

Quality Assurance Plan (QAP) for Intoximeters Alco-Sensor® IV

Designated Methods for External Calibration (“Accuracy”) Checks and Calibrations

Intoximeters, Inc. (Intoximeters) recommends that external accuracy checks and calibrations be performed using a dry gas standard which has a stated equivalent value of .038 BrAC* +/- .002 grams per 210 liters of breath at 760mm of Hg** and is approved for use by both NHTSA and Intoximeters. Alternatively, wet bath simulators that have been approved for use by NHTSA and Intoximeters can be utilized with properly certified and maintained ethanol solutions. These solutions produce an apparent breath alcohol concentration of .040 +/- .002 grams per 210 liters of breath.

In all cases the compressed gas tanks, 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 insure 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.

Intervals for Accuracy Checks

Intoximeters Minimum Requirement for Accuracy Checks

If an accuracy check has not occurred within the past 31 days, an accuracy check must be run prior to running a subject test.

Additional Recommendations for Accuracy Checks

Intoximeters also highly recommends that an accuracy check be run on the instrument as soon after a positive confirmation test as is practical. An accuracy check that produces a result outside of the expected tolerances outlined below throws into doubt the validity of all previous breath tests since the last successful accuracy check. Performing this procedure insures that only one positive test (the last one) will be compromised if the instrument is found to be out of calibration. This procedure also allows the BAT an opportunity to retest the subject as is allowed under DOT’s rules, after a calibration and successful accuracy check have been accomplished.

Intoximeters suggests, if practical, that an accuracy check be run before the first test on each day that the instrument is used. This procedure offers additional assurances that the instrument is functioning properly especially when there is a long period during which there are no positive tests and an accuracy check would not otherwise be run according to the procedures outlined above.

Acceptable Tolerances on an External Accuracy Check

The result of an accuracy check should not differ by more than $\pm .005$ grams per 210 liters of breath of the expected value of the standard gas sample.

*Dry gas tanks shipped by Intoximeters prior to January 1, 1996 may be labeled as 105 PPM. These tanks and approved tanks shipped by other vendors should only be used up to the stated expiration date. Each of these tanks should have either an altitude conversion chart or TRUE-CAL® Device for calculating BrAC equivalent value.

**760mm of Hg equates to standard atmospheric pressure at sea level.

For wet bath simulators, the requirement is met by using simulator solution manufactured to produce an apparent breath alcohol concentration of $.040 \pm .002$ grams per 210 liters of breath.

For compressed dry gas standards, the requirement is met by using an approved compressed dry gas standard labeled with a gas value of .038 grams of alcohol per 210 liters of breath at 760mm of Hg. Although expected dry gas values change with changes in atmospheric pressure, the value of a sample gas delivered should not differ by more than $\pm .005$ grams per 210 liters of breath of the expected value of the standard gas sample.

Both weather conditions and operating at elevations other than sea level will change the absolute pressure from 760mm of Hg and cause the expected value for the dry gas standard to change. It is important to account for changes in absolute pressure when running accuracy checks and calibrations. Using an elevation table supplied with an approved compressed dry gas standard allows you to make a determination of the dry gas standard's expected value if you know the elevation at which you run the accuracy check. *Example: in Santa Fe, New Mexico at 7,000 ft. elevation, given normal atmospheric conditions, using an approved dry gas standard labeled with a gas value of .038 grams of alcohol per 210 liters of breath, the elevation table will show 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 $+ .005$ grams per 210 liters of breath of the expected (.029) value.*

Using an optional TRUE-CAL® device with a dry gas standard offers a user the ability to precisely calculate the effects of both elevation and barometric pressure changes. The TRUE-CAL device contains a precision pressure sensor which monitors the absolute pressure and automatically corrects the expected value of the dry gas standard for the current pressure at that moment. The current expected value information is available on the TRUE-CAL device by pushing the button on its face. (Make certain the TRUE-CAL device you are using is designed for the ethanol nitrogen dry gas concentration described in this QAP.)

When an accuracy check is run on an instrument and the displayed result differs by more than $+ .005$ grams of alcohol per 210 liters of breath, as compared with the expected value of the standard gas sample, the employer shall take the instrument out of service as per 49 CFR, Part 40.233(c)(3) and have it recalibrated and checked for accuracy by a properly certified calibration technician before putting the instrument back into service.

Inspection, Maintenance and Calibration Requirements

The instrument must be calibrated when the displayed result of an accuracy check differs by more than $\pm .005$ from the expected result of the standard gas sample.

The instrument must be taken out of service if:

- the instrument repeatedly fails to maintain its calibration (i.e. if after two successive 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 grams per 210 liters of breath.

It is highly recommended that the instrument be inspected by a certified 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 insure accurate test results.