	Technical Specification of Verification and Inspection for Breath Testers and Analyzers	S/N	CNMV 126
		Rev	4

1. These Guidelines are formulated in accordance with Paragraph 2 of Article 14 and Paragraph 2 of Article 16 of the Weights and Measurements Act.
2. The promulgation dates, document numbers, enforcement dates, and made revisions of these Guidelines are as follows:

Edition	Promulgation Date	Document No. (Ching-Piao-Szu-Tsu)	Enforcement Date	Revision
1	2003-05-16	No. 09240004760	2003-07-01	
2	2006-11-08	No. 09540004710	2006-11-08	Table 2 revised
3	2010-03-12	No. 09940001190	2010-07-01	1.Specify the intend use of breath testers and analyzers for law enforcement and pertaining classification. 2.To meet the intend use of breath testers and analyzers, for the applicants of verification asked to submit necessary documents, technical papers, and management requirements to prove breath testers and analyzers for their purposes. 3.Addition of regulation on the time required for the said devices to enter the proper function mode in order to ensure accurate measurement. 4.Addition of regulations for increased test items in verification of new and old breath testers and analyzers to ensure measurement accuracy and prevent errors. 5. Addition of regulations for specifications to be registered in breath tester and analyzer certificates; the contents of Attached Tables 1 and 2 of the original technical guidelines have been moved to Section 3.8 and Section 8.3.
4	2013-10-31	No. 10240020980	2015-01-01	1.In reference to international specification, the scope of application is not limited to the sensor component types, testing principles and names. 2.Listing the uncertainty of verification and inspection equipments for alcohol gas concentration exhaled shall not be greater than 1/3 of Maximum Permissible Errors. 3.Listing the requirements of ambient temperature effect testing reports of alcohol breath analyzers conducted by domestic laboratories or foreign laboratories. 4.The memory and residual verification shall be performed for the re-verification for electro-chemical measuring principles and other measuring principles breath testers and analyzer. Additionally, referring to the recommendation issued by OIML and considering of the different measurement principles, to add the items of verification for physiological influence quantities. 5.Redefining the Maximum Permissible Errors of verification and the requirements of repeatability, in order to harmonize with OIML R126. 6.For the testers or analyzers verified prior to this version entering to force it will not be applied to this version until January 1, 2017.

3. This specification is formulated with reference to the following international specifications:
   OIML R126 Evidential breath analyzers（2012）

Date of Promulgation	**Bureau of Standards, Metrology and Inspection Ministry of Economic Affairs**	Date of Enforcement
2013-10-31		2015-01-01

1. Application

1.1 This technical specification applies to electro-chemical, infrared breath testers and analyzers or breath testers and analyzers with other measuring principles used for law enforcement and subject to verification and inspection.

1.2 Breath testers and analyzers are applied to measures automatically within specified error limits and displays the breath alcohol mass concentration by analyzing exhaled human breath representative of the level of the alcohol intoxication of the subject. The term “alcohol” used in this technical specification refers to the blood alcohol level in the breath only.

2. Terminology

2.1 Evidential breath tester: A breath tester is a device for measuring the alcohol mass concentration in the deep lung air and accurately measuring by digitization for law enforcement.

2.2 Evidential breath analyzer: An evidential breath analyzer is a device for measuring the alcohol mass concentration in the deep lung air and accurately measuring by digitization for law enforcement. It shall monitor the continuity of exhalation by detecting the mass concentration of alcohol existing in mouth, continuously taking breath alcohol mass concentration, flow variation (exhalation volume, exhalation duration) and overcoming ambient temperature effect to ascertain the completeness of the test.

2.3 Standby mode: The mode in which only certain circuits are energized in order to conserve power and/or prolong components life, and to attend the measuring mode more rapidly than would be possible if starting from the un-powered state.

2.4 Measuring mode: The mode in which instruments can make measurements at the rate normally expected in service and in which they shall meet the performance requirements of this specification.

2.5 Maintenance mode: Mode in which the breath alcohol analyzer can be adjusted and is subject to metrological control.

2.6 Delivered volume: Referring to an average examinee variable exhalation, use a given alcohol mass concentration air to conduct a test.

2.7 Duration of exhalation: The duration of exhalation refers to the test of maintaining long-term exhalation and without uninterrupted exhalation by a given alcohol mass concentration gas.

2.8 Duration of plateau: A test that uses a given alcohol mass concentration air to simulate the plateau status of the difference alcohol mass concentration air duration exhale process.

2.9 Drift: The change in the indication which occurs during a stated period of time at a given alcohol mass concentration in air.

2.10 Memory and residual (Memory effect): The difference between the indications obtained with two inputs of gas of a given alcohol mass concentration, a gas of a specified higher mass concentration being injected between these two inputs.

2.11 Ambient Temperature effect: Referring to the degree of influence on the ambient temperature that using specified mass concentration of breath alcohol at high and low temperature respectively to realize the influence of the temperature to the evidential alcohol analyzer..

2.12 Physiological influence quantities: Referring to the use of the testing gas of physiological influence substance with known concentration to test the d physiological influence quantities of alcohol breath testers and analyzers affected by interfering substance. .

3. General requirements

3.1 The following documents shall be submitted when first time applying for initial verification for each model:

(1) Documents to identify for law enforcement use.

(2) User manual and product specifications (including operation instructions in which the electrical specifications, instrument classification, measurement procedures, tolerated error range, calibration approaches, applicable range of temperature, complete product structure diagram and related technical information of the breath tester or analyzer.)

(3) For alcohol breath analyzers, the ambient temperature effect test report conducted by domestic laboratories or foreign laboratories shall be submitted:

i. Domestic laboratories' test report: The breath analyzer shall be placed in a constant temperature cabinet at 23℃ for 2 hours with power on-mode before conducting temperature effect testing. When conducting testing at low temperature, the lower-rate of temperature shall be less than 1℃/min to 0℃ and lasting for 2 hours. Then use wet alcohol gases with 0.250mg/L concentration to implement the accuracy and repeatability verification as Section 7.2. Heating the temperature with heating-rate less than 1℃/min to 40℃ for high-temperature test. Conduct verification according to the before-mentioned conditions and the result of ambient effect verification shall meet the Maximum permissible errors of verification.

ii. Foreign laboratories' test report: Comply with the recommended specification of OIML R126 and shall cover the temperature range from 0℃to 40℃.

3.2 Under no circumstance can a breath tester or analyzer be changed the test mode to affect its accuracy by using software or hardware after passing verification.

3.3 All breath testers and evidential breath analyzers presented for initial verification shall be equipped with the function of print out:

(1) The printing data shall include the test date, test time, number of tests, model, serial number, test results and unit.

(2) The printed result shall be same as the value showed on the indication device.

3.4 When submitting a breath tester and evidential breath analyzer for initial verification or re-verification after changing the sensor component, the applicant shall commit to provide serial number and relative data of the sensor component. When the sensor component is changed, a re-verification is required.

3.5 When submitting breath testers without the function of "detecting oral alcohol content" for verification, documents of detailed function description, substitute measures, and operating procedures is required.

3.6 The owners or operators shall check their breath testers or breath analyzers while the certification remains valid are required to apply a certified dry standard gas to test the device before using the device.

3.7 Under the measuring mode, the measuring result of breath tester and analyzer shall be

rounded off to 2 decimals when the measuring result is 3 decimals.

3.8 Under the maintenance mode, when the measuring result of breath tester and analyzers is not larger than 0.050mg/L, the indication shall not indicate 0.000mg/L.

4. Verification and inspection equipment

4.1 The evaluation of the uncertainty of the verification and inspection equipment shall be completed before the verification and inspection equipment can be used and the verification and inspection equipment shall be traceable to national standards. The requirements for the equipment shall include:

(1) Moist simulator: capable of producing at least 95±5% relative humidity and moist standard alcohol mass concentration air with relative humidity at least 90% (hereinafter referred to as moist gas in short) at the temperature of 34.0℃ ± 0.5℃.

(2) Dry simulator: capable of producing dry standard alcohol mass concentration air (hereinafter referred to as dry gas in short) at the temperature of 34.0℃ ± 0.5℃.

(3) Thermometer: resolution ≦ 0.1℃.

(4) Barometer: accuracy ± 0.5kPa.

(5) Flow meter: resolution ≦ 0.1L/min.

(6) For alcohol gas concentrations used for verification, their uncertainty shall less than 1/3 of each Maximum permissible error.

5. Structure

5.1 Labeling of name of manufacturer, model number, serial number, measurement unit, and sensor serial number are required on breath testers and breath analyzers.

5.2 There shall be no mechanical damage in the external panels and casing of breath testers or breath analyzers that might affect the function and readings of instruments. All the control switches shall be easy to operate, handy-touching, well secured, and correctly positioned.。

5.3 The measurement results must be displayed in digits, and the name and symbol of the measurement unit must be indicated.

5.4 All breath testers and analyzers must be equipped with the automatic zero setting function or reset them to zero prior to activated for a new test and measurement each time.

5.5 The measurement range of all breath testers and analyzers shall be at least between 0.00 mg/L and 2.00 mg/L. The resolution of breath testers or analyzers shall be 0.01 mg/L under normal operation status. However, when under maintenance mode, the resolution shall be 0.001 mg/L.

5.6 All breath testers and analyzers shall be equipped with the function to indicate low voltage, insufficient exhalation and unsuccessful testing. In addition, breath analyzers shall be equipped with the function to detect and measure oral alcohol mass concentration, continuously read alcohol concentration from exhalation and flow variation (exhalation volume, exhalation duration).

5.7 All breath testers and analyzers must be ready for testing and measuring within 15 minutes after switching on or within 5 minutes from the standby mode switching to measurement mode.

6. Verification procedures for breath testers.

6.1 Verification shall be conducted in accordance with the following sequence:

(1) Structure.

(2) Accuracy and repeatability.

(3) Effect of delivered volume.

(4) Effect exhalation rate and injection duration.

(5) Effect of exhalation interruption.

(6) Drift.

(7) Memory and residual verification (required for initial verification, and for re-verification for electro-chemical and any other principles of measurement).

(8) Physiological influence quantities (required for initial verification and for re-verification for infrared type)

6.2 Accuracy and repeatability

6.2.1 Initial verification

First, tests with different concentrations dry gasesNo.1 to No.8 listed in Table 1 shall be implemented for 5 times respectively. Then, a test with dry gas concentration No. 9 listed in Table 1 shall be implemented. Following with tests with wet alcohol gas (relative humidity of 95%±5% without condensation) with alcohol mass concentration 0.150mg/L, 0.250mg/L and 0.550mg/L shall be implemented 5 times respectively.

6.2.2 Re-verification

First, tests with different concentrations dry gases No. 1, 3, 6, and 7 of listed in Table 1 shall be implemented for 5 times respectively. Then, a test with dry gas concentration No. 9 listed in Table 1 shall be implemented. Following with tests with wet alcohol gas (relative humidity of 95%±5% without condensation) with alcohol mass concentration 0.150mg/L, 0.250mg/L and 0.550mg/L shall be implemented 5 times respectively.

Table 1. Standard Gas concentration

Test Gas No.	Concentration (mg /L)
1	0.000~0.050
2	0.150
3	0.250
4	0.350
5	0.450
6	0.550
7	0.650
8	1.000
9	2.000

Unless specified, the test gases shall be characterized by the following parametric values:

(1) Delivered volume: 2.0±0.3 liters.

(2) Total duration of injection: 5±0.5 seconds.

(3) Exhalation Method: Fixed Rate or human body exhalation mode.

(4) Carrier gas: pure air.

(5) Gas temperature: 34.0℃ ± 0.5℃

Other gases complying with the following requirements can also be used:

(1) Proof of no effect on test results or differences to be taken into account and requiring modification.

(2) With dry gases, proof of device capacity to test and measure wet gases.

(3) If gases in containers are used, variations of atmospheric pressure and variations of the compressibility factor between filling and usage conditions shall be taken into consideration.

(4) Test reports shall indicate when dry gases were used and how their equivalence with moist gases was established.

6.3 Delivered volume verification:

Tests s with dry gas concentration No. 3 listed in Table 1 shall be implemented under each of the following test conditions for 5 times respectively. Each testing result tests shall comply with the Maximum permissible error of verification as shown in Table 2:

(1) First test condition:

i. 1.5±0.1 liters of delivered volume

ii. 5±0.5 seconds for lasting injection.

(2) Second test condition:

i. 4.5±0.3liters of delivered volume

ii. 15±0.5 seconds for lasting.

6.4 Exhalation rate and injections of duration verification:

Tests with dry gas concentration No. 3 listed in Table 1 shall be implemented under each of the following test conditions for 5times respectively. Each testing result shall comply with the Maximum Permissible errors of verification as shown in Table 2:

(1) 3±0.2 liters of delivered volume

(2) Total duration of each injection: 15±0.5 seconds.

6.5 Exhalation interruption verification:

Test with dry gas concentration No. 3 listed in Table1 shall be implemented under following test conditions. During the test, there shall be no value indicated:

(1) First Test condition:

i. Inject for 1±0.5 seconds and stop.

ii. Rate is 0.4L/s.

(2) Second Test condition:

i. At least 15 seconds for duration of injection

ii. Inject 4±1 seconds and stop.

iii. Rate is 0.2L/s.

6.6 Drift test:

Tests shall be implemented with different concentration dry gases on 0.000mg/L and 0.550mg/L dry gases for five times respectively. Four hours later, tests with different concentrations dry gases

on 0.000mg/L and 0.550 mg/L dry gases shall be re-implemented for 5 times respectively. The errors of drift shall not exceed the Maximum permissible errors of verification.

6.7 Memory and residual effect (Residual memory) verification:

(1) When implement memory and residual detection (Residual memory) verification, tests dry gas concentration No. 3 listed in Table 1 shall be implemented five times to get the average value X.

(2) Then a test shall be implemented with gas concentration No. 8 listed in Table 1.

(3) Following a test with dry gas concentration No. 3 listed in Table 1 shall be implemented. Record the test result .

(4) Repeat Steps (2) and (3) for five times and get the average value Y of the five test values of (3). The errors of the average values X and Y and the difference between X and Y shall not exceed the stipulated verification permissible errors.

6.8 Physiological influence quantities

6.8.1 Carbon Monoxide

(1) Tests with dry gas containing 0.2mg/L±5% carbon monoxide shall be implemented five times. If each testing indication is less than 0.1mg/L, it means the instrument has not been affected by interference substance, carbon monoxide, and the verification pass.

(2) If one indication exceeds 0.1mg/L without error message, it means the interfering substance, carbon monoxide, affects the instrument and the verification fails. .

(3) If one indication exceeds 0.1mg/L with error message, conduct another 5 tests with 0.04mg/L±5% carbon monoxide again. If one of the indications exceeds 0.02mg/L, it means, regardless of the indication of error message, interfering substance, carbon monoxide, affects the instrument and as the verification fails.

6.8.2 Acetone

(1) Tests with dry gas containing 0.5mg/L±5% acetone shall be implemented for five times. If each indication is below 0.1mg/L, it means the interference substance, acetone, has not affected the instrument and the verification pass.

(2) If one indication exceeds 0.1mg/L without error message, it means the interference substance, acetone, affect the instrument and the verification fails.

(3) If one indication exceeds 0.1mg/L with error message, another 5 tests with 0.1mg/L±5% acetone shall be implemented. If one of the indications exceeds 0.02mg/L, regardless of the indication of error message, it means the interference substance, acetone, affect the instrument and the verification fails.

7. Verification procedures for Alcohol Analyzers

7.1 Verification shall be conducted in accordance with the following items in sequence:

(1) Structure.

(2) Accuracy and repeatability verification.

(3) Effect of delivered volume.

(4) Continuous effect of duration of exhalation rate and injection.

(5) Exhalation injection of plateau duration effect

(6) Effect of exhalation interruption verification.

(7) Drift verification.

(8) Memory and residual verification (required for initial verification, and re-verification for electro-chemical measuring principle and other principles.)

(9) Physiological influence quantities (required for initial verification, and re-verification for infrared measuring principle.).

7.2 Accuracy and Repeatability

First, tests with different concentrations dry gases No. 1, 3, 6, and 8 of listed in Table 1 shall be implemented for 5 times respectively. Then, a test with dry gas concentration No. 9 listed in Table 1 shall be implemented. Following with tests with wet alcohol gas (relative humidity of 95%±5% without condensation) with alcohol mass concentration 0.150mg/L, 0.250mg/L and 0.550mg/L containing 5%±0.5% in volume of CO_2 shall be implemented 5 times respectively.

Unless specified, the test gases shall be characterized by the following parametric values:

(1) Delivered volume: 2.0±0.3 liters.

(2) Total duration of injection: 5±0.5 seconds.

(3) Exhalation Method: Fixed Rate

(4) Carrier gas: pure air.

(5) Gas temperature: 34.0℃ ± 0.5℃.

Other gases complying with the following requirements can also be used:

(1) Proof of no effect on test results or differences to be taken into account and requiring modification.

(2) With dry gases, proof of device capacity to test and measure wet gases.

(3) If gases in containers are used, variations of atmospheric pressure and variations of the compressibility factor between filling and usage conditions shall be taken into consideration.

(4) Test reports shall indicate when dry gases were used and how their equivalence with moist gases was established.

7.3 Delivered volume verification:

Tests s with dry gas concentration No. 3 listed in Table 1 shall be implemented under each of the following test conditions for 5 times respectively. Each testing result tests shall comply with the Maximum permissible error of verification as shown in Table 2:

(1) First test condition:

i. 1.5±0.1 liters of delivered volume

ii. 5±0.5 seconds for lasting injection.

(2) Second test condition:

i. 4.5±0.3liters of delivered volume

ii. 15±0.5 seconds for lasting.

7.4 Exhalation rate and injections of duration verification:

Tests with dry gas concentration No. 3 listed in Table 1 shall be implemented under each of the following test conditions for 5times respectively. Each testing result shall comply with the Maximum Permissible errors of verification as shown in Table 2:

(1) Test 1:

i. 1.5±0.1 liters of delivered volume

ii. Total duration of each injection: 10±0.5 seconds.

(2) Test 2:

i. 3.0±0.2 liters of delivered volume

ii. Total duration of each injection: 15±0.5 seconds.

(3) Test 3:

i. 4.5±0.3 liters of delivered volume

ii. Total duration of each injection: 7.5±0.5 seconds.

7.5 Exhalation injection of plateau duration effect

Test with dry gas concentration No. 3 listed in Table1 shall be implemented under following test conditions for 5 times respectively. Each testing result must comply with the Maximum permissible errors for accuracy as shown in Table 2:

(1) First test ondition:

i. 3±0.2 liters of delivered volume

ii. Total duration of each injection: 5±0.5 seconds

iii. Plateau duration: 3 seconds.

(2) Second test condition:

i. 3±0.2 liters of delivered volume

ii. Total duration of each injection: 5±0.5 seconds

iii. Plateau duration: 1.5 seconds.

7.6 Exhalation interruption verification:

Test with dry gas concentration No. 3 listed in Table1 shall be implemented under following test conditions.

(1) First Test condition:

i. Inject for 1±0.5 seconds and stop.

ii. Rate is 0.4L/s.

(2) Second Test condition:

i. Inject for at least 15 seconds.

ii. Inject for 6±1 seconds and stop.

iii. Rate is 0.2 L/s.

(3) Third Test condition: Exhalation verification

Injection rate reduces from 0.15 L/s to 0.03 L/s.

(4) Fourth Test condition: Short flow interruption

i. 2±0.3 liters of delivered volume

ii. Duration of injection: 5±0.5 seconds.

iii. Stop for 0.5 seconds and continue injection.

(5) During the 4 tests, there shall be no value indication.

7.7 Drift test:

Tests shall be implemented with different concentration dry gases on 0.000mg/L and 0.550mg/L dry gases for five times respectively. Four hours later, tests with different concentrations dry gases on 0.000mg/L and 0.550 mg/L dry gases shall be re-implemented for 5 times respectively. The errors of drift shall not exceed half the Maximum permissible errors of verification.

7.8 Memory and residual effect (Residual memory) verification:

(1) When implement memory and residual detection (Residual memory) verification, tests dry gas concentration No. 3 listed in Table 1 shall be implemented five times to get the average value X.

(2) Then a test shall be implemented with gas concentration No. 9 listed in Table 1.

(3) Following a test with dry gas concentration No. 3 listed in Table 1 shall be implemented. Record the test result.

(4) Repeat Steps (2) and (3) for five times and get the average value Y of the five test values of (3).

(5) The errors of the test results in step (2) and step (3) shall meet the requirement of Maximum permissible errors and the difference between X and Y shall not exceed 0.010 mg/L.

7.9 Physiological Influence Quantities

7.9.1 Carbon Monoxide

(1) Tests with dry gas containing 0.2mg/L±5% carbon monoxide shall be implemented five times. If each testing indication is less than 0.1mg/L, it means the interference substance, carbon monoxide, does not affect the instrument and the verification pass.

(2) If one indication exceeds 0.1mg/L without error message, it means the interfering substance, carbon monoxide, affects the instrument and the verification fails..

(3) If one indication exceeds 0.1mg/L with error message, conduct another 5 tests with 0.04mg/L±5% carbon monoxide again. If one of the indications exceeds 0.02mg/L, it means, regardless of the indication of error message, interfering substance, carbon monoxide, affects the instrument and as the verification fails

7.9.2 Acetone

(1) Tests with dry gas containing 0.5mg/L±5% acetone shall be implemented for five times. If each indication is below 0.1mg/L, it means the interference substance, acetone, has not affected the instrument and the verification pass.

(2) If one indication exceeds 0.1mg/L without error message, it means the interference substance, acetone, affect the instrument and the verification fails.

(3) If one indication exceeds 0.1mg/L with error message, another 5 tests with 0.1mg/L±5% acetone shall be implemented. If one of the indications exceeds 0.02mg/L, regardless of the indication of error message, it means the interference substance, acetone, affect the instrument and the verification fails.

8. The verification procedures for breath testers and analyzers shall be implemented in accordance with all or part of the verification items under this technical specification.

9. Verification and inspection tolerances

9.1 The maximum permissible errors of verification of breath testers and evidential breath analyzers shall meet the requirements in Table 2.

Table 2. Maximum permissible errors (MPE) of verification

Mass concentration (㎎/L)	MPE
Mass concentration < 0.400	±0.020 ㎎/L
0.400 ≦Mass concentration < 2.000	±5 %
2.000 ≦Mass concentration	±Mass concentration /2－0.9 mg/L

9.2 Repeatability is the sample's standard deviation calculated from the results of five continuous tests performed on different concentrations of the accuracy verification items. It is described with the standard deviation and the relative standard deviation. The standard deviation equation is shown as below:

$$SD = \sqrt{\frac{\sum_{i=1}^{n}(Yi - \overline{Y})^2}{n-1}}$$

The relative standard deviation equation is shown as below: $RSD = \frac{SD}{\overline{Y}} \times 100\%$

where

SD: standard deviation,

RSD: relative standard deviation,

N: a fixed number of tests on established concentrations,

Yi: the result value of the ith test,

$\overline{Y}$: the average value of n number of tests performed.

The standard deviations tolerated in this specification are as shown in Table 3.

Table 3. Repeatability

Mass concentration (mg/L)	Repeatability
Mass concentration < 0.400	<0.007 mg/L
0.400 ≦ Mass concentration < 2.000	<1.67 %
2.000 ≦ Mass concentration	< (Mass concentration /2－0.9 mg/L)/3

9.3 The inspection permissible errors are 1.5 times those of the verification.

9.4 The period of validity of verification is one year, commencing from the day that the verification compliance mark is attached to the first day of the month of the next third months. For breath testers or evidential breath analyzers with electro-chemical measuring or other principles, the validity are expired after being used 1,000 times even if the certificate still

remains valid.

10. For breath testers or evidential breath analyzers with other measuring principles, follow the electro-chemical specifications.

11. Verification compliance mark and certificate.

11.1 The verification compliance mark for breath testers and evidential analyzers shall be attached on the front of the device.

11.2 An official certificate shall be granted for verified breath testers and analyzers.

11.3 The said certificate shall indicate the following data:

(1) Breath testers: name and address of applicant, principles of measurement, brand, model number, instrument and sensor component serial numbers, verification certificate number, verification date, length of validity period, and other required information.

(2) Evidential breath analyzers: name and address of applicant, principles of measurement, brand, model number, instrument and sensor component serial numbers, certification certificate number, verification date, length of validity period, and other required information.

12. This version enters into effect on January 1st, 2015; however the breath testers and evidential breath analyzers having already applied and passed for initial verification prior to the implementation of this revision are still subject to be applied the version published on March 12, 2010 until December 31st, 2017.