

DRIVER ALCOHOL DETECTION SYSTEM FOR SAFETY (DADSS) – A STATUS UPDATE.

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ABSTRACT

The National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS) began research in February 2008 to try to find potential in-vehicle approaches to the problem of alcohol-impaired driving. Members of ACTS comprise motor vehicle manufacturers representing approximately 99 percent of light vehicle sales in the U.S. This cooperative research partnership, known as the Driver Alcohol Detection System for Safety (DADSS) Program, is exploring the feasibility, the potential benefits of, and the public policy challenges associated with a more widespread use of non-invasive technology to prevent alcohol-impaired driving. The 2008 cooperative agreement between NHTSA and ACTS for Phases I and II outlined a program of research to assess the state of detection technologies that are capable of measuring blood alcohol concentration (BAC) or Breath Alcohol Concentration (BrAC) and to support the creation and testing of prototypes and subsequent hardware that could be installed in vehicles. This paper will outline the technological approaches and program status.

INTRODUCTION

Alcohol-impaired driving (defined as driving at or above the legal limit in all states of 0.08 g/dL or 0.08 percent) is one of the primary causes of motor vehicle fatalities on U.S. roads every year and in 2011 alone resulted in almost 10,000 deaths. There are a variety of countermeasures that have been effective in reducing this excessive toll, many of which center around strong laws and visible enforcement. Separate from these successful countermeasures, the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS) began research in February 2008 aimed at identifying potential in-vehicle approaches to the problem of alcohol-impaired driving. Members of ACTS comprise motor vehicle manufacturers representing approximately 99 percent of light vehicle sales in the U.S. This cooperative research partnership, known as the Driver Alcohol Detection System for Safety (DADSS) Program, is exploring the feasibility, the potential benefits of, and the public policy challenges associated with a more widespread use of non-invasive technology to prevent alcohol-impaired driving. The 2008 cooperative agreement between NHTSA and ACTS (the “Initial Cooperative Agreement”) for Phases I and II outlined a program of research to assess the state of detection technologies that are capable of measuring blood alcohol concentration (BAC) or Breath Alcohol Concentration (BrAC) and to support the creation and testing of prototypes and subsequent hardware that could be installed in vehicles.

Since the program’s inception it has been clearly understood that for in-vehicle alcohol detection technologies to be acceptable for use among drivers, many of whom do not drink and drive, they must be seamless with the driving task, they must be non-intrusive, that is, accurate, fast, reliable, durable, and require little or no maintenance. To that end, the DADSS program is developing non-intrusive technologies that could prevent the vehicle from being driven when the device registers that the driver’s blood alcohol concentration (BAC) exceeds the legal limit (currently 0.08 percent throughout the United States).

To achieve these challenging technology goals, very stringent performance specifications are required. These specifications have been formally documented in the DADSS Performance Specifications, which provide a template to guide the overall research effort. Another important challenge will be to ensure that the driving public will accept in-vehicle alcohol detection technology once it meets the stringent criteria for in-vehicle use. A parallel effort is underway to engage the driving public in discussions about the technologies being researched so that their feedback can be incorporated into the DADSS Performance Specifications as early as possible. The challenges to meet these

requirements are considerable, but the potential life-saving benefits are significant. An analysis of NHTSA's Fatality Analysis Reporting System (FARS) estimates that if driver BACs were no greater than 0.08 percent, 7,082 of the 10,228 alcohol-impaired road user fatalities occurring in 2010 would have been prevented.

The research effort that comprised the Initial Cooperative Agreement followed a phased process. The five-year Initial Cooperative Agreement began with a comprehensive review of emerging and existing state-of-the-art technologies for alcohol detection in order to identify promising technologies. Phase I, completed in early 2011, focused on the creation of proof-of-principle prototypes. The objective of Phase I was to determine whether there were any promising technologies on the horizon. Three prototypes were delivered and tested at the DADSS laboratory that yielded promising results for two of the three technologies.

The Phase II effort, begun in late 2011 and completed in late 2013, focused on the continued research of the technology to narrow gaps in performance against the DADSS Performance Specifications and meet the DADSS Performance Specifications within the needs of an in-vehicle environment.

Phase III and subsequent phases of research – the focus of the current Cooperative Agreement – will permit further refinement of the technology and test instruments as well as basic and applied research to understand human interaction with the sensors both physiologically and ergonomically – that is how these technologies might operate in a vehicle environment. At the culmination of this Agreement will be a device or devices that will allow a determination to be made regarding whether the DADSS technologies can ultimately be commercialized. If it is determined that one or more of these technologies can be commercialized, it is currently anticipated that the private sector will engage in additional product development and integration into motor vehicles.

The purpose of this paper is to outline the technological approaches taken in developing alcohol detection hardware. These approaches are founded on a clear understanding of the processes by which alcohol is absorbed into the blood stream, distributed within the human body, and eliminated from it. Not only must technologies under consideration quickly and accurately measure BAC, but the medium through which it is measured (e.g., breath, tissue, sweat, etc.) must provide a valid and reliable estimation of actual BAC levels. Alcohol absorption, distribution, and elimination measurement is a topic about which much has been written yet some large gaps in our understanding still remain. This paper will provide an overview of what is known regarding alcohol measurement via various methods and their implications for the decisions about which technologies deserve further study. The paper also will provide an overview of the current performance specifications developed to assess the in-vehicle advanced alcohol detection technologies and the rationale for them as well as an overall status of progress made to date.

ALCOHOL ABSORPTION, DISTRIBUTION, AND ELIMINATION IN HUMANS

The science of pharmacokinetics is concerned with the ways in which drugs and their metabolites are absorbed, distributed, and eliminated from the body (Jones, 2008). This is separate from pharmacodynamics which is the study of the physiological effects of drugs and their actions on the body (Buxton, 2006 see Jones paper). Ethyl alcohol or ethanol, more commonly referred to as alcohol, is only one of a family of organic compounds known as alcohols. Ethanol, referred to hereafter as alcohol, is highly soluble in the body's water, which makes up 50-60 percent of body weight. Even though alcohol is a central nervous system depressant, people perceive it as a stimulant and in the early stages it can produce feelings of euphoria (Jones, 2008). With the consumption of larger amounts of alcohol, performance and behavior can be impaired resulting in reduced coordination, loss of motor control, lack of good judgment, and at very high concentrations (greater than 0.4 g/dL) loss of consciousness and death. Figure 1 portrays schematically the pathways by which alcohol is absorbed into the blood stream, is distributed throughout the body, and eliminated from it.

After ingestion, alcohol enters the stomach where it is partially absorbed through the stomach wall (about 20 percent), and then to the small intestines where most of the absorption takes place (about 80 percent). Alcohol is then transported to the liver and on to the heart before it is distributed by the arteries throughout all body fluids and tissues. Alcohol easily passes the blood-brain barrier where it affects central nervous system functioning. The time required for reaching equilibrium depends on the blood flow to the various organs and tissues, but over time alcohol mixes completely with all the water in the body and reaches into all fluid compartments within the body.

The characteristics of alcohol's distribution and elimination can point to potential ways in which BAC can be measured. There are two mechanisms by which alcohol is eliminated from the body, metabolism and excretion. The liver is the primary organ responsible for the elimination of alcohol and it is where about 95% of ingested alcohol is metabolized. The remainder of the alcohol, about 2-5 percent, is excreted unchanged wherever water is removed from the body; through the skin in sweat, from the lungs in breath, from the eyes in tears and from the

kidneys in urine. As noted above, alcohol distributes completely into all the body's compartments so alcohol can be measured in vivo in bodily tissue.

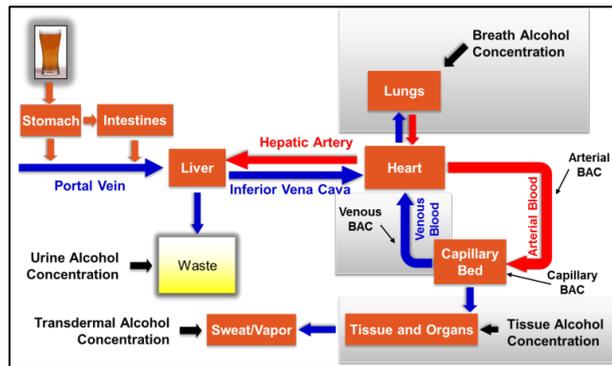


Figure 1. Alcohol absorption, distribution and elimination through the body

Methods used to measure blood alcohol concentration

For many years the only means to determine BAC was through blood and urine testing. As early as 1874 it was recognized that ingested alcohol can be measured in breath (Jones, 2008), and the smell of alcohol on breath is a well-known indication that someone has been drinking. Accurate measurement of alcohol in expired air has a physiological basis. Under normal lung function there is an efficient gas exchange between blood and gases, thus resulting in a close correlation between blood and gas concentrations of alcohol (Hök, 2006). Furthermore, a recent study (Lindberg et al., 2007) has established that the concentration of alcohol in breath is in very close agreement to that of alcohol in arterial blood (Figure 2), even though the gold standard for equating breath to blood alcohol is venous BAC. Of note is that arterial BAC is a better indication of brain alcohol and hence impairment than venous blood, so BrAC is particularly well suited as a measure of driver impairment.

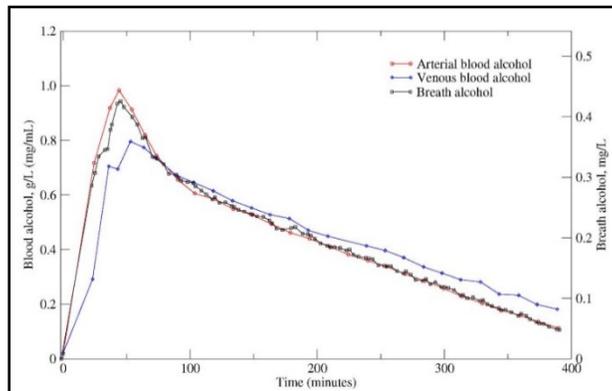


Figure 2. Pharmacokinetic profile in one subject showing concentrations of alcohol in arterial blood (ABAC), venous blood (VBAC) and breath after oral ingestion of 0.6 g of alcohol per kg body weight

Dr. Robert Borkenstein is recognized as the inventor of the first system that measured alcohol on a person's breath. In 1954, he invented the first breath testing device, which used chemical oxidation and photometry to measure alcohol concentration. Subsequently physiochemical methods were developed for the measurement of alcohol in breath such as gas chromatography, electrochemical oxidation, and infra-red analysis. Breath testing has flourished because it is non-invasive and, in contrast to urine and blood samples that have to be sent away for testing, provides on-the-spot results. As a result most countries have adopted breath testing both for roadside screening and evidential purposes to establish BAC.

In recent years a number of other approaches have been identified that could be used to measure alcohol in perspiration (either vapor phase or liquid phase) or from measurements of alcohol in a person's tissue. As noted below, these techniques have not yet been widely used to measure to measure alcohol concentration.

TECHNOLOGICAL APPROACHES

One of the first tasks of the project team was to perform a comprehensive review of emerging and existing state-of-the-art technologies for alcohol detection (Ferguson et. al., 2010). Technology scans were undertaken through patent and literature reviews. Based on these reviews four categories of technologies were identified with potential for measuring driver BAC within the vehicle environment:

1. Electrochemical/Transdermal Systems

Electrochemical Systems are chemical-reaction-based devices such as transdermal and breath-based systems. Alcohol in the presence of a reactant chemical will produce colorimetric changes measured by spectral analysis or a semi-conductor sensor. In fuel cell systems (typically used in current technology – breath-alcohol ignition interlocks), exhaled air containing alcohol passes over platinum electrodes which oxidize the alcohol and produce an electrical current; the more alcohol in the air sample, the greater the electrical current. The electrical current level permits accurate calculation of breath alcohol concentration (BrAC) which can be converted to blood alcohol concentration (BAC) using a standardized conversion factor.

2. Tissue Spectrometry Systems

Tissue Spectrometry Systems allow estimation of BAC by measuring the alcohol concentration in tissue. This is achieved through detection of light absorption at a particular wavelength from a beam of Near-Infrared (NIR) reflected from within the subject's tissue. As classified herein, they are touch-based systems and require skin contact. Variations of tissue spectrometry systems include Michelson, Raman, Fabry-Perot, Laser Diode and Light Emitting Diode (LED) based devices.

3. Distant/Offset Spectrometry Systems

Distant Spectrometry Systems use an approach that is similar to Tissue Spectrometry, except that no skin contact is required. Infrared (IR) is transmitted toward the subject from a source that also has a sensor to receive and analyze the reflected and absorbed spectrum to assess alcohol concentration in the subject's exhaled breath.

4. Behavioral Systems

Behavioral Systems detect impaired driving through objective behavioral measures. These include ocular indices such as gaze and eye movement, driving performance measures, as well as other performance measures believed to be related to driving performance.

In addition to the technology scans, a Request for Information (RFI) was published as a means by which the DADSS program was first communicated to potential technology developers. The goal of the RFI was to establish the level of interest among technology developers in taking part in the research, the kinds of technologies available, and their states of development relevant to in-vehicle applications. Based on information gleaned during the RFI process, a subset of technology companies were selected to receive a Request for Proposal. Detailed evaluation of the proposals that were received resulted in awards to technology companies based on two of the technological approaches outlined above; tissue spectroscopy and distant spectroscopy. The electrochemical/transdermal and behavioral approaches were not being pursued due their limitations for the DADSS application.

Current breath-based measurement systems as well as transdermal systems that measure alcohol in vapor or liquid phase perspiration, utilize electrochemically-based fuel-cell technology which has several limitations. Fuel cells must be warmed up to breath temperature to meet accuracy requirements, which in cold climates can take several minutes to accomplish. Furthermore, fuel cell alcohol measurements experience drift over time and require recalibration within one year or less. Both of these aspects render fuel cell technologies unsuitable for every-day use by the general public. Transdermal fuel-cell based devices suffer from the same disadvantages; however, there is an additional concern due to the long lag time of peak alcohol concentration in sweat versus blood. Various studies have identified the lag times to be on the order of two hours or more and it is not clear how future technological approaches to measuring TAC at a point in time can address this fundamental physiological difference.

Interest in behavioral-based approaches to measuring alcohol impairment dates back to the 1970s when the government and industry collaborated on possible vehicle-based measures of impairment (Ferguson et. al., 2010). There are a large number of measurable behaviors that have been identified that are affected by alcohol, including eye movements, reaction times, and vehicle-based measures of impairment such as lane position variability/lateral position, changes in driving speed and speed variability, pedal and steering control, distance from the car in front, and delay in motor actions and responses such as braking reaction times. Researchers have examined the

relationship of BAC to changes in these behaviors; however, close correlations between these measures have not yet been established. Another issue is that behavioral task performance may change as a result of a variety of impairments, whether from fatigue, illness, alcohol, medications, illegal drugs, or other sources. Furthermore, in order to measure impairment there has to be some measure of “normal” abilities on the specific task that can act as a baseline measurement for comparison. It should be noted that other sources of impairment can result in unsafe driving, and research continues to identify those risks and determine potential countermeasures. However, the limitations outlined above would be hard to deal with in an unobtrusive device to measure alcohol.

PERFORMANCE SPECIFICATIONS

ACTS developed performance specifications to assess the in-vehicle advanced alcohol detection technologies that are being developed. The specifications are designed to focus the current and future development of relevant emerging and existing advanced alcohol detection technologies (Ferguson et. al., 2010). In addition to requirements for a high level of accuracy and very fast time to measurement, the influences of environment, issues related to user acceptance, long-term reliability, and system maintenance also will be assessed. The resulting list of specifications with definitions, measurement requirements, and acceptable performance levels are documented in the DADSS Subsystem Performance Specification Document. The accuracy and speed of measurement requirements adopted by the DADSS Program are much more stringent than currently available commercial alcohol measurement technologies are capable of achieving. As noted above, the devices would need to be seamless with the driving task and not inconvenience drivers. Translating that to appropriate performance specifications was approached by estimating the potential for inconvenience if reliability, accuracy, and time to measurement were set at various levels. Presented below are the processes used to derive them.

Reliability Developing an alcohol detection device as original equipment for the vehicle environment brings with it special challenges. Reliability is defined as the ability of a system or component to perform its required functions under stated conditions for a specified period of time. Levels of reliability that are too low would result in an unacceptable number of failures to operate the vehicle. It has been estimated that at the 3σ reliability (sigma - Greek letter σ - is used to represent the standard deviation of a statistical population) there could be the potential for 66,800 defects per million opportunities, where an opportunity is defined as a chance for nonconformance. The accepted level of reliability within the industry is 6σ . The term "six sigma process" comes from the notion that with six standard deviations between the process mean and the nearest specification limit, there will be practically no items that fail to meet specifications. In practice, 6σ is equivalent to 99.9997% efficiency. Processes that operate with "six sigma quality" over the short term are assumed to produce long-term defect levels below 3.4 defects per million opportunities.

Accuracy and Precision Accuracy is defined as the degree of closeness of a measured or calculated quantity to its actual (true) value (also referred to as the Systematic Error – SE). Precision is the degree of mutual agreement among a series of individual measurements or values (also referred to as the Standard Deviation – SD). To limit the number of misclassification errors, accuracy and precision must be very high, otherwise drivers may be incorrectly classified as being over the threshold (false positives), or below the legal limit (false negatives). To assure that drivers with BACs at or above the legal limit will not be able to drive, while at the same time allowing those below the limit to drive unhindered, SE and SD requirements at a BAC of 0.08 g/dL will need to achieve levels of 0.0003%. See Table 1 for the accuracy (SE) and precision (SD) requirements at other BACs.

Table 1. DADSS Performance Specifications (% BAC or % BrAC)

Ethanol concentration	SE	SD
0.020	0.0010	0.0010
0.040	0.0010	0.0010
0.060	0.0007	0.0007
0.080	0.0003	0.0003
0.120	0.0010	0.0010

Speed of measurement Another important performance requirement is that time to measurement be very short. Sober drivers should not be inconvenienced each and every time they drive their vehicle by having to wait for the

system to function. Current breath-based alcohol measurement devices can take 30 seconds or more to provide an estimate of BAC. However, it was determined that the DADSS device should take no longer to provide a measurement than the current industry standard time taken to activate the motive power of the vehicle. Thus, the subsystem should be capable of providing a reading of the current BAC and communicating the result within 325 msec. It should be capable of providing a second reading, if necessary, within 400 msec.

THE DADSS SUBSYSTEMS

Tissue Spectrometry: Takata-TruTouch Touch-based Subsystem

Also known as near-infrared (NIR) spectrometry, this is a noninvasive approach that utilizes the near infrared region of the electromagnetic spectrum (from about 0.7 μm to 2.5 μm) to measure substances of interest in bodily tissue (Ferguson et. al., 2010). NIR spectroscopy is the science that characterizes the transfer of electromagnetic energy to vibrational energy in molecular bonds, referred to as absorption, which occurs when NIR light interacts with matter. Most molecules absorb infrared electromagnetic energy in this manner. The specific structure of a molecule dictates the energy levels, and therefore the wavelengths, at which electromagnetic energy will be transferred. As a result, the absorbance spectrum of each molecular species is unique. Better-known applications include use in medical diagnosis of blood oxygen and blood sugar, but devices have been developed more recently that can measure alcohol in tissue (Ridder et al., 2005).

Although the entire NIR spectrum spans the wavelengths from 0.7 – 2.5 μm , TruTouch has determined that the 1.25-2.5 μm portion provides the highest sensitivity and selectivity for alcohol measurement. The 0.7-1.25 μm portion of the NIR is limited by the presence of skin pigments such as melanin that can create large differences among people, particularly of different ethnicities. In contrast, the longer wavelength portion of the NIR, from 1.25-2.5 μm , is virtually unaffected by skin pigment (Anderson et al., 1981). One other advantage of using this part of the spectrum is that the alcohol signal in the 1.25-2.5 μm region is hundreds of times stronger than the signal in the 0.7-1.25 μm part of the NIR.

For the 1st generation prototype, as shown in Figure 2, the measurement begins by illuminating the user's skin with NIR light which propagates into the tissue (the skin has to be in contact with the device). A portion of the light is diffusely reflected back to the skin's surface and collected by an optical touch pad. The light contains information on the unique chemical information and tissue structure of the user. This light is analyzed to determine the alcohol concentration and, when applicable, verify the identity of the user. Because of the complex nature of tissue composition, the challenge is to measure the concentration of alcohol (sensitivity) while ignoring all the other interfering analytes or signals (selectivity).

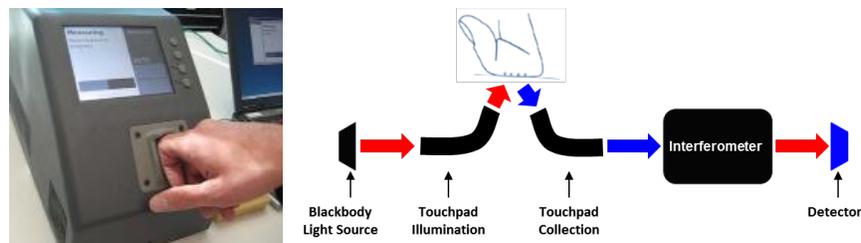


Figure 2. Touch-based subsystem 1st generation sensor and block diagram

Currently, the 2nd generation prototype is undergoing a fundamental change in system architecture; namely, a shift from a bulky spectrometer engine with moving parts to a fully solid-state sensor. This new approach, shown in Figure 3, requires extensive hardware and software research, the aims of which are to transform the touch-based sensor to improve suitability for long-term in-vehicle use and to improve the signal to noise ratio for better accuracy, precision, and shorter measurement times. The key enabling innovation is the ability to define an optimized subset of optical wavelengths which provide a high quality non-invasive alcohol measurement in humans. The 2nd generation uses modulated laser diodes to generate 40 unique wavelengths of light for alcohol measurement. The necessary laser diode target specifications were derived from an analysis of the human subject system data with accurate comparative reference data. The proposed design is also based on a Hadamard laser modulation scheme, a multiplexing technique, to improve signal to noise, along with re-design of the electronics, fiber-optical assembly, reference, touchpad and software controls to approach the necessary environmental and durability requirements for an automotive sensor device.

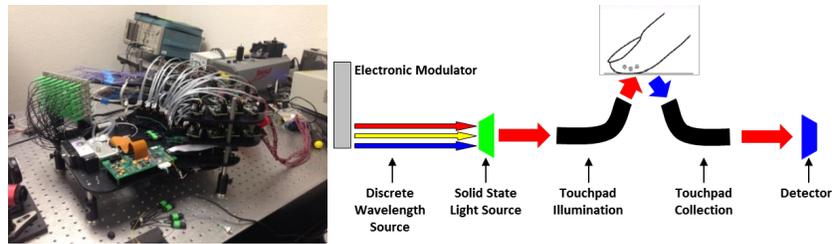


Figure 3. Touch-based subsystem 2nd generation sensor and block diagram

The focus of the current effort is to validate the new system architecture using 40 single laser packages with the goal of acquiring, verifying and integrating the full set of required multi-lasers packages into the 3rd generation benchtop system. Based on success of the 3rd generation sensor, the plan is to evolve and integrate into the DADSS research vehicle as show in Figure 4.

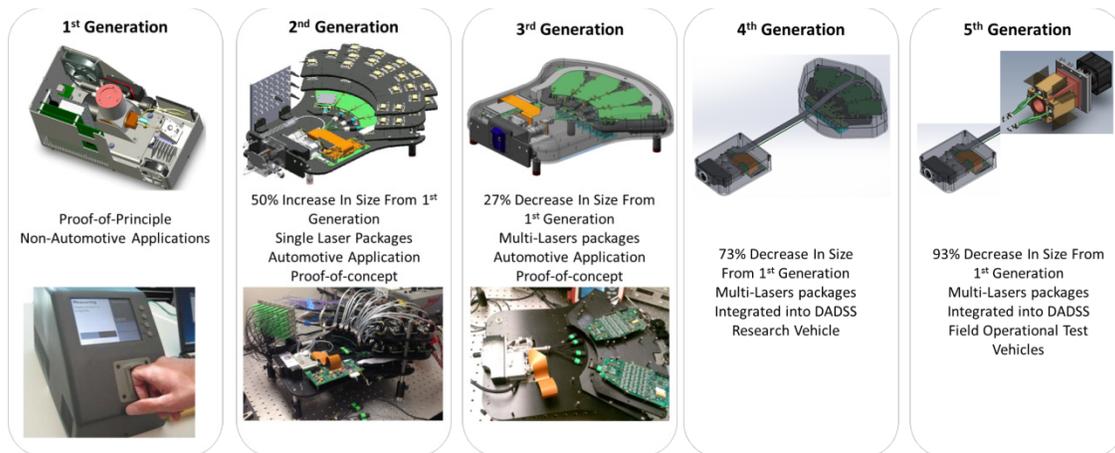


Figure 4. Evolution of solid state touch-based DADSS subsystem

Autoliv Breath-based Subsystem

Distant spectrometry systems use an approach similar to tissue spectrometry, in that they utilize the mid infrared (MIR) region of the electromagnetic spectrum (2.5-25 μm), except that no skin contact is required (Ferguson et. al., 2010). Infrared light is transmitted toward the subject from a source that receives and analyzes the reflected and absorbed spectrum to assess alcohol concentration in the subject's exhaled breath. There are a number of approaches under development that aim to remotely analyze alcohol in breath either within the vehicle cabin or around the driver's face without the driver having to provide a deep-lung breath sample.

As mentioned above, under normal lung function there is an efficient gas exchange between blood and gases, resulting in a close correlation between blood and breath alcohol concentrations (Hök, 2006) reflecting the very rapid equilibrium kinetics between pulmonary capillary blood and alveolar air (Opdam et al., 1986). In fact, as seen in Figure 2, BrAC measurements (converted to units of BAC) track arterial BACs throughout the blood alcohol time curve; only slightly below during the ascending curve, then virtually identical on the descending limb of the BAC time curve (Lindberg et al., 2007).

Current breath-based alcohol measurement techniques require direct access to undiluted deep-lung air, and therefore employ a mouthpiece. The challenge in measuring alcohol in breath from around the driver's face or within the vehicle cabin is that the breath is diluted with the cabin air. With funding from the Swedish Road Administration, Autoliv, Hök Instruments AB, and SenseAir AB have collaborated in the development of a non-contact method to measure alcohol in breath. The measuring principle of the sensor is to use measurements of expired carbon dioxide (CO_2) as an indication of the degree of dilution of the alcohol concentration in expired air. Normal concentration of CO_2 in ambient air is approximately 400 parts per million or 0.04%. Furthermore, CO_2 concentration in alveolar air is both known and predictable, and remarkably constant. Thus, by measuring CO_2 and alcohol at the same point, the degree of dilution can be compensated for using a mathematical algorithm. The ratio between the measured

concentrations of CO₂ and alcohol, together with the known value of CO₂ in alveolar air, can provide the alveolar air alcohol concentration.

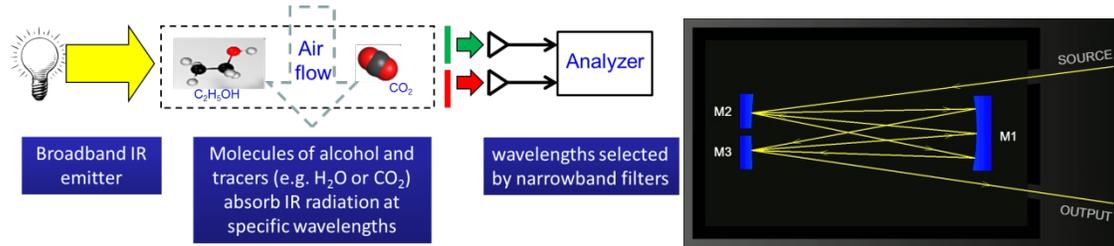


Figure 5. Breath-based sensor block diagram

The sensor technology under development by Autoliv and its partners uses infrared (IR) spectroscopy, which is superior to conventional fuel-cell devices in two ways. The IR-based sensors can be stable over the full product lifetime, eliminating the need for recurrent calibrations. Furthermore, the IR sensor is not as sensitive as the fuel-cell to major variations in ambient temperature. The 1st generation prototype uses a patented optical device in which multiple reflections of the IR beam within a closed space enables the calculation of alcohol concentration with high resolution. The expired breath from the driver is drawn into the optical module through the breathing cup. Once in the chamber, IR light is emitted from a light source and reflected by mirrors to increase the overall length of the IR optical path as shown in Figure 5, thus increasing the prototype’s resolution. Detectors in the module then measure the ethanol and CO₂ concentrations. For the purposes of human subject testing, the current device requires drivers to blow towards the sensor, which is positioned at a distance of 5 inches.

The 2nd generation sensor underwent incremental improvement that primarily involved a change in material composition of the sensor optical housing as well as significant improvements in mirror fabrication, coating, and integrated heaters designed to improve startup time, accuracy and precision. Significant progress was made in the 2nd generation with improvement to the startup time, dynamic accuracy and measurement performance at very low temperatures. The sensor underwent a series of Verification and Validation (V&V) tests as per the DADSS Performance Specification. The results from the V&V tests showed that there was no observed degradation or aging after these tests which simulated a vehicle life time of fifteen years.

The 2nd generation optical sensing element is too bulky and not suitable for vehicle integration. Further improvements are required to meet the DADSS specification. In addition, the improved sensor should be more robust when exposed to thermal gradients during the startup sequence. The focus of the current effort is to design, test, and validate a smaller, more robust optical sensor cavity that may be more easily packaged into a motor vehicle, with the objective remaining that the devices meet or exceed the DADSS Performance Specifications. Figure 6 shows the evolution of the Autoliv sensors.

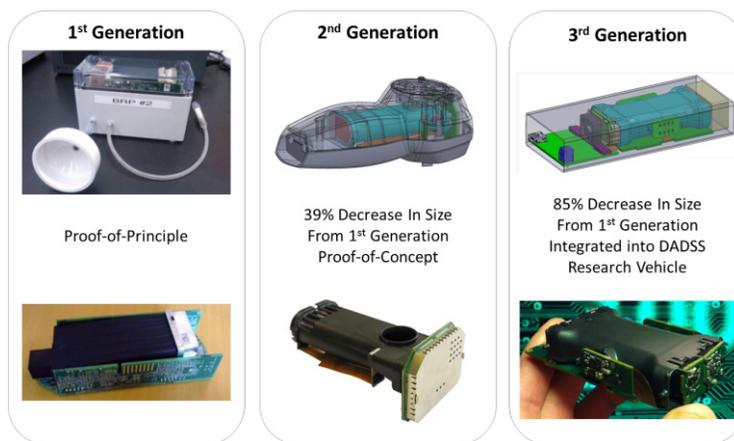


Figure 6. Evolution of Breath-based DADSS Sensor

TECHNOLOGY & MANUFACTURING READINESS LEVELS

To manage, measure, and assess the progress and maturity of both technologies during the research and development phase, Technology Readiness Levels (TRL) and Manufacturing Readiness Levels (MRL) will be used throughout the program. These Readiness levels provide common terms to define technology from concept to commercial production, and have a proven effectiveness from the aerospace and defense sectors. Independently, readiness levels can also assist with self-assessment, monitoring progress and planning goals and actions. The advantages of using readiness levels are:

- provide a common understanding of technology and manufacturing readiness status
- risk management
- make decisions concerning technology funding
- make decisions concerning transition of both technologies to the automotive industry

The readiness levels used for the program are based on the “Automotive Technology and Manufacturing Readiness Levels, A guide to recognized stages of development within the Automotive Industry” by Professor Richard Parry-Jones CBE, Co-Chairman of the Automotive Council. These levels were revised and updated by the DADSS Technical Working Group (TWG) to incorporate DADSS specific milestones to achieve demonstrated commercial feasibility as shown in Figure 5.

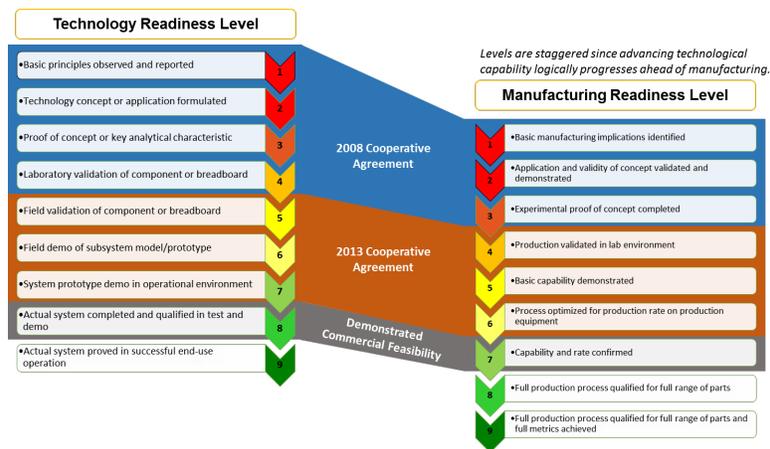


Figure 7. TRL/MRL Demonstrated Commercial Feasibility

Table 2 summarizes a preliminary evaluation of the “readiness” of the breath-based and touch-based technologies at the end of Phase II. As Figure 7 indicates, at the end of the 2008 cooperative agreement, the breath based technology achieved the expected TRL 4 level. The touch-based technology on the other hand was behind both TRL and MRL expectations. However, a number of technological challenges are ahead for the breath-based system relating to sampling in a vehicle cabin with the windows open and the air conditioning or heater on, which are not expected to be challenges that the touch-based system will need to surmount. Furthermore, the touch-based system readiness levels are anticipated to increase rapidly once development and integration of the full set of required multi-lasers packages is complete.

Table 2. Technology and Manufacturing Readiness Levels by Technology Type

Technology	TRL	MRL
Breath-based	4	4
Touch-based	3	2

STANDARD CALIBRATION DEVICE (SCD) DEVELOPMENT

Standard Calibration Devices (SCD) were developed to assess and document the accuracy and precision of the Phase I prototypes. Two different SCDs were developed for prototype testing; one breath-based and one touch-

based. There are two aspects that were addressed (Ferguson et. al., 2010). First, samples of simulated “breath” and “tissue” were developed to provide a calibrated (known) and consistent ethanol concentration in vapor and/or liquid to the prototype. These samples also had to provide reasonable facsimiles of human breath and tissue. As noted above, the DADSS Performance Specifications for accuracy (SE) and precision (SD) are significantly more stringent than current evidential calibration instruments, thus the sample sources of breath and tissue had to exceed the DADSS specifications by an order of magnitude. The second requirement necessitated the development of delivery methods so that the targeted samples could be effectively delivered to the prototypes.

Tissue Spectrometry SCD

An SCD sample that simulates human tissue must produce a consistent ethanol response from the sensor at all concentrations of BAC, mimic the average optical scattering properties of human tissue over the target NIR wavelength range, and maintain the test material at normal human skin temperature (34 °C). Figure 8 compares NIR reflectance of human versus simulated tissue and demonstrates the high level of concordance at the relevant wavenumbers. The system also must support varying concentrations of ethanol over the target BAC test range of 0.02% through 0.12 % BAC.

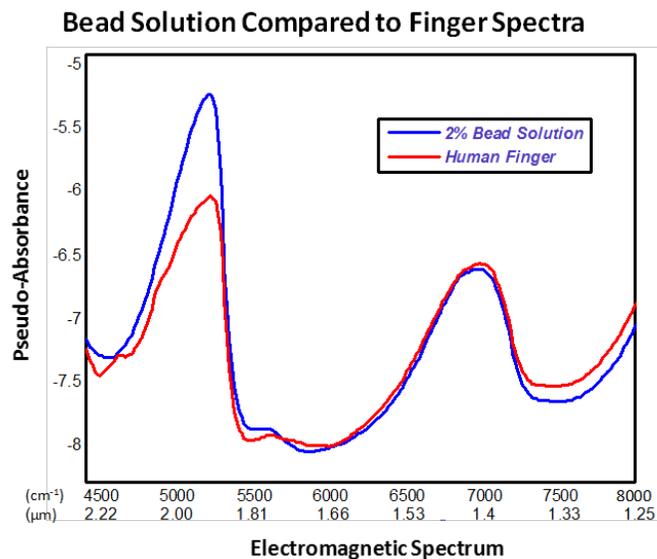


Figure 8. Comparison of NIR reflectance of simulated tissue solution with human tissue

Working with TruTouch Technologies, an SCD system was developed that comprised standardized aqueous test samples representative of human tissue and an electromechanical fluidic system for introducing the samples to the sensor. The standardized aqueous test samples are gravimetrically prepared solutions that use mono-dispersive polystyrene microspheres as an optical scattering agent. Quantities of ethanol in the solutions are certified by GC analysis to meet the required concentration levels after the beads are added. The simulated tissue solutions were stored in individual 15 mL vials. In addition to water and alcohol the “tissue” samples contain normal components of human blood such as urea, salt, and creatinine, as well as albumin that simulates blood density, microspheres that simulate the reflectance and scattering properties of collagen, and Triton that prevents the beads from clumping. An automated pipette delivery system made by Hamilton eliminates human error and operator variability, as well as improves accuracy and precision during gravimetric preparation of the solutions. The system consists of the Nimbus independent two channel work station, the pedestals and deckware custom containers, and a third party Mettler Toledo scale to accommodate 10, 20, 40, 100mL vials (Figure 9).

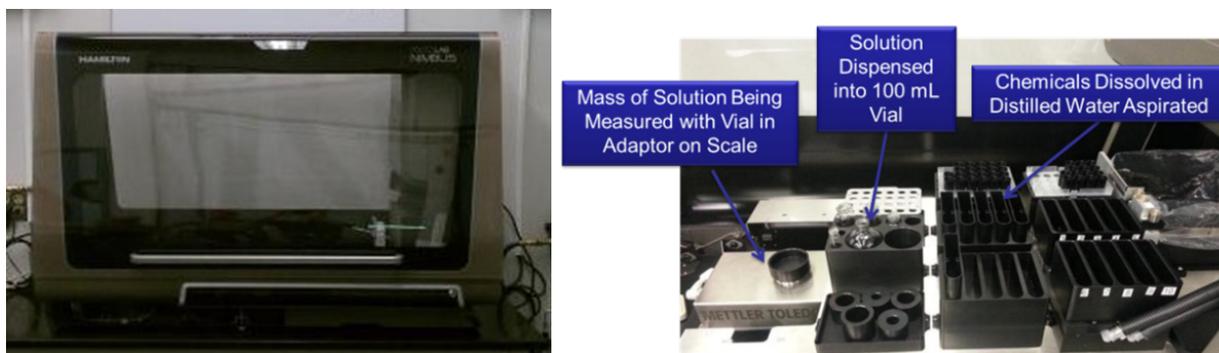


Figure 9. Hamilton Nimbus Automated pipette delivery system

The fluidic delivery system module was designed to easily attach to the TruTouch prototype sensor touch pad. The system module creates a liquid seal interface to support direct coupling between the optical sensor and the SCD test sample. The system also includes an agitation mechanism to prevent settling of the microspheres without introducing bubbles into the sample at the optical surface. The sealed system prevents evaporation loss, allows for sample removal, cleaning, and drying between sample measurements to prevent cross-contamination, and provides a reasonable degree of automation to avoid operator error. The prototype fluidics system is illustrated in Figure 9.



Figure 10. Liquid coupling interface and prototype delivery system

Distant Spectrometry SCD

The first step in the development of highly accurate breath samples was the production of standardized calibration dry gases (Ferguson et. al., 2010). Then the next step was to develop the DADSS dry gas mixture with the potential to exceed the DADSS Performance Specifications.

Two ethanol gas mixtures in 110 L pressurized bottles were developed in cooperation with ILMO Products Company:

1. Ethanol/Nitrogen (N₂)
2. Ethanol/N₂/5 % CO₂/16 % oxygen (O₂)

Each mixture was gravimetrically prepared at concentrations of 0.02, 0.04, 0.06, 0.08, 0.12 % BrAC. The mixtures were certified at ± 0.5 ppm (± 0.0002 % BrAC) by the vendor, exceeding the 0.0003 % BAC SE and SD when tested at 0.08 % BAC. In-house GC testing confirmed that the gas mixtures provided the levels of accuracy and precision for ethanol and other gases to the DADSS specifications over the complete range of gas concentrations. Additional testing verified acceptable shelf-life stability of the gas bottles.

Having validated that the dry gas mixtures complied with DADSS specifications, the next step was to humidify the gases to simulate human breath. Tests were conducted using a spirometer on a healthy male subject to measure the average flow rate and time of an exhaled breath. The ACTS team then developed a Wet Gas Breath Alcohol Simulator (WGBAS), shown in Figure 11, to add the necessary humidity.

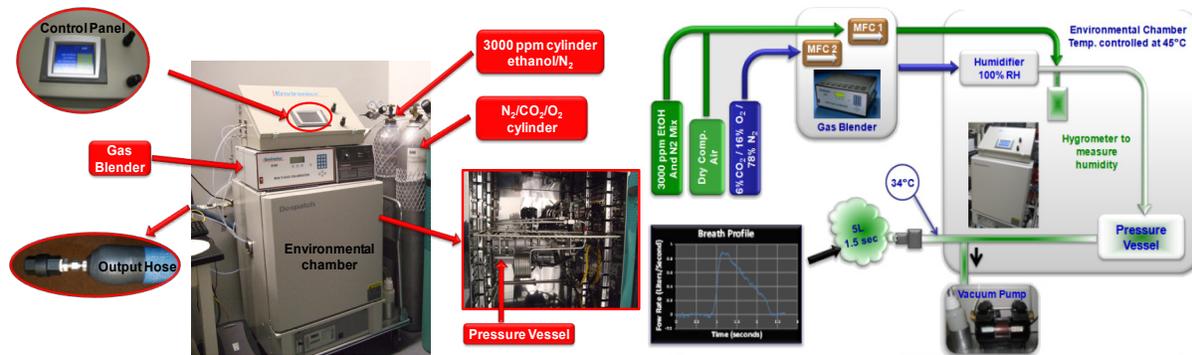


Figure 11. WGBAS Configuration and principal of operation

The WGBAS uses two dry gas sources: the first a mixture of N₂/CO₂/O₂, and the second a 3000 ppm cylinder of ethanol, balanced with nitrogen. Mass flow controllers (MFC) generate the range of humidified ethanol from 0.02 % BAC to 0.12 % BAC. The gas in the premixed cylinder of N₂/CO₂/O₂ enters the gas mixing module, flowing through humidifier metering valves located in an enclosure on top of the heated chamber. The proportional control of these valves allows the humidity to be adjusted. The ethanol/ N₂ mixture flows out of the second MFC and into the bypass line that flows around the humidifier. The humidified N₂/CO₂/O₂ mixture and the ethanol mixture meet before entering the hygrometer, which reports the dew point, humidity and gas temperature values, allowing for any necessary adjustments to obtain the required output of the humidifier. The humidified gas mixture then passes into the evacuated pressure vessel where it accumulates to a preset pressure, as monitored by an absolute pressure transmitter. When the preset pressure is met, the pressurized gas is expelled into the evacuated output tubing. As the gas leaves the system it is cooled to 34 °C, the dew point temperature of the mixture, at a rate of approximately 1 liter in 2-3 seconds, thus simulating a humidified gas flow of breath. Figure 11 shows the WGBAS principle of operation described above.

The SCD dry gas, when passed directly through the WGBAS, was capable not only of meeting but also exceeding the DADSS SEs and SDs. In the second set of verification tests, humidity was added to the mixed gases with an output dew point of 34 °C. The addition of humidity resulted in much larger SE values than the DADSS specifications and the SD values were influenced by differences in the ethanol concentration, with only the lowest ethanol concentration being able to meet and exceed the specifications.

The WGBAS was not used in the Phase I evaluation process due to its current early development status. The system will undergo additional enhancements in Phase II to improve accuracy and precision through the introduction of a closed-loop feedback system to control the amount of ethanol concentration mixed into the gas stream. Therefore, the system is planned to be used for prototypes evaluation in Phase II.

Verification Process

An SCD qualification process was developed to document that the breath and tissue sample performance meet the requisite performance specifications. Initially, components of the breath and tissue SCD were measured with a Gas Chromatograph (GC) using a Flame Ionization Detector (FID) to verify that the critical SEs and SDs were achieved. The primary function of a GC is to separate and detect chemicals in a gas flow passing through a thin column lined with specific coatings that interact with the components in the flow. The FID ignites the gases flowing out of the column with hydrogen gas. The detector then generates an electrical signal corresponding to the amount of ionized products from the combustion. The area under the curve of the electrical signal is integrated to correspond to the concentration of the gases at the column exit. Temperature, flow rate, and column selection influence the retention time of gas flow components.

The tubing and connections to the GC and the mass flow controller are heated to 34 °C, the exit temperature of human breath, to ensure the incoming gases are uniform and to assure consistent results. Several variables were found to affect and improve the GC ethanol measurement, including:

- Operating at low temperature vs. high temperature;
- Obtaining a homogeneous system, with uniform equilibrium temperature for each part of the system;
- Passivating (ability to treat a surface (typically metal) so that it is less reactive chemically) the sample line and regulator;

- Reducing the surface area of the sample line;
- Creating a constant backpressure on the actuator valve exhaust line;
- Producing a purging process for the regulator and sample loop.

The influence of the variables were quantified and examined before an optimal operating condition was obtained for the ethanol gas measurement process. Once the optimal operating conditions were identified, the dry and wet gases were then measured using the improved system shown in Figure 12.

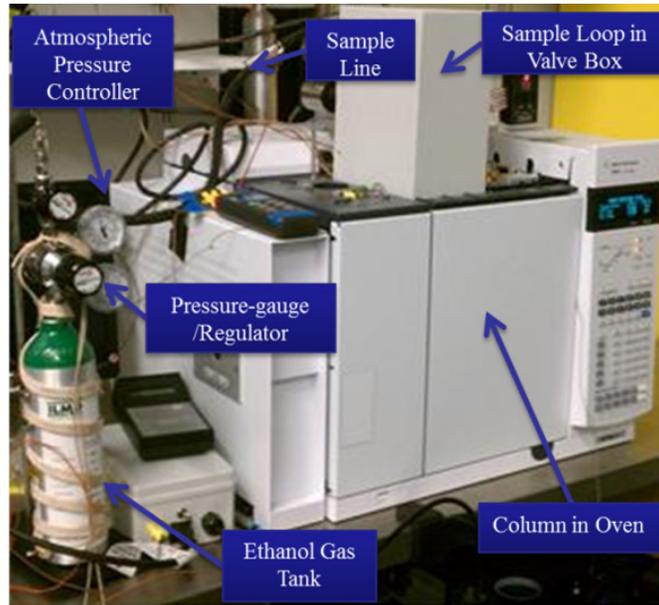


Figure 12. GC system used to measure ethanol gas

Figure 13 shows the dry gas ethanol gas measurement that is inaccurate and imprecise (left) compared with a measurement, using the developed measurement process, that shows accurate and precise measurements within the DADSS specification (right). Figure 14 shows the WGBAS measurements within the DADSS tolerance specification.

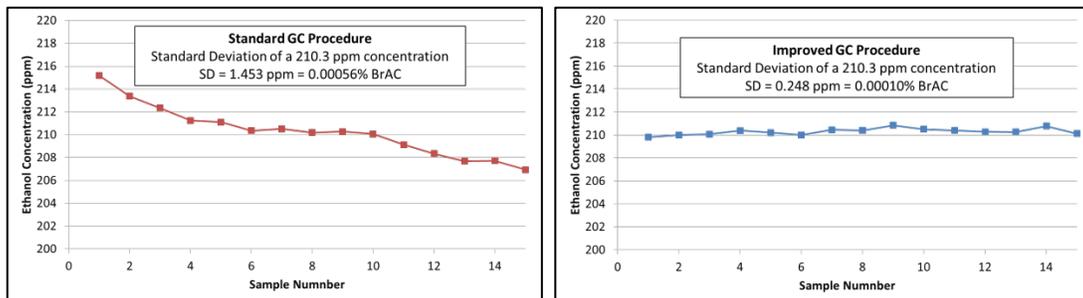


Figure 13. Standard and improved dry gas measurements comparison

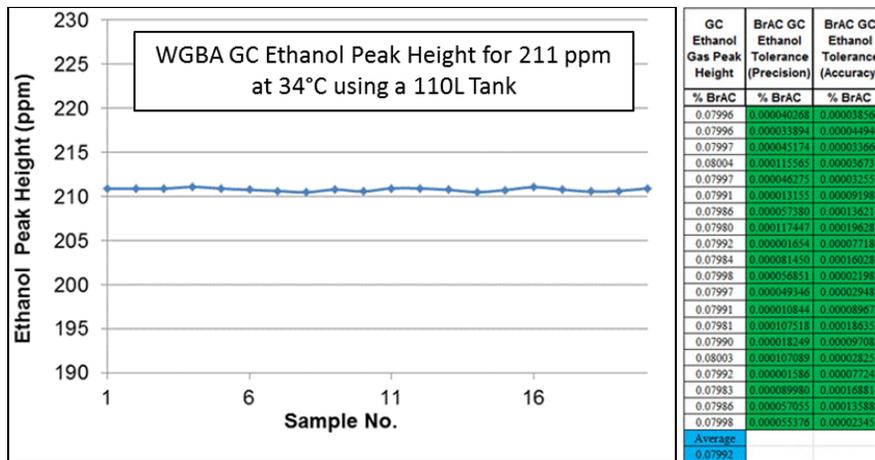


Figure 14. WGBAS accuracy and precision using the improved GC system

CONCLUSIONS

Significant progress has been made to identify DADSS technologies that have the potential to be used on a more widespread basis in passenger vehicles. Two specific approaches have been chosen for further investigation; tissue spectrometry, or touch-based, and distant/offset spectrometry, or breath-based sensors. Proof-of-principle prototype DADSS sensors have been developed, one designed to remotely measure alcohol concentration in drivers' breath from the ambient air in the vehicle cabin, and the other is designed to measure alcohol in the driver's finger tissue through placement of a finger on the sensor.

Progress also has been made to develop calibration devices for both breath-and touch-based bench testing that will be able to measure whether the DADSS devices can meet the stringent criteria for accuracy and precision. Unique standard calibration devices have been developed for both the breath- and touch-based systems that go well beyond current alcohol-testing specifications.

In summary, the DADSS Program so far has accomplished the goals set at the onset of the program. Prototype testing has indicated that there are potential technologies that ultimately could function non-invasively in a vehicle environment to measure a driver's BAC. Furthermore, the DADSS Program is on track to develop research vehicles to demonstrate the technologies by the end of 2015.

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