THE FACTS

ABOUT WORKPLACE EVIDENTIAL

BREATH TESTER CALIBRATION

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EBT Calibration and Calibration Checks

A U.S. Department of Transportation approved handheld Evidential Breath Testing instrument (EBT) is a complex system that includes a platinum fuel cell sensor, a sampling pump, electronics, alarms, batteries and a display. When you turn the unit on you can easily see if the batteries are charged, hear if the alarms are working, and see if the display is working. But what about its measurement accuracy? EBT measurement accuracy is the purpose of instrument calibration and the subject of this article.

Calibration and Calibration Checking—Definitions

Evidential breath alcohol instrument calibration can be thought of as a two-part process that includes

- Performing a calibration; that is, adjusting the internal settings of the instrument by comparing and setting its test results to a known alcohol standard.
- instrument was calibrated correctly and is within the acceptable accuracy range.

 Both "Calibration Checking" and "Calibration" are conducted under the Department of

Transportation Regulations as set forth in 49 CFR Part 40 and as spelled out by every manufacturer of DOT approved EBT instruments in their Quality Assurance Plan (QAP). Proper calibration, according to the device QAP, ensures that the instrument will provide measurement accuracy to a standard that meets or exceeds DOT requirements. See figure 1.

The only way a user can be certain that an EBT is reading correctly is by performing a calibration check and if the unit is out of specification, performing a calibration followed by successful calibration check.

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Figure 1. Extracts from a Lifeloc Technologies Instrument QAP, (for illustration only)



Calibrations

- 1. Must be performed by a certified Calibration Technician.
- Must be done every 12 months or when the instrument fails two consecutive calibration checks.
- 3. Must be followed by a calibration check.
- Must use the most common alcohol standards for calibration including but not limited to .040, .080, and .100 BAC.



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Calibration Checks

- 1. Must utilize Dry Gas or a Wet Bath method.
- 2. Must be conducted at least once every 30 days.
- 3. Must be performed as soon as conveniently possible after a positive alcohol test.
- 4. Must be performed if the unit has undergone repair.

Another Good Reason to Calibrate

Calibration also provides insight into the condition of the electro-chemical fuel cell sensing system in the instrument. Fuel cell sensitivity, response to breath alcohol, and output, can degrade slowly over time. Contaminants such as cigarette smoke, dust, and dirt may contribute to sensor changes over long usage.

Calibration adjusts the instrument readings to account for changes due to these factors.

Calibration problems also signal that your unit is in need of manufacturer's service. Good manufacturers are fully equipped to support prompt instrument diagnosis, repair or replacement of critical components to keep your units functioning to specification for many years. Recognizing that an EBT is critical to your operations, some manufacturers also provide free rental units to keep you going during factory service.

The Calibration Process

Instrument calibration is a critical operation in most analytical processes. The quality of the test data is often directly related to the quality of the calibration standards used. For this reason the DOT maintains a Conforming Products List of Calibrating Units for Breath Alcohol Testers which lists approved manufacturers and products for the calibration and calibration check of DOT approved instruments that measure breath alcohol. Ensure that your calibration equipment and standards ultimately originate from one of these providers. The list of conforming BAC units and calibration instruments can be found here: http://www.dot.gov/ sites/dot.dev/files/docs/20121022_CPL_ Calibrating_Units.pdf

There are two methods of calibrating a handheld EBT, the Wet Bath and the Dry Gas² method. Each method requires specialized equipment and trained technicians.

The Wet Bath method utilizes an alcohol/water standard in a precise alcohol concentration, contained and delivered in specialized simulator equipment. Wet bath apparatus has a higher initial cost than Dry Gas, requires a live power source, and is not intended to be portable. The alcohol/water standard must be fresh and replaced regularly. The Wet Bath method is more widely used by law enforcement than in workplace testing, and is therefore not covered in this article.

The Dry Gas method utilizes a gas regulator and a portable National Institute of Standards and Technology (NIST) traceable calibration standard, which is a precise mixture of ethanol and inert nitrogen in a pressurized canister. Initial equipment costs are less than with wet bath and the steps required are fewer. Dry Gas calibration equipment is very portable allowing calibrations to be done when and where required.

Who Can Perform Equipment Calibrations?

Calibrating Evidential Breath Testing instruments is not a procedure that can be conducted by untrained users. Only properly qualified individuals called "Calibration Technicians" may perform EBT calibrations. A calibration performed by an unqualified technician may be considered invalid causing an entire testing program to be called into question.

The U.S. Department of Transportation (DOT) requires that an individual who conducts valid breath alcohol testing undergo "Breath Alcohol Technician" (BAT) qualification. While BAT qualification includes the fundamentals of proficiency on the instrument being used, it is a common misconception that BAT training authorizes the BAT to perform equipment calibrations. It does not.

EBT calibration qualification is distinct from BAT proficiency qualification.

For the convenience of students and instructors, Calibration Technician qualifica-

tion is often conducted in conjunction with BAT proficiency training. However, BATs are not automatically trained as Calibration Technicians. Separate qualification is required. It is recommended that Calibration Technicians be available whenever testing is being performed in case a situation requiring calibration arises. This is why most BATs also become Calibration Technicians.

Some organizations, such as hospitals, may choose to qualify different personnel as Breath Alcohol Technicians and Calibration Technicians. In these cases the Calibration Technician role may be filled by a lab technician who is very experienced with instrument calibration.

Verify that your Calibration Technician qualification instruction is provided by an authorized representative of the instrument's manufacturer.

Calibration Technician training is instrument specific. Training must not be performed on a different make and model than the one the Calibration Technician will be responsible for calibrating. If multiple makes and models of EBTs are used in an operation, there needs to be a Calibration Technician qualified on each type of device. When organizing Calibration Technician training, ensure that your instructor is officially authorized by the manufacturer

for the specific instrument with which you are working. Failure to do so can result in test results being disqualified. The best way to be certain is to contact your instrument manufacturer before your training.

Confirm your Dry Gas Standard

It is crucial to confirm that the Dry Gas standard to which your instrument is set matches the standard listed on the Dry Gas cylinder being used and is adjusted appropriately for altitude. If set incorrectly, your calibration check and tests results will be inaccurate. Most devices will store a standard once it is set, but it is a best practice to verify before every calibration and/or calibration check.



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Figure 2: A common 34 Liter NIST traceable Dry Gas Cylinder and Regulator.



Effects of Altitude on Dry Gas Standards

Changes in atmospheric pressure explain why water boils at 212°F at sea level but only 202°F in Denver.

Atmospheric pressure change also explains why Dry Gas standards must be adjusted for altitude. Neither the stove nor the Breathalyzer behave differently in Denver than at sea level. However, since the Dry Gas standard used for calibration is manufactured to give the correct ethanol vapor concentration and pressure at sea level, correction factors are required when the instrument is calibrated at higher altitudes.

Users will be familiar with Altitude Correction Charts found on Dry Gas cylinder labels that correct gas standards for the effects of altitude. These charts provide correction factors in 500 foot increments. An easier and more accurate method is to use EBTs equipped with on-board barometric pressure sensors, which automatically

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adjust calibration standards based on the actual atmospheric pressure at the elevation of calibration.

The **QAP**

A Quality Assurance Plan (QAP) regulates equipment operation and training when used in evidential workplace testing. A QAP is issued by each manufacturer for their model of device and is approved by National Highway Traffic Safety Administration (NHTSA) before the device is added to the Conforming Products List (CPL) as an Evidential Breath Testing device. Both the instrument manufacturer and the user have responsibilities outlined in the QAP.

Manufacturers QAP Responsibilities

- 1. The manufacturer must specify the methods used to perform external calibration checks on the EBT, the tolerances within which the EBT is regarded as being in proper calibration, and the intervals at which these checks must be performed. In designating these intervals, the QAP must take into account factors like frequency of use, environmental conditions (e.g., temperature, humidity, altitude) and type of operation (e.g., stationary or mobile).
- 2. The QAP must also specify the inspection, maintenance, and calibration requirements and intervals for the EBT.
- The manufacturer must include, with each EBT, instructions for its use and care consistent with the QAP.

User/Service Agent/Employer QAP Responsibilities

 Users must follow the manufacturer's instructions including performance of external calibration checks at the intervals the instructions specify. If the Cal Check result is within the acceptable tolerance defined in the QAP for that device, the EBT is considered accurate. If the result is outside of the acceptable

- tolerance, the EBT is not providing accurate readings and must be calibrated.
- In conducting external calibration checks, users must use only calibration devices appearing on NHTSA's CPL for "Calibrating Units for Breath Alcohol Tests."
- 3. If an EBT fails an external check of calibration, users must take the EBT out of service immediately and may not use the EBT again for DOT alcohol testing until it passes an external calibration check.
- Users must maintain records of the inspection, maintenance, and calibration of EBTs.
- Users must ensure that the inspection, maintenance, and calibration of the EBT is performed by its manufacturer or a maintenance representative certified either by the manufacturer or by a state health agency or other appropriate state agency.

Record keeping is an important user responsibility. Under DOT regulations, inspection, maintenance and calibration records of EBTs must be kept for a minimum of two years. Federal Motor Carrier Safety Administration (FMCSA) requires 5-year record retention. Calibration Log Books are available for record keeping. Information may be handwritten but best practice is to retain and sign the actual calibration and calibration check printouts.

How Often Do I Calibrate My Instruments?

Calibration and cal checks are required for all EBTs. The DOT Regulations for calibration checks and calibrations are very clear. Every EBT has a manufacturer supplied, and DOT approved, Quality Assurance Program (QAP) which spells out the device specific requirements for both the manufacturer and the users. QAPs are not identical across all makes and models of instruments because the steps required (and with some units, the tools required) to properly calibrate devices differ by manufacturer. Differences between makes

and models of EBTs also reinforce why Calibration Technician qualification is device specific and must only be performed by the manufacturer or their authorized representatives. Best practice is to follow the frequency of calibration requirement as outlined in your instrument's QAP.

Calibration versus a Calibration Check after a positive confirmation test

It is recommended by most manufacturers that a calibration check be performed after a positive confirmation test of .020 BAC or greater. A positive test does fluster some BATs and they may inadvertently perform a calibration after a positive confirmation

rather than the cal check. Since a calibration basically "resets" the device this makes it difficult to prove that the device was within its accuracy range when the positive test result was received.³ Make sure you thoroughly understand the difference between a check and a calibration: a calibration sets the measurement of your instrument to a known standard such as .038, .040, .100 etc. while a calibration check compares the measurement of your device to the standard.

A calibration check is always required after a calibration

A calibration check is always required after a calibration and before the device can be returned to service. The result of a calibration check (assuming it is within the manufacturer's acceptable range) provides the technician with a numerical value and must be recorded in the Calibration Log.

What to do after a failed calibration check?

Refer to your instrument's QAP, which will give guidance on how to proceed. In many cases, the QAP will advise you to perform a calibration. Failed calibration checks should be included in your log book as well as the follow-up action.

Is using expired gas OK?

Never. This is one of the most common and worst calibration mistakes users

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can make. Calibration gas cylinders are always identified with an expiration date. Your expiration date may pass before your cylinder is completely used. Always have a procedure in place to ensure you check and replace your Dry Gas before it expires and you are left without a calibration gas. Checking the date just as you confirm the standard every time you use the cylinder is a best practice.

I found a good deal on 34-Liter calibration gas on EBay. Should I buy it?

Most likely not. All calibration gas manufacturers attach an expiration date to their cylinders. Your eBay Dry Gas cylinder may have never been used but it may also be expired or well along the path to expiration. Always check expiration dates when using and receiving a calibration gas cylinder. Always get your calibration gas from a reputable supplier who you know to have Hazmat certified shipping personnel.

Can I carry Dry Gas onto a plane or transport it with checked luggage?

No. Dry Gas falls under Hazmat rules and regulations which require any employee who is physically responsible for packaging and shipping Dry Gas to be Hazmat certified. Companies are not Hazmat certified,

Figure 3: A Dry Gas cylinder recycling tool. Safely and easily remove the cylinder valve stem and open the cylinder contents to the atmosphere allowing the empty cylinder to be recycled.



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individuals are. Hazmat rules and regulations are another good reason to purchase your Dry Gas from a reputable supplier who complies with Hazmat regulations (for more information on Hazmat regulations see http://www.phmsa.dot.gov/hazmat/regs).

Is it Damaging or Dangerous if a Dry Gas cylinder is left in the car overnight during the summer or winter?

Dry Gas is safe to handle and use with proper care. The DOT does not provide for Calibration Technician review and study of The Material Safety Data Sheet (MSDS) for Dry Gas. The MSDS covers a broad range of important safety information and procedures including "Hazard Identification", "Handling and Use" and "First-Aid Measures." The MSDS should be included with every canister of gas received. A best practice is to retain MSDS sheets in all locations where Dry Gas is used including in instrument travel cases. Anyone in your business who is responsible for Dry Gas handling and use, should ensure they have have reviewed the MSDS.

Dry Gas cylinders are pressurized and should always be handled with respect. Use safety glasses when handling cylinders under pressure. Always let your Dry Gas adjust to room temperature before use and use in a well-ventilated area. Extreme cold or hot will modify the alcohol level in the vapor exiting a Dry Gas cylinder. For this reason, cylinders should be allowed to come to room temperature prior to use.

In extreme cold situations it is possible for ethanol in a Dry Gas cylinder to condense inside the tank. While not dangerous this could cause lower than expected BAC readings on the instrument. High heat will raise the pressure inside the cylinder causing the tank to automatically vent gas. A rule of thumb is that you can expect a 1 psi increase per 10°F in temperature increase. So a standard 500 psi 34L Dry Gas tank left in a car at 130°F will experience about a 6 psi increase

in pressure. In order to prevent extreme pressure build-up, Dry Gas cylinders are manufactured to automatically vent gas at pressures well below that needed to raise cylinder pressure to dangerous levels.

The risk of storing Dry Gas cylinders in a hot car is not that the tank will burst, it is that the cylinder will have a shorter life as it is likely to automatically vent gas at elevated temperatures. Most cylinder labels will state the following: "Do not use or store near heat or open flame. Exposure to temperatures above $125 \, ^{\circ} \, F \, (51.6 \, ^{\circ} \, C)$ may cause contents to vent or cause bursting."

What exactly does NIST traceable mean and is it important?

The National Institute of Standards (NIST) is a U.S. government organization that is the official keeper of calibration. They hold the highest level of measurement accuracy in the United States. "Traceability" can be defined as an unbroken record of documentation or an unbroken chain of measurement from the user through the supply chain back to NIST. The elements comprising NIST traceability are:

- An unbroken chain. The instrument's calibrated indications must be able to be traced along an unbroken chain to NIST.
- Measurement uncertainty. The measurement uncertainty for each step in the traceability chain must be calculated or estimated. Therefore, the overall uncertainty for the whole chain can be calculated or estimated.
- Documentation. Each link in the chain must be performed according to previously documented and agreed upon procedures.
- 4. The intervals of calibration. Calibrations must occur at regularly repeated intervals.

Traceability is implemented via date and lot codes on your gas cylinder. This traceability has proven its worth in past recall situations where each level of the supply chain can help its customers identify and

remove a product. It is a best practice for your gas supplier to keep a record of lot codes and to whom the products were sold.

What is a Certificate of Analysis (COA)?

The COA is a document that also provides evidence of traceability back through the supply chain to the NIST certification of the gas concentration in your cylinder. This document should be readily available from your gas provider and can be useful in the event instrument calibration or gas standard accuracy is challenged.

How do I dispose of Dry Gas cylinders?

As specified by DOT regulations, a disposable (non-refillable) compressed gas

cylinder is a container that must not be refilled and transported more than once. Cylinders of this type are always marked "DOT-39" on the bottom or shoulder of the tank. The design of non-refillable cylinders does not allow for safe multiple pressurizations of the cylinder. Federal law prohibits transportation if refilled. It is both dangerous and a serious offense to do so. These non-refillable cylinders are not hazardous when empty. Guidelines for Compressed Gas Cylinder disposal follow.

- 1. Dispose of contents in accordance with federal, state and local regulations.
- Wear safety glasses, attach an appropriate compressed gas regulator to the cylinder valve and allow any residual gas to vent slowly in an unconfined,

- well-ventilated area, exhaust hood or outside. Once you no longer hear the gas venting or the regulator reads "0" or "empty" the cylinder is empty.
- 3. Remove the regulator prior to disposal.
- 4. Render the cylinder unusable either by putting a hole in the cylinder (after the tank is completely vented) or by using a recycling tool like the one shown below to safely remove the cylinder valve from the neck of the tank. The tool will also permit residual gas to vent safely. Your gas supplier will offer specially designed tools to do this. See Figure 3.
- Dispose of the cylinder with solid waste or recycle in accordance with federal, state and local regulations. Never attempt to incinerate the cylinder.

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What does the Future Hold for EBT Calibration?

Calibration gas manufacturers continue to work at improving the logistics and options associated with cylinder disposal. Expect to see easier ways to return non-refillable cylinders to their manufacturers rather than have them end up in landfill as is common practice today. A greater range of cylinder sizes will also be forthcoming.

Manual calibration checking and calibration of EBTs is a necessity today. In other industries gas detection equipment manufacturers have developed automated calibration stations for performing routine calibrations, cal checks and automating record keeping.

Automatic calibration and calibration checking is also available with some fixed station evidential breathalyzers. In both cases routine tasks are simplified and the chances and consequences of human error are reduced. The result is better compliance and greater efficiencies to the organization.

It would seem to be only a matter of time before automation and convenience of this type comes to handheld evidential breath alcohol testers. And, as this author thinks, the sooner the better.

Endnotes

¹ Calibration Checking is also referred to as: External Calibration Check, Cal Check, Accuracy Check and Verification.

- ² Dry gas for EBT calibration is known by various trade names and descriptors. Some of these include: Calibration Gas, Ethanol in Nitrogen Breath Alcohol Standard, Ethanol Breath Standards (EBS), Dry Gas Ethanol Standard, Calibrated Dry Gas Standard, Ethanol Breath Alcohol Standard, and so on. The term DRYGAS® is a registered trademark of Cristy Corporation and has nothing to do with EBT Calibration Gas standards. Throughout this article I use the most commonly used term: dry gas.
- In some instances a calibration may be required after a failed Calibration Check—this is dependent on the manufacture's QAP.

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