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Standard for Breath Alcohol Instrument Specifications

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Foreword

This document was developed to provide minimum requirements for the technical capabilities of evidentiary breath alcohol instruments. This standard specifically addresses breath alcohol instruments that analyze human breath samples related to human performance investigations (e.g., driving-under-the influence of alcohol).

This document is not intended to include instruments used for preliminary (non-evidentiary), ignition interlock, or federally-regulated testing. Standards associated with those uses may be found in the Federal Register. Background information related to regulatory impacts may also be found in the 2016 Forensic Technology Center of Excellence publication "Mobile Evidential Breath Alcohol Instruments". See Annex B, the Bibliography for relevant citations.

This document was developed as part of a series for forensic breath alcohol programs and is not intended to address subject testing protocols or instrument calibration.

The American Academy of Forensic Sciences established the Academy Standards Board (ASB) in 2015 with a vision of safeguarding Justice, Integrity and Fairness through Consensus Based American National Standards. To that end, the ASB develops consensus based forensic standards within a framework accredited by the American National Standards Institute (ANSI), and provides training to support those standards. ASB values integrity, scientific rigor, openness, due process, collaboration, excellence, diversity and inclusion. ASB is dedicated to developing and making freely accessible the highest quality documentary forensic science consensus Standards, Guidelines, Best Practices, and Technical Reports in a wide range of forensic science disciplines as a service to forensic practitioners and the legal system.

This document was revised, prepared, and finalized as a standard by the Toxicology Consensus Body of the AAFS Standards Board. The draft of this standard was developed by the Forensic Toxicology Subcommittee of the Organization of Scientific Area Committees (OSAC) for Forensic Science

Questions, comments, and suggestions for the improvement of this document can be sent to AAFS-ASB Secretariat, asb@aafs.org or 401 N 21st Street, Colorado Springs, CO 80904.

All hyperlinks and web addresses shown in this document are current as of the publication date of this standard.

ASB procedures are publicly available, free of cost, at www.aafs.org/academy-standards-board.

Keywords: *alcohol, breath alcohol instrument, instrument specifications, human performance testing.*

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Standard for Breath Alcohol Instrument Specifications

1 Scope

This document defines the minimum technical capability of evidential breath alcohol instruments used in law enforcement applications. The document emphasizes analytical performance, quality assurance measures, and design features that can affect analytical performance. This standard is not intended to include instruments used for preliminary (non-evidentiary), ignition interlock, or federally-regulated testing.

2 Normative References

The following references are documents that are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ANSI/IEC 60529-2004 *Degrees of Protection Provided by Enclosures (IP Code)*[a]

CISPR 11 Ed. 6.0 b:2015 *Industrial, scientific and medical equipment, Radio-frequency disturbance characteristics - Limits and methods of measurement*[b]

Federal Communications Commission (FCC), *Code of Federal Regulations*, *Title 47,* Part 15 (47 CFR 15)[c]

IEC 61000, Part 4, *Electromagnetic Compatibility (EMC)*[d]

IEC 61000-4-2 Ed. 2.0 b:2008, *Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3 Ed. 4.0 en:2020, *Testing and measurement techniques –Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4 Ed. 3.0 b:2012, *Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61000-4-5 Ed. 3.1 b:2017, *Testing and measurement techniques – Surge immunity test*

IEC 61000-4-6 Ed. 3.0 b:2008, *Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*[d]

IEC 61000-4-8 Ed. 2.0 b:2009, *Testing and measurement techniques – Power frequency magnetic field immunity test*[d]

IEC 61000-4-11 Ed. 2.1 b:2017, *Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity test*[d]

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[a] Available from: https://webstore.ansi.org/Standards/SAI/605292004.
[b] Available from: https://webstore.ansi.org/Standards/IEC/CISPR11Ed2015
[c] Available from: https://www.fcc.gov/wireless/bureau-divisions/technologies-systems-and-innovation-division/rules-regulations-title-47
[d] Available from: https://webstore.ansi.org/Search/Find?in=1&st=IEC+61000-4.

3 Terms and Definitions

For purposes of this document, the following terms and definitions apply.

3.1
accuracy
Closeness of agreement between a measured quantity value and a true quantity value of a measurement.

3.2
bias
An estimate of systematic measurement error, calculated as the difference between the mean of several measurements under identical conditions, to a known "true" value. It is often reported as a percent difference.

3.3
calibration
Operation that, under specified conditions, in a first step, established a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with association measurement uncertainties and, in a second step, uses this information to establish a relation of obtaining a measurement result from an indication[e].

3.4
interference
A non-targeted analyte (i.e., matrix components, other volatiles) which may impact the ability to detect, identify, or quantitate a targeted analyte.

3.5
lower limit of quantitation
LLOQ
An estimate of the lowest concentration of an analyte in a sample that can be reliably measured with acceptable bias and precision.

3.6
precision
The measure of the closeness of agreement between a series of measurements obtained from multiple samplings of the same homogenous sample. It is expressed numerically as imprecision.

4 Requirements

The following instrument capabilities and specifications shall be achieved prior to use in human performance testing. Records to support conformance may be provided by the manufacturer, external providers (e.g., electrical testing facility), and/or the end user (i.e., Breath Alcohol Program).

[e] Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)* (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200).

4.1 Electrical

4.1.1 Breath alcohol instruments shall meet or exceed the standards for Electromagnetic Compatibility (EMC) and electrical safety in 4.1.2 through 4.1.3. Where not specifically defined, compatibility or immunity shall be defined as either having no change in performance when exposed to the described condition or detecting an EMC interference and restoring the device to proper operating condition.

4.1.2 This instrument shall conform to the following standards for EMC conducted and radiated emissions.

a) FCC Part 15 and IC 003 (Class A).

b) FCC 47 CFR 15 Industrial, Scientific, and Medical Equipment.

c) CISPR 11, Industrial, scientific and medical Equipment, Radio-frequency disturbance characteristics - Limits and methods of measurement.

4.1.3 This instrument shall conform to the following standard for EMC immunity.

a) IEC 61000-4 Series performance criteria is specified in Table 1.

b) Performance criteria is defined as follows.

1) **Class A** - The apparatus shall continue to operate as intended. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer when the apparatus is used as intended.

2) **Class B** - The apparatus shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer when the apparatus is used as intended. In some cases, the performance level may be replaced by a permissible loss of performance. During the test, degradation of performance is, however, allowed. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, then either of these may be derived from the product description and documentation (including leaflets and advertising) and what the user may reasonably expect from the apparatus if used as intended.

3) **Class C** - Temporary loss of function is allowed, provided the loss of function is self-recoverable or can be restored by the operation of the controls.

4.1.4 Breath alcohol instruments which are stationary or mobile electrical devices (not solely battery operated), shall comply with the requirements of commercial products category of one or more of the following safety standards groups:

a) Underwriters Laboratory (UL),

b) Canadian Standards Association (CSA),

c) Conformité Européene (CE),

d) Electrical Testing Laboratories (ETL).

Table 1—Electrical Performance Criteria

Category	Standard	Criteria Class (A-C)
Electrostatic Discharge (ESD) 1 ns rise time, 30 ns pulse width Air: 20 times Contact: 20 times	IEC/EN 61000-4-2	C
Radiated Electromagnetic Field Immunity Freq: 26-3000 MHz Amplitude: 10 v/m AM Modulated: 80% at 1kHz	IEC/EN 61000-4-3	A
Electrical Fast Transient (EFT) Immunity 5 ns rise, 50 ns pw at 5kHz rep rate A/C power cable: ±2kV Peripherals: ±1 kV	IEC/EN 61000-4-4	B
Surge Voltage Immunity Differential: ±2 kV Common mode: ±1 kV	IEC/EN 61000-4-5	B
RF Conducted Immunity Frequency: 15-80 MHz Amplitude: 10 v RMS Modulation: 80% AM at 1kHz	IEC/EN 61000-4-6	B
Radiated 50Hz Magnetic Immunity Amplitude at 60Hz: 30 V/m	IEC/EN 61000-4-8	A
Voltage Dips, Interruptions and Voltage Variations Dips: 30% drop at 10 ms Interrupts: 95% loss at 5000 ms Variations: 10%	IEC /EN 61000-4-11	C C A

4.2 Environmental and Mechanical

NOTE Operation in this section means meeting the analytical requirements listed in Section 4.4 of this document.

4.2.1 Operating Temperature

4.2.1.1 Stationary instruments shall be capable of operation at ambient temperatures from 10°C to 40°C.

4.2.1.2 Mobile instruments shall be capable of operation at ambient temperatures from 0°C to 50°C.

4.2.2 Operating Barometric Pressure

Stationary and mobile instruments shall be capable of operation at ambient pressures from 500 mmHg to 780 mmHg.

4.2.3 Operating Humidity

Stationary and mobile instruments shall be capable of operation at ambient humidity of 10% to 100%.

4.2.4 Ingress

4.2.4.1 Instruments shall meet selected requirements within ANSI/IEC 60529-2004 *Degrees of Protection Provided by Enclosures (IP Code*).

4.2.4.2 Stationary instruments shall be designed with protection from the ingress of foreign liquids and solids meeting or exceeding a rating of IP 41 where:

a) ingress of solid objects larger than 1 mm is prevented;

b) vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.

4.2.4.3 Mobile instruments shall be designed with protection from the ingress of water and dust meeting or exceeding a rating of IP 51 where:

a) ingress of dust is not entirely prevented, but it shall not enter in sufficient quantity to interfere with the satisfactory operation of the equipment, complete protection against contact;

b) vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position.

4.3 Breath Samples and Reference Standards

4.3.1 Instruments shall provide a route for breath samples either directly into the analytical component(s) or via a breath tube heated to prevent condensation which could adversely affect analysis.

4.3.2 Instruments shall provide a route for either aqueous (wet) simulator ethanol standards, compressed (dry) gas ethanol standards, or both, to be analyzed by the same components as a breath sample. This route may be via the breath tube, directly into the analytical component(s), or via a sample tube.

4.3.2.1 If using a wet bath simulator, the path shall be either heated or short and direct enough to prevent condensation which could adversely affect analysis.

4.3.2.2 If using compressed gas ethanol standards, the instrument shall be able to account for variations in atmospheric pressure. The instrument shall be capable of monitoring ambient pressure and making the appropriate adjustments.

4.3.2.3 If the instrument technology requires a wet/dry offset for use of compressed gas standards, the correction may be made in instrument software or as a correction to the compressed gas standard. The manufacturer should provide information to the Breath Alcohol Program related to the process utilized (if any).

4.4 Analytical Specifications

4.4.1 Bias and Precision

4.4.1.1 The instrument shall be capable of measuring a known traceable standard (e.g., aqueous solution or compressed gas) within an accuracy range of ± 5% or 0.005 g/210 L, whichever is greater.

4.4.1.2 Bias shall be calculated using all replicates at each concentration analyzed in the calibration method with the applicable formula:

$$Bias\ (\%)\ at\ Concentration = \left[\frac{Mean\ of\ Measured\ Conc - Known\ Concentration}{Known\ Concentration}\right] * 100 \quad (1)$$

or

$$Bias\ (g/210\ L)\ at\ Concentration = Mean\ of\ Measured\ Concentration - Known\ Concentration \quad (2)$$

4.4.1.3 Precision is expressed as the coefficient of variation (%CV). The mean and standard deviation (*std dev)* of the response is calculated using all replicates at each concentration analyzed in the calibration method to determine the %CV. Calculate with the following formula:

$$\%CV = \frac{std\ dev}{mean\ response}\ x\ 100 \quad (3)$$

The %CV shall not exceed ±10% CV

4.4.2 Lower Limit of Quantitation

For the lower limit of quantitation (LLOQ) testing, the instrument shall be capable of accurately measuring known traceable standards (e.g., aqueous solution or compressed gas) at 0.02 g/210 L.

4.4.3 Measurement Range and Linearity

At a minimum, the instrument shall be capable of accurately measuring known traceable standards (e.g., aqueous solution or compressed gas) across the range of 0.02 through 0.40 g/210 L.

4.4.4 Physiological Interference

4.4.4.1 At a minimum, the instrument shall either:

a) have a maximum variation of 0.01 g/210 L from a known traceable ethanol standard when combined with any concentration of acetone, methanol, or isopropanol; or

b) have a maximum result of 0.01 g/210 L when sampling any concentration of acetone, methanol, or isopropanol; or

c) detect the presence of the interferent and notify the operator (e.g., stop the test) accordingly when sampling a concentration of acetone, methanol, or isopropanol, with or without a known concentration of ethanol.

4.4.5 Robustness and Ruggedness

4.4.5.1 The instrument shall be capable of accurately testing in varying ambient conditions relevant to the Breath Alcohol Program (e.g., temperature changes, pressure changes) and be rugged enough to not be affected by changes in location as outlined in 4.2.

4.4.5.2 The instrument shall be capable of retaining performance criteria after transport or shipping.

4.4.6 Calculations

4.4.6.1 The instrument shall be able to display and/or report ethanol concentrations up to three (3) decimal places.

4.4.6.2 Final breath tests results, if derived from measured or calculated values with more significant digits, shall be truncated.

4.4.7 Breath Sample Acceptance

4.4.7.1 The instrument shall be capable of making a determination of breath sample acceptance criteria and automatically evaluate a breath sample.

4.4.7.2 The instrument shall be capable of using a minimum breath volume criteria in the determination of sample acceptance. A breath sample minimum volume shall not be less than 1.1 L.

4.4.7.3 The instrument shall be capable of detecting an anomaly in the delivered breath sample as could be indicative of alcohol originating in the mouth or upper respiratory tract.

4.4.8 Changes to the Computer System

Any software/firmware changes that impact the analytical process shall be tested to ensure conformance with this section. Software/firmware changes that may affect analytical processes would include changes to linearity, physiological interference, precision, or bias.

4.4.9 Prior Versions of Computer Systems

Current software/firmware that was validated prior to the promulgation of this document shall demonstrate and document that the software/firmware is fit-for-purpose under this standard.

4.4.10 Summary of Analytical Requirements

Specifications are summarized in Table 2.

Table 2—Summary of Analytical Requirements

Parameter	Minimum Specifications
Bias	Shall not exceed ±5%, or ±0.005 g/210 L, whichever is greater
Interference	No interfering signal from matrix or common volatiles. See Annex A
LLOQ	0.02 g/210 L
Measurement Range	0.02 - 0.40 g/210 L
Precision	%CV shall not exceed ±10%
Robustness and Ruggedness	Day-to-day variations shall not affect the calibration or accuracy per specifications in Section 4.2

4.5 Quality Control

4.5.1 Hardware and Software Integrity

4.5.1.1 The evidential breath alcohol instrument shall have a unique serial number, visible on the outside of the instrument, and stored electronically.

4.5.1.2 The evidential breath alcohol instrument shall be designed with self-diagnostic features, including means to monitor hardware and software integrity throughout the test sequence. If the instrument identifies a condition with hardware or software outside of expected thresholds, it shall abort the test and identify the issue.

4.5.2 Analytical Integrity

The evidential breath alcohol instrument shall be designed with features to monitor the test environment and the quality of samples provided and identify such conditions which could affect a result and inform the operator.

4.5.3 Automation of Quality Control (QC) Test Sequences

4.5.3.1 The evidential breath alcohol instrument shall be designed with a means for manual or automated quality control checks with ethanol reference materials.

4.5.3.2 The evidential breath alcohol instrument shall be designed with the capability of enforcing an interval-based quality control check, notification, or lockout.

4.5.4 Reference Materials

4.5.4.1 The evidential breath alcohol instrument shall be designed with the capability of using either compressed gas or aqueous simulator reference materials (or both) as defined in 4.3.

4.5.4.2 The evidential breath alcohol instrument shall be designed with the capability of entering reference material information, such as lot numbers and expiration dates, to be stored as part of test records.

4.6 User Interface

4.6.1 Input

4.6.1.1 The evidential breath alcohol instrument shall be designed to allow the user to input relevant test data, including but not limited to:

a) subject identification,

b) operator identification,

c) test location,

d) other information required by jurisdiction.

4.6.1.2 Date and time of test shall be recorded by the instrument as part of the test record.

4.6.1.3 Any data entry peripheral device that the manufacturer provides with the instrument, such as keyboards or card readers, shall be designed to not negatively impact results.

4.6.1.4 The evidential breath alcohol instrument shall be designed with the capability for the user to control access to performing breath tests and quality control tests.

4.6.2 Output

4.6.2.1 The evidential breath instrument shall be designed with the capability for the user to access the last date of calibration (display and/or print).

4.6.2.2 The instrument shall print or print and display the measured results from tests and calibrations.

4.6.2.3 The instrument shall be capable of displaying and/or printing the results/outcome or status (e.g., pass/fail).

4.6.2.4 The instrument display shall be clear and legible in all appropriate levels of lighting. For instruments designed for mobile or outdoor testing, this includes direct sunlight as well as darkness.

4.6.2.5 The instrument shall be capable of printing a test record which includes:

a) serial number of the instrument;

b) date and time of the test;

c) location of the test;

d) identification of the subjects;

e) identification of the operator;

f) results of each sequence event;

g) status messages where applicable (e.g., Refusal, Insufficient Sample);

h) space for signature of the operator and/or subject where required.

4.6.2.6 The printed and displayed results shall not differ from that recorded by the instrument at the time of the test.

4.6.2.7 The instrument shall be capable of reporting an additional value known as a "final breath test result" (however named), which may be a reduced, truncated, or averaged result derived from raw measured samples. The raw measured results shall be retained.

4.6.2.8 Instrument printouts shall be legible for at least six (6) months from the time of printing, when stored within the manufacturers' recommended environmental conditions.

4.7 Security

4.7.1 Access to the menus of an evidential breath alcohol instrument shall be protected, by passwords or similar means. The instrument shall be capable of different levels of access depending on the user (e.g., operator, technician).

4.7.2 The evidential breath alcohol instrument shall be designed with features to protect the identification of ethanol reference materials used.

4.7.3 The instrument and the software shall ensure the protection of data. A method shall be utilized by the instrument to ensure software integrity (e.g., check sum or cyclic redundancy check).

4.7.4 The instrument software shall be identified by a version identifier. Revisions to the software shall require a new version identifier to be issued. The software identifier shall be available to the operator by display, printing, or both.

4.8 Memory

4.8.1 Storage of Evidential Breath Test Data

4.8.1.1 The evidential breath alcohol instrument shall allow the review and editing of data entry fields prior to recording the test sequence.

Note Data entry fields may include, but are not limited to, subject name, jurisdiction, gender, and personally identifiable data. These fields are specific to the Breath Alcohol Program and are contained within the program.

4.8.1.2 The instrument shall be capable of storing all data entered by the operator and assigning a unique sequential test number to the record.

4.8.1.3 After data confirmation and assignment of a sequential test number (if required), the instrument shall retain this record.

4.8.1.4 The instrument shall be capable of identifying a loss of power during a test sequence and identify the interrupted test record as such.

4.8.2 Minimum Test Storage

4.8.2.1 The instrument shall be capable of electronically storing evidential breath tests, independent of any other procedures.

4.8.2.2 The instrument shall be capable of storing test records in a FIFO (First-In, First-Out) convention or otherwise prevent initiation of further breath tests if memory is full.

4.8.2.3 All test data shall be stored in power-independent, non-volatile memory [e.g., electrically erasable programmable read-only memory (EEPROM)].

4.8.3 On-Site Recovery/Reprint of Tests

The instrument shall be capable of reprinting previously performed tests, as long as the test data are still residing in the instrument's memory.

4.8.4 Data Integrity

4.8.4.1 The instrument shall be capable of protecting the stored data by either preventing extraction of records without the use of a secure software application, and/or storing data in an advanced encryption format, such as Advanced Encryption Standard (AES) with a key length of ≥ 128 bits.

4.8.4.2 When transmitting test records to an external database management system or other software application, the instrument shall be able to transmit all stored data in an advanced encryption format, such as AES with a key length of ≥ 128 bits.

4.8.4.3 When transmitting or exporting test records, the instrument shall verify every data transmission to a server, depository or external memory drive by means of checksum validation or similar before the data can be automatically deleted from the instrument.

4.8.4.4 If the instrument is capable of being controlled by offsite remote access, the instrument shall have measures to prevent unauthorized persons from obtaining access.

Annex A
(informative)

Example Test Plan for the Evaluation of Physiological Interference[f]

A.1 Example Test Plan for the Evaluation of Physiological Interferences

A.1.1 Standards Used:

Either compressed gas or aqueous mixtures as defined in Table A.1.

A.1.2 Test Procedure:

a) Perform 5 replicates of a breath test, verification, or metrological type test with each of the mixtures listed.

b) Verify each sample does not exceed the maximum variation or maximum result provided in Table A.1, or provides a signal indicating the presence of an interfering substance.

Table A.1—Interfering Substances Sensitivity Criteria

Aqueous Mixture (vapor concentration)	**Compressed Gas Composition**	**Max Variation** (to known traceable standard)
0.080 g/210 L Ethanol + 0.060 g/210 L of Acetone	208 ppm Ethanol, 124.1 ppm Acetone, Nitrogen Balance	0.010 g/210 L or interference flag, test aborted
0.080 g/210 L Ethanol + 0.010 g/210 L of Isopropanol	208 ppm Ethanol, 20.1 ppm Isopropanol, Nitrogen Balance	0.010 g/210 L or interference flag, test aborted
0.080 g/210 L Ethanol + 0.010 g/210 L of Methanol	208 ppm Ethanol, 37.8 ppm Methanol, Nitrogen Balance	0.010 g/210 L or interference flag, test aborted
Interferent	**Compressed Gas Composition**	**Max Result**
0.060 g/210 L of Acetone	124.1 ppm Acetone, Nitrogen Balance	0.010 g/210 L or interference flag, test aborted
0.010 g/210 L of Isopropanol	20.1 ppm Isopropanol, Nitrogen Balance	0.010 g/210 L or interference flag, test aborted
0.010 g/210 L of Methanol	37.8 ppm Methanol, Nitrogen Balance	0.010 g/210 L or interference flag, test aborted

[f] This is an example of a method to determine the extent of physiological interference.

Annex B
(informative)

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