



U.S. Department of Transportation  
**National Highway Traffic Safety  
Administration**



Intoximeters, Inc.  
Attn: Chris Dalton  
2081 Craig Road  
St. Louis, MO 63146

JUN 27 2017

Dear Mr. Dalton:

This letter confirms that Intoximeters, Inc. submitted the **Intox EC/IR II** breath alcohol testing device (with a new Internal Enhancement Module option fitted) to be evaluated by the Volpe Transportation Systems Center. This device was already on the Conforming Products List (CPL) for evidential breath measurement devices (EBTs). The instrument was re-tested because Intoximeters developed a new production option for the Intox EC/IR II instrument that provides the instrument with USB compatibility and Ethernet connectivity. This optional configuration of the Intox EC/IR II instrument consists of an internal subassembly which communicates with the instrument main board and supports 5 USB ports and an Ethernet port. The device, with this new option, was evaluated by Volpe and found to meet the model specifications for evidential EBTs. We will include the **Intox EC/IR II** (with an Internal Enhancement Module option fitted) in the next update of the Conforming Products List (CPL) for EBTs. Enclosed for your convenience is a copy of the test report.


In order for this device to be used as a breath alcohol measuring instrument by workers in the U.S. Department of Transportation 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 instructions, and the instructions provided by the manufacturer of a calibrating unit listed on the CPL for calibrating units. We have reviewed the Quality Assurance Plan (QAP) dated June 2017 for the **Intox EC/IR II** (with an Internal Enhancement Module option fitted) breath alcohol testing (EBT) device, submitted in response to 49 CFR Part 40, and we are pleased to inform you that this submission has been approved.

We will place the QAP on file at NHTSA, together with a copy of this letter for interested agencies. A copy will also be provided to the U.S. Department of Transportation Office of Drug and Alcohol Policy and Compliance for their records. As a reminder, only those devices that are approved by NHTSA and appear on NHTSA's CPL are authorized for use in the DOT alcohol testing program [see 49 CFR Part §§ 40.229, 40.231, 40.233, 40.235 as applicable].

Please be advised that this office is to be notified immediately of any revisions or modifications to the device or the QAP.

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 202-366-5597.

Sincerely,

A handwritten signature in black ink, appearing to read "Randolph Atkins", with a long horizontal flourish extending to the right.

Randolph Atkins, Ph.D.  
Social Science Researcher

Enclosure

CC: Patrice Kelly, OST  
Edward Conde, Volpe

**Quality Assurance Plan (QAP)**  
**Portable Intox EC/IR**  
**Intox EC/IR**  
**Intox EC/IR II**  
**Intox EC/IR II (Enhanced with serial number 10,000 or higher)**  
**Intox EC/IR II.t**

**As Required by 49 CFR Part 40.233**

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

**1. Approved Methods for Accuracy Checks and Calibrations (what type of standard is used?)**

Intoximeters, Inc. (Intoximeters) recommends that accuracy checks and calibrations be performed using a dry gas standard which has a value between .020 and .150 g/210L\* at sea level\*\* and is approved for use by both NHTSA and Intoximeters. Alternatively, wet bath simulators which have been approved for use by NHTSA and Intoximeters can be utilized with properly certified and maintained ethanol solutions. These simulator solutions should have a stated breath alcohol concentration between .020 and .150 g/210L.

Intoximeters further recommends that accuracy checks be performed with a standard which has a stated value at or near the level of interest for your alcohol testing program. *For Example: In workplace applications in the U.S., the level of interest may be .020 or .040 g/210L in order to meet the DOT procedural requirements. In some applications the level of interest may be consistent with state DUI laws, e.g., .080 g/210L.*

In all cases, the dry gas standards, simulators and simulator solutions should be used and maintained only in accordance with the quality assurance plans provided by their respective manufacturers in order to ensure that they produce consistent and reliable samples. Instruction for use of these standards with the instrument can be found in the documentation provided with the instrument.

\* g/210L = grams of alcohol per 210 liters of breath

\*\* Standard atmospheric pressure at sea level equals 760 millimeters of mercury (760mm Hg).

**2. Intervals for Accuracy Checks (how often is the device checked for accuracy?)**

**Intoximeters' Recommendation for Workplace Testing**

Intoximeters suggests that accuracy checks be performed at least every 31 days to validate accuracy and to establish a performance record. If an accuracy check has not occurred within the past 31 days, Intoximeters' best practices suggest an accuracy check be run prior to running a subject test.

**Additional Suggestions for Accuracy Checks**

Intoximeters also recommends that an accuracy check be run on the instrument as soon after a positive confirmation test as is practical. While monthly accuracy checks are adequate to demonstrate the precision and accuracy of the instrument, more frequent checks will provide additional credibility for your testing program.

### **3. Acceptable Tolerances on an External Accuracy Check (what is the allowed variance on a check?)**

#### **Acceptable Tolerance**

The result of an accuracy check should not differ by more than .005 g/210L from the expected value of the standard.

When an accuracy check is run on an instrument and the displayed result differs by more than .005, as compared with the expected value of the standard gas sample, the user shall take the instrument out of service and have it recalibrated and checked for accuracy by a properly certified calibration technician before putting the instrument back into service. Reference 49 CFR Part 40.233(c).

#### **Using Dry Gas Standards**

Both weather conditions and operating at elevations other than sea level will change the absolute pressure from 760mm Hg and cause the expected value for the dry gas standard to change. It is important to account for changes in absolute pressure when performing accuracy checks and calibrations with dry gas standards. Although expected dry gas values vary with changes in atmospheric pressure, the analyzed result of a gas sample delivered must not differ by more than .005 g/210L from the *expected value* of the standard gas sample.

The instrument contains a precision pressure sensor which monitors the absolute pressure and automatically corrects the expected value of the dry gas standard for the current atmospheric pressure at that moment. **Example:** *in Santa Fe, New Mexico at 7,000 ft. elevation, given normal atmospheric conditions, using an approved dry gas standard labeled with a sea level value of .038 g/210L, the instrument will display the expected dry gas value as .029. If an accuracy check is run when the expected value of the dry gas standard is .029, the tolerance requirement is met if the accuracy check result does not differ by more than .005 g/210L from the expected (.029) value.*

The instrument may prompt the operator to enter or verify the value of the gas standard being used when performing an accuracy check or a calibration.

### **4. Inspection, Maintenance and Calibration Requirements (when is maintenance required?)**

As previously stated, the instrument must be removed from service and calibrated by an authorized technician when the displayed result of an accuracy check differs by more than .005 from the expected value of the standard gas sample.

In addition, the instrument must be taken out of service for factory maintenance if:

- after two attempts to calibrate the device, a successful accuracy check was not obtained;
- the instrument fails to maintain its calibration on three consecutive monthly accuracy checks;
- the instrument consistently takes more than two minutes to perform a breath analysis on a sample with a concentration less than .100 g/210L.

It is highly recommended that the instrument be inspected by a factory technician at least once every two years in service. Routine maintenance procedures are specified in the manuals of each instrument and must be followed in order to ensure accurate test results.