

CMI INC.
316 East Ninth Street
Owensboro, KY 42303
866-835-0690
www.alcoholtest.com

March 7, 2012

Letter of Self-Certification

CMI, Inc., the manufacturer of evidential breath alcohol testing devices, certifies that it meets the requirements according to the U.S. Food and Drug Administration's (FDA) Good Manufacturing Practices regulations for devices used for medical purposes as outlined in 21 CFR Part 820. Furthermore, the Intoxilyzer 9000 is labeled in accordance with the labeling requirements in FDA's Labeling regulations for devices used for medical purposes under 21 CFR Part 809.10.

Sincerely,



Brian T. Faulkner
Manager of Engineering
CMI, Inc.

RESULTS OF CONFORMANCE TESTING OF
EVIDENTIAL
BREATH ALCOHOL TESTING DEVICES

July, 2012

ED CONDE

PREPARED FOR

U. S. DEPARTMENT OF TRANSPORTATION
NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION
OFFICE OF IMPAIRED DRIVING and OCCUPANT PROTECTION

and

OFFICE OF BEHAVIORAL SAFETY RESEARCH
WASHINGTON, DC 20590

The Department of Transportation Volpe National Transportation Systems Center carried out the testing.

The Model Specifications do not address optional features of breath testers that do not bear on precision and accuracy. The specifications do not address quality control matters, which are considered to be the responsibility of the manufacturer for delivering, and the user for accepting, defect free equipment. The user has the additional responsibility for monitoring the quality of the breath test program in which the device is used so that the device can be removed from service when performance is not at the required level.

The tests were:

1. Precision and accuracy at 0.020, 0.040, 0.080, and 0.160 BrAC. A test at 0.300 BrAC was also performed for information to potential users but there is no performance requirement for this additional test.
2. Acetone interference.
3. Blank reading.
4. Breath Sampling efficiency at delivery rates of 0.2, 0.33, and 0.5 liters per second.
5. Power at 108 and 123 AC volts and 11 and 15 DC volts.
6. Precision and accuracy at low and high ambient temperatures for devices to be used in mobile applications. Additional tests at 10 degrees and 35 degrees Centigrade were performed since this device may be used outside of protected environments.
7. Precision and accuracy after vibration.
8. An inspection for electrical safety was performed.

The instrument tested was the CMI, Inc. Intoxilyzer 9000. The Intoxilyzer 9000 is manufactured by CMI, Inc., 316 E. 9th Street, Owensboro, KY 42303. Phone: (800) 835-0690.

The device is a bench-top Evidential Breath Tester that is intended for use in stationary or mobile operations. This device uses an infrared (IR) sensor to measure ethanol concentration. The Intoxilyzer 9000 can be powered by either 110 volts AC or 12 volts DC.

The device conformed to the requirements of the Model Specifications. The test data are given in the table below.

The Model Specifications are appended.

Intoxilyzer I9000 SN: 90-000113

6/26/2012

Test	1	2	3	4	5	6	7	8	9	10	Mean	SD	SE	Pass
[target BAC indicated in brackets]														
1. Precision and Accuracy														
{0.020}	0.019	0.021	0.020	0.020	0.020	0.021	0.021	0.021	0.021	0.022	0.021	0.0008	0.001	YES
{0.040}	0.041	0.041	0.042	0.041	0.042	0.042	0.042	0.041	0.040	0.042	0.041	0.0007	0.001	YES
{0.080}	0.084	0.083	0.083	0.081	0.083	0.081	0.083	0.084	0.081	0.081	0.082	0.0013	0.002	YES
{0.160}	0.159	0.159	0.155	0.157	0.158	0.160	0.158	0.156	0.155	0.155	0.157	0.0019	-0.003	YES
{0.300}	0.303	0.302	0.303	0.301	0.300	0.300	0.299	0.297	0.297	0.295	0.300	0.0027	0.000	YES
2. Acetone Interference														
{0.020} Low 70µL	0.021	0.022	0.020	0.021	0.021	0.019	0.021	0.021	0.020	0.023	0.021	0.0011	0.001	‡ YES
{0.020} High 115µL	0.021	0.023	0.021	0.022	0.021	0.022	0.021	0.022	0.020	0.022	0.022	0.0008	0.002	‡ YES
3. Blank Reading {0.000}														
	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.0000	0.000	YES
4. Breath Sampling {0.080}														
0.2 Liters/sec.	0.078	0.077	0.080	0.079	0.078	0.079	0.079	0.077	0.076	0.078	0.078	0.0012	-0.002	YES
0.3 Liters/sec.	0.075	0.074	0.076	0.076	0.075	0.075	0.076	0.077	0.075	0.075	0.075	0.0008	-0.005	YES
0.5 Liters/sec.	0.080	0.080	0.079	0.079	0.079	0.078	0.078	0.077	0.078	0.078	0.079	0.0010	-0.001	YES
5. Power {0.080}														
108 VAC	0.080	0.079	0.079	0.079	0.077	0.078	0.078	0.077	0.079	0.078	0.078	0.0010	-0.002	YES
123 VAC	0.081	0.080	0.080	0.079	0.079	0.079	0.078	0.079	0.079	0.079	0.079	0.0008	-0.001	YES
11 VDC	0.079	0.078	0.078	0.078	0.078	0.079	0.079	0.079	0.079	0.078	0.079	0.0005	-0.002	YES
15 VDC	0.080	0.081	0.079	0.079	0.079	0.079	0.078	0.078	0.078	0.075	0.079	0.0016	-0.001	YES
6. Temperature {0.080}														
20 deg. C	0.079	0.077	0.077	0.076	0.077	0.082	0.077	0.078	0.078	0.078	0.078	0.0017	-0.002	YES
30 deg. C	0.081	0.083	0.082	0.082	0.082	0.081	0.081	0.081	0.081	0.082	0.082	0.0007	0.002	YES
10 deg. C	0.082	0.080	0.077	0.078	0.078	0.079	0.077	0.074	0.075	0.074	0.077	0.0026	-0.003	YES
35 deg. C	0.080	0.080	0.082	0.081	0.080	0.080	0.078	0.081	0.079	0.079	0.080	0.0012	0.000	YES
7. Post Vibration {0.080}														
	0.081	0.083	0.081	0.082	0.080	0.082	0.080	0.081	0.081	0.080	0.081	0.0010	0.001	YES
8. Electrical Safety Insp.														
														YES

Units
 BAC: gm/210L Air
 SD: Standard Deviation
 SE: Syst. Error, Mean -target BAC

Requirements
 SD: 0.0042 or less
 SE: plus or minus 0.005 BAC or 5 % whichever is greater
 *No single result greater than 0.005 BAC
 **No requirement (information only)
 ***No requirement (information only for hand-held devices)
 ‡ Interferent Detected. Values detected were visual from screen.
 Print outs did not reflect a value, only Interferent Detected.

Appendix: **Federal Register** / Vol. 58, No. 179 / pp 48705-48710 / Friday, September 17, 1993

Federal Register / Vol. 58, No. 179 / pp 48705-48710 / Friday, September 17, 1993 / Notices (58 **FR** 48705)

Highway Safety Programs; Model Specifications for Devices to Measure Breath Alcohol

Agency: National Highway Traffic Safety Administration, DOT.

Action: Notice.

Summary: This notice amends the Model Specifications for evidential breath testing devices published in 1984 and updates the list of conforming products. Recent trends indicate that the states are lowering the alcohol levels that indicate drunk driving (e.g., "zero tolerance" laws for underage offenders). Moreover, these specifications address comment received in response to a Department of Transportation Notice of Proposed Rulemaking published in the **Federal Register** on December 15, 1992 (57 **FR** 59382). The Model Specifications and the Conforming Products List set forth below reflect new lower evaluation thresholds for devices to measure breath alcohol, to better reflect the range of critical measurements during actual use.

Dates: This notice becomes effective October 18, 1993.

For further information contact: Ms. Robin Mayer, Office of Alcohol and State Programs, NTS-21, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Telephone (202) 366-9825.

Supplementary information: On December 14, 1984 (49 **FR** 48854), the National Highway Traffic Safety Administration (NHTSA) issued a notice converting the mandatory standards for breath test devices (38 **FR** 30459) to Model Specifications for such devices. The Notice indicated the Agency would continue to test evidential breath testers (EBTs) and would release its findings to provide States which choose not to conduct their own testing with adequate information upon which to base their purchasing decisions.

Since publication of the Model Specifications in 1984 (49 **FR** 48855), States have been moving toward a lowering of alcohol levels which indicate drunk driving and enacting new laws targeting youthful offenders (i.e., "zero tolerance" laws).

On December 15, 1992, the U.S. Department of Transportation (DOT) published Notices of Proposed Rulemaking (NPRMs) proposing rules to implement the "Omnibus Transportation Employee Testing Act of 1991", which requires alcohol testing programs in aviation, motor carrier, rail, and mass transit industries in the interest of public safety. The Research and Special Programs Administration (RSPA) has proposed similar regulations for the pipeline industry. In general, the proposed rules would prohibit covered employees from performing safety-sensitive functions when test results indicate a breath alcohol concentration (BAC) of 0.04 or greater. Slightly different consequences would apply with respect to an employee having a BAC of 0.02 or greater but less than 0.04. If NRPMs are adopted as final rules, transportation workers in safety-sensitive positions will be tested at lower alcohol levels (commercial motor vehicle driver are already subject to DWI standards at ≥ 0.04).

DOT received comments in response to the rulemaking actions recommending that if NHTSA's Model Specifications are to be used for the transportation workplace alcohol testing programs, then the Model Specifications should be consistent with the requirements of the rules.

In light of the trend toward lowering alcohol levels and to address the comments received in response to DOT's NPRMs NHTSA has decided to revise its Model Specifications by lowering the BACs at which instruments are evaluated.

Under the earlier specifications, EBTs were evaluated for precision and accuracy at 0.000, 0.050, 0.101, and 0.151 BAC, and tests for operation of the devices at various conditions of operation were performed at 0.101 BAC. The Specifications below establish evaluations for precision and accuracy at 0.000, 0.020, 0.040, 0.080, and 0.160 BAC, and evaluations at various conditions of operation at 0.080. Tests for acetone interference will also be conducted at 0.020 BAC. NHTSA is also expanding its definition of alcohol to better reflect State laws and the capabilities of testing devices.

These revisions will assist the States and local communities by providing a centralized qualification test program for breath testing devices designed to collect evidence in law enforcement programs. The Model Specifications are not intended to replace the current qualification programs required in certain States for this equipment or to directly regulate the manufacture of EBTs. However, some States may wish to make use of this program in addition to setting their own requirements. While the agency is not imposing these Model Specifications on State and local governments, NHTSA encourages each State to consider adopting them.

Procedures

Testing of EBTs submitted by manufacturers to these model specifications will continue to be conducted by the DOT Volpe National Transportation Systems Center (VNTSC). Procedures for submitting instruments for evaluation have not changed. Tests will continue to be conducted semi-annually or as necessary. Manufacturers wishing to submit EBTs for testing must apply to NHTSA for a test date (Office of Alcohol and State Programs, NTS 21, NHTSA, 400 Seventh Street, S.W., Washington, D.C. 20590). Normally, at least 30 days will be required from the date of notification until the test can be scheduled. One week prior to the scheduled initiation of the test program, the manufacturer will deliver the device to be tested to VNTSC, DTS 75, Kendall Square, Cambridge MA 02142. The manufacturer shall be responsible for ensuring that the device is operating properly and is in proper calibration. If the manufacturer wishes to submit a duplicate backup device, he may do so. The Operator's Manual and the Maintenance Manual will be delivered with the EBT with specifications and drawings which fully describe the device. Proprietary information will be respected. (See 49 CFR Part 512, regarding the procedure by which NHTSA will consider claims of confidentiality.)

The manufacturer will have the right to check the EBT between arrival in Cambridge and the start of the test and to ensure that the EBT is in proper calibration but will have no access to it during the tests. Any malfunction of the EBT which results in failure to complete any of the tests satisfactorily will result in a finding that it does not conform to the Model Specifications. If the EBT fails to conform, it may be resubmitted for testing.

On the basis of these results, NHTSA will continue to publish a Conforming Products List (CPL) identifying the EBTs that meet the performance criteria set forth in these Model Specification.

In anticipation of the publication of this notice and DOT's final rules to implement the Omnibus Transportation Employee Testing Act of 1991, NHTSA invited manufacturers currently known to produce EBTs to submit their instruments for evaluation utilizing these amended specifications. Instruments provided by the manufacturers have been evaluated under these Model Specifications, and this notice includes, as Appendix A, a revised CPL. This CPL identifies those instrument found to conform with the Model Specifications, as amended by this notice. It also identifies those instruments that meet the Model Specifications detailed in 49 FR 48850 (December 14, 1984).

Re-testing of instruments will continue to be conducted as necessary. NHTSA intends to modify and improve these model specifications as new data and improved test procedures become available. (The test procedures may be altered in specific instances, if necessary, to meet unique design features of an EBT.) If these model specifications are modified, notification will be provided in the Federal Register. If NHTSA determines that re-testing to the modified specification is necessary, a manufacturer whose equipment is listed on the CPL will be notified to resubmit the equipment for testing to the modified specification only. Also, if at any time a manufacturer wishes to change the design of an EBT currently on the CPL, the manufacturer shall submit the proposed changes to OASP for review. Based on this review, a determination will be made regarding whether re-testing is required. Guidance to manufacturers on considerations governing this decision is given in Appendix B.

OASP will continue to be the point of contact for information about acceptance testing and field performance of equipment already on the list. When it is available, NHTSA requests that the State and local agencies provide both acceptance and field performance data to OASP. Information from users will be used to: (1) Help NHTSA determine whether EBTs continue to perform according to the NHTSA Model Specifications and (2) ensure that field use does not indicate excessive breakdown or maintenance problems.

If information gathered indicates that an instrument on the CPL is not performing in accordance with the Model Specifications, NHTSA will direct VNTSC to conduct a special investigation. This study may include visits to users and additional tests of the instrument obtained from the open market. If the investigation indicates that the instruments actually sold on the market area not meeting the Model Specifications, then the manufacturers will be notified that the instrument may be dropped from the list. In this event the manufacturer shall have 30 days from the date of notification to reply. Based on the VNTSC investigation and any data provided by the manufacturer, NHTSA will decide whether the instrument should remain on the list. Upon resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems which led to the dropping of the instrument in question from the list.

This notice addresses comments received by DOT in response to its NPRMs on The Omnibus Transportation Employee testing Act of 1991 published in the **Federal Register** on December 15, 1992. The changes to the Model Specifications for evidential breath testers contained in this notice become effective on the date noted above. If any person believes NHTSA should reconsider the changes made in this notice, that person may submit a petition for reconsideration. The petition shall be submitted to the Administrator, National Highway Traffic Safety Administration, 400 7th Street, SW, Washington, DC 20590. It is requested, but not required, that 10 copies be submitted. The petition must be received by the date noted above and contain a brief statement of the basis for the petition. The statement may not exceed 15 pages in length, but necessary attachments may be appended to

the submission without regard to the 15 page limit. The filing of a petition will not stay the effective date of this notice.

In accordance with the foregoing, the Model Specifications for performance testing of EBTs are set forth below.

Authority: 23 U.S.C. 402, 403, 408 410; delegations of authority at 49 **CFR** 1.50 and 501.

Michael B. Brownlee,

Associate Administrator for TSP.

Model Specifications for Evidential Breath Testers

1. Purpose and Scope

These specifications establish performance criteria and methods for testing of evidential breath testers (EBT). EBTs measure the alcohol content of deep lung breath samples with sufficient accuracy for evidential purposes. These specifications are intended primarily for use in the conformance testing of EBTs.

2. Classification

2.1. Mobility

2.2.1. Mobile EBT. EBTs that are designed to be transported to non-fixed operational sites in the field.

2.1.2. Non-mobile EBT. EBTs that are designed to be operated at a fixed location.

2.2 Power Source.

2.2.1. Battery EBT. EBTs that are powered by batteries.

2.2.2. AC Powered EBT. EBTs that are powered from the AC power lines.

3. Definitions.

3.1. Alcohol. The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols including methyl or isopropyl alcohol.

3.2. BAC, BrAC. Blood alcohol concentration: grams alcohol per 100 milliliters blood or grams alcohol per 210 liters of breath by breath in accordance with the Uniform Vehicle

Code, Section 11-903(a)(5)¹. BrAC is often used to indicate that the measurement is a breath measurement. In these Model Specifications, concentration units of test samples are referred to as BAC units and are grams of alcohol per 210 liters of air.

- 3.3. Conformance Tests. Tests performed to check the compliance of a product with these specifications.
- 3.4. Standard Deviation. An indication of measurement precision of the EBT in a test, expressed as follows:

$$\text{Standard deviation} = \{\text{Sum } (X_i - X_m)^2 / (N - 1)\}^{1/2}$$

where X_i = a single measurement result

X_m = the average of the measurements

N = the number of measurements made in the test

3.5 Systematic Error. An indication of the accuracy of the EBT in a test.

$$\text{Systematic error} = \{(X_m - \text{test BAC}) / \text{test BAC}\} 100$$

3.6 Calibrating Unit (CU). A device that produces an alcohol-in-air test sample of known concentration that meets the Model Specifications for Calibrating Units (FR 48 48865).

3.7 BASS. Breath alcohol sample simulator. A device which provides an alcohol-in-air test sample with known and adjustable alcohol concentration profile, flow rate, and air composition at 34^ocentigrade (See NBS Special Publication 480-41, July 1981²², for a description of a BASS unit suitable for use in Test 4.)

4. Test Methods and Requirements.

Each of the tests below require 10 measurements to three decimal places made at 0.080 BAC or other specified BAC using the EBT being evaluated. Procedures specified by the manufacturer will be followed. Unless otherwise specified, the tests will be performed in the absence of drafts and at prevailing normal laboratory temperature, humidity, and barometric pressure. Ethyl alcohol will be used to prepare the test samples in this Model Specifications. A CU of the type which uses aqueous alcohol solutions thermostated at 34^oC and a ratio of headspace concentration of 0.000393 (see FR 48865) will be used to provide the BAC samples. The CU shall be capable of delivering 10 complete vapor samples with alcohol depletion of not more than 1%. Human breath will be used to drive the CU. (For Test 4, the BASS device will be used.) Performance requirements are indicated in square brackets. [SE=systematic error, SD=standard deviation].

¹ Available from National Committee on Uniform Traffic Laws and Ordinances, 405 Church Street, Evanston IL 60201.

² Available from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Test 1. Precision and Accuracy. Test at each of the specified BAC [$SE \leq 0.005$ BAC; $SD \leq 0.0042$].

Test 1.1: 0.020 BAC [$SE \leq 0.005$ BAC; $SD \leq 0.0042$]

Test 1.2: 0.040 BAC [$SE \leq 0.005$ BAC; $SD \leq 0.0042$]

Test 1.3: 0.080 BAC [$SE \leq 0.005$ BAC; $SD \leq 0.0042$]

Test 1.4: 0.160 BAC [$SE \leq 0.008$ BAC; $SD \leq 0.0042$]

The following test is information only for the potential users. There is no performance requirement.

Test 1.5: 0.300 BAC

Test 2. Acetone Interference. Test at 0.020 BAC with the specified amount of acetone added to the CU solution³. Replace the solution if acetone depletion is indicated during the test. [$SE \leq 0.005$ BAC; $SD \leq 0.0042$]

Test 2.1: 70 microliters acetone per 500 ml solution.

Test 2.2: 115 microliters acetone per 500 ml solution.

Test 3. Blank Reading. Test at 0.000 BAC. The tester shall use his or her own breath for this test and he or she may not consume alcohol for a period of 48 hours prior to this test nor smoke for a period of 20 minutes prior to this test. [$SE \leq 0.005$ BAC with no single result greater than 0.005 BAC]

Test 4. Breath Sampling (Alternate test in Appendix C may be used). Prepare the BASS solutions so that the BAC of each of the three segments of the simulated breath sample increases from 0.048, to 0.072, to 0.080. Use compressed breathing air to drive the samples. If the EBT is sensitive to carbon dioxide at concentrations found in human breath, the driver gas will contain this gas at that concentration. Use a spirometer to measure sample volumes and, if necessary, place the EBT in a glove box to make that measurement. Perform three tests at each of the following volume-time combinations [$SE \leq 0.005$ BAC; $SD \leq 0.0042$]:

	volume of each segment (liters)	time of each segment (seconds)
Test 4.1:	0.67	3.3
Test 4.2:	0.67	2
Test 4.3:	2	4

³ The amounts of acetone have been specified on the basis of an experimentally determined water to air partition factor of 365 to 1 at 34°C to yield a sample of acetone-in-air at concentrations of 0.3mg/l and 0.5mg/l.

Test 5. Input Power. If the EBT is powered by nominal voltages of 120 volts AC or 12 volts DC, condition the device for one half hour at the appropriate input voltage specified below, then test at that voltage. Monitor the input power with a voltmeter accurate to +2% full scale in the range used and re-adjust the voltage, if necessary. [SE \leq 0.005 BAC; SD \leq 0.0042]

Test 5.1: 108 VAC

Test 5.2: 123 VAC

Test 5.3: 11 VDC

Test 5.4: 15 VDC

Test 6. Ambient Temperature. Use a temperature chamber controllable to $\pm 1^{\circ}\text{C}$. Soak the EBT at the specified temperature for 1 hour before each test, then test at that temperature [SE \leq 0.005 BAC; SD \leq 0.0042].

Test 6.1: 20 $^{\circ}\text{C}$

Test 6.2: 30 $^{\circ}\text{C}$

The following portion of Test 6 is applicable to hand held EBT and is for information to potential users only. Soak hand-held EBT at specified temperature for one hour before each test, then test at that temperature. Operate the CU outside of the temperature chamber, if necessary, to ensure that it remains at normal operating temperature. There is no performance requirement.

Test 6.3: 10 $^{\circ}\text{C}$

Test 6.4: 35 $^{\circ}\text{C}$

Test 7. Vibration Stability. Use a programmable shake table with sufficient power to drive the weight of the EBT to be tested. Through each of its three major axes, subject the EBT to simple harmonic motion of the specified amplitude and frequency. Sweep through each frequency range in 2.5 minutes, then reverse sweep to the starting frequency in 2.5 minutes. After vibration, test the EBT. [SE \leq 0.005 BAC; SD \leq 0.0042]

frequency range (inches, peak to peak)	Amplitude	(Hertz)
10 to 30	0.030	
30 to 60	0.015	

Test 8. Electrical Safety Inspection. Examine the EBT for protection of the operator and person being tested from electrical shock. Examine for proper use of input power fuses, and verify that there are no exposed male connectors at high potential. Determine that overheating does not occur during operation and that undue fire hazards do not exist.

APPENDIX B. Guidelines for Re-testing of Modified EBT.

Manufacturers contemplating revisions to an EBT which is currently listed on the Conforming Products List are advised that the revision may effect the status of the device on the List. It may or may not be necessary to re-test the revised EBT. The manufacturer should inform NHTSA of the contemplated change so that a judgment can be made. The following lists the type of information NHTSA uses in determining the necessity to re-test an instrument, and is provided as guidance to manufacturers:

- * Manufacturer and Model Name.
- * Nature and reason for change.
- * Scope of change (e.g., will existing devices be retrofitted? Will the change apply to some users but not others?).
- * Will the change affect performance of the device as regards the Model Specifications? (Precision and accuracy, acetone interference, blank reading, linearity, sampling efficiency, low or high temperature operation, low or high input power operation, mobile operation, electrical safety)
- * Will the change alter performance with regard to the possibility of chemical or electrical interference or unusually high relative humidity?
- * How will the changes be documented for the benefit of the user? (e.g., will the changes be documented in service bulletins and/or service manuals? If not, why not?)

APPENDIX C. Alternate Breath Sampling Test.

Select eight human subjects who are in good health. Their oral temperatures prior to the start of testing shall be between 97.0°F and 99.5°F

Divide the subjects into two groups of four. The target BAC range for group 1 shall be from 0.04 to 0.10. The target BAC range for group 2 shall be from 0.10 to 0.20. In order to obtain a distribution of BACs, each subject shall be given a different amount of alcohol to drink. As a rough guide to dose vs. peak resultant BAC, and based on ingestion of a 100 proof beverage, a body weight of 160 lbs., and a 2 hour drinking period, 3 oz. of beverage should produce a BAC of 0.04; 6 oz. should produce a BAC of 0.10; and 8 oz. should produce a BAC of 0.15.

Blood samples taken shall be either from a vein in the arm or from capillaries in the finger tip. Non-alcoholic swabs shall be used to prepare the skin surface. If finger tip blood is to be taken, a 90 minute waiting period will be observed before beginning breath sample testing and if venous blood is to be taken, a 120 minute period will be observed. No subject may smoke during the 20 minute period before testing begins.

Use the EBT to measure the subject's breath, then take a blood sample, then measure the subject's breath again. Allow no more than five minutes between the taking of the first and second breath sample.

The blood samples shall be analyzed within 72 hours of being taken and at least two alcohol determinations shall be made on each sample. A reference sample of known BAC in the range 0.05 to 0.15 shall be prepared by the analyzing laboratory. Five determinations of the reference sample shall be made concurrently with the analysis of the human subject blood samples. The SD of the reference sample analysis shall not exceed 0.005 BAC and the SE shall not exceed ± 5 per cent of the known BAC.

Calculate the average blood result and the average breath result for each subject. Label each average blood result X_i ($i=1$ to 8 for each of the subjects, in ascending order of BAC). For each such result X_i , label the companion average breath result Y_i .

Calculate X_H , the average of the three highest blood results, and X_L , the three lowest. For the three highest blood results, and for the three lowest blood results, calculate the companion averages of the breath results, Y_H and Y_L .

Calculate X_M , the average of the eight blood results, and Y_M , the average of the eight breath results.

On graph paper, plot the points corresponding to (X_M, Y_M) , (X_H, Y_H) , (X_L, Y_L) , and the eight points (X_i, Y_i) .

Draw a straight line, the blood-breath correlation line, through the point (X_M, Y_M) and parallel to the line joining the points (X_L, Y_L) and (X_H, Y_H) .

At $X=0.100$ on the blood-breath correlation line, mark a point on the perpendicular at $Y=-0.020$ and another at $Y=+0.020$. Draw a line through each of these points, the negative bias and positive bias lines, parallel to the blood-breath correlation line. Requirements:

1. The value on the Y axis which corresponds to the point $X=0.100$ shall lie at or between 0.080 and 0.100.
2. At least seven of the eight averaged breath results shall lie within the area between the positive and negative bias lines



316 East Ninth Street
Owensboro, KY 42303
866-835-0690
www.alcoholtest.com

Instrument Quality Assurance Plan

Instrument Type: Intoxilyzer 9000

Revision: 1.01

Revision Date: March 7, 2012

Under the U. S. Department of Transportation workplace testing program (see 49 CFR, Part 40), transportation employers are required to test employees working in certain safety sensitive positions for alcohol under certain conditions. The DOT workplace testing program requires that breath test instrument manufacturers provide employers with this Quality Assurance Plan, which, together with the operating instructions that are provided with the Intoxilyzer 9000, will assist in assuring that breath testers are calibrated to the required degree of accuracy.

Instrument Accuracy

The accuracy of the Intoxilyzer 9000 meets DOT specifications for breath alcohol testing instruments. Accuracy at the levels of 0.020, 0.040, 0.080 and 0.160 BrAC is within ± 0.003 BrAC or $\pm 3\%$ (whichever is greater) of the actual value.

Calibration Media (Solution and Gas)

Gas: With the availability of an appropriate NIST standard, it is possible for end users to obtain ethanol gas standards with direct traceability back to NIST approved standards from CMI's approved supplier. Each lot of cylinders will be marked with batch and cylinder numbers for direct traceability with the records being kept by the gas manufacturer. Ethanol gas standards used must be included on the US Department of Transportation Conforming Products List of Calibrating Units for Breath Alcohol Tests.

Solution: With the availability of an NIST standard for aqueous ethanol solutions, it is possible for end users to produce NIST traceable aqueous ethanol solutions to be used in wet bath simulators. Failure to use approved NIST traceable solutions may invalidate the results of subsequent tests performed on an instrument that was checked with an improperly mixed solution. Simulators used in wet bath testing must be included on the US Department of Transportation Conforming Products List of Calibrating Units for Breath Alcohol Tests.



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The manufacturers of wet bath solutions should certify both the BrAC accuracy and provide the appropriate documentation for fabrication and verification.

Shelf life and operation procedures for the aqueous ethanol solutions and dry gas mixtures will be supplied by the manufacturer of these materials.

Frequency of Calibration Verifications

The allowable interval between calibration verification tests for the Intoxilyzer 9000 breath testing instrument should not exceed 30 days or 150 tests. The time period and number of tests are enforced by Cal-Guard™, an optional, proprietary software "watchdog" that will force the execution of a calibration verification test if either of the limits has been reached. The frequency of the verification tests can exceed the recommendation. Each time a calibration verification test is performed, the Cal-Guard™ timer and test counter are reset to allow another 30 days or 150 tests. With Cal-Guard™, the instrument will not allow a subject test to be performed if the minimum calibration verification test parameters are not met.

Removal From Service

The Intoxilyzer 9000 requires no fixed period for performing instrument calibration or annual maintenance. Failure to comply with preventive maintenance and inspection procedures outlined in the Users Manual may cause premature failure of the instrument. Manifestations of neglect will result in a diagnostic or calibration verification failure before test credibility is compromised.

The Intoxilyzer 9000 should be removed from service if it does not pass the self diagnostics tests or the instrument fails an external calibration verification test. The instrument will respond by printing out a diagnostic test report identifying the error.

The occurrence of a diagnostic error will prevent a subject test from being performed until an appropriate corrective action has been taken. Consult the Users Manual for more information on what course to follow.

The calibration of the Intoxilyzer 9000 may be verified with a standard whose concentration is between 0.020 and 0.110 BrAC and manufactured to a tolerance of ± 0.002 BrAC. The tolerance for acceptable calibration verification is the chosen concentration ± 0.005 BrAC as displayed by the instrument.



U.S. Department
of Transportation

National Highway
Traffic Safety
Administration

100 New Jersey Avenue, NE
Washington, DC 20355

Mr. Brian T. Faulkner
Manager of Engineering
CMI, Incorporated
316 E. 9th Street
Owensboro, KY 42303

JUL 23 2012

Dear Mr. Faulkner:

This letter confirms that CMI, Inc. **Intoxilyzer 9000** evidential breath testing device has been evaluated by the Volpe Transportation Systems Center and found to meet the model specifications for EBT devices. Enclosed is a copy of the evaluation report. The **Intoxilyzer 9000** device will be included in the next update of the Conforming Products List (CPL) for breath EBTs.


In order for this device to be used as a breath alcohol measuring instrument by workers in the U.S. Department of Transportation (USDOT) workplace testing program, a quality assurance plan (QAP) must be approved by NHTSA, as required by 49 CFR Part 40, "Procedures for Transportation Drug and Alcohol Testing Program" (59 FR 7340). The QAP requires users to calibrate your equipment following your device's instruction, and the instructions provided by the manufacturer of a calibrating unit listed on the CPL for calibrating units. We have reviewed the QAP dated March 7, 2012 for the **Intoxilyzer 9000** and are pleased to inform you that this submission has been approved.

We will place this QAP on file at NHTSA, together with a copy of this letter for interested agencies. A copy will also be provided to the USDOT Office of Drug and Alcohol Policy and Compliance for their records.

Please be advised that this office is to be notified immediately of any revisions or modifications to the device or its quality assurance plan.

If you require further assistance or have any questions regarding NHTSA's quality assurance program in relation to 49 CFR Part 40, please do not hesitate to contact me at 202-366-1694.

Sincerely,


J. De Carlo Ciccel
Program Analyst

Enclosure

CC: Jim L. Swart, OST
Edward Conde, Volpe

From: Faulkner, Brian [btfaulkner@alcoholtest.com]
Sent: Friday, March 30, 2012 9:45 PM
To: Ciccel, DeCarlo (NHTSA)
Cc: Hall, Toby; Conde, Edward (VOLPE)
Subject: RE: CMI Instruments
Attachments: 9000FDA.PDF; I-9000 QAP.pdf

Hi De Carlo,

I would like to officially submit the Intoxilyzer 9000. The Intoxilyzer 9000 is being submitted for approval to the **Evidential** Model Specification. It uses Non-dispersive Infrared technology to quantify ethanol from exhaled breath. Results are reported as a numeric result in BAC units, typically in g/210L of breath. Tests are administered by inserting a disposable mouthpiece into a breath hose attached to the side of the instrument. The subject then blows into the mouthpiece. The instrument is a multi-use device, not disposable. The device's calibration can be adjusted by entering a protected software mode and delivering samples of NIST-traceable ethanol calibration solution. We recommend periodic calibration checks, these can be performed by a qualified operator as noted in the QAP. Attached are the QAP and FDA Self Certification. We will send the test data, Operator's Manual and technical drawings upon scheduling a date for testing with Volpe Labs.

Regards,

Brian Faulkner
Manager of Engineering
CMI, Inc.
316 E 9th St
Owensboro, KY 42303
Phone (270) 685 6321
Fax (270) 685 6525

Colossians 3:17: "And whatever you do in word or deed,
do all in the name of the Lord Jesus,
giving thanks to God the Father through Him."

IMPORTANT WARNING: The information in this message (and the documents attached to it, if any) is confidential and may be legally privileged. It is intended solely for the addressee. Access to this message by anyone else is unauthorized. If you are not the intended recipient, any disclosure, copying, distribution or any action taken, or omitted to be taken, in reliance on it is prohibited and may be unlawful. If you have received this message in error, please delete all electronic copies of this message (and the documents attached to it, if any), destroy any hard copies you may have created and notify me immediately by replying to this email.