INTERNATIONAL RECOMMENDATION

OIML R 126-1

Edition 2021 (E)

Evidential breath analysers

Part 1: Metrological and technical requirements

Ethylomètres

Partie 1 : Exigences métrologiques et techniques

OIML R 126-1 Edition 2021 (E)

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

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Foreword

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Part 1 - Metrological and technical requirements

1 Introduction

Evidential breath alcohol analysers (EBA) are used worldwide in professional applications such as law enforcement, traffic safety, and work safety. Test results may lead to severe consequences for everybody involved. Therefore, the test results must be reliable and acceptable.

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

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

2 Scope

This Recommendation applies to evidential breath alcohol 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 instance, with national policy for fighting against alcohol abuse and/or for the advancement of public safety.

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

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).

For the purpose of this Recommendation, 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.

Additionally, some national authorities may require that EBAs 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).

The purpose of this Recommendation is to enumerate the minimum metrological specifications and tests applicable to type approval of quantitative EBAs, recognising national differences in legal systems. It also gives guidance for establishing metrological specifications for initial and subsequent verifications.

The scope of this Recommendation is limited to the types of EBAs that use mouthpieces for sampling the breath.

3 Terms and definitions

3.1 General metrology and legal metrology terms

The basic terminology used in this Recommendation is consistent with the definitions in OIML V 2 *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms*, edition 2012 (OIML V 2-200) [2] and OIML V 1 *International Vocabulary of Terms in Legal Metrology*, edition 2013 (OIML V 1) [1]. For convenience, the most important definitions concerning this Recommendation are also given below. Additional definitions are adapted or replicated from OIML D 9:2004 [3], OIML D 11:2013 [4], OIML D 31:2019 [5], and OIML G 1-100:2008.

3.1.1 measurement error (OIML V 2-200, 2.16) [2]

measured quantity value minus a reference quantity value

3.1.2 adjustment of a measuring system (OIML V 2-200, 3.11) [2]

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

3.1.3 calibration (OIML V 2-200, 2.39) [2]

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

3.1.4 verification of a measuring instrument (OIML V 1, 2.09) [1]

conformity assessment procedure (other than type evaluation) which results in the affixing of a verification mark and/or issuing of a verification certificate

Note: See OIML V 2-200:2012, 2.44 for more information.

3.1.5 initial verification (OIML V 1, 2.12) [1]

verification of a measuring instrument which has not been verified previously

3.1.6 subsequent verification (OIML V 1, 2.13) [1]

verification of a measuring instrument after a previous verification

Note 1: Subsequent verification of a measuring instrument includes

- mandatory periodic verification,
- verification after repair, and
- voluntary verification.

Note 2: Subsequent verification of a measuring instrument may be carried out before expiry of the period of validity of a previous verification either at the request of the user (owner) or when its verification is declared to be no longer valid.

3.1.7 mandatory periodic verification (OIML V 1, 2.14) [1]

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

3.1.8 putting into service (use) (OIML D 9, 2.23) [3]

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

3.1.9 being in service (use) (OIML D 9, 2.25) [3]

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

3.1.10 disturbance (OIML V 1, 5.19) [1]

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

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

3.1.11 fault (OIML V 1, 5.12) [1]

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

3.1.12 fault limit (OIML V 1, 5.12) [1]

value specified in this Recommendation delimiting non-significant faults

3.1.13 significant fault (OIML V 1, 5.14) [1]

fault exceeding the applicable fault limit

Note: Significant faults are only relevant to electronic measuring systems.

3.1.14 significant defect

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

3.1.15 intrinsic error (adapted from OIML V 1, 0.06) [1]

error of a measuring instrument, determined under reference conditions

3.1.16 initial intrinsic error

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

3.1.17 experimental standard deviation (OIML G 1-100, 4.22) [6]

for a series of n measurements of the same measurand, the quantity $s(q_k)$ characterising the dispersion of the results and given by the formula:

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

with: q_k being the result of the kth measurement and $\bar{q}$ being the arithmetic mean of the n results considered.

3.1.18 measurement precision (OIML V 2-200, 2.15) [2]

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

3.1.19 measurement repeatability (OIML V 2-200, 2.21) [2]

measurement precision under a set of repeatability conditions of measurement

3.1.20 repeatability condition of measurement (OIML V 2-200, 2.20) [2]

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

3.1.21 measurement reproducibility (OIML V 2-200, 2.25) [2]

measurement precision under reproducibility conditions of measurement

3.1.22 reproducibility condition of measurement (OIML V 2-200, 2.24) [2]

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

3.1.23 stability of a measuring instrument (OIML V 2-200, 4.19) [2]

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

3.1.24 uncertainty of a measurement (OIML V 2-200, 2.26) [2]

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

Note: For more information, see OIML G 1-100 *Evaluation of measurement data - Guide to the expression of uncertainty in measurement*.

3.1.25 sensitivity (OIML V 2-200, 4.12) [2]

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 Recommendation, sensitivity relates to the added substance which is not identical with the measurand.

3.2 Specific terms

3.2.1 evidential breath alcohol analyser (EBA)

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

3.2.2 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 Recommendation, stationary EBAs are designated as use-case 1.

3.2.3 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 Recommendation, transportable EBAs are designated as use-case 2.

3.2.4 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 Recommendation, portable EBAs are designated as use-case 3.

3.2.5 alveolar air

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

3.2.6 end expiratory breath

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

3.2.7 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

Note: The volume of the dead space varies between individuals.

(Cited from Webster's Medical Dictionary, online version: www.merriam-webster.com/medical).

3.2.8 measuring mode

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

3.2.9 metrological test mode

mode in which the EBA is subject to metrological control 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.

3.2.10 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

3.2.11 checking facility (adapted from OIML V 1, 5.07) [1]

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

Note: "Act upon" refers to any adequate response by the measuring instrument (luminous signal, acoustic signal, prevention of the measurement process, etc.) These significant defects could be for example

- events that otherwise will result in significant faults, and/or
- incorrect functioning of a specific device of the measuring instrument, and/or
- disturbed communication between specific devices of the measuring instrument.

3.2.12 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

Note: Since national authorities may define specific measurement cycles for their country, "standard" refers to the respective country.

3.2.13 drift (adapted from OIML V 2-200, 4.21) [2]

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

3.2.14 memory effect

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

3.2.15 plateau of alcohol concentration

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

Note: Plateau of alcohol concentration is described in R 126-2, Annex A.4.

3.3 Software terms

3.3.1 authenticity (OIML D 31, 3.1.3) [5]

result of the process of authentication (passed or failed)

3.3.2 authentication (OIML D 31, 3.1.2) [5]

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.

3.3.3 cryptographic means (OIML D 31, 3.1.8) [5]

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

3.3.4 error log (OIML D 31, 3.1.15) [5]

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

3.3.5 hash function (OIML D 31, 3.1.20) [5]

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

Note: A “good” hash function is such that the results of applying the function to a (large) set of values in the domain will be evenly distributed (and apparently at random) over the range.

3.3.6 integrity (of programs, data, or parameters) (OIML D 31, 3.1.21) [5]

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

3.3.7 interface (OIML D 31, 3.1.22) [5]

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

3.3.8 legally relevant (OIML V 1, 4.08) [1]

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

3.3.9 sealing (OIML V 1, 2.20) [1]

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

Note: This may be achieved by hardware, software, or a combination of both.

3.3.10 software examination (OIML D 31, 3.1.47) [5]

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)

3.3.11 software identification (OIML D 31, 3.1.48) [5]

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

Note: The identification can be checked on an instrument whilst it is in use.

3.3.12 transmission of measurement data (OIML D 31, 3.1.56) [5]

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

3.3.13 user interface (OIML D 31, 3.1.60) [5]

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.

3.4 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
$T_{amb\text{-}low}$	low ambient temperature
$T_{amb\text{-}high}$	high ambient temperature
T_R	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 R 126-2, 2.3.2.

4 Description of the instrument

4.1 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 nationally 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.

4.2 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 7.1.9.

4.3 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.

4.4 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 respective national requirements.

4.5 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.

Depending on national regulations, a complete measurement cycle may consist of one or more breath samples.

5 Units of measurement and decimal sign

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

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. Admissibility of the comma and/or the dot is left to national legislation.

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

6 Metrological requirements

6.1 Measuring range

The measuring range of the EBA shall be from 0.00 mg/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 fulfil the requirements of this Recommendation for the complete specified measuring range.

6.2 Masking of low results

National authorities may require a masking function 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.

6.3 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.

6.4 Multiple indicating devices

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

6.5 Durability of the EBA

The provisions in 6.6, 6.7, 6.8, 6.9, 6.10 and 6.11 shall be met durably.

The EBA shall be designed to maintain stability of its metrological characteristics over a period of time (to be specified by the manufacturer) which shall be at least as long as the verification period.

The verification period is defined under the responsibility of the national authorities (subsequent verifications).

6.6 Maximum permissible errors (MPE)

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

6.6.1 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:

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

National regulations may require that the MPE as specified in the present subclause also apply to verification after repair or for mandatory periodic verification.

6.6.2 Maximum permissible errors for subsequent 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:

$\frac{\beta \times 3}{4} - 1.35\ \mathrm{mg}/L$ for all mass concentrations of alcohol greater than 2.000 mg/L.

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

Reference values for alcohol concentration β	MPE of 6.6.1	MPE of 6.6.2	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	$\frac{\beta}{2} - 0.9\ \mathrm{mg/L}$	$\frac{3 \times \beta}{4} - 1.35\ \mathrm{mg/L}$	Only applicable for enlarged measuring range

6.6.3 Fault limit

The fault limit shall be 0.020 mg/L.

6.7 Repeatability

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

The experimental standard deviation 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 3.1.17.

6.8 Drift

6.8.1 Zero drift

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

6.8.2 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.

6.8.3 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.

6.9 Memory effects

6.9.1 Memory effect with large differences in mass concentration

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

6.9.2 Memory effect with small differences in mass concentration

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

6.9.3 Effect of water vapor (condensation)

EBAs shall be designed and manufactured such that their errors do not exceed the MPE specified in 6.6.1 when repeatedly tested with wet test gas at the respective low ambient temperature condition as specified in 6.10.1.

6.10 Operating conditions

6.10.1 Physical influence factors

EBAs shall be designed and manufactured such that their errors do not exceed the MPE specified in 6.6.1 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 $m \cdot s^{-2}$, 1 $m^2 \cdot s^{-3}$, –3 dB/octave	
e	DC mains voltage	As specified by the manufacturer	
f	AC mains voltage	U_{nom} – 15 % to U_{nom} + 10 %	
g	AC mains frequency	f_{nom} – 2 % to f_{nom} + 2 %	
h	Voltage of internal battery	All voltages between a new or freshly charged battery, down to the lowest voltage at which the instrument functions 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.

6.10.2 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.

6.11 Disturbances and physiological influence substances

6.11.1 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 ($U_{peak\text{-}peak}/U_{DC}$)	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

			Stationary EBAs	Transportable EBAs	Portable EBAs
a	Mechanical shocks	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	Damp heat, cyclic (condensing)		Stationary EBAs	Transportable EBAs	Portable EBAs
		Temperature	Not applicable	55 °C	55 °C
		Duration		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 $m \cdot s^{-2}$, 0.05 $m^2 \cdot s^{-3}$, –3 dB/octave			

6.11.2 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 R 126-2, 2.5.9), 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: National regulations may require additional substances to be tested.

6.11.3 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 6.10 or 6.11, national authorities may request 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 disturbances expected in specific environmental conditions

a	Sand and dust	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: as specified in 3.2.1 of IEC 60512-11-8 [17]	
b	Salt mist	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	
c	Water	Test level index	2[(1)]
		Test condition	According to the protection class IPX4 of IEC 60529 [18]

(1) For protection against water, the required test level 2 of D 11 corresponds with IPX4 of IEC 60529 [18].

7 Technical requirements

The technical requirements for EBAs are divided into two sections:

- 7.1 covers the basic technical requirements; and
- 7.2 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), and if national regulations specify these extra functionalities.

7.1 Basic technical requirements

7.1.1 Presentation of the measurement result

7.1.1.1 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 3 mm 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.

7.1.1.2 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.

7.1.1.3 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.

7.1.2 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.

7.1.3 Checking operations

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

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

7.1.4 Warm-up time

Under reference conditions (R 126-2, 2.4.1), the EBAs used in different use-cases (see 3.2) 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
3.2.2	Use-case 1: stationary EBA	15 min
3.2.3	Use-case 2: transportable EBA	15 min
3.2.4	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.

7.1.5 Availability for measurement

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

7.1.6 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.

7.1.7 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 6.10.2.

7.1.8 Alcohol in the upper respiratory tract

The EBA shall be equipped with a function which automatically detects whether the measurement result is affected by the presence of alcohol in the upper respiratory 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 R 126-2, Annex B, and the basic requirements for a corresponding test performance are described in R 126-2, 2.5.6.2.

7.1.9 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.

7.1.10 Software

The following requirements (7.1.10.1 to 7.1.10.7) established in OIML D 31 [5] shall be fulfilled. The severity of testing shall be selected independently for each requirement.

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

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

7.1.10.1 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 type approval certificate/certificate of conformity.

7.1.10.2 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 as described in OIML D 31 [5]).

7.1.10.3 Protection of the software against fraud

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

a) 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;

b) 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;

c) 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.

7.1.10.4 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.

7.1.10.5 Interfaces

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

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

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

c) only allowed and documented commands are permitted to activate functions through the interfaces.

7.1.10.6 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.

7.1.10.7 Software documentation

In addition to the general documentation required in R 126-2, 2.2, the manufacturer shall submit the following documentation:

a) Description of the software and how the requirements are met, with
   i. list of software modules that perform legally relevant functions;
   ii. description of the software interfaces that perform legally relevant functions and of the commands and data flows via this interface;
   iii. if a raised risk level (Level B) is required by national authorities, the source code shall be made available to the type evaluation authority;
   iv. list of parameters to be protected and description of the protection means;

b) Description of the system configuration and minimal required resources;

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

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

e) 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;

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

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

h) 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;

i) List of commands of each hardware interface of the EBA;

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

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

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

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

7.2 Optional technical requirements

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

7.2.1 Durable recording of measurement results

7.2.1.1 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:

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

b) The printout shall at least contain the following information:

   i. instrument reference;

   ii. date and time of the measurement;

   iii. measurement results and their units;

   iv. if applicable according to national regulations: identification on the printout of the person subjected to the test;

c) The printed scale interval shall comply with the requirements defined in 6.3 “Scale interval”.

d) 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:

   i. presence of paper and ink (if applicable);

   ii. the status of the printer and its readiness for operation;

e) When the internal printing device is exposed to the disturbances of 6.11, either significant faults do not occur, or significant faults are detected and acted upon by means of a checking facility;

f) The data transmission to external printing devices considered as legally relevant shall comply with the requirements of 7.2.1.2 “Storage and transmission of data”.

7.2.1.2 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, according to national regulations. In such cases, the requirements defined below apply:

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

b) 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.

c) The EBA shall have sufficient permanency to store the data until it is no longer legally required, according to national regulations. 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: General national regulations may contain strict limitations for the deletion of stored measurement data.

d) 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. For further information and examples refer to D 31 [5].

e) 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.

f) If data is transmitted from the EBA (secure environment) to an external environment, national authorities shall decide on the risk level according to OIML D 31 [5] for the transmission and storage of data. 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.

g) 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.

h) 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.

7.2.2 Redundancy

National regulations 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 subclauses will apply accordingly.

7.2.2.1 Configuration of the measuring instrument

National authorities 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:

a) 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.

b) 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.

c) 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 R 126-2, Annex B.

7.2.2.2 Measurement results

The results generated shall comply with the following requirements:

a) As configuration with two independent measuring systems:

   i. Each measuring system shall fulfil the requirements of 6.6.1 for MPE independently.

   ii. 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 6.6.1 for the lower of both the interim results.

b) 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.

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

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

   ii. National regulations shall prescribe the number of breath samples to be measured and how the final result is determined out of the measurement result for each breath sample.(2)

   iii. National regulations shall prescribe which details of the multiple measurements shall be given on the printout.

   iv. If these multiple breath samples are also used for the detection of alcohol in the upper respiratory tracts, either the requirements of R 126-2, B.2.1 or R 126-2, B.2.3 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.

8 Operating instructions

8.1 Instruction manual

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

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

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

b) maximum and minimum storage temperatures;

c) rated operating conditions;

d) warm-up time after switching on the electrical power;

e) all other relevant mechanical and electromagnetic environmental conditions;

f) mechanical and electromechanical environment classes; and

g) safety and security conditions.

8.2 Additional instructions

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

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.

9 Inscriptions and sealing

9.1 Inscriptions

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

a) mandatory on the label in all cases:
   - manufacturer's trademark/corporate name;
   - type designation/model number;
   - type approval mark according to national regulations;
   - 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;

b) 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.

9.2 Sealing

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

a) adjustment means;

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

c) software integrity.

Annex A
Comparison table of R 126:2021 to R 126:2012
(Informative)

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

Table A.1 - Comparison table for R 126-1

R 126:2012 (E)		R 126:2021 (E)		
Ref.	**Description**	**Ref.**	**Description**	**Remarks**
	Foreword		Foreword	-
		1	Introduction	New clause
1	Scope	2	Scope	The scope is now limited to the types of EBAs that use mouthpieces for sampling the breath
2	Terminology	3	Terms and definitions	Definitions revised/updated, new definitions Terms were grouped into three subclauses for a more systematic approach
		3.1	General metrology and legal metrology terms	
		3.2	Specific terms	
		3.3	Software terms	
		3.4	Abbreviations and symbols	New subclause
Part 1				The three parts of the Recommendation are now published as separate documents
3	Description of the instrument	4	Description of the instrument	
		4.1	Schematic description	Revised text with a list of typical components
3.1	Sampling	4.2	Sampling and mouthpiece	Revised text
3.2	Analysis	4.3	Analysis	-
3.3	Determination, presentation and storage of the result	4.4	Presentation and storage of the result	-

R 126:2012 (E)		R 126:2021 (E)		
Ref.	**Description**	**Ref.**	**Description**	**Remarks**
		4.5	Measurement cycle	New subclause to specify the typical steps of a complete measurement performed by an EBA
4	Units of measurement and decimal sign	5	Units of measurement and decimal sign	-
5	Metrological requirements	6	Metrological requirements	New sentence “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).”
5.1	Measuring range	6.1	Measuring range	Only editorial changes
		6.2	Masking of low results	Masking of low results is now a separate clause
5.3	Scale interval	6.3	Scale interval	Only editorial changes
5.7	Multiple indicating devices	6.4	Multiple indicating devices	-
5.11	Durability	6.5	Durability of the EBA	-
5.2	Maximum permissible errors (MPEs)	6.6	Maximum permissible errors (MPE)	-
5.2.1	Maximum permissible errors for type approval and initial verification and verification after repair	6.6.1	Maximum permissible errors for type approval and initial verification	Change of title New note that these MPEs might also be applied for verification purposes, according to national regulations
6.6.2	Maximum permissible errors for breath alcohol analysers in service	6.6.2	Maximum permissible errors for subsequent verification and for EBA in service	Change of title
			Table 1 - MPE for type approval, initial verification, subsequent verification and for EBAs in service	New table with the compilation of the MPEs
5.9	Significant fault	6.6.3	Fault limit	Specification of the fault limit as a numerical value
5.4	Repeatability	6.7	Repeatability	Equation of Ed. 2012 moved to definitions
5.5	Drift	6.8	Drift	-

R 126:2012 (E)		R 126:2021 (E)		
Ref.	**Description**	**Ref.**	**Description**	**Remarks**
5.5.1	Zero drift	6.8.1	Zero drift	Revised to a general phrase for the requirement
5.5.2	Short-term drift	6.8.2	Short-term drift	Revised to a general phrase for the requirement
5.5.2	Long-term drift	6.8.3	Long-term drift	Revised to a general phrase for the requirement Extension to six months stability and definition of the test scheme
5.6	Memory effects	6.9	Memory effects	
5.6.1	Memory effect with large differences in mass concentration	6.9.1	Memory effect with large differences in mass concentration	Revised to a general phrase for the requirement
5.6.2	Memory effect with small differences in mass concentration	6.9.2	Memory effect with small differences in mass concentration	Revised to a general phrase for the requirement
		6.9.3	Effect of water vapour (condensation)	New subclause
5.8	Minimum requirements for rated operating conditions	6.10	Operating conditions	
5.8.1	Physical influence factors Table	6.10.1	Physical influence factors Table 2 - Minimum rated operating conditions	Changes in Table 2: Low and high ambient temperatures limits modified Ambient relative humidity for all EBA use-cases CO_2 concentration in the test gas decreased Note to explain “methane equivalent”
5.8.2	Conditions of exhalation	6.10.2	Conditions of exhalation	The requirement for back pressure is deleted here and included in 7.1.9 mouthpieces
5.10	Disturbances and other influence quantities	6.11	Disturbances and physiological influence substances	

R 126:2012 (E)		R 126:2021 (E)		
Ref.	**Description**	**Ref.**	**Description**	**Remarks**
5.10.1	Disturbances	6.11.1	Disturbances	Combined into one text
5.10.1.3	Application			
5.10.1.1	During the following disturbances		Table 3 - Disturbances to which EBAs shall be immune during exposure and while in operation	Changes in Table 3: Radiated RF-EM fields: range extended to 6 000 MHz New: surges on mains supply lines New: ripple on DC mains power port Mains supply voltage dips, interruptions, variations: *For AC*: changed layout (amplitude instead of reduction in the voltage, but requirements are the same *New:* also required for DC Surges on mains supply lines: editorial: balanced/unbalanced lines are now called unsymmetrical/ symmetrical shielded Electrical transient conduction along supply lines from the on-board: updated test levels New: Electrical transient conduction via lines other than supply lines
5.10.1.2	And after the following disturbances		Table 4 - Disturbances to which EBAs shall be immune after exposure	Changes in Table 4: Mechanical shocks: number of falls reduced for portable EBAs New: vibration requirement for stationary EBAs
5.10.2	Physiological influence quantities	6.11.2	Physiological influence substances Table 5 - physiological influence substances	New approach: sensitivity with individual values for the respective substances instead of a fixed limit
5.12	Presumption of compliance			Deleted

R 126:2012 (E)		R 126:2021 (E)		
Ref.	**Description**	**Ref.**	**Description**	**Remarks**
		6.11.3	Optional disturbances expected in specific environmental conditions Table 6 - Optional disturbances expected in specific environmental conditions	New subclause: optional disturbances
6	Technical requirements	7	Technical requirements	
		7.1	Basic technical requirements	New subclause to distinguish between basic and optional requirements
6.1	Presentation of the measurement result	7.1.1	Presentation of the measurement result	
6.1.1	Display	7.1.1.1	Indicating device	Requirements for the scale interval are now placed in 6.3 All indications (displays, printout, stored, transmitted data) shall show the same value for one measurement result (transferred from Ed. 2012, 6.5.1.4)
6.1.2	Availability of measurement results	7.1.1.2	Availability of measurement results	-
		7.1.1.3	Presentations when in metrological test mode	New subclause
6.2	Protection against fraud	7.1.2	Protection against fraud	Editorial corrections to clarify the paragraph
6.3	Checking operations	7.1.3	Checking operations	Second paragraph revised to a general phrase for the requirement
6.3.1	Warm-up time	7.1.4	Warm-up time Table 7 - warm-up time for different use-cases	Introduction of specific maximum warm-up times depending on the use-case type of EBA
6.3.2	Availability for measurement	7.1.5	Availability for measurement	Editorial corrections
		7.1.6	Power supply duration of internal batteries	New subclause

R 126:2012 (E)		R 126:2021 (E)		
Ref.	**Description**	**Ref.**	**Description**	**Remarks**
6.3.3	Continuity of the exhalation	7.1.7	Continuity of the exhalation	-
6.3.4	Alcohol in the upper respiratory tract	7.1.8	Alcohol in the upper respiratory tract	-
		7.1.9	Mouthpieces	New subclause to group together all the requirements for mouthpieces from Ed. 2012, 5.8.2 and 8.2
6.4	Software	7.1.10	Software	Reference to D 31 for software requirements
6.4.1	Software identification	7.1.10.1	Software identification	Identification with version number and hash function or checksum Deleted specification of the type of algorithm for the checksum
		7.1.10.2	Correctness of algorithms and functions	New subclause
6.4.2	Fraud protection	7.1.10.3	Protection of the software against fraud	-
		7.1.10.4	Detection of significant defects	New subclause derived from the requirements of D 31
		7.1.10.5	Interfaces	New subclause derived from the requirements of D 31
		7.1.10.6	Maintenance and verification of EBA software	New subclause derived from the requirements of D 31
		7.1.10.7	Software documentation	New subclause derived from the requirements of D 31
		7.2	Optional technical requirements	New subclause to enhance the structure
6.5	Durable recording of measurement results	7.2.1	Durable recording of measurement results	-

R 126:2012 (E)		R 126:2021 (E)		
Ref.	**Description**	**Ref.**	**Description**	**Remarks**
6.5.1	Printing device	7.2.1.1	Printing device	Deleted sentence about printing devices not under legal control Deleted sentence about pre-printed units of measurement Extended list of information on the printout Printout shall not differ from the indication is transferred to 7.1.1.1
6.5.2	Storage of data	7.2.1.2	Storage and transmission of data	Subclause extended to include transmission of data Definition of a minimum storage capacity Restrictions for the deletion of stored data Requirements for the protection of transmitted data
6.5.3	Automatic storing			
		7.2.2	Redundancy	New subclauses for an optional configuration of an EBA
		7.2.2.1	Configuration of the measuring instrument	
		7.2.2.2	Measurement results	
8	Operating instructions	8	Operating instructions	
8.1	Instruction manual	8.1	Instruction manual	Manual shall also include instructions regarding the use of mouthpieces
8.2	Additional instructions	8.2	Additional instructions	Requirements regarding the use of mouthpieces are moved from here
		9	Inscriptions and sealing	
7	Inscriptions	9.1	Inscriptions	Inscriptions for measuring range and ambient temperature are allowed to be written only in the instruction manual if the size of the EBA is not sufficient
9	Sealing	9.2	Sealing	Deleted sentences about air filters
		Annex A	Comparison table of R 126:2021 to Edition 2012	New subclause

R 126:2012 (E)		R 126:2021 (E)		
Ref.	**Description**	**Ref.**	**Description**	**Remarks**
Annex D	Bibliography	Annex B	Bibliography (Informative)	

Annex B
Bibliography (Informative)

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

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

IEC Publications: http://www.iec.ch/searchpub/cur_fut.htm

ISO Publications: http://www.iso.org

OIML Publications: https://www.oiml.org/en/publications/ (free download of PDF files).

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

Ref.	Standards and reference documents	Description
[1]	OIML V 1:2013 International Vocabulary of Terms in Legal Metrology (VIML)	The VIML includes only the concepts used in the field of legal metrology. These concepts concern the activities of the legal metrology service, the relevant documents, as well as other problems linked with this activity. Also included in this Vocabulary are certain concepts of a general character which have been drawn from the VIM.
[2]	OIML V 2-200:2012 International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM), 3rd Edition	Vocabulary, developed by the Joint Committee for Guides in Metrology (JCGM).
[3]	OIML D 9:2004 Principles of metrological supervision	
[4]	OIML D 11:2013 General requirements for measuring instruments – Environmental conditions	Guidance for establishing appropriate metrological performance testing requirements for influence quantities that may affect measuring instruments.
[5]	OIML D 31:2019 General requirements for software-controlled measuring instruments - Consolidated edition with Amendment 1 (2020)	General requirements for software-controlled measuring instruments.
[6]	OIML G 1-100:2008 Evaluation of measurement data -Guide to the expression of Uncertainty in Measurement	Evaluation of measurement data - Guide to the expression of uncertainty in measurement.

[7]	OIML G 1-104:2009 Evaluation of measurement data – An introduction to the „Guide to the expression of Uncertainty" and related documents	This Guide introduces measurement uncertainty, the GUM, and the GUM Supplements and other documents that support the GUM. It is directed predominantly at the measurement of quantities that can be characterised by continuous variables such as length, temperature, time, and amount of substance.
[8]	IEC 60068-2-1:2007 Environmental testing - Part 2-1: Tests - Test A: Cold	Deals with cold tests applicable to both non heat-dissipating and heat-dissipating specimens. The object of the cold test is limited to the determination of the ability of components, equipment or other articles to be used, transported or stored at low temperature.
[9]	IEC 60068-2-2:2007 Environmental testing - Part 2-2: Tests - Test B: Dry heat	Deals with dry heat tests applicable both to heat-dissipating and non heat-dissipating specimens. The object of the dry heat test is limited to the determination of the ability of components, equipment or other articles to be used, transported or stored at high temperature.
[10]	IEC 60068-2-11:1981 Basic environmental testing procedures - Part 2-11: Tests - Test Ka: Salt mist	Compares resistance to deterioration from salt mist between specimens of similar construction. May be used to evaluate the quality and the uniformity of protective coatings.
[11]	IEC 60068-2-18:2017 Environmental testing - Part 2-18: Tests - Test R and guidance: Water	Provides methods of test applicable to products which, during transportation, storage or in service, can be subjected to falling water drops, impacting water, immersion or high pressure water impact.
[12]	IEC 60068-2-30:2005 Environmental testing - Part 2-30: Tests - Test Db: Damp heat, cyclic (12 h + 12 h cycle)	Determines the suitability of components, equipment or other articles for use, transportation and storage under conditions of high humidity - combined with cyclic temperature changes and producing condensation on the surface of the specimen.
[13]	IEC 60068-2-31:2008 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	Deals with a test procedure for simulating the effects of rough handling shocks, primarily in equipment-type specimens, the effects of knocks, jolts and falls which may be received during repair work or rough handling in operational use.
[14]	IEC 60068-2-47:2005 Environmental testing - Part 2-47: Test - Mounting of specimens for vibration, impact and similar dynamic tests	Provides methods for mounting products, whether packaged or unpackaged, as well as mounting requirements for equipment and other articles, for the series of dynamic tests
[15]	IEC 60068-2-64:2008 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	Demonstrates the adequacy of specimens to resist dynamic loads without unacceptable degradation of its functional and/or structural integrity when subjected to the specified random vibration test requirements.

[16]	IEC 60068-2-78:2012 Environmental testing – Part 2-78: Tests – Test Cab: Damp heat, steady state	Establishes a test method for determining the ability of components or equipment to withstand transportation, storage and use under conditions of high humidity.
[17]	IEC 60512-11-8:1995 Electromechanical components for electronic equipment - Basic testing procedures and measuring methods - Part 11: Climatic tests - Section 8: Test 11h - Sand and dust	Defines a standard test method to assess the ability of a connector to withstand driving fine sand and dust.
[18]	IEC 60529:1989+AMD1:1999+AMD2:2013 Degrees of protection provided by enclosures (IP Code)	Applies to the classification of degrees of protection provided by enclosures for electrical equipment with a rated voltage not exceeding 72.5 kV.
[19]	IEC 60654-2:1979 +AMD1:1992 Operating conditions for industrial-process measurement and control equipment. Part 2: Power	Gives the limiting values for power received by land-based and offshore industrial process measurement and control systems or parts of systems during operation. Maintenance and repair conditions are not considered
[20]	IEC 60721-2-5:1991 Classification of environmental conditions - Part 2: Environmental conditions appearing in nature - Section 5: Dust, sand, salt mist	Presents characteristics of dust, sand and salt mist appearing in nature, and describes the influences from these environmental factors to which products are liable to be exposed during storage, transportation and use.
[21]	IEC TR 61000-4-1:2016 Electromagnetic compatibility (EMC) - Part 4-1: Testing and measurement techniques - Overview of IEC 61000-4 series	Gives information and guidance on the EMC basic standards and other basic EMC documents published in the IEC 61000-4 series.
[22]	IEC 61000-4-2:2008 Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	Relates to the immunity requirements and test methods for electrical and electronic equipment subjected to static electricity discharges, from operators directly, and from personnel to adjacent objects.
[23]	IEC 61000-4-3:2006 +AMD1:2007+AMD2:2010 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	Is applicable to the immunity requirements of electrical and electronic equipment to radiated electromagnetic energy. It establishes test levels and the required test procedures.

[24]	IEC 61000-4-4:2012 Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test	Relates to the immunity of electrical and electronic equipment to repetitive electrical fast transients. It gives immunity requirements and test procedures related to electrical fast transients/bursts.
[25]	IEC 61000-4-5:2014+AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test	Relates to the immunity requirements, test methods, and range of recommended test levels for equipment with regard to unidirectional surges caused by over-voltages from switching and lightning transients.
[26]	IEC 61000-4-6:2013 Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	Relates to the conducted immunity requirements of electrical and electronic equipment to electromagnetic disturbances coming from intended radio-frequency (RF) transmitters in the frequency range 150 kHz up to 80 MHz.
[27]	IEC 61000-4-11:2004+AMD1:2017 Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	Defines the immunity test methods and range of preferred test levels for electrical and electronic equipment connected to low-voltage power supply networks for voltage dips, short interruptions, and voltage variations.
[28]	IEC 61000-4-17:1999 +AMD1:2001+AMD2:2008 Electromagnetic compatibility (EMC) - Part 4-17: Testing and measurement techniques - Ripple on d.c. input power port immunity test	Defines test methods for immunity to ripple at the d.c. input power port of electrical or electronic equipment. Applies to low-voltage d.c. power ports of equipment supplied by external rectifier systems, or batteries which are being charged.
[29]	IEC 61000-4-20:2010 Electromagnetic compatibility (EMC) - Part 4-20: Testing and measurement techniques - Emission and immunity testing in transverse electromagnetic (TEM) waveguides	Relates to emission and immunity test methods for electrical and electronic equipment using various types of transverse electromagnetic (TEM) waveguides.
[30]	IEC 61000-4-29:2000 Electromagnetic compatibility (EMC) - Part 4-29: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations on d.c. input power port immunity tests	Establishes a common and reproducible basis for testing electrical and electronic equipment when subjected to voltage dips, short interruptions or voltage variations on d.c. power ports.
[31]	IEC 61000-6-1:2016 Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments	Applies to electrical and electronic equipment intended for use in residential, commercial, public and light-industrial locations. Immunity requirements in the frequency range 0 Hz to 400 GHz are covered.

[32]	IEC 61000-6-2:2016 Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments	Applies to electrical and electronic equipment intended for use in industrial locations, as described below. Immunity requirements in the frequency range 0 Hz to 400 GHz are covered.
[33]	ISO 7637-2:2011 Road vehicles — Electrical disturbances from conduction and coupling — Part 2: Electrical transient conduction along supply lines only	Specifies test methods and procedures to ensure the compatibility to conducted electrical transients of equipment installed on passenger cars and commercial vehicles fitted with 12 V or 24 V electrical systems.
[34]	ISO 7637-3:2016 Road vehicles — Electrical disturbances from conduction and coupling — Part 3: Electrical transient transmission by capacitive and inductive coupling via lines other than supply lines	Defines bench test methods to evaluate the immunity of devices under test (DUTs) to transient pulses coupled to lines other than supply lines.
[35]	ISO 16750-2:2012 Road vehicles — Environmental conditions and testing for electrical and electronic equipment — Part 2: Electrical loads	Applies to electric and electronic systems/components for road vehicles. This part of ISO 16750 describes the potential environmental stresses and specifies tests and requirements recommended for the specific mounting location on/in the road vehicle
[36]	OIML G 19:2017 The role of measurement uncertainty in conformity assessment decisions in legal metrology	
[37]	David Grubb, Lars Lindberg: “Exhalation profile and elimination kinetics of mouth alcohol”, Blutalkohol Vol 48/2011, p. 57 - 66	