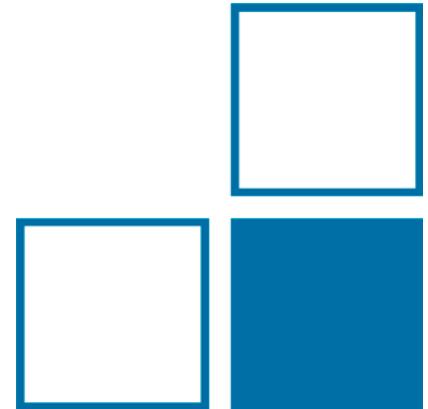


# **„Evidential“ breath alcohol analyzer**

OIML R 126 as basis for tests

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## OIML R 126 „**Evidential Breath Analyzer**“ (Edition 2012)

- Basic performance characteristics of evidential breath analysers are defined in the OIML Recommendation R 126.
- In many countries the national requirements for evidential breath analysers are equal to this recommendation.
- It covers recommendations for the verification limits as well as minimum requirements for mechanical and electrical behaviour and much more.
- The 2012-edition covers only the type approval of EBAs. Currently under revision, the next version will include detailed recommendations for test for initial and periodic verification

Requirements to an evidential breath analyzer

2 main groups of requirements:

Metrological requirements	Technical requirements
Measuring range, scale interval	Presentation and availability of the measurement result,
Maximum permissible errors, repeatability	Protection against manipulation, Prevention of misuse
Drift (zero- short-term, long-term) Memory effects	Checking operations, warm-up time
Rated operating conditions	Software (identification, protection against fraud, correctness of functions)
Physical influence factors Disturbances physiological influence factors	Continuity of exhalation, alcohol in the upper respiratory tract
Conditions of exhalation	Printer, data storage

OIML tries to define the *minimum* recommendations, but many issues have to be decided by National regulations.

In the 29012-edition, this would be explicitly:

Masking function	5.1 measuring range “... If the breath alcohol analyzer may indicate 0.00 mg/L for mass concentrations equal to or smaller than a given value defined under the responsibility of national authorities”
Interfering substances	5.10.2 Physiological influence quantities “... National regulations may require additional substances to be tested”
Verification period	5.11 Durability “... The verification period is defined under the responsibility of the National Authorities (subsequent verifications).”
Mouth rest alcohol	6.3.4 Alcohol in the upper respiratory tract “The breath alcohol analyzer <b>may</b> be equipped with a function which automatically detects whether the measurement result is affected by the presence of alcohol in the upper respiratory tracts. Examples of compliance are given in Annex A.”

# **Open to national regulations (2)**

Continuation of issues to be decided by National regulations:

Printer	6.5.1 Printing device “The breath alcohol analyzer may be fitted with a printing device under legal metrological control. In such a case, the requirements defined below apply.”
Data storage	6.5.2 Storage of data “The breath alcohol analyzer may store measurement data for further applications under legal metrological control. In such a case, the requirements defined below apply “
Electric safety	8.2 Additional instructions “The breath alcohol analyzer shall conform to relevant national regulations and standards for electrical safety and, where appropriate, for compressed gases. Verification of compliance with these regulations and standards is not within the scope of this Recommendation.”
Software validation	11.3.3 software validation procedure “... National regulations may require higher levels for the validation and examination steps.”

Issues which is not covered by OIML at all:

- Procedure of the actual measurement cycle
- The rating of the achieved result

Almost each country has its own concept of what an evidential measurement should consist:

- Number of breath samples, e.g.:  
1 blow ↔ 2 blows when first crosses a limit ↔ 2 blows ↔ more...
- Rating the result, e.g.:  
display it as it is ↔ only displayed as number over the limit ↔  
smallest result ↔ average result ↔ corrected for temperature...
- Additional checking operations: e.g.:  
relying on the prescribed internal checking operations ↔  
additional tests performed with an external standard,...

## **Definition of metrological supervision by VIML**

### **Edition 2013:**

“activity of legal metrological control to check the observance of metrology laws and regulations”

*Note 1:* Metrological supervision also includes checking the correctness of quantities indicated on and contained in prepackages.

*Note 2:* To achieve these purposes, means and methods such as market surveillance and quality management may be utilized.

### **Edition 2000:**

“Control exercised in respect of the manufacture, import, installation, use, maintenance and repair of a measuring instrument and/or in respect of its use, performed in order to check that it is used correctly as regards the observance of metrology laws and regulations.”

In general, OIML D9 “principles of metrological supervision” recommends for instruments under legal control the following steps:

- 1) Type approval  
“Decision of legal relevance, based on the evaluation report, that the type of measuring instrument complies with the respective statutory requirements and is suitable for use in the regulated area in such a way that it is expected to provide reliable measurement results over a defined period of time.”
- 2) Verification of a measuring instrument  
“Procedure (other than type approval) which includes the examination and marking and/or issuing of a verification certificate, that ascertains and confirms that the measuring instrument complies with the statutory requirements“.



In practice, this means:

- 1) Type evaluation to proof that the type of instrument fulfils the National requirements:  
→ type approval by national authorities (e.g. national type approval or recognition of a certificate of another country)
- 2) Initial verification to proof that each single instrument is correctly adjusted  
→ verification certificate by national authorities or by an accredited body/ service of the manufacturer
- 3) Periodic re-verification to proof that each single instrument still measures correctly and is not tampered  
→ verification certificate by national authorities or by an accredited body/ service of the manufacturer

Current condition of OIML R 126(E 2012) :

- For type evaluation  
detailed requirements and the respective tests are described
  
- For initial and periodic verification  
only the maximum permissible errors are described,  
but no tests are recommended nor further advice given

For type approval according to the requirements of OIML R 126(E 2012) all tests as described in part 2, chapter 11 “type evaluation approval” should be performed .

- The aim of the type approval test is to verify that the EBA in the way the manufacturer has constructed it, is able to fulfil **all** requirements and functions as it should under all possible conditions and influences. The certificate which then will be granted allows the manufacturer to sell this exact model or type to the market of the respective country.
- When the manufacturer wants to change any detail (hardware or software), he is obliged to report to the issuing authority of the certificate. The authority decides if additional tests will be necessary to allow these changes.

For initial verification, it is assumed that the general type of the instrument is already checked.

So, at this stage, the aim is check and control all instruments entering the market and that they are similar to the approved type and that they are working like they should.

### **Tests:**

- Similarity to the approved type ( software-version, housing, ports and interfaces,..)
- All adjustable quantities are correctly adjusted within the mpe (accuracy of ethanol concentration, expiration volume, ...)

### **Results:**

- Application of verification mark and protective sealing
- Issue of a verification certificate (if needed)

For periodic verification, the aim is to check that the instruments are still measuring correctly and that no tampering has happened to the instrument.

## **Tests:**

- Check of that housing and protective seals are undamaged and the software-version/ checksums are not changed
- All adjustable quantities are correctly adjusted within the mpe (accuracy of ethanol concentration, expiration volume, ...)

## **Results:**

- Replacement of the verification mark and protective sealing (if needed)
- Issue of a verification certificate (if needed)

At periodic verification, the following peculiarities could occur:

- **Maintenance in front of verification**

A commonly used procedure is to perform a maintenance of the instrument before it is given to the notified body for verification. This means:

- the protective seals might be broken
- A possible drift which might have occurred in the field will not be recognized since the instrument is already re-adjusted
- qualified documentation of the maintenance is necessary to handle it correctly

- **Tampered instrument** (e.g. change of software-version, damage of the protective seals or instrument)

- Correspondence of the tampered instrument to the type approval can't be assumed without further control
- procedure for initial verification has to be performed

For periodic verification, the following tests should be considered:

- Checking of accuracy (MPE/ linearity) of ethanol sensors:
  - at least at 3 different concentrations with at least 3 test at each concentration.
  - For each target concentration, the standard deviation shall be less than or equal to the requirements of repeatability and accuracy
  - National regulations have to define the concentrations to be tested. This could be spread to only the range close to the legal limits or even over the complete measuring range
- Checking of accuracy of other sensors  
e.g. the flow or volume sensor to ensure that the minimum volume is correctly measured ( accuracy requirements to be specified)
- Additional tests according to specific National regulations might also be performed

- OIML R 126 (E 2012) provides the basic requirements and tests for type evaluation, National regulations have to specify in detail several requirements
- For initial and periodic verification tests have to be specified completely by National regulations
- Type evaluation tests are covering all aspects of a measuring instrument and its rated conditions of use
- Tests for initial and periodic verification cover the aspects of an instrument which are adjustable and might undergo changes





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