 L Flowrate: 0.6 L/s ± 0.08 L/s Variation of flowrate as a function of time: no variation. **Second test**: Delivered volume: 3.0 L ± 0.2 L Variation in the flowrate as a function of time: - Initial flowrate: 0.6 L/s during 1.5 s - between 1.5 s and 5 s the flowrate decreases to 0.2 L/s - after 5 s, the flowrate remains equal to 0.2 L/s until the end of the injection.
	d) Influence of duration of the plateau during injection	**Test gas generator:** type 2 Variation of the flowrate as a function of time: no variation. **First test:** Delivered volume: 3.0 L ± 0.2 L Duration of the injection: 5 s ± 0.5 s Duration of the plateau: 3 s **Second test:** Delivered volume: 3.0 L ± 0.2 L Duration of the injection: 5 s ± 0.5 s Duration of the plateau: 1.5 s
	e) Influence of an interruption in the breath flow	**Test gas generator:** type 1 or type 2 Variation of the alcohol concentration as a function of time: - no variation (type 1 test gas generator); or - plateau duration equal to 3 s (type 2 test gas generator). **First test**: **Abruption at the beginning of the exhalation** Delivered volume: 2.0 L ± 0.2 L Duration of the injection: 5 s ± 0.5 s Flowrate: 0.4 L/s ± 0.08 L/s Variation of the flowrate as a function of time: no variation. The injection shall be stopped 1 s ± 0.5 s after the start of the injection.

		Second test: verification of the minimum exhaled volume Flowrate: 0.2 L/s ± 0.02 L/s Duration of the injection: 15 s ± 0.5 s Variation of the flowrate as a function of time: no variation. The injection shall be stopped at 6 s ± 1 s after the start (delivered volume <1.2 L). **Third test: Verification of the detection of the end of exhalation** Flowrate: 0.15 L/s ± 0.02 L/s The injection of a gas shall be supplied at a flowrate of 0.15 L/s for 6 s ± 1 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. **Fourth test: Short flow interruption**. Flowrate 0.4 L/s ± 0.08 L/s The injection shall be interrupted after 1 to 2 s for a short period (e.g. 0.5 s), and then continued.
Test method		**Variations of the test gas parameters**
	f) Operation at the minimum exhaled volume and minimum exhalation time (t_{min})(1)	**Test gas generator:** type 1 or type 2 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 L/s ± 0.08 L/s Delivered volume: 1.2 L to 1.3 L **First test:** Duration of the injection: (t_{min} − 0.5 s) ± 0.4 s **Second test**: Duration of the injection: t_{min}(2)
EUT performance		Number of test sequences per test condition: at least 5. Time schedule: consecutively at each test condition. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II .
Acceptance criteria		All functions shall operate as designed. For test conditions a) to d): - Each measurement result shall comply with the MPE specified in Para 1(6)(i) of Part II. For test condition e) - The EBA shall not provide a measurement result. No significant fault shall occur. For test condition f): - First test: The EBA shall not accept a measurement with a duration of injection shorter than tmin. - Second test: Each measurement result shall comply with the MPE specified in Para1(6)(i) of Part II .

(1) t_{min} shall be 3 s as defined in Para 1(10)(ii) of Part II or a value between 3 s and 5 s according to the manufacturer and as per requirement specified by Director (Legal Metrology).

(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.

(b) **Alcohol in the upper respiratory tract**

Depending on which solution is prescribed 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. 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.

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 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 Para 6(5)(iii) of Part II.
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.

(vii) **Tests for operating conditions and physical influence factors**

(a) **Temperature test (dry heat and cold)**

Table 13 - Temperature test (dry heat and cold)

<table>
<tr><td>Test method</td><td colspan="4">Gradual exposure to high and low temperatures not allowing condensation to occur</td></tr>
<tr><td>Applicable Standards</td><td colspan="4">IS or International Standards</td></tr>
<tr><td>Applicability</td><td colspan="4">Applicable to all EBAs.</td></tr>
<tr><td>Object of the test</td><td colspan="4">Verification of compliance with the provisions in Para 1(6) (i) of Part II under conditions of high and
low temperature specified in Para1(10) of Part II Table 2, clause a.</td></tr>
<tr><td>Condition of the EUT</td><td colspan="4">Power is to be "on" for the duration of the test.</td></tr>
<tr><td>Test procedure in brief</td><td colspan="4">The test comprises gradual exposure of the EUT to high and low temperatures not allowing condensation to occur.
- Climatic condition: "free air" (= sufficient air circulation to maintain the temperature at a stable level)
- Change of temperature: ≤1^{0}C/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 Test sequence:
1) Reference temperature of T_R (1)
2) Specified high temperature T_{amb}-high
3) Specified low temperature T_{amb}-low
4) Reference temperature T_R(1)</td></tr>
<tr><td rowspan="7">Test levels</td><td></td><td></td><td>Temperature</td><td>relative humidity</td></tr>
<tr><td rowspan="3">Low ($T_{amb-low}$)</td><td>stationary EBA</td><td>0 °C</td><td>≤ 50 %</td></tr>
<tr><td>transportable EBA</td><td>–5 °C</td><td>≤ 50 %</td></tr>
<tr><td>portable EBA</td><td>–10 °C</td><td>≤ 50 %</td></tr>
<tr><td rowspan="3">High ($T_{amb-high}$)</td><td>stationary EBA</td><td>40 °C</td><td>≤ 30 %</td></tr>
<tr><td>transportable EBA</td><td>45 °C</td><td>≤ 30 %</td></tr>
<tr><td>portable EBA</td><td>45 °C</td><td>≤ 30 %</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: delivered volume: 1.5 L ± 0.1 L
duration of injection: 5 s ± 0.5 s
all other parameters as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(b) of Part II, Table 6.
Ambient conditions: temperature and humidity at the respective test level, all other parameters within reference conditions as defined in Para 6(4)(i) of Part II.</td></tr>
</table>

EUT performance	Number of measurements per temperature: 5. Time schedule: after stabilisation, towards the end of exposure time at each temperature Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II.
Acceptance criteria	All functions shall operate as designed. All errors shall be within the MPE specified in Para 1(6) (i) of Part II

(1) Default reference temperature: T_R = 20 °C

(b) **Damp heat, steady state (non-condensing)**

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

<table>
<tr><td>Test method</td><td colspan="4">Exposure to damp heat in steady-state</td></tr>
<tr><td>Applicable Standards</td><td colspan="4">IS or International Standards</td></tr>
<tr><td>Applicability</td><td colspan="4">Applicable to all EBAs, but not applicable to those stationary EBAs which are expected to be used only in a climate-controlled environment.</td></tr>
<tr><td>Object of the test</td><td colspan="4">Verification of compliance with the provisions for MPE in Para1(6)(i) of Part II under conditions of high humidity and constant temperature, specified in Para1(10) of Part II, Table 2, clause a “High”and clause b.</td></tr>
<tr><td>Condition of the EUT</td><td colspan="4">Power is to be “on” for the duration of the test.</td></tr>
<tr><td rowspan="5">Test procedure in brief</td><td colspan="4">The test comprises exposure of the EUT to the specified high level temperature and thespecified 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</td></tr>
<tr><td></td><td>Stationary EBAs</td><td>Transportable EBAs</td><td>Portable EBAs</td></tr>
<tr><td>Ambient temperature</td><td>40 °C</td><td>45 °C</td><td>45 °C</td></tr>
<tr><td>Relative humidity</td><td colspan="3">85 %</td></tr>
<tr><td>Duration</td><td colspan="3">2 periods of 24 hours after the EUT has reached temperature
stability.</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(b) of Part II, Table 6.
Ambient conditions: temperature and humidity at the respective test level, all other parameters within reference conditions as defined in Para 6(4)(iii)(a) of Part II.</td></tr>
</table>

EUT performance	Number of measurements and time schedule: • during exposure: 5 measurements every 24 hours at test conditions • after exposure: after a recovery period of one hour, 5 measurements at reference conditions. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II,
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 Para1(6)(i) of Part II

(c) **Static atmospheric pressure**

Table 15 - Static atmospheric pressure

Test method	**Exposure to low and high atmospheric pressure**	
Applicability	Applicable to all EBAs.	
Object of the test	Verification of compliance with the provisions for MPE in Para1(6)(i) of Part II under conditions of static atmospheric pressure changes to upper and lower limit specified in Para1(10) of Part II Table 2, clause c.	
Condition of the EUT	Power is to be "on" for the duration of the test.	
Test procedure in brief	The test comprises exposure of the EUT to the specified upper and lower atmospheric pressures limits. Exposure is to be established for at least 10 minutes at each pressure. Test sequence: 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	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(a) of Part II, Table 6. Ambient conditions: ambient pressure at respective test level, all other parameters within reference conditions as defined in Para6(4)(i) of Part II.	
EUT performance	Number of measurements at each pressure level: 5. Time schedule: after stabilisation at the respective pressure. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II.	
Acceptance criteria	All functions shall operate as designed. All errors shall be within the MPE specified in Para 1(6)(i) of Part II.	

(d) **Random vibration**

Table 16 - Random vibration

Test method	**Exposure to random vibration**	
Applicable Standards	IS or International Standards	
Applicability	Applicable to portable and transportable EBAs.	
Object of the test	Verification of compliance with the provisions for MPE in Para1(6)(i) of Part II under conditions of random vibration specified in Para1(10) of Part II 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	The test comprises exposure of the EUT to the vibration for at least 2 minutes per axis. TheEUT shall subsequently be tested in three mutually perpendicular axes mounted on a rigid fixture by its normal mounting means. The EUT shall normally be mounted in such a way that the gravity vector points in the samedirection as it would in normal use. If the measurement principle is such that the effect of the direction of the gravity vector can beconsidered negligible, the EUT may be mounted in any position. Test sequence: 1) Measurements before application of the influence (at reference conditions) 2) The influence quantity shall be applied 3) Measurements after application of the influence (at reference conditions)	
Test level		Test level
	Total frequency range	10 – 150 Hz
	Total RMS level (mean value of acceleration)	7 $m \cdot s^{-2}$
	ASD level 10–20 Hz	1 $m^2 \cdot s^{-3}$
	ASD level 20–150 Hz	–3 dB/octave
	Duration per axis	For each of the orthogonal directions the vibration exposure time shall be 2 minutes.
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(a) of Part II, Table 6. Ambient conditions: ambient pressure at respective test level, all other parameters within reference conditions as defined in Para6(4)(i) of Part II.	
EUT performance	Number of measurements (before and after application): 5. Time schedule: before and after application of the influence quantity, the EUT shall be switched on and the measurements shall be performed consecutively afterstabilisation. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II.	

Acceptance criteria	All functions shall operate as designed. The error of the EBA is determined at the reference conditions before and after the influence is applied. All errors shall be within the MPE specified in Para 1(6)(i) of Part II.

(e) **DC mains voltage variations**

Table 17 - DC mains voltage variations

Test method	**Applying low and high level DC mains power voltage**	
Applicable Standards	IS or International Standards	
Applicability	Applicable to 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 Para1 (6)(i) of Part II under conditions of DC mains power voltage changes between the upper and lower limits specified in Para 1(10) of Part II Table 2, clause e.	
Condition of the EUT	Power is to be "on" for the duration of the test. ≤ ≤	
Test procedure in brief	The test comprises exposure of the EUT to the specified power supply condition for a period of time sufficient for achieving stability at the relevant voltage level and subsequently performing the required measurements. Test sequence: 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 %)≤ U_{nom}≤ (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	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(a) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.	

EUT performance	Number of measurements at each voltage level: 5. Time schedule: after stabilisation at the relevant voltage level. Parameters at least to be recorded: a) as defined in Para 6(5)(iii) of Part II, plus b) reference voltage at beginning and end, high voltage and low voltage.
Acceptance criteria	All functions shall operate as designed. The errors of the EUT shall be determined for the reference voltage, the upper voltage and the lower voltage. All errors shall be within the MPE specified in Para 1(6)(i) of Part II.

(f) **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 Standards	IS or International Standards	
Applicability	Applicable to 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 Para1(6)(i) of Part II under conditions of AC mains network voltage changes between the upper and lower limits specified in Para 1(10) of Part II Table 2, clause f.	
Condition of the EUT	Power is to be "on" for the duration of the test.	
Test procedure in brief	The test comprises exposure of the EUT to the 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. Test sequence: 1) Reference voltage level 2) Upper voltage level 3) Lower voltage level 4) Reference voltage level In the case of three-phase power supply, the voltage variation shall apply for each phase successively.	
Test levels	Uhom	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 (Uhom) 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	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and - Para 6(4)(iii)(a) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.	
EUT performance	Number of measurements per voltage level: 5. Time schedule: after stabilisation at the relevant voltage level. Parameters at least to be recorded: a) as defined in Para 6(5)(iii) of Part II, plus b) reference voltage at beginning and end, high voltage and low voltage.	
Acceptance criteria	All functions shall operate as designed. The errors of the EUT shall be determined for the reference voltage, the upper voltage and the lower voltage. All errors shall be within the MPE specified in Para 1(6)(i) of Part II.	

(g) **AC mains frequency variations**

Table 19 - AC mains frequency variations

Test method	**Variation in AC mains power frequency**	
Applicable Standards	IS or International Standards	
Applicability	Only applicable to 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 Para 1(6)(i) of Part II under conditions of AC mains network power frequency changes between upper and lower limit specified in Para 1(10) of Part II Table 2, clause g.	
Condition of the EUT	Power is to be "on" for the duration of the test.	
Test procedure in brief	The test comprises exposure of the EUT to a variation in AC mains power frequency for a period of time sufficient for achieving stability at the relevant frequency level and for performing the required measurements. Test sequence: 1) Reference frequency 2) Upper frequency 3) Lower frequency 4) Reference frequency	
Test levels	f_{nom}	Nominal mains frequency value as specified by the manufacturer
	If a range is specified by the manufacturer	f_{nom1} concerns the highest and f_{nom2} concerns the lowest value
	If only one nominal mains frequency value (f_{nom}) is specified by the manufacturer	$f_{nom1} = f_{nom2} = f_{nom}$

	Reference frequency	(f_{nom1} + f_{nom2}) / 2
	Upper level	f_{nom1} + 2 %
	Lower level	f_{nom2} - 2 %
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(a) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.	
EUT performance	Number of measurements per frequency level: 5. Time schedule: after stabilisation at the relevant frequency level. Parameters at least to be recorded: a) as defined in Para 6(5)(iii) of Part II., plus b) reference frequency at beginning and end, high frequency and low frequency.	
Acceptance criteria	All functions shall operate as designed. The errors of the EUT shall be determined for the reference frequency, the upper frequency and the lower frequency. All errors shall be within the MPE specified in Para 1(6)(i) of Part II.	

(h) **Low voltage of internal battery**

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

Test method	**Applying minimum supply voltage**
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 Para 1(6)(i) of Part II during low battery voltage specified in Para 1(10) of Part II Table 2, clause h.
Precondition	The maximum internal impedance of the battery and the minimum battery supply voltage level (U_{bmin}) are to be specified by the manufacturer of the instrument. If an alternative power supply source is applied instead of the internal battery, the internal impedance of the specified type of battery shall also be simulated. The alternative power supply shall be capable of delivering sufficient power at the required supply voltage. The electrical power is supplied to the EUT and switched on for a time period of at least the warm-up time specified by the manufacturer.
Condition of the EUT	Power is to be "on" for the duration of the test.
Test procedure in brief	The test comprises exposure of the EUT to the specific low battery level condition during a period of time sufficient for achieving stability at the relevant voltage level and for performing the required measurements. Test sequence: 1) Reference voltage level 2) Lower voltage level 3) 0.9 × 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	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(a) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.	
EUT performance	Number of measurements at each voltage level: 5. Time schedule: after stabilisation at the relevant voltage level. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II.	
Acceptance criteria	All functions shall operate as designed. At 0.9 × U_{bmin}: the EUT shall either: a) cease to function (turn itself off); b) not allow any measurements and give an appropriate error message; or c) shall measure correctly. In case c the voltage shall be reduced until case a or b does occur. The errors of the EUT shall be determined for the lower voltage level(s) and the reference voltage level. All errors shall be within the MPE specified in Para 1(6)(i) of Part II.	

(i) **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) (Para 2(1)(vi) of Part II)
Condition of the EUT	Power is to be "on" for the duration of the test.
Test procedure in brief	The tests comprise of repeated measurements at different ambient conditions starting with a fully charged internal battery. Test sequence: 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, with a test gas concentration of 0.40 mg/L.
Measurement conditions	Ethanol concentrations: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(a) of Part II, Table 6. Ambient conditions: for (2): reference conditions as defined in Para 6(4)(i) of Part II. for (3): ambient temperature: –10 °C, all other

	parameters within reference conditions as defined in Para 6(4)(i) of Part II.
EUT performance	Number of measurements: for test sequence no. 2): 50 for test sequence no. 4): 20 Time schedule: consecutively Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II.
Acceptance criteria	Each individual measurement shall comply with the MPE as defined Para 1(6)(i) of Part II. The EBA shall be capable of performing all the tests on one set of batteries, or a single charge of batteries.

(j) **Voltage variations of a road vehicle battery**

Table 22 - Voltage variations of a road vehicle battery

Test method	**Variation in supply voltage**			
Applicable Standards	IS or International Standards			
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 Para 1(6)(i) of Part II under conditions of high (while charging) and low battery voltage specified in Para 1(10)(i) of Part II, Table 2, clause i.			
Condition of the EUT	Power is to be "on" for the duration of the test.			
Test procedure in brief	The test comprises exposure of the EUT to the specified maximum and minimum power supply voltage conditions for a period of time sufficient for achieving stability at the relevant voltage level and performing the required measurements at these conditions. Test sequence: 1) Upper voltage level 2) Lower voltage level 3) Reference voltage level			
Test level	Nominal battery voltage	U_{nom} = 12 V		U_{nom} = 24 V	
		Lower limit	Upper limit	Lower limit	Upper limit
		9 V	16 V	16 V	32 V
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para6(4)(iii)(a) of Part II , Table 6. Ambient conditions: within reference conditions as defined in Para6(4)(i) of Part II			
EUT performance	Number of measurements per voltage level: 5. Time schedule: after stabilisation at the relevant voltage level. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II			

Acceptance criteria	All functions shall operate as designed. The errors of the EUT shall be determined for the upper voltage level, for the lower voltage level and for the reference voltage level. All errors shall be within the MPE specified in Para 1(6)(i) of Part II.

(k) **Hydrocarbons in the environment**

Table 23 - Hydrocarbons in the environment

Test method	**Exposure to an environment containing hydrocarbons**	
Applicability	Applicable to all EBAs.	
Object of the test	Verification of compliance with the provisions for MPE in Para 1(6)(i) of Part II under conditions of exposure to the level of hydrocarbons in the environment specified in Para 1(10) of Part II 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 of the EUT to a simulated environment containing a specific fraction of hydrocarbons. Test sequence: 1) Measurements at influence conditions 2) Measurements at reference conditions	
Test level	Volume fraction of hydrocarbons (as methane equivalent)	5 ppm ± 1 ppm
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.	
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: a) as defined in Para6(5)(iii) of Part II, plus b) type and volume 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 Para 1(6)(i) of Part II.	

(l) **Raised fraction of CO_2 in the test gas**

Table 24 - Raised fraction of CO_2 in the test gas

Test method	**Measurements with raised CO2-content in the test gas**
Applicability	Applicable to all EBAs.
Object of the test	Verification of compliance with the provisions for MPE in Para 1(6)(i) of Part II under conditions of raised CO2 in the test gas as specified in Para 1(10) of Part II 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 CO2-content and 5 measurements with a standard test gas, both of the same ethanol concentration. Test sequence: 1) Measurements with test gas with raised CO2-content 2) Measurements with standard test gas
Measurement conditions	Ethanol concentrations: 0.40 mg/L (test gas no. 4) with 80 mmol/mol CO2 0.40 mg/L (test gas no. 4) with 50 mmol/mol CO2 (standard test gas). Test gas conditions: CO_2-concentration as specified, all other parameters within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
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 Para 6(5)(iii) of Part II
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 Para 1(6)(i) of Part II.

(viii) **Disturbances tests**

(a) 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 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.

(A) 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. 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.

(B) 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

<table>
<tr><td>Test method</td><td colspan="4">Injection of RF currents representing exposure to RF electromagnetic fields</td></tr>
<tr><td>Applicable Standards</td><td colspan="4">IS or International Standards</td></tr>
<tr><td>Applicability</td><td colspan="4">Applicable to all those EBAs that are or can be equipped with external electrical wiring (mains power, signal, data and control lines).</td></tr>
<tr><td>Object of the test</td><td colspan="4">Verification of compliance with the provisions for disturbances in Para 1(11) of Part II while exposed to electromagnetic fields specified in Para 1(11) of Part II, Table 3, clause a.</td></tr>
<tr><td>Condition of the EUT</td><td colspan="4">Power is to be “on” for the duration of the test.</td></tr>
<tr><td>Test procedure in brief</td><td colspan="4">An RF EM current, simulating the influence of EM fields shall be coupled or injected into the power ports and I/O ports of the EUT using coupling/decoupling devices as defined in the referred standard.
The characteristics of the test equipment consisting of an RF generator, (de-) coupling devices, attenuators, etc. shall be verified before connecting the EUT.
If the EUT comprises several devices, the tests shall be performed at each extremity of the cable if both of the elements are part of the EUT.
Test sequence:
1) Measurements before disturbance (at reference conditions)
2) Measurements during disturbance</td></tr>
<tr><td rowspan="2">Test level</td><td>Frequency range</td><td>RF amplitude</td><td colspan="2">AM, sine wave modulation</td></tr>
<tr><td>0.15 MHz – 80 MHz</td><td>10 V (e.m.f.)</td><td>80 %</td><td>1 kHz</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of</td></tr>
</table>

	Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
EUT performance	Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): Depending on the actual test setup. Parameters at least to be recorded: a) as defined in Para 6(5)(iii) of Part II plus b) applied RF (e.m.f). voltage level.
Acceptance criteria	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. Test scheme B: The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II. 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.

(b) **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, 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.

(A) 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. 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) at the maximum test frequency permitted by the EBA.

(B) 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

<table>
<tr><th>Test method</th><th colspan="4">Exposure to radiated radio frequency electromagnetic fields</th></tr>
<tr><td>Applicable Standards</td><td colspan="4">IS or International Standards</td></tr>
<tr><td>Applicability</td><td colspan="4">Applicable to all EBAs.</td></tr>
<tr><td>Object of the test</td><td colspan="4">Verification of compliance with the provisions for disturbances in Para 1(11) of Part II under conditions of exposure to electromagnetic fields specified in Para 1(11) of Part II Table 3, clause a.</td></tr>
<tr><td>Condition of the EUT</td><td colspan="4">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.</td></tr>
<tr><td>Test procedure in brief</td><td colspan="4">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 un modulated carrier wave.
The EUT shall be exposed to the modulated wave field. The frequency sweep shall be made only pausing to adjust the RF signal level or to switch RF-generators, amplifiers and antennas if necessary. Where the frequency range is swept incrementally, the step size shall not exceed 1 % of the preceding frequency value.
The dwell time of the amplitude modulated carrier at each frequency shall not be less than the time necessary for the EUT to respond, but shall in no case be less than 0.5 s.
Adequate EM fields can be generated in facilities of different type and setup, the use of which is limited by the dimensions of the EUT and the frequency range of the facility.
Test sequence:
1) Measurements before disturbance (at reference conditions)
2) Measurements during disturbance</td></tr>
<tr><td rowspan="3">Test level</td><td>Frequency range</td><td>RF amplitude</td><td colspan="2">AM, sine wave modulation</td></tr>
<tr><td>26 MHz – 80[(1)] MHz</td><td>10 V/m</td><td>80 %</td><td>1 kHz</td></tr>
<tr><td>80 MHz – 6 000 MHz</td><td>10 V/m</td><td>80 %</td><td>1 kHz</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II , Table 6.
Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.</td></tr>
</table>

EUT performance	Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): Depending on the actual test setup. Parameters at least to be recorded: a) as defined in Para6(5)(3) of Part II, plus b) field strength level.
Acceptance criteria	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. Test scheme B: The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II. 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.

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

(c) Electrostatic discharges

Table 27 - Electrostatic discharges

Test method	**Exposure to electrostatic discharges (ESD)**
Applicable Standards	IS or International Standards
Applicability	Applicable to all EBAs.
Object of the test	Verification of compliance with the provisions for disturbances in Para 1(11) of Part II in the case of direct exposure to electrostatic discharges or such discharges in the neighbourhood of the EUT specified in Para 1(11) of Part II, Table 3, clause b.
Condition of the EUT	Power is to be "on" for the duration of the test.

<table>
<tr><td>Test procedure in brief</td><td colspan="3">The test comprises exposure of the EUT to electrical discharges.
An ESD generator as defined in the referred standard shall be used and the test setup shall comply with the dimensions, materials used and conditions as specified in the referred standard. Before starting the tests, the performance of the generator shall be verified.
An EUT not equipped with a safety ground connection shall first be fully discharged before exposure to the following discharge.
At least 10 discharges per preselected discharge location shall be applied.
The number of points of application on each surface will depend on the size of the instrument. The tested points shall be described in the test report.
Contact discharge is the preferred test method. Air discharge is far less defined and reproducible and therefore shall be used only where contact discharge cannot be applied.
- Direct application:
In the contact discharge mode to be carried out on conductive surfaces, the electrode shall be in contact with the EUT before activation of the discharge. In such 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.
Test sequence:
1) Measurements before disturbance (at reference conditions)
2) Measurements during disturbance</td></tr>
<tr><td rowspan="4">Test level</td><td rowspan="2">Charge voltage</td><td>Contact discharge:</td><td>6 kV</td></tr>
<tr><td>Air discharge:</td><td>8 kV</td></tr>
<tr><td colspan="2">Time interval between successive discharges:</td><td>At least 1 s</td></tr>
<tr><td colspan="2">Number of discharges per preselected discharge location:</td><td>At least 10</td></tr>
<tr><td>Measurement conditions</td><td colspan="3">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para6(4)(iii)(a) of Part II, Table 6.
Ambient conditions: within reference conditions as defined Para 6(4)(i) of Part II.</td></tr>
<tr><td>EUT performance</td><td colspan="3">Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): 5.
Parameters at least to be recorded:</td></tr>
</table>

	a) as defined in Para 6(5)(iii) of Part II, plus b) discharge type, level and surface.

Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II, 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.

(d) 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 Standards	IS or International Standards	
Applicability	Applicable to 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 Para 1(11) of Part II during conditions where electrical bursts are superimposed on the mains voltage specified in Para 1(11) of Part II, Table 3, clause c.	
Condition of the EUT	Power is to be "on" for the duration of the test.	
Test procedure in brief	The test comprises exposure of the EUT to bursts of voltage spikes for which the output voltage on 50 Ω and 1000 Ω load are defined in the referred standard. A burst generator as defined in the referred standard shall be used. The characteristics of the generator shall be verified before connecting the EUT. Both positive and negative polarity of the bursts shall be applied. The injection network on the mains shall contain blocking filters to prevent the burst energy from being dissipated in the mains. At least 10 positive and negative randomly phased bursts shall be applied. The bursts are applied during all the time necessary to perform the test; therefore, more bursts than indicated above may be necessary. Test sequence: 1) Measurements before disturbance (at reference conditions) 2) Measurements during disturbance	
Test level	Amplitude (peak value)	1 kV
	Repetition rate	5 kHz
	Duration of the test for each amplitude and	$\geq$ 1 min

	polarity	
	Number of bursts (each for positive and negative polarity)	10
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(a) of Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II..	
EUT performance	Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): 5. Time schedule: consecutively at each test condition. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II.	
Acceptance criteria	The errors and fault of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II. 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.	

(e) 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 Standards	IS or International Standards
Applicability	Only applicable to 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 Para 1(11)(i) of Part II during conditions where electrical surges are superimposed on the mains voltage specified in Para 1(11)(i) of Part II Table 3, clause d.
Condition of the EUT	Power is to be "on" for the duration of the test.

<table>
<tr><td>Test procedure in brief</td><td colspan="5">The test comprises exposure of the EUT 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.
A surge generator as defined in the referred standard shall be used.
The characteristics of the generator shall be verified before connecting the EUT.
The 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.
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.
The surges are applied during all the time necessary to perform the test; therefore, more surges than indicated above may be necessary.
Test sequence:
1) Measurements before disturbance (at reference conditions)
2) Measurements during disturbance</td></tr>
<tr><td rowspan="4">Test level</td><td>Mains mode</td><td colspan="2">AC</td><td colspan="2">DC</td></tr>
<tr><td></td><td>Line to line</td><td>Line to ground</td><td>Line to line</td><td>Line to ground</td></tr>
<tr><td></td><td>1.0 kV</td><td>2.0 kV</td><td>1.0 kV</td><td>2.0 kV</td></tr>
<tr><td>Number of surges</td><td>3 positive
3 negative</td><td>3 positive
3 negative</td><td>3 positive
3 negative</td><td>3 positive
3 negative</td></tr>
<tr><td>Measurement conditions</td><td colspan="5">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II Table 6.
Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.</td></tr>
<tr><td>EUT performance</td><td colspan="5">Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): 5.
Time schedule: consecutively at each test condition.
Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II.</td></tr>
<tr><td>Acceptance criteria</td><td colspan="5">The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II
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.</td></tr>
</table>

(f) 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 Standards	IS or International Standards	
Applicability	Applicable to 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 Para 1(11)(i) of Part II during conditions where electrical bursts are superimposed on I/O and communication ports specified in Para 1(11)(i) of Part II Table 3, clause e.	
Condition of the EUT	Power is to be "on" for the duration of the test.	
Test procedure in brief	The test comprises exposure of the EUT to bursts of voltage spikes for which the output voltage on 50 Ω and 1000 Ω loads are defined in the referred standard. A burst generator as defined in the referred standard shall be used. The characteristics of the generator shall be verified before connecting the EUT. Both positive and negative polarities of the bursts shall be applied. Test sequence: 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	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para6(4)(iii)(b) of Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.	
EUT performance	Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): 5. Time schedule: consecutively at each test condition. Parameters at least to be recorded: a) as defined in Para 6(5)(iii) of Part II, plus b) exposed conductors.	

Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II 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.

(g) 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 Standards	IS or International Standards	
Applicability	Applicable to 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. Not applicable to: 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 Para 1(11)(i) of Part II under conditions of a ripple on the DC mains voltage specified in Para 1(11)(i) of Part II Table 3, clause f.	
Condition of the EUT	Power is to be "on" for the duration of the test.	
Test procedure in brief	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. 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 frequency of the ripple voltage is the applicable power frequency or a multiple (2, 3 or 6) dependent on the rectifier system used for the mains. The waveform of the ripple, at the output of the test generator, has a sinusoidal-linear character. The test level is a peak-to-peak voltage expressed as a percentage of the nominal DC voltage U_{DC}. Test sequence: 1) Measurements before disturbance (at reference conditions) 2) Measurements during disturbance	
Test level	Percentage of the nominal DC voltage U_{DC}	2 %

Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para6(4)(iii)(b) of Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
EUT performance	Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): 5. Time schedule: consecutively at each test condition. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II.
Acceptance criteria	The errors and fault of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II 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.

(h) 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 Standards	IS or International Standards
Applicability	Applicable to 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 Para 1(11)(i) of Part II under conditions of disturbances on the DC mains voltage specified in Para 1(11)(i) of Part II 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

<table>
<tr><td></td><td colspan="4">the test; therefore, more disturbances than indicated above may be necessary.
Test sequence:
1) Measurements before disturbance (at reference conditions)
2) Measurements during disturbance</td></tr>
<tr><td rowspan="11">Test level</td><td></td><td></td><td>Amplitude of the rated voltage</td><td>Durati on</td></tr>
<tr><td rowspan="4">Voltage dips</td><td>Test a</td><td rowspan="2">40 %</td><td>0.01 s</td></tr>
<tr><td>Test b</td><td>1 s</td></tr>
<tr><td>Test c</td><td rowspan="2">70 %</td><td>0.01 s</td></tr>
<tr><td>Test d</td><td>1 s</td></tr>
<tr><td rowspan="2">Short interrupti ons</td><td>Test e</td><td rowspan="2">0 %</td><td>0.001 s</td></tr>
<tr><td>Test f</td><td>1 s</td></tr>
<tr><td rowspan="4">Voltage variatio ns</td><td>Test g</td><td rowspan="2">85 %</td><td>0.1 s</td></tr>
<tr><td>Test h</td><td>10 s</td></tr>
<tr><td>Test i</td><td rowspan="2">120 %</td><td>0.1 s</td></tr>
<tr><td>Test j</td><td>10 s</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II Table 6.
Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.</td></tr>
<tr><td>EUT performance</td><td colspan="4">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 Para 6(5)(iii) of Part II , plus
b) percentage of voltage reduction and duration.</td></tr>
</table>

Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II 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.

(i) AC mains voltage dips, short interruptions and voltage variations

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

<table>
<tr><td>Test method</td><td colspan="4">Introducing short-time reductions of mains voltage using the test setup defined in the applicable standard</td></tr>
<tr><td>Applicable Standards</td><td colspan="4">IS or International Standards</td></tr>
<tr><td>Applicability</td><td colspan="4">Applicable to 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.</td></tr>
<tr><td>Object of the test</td><td colspan="4">Verification of compliance with the provisions for disturbances in Para 1(11)(i) of Part II under conditions of short time mains voltage reductions specified in Para 1(11)(i) of Part II Table 3, clause g.</td></tr>
<tr><td>Condition of the EUT</td><td colspan="4">Power is to be “on” for the duration of the test.</td></tr>
<tr><td>Test procedure in brief</td><td colspan="4">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</td></tr>
<tr><td rowspan="5">Test level</td><td></td><td></td><td>Amplitude</td><td>Duration</td></tr>
<tr><td rowspan="3">Voltage dips</td><td>Test a</td><td>0 %</td><td>0.5 cycles</td></tr>
<tr><td>Test b</td><td>0 %</td><td>1 cycle</td></tr>
<tr><td>Test c</td><td>70 %</td><td>25 cycles</td></tr>
<tr><td>Short interruptions</td><td>Test d</td><td>0 %</td><td>250 cycles</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II ,Table 6.
Ambient conditions: within reference conditions as defined Para 6(4)(i) of Part II.</td></tr>
</table>

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 Para 6(5)(iii) of Part II plus b) percentage of voltage reduction and duration.
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II 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.

(j) Surges on signal, data and control lines

Table 34 - Surges on signal, data and control lines

<table>
<tr><th>Test method</th><th colspan="4">Introducing electrical surges on signal, data and control lines</th></tr>
<tr><td>Applicable Standards</td><td colspan="4">IS or International Standards</td></tr>
<tr><td>Applicability</td><td colspan="4">Only applicable to those EBAs which are designed, during operation, to 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.</td></tr>
<tr><td>Object of the test</td><td colspan="4">Verification of compliance with the provisions for disturbances in Para1 (11)(i) of Part II during conditions where electrical surges are superimposed on I/O and communication ports specified in Para 1(11)(i) of Part II Table 3, clause h.</td></tr>
<tr><td>Condition of the EUT</td><td colspan="4">Power is to be “on” for the duration of the test.</td></tr>
<tr><td>Test procedure in brief</td><td colspan="4">The test comprises exposure of the EUT 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.
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.
Test sequence:
1) Measurements before disturbance (at reference conditions)
2) Measurements during disturbance</td></tr>
<tr><td rowspan="3">Test level</td><td colspan="2">Unsymmetrical lines</td><td>Symmetrical lines</td><td>Shielded I/O and communication lines</td></tr>
<tr><td>Line to line</td><td>Line(s) to ground</td><td>Line(s) to ground</td><td>Shield to ground</td></tr>
<tr><td>1.0 kV</td><td>2.0 kV</td><td>2.0 kV</td><td>2.0 kV</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para6(4)(iii)(b) of Part II Table 6.
Ambient conditions: within reference conditions as defined.</td></tr>
<tr><td>EUT performance</td><td colspan="4">Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): 5.
Time schedule: consecutively at each test condition. Parameters at least to</td></tr>
</table>

	be recorded: a) as defined in Para6(5)(iii) of Part II plus b) exposed conductors.
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II 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.

(k) Electrical transient conduction along supply lines

Table 35 - Electrical transient conduction along supply lines

Test method	**Electrical transient conduction along supply lines**
Applicable Standards	IS or International Standards
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	This test is applied to verify compliance of the EUT with the requirements in Para 1(11)(i) of Part II 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 Para 1(11)(i) of Part II (Table 3, clause i). Verification of compliance with the provisions for disturbances in Para 1(11)(i) of Part II-under the following conditions: - 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 Para1(11)(i) of Part II Table 3, clause i).
Condition of the EUT	Power is to be "on" for the duration of the test.
Test procedure in brief	The test comprises exposure of the EUT to disturbances on the power voltage by direct coupling into the supply lines. Test sequence: 1) Measurements before disturbance (at reference conditions) 2) Measurements during disturbance

Test level	Test pulse	Pulse voltage U_s	
		U_{nom} = 12 V	U_{nom} = 24 V
	2 a	112 V	112 V
	2 b	10 V	20 V
	3 a	–220 V	–300 V
	3 b	150 V	300 V
Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II, Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.		
EUT performance	Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): 5. Time schedule: consecutively at each test condition. Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II		
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iii) of Part II 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.		

(l) 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 Standards	IS or International Standards
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 Para 1(11)(i) of Part II under conditions of transients which occur on other lines as a result of the switching processes (pulses a and b) (Para 1(11)(i) of Part II , Table 3, clause j).
Condition of the EUT	Power is to be "on" for the duration of the test.

<table>
<tr><td>Test procedure in brief</td><td colspan="4">The test consists of exposure of the EUT to bursts of voltage spikes by capacitive coupling via lines other than supply lines, using only the Capacitive Coupling Clamp method.
Test sequence:
1) Measurements before disturbance (at reference conditions)
2) Measurements during disturbance</td></tr>
<tr><td rowspan="3">Test level</td><td></td><td>U_{nom}</td><td>12 V</td><td>24 V</td></tr>
<tr><td>Pulse a</td><td>U_S</td><td>–60 V</td><td>–80 V</td></tr>
<tr><td>Pulse b</td><td>U_S</td><td>40 V</td><td>80 V</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(b) of Part II Table 6.
Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.</td></tr>
<tr><td>EUT performance</td><td colspan="4">Number of measurements at reference conditions (before disturbance): 5. Number of measurements (during disturbance): 5.
Time schedule: consecutively at each test condition. Parameters at least to be recorded:
a) as defined in Para 6(5)(iii) of Part II, plus
b) exposed conductors.</td></tr>
<tr><td>Acceptance criteria</td><td colspan="4">The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II
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.</td></tr>
</table>

(m) Mechanical shock

Table 37 - Mechanical shock

Test method	**Dropping the EUT onto a rigid surface**
Applicable Standards	IS or International Standards
Applicability	Applicable to all EBAs.
Object of the test	Verification of compliance with the provisions for disturbances in Para 1(11)(i) of Part II under conditions of mechanical shocks specified in Para1(11)(i) of Part II Table 4, clause a.

<table>
<tr><td>Condition of the EUT</td><td colspan="4">Power is to be "on" for the duration of the test.</td></tr>
<tr><td>Test procedure in brief</td><td colspan="4">For stationary or transportable EBAs:
- the EUT, standing in its normal position of use on a rigid surface, is tilted along one bottom edge and subsequently is allowed to fall freely back on to the test surface.
The height of fall is the distance between the opposite bottom edge and the test surface. However, the angle between the bottom and the test surface shall not exceed 30°.
For portable EBAs:
- 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.
Test sequence:
1) Measurements before disturbance (at reference conditions)
2) The disturbance shall be applied
3) Measurements after disturbance (at reference conditions)</td></tr>
<tr><td rowspan="3">Test level</td><td></td><td>Stationary EBAs</td><td>Transportable EBAs</td><td>Portable EBAs</td></tr>
<tr><td>Height of fall</td><td>25 mm</td><td>50 mm</td><td>1 000 mm</td></tr>
<tr><td>Number of falls (on each bottom edge)</td><td>1</td><td>1</td><td>6</td></tr>
<tr><td>Measurement conditions</td><td colspan="4">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(b) of Part II Table 6.
Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.</td></tr>
<tr><td>EUT performance</td><td colspan="4">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 Para 6(5)(iii) of Part II.</td></tr>
<tr><td>Acceptance criteria</td><td colspan="4">The errors and fault of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II
Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</td></tr>
</table>

(n) Shakes

Table 38 - Shakes

Test method	**Exposure to shakes while not in operation**
Applicable Standards	IS or International Standards
Applicability	Applicable to portable and transportable EBAs.
Object of the test	Verification of compliance with the provisions for disturbances in Para 1(11)(i) of Part II after being exposed to shakes likely to be experienced in a car boot and specified in Para 1(11)(i) of Part II, 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 is 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 of the EUT 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 m/s^2) duration: 6 ms frequency: 2 Hz number of axes: 3 perpendicular axes number of shakes: 1000 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 Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(a) of Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
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 Para 6(5)(iii) of Part II.
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from

	occurring.

(o) Damp heat cyclic (condensing)

Table 39 - Damp heat, cyclic (condensing)

Test method	**Exposure to damp heat with cyclic temperature variation**	
Applicable Standards	IS or International Standards	
Applicability	Applicable to transportable and portable EBAs.	
Object of the test	Verification of compliance with the provisions for disturbances in Para 1(11)(i) of Part II under conditions of high humidity combined with cyclic temperature changes specified in Para 1(11)(i) of Part II 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	The test comprises exposure of the EUT 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. Condensation is expected to occur on the EUT during the temperature rise. The 24 h cycle comprises of: - 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. 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. Special electrical conditions and recovery conditions may need to be specified. Test sequence: 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	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II Table 6. Ambient conditions: temperature and humidity at the respective test level, all other parameters within reference conditions as defined in Para 6(4)(i) of Part II.		
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 Para 6(5)(iii) of Part II		
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.		

(p) Storage test

Table 40 - Storage test

Test method	**Exposure to changing temperatures while not in operation**
Applicable Standards	IS or International Standards
Applicability	Applicable to all EBAs.
Object of the test	Verification of compliance with the provisions for disturbances in Para 1(11)(i) of Part II after being exposed to the extreme situations which may occur during storage of the instrument as specified in Para 1(11)(i) of Part II 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 test comprises exposure of the EUT 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: 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 Para 6(4)(iii)(a) of Part II, Table 4 and Para 6(4)(iii)(b) of Part II Table 6. Ambient conditions: temperatures at the respective test levels, all other parameters within reference conditions as defined in Para 6(4)(i) of Part II.
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 Para 6(5)(iii) of Part II
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.

(q) Vibration (as disturbance)

Table 41 - Vibration (as disturbance)

Test method	**Exposure to random vibration**
Applicable Standards	IS or International Standards
Applicability	Applicable to stationary EBAs.
Object of the test	Verification of compliance with the provisions for disturbances in Para 1(11)(i) of Part II after being exposed to the extreme situations which may occur during transport of the instrument as specified in Para 1(11)(i) of Part II Table 4, clause e.

<table>
<tr><td>Condition of the EUT</td><td colspan="2">Power is to be "off" for the duration of the test.
The EUT shall be switched on immediately after this exposure.</td></tr>
<tr><td>Test procedure in brief</td><td colspan="2">The EUT shall subsequently be tested in three mutually perpendicular axes mounted on a rigid fixture by its normal mounting means.
The EUT shall normally be mounted in such a way that the gravity vector points in the same direction as it would in normal use.
If the measurement principle is such that the effect of the direction of the gravity vector can be considered negligible, the EUT may be mounted in any position.
After the exposure, the external electrical power (where applicable) shall be connected and the EUT shall be switched on. Then, 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)</td></tr>
<tr><td rowspan="5">Test level</td><td>Total frequency range</td><td>10 Hz – 150 Hz</td></tr>
<tr><td>Total RMS level</td><td>1.6 $m \cdot s^{-2}$</td></tr>
<tr><td>ASD level 10 Hz – 20 Hz</td><td>0.05 $m^2 \cdot s^{-3}$</td></tr>
<tr><td>ASD level 20 Hz – 150 Hz</td><td>–3 dB/octave</td></tr>
<tr><td>Duration per axis</td><td>For each of the orthogonal directions the vibration exposure
time shall be at least 2 minutes</td></tr>
<tr><td>Measurement conditions</td><td colspan="2">Ethanol concentration: 0.40 mg/L (test gas no. 4).
Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para6(4)(iii)(b) of Part II Table 6.
Ambient conditions: within reference conditions as defined Para 6(4)(i) of Part II.</td></tr>
<tr><td>EUT performance</td><td colspan="2">Number of measurements at reference conditions (before disturbance): 5. Number of measurements at reference conditions (after disturbance): 5.
Time schedule: test consecutively after switching on the EUT and after the warm-up period of the EUT at reference condition.
Parameters at least to be recorded: as defined in Para 6(5)(iii) of Part II</td></tr>
<tr><td>Acceptance criteria</td><td colspan="2">The errors and fault of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II
Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.</td></tr>
</table>

(r) Durability

The instrument is presumed to comply with the requirement defined in Para 1(5) of Part II. if the instrument submitted to the accuracy tests and disturbance tests passes each of the

tests.

(ix) Physiological influence substances

Table 42 - Physiological influence substances

Test method	**Test gases with additionally one interfering substance at a time**
Applicable Standards	IS or International Standards
Applicability	Applicable to all EBAs.
Objective of the test	Verification of compliance with the provisions in Para 1(11)(i) of Part II
Condition of the EUT	The EUT electrical power shall be switched on during the test.
Test procedure in brief	The test comprises of at least 5 measurements per test gas. Test sequence: 1) Measurement with test gas no. 4 2) Measurement with test gas no. 4 with one additional substance For each substance, this test sequence shall be repeated 4 times
Test gases mass concentration of substances	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 Depending on the results, additionally test gases with reduced concentrations of the interfering substances may be needed (see acceptance criteria).
Measurement conditions	Test gas conditions: test gas composition as defined for this test, other parameters within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II , Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
EUT performance	Number of measurements with each test gas and concentration: 5. At least the following parameters shall be recorded: as defined in Para6(5)(iii) of Part II
Calculation of results	- Calculation of deviation the deviation 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: $sensitivity_{is} = \frac{\Delta_{is[1\ldots5]}}{mass\ concentration\ of\ interfering\ substance}$ -
	a) If none of the calculated values for sensitivity is equal or below the value defined in Para1(11)(i) of Part II the EBA has passed the test for the interference substance concerned; b) if a calculated value for sensitivity exceeds the value defined in Para 1(11)(ii) of Part II and no error message is given, the EBA

Acceptance criteria	has failed; c) if an error message is displayed, another sequence of 5 tests 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 Para 1(11)(ii) of Part II; 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 Para 1(11)(ii) of Part II the EBA has passed the test for the interference substance concerned. This requirement shall be fulfilled for each measurement with each interfering substance.

(6) Tests for optional disturbances and requirements

(i) Sand and dust

Table 43 - Sand and dust

Test method	**Exposure to sand and dust**	
Applicable Standards	IS or International Standards	
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 Para 1(11)(iii) of Part II under a sand or dust-laden atmosphere.	
Condition of the EUT	The EUT electrical power shall be switched off during the test.	
Test procedure in brief	The test comprises of exposure of the EUT to cyclic temperature variation between 30 °C and 65 °C, maintaining the following conditions: - Relative humidity: less than 25 %, - Air velocity: 3 m/s, - Particle concentration: 5 g/m^3, Composition of the particles: Test sequence: 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 duration	2 hours

Measurement conditions	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
EUT performance	Number of measurements at reference conditions before exposure: 5. Number of measurements at reference conditions after exposure: 5. At least the following parameters shall be recorded: as defined in Para 6(5)(iii) of Part II.
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.

(ii) Salt mist

Table 44 - Salt mist

Test method	**Exposure to salt mist**
Applicable Standards	IS or International Standards
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 Para 1(11)(iii) of Part II under salt mist atmosphere.
Condition of the EUT	The EUT electrical power shall be switched off during the test.
Test procedure in brief	The test comprises exposure of the EUT to salt mist atmosphere at the following conditions: - Temperature of environment and salt solution: 35 °C - Mass fraction of NaCl of the salt solution: (5 ± 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 cm^2 Test sequence: 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	Ethanol concentration: 0.40 mg/L (test gas no. 4). Test gas conditions: within reference gas conditions as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(a) of Part II Table 6.

	Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
EUT performance	Number of measurements at reference conditions before exposure: 5. Number of measurements at reference conditions after exposure: 5. At least the following parameters shall be recorded: as defined in Para 6(5)(iii) of Part II
Acceptance criteria	The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.

(iii) Water

Table 45 - Water

Test method	**Exposure to water droplets**		
Applicable Standards	IS or International Standards		
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 Para 1(11)(iii) of Part II 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 EUT to water droplets in defined angles: - 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: 1) Measurements before disturbance (at reference conditions) 2) The disturbance shall be applied 3) Measurements after disturbance (at reference conditions)		
Test level	Test level index	2	
	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/m^2 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 Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.		

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 Para 6(5)(iii) of Part II
Acceptance criteria	Water shall have no harmful effects. The errors and faults of the EUT shall be determined as prescribed in Para 6(5)(iv) of Part II Either significant faults do not occur, or checking facilities detect and act on potential significant faults, thus preventing such faults from occurring.

7. Verification and re-verifications (Initial and subsequent verifications)

(1) General considerations

Individual EBAs within the scope of this Specification shall require initial verification when newly produced according to the approved type and shall require re verification when in service.

(i) 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.

(ii) Re verification

Re verification is defined as verification of a measuring instrument after a previous verification and including mandatory periodic verification and verification after repair.

(2) Legal status of the instrument submitted for verification

All EBAs produced and ready for initial verification/ re-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, the manufacturer has the full responsibility that the instrument complies with all the applicable requirements according to this specification and other relevant requirements.

(3) Visual examination

Before starting the practical tests, the following examinations are to be performed (as far as they are 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 or specified by Director (Legal Metrology)

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.

(4) **Metrological examination**

(i) Metrological precondition for performing tests

The performance tests shall be executed under reference conditions 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.

(ii) Test gases used for verification

The gas used for verification shall comply with the requirements of Para 6(4)(iii)(a) of Part II (Table 4). Director (Legal Metrology) may dictate whether simplified means (as those defined in Para 6(4)(iii)(b) of Part II) have to be used.

If the use of simplified means is prescribed, the requirements of Para 6(4)(iii)(b) of Part II and Para 6(4)(iii)(c) of Part II shall be taken into account. Verification reports shall indicate when other gases were used and how their equivalence with the reference gases was established.

(iii) Tests for initial or re 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 and
- a metrological examination of the EBA.

(iii)(a) Metrological examination

The following metrological examination tests are 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.

  Director (Legal Metrology) 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 Para 1(6)(i) of Part II or Para1(6)(ii) of Part II 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 an 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 Director (Legal Metrology).

(iii)(b) 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.

Annex A
General examples for test gas generators

(Informative)

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 thegas phase can be calculated with one of the following equations:

(1) Dubowski's formula

Let $\gamma(t)$ be the mass concentration of ethanol of an aqueous solution of ethanol. When air is bubbled throughsuch a solution, the mass concentration $\beta(t)$ of ethanol in the produced test gas is given by the following formula:

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

with: $\beta(t)$ mass concentration of ethanol in the test gas at a given temperature t in mg/L0.04145 × 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 °CFor t = 34 °C the equation can be simplified to:

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

(2) Harger's formula

If required other formulas may be required such as Harger'sformula.

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

Ka/w = 0.000393

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

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 gasphase 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-flask-bubble train.

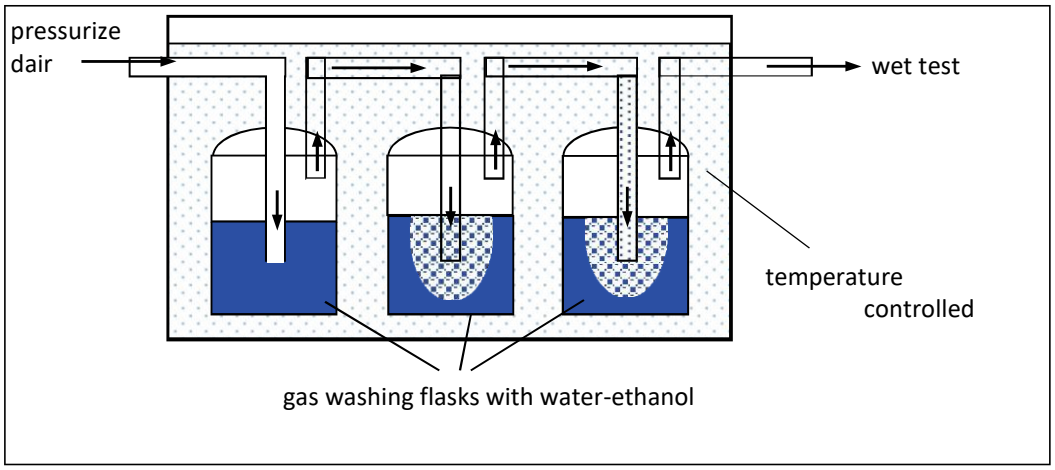


Figure A.1 - Diagram of a 3-flask-bubble train as a type 1 test gas generator

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.

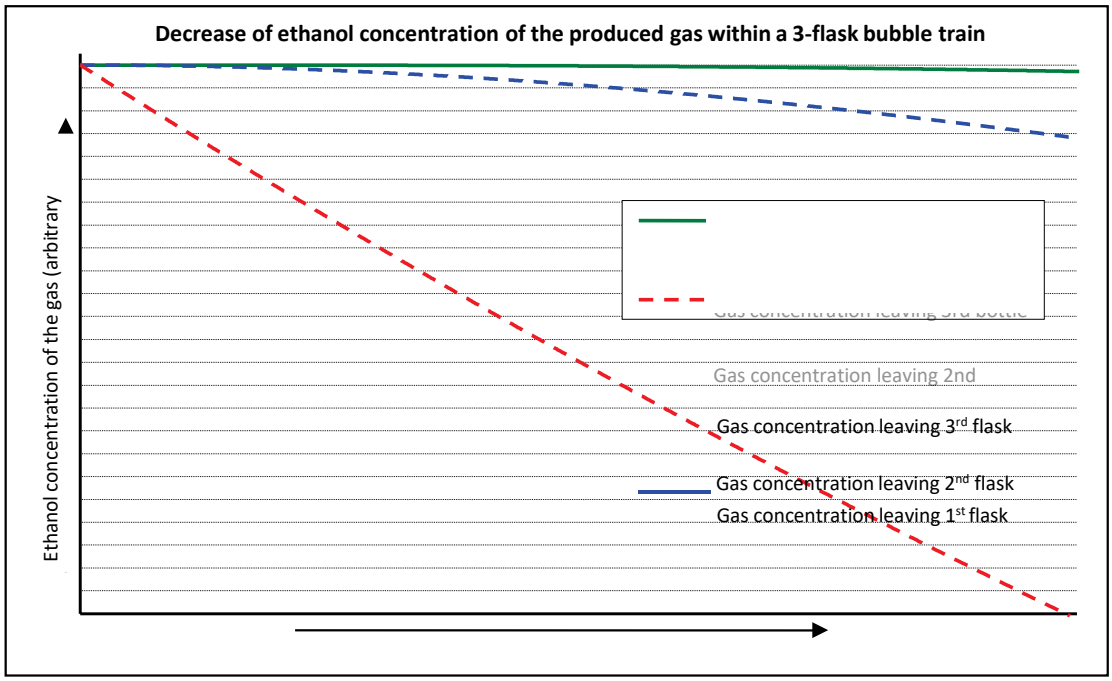


Figure A.2 - Example of the evolution of the gas concentrations in a 3-flask-bubble train

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.

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 Para 6(4)(iii) of Part II

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.

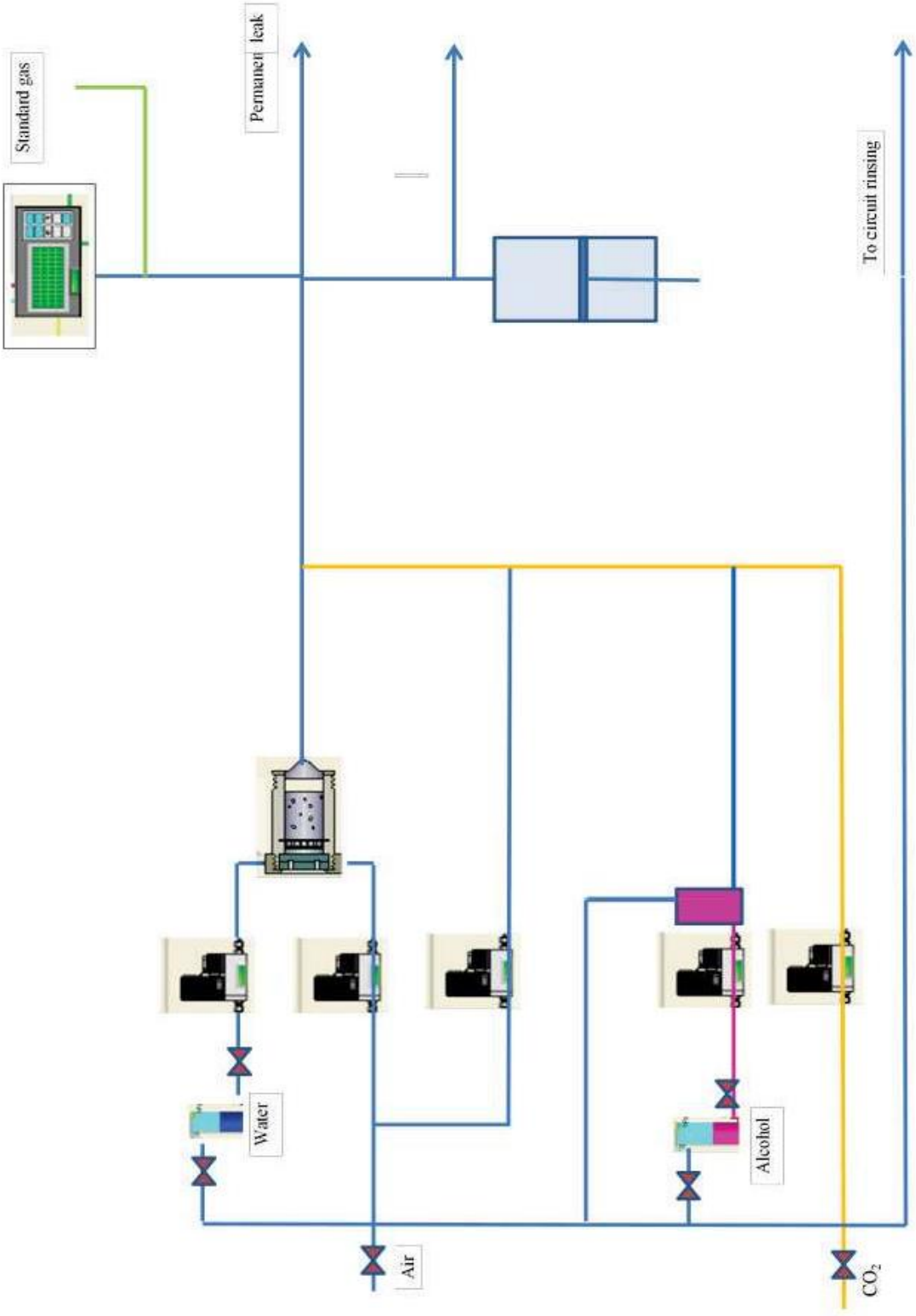
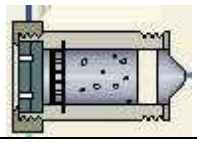
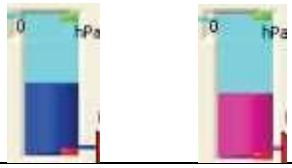
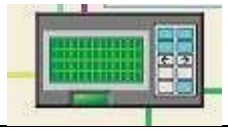
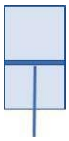


Figure A.3 - Example of a type 2 test gas generator

Legend for Figure A.3:

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

4 General information about breath profiles

As defined in the Scope, the purpose of this Specification 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 Para 4 of Annex A is to characterise the breath profile and define possible means to simulate it.

(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.

(i) Flow profile

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

- the first part (located in the first ¼ of the time of exhalation) represents the peak of the flow at the time of the exhalation;
- the second part is either a stable or a decreasing flow of breath,
- depending on the subject; the third part is a fast decrease of the flow when the subject terminates the exhalation.

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

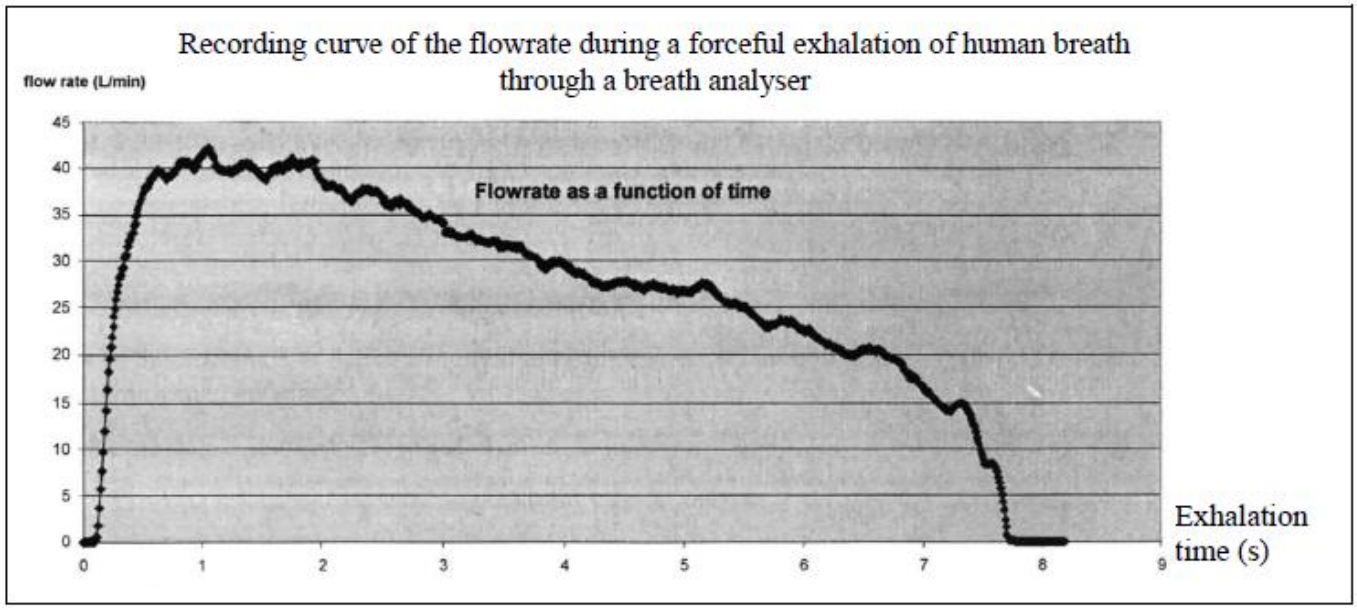


Figure A.4 - Example of a flow profile of a human being

(ii) 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 shows a volumetric expirogram of breath alcohol concentration.

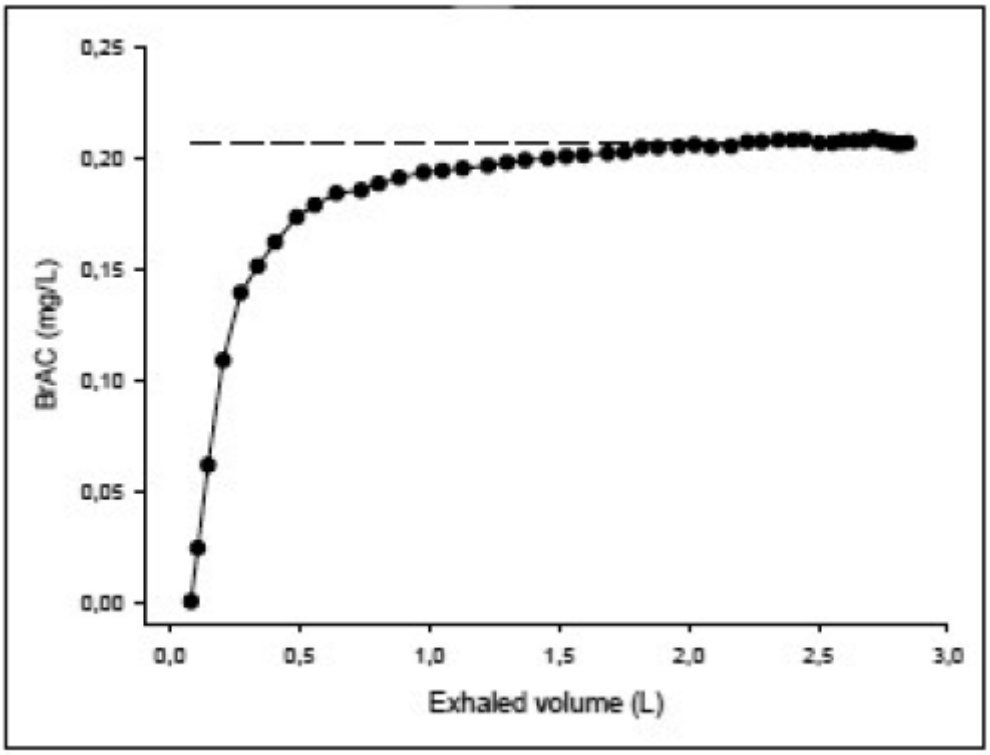


Figure A.5 - Example of a volumetric expirogram of breath alcohol concentration

(2) Simulation of breath profiles with test gas generators

The characteristics of the breath profiles needed for the tests in Part II of this Specification 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.

(i) Simulated exhalation profiles

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

- in Para6(5)(vi)(a)(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.

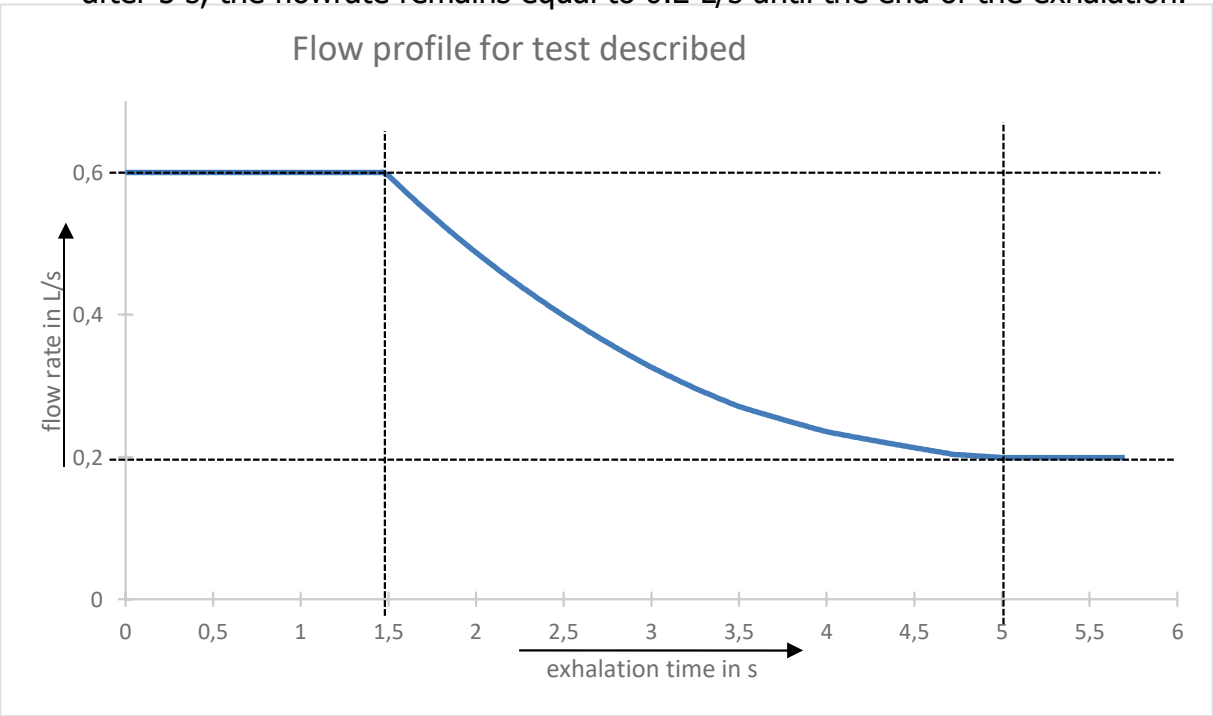


Figure A.6 - Simulated flow profile

(ii) 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 × 2.

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 afunction of time obtained on a simulation test bench.

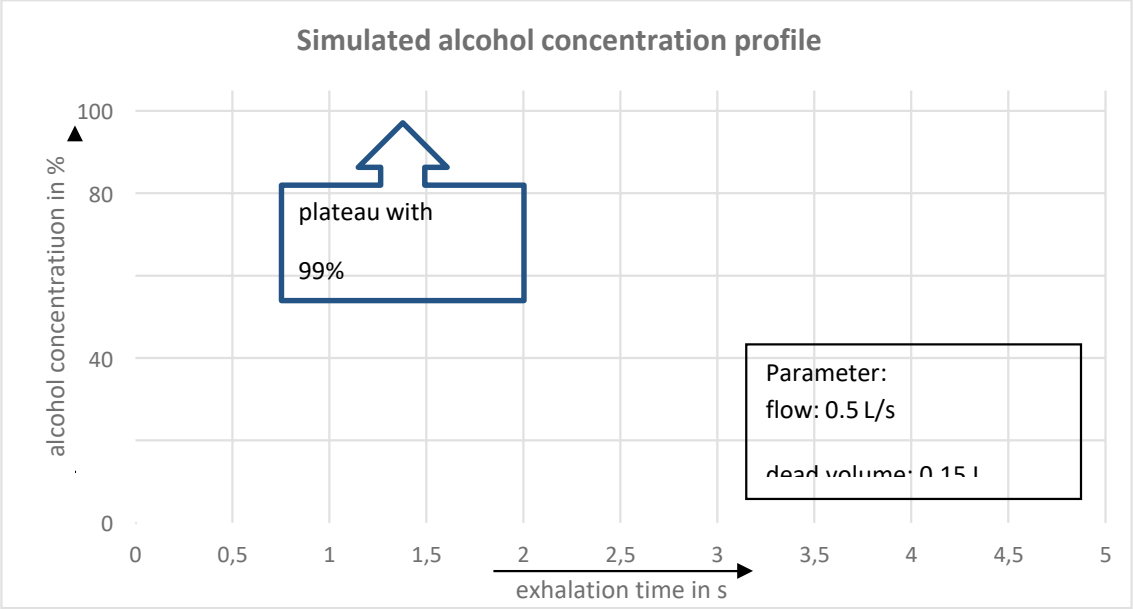


Figure A.7 - Example of a calculated alcohol concentration profile

In practice, the alcohol concentration profile generated by the test gas generators should look similar to thesimulated 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 nolonger 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.

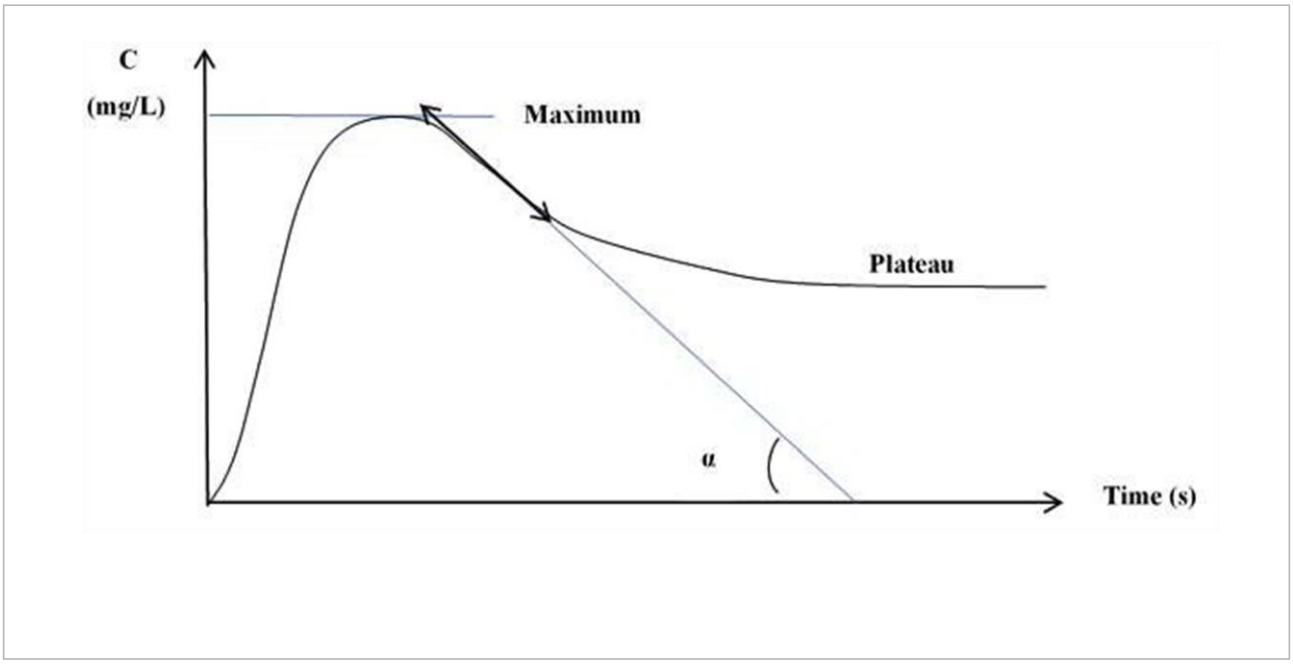
The corresponding tests are also described in the following clauses.

1 Peak method

(1) Principle of the peak method

The peak method is applicable only to EBAs which constantly monitor 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. α_{max} – $^{-1}$ $^{-1}$ $^{-1}$ $^{-1}$

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).

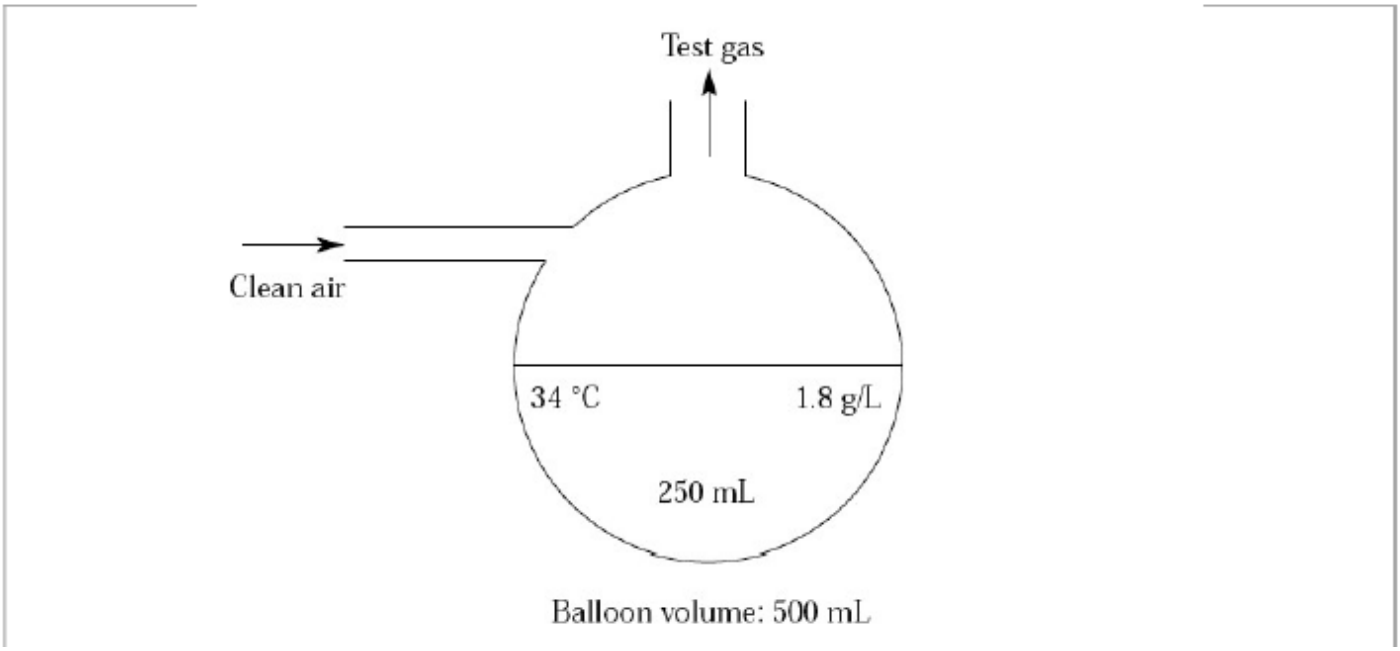


Figure B.2 - Example of a test balloon flask for creating concentration peaks

(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 Para 2(1)(viii) of Part II. under ambient reference conditions.
Precondition	As defined in Para 6(5)(ii) of Part II
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	Test gas generator: type 2 (enhanced) or example given in Figure B.2. Variation of the alcohol concentration as a function of time according to the evolution shown in Figure B.1. Ethanol concentration: concentration profile as described in .Para1(1)of Annex B Test gas conditions: delivered volume: 3 L ± 0.1 L duration of injection: 15 s ± 0.5 s all other parameters as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para6(4)(iii)(b) of Part II ; Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
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 Para6(5)(iii) of Part II
Acceptance criteria	The EUT shall detect the presence of alcohol in the upper respiratory tracts and shall cancel the measurement cycle. It shall not deliver any measurement result and shall display an appropriate error message.

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.

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.

(1) Principle of the two-measurement 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:

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

it may be 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, the unique available result

to be indicated as an indicative result, for instance indicating "measurement cycle not completed".

(ii) result of the second measurement is less than the 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, it may be defined that the smallest result shall be displayed and printed (if applicable). In this case, a comparison between the two results is not necessary.

(iii) The results of both measurements are greater than or equal to the 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.

Actions to be taken following the measurement depend 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. one of the two following solutions may be chosen:
  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.

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(2) Test procedure of the two-measurement 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-measurement cycle - first method

<table>
<tr><td>Test method</td><td>Measurements with defined differences of ethanol concentration</td></tr>
<tr><td>Applicability</td><td>Applicable to all EBAs with a two-measurement cycle for detecting alcohol in the upper
respiratory tract.</td></tr>
<tr><td>Object of the test</td><td>Verification of compliance with the provisions in Para 2(1)(viii) of Part II. under ambient reference
conditions.</td></tr>
<tr><td>Precondition</td><td>As defined in Para 6(5)(ii) of Part II</td></tr>
<tr><td>Condition of the EUT</td><td>Power is to be "on" for the duration of the test.</td></tr>
<tr><td>Test procedure in
brief</td><td>The test comprises of 5 measurements with a two-measurement cycle for each
incident and case.</td></tr>
<tr><td>Test gases
Mass concentration of ethanol</td><td>
<u>Incident a)</u> Test gas A: legal limit minus 0.03 mg/L = 0.22 mg/L
<u>Incident b)</u> Test gas B: legal limit plus 0.03 mg/L = 0.28 mg/L and Test gas A: legal limit minus 0.03 mg/L = 0.22 mg/L
<u>Incident c)</u> First test gas: test gas B: legal limit plus 0.03 mg/L = 0.28 mg/L
Second test gas:
Case 1:
One of these test gas concentrations shall be chosen as second test gas C, depending on the time delay:
<table>
<tr><td></td><td>Test gas C</td><td></td></tr>
<tr><td>Time delay (min)</td><td>Second test gas (mg/L)</td><td>Theoretical ratio R (min^{-1})</td></tr>
<tr><td>2</td><td>0.29</td><td>0.017</td></tr>
<tr><td>2.5</td><td>0.29</td><td>0.014</td></tr>
<tr><td>3</td><td>0.30</td><td>0.022</td></tr>
<tr><td>3.5</td><td>0.30</td><td>0.019</td></tr>
<tr><td>4</td><td>0.30</td><td>0.017</td></tr>
<tr><td>4.5</td><td>0.31</td><td>0.022</td></tr>
<tr><td>5</td><td>0.31</td><td>0.019</td></tr>
</table>
Case 2:
One of these test gas concentrations shall be chosen as second test gas D, depending on the time delay:
<table>
<tr><td></td><td>Test gas D</td><td></td></tr>
<tr><td>Time delay (min)</td><td>Second test gas (mg/L)</td><td>Theoretical ratio R (min^{-1})</td></tr>
<tr><td>2</td><td>0.30</td><td>0.033</td></tr>
<tr><td>2.5</td><td>0.31</td><td>0.039</td></tr>
<tr><td>3</td><td>0.31</td><td>0.032</td></tr>
<tr><td>3.5</td><td>0.32</td><td>0.036</td></tr>
<tr><td>4</td><td>0.32</td><td>0.031</td></tr>
<tr><td>4.5</td><td>0.33</td><td>0.034</td></tr>
<tr><td>5</td><td>0.34</td><td>0.035</td></tr>
</table>
</td></tr>
</table>

Measurement conditions	Test gas generator: Type 1 or type 2 Variation of the alcohol concentration as a function of time: • no variation (type 1 test gas generator) or plateau duration equal to 3 s (type 2 test gas generator). Ethanol concentrations: See above Test gas conditions: Delivered volume: 3 L ± 0.1 L Duration of injection: 5 s ± 0.5 s All other parameters as defined in Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II Table 6. Ambient conditions: Within reference conditions as defined in Para 6(4)(i) of Part II.
Test schemes	Test scheme for incident a) • 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). Test scheme for incident b) • test gas concentration for the first measurement: test gas B • test gas concentration for the second measurement: test gas A Test scheme for incident c) **Case 1**: R is less than 0.03 min^{-1}: 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 **Case 2**: R is greater than or equal to 0.03 min^{-1}: 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	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 Para 6(5)(iii) of Part II

Acceptance criteria	For incident a) - The EUT shall verify that the result $\beta 1$ of the first measurement is below the legal limit ($\beta 1$ < 0.25 mg/L), and shall display and print (if applicable) the result. For incident b) - The EUT shall verify that the result of the second measurement $\beta 2$ is below the legal limit ($\beta 2$ < 0.25 mg/L), and shall display and print (if applicable) the smallest result. For incident c), case 1: - The EUT shall verify that the ratio R obtained from both results $\beta 1$ and $\beta 2$ is smaller than 0.03 min^{-1} and shall, either display and print (if applicable) the smallest result of $\beta 1$ and $\beta 2$ as the final result of a valid measurement cycle, or display and print (if applicable) both results $\beta 1$ and $\beta 2$. For incident c), case 2: - The EUT shall verify that the ratio R obtained from both results $\beta 1$ and $\beta 2$ is greater than or equal to 0.03 min^{-1} and shall cancel the measurement cycle and display an appropriate error message.

(3) Principle of the two-measurement 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 and 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.

(4) Test procedure of the two-measurement cycle second method

Table B.3 - Two-measurement 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-measurement cycle for detecting alcohol in the upper respiratory tract.
Object of the test	Verification of compliance with the provisions in Para 2(1)(viii) of Part II. under ambient reference conditions.
Precondition	As defined in Para 6(5)(ii) of Part II
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: - 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 Para 6(4)(iii)(a) of Part II Table 4 and Para 6(4)(iii)(b) of Part II Table 6. Ambient conditions: within reference conditions as defined in Para 6(4)(i) of Part II.
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 Para 6(5)(iii) of Part II
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 two 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.

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.

A mandatory observation period before each measurement in the field may be decided by the Director (Legal Metrology).

[File No. WM-9(9)/2024]

(Anupam Mishra)

Joint Secretary to the Government of India

Note:- The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* notification number G.S.R.71(E), dated the 7th February, 2011 and was last amended, *vide* notification number G.S.R. 763 (E), dated the 4th October, 2021.