

## **DRIVER ALCOHOL DETECTION SYSTEM FOR SAFETY (DADSS) – PHASE I PROTOTYPE TESTING AND FINDINGS**

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### **ABSTRACT**

The Driver Alcohol Detection System for Safety Program is a research partnership between the National Highway Traffic Safety Administration and the Automotive Coalition for Traffic Safety. The cooperative agreement seeks to assess the current state of detection technologies that are capable of measuring blood alcohol concentration, and to support the development and testing of prototypes and subsequent hardware that could be installed in vehicles. Three Phase I proof-of-principle prototype sensors now have been developed. Two of the sensors are designed to remotely measure alcohol concentration in drivers' breath from the ambient air in the vehicle cabin, and the third is designed to measure alcohol in the drivers' finger tissue through placement of a finger on the sensor. To validate the performance of the prototypes, unique standard calibration devices have been developed for both the breath- and touch-based systems that exceed current alcohol-testing specifications. A testing program was undertaken to provide an understanding of whether the devices ultimately can meet the performance specifications needed for non-invasive alcohol testing. Bench testing determined the prototypes' accuracy, precision, and speed of measurement and established what additional development will be needed in Phase II. Limited human subject testing permitted an understanding of the in vivo relationship among the various measures of blood alcohol as provided by blood, breath, and the prototype devices.

This paper provides the results of prototype testing and outlines further development needed.

### **INTRODUCTION**

The Driver Alcohol Detection System for Safety (DADSS) Program is a research partnership between the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS) to explore 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 five-year program is a cost-sharing program between the parties, and funding for ACTS currently is provided by motor vehicle manufacturers (BMW, Chrysler, Ford, General Motors, Honda, Hyundai/Kia, Jaguar Land Rover, Mazda, Mercedes Benz, Mitsubishi, Nissan, Porsche, Toyota, Volkswagen, and Volvo). To be acceptable for use among all drivers, many of whom do not drink and drive, in-vehicle alcohol detection technologies must be seamless with the driving task; they must be non-intrusive, reliable, durable, and require little or no maintenance. The cooperative agreement seeks to assess the current state of detection technologies that are capable of measuring blood alcohol concentration (BAC) or Breath Alcohol Concentration (BrAC), and to support the development and testing of prototypes and subsequent hardware that could be installed in vehicles. The goal, at the end of the five-year program, is the practical demonstration in a research

vehicle of alcohol detection subsystems suitable for subsequent installation in a vehicle.

DADSS devices have the potential to significantly reduce alcohol-impaired driving and the crash deaths and injuries that ensue. The technical challenges are substantial, however the possible benefits to society are compelling, with the potential to prevent up to 8,000 motor vehicle deaths every year if all drivers with BACs at or above the legal limit (0.08 g/dL) were unable to drive (IIHS, 2011).

The purpose of this paper is to provide a summary of research to date, including the technology review process, details about technologies chosen for Phase I development and the prototypes developed, as well as the development of bench testing devices, and the results of bench and human subject testing. The paper will conclude with a discussion of further development that is needed to meet DADSS specifications and next steps.

## **THE DADSS PROGRAM**

### **A two-phased R&D program**

The DADSS research and development effort is following a two-stage process. The Phase I effort, now complete, focused on the development of working proof-of-principle (PoP) prototypes. Phase II is the major development effort that will lead to a research vehicle to demonstrate the technologies.

The specific objective for Phase I was to develop PoP prototypes intended to represent devices capable of rapidly and accurately measuring the driver's BAC non-intrusively. The prototypes, which were required to address just the accuracy, precision, and speed of measurement specifications, did not attempt to simulate the visual appearance, choice of materials or intended manufacturing process. The overall aim was to validate the potential design approach, as well as point to areas where further development and testing may be necessary. The Phase I development comprised a 12-month period of performance and involved three companies.

The Phase II development stage will result in the practical demonstration of an alcohol detection subsystem suitable for subsequent installation in a vehicle. The program is envisaged to span

approximately two years. Phase II awards will be made only to those bidders that have achieved successful Phase I progress with regard to the merits of the technological approach adopted. It is anticipated that funding for Phase II development will be awarded during the first half of 2011 following which technology companies will work towards the development of a research vehicle to demonstrate the DADSS technologies by the second half of 2013.

### **DADSS Program Details**

The first tasks to be undertaken in Phase I included a comprehensive review of emerging and existing state-of-the-art technologies for alcohol detection and the development of performance specifications. A Request For Information (RFI) was published as a means by which the DADSS program was first communicated to potential vendors. 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 application. Based on an evaluation of the 17 responses received, a Request for Proposals (RFP) was sent to eight businesses with prior experience in alcohol detection or related technologies, and three contracts were awarded for the development of Phase I PoP prototypes.

Two technology approaches were chosen for Phase I development; Tissue Spectrometry Systems (touch-based) and Distant/or Offset Spectrometry Systems (breath-based). For a full discussion of the decision process by which these approaches were identified see Ferguson et al., 2010. Two companies, Autoliv and Alcohol Countermeasure Systems (ACS) were chosen to develop prototypes that used the breath-based approach, and TruTouch Technologies was chosen to develop a prototype that used the touch-based approach.

### **PoP Prototypes and Principles of Operation**

**Tissue spectrometry systems** – 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  $\mu\text{m}$  to 2.5  $\mu\text{m}$ ) to measure substances of interest in bodily

tissue. 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). The beam of light can penetrate tissue at depths of up to 5 mm to reach the dermal layer where alcohol that is dissolved in water resides. 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).

Although the entire NIR spectrum spans the wavelengths from 0.7-2.5  $\mu\text{m}$ , TruTouch has determined that the 1.25-2.5  $\mu\text{m}$  portion provides the highest sensitivity and selectivity for alcohol measurement. The 0.7-1.25  $\mu\text{m}$  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  $\mu\text{m}$ , is virtually unaffected by skin pigmentation (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  $\mu\text{m}$  region is hundreds of times stronger than the signal in the 0.7-1.25  $\mu\text{m}$  part of the NIR.

The TruTouch prototype system is based on a proprietary Fourier transform spectrometer coupled with a compact, fiber optic touchpad with which the user interfaces. To conduct a test, the user makes contact with the intermediate phalanges of their index finger onto the fiber optic touchpad (Figure 1). The prototype automatically detects the presence of the finger and initiates an alcohol test. Once the spectral data have been collected, automated quality control metrics ensure that the test sample is a valid human finger and that all test parameters are within acceptable limits. An alcohol test result then is calculated and displayed on-screen.

The prototype system is a stand-alone test unit with the sensor, data processing unit, and operating

software fully contained inside the unit. For operation in Phase I benchmark testing, a PC-based application is run on an external computer and communicates with the prototype via a wired Ethernet connection. This setup allows for flexible configuration and data logging requirements for this phase of testing. All data collection, quality control screening, and measurement calculations are performed within the prototype itself.



**Figure 1. TruTouch prototype with user's index finger during measurement**

**Distant/Offset Spectrometry systems** – 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  $\mu\text{m}$ ); however no skin contact is required. The two approaches under development aim to remotely analyze alcohol in breath within the vehicle cabin without the driver having to specifically provide a deep-lung breath sample. The working principle of the sensor is to use measurements of expired carbon dioxide ( $\text{CO}_2$ ) as an indication of the degree of dilution of the alcohol in expired air. Normal concentration of  $\text{CO}_2$  in ambient air is close to zero. Furthermore,  $\text{CO}_2$  concentration in alveolar air is both known and predictable, and remarkably constant. Thus, by simultaneously measuring  $\text{CO}_2$  and alcohol, the degree of dilution can be compensated for using a mathematical algorithm. According to Hök (2006), the ratio between the measured concentrations of  $\text{CO}_2$  and alcohol, together with the known value of  $\text{CO}_2$  in alveolar air, can provide the alveolar air alcohol concentration. The sensor technologies under development use MIR spectroscopy for both alcohol and  $\text{CO}_2$ . The MIR-based sensors can be stable over the full product

lifetime, eliminating the need for recurrent calibrations.

For in-vehicle use the system could employ multiple sensors placed strategically around the cabin of the vehicle close to the driver. The challenge is to determine the number and placement of sensors needed to measure alcohol quickly and accurately given the dynamics of the cabin air, and to ensure that there is no potential bias introduced as a result of passengers who may have been drinking.

The Autoliv prototype is shown in Figure 2. This 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, thus increasing the prototype's resolution. Detectors in the module then measure the ethanol and CO<sub>2</sub> 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.



**Figure 2. Autoliv prototype**

Autoliv provided two prototypes at the completion of Phase I. The first prototype (Version 1) used an injection molded optical module with integrated mirrors. Upon initial testing, it was determined that the radii and location of the mirrors did not conform to the required specifications, which significantly reduced the accuracy and precision of the unit. This

issue was addressed by providing a second prototype (Version 2) with add-on glass mirrors. However, during bench testing a small gas leakage was discovered in the optical module of the Version 2 prototype. This leakage, due to the add-on glass mirrors, did not have an impact on ethanol measurements since it only affected a very small part of the optical path. But for the CO<sub>2</sub> measurement which has a short optical path, the effect was significant.

The ACS prototype also relies on MIR detection methodology to detect alcohol in the cabin air using a Daylight Solutions Swept Sensor™ that enables identification and analysis of ethanol.

The sensor unit contains a broadly tunable external cavity quantum cascade laser (ECqCL™), capable of scanning a particular wavelength band of the MIR spectrum in less than 100 ms. It also contains optical detection components and electronics to convert the returned optical signal into an electronic signal that can be further processed by the unit. This system includes an extraction pump that allows gas samples to be pulled through the sample cell. The control electronics are contained underneath the sensor unit. Spectroscopic data are transmitted to a PC for further processing and analysis. For the prototype shown in Figure 3, a chiller was used to keep the Swept Sensor™ at a constant temperature.





**Figure 3. ACS prototype with DLS Swept Sensor™ technology and required chiller to maintain constant temperature**

The Swept Sensor™ was designed to measure ethanol and CO<sub>2</sub> simultaneously in ambient air. The sensor’s laser continuously “sweeps” across the wavelength band. Upon initial evaluation of the Swept Sensor™ by ACS, they discovered a very weak CO<sub>2</sub> absorption in the spectral range where ethanol absorption was identified, and the Swept Sensor™ prototype CO<sub>2</sub> sensitivity did not measure below 5000 parts per million (ppm). Because of the amount of dilution of the expired breath as it mixes with the ambient air in the vehicle cabin, CO<sub>2</sub> detection in the range of 400-500 ppm is required. Therefore the sensor was unable to measure CO<sub>2</sub> at the necessary dilution. ACS modified the unit to incorporate a SenseAir CO<sub>2</sub> detector; a state-of-the-art sensor which is able to measure CO<sub>2</sub> concentrations at the required ppm level. This modification was intended to allow the simultaneous detection of ethanol and CO<sub>2</sub> in the diluted human breath, however, the modification did not achieve the desired results.

**Performance Specifications**

Based on input from the ACTS Blue Ribbon Panel, a group of experts formed to help advise the DADSS program, ACTS has developed performance specifications that are designed to focus the current and future development of relevant emerging and existing alcohol detection technologies. In addition to requirements for a high level of accuracy and precision and very fast time to measurement, the

influences of environment, issues related to user acceptance, long-term reliability, and system maintenance requirements will be assessed. The performance specifications with definitions, measurement requirements, and acceptable performance levels are provided in the DADSS Subsystem Performance Specification Document ([http://dev.dadss.org/sites/default/files/dadss001-draft\\_100908.pdf](http://dev.dadss.org/sites/default/files/dadss001-draft_100908.pdf)). The accuracy, precision, 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.

**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** – Sober drivers should not be inconvenienced each 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 longer to provide an estimate of BrAC. However, 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 BAC reading and communicating the result within 325 milliseconds. It should be capable of providing a second reading, if necessary, within 400 milliseconds.

### 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. 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 PoP 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.

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. To establish SCD repeatability, the GC testing was repeated for each increment of the specification’s target physiological test range of 0.02 % BAC through 0.12 % BAC.

### 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 4 compares NIR reflectance of human versus simulated tissue and demonstrates the high level of concordance at the relevant wavenumbers.

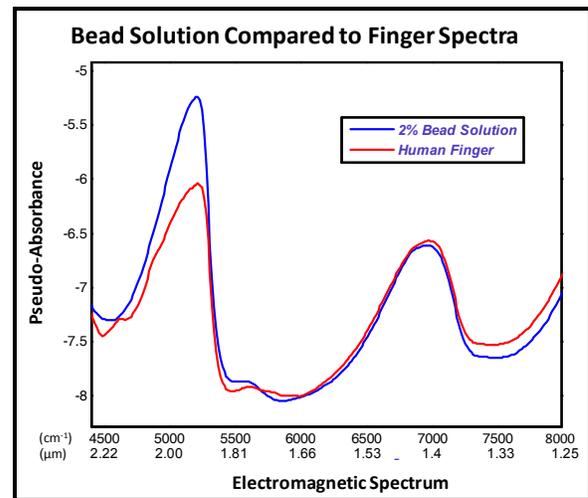


Figure 4. Comparison of NIR reflectance of simulated tissue solution with human tissue

The system also must support varying concentrations of ethanol over the target BAC test range of 0.02% through 0.12 % BAC.

**Tissue calibration mixtures** – 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.

**Electromechanical Fluidic System** – The fluidic delivery system module was designed to easily attach to the TruTouch prototype sensor. 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 5.



**Figure 5. Liquid coupling interface and prototype delivery system**

TruTouch provided SCD samples to S.E.D. Medical Laboratories, a third-party laboratory, for independent analysis of the ethanol concentration in the SCD simulated tissue solutions. Based on these

analyses, the tissue SCD does not currently meet the DADSS Performance Specifications. It is not known whether this inability to meet the specifications is due to the properties of the tissue samples themselves or to S.E.D.'s equipment capabilities. However, ACTS intends to verify the results in-house. Further development also will be undertaken to improve accuracy and precision of the tissue SCD and the usability of the delivery system.

### Distant Spectrometry SCD

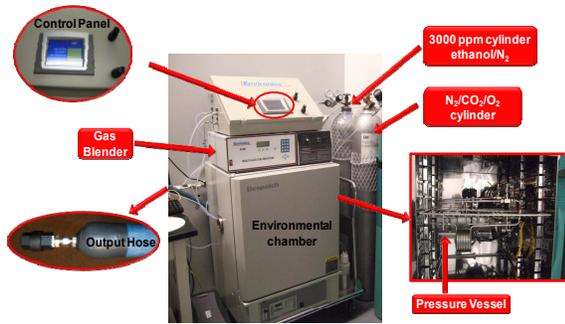
The first step in the development of highly accurate breath samples was the production of standardized calibration dry gases. Then the next step was to develop the DADSS dry gas mixture with the potential to exceed the DADSS Performance Specifications.

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

1. Ethanol/Nitrogen ( $N_2$ )
2. Ethanol/ $N_2$ /5 %  $CO_2$ /16 % oxygen ( $O_2$ )

Each mixture was gravimetrically prepared at concentrations of 0.02, 0.04, 0.06, 0.08, 0.12 % BrAC. The mixtures were certified at  $\pm 0.5$  ppm ( $\pm 0.0002$  % 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 6, to add the necessary humidity.



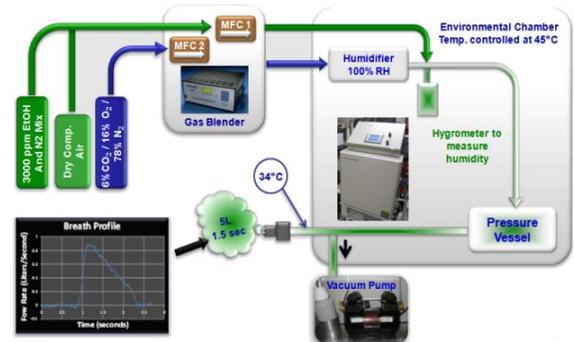
**Figure 6. WGBAS Configuration**

The WGBAS uses two dry gas sources: the first a mixture of N<sub>2</sub>/CO<sub>2</sub>/O<sub>2</sub>, 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 N<sub>2</sub>/CO<sub>2</sub>/O<sub>2</sub> 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/ N<sub>2</sub> mixture flows out of the second MFC and into the bypass line that flows around the humidifier. The humidified N<sub>2</sub>/CO<sub>2</sub>/O<sub>2</sub> 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 7 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.



**Figure 7. WGBAS principal of operation**

## PROTOTYPE TESTING

### Bench Test Protocols

To undertake the prototype verification, equipment and materials were organized in a dedicated laboratory wherein both bench and human subject tests were conducted. Human subject testing of the prototypes required a BioSafety Level-1 Laboratory for safe handling of human blood.

The prototypes were tested in a standardized manner using bench tests. SCDs were used to provide accurate and consistent samples to the prototypes. The bench tests of each system were divided into test matrices to characterize the performance of the prototypes under different conditions. One matrix tested the sensor in an ideal or best-case scenario for comparison with the DADSS specifications. Another matrix tested the sensors as used in the human subject tests. SE was calculated using:

$$SE = |\bar{x} - SCD \text{ ethanol concentration}|$$

Where  $\bar{x}$  is the data averaged using:

$$\bar{x} = \frac{1}{n} \sum_{i=1}^n x_i$$

and SD was calculated using:

$$SD = \sqrt{\frac{1}{(n-1)} \sum_{i=1}^n (x_i - \bar{x})^2}$$

**Tissue Spectrometry System Test Protocols** – The tissue spectrometry prototype was tested using the developed calibration mixture and the electromechanical fluidic system. Matrix I tested the sensor’s accuracy and precision as a function of different sampling times and BACs (0.02, 0.04, 0.06, 0.08, 0.12%). This matrix provided the longest continuous sample exposure time and was used to characterize the sensor’s performance and capabilities to meet the DADSS specifications. The solutions were tested for 60 seconds, 30 seconds, 15 seconds, and 5 seconds respectively.

In Matrix II, sampling times were changed to determine whether the prototype can distinguish between one long continuous reading versus multiple shorter readings combined into a longer reading. Solutions at BACs of 0.02, 0.04, 0.06, 0.08, 0.12% were tested at 60 seconds divided into two 30 seconds intervals (30x2), 60 seconds divided into four 15 second intervals (15x4), or 30 seconds divided into two 15 second intervals (15x2). Note that all human subject tests provided a 60 second sample divided into four 15 second intervals for participant comfort.

**Distant Spectrometry Systems Test Protocols** – The distant spectrometry prototypes were tested using the developed dry gas mixtures. The first four seconds of the dry gas release allowed the system to stabilize. The prototype software stored the next five seconds of data while the dry gas steadily released from the cylinder. This was done to ensure that the prototype was exposed to a steady gas sample. One second after the prototype data collection was completed the dry gas flow was stopped. The prototype was passively purged with ambient air for 30 seconds between each test.

Matrix I tested the prototype’s accuracy and precision to various alcohol concentrations when the SCD dry gas, which contained a mixture of ethanol, 5 % CO<sub>2</sub>, 16 % O<sub>2</sub>, and N<sub>2</sub>, was directly connected to the prototypes. This test matrix provided the best-case

scenario for the sensors due to the lack of dilution and was used to characterize the sensor’s performance and capabilities to meet the DADSS Performance Specifications.

Matrix II tested the prototypes’ accuracy and precision to alcohol concentrations when the SCD dry gas mixture was released at a distance of five inches from the sensor thus diluting the CO<sub>2</sub> concentration to 0.9 % . This configuration simulated dilution of the human breath in an automobile cabin environment. Note that the protocol used for human subject testing required the breath sample be delivered into a collection cup at a distance of about five inches from the subject’s mouth.

A series of device validation experiments using human subjects were conducted in collaboration with the Behavioral Psychopharmacology Research Laboratory (BPRL), McLean Hospital, Harvard Medical School. BrAC was measured using a highly-accurate evidential breath device (the Nanopuls Evidenzer Mobil 240). Venous blood samples were drawn to provide measurements of BAC, and both the Autoliv and TruTouch prototypes were used to provide estimates of BrAC and tissue alcohol concentration (TAC). The aim of the study was to assess the prototypes’ ability to provide accurate measurements of blood alcohol concentrations over a wide range of blood alcohol concentrations, both during the absorption and elimination stages, in an extended period of time (7 hours). Human volunteers were dosed with alcohol to produce blood alcohol concentrations in the range of 0.10 to 0.12 % BAC.

Attempts to use the ACS prototype for human subject testing yielded inconsistent data. Furthermore, the device required a significant effort to incorporate it into the testing program due to the complexity of the system and its operating software. Use of this device not only produced inconsistent results but also was time-consuming to use with the subjects, thereby jeopardizing the sequence and frequency of testing of the other devices. Therefore, the ACS prototype was eliminated from human subject tests.

All protocols, recruitment procedures, informed consent documents and experimental details of the study were approved by the McLean Hospital

Institutional Review Board. Sixteen individuals participated in the test series. The alcohol dose and drinking regimen were adjusted during the first four participants to optimize the drinking protocol and alcohol dose. In addition, fine adjustments to the sampling procedure were made in order to achieve the target blood levels and sustained peak of intoxication. Adjustments also were made to the drinking regimen so that there were times during the absorption phase when mouth alcohol had dissipated and breath samples could be collected.

## RESULTS

### TruTouch Technologies Bench Tests Results

One concern was whether the SCD simulated tissue solution would degrade over time. TruTouch had reported that the lifespan of the solution was 20 minutes. The first tests with the TruTouch prototype and the fluidic system (Figure 8) characterized the simulated tissue solution degradation over time. Several vials were run with sequential 60 second sample times for 25 minutes to verify the reported lifespan. It was found that samples began to degrade after ten minutes. As a result it was decided to conduct tests for the full 20 minutes for quality control and future studies of vial-to-vial variability, however only the first ten minutes of collected data were used for all subsequent analysis.

Results of Matrix I testing at 0.08 %BAC are shown in Figure 9. An inverse relationship was observed between sampling time and estimated accuracy and precision (SEs and SDs, respectively). This indicates the sensor's signal-to-noise ratio (SNR) influenced the prototype's accuracy and precision since higher signal strength (longer sampling time) resulted in lower noise (lower SE and SD) and vice versa. The similarity between the findings at 60 seconds and 30 seconds sample times indicates that the minimum sample exposure time to achieve the sensor's maximum capabilities was between 30 and 60 seconds; longer sampling exposure times would not produce significant performance improvements.

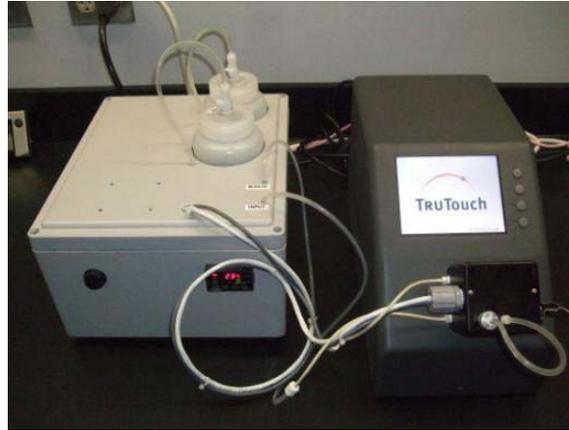
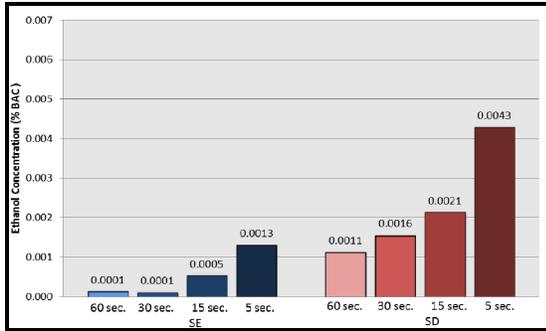


Figure 8. TruTouch bench test configuration

With respect to accuracy (SE), the sensor was able to exceed the DADSS specification at 60 seconds and 30 seconds, and was close to the specification at 15 seconds. However, with respect to precision (SD) the prototype failed to meet the DADSS specifications at all of the sampling time/BAC combinations, being higher by an order of magnitude.

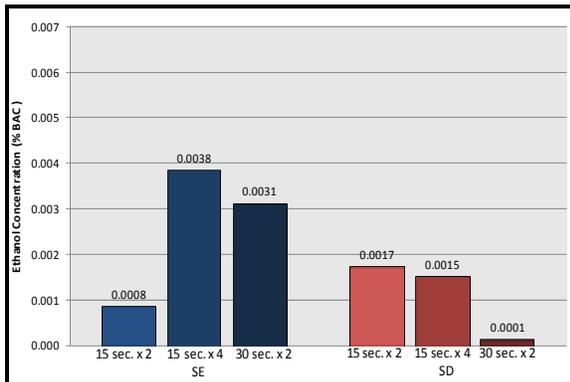
Figure 10 provides the results of Matrix II testing. It should be noted that fewer tests were conducted for each sampling time/BAC combination than in Matrix I with correspondingly lower confidence in the results. Comparing the precision estimates (SD) derived from the 60 second Matrix I results and the 30x2 and 15x4 Matrix II results indicated comparable results can be obtained from each testing method. Accuracy estimates (SE) derived using the shorter intervals that were combined (30x2, 15x4, and 15x2) generally resulted in higher precision estimates than the longer continuous interval (60 and 30 seconds). The dissimilar SE among the different testing sequences may indicate a system recalibration or algorithm adjustment should be considered (combining numerous short readings into a longer reading). Another possibility is that the discrepancies could be attributed to SCD limitations, such as vial-to-vial variability. Additional testing would be required to provide insight into the nature of the inconsistencies.



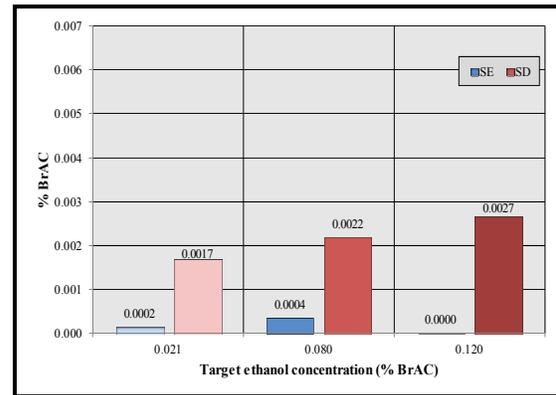
**Figure 9. TruTouch bench test Matrix I SE and SD results at 0.08 % BAC**



**Figure 11. Autoliv bench test Matrix I configuration**



**Figure 10. TruTouch bench test Matrix II SD and SE results at 0.08 % BAC**

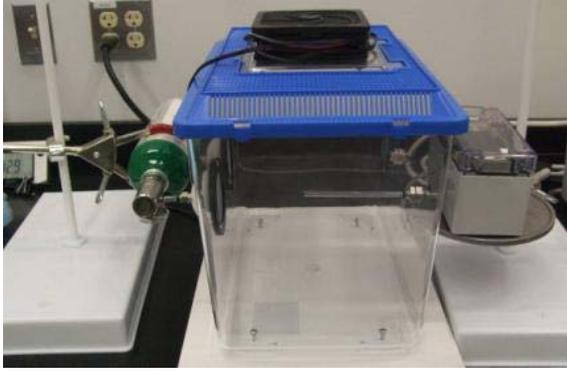


**Figure 12. Autoliv bench test Matrix I results using direct connection of dry gas**

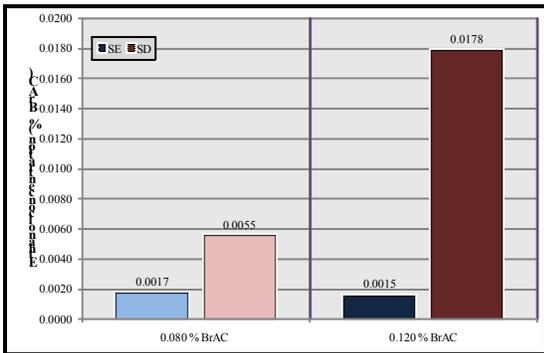
### Autoliv Development AB Bench Tests Results

Figure 11 provides an image of the assembly of the Autoliv PoP prototype and SCD dry gas cylinder for Matrix I bench tests. Figure 12 illustrates the results when dry gas is connected directly to the prototype. At a 5 seconds gas exposure time, the Autoliv prototype was able to closely approximate and even exceed the DADSS accuracy specifications (SE) at BACs of 0.02, 0.08, and 0.12%. These results indicate the prototype may have been accurately calibrated or tuned. The precision estimates (SD) all exceeded the DADSS specifications and exhibited a slight upward trend as a function of BAC. This may be the result of the sensor's sensitivity to the internal CO<sub>2</sub> leak.

Figure 13 provides an image of the assembly of the Autoliv prototype, SCD dry gas cylinder, and dilution chamber for Matrix II bench tests. Figure 14 shows the results when the dry gas is diluted before entering the prototype. The dilution distance was 5 inches and according to the reading from the CO<sub>2</sub> sensor, the concentrations were diluted from 5.0 % to 0.9 %. As with Matrix I tests, the lower SE values indicate the prototype may have been adjusted to produce accurate results. However, the SD was an order of magnitude greater when the SCD dry gas was diluted instead of directly connected. This finding demonstrated the sensor's sensitivity to SNR because the diluted gas produced a much smaller signal (lower ethanol concentration as a result of the dilution). Amplification of noise in the smaller signal results in increased variability in the prototype's output.



**Figure 13. Matrix II diluted dry gas bench test configuration**

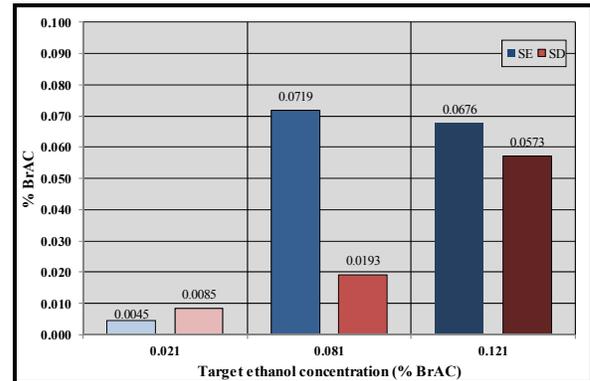


**Figure 14. Autoliv bench test Matrix II results using diluted dry gas samples**

### Alcohol Countermeasure Systems Bench Test Results

The initial bench tests of the ACS prototype (using direct connection of SCD dry gases) were performed to evaluate the system’s operations. Due to software limitations of the prototype software, the dry gas valve and data collection processes could not be automatically controlled. To complete a test, the dry gas SCD had to be controlled separately which meant that the prototype was not exposed to a constant SCD gas flow. ACS developed their software to automatically detect the increase in CO<sub>2</sub>, thus triggering the ethanol reading once a defined CO<sub>2</sub> threshold was reached. Although this method is more representative of the system application in a vehicle, the DLS Swept Sensor’s™ capabilities cannot be tested independently from the SenseAir CO<sub>2</sub> sensor. Additionally, the ACS system’s sensor, hardware, and software were extremely cumbersome to work with, which made the ACS prototype far more difficult and time consuming to operate than the other prototypes.

Figure 15 shows Matrix I bench test results after ten tests. The results of the SCD dry gas connected directly to the ACS prototype yielded ambiguous results for both accuracy and precision. It should be noted that the scale of the graph is different than the other results graphs presented due to the higher values recorded.



**Figure 15. ACS bench test Matrix I results**

The Matrix II bench tests, in which the dry gas mixtures at various BrACs were diluted before introduction to the sensor, also yielded highly erratic accuracy and precision estimates for ethanol concentration.

### Human Subject Tests

A couple of examples of the time course results of repeated whole blood, tissue, and breath samples for sixteen participants are shown in Figure 16 and Figure 17. Missing data points for whole blood measurements were due to technical problems with the sampling devices or with blood clots in the catheter. No breath samples were collected during the lunch period (about 3.5 to 4.5 hours from the start of the study). There were some variations in peak alcohol levels from about 0.105 % to 0.171 % BAC indicating some individual variability in absorption and metabolism despite a standardized dosing regimen. The absorption phase was characterized by a steady rise in alcohol levels, peaking around 2 hours, as measured by whole blood analysis and all three devices. Peak levels were observed for variable lengths of time across participants with some displaying a “plateau” in alcohol levels while others showed more of a sharp peak that then settled into a plateau.

Elimination of alcohol was characteristically a linear function. Sampling continued until breath alcohol levels were at or below 0.02 % or 7 hours after the start of the session and the participants passed a Field Sobriety Test.

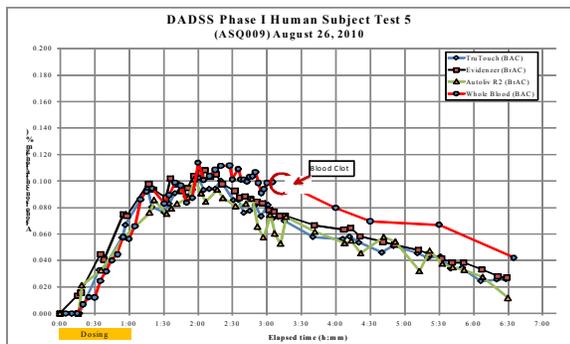


Figure 16. Human subject test 5 results

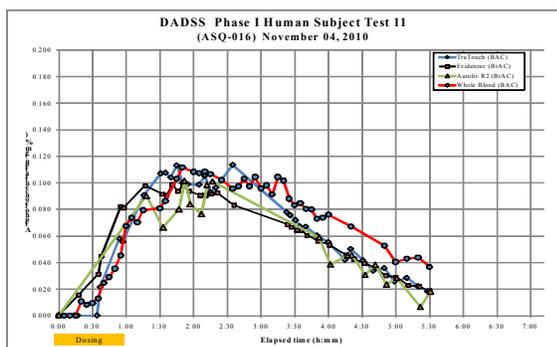


Figure 17. Human subject test 11 results

Across the participants studied to date, the estimates of blood alcohol concentrations obtained from the Autoliv breath device were the most variable and correlated less with the evidential breath results and results from the "gold standard" analysis of venous blood alcohol. The increased variability of the Autoliv prototype may be a function of the CO<sub>2</sub> leak and high directional dependence of the sample source (i.e., the angle at which subjects blow into the collection cup). The results obtained from the TruTouch device more closely tracked both the Evidenzer and blood alcohol levels over a wider range of alcohol concentrations and over the entire session.

A comparison of alcohol concentrations derived from whole blood analysis and breath from the Evidenzer breath analyzer revealed that whole blood values were lower than breath samples during the early absorption phase of alcohol (zero to two hours) and

higher than breath samples during the elimination phase (two to three hours) after acute alcohol administration. This relationship is a well-known profile of alcohol kinetics that is observed when comparing the absorption and elimination/metabolism phases of acute alcohol administration. These differences are less apparent after multiple drinks have been consumed.

## GAP ANALYSIS

A detailed gap analysis was required from each of the technology developers to address the specifications with which their prototype did not conform. They were then required to identify any limitations that would prevent a technology from providing the necessary performance, including the ability of the technology to be deployed in a vehicle as an item of standard equipment. In addition they were required to identify the level of effort needed to meet the DADSS specifications.

Both TruTouch and Autoliv indicated that the performance limitations are not due to fundamental limits of the technology and can be addressed in the Phase II development effort. They also provided details of the necessary modifications to meet the DADSS specifications to be implemented in Phase II. ACS on the other hand indicated that in their assessment, the performance limitations were the result of the technology implementation used, and will not be pursuing this approach further.

## CONCLUSIONS

In the last two years 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 (Ferguson et al., 2010). Three Phase I proof-of-principle prototype DADSS sensors now have been developed. Two of the sensors are designed to remotely measure alcohol concentration in drivers' breath from the ambient air in the vehicle cabin, and the third is designed to measure alcohol in the drivers' finger tissue through placement of a finger on the sensor.

Phase I development now has been completed. The aim of Phase I was to validate potential design approaches, as well as point to areas where further development and testing are necessary. Three prototype devices have been delivered and have undergone testing. Based on the results of testing, one touch-based approach and one breath-based approach are judged to have the potential with future development to measure BAC quickly, and with high levels of accuracy and precision. These approaches should commence Phase II development during the first half of 2011. Significant additional research and development is needed, but the technology companies have identified potential technological modifications to the devices that will enable them to meet the DADSS specifications at the end of the Phase II development.

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. Further development will be required during Phase II to optimize the usability of the standard calibration devices as well as to improve accuracy and precision of the breath and tissue simulated samples.

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 second half of 2013.

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