DRIVER ALCOHOL DETECTION SYSTEM FOR SAFETY (DADSS) – A NON-REGULATORY APPROACH IN THE RESEARCH AND DEVELOPMENT OF VEHICLE SAFETY TECHNOLOGY TO REDUCE ALCOHOL-IMPAIRED DRIVING – A STATUS UPDATE.

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ABSTRACT

Alcohol-impaired driving continues to exact a significant toll among road users both in the United States and around the world. In 2017, in the U.S. alone, alcohol-impaired motor vehicle fatalities totaled almost 11,000 – a number that has seen very little change since 2009. To better address this ongoing problem, in 2008 the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS) formed a cooperative research partnership to explore the feasibility, the potential benefits of, and the public policy challenges associated with the widespread use of non-invasive technology to prevent alcohol-impaired driving. This partnership, known as the Driver Alcohol Detection System for Safety (DADSS) Program has made great strides forward in the development of in-vehicle technologies that will measure blood or breath alcohol and prevent alcohol-impaired drivers from driving their vehicles. Exploratory research in Phases I and II established the feasibility of two sensor approaches, breath- and touch-based, for in-vehicle use. In Phase III, the sensors have become increasingly refined, in terms of both hardware and software, as the program strives to meet the very high standards required for unobtrusive and reliable alcohol measurement. Numerous parallel research programs are currently underway including sensor development, development of calibration processes, materials and instrumentation that will verify the technologies are meeting these elevated standards, human subject testing in conditions that replicate those likely to be experienced in the real world, and real-world pilot field operational trials in diverse settings. At the completion of this effort a determination will be made as to whether the DADSS technologies can ultimately be commercialized. This paper will outline the technological approaches and the status of the various DADSS research programs.

INTRODUCTION

Alcohol-impaired driving (defined as driving at or above the legal limit of 0.08 g/dL or 0.08 percent in all US States except in Utah where the limit is 0.05 g/dl) is one of the primary causes of motor vehicle fatalities on U.S. roads every year (IIHS, 2018). In 2017 alone, crashes involving at least one driver with a blood alcohol concentration (BAC) of 0.08 g/dl resulted in 10,874

deaths of U.S. road users (NHTSA, 2018). Although strong laws and enforcement have led to fewer alcohol-impaired deaths on the roadways (Ferguson, 2012), to effectively reduce or eliminate the problem it will be necessary to prevent alcohol-impaired drivers from driving in the first place. In 2008, the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS)[1] began research to develop in-vehicle solutions to the problem of alcohol-impaired driving. The alcohol sensors under development are required to be seamless with the driving task, that is, accurate, fast, reliable, durable, and require little or no maintenance. Ultimately, the vehicle will not be able to be driven when the device registers that the driver's blood alcohol concentration (BAC) exceeds

[1] Members of ACTS comprise motor vehicle manufacturers representing approximately 99 percent of light vehicle sales in the U.S.

0.08 g/dl (%), although other limits could be programmable. This cooperative research partnership, known as the Driver Alcohol Detection System for Safety (DADSS) Program, has been developing both breath-based and touch-based non-invasive technologies that will be able to prevent alcohol-impaired driving, (Ferguson et al., 2009, Ferguson et al., 2010, Ferguson et al., 2011, Zaouk et al., 2015, Zaouk et al., 2017).

To effectively measure blood and breath alcohol in real time with negligible misclassification errors, stringent performance specifications have been developed that provide a template to guide the overall research effort. The ability to calibrate the performance of each generation of sensor prototypes is a critical component of the development process. These elevated standards, especially those for accuracy and precision, have necessitated the development of innovative approaches that will enable measurement of the technologies' performance on an ongoing basis. Specifically, calibration processes, materials, methodologies and instrumentation have been the subject of extensive cutting-edge research to enable the requisite testing.

Research vehicles have been readied for Field Operational Testing (FOT) and the latest versions of the sensors are being seamlessly integrated within the vehicle interiors. Instrumentation packages also have been developed that will provide a myriad of data on sensor performance under challenging real-world driving conditions. Along with determining whether the DADSS sensors are working as anticipated, the FOT data collection effort will allow the identification of areas for system improvement.

A comprehensive program of human subject research is being carried out, starting with the laboratory environment where better control of conditions can be exerted, and in the vehicle where the sensors can be tested in the environment in which they will be used. This research aims to establish that alcohol measurements made with diluted breath as well as capilary blood (in the tissue of the finger) are comparable to the well-accepted standards of venous blood and deep-lung air widely used in traffic law enforcement.

At the same time, media coverage and consumer sentiments are being monitored in anticipation of a future launch of the technology. These efforts will be ramped up once the technology is available for public scrutiny because the driving public must be onboard with the DADSS technology if it has any chance of being widely implemented.

The purpose of this paper is to provide a status update on the following key DADSS program areas:

- Touch-based DADSS subsystem research
- Breath-based DADSS subsystem research
- Field Operational Testing
- Standard Calibration Devices
- Human Subject Testing

PROGRAM PROGRESS

DADSS Sensor Development

Senseair breath–based subsystem The sensor technology under development by Senseair and its partners uses infrared (IR) spectroscopy, which is stable over the full product lifetime, eliminating the need for recurrent calibrations. The challenge in measuring breath alcohol within the vehicle cabin is that the breath is diluted with the cabin air. The breath-based approach uses sensors to measure the concentration of alcohol and carbon dioxide (CO_2) in diluted breath simultaneously. The use of CO_2 in human breath as a tracer chemical allows it to be used as an indicator for the degree of breath dilution, and thus the dilution of the alcohol concentration in the expired breath. A fan draws diluted breath into a chamber where a detector measures the interaction with the alcohol and CO_2 in the sample (Hök et al., 2006). Breath alcohol concentration is then quickly and accurately calculated (see Figure 1).

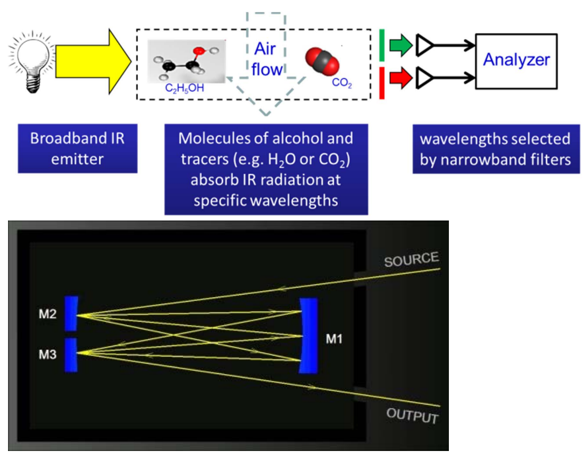

Figure 1. Breath-based sensor block diagram

The goal of the DADSS sensors is to passively measure breath alcohol within the vehicle cabin without directed input from the driver. The challenge is to meet the stringent performance requirements while measuring highly diluted breath. Thus, a significant component of the research is focused on understanding the behavior and flow patterns of the expired breath plume within the vehicle cabin and identifying effective locations for the sensors.

The breath-based sensor has been updated in Phase III with the goal of improving the ability to accurately detect breath alcohol passively. The latest, 3rd Generation version (Gen 3), underwent a complete re-design to increase sensitivity for measurements of passive samples through improvements in the overall signal-to-noise ratio (SNR), reduce the overall size, and improve performance over the full temperature range of -40°C to +85°C as specified by the DADSS Performance Specifications (Biondo et. al. 2017). A major improvement of the Gen 3 sensor is the optical module configuration. Ethanol detection takes place over the full length of the cavity, whereas CO_2 is detected cross-wise to eliminate systematic timing differences between the two signals. This enables the possibility of passive in-vehicle sensing (Ljungblad, 2017). See Figure 2 for a graphic representation of the Gen 3 sensor evolution, key performance metrics and planned Gen 4.

GEN 3.1 (Engineering Samples)	GEN 3.2 (Limited Engineering Samples)	GEN 4.0 (targeted 2020)
Directed BrAC measurement	Directed BrAC measurement	Passive BrAC measurement
	Passive in–cabin alcohol "sniffing"	Passive in–cabin alcohol "sniffing"
	Enhanced alcohol sensitivity	Designed for scaled production
Suitable for fleet & accessory applications	Suitable for fleet & accessory applications	Widely–deployable for POVs

Key Performance Specifications Targeted											
Speed	Accuracy	Precision	Size	Speed	Accuracy	Precision	Size	Speed	Accuracy	Precision	Size
< 1 sec	+/- 0.002	+/- 0.0008	76 x 140 x 38 mm	< 1 sec	TBA	+/- 0.0004	76 x 140 x 38 mm	325 ms	+/- 0.0003	+/- 0.0003	51 x 25 x 19 mm

Figure 2. Evolution of Breath-based DADSS Sensor

Recently, significant improvements have been made. The detector and sensor fan were modified to allow more homogeneous airflow through the system. This resulted in improved SNR and increased peak gas levels when measuring breath exhalations at the same distance. See Figure 3 for a graphic representation of the SNR improvements. This is a critical step for passive breath measurement. Software algorithms for passive detection of breath alcohol also have been enhanced, whereby several consecutive signal features can be accumulated to provide sufficient data for reliable measurement.

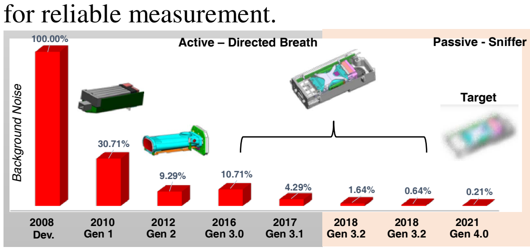

Figure 3. Breath-based DADSS sensor SNR improvements

Further investigations of critical components, including detectors, emitters and mirrors, have shown noteworthy options for more production friendly choices which may be integrated in the future. Sensor calibration procedures have been upgraded in laboratories in Sweden and are now in-line with those used in the United States. These additions have increased the calibration accuracy over the entire concentration span. The latest generation 3.2 sensors have undergone rigorous environmental testing aimed to simulate a sensor life time of fifteen years.

As a result of all these advances, the Gen 3.2 breath sensors now are sufficiently advanced to undergo on-the-road testing. In preparation for fitment of the new Gen 3.2 sensors in the FOT vehicles, the outer housing remained unchanged from the Gen 3.1 version to facilitate rapid exchange of in-vehicle installed sensors. Also, to facilitate exchangeability, a connector printed circuit board (PCB) was developed to avoid the removal of the HMI board with every disassembly/reassembly.

<u>TruTouch touch-based subsystem</u> The touch-based subsystem, developed by TruTouch Technologies, uses near-infrared (NIR) spectrometry - 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, Ridder et al., 2005). TruTouch has determined that the 1.25-2.5 µm portion of the spectrum provides the highest sensitivity and selectivity for alcohol measurement because the alcohol signal is hundreds of times stronger than the signal in the 0.7-1.25 µm part of the NIR.

The measurement begins by illuminating the user's skin with NIR light (similar to a low power flashlight). The light propagates into the tissue (the skin has to be in contact with the device) and a portion of it is diffusely reflected back to the skin's surface where it is 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. The challenge is to measure the concentration of alcohol (sensitivity) while ignoring all the other interfering analytes or signals within the skin (selectivity).

The shift from the Gen 1 prototype, which used a traditional Michelson interferometer that utilizes moving parts, to a solid-state laser spectrometer (which is better suited to the automotive environment) has required extensive hardware and software research (Ver Steeg et al., 2017). The key to enabling such innovation is the ability to define an optimized subset of optical wavelengths which will provide the high quality non-invasive alcohol measurement in humans that is needed (see Figure 4 for a schematic representation of this approach). It was determined that the new spectrometer requires the use of modulated laser diodes to generate 40 unique wavelengths of light that are physically configured for optimal alcohol measurements. The laser diode specifications were derived from the comparison and analysis of human subject data and comparative reference data.

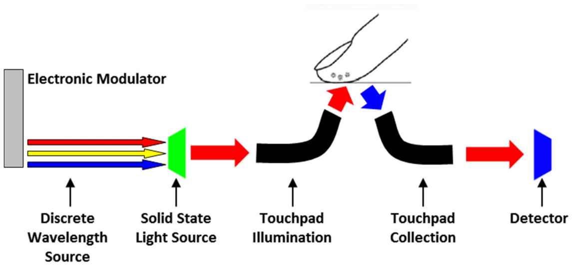

Figure 4. Touch-based subsystem solid-state laser spectrometer approach

The highest risk technical element of the touch-based system is the fabrication of the laser device in order to meet target specifications. Extensive, cutting-edge research has been undertaken to develop the requisite lasers, many of which have not been manufactured before, and assembling them in a multi-laser butterfly package.

The Gen 2 prototype included the first implementation of the 4 multi-laser butterfly packages that interrogate the 40 wavelengths required. Each multi-laser butterfly package, as shown in *Figure 5*, includes 10 laser diodes at 10 unique wavelengths.

Figure 5. Gen 2 multi-laser butterfly packages

The combined light source is generated by the laser packages and routed onto the touchpad. This light then illuminates the finger and is reflected back to the detector where alcohol measurements are made. After initial work to develop the laser diodes and packaging, Nanoplus, a new supplier, with greater expertise in these areas, was selected. Each stage of the development process has required painstaking research which has been the subject of multiple patent applications.

As with any new technology development, complications have been experienced along the way. For example, research on the Gen 2 touch-based system revealed a problem with laser intensity fluctuations resulting in unreliable tissue alcohol measurements.

In 2017, laser fluctuations were discovered, the source of which was pinpointed to the reference channel. Research has been undertaken to correct for that through redesign of the optical subsystems. Multiple optical laser mixing and delivery systems were evaluated via simulations and modelling and four of the best candidates were fabricated and bench tested. The best performing combinations were incorporated into the Gen. 3 system, shown in Figure 6.

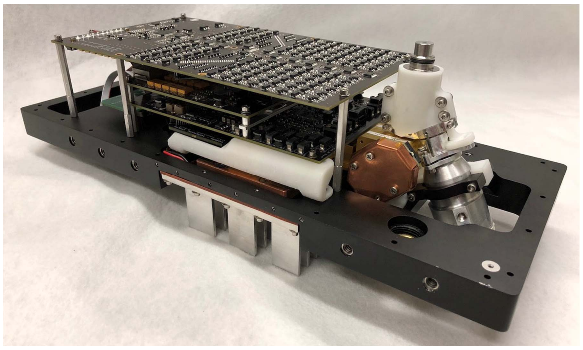

Figure 6. Touch-based Gen 3 prototype

The Gen 3 prototype includes the first implementation of a single package, Stingray, that interrogates all 40 wavelength. The package, as show in Figure 7, includes 20 chips with each chip able to interrogate 2 wavelength, thus reducing the number of chips from 40 to 20 while maintaining the ability to interrogate the required 40 wavelength.

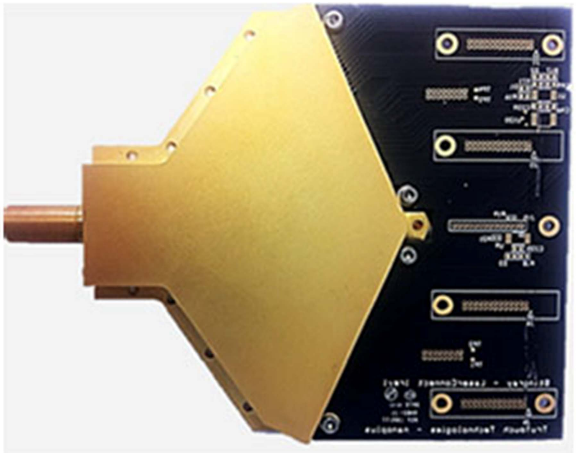

Figure 7. Gen 3 single Stingray lasers package

In anticipation of delivery of functioning stingray laser packages, mechanical enclosures and electronic subsystems were designed, fabricated and tested. Firmware and software that oversee and control the touch system operation were updated. A custom, automated laser calibration system also was built to test the power and wavelengths of the incoming laser packages.

The Gen. 3 laser packages were incorporated into the Gen. 3 touch-based system and underwent in vitro (bench) testing. These tests identified an elevated error rate due to laser dynamic behavior and optical system throughput. Improvements to the optical subsystem mixing and delivery are underway to address this shortcoming.

DADSS Pilot Field Operational Trials

Now in Phase III of development, the breath-based technology is ready for real-world testing. (The touch-based sensors will be integrated once they are ready for installation). Currently, two different research programs are underway to evaluate the DADSS sensors in naturalistic on-road settings in pilot and field operational trials (PFOTs, FOTs). The first PFOTs are currently taking place in Virginia, U.S.A (Fournier et al., 2019). The second set of initial PFOTs are taking place in Massachusetts (Willis et al., 2019).

The Driven to Protect, Powered by DASS initiative, a partnership with the Virginia Department of Motor Vehicles, Highway Safety Office and ACTS, has partnered with James River Transportation (JRT), a transportation company with offices in Richmond and Norfolk, VA, to conduct the first in-vehicle, on-road naturalistic test trials with prototype breath-based alcohol sensors in their vehicles.

KEA Technologies has instrumented and deployed a small fleet of demonstration vehicles to determine if a) the system is generally accepted by drivers, b) there are any technical modifications required to significantly improve the system, and c) the system is ready for wider implementation in fleet, privately-owned, commercial, or other vehicles.

Four 2015 Ford Flex “For Hire” commercial livery service vehicles (see Figure 8) have been instrumented with the latest in-vehicle breath-based alcohol detection systems including supporting data collection and transmission systems (Fournier et al., 2019). The goal is to collect approximately 15,000 data points from the sensors. It is not anticipated that the transportation company drivers will have measurable alcohol on their breath but directed breath measurements are taken at the start and end of each day, and passively throughout the day. Lessons learned will be used to refine the performance specifications, sensor technology as well as data acquisition systems for future on-road vehicle testing.

Figure 8. James River Transportation Ford Flex Driven to Protect Vehicle

Each vehicle is equipped with two Gen 3.1 prototype sensors, one data acquisition system (DAS), two data transmission technology systems (i.e., WIFI and 4G), and one video system including two cameras and a digital video recorder. Breath samples are collected by the sensors both in “directed” mode, where drivers direct their breath toward each of the sensors, and in “sniffer” mode to capture breath alcohol present in the ambient air. The sensors were adapted for installation in the DADSS research vehicles in two different positions: the top of the steering column clamshell, directly in front of the driver’s face and in the driver’s door panel (see Figure 9). These positions improved analysis of the impact of cabin air flow and the driver’s position on alcohol measurements and optimized performance.

The DAS is the central processing system or “brain” of the DADSS system (see Figures 10 and 11). The DAS obtains power from the vehicle battery and distributes to the other system components. It powers the reference sensor and collects acquired serial data. The DAS relays power to the two SenseAir breath sensors and receives the Control Area Network (CAN) data coming from those sensors. Objective data collected consists of numerical and video data that capture host vehicle states and maneuvers, surrounding traffic, system operation, and driver behavior. All these data are stored by the DAS. Subjective data collected includes driver background information before participation in the FOT and at the conclusion of each day.

Figure 9. DADSS Breath-based sensors; Steering column (top) and driver-side door (bottom)

Figure 10. Data Acquisition System (DAS)

Figure 11. Location of Data Acquisition System (DAS) in Ford Flex vehicle

The second series of PFOTs are utilizing Chevy Malibus donated by General Motors. Forty vehicles are being fitted with the latest breath-based alcohol sensors and comprehensive DAS at the KEA Technology laboratory in Marlborough, MA (see Willis et al., 2019 for more details). The Chevrolet Malibus have been prepared to gather sensor validity, reliability, and durability data as well as to assess the real-world use of the sensors with vehicle passengers who have been drinking. The sensors will be tested in extreme real-world environmental conditions, including high heat, cold, varying humidity, corrosive environments, etc. to ensure that they will be operational for the harshest real-world conditions that they are likely to encounter.

As with the Virginia PFOTs, DADSS breath sensors (Gen 3.2) and a reference sensor are being installed along with the DAS, video cameras and DVR, and wireless modem (see Figure 12 for sensor locations).

The initial 10 DADSS vehicles will be equipped with two Gen 3.2 breath sensors and thereafter the vehicles will include four Gen 3.2 breath sensors; two on the driver side and two on the passenger side.

The majority of the hardware for the DADSS system is mounted onto a plate that resides in the trunk of the Chevrolet Malibu (see Figure 13). From left to right the systems are: DAS, Network switch (MP70E), and DVR (Axis).

Figure 12. Breath sensors; Driver-side door (top)Steering wheel (bottom)

Figure 13. From left to right, the DAS, WiFi LTE, and DVR located in the vehicle's trunk

The PFOT/FOT program will be conducted in three phases, each involving five integrated Chevrolet Malibu vehicles. Phases 1 and 2 will include only drivers and Phase 3 will also include passengers who will be dosed with alcohol.

Prior to the PFOT, the vehicles are undergoing a "shakedown" stage, in which DADSS Program researchers are driving five fully-equipped test Chevrolet Malibu vehicles to and from work, to ensure that the sensors, DAS, cameras, and communications systems etc. are fully operational. These initial tests will provide a detailed insight into the necessary requirements of the PFOT test site set up and will be used to complete the development of the PFOT Test Plan (test routes, number of starts/stops, number of samples required, etc.).

These data will be critical in determining the effectiveness (accuracy, precision) of the DADSS sensors in diverse real-world driving environments. They will also be used to evaluate the effects of repeated use and vehicle mileage on sensor function, analyze driver behavior and user acceptance, analyze and assess the impact of the DADSS sensors using real-world data, improve awareness of in-vehicle alcohol detection systems and assess potential impact of the sensors on alcohol-impaired driving.

Standard Calibration Devices (SCD)

As each new generation of the breath-and touch-based sensors are developed, researchers need to evaluate the sensors' performance. Instrument and/or sensor calibration is one of the primary processes used to confirm and maintain a sensor's accuracy and precision. An important component of the calibration process is to develop a qualification and verification process that is able to illustrate in a traceable manner that the breath-based and tissue surrogates meet the requisite performance specifications. The calibration process involves using reference or calibration standards (SRMs or CRMs), that is, samples of known value. The calibration standard in the U.S is normally traceable to a national standard held by the National Institute of Standards and Technology (NIST). Using the NIST procedures allows calibration materials to be certified that they conform to the stated concentrations.

Considering that the accuracy and precision requirements for DADSS alcohol sensors exceed those established for commercially available alcohol measurement devices, it has not been possible to find NIST certified sources of gas and liquid with the requisite accuracy and precision from which to produce the surrogate samples. Existing NIST reference materials have been used to measure accuracy and precision, but going forward, reference materials for the specified levels of accuracy and precision are being developed by the DADSS team. The SRMs, when combined with the delivery systems are considered to be the SCD.

A multi-pronged program of research and development is underway to address the various aspects of the calibration process. The initial efforts focused on the development of breath and tissue surrogates that could meet the DADSS accuracy and precision requirements. This ongoing research is conducted in-house at the DADSS laboratory and in concert with outside providers of relevant materials. Once developed, the materials' composition, accuracy, and precision has to be confirmed at these elevated specifications. The instrumentation necessary for such verification has to exceed the DADSS performance requirements by a significant order of magnitude.

Initially, components of the breath and tissue SCD were measured with a Gas Chromatograph (GC) using a Flame Ionization Detector (FID). The GC-FID system underwent numerous tests and incremental improvements to reduce the variability of the gas delivery system for the breath-based SCDs (see *Figure 14*).

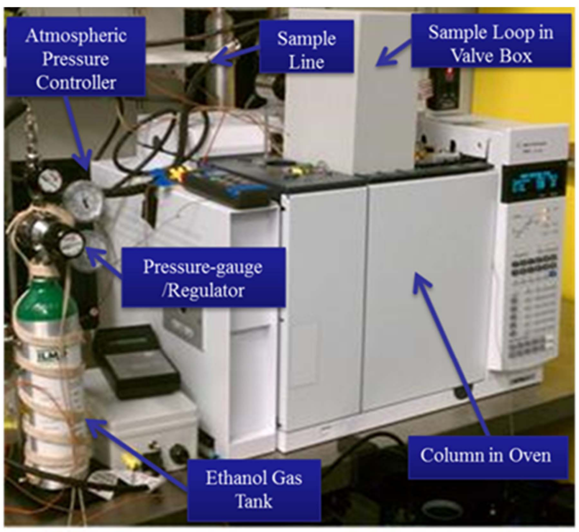

Figure 14. GC system used to measure ethanol gas

The GC-FID system was optimized for dry gas. However, introducing humidified gas revealed unexpected weaknesses in the system. The water in the gas stream increased measurement variability due to the nature of the GC-FID's ability to separate water. This initiated a comprehensive study of the state-of-the-art technologies currently available from over a dozen manufacturers across the globe using different chemical properties to quantitate and identify the components in the breath and tissue SCDs.

As research progressed, it became clear that two different measurement technologies would be required for sample and sensor calibration: one for the breath-based SCD and another for the tissue-based SCD. Various instruments using methods such as gas chromatography, liquid chromatography, and infrared spectroscopy were evaluated. The chosen instrumentation must quantify the chemical components within the samples with better precision and accuracy than the touch and breath-based surrogates. The specified accuracy and precision of the DADSS sensors is 0.0003% at a BAC of 0.08%. This requires the surrogates to be measured with instrumentation that can meet a precision and accuracy target of 0.000075%. Another requirement is that the instruments not only quantify accuracy and precision but also identify substances in the tissue and breath samples.

Breath-based SCD verification An MKS MultiGas™ 2030 FTIR Continuous Gas Analzyer, specifically designed for gases, was selected over other technologies due to its ability to identify and measure ethanol, CO_2, and H_2O in the breath-based SCDs (see *Figure 15*). This ability to identify materials in the sample has enabled detection of contaminants in the breath SCDs. Initial measurements of dry gas cylinders and humidified gases yielded significant precision improvements. The standard deviation for 105 measurements was 0.00006 %BrAC - well below the DADSS Performance Specification.

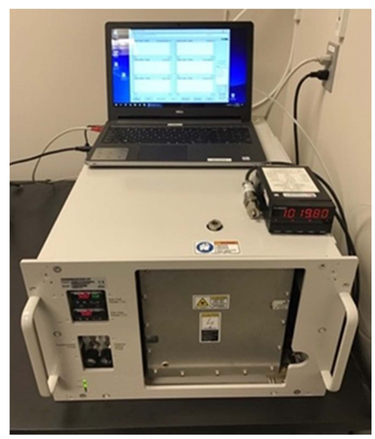

Figure 15. FTIR used for verification of the breath-based SCDs

Sensor testing is implemented in two different settings; a) in the ambient air of the laboratory (at about +22°C), and b) using an environmental chamber where temperature and humidity can be controlled. Sensor performance has been measured at temperatures of: -40°C, +22°C, and +85°C and at alcohol concentrations of (0.000, 0.020, 0.050, 0.080, and 0.100) % BrAC. The overlapping tests at +22°C allows estimation of the effects of the environmental chamber.

Improvements were made to the gas delivery systems by creating the humidified gasses as steady flow and diverting them into the sensors in a pulsed fashion for maximum performance. This procedure improves control of the gas delivery to the breath-based alcohol sensor and allows for simultaneous testing of multiple breath-based alcohol sensors to improve testing efficiency.

New testing procedures have been developed to understand what the DADSS breath sensor is measuring in real time by drawing on a flow through approach to sample measurement. In the laboratory environment, the MKS FTIR is run in-line with the WGBAS and sensors to allow effluent from the WGBAS to confirm the precision of the gas sample before entering the sensor. (see Fratto et al., 2015, in press, Verma et al., 2016, Katz et al., 2016). In the future, the MKS also will be utilized for the environmental chamber testing to study the atmospheric effects on the SCD.

Recent updates to the SCD gas sources have been investigated as well. Researchers at KEA Technologies, Inc. have developed an Automated Breath-Based SCD (ABBS) whereby independent gas sources are combined to generate the SCD rather than blended gas cylinders manufactured by a gas supplier. By keeping the gases independent it is possible to better control the concentrations of all the gases. An added advantage of the ABBS is that it facilitates testing of multiple sensors at a time.

As FOTs ramp up, there is a need to increase the throughput of sensor testing and characterize multiple sensors simultaneously. A new manifold has been developed in the KEA chemistry laboratory to test eight sensors at once both in the ambient conditions of the laboratory and the environmental chamber (see Figure 16).

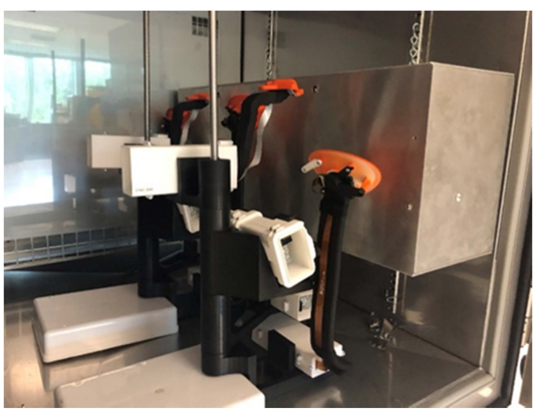

Figure 16. Concurrent testing of multiple breath sensors

Efforts are underway to identify additional sources of traceable gases that can be NIST certified or produced by another country's national laboratory as a CRM. Additionally, the use of a Liquid Ethanol Gas Generation System (LEGGS) has been researched and implemented where applicable. This device is capable of creating a highly accurate and precise alcohol dry gas in real-time.

With the start of in-vehicle testing, work has begun on a device that permits controlled and uniform gas delivery to the breath sensors outside of the controlled laboratory conditions. The initial concept for the portable SCD delivers dry compressed gas from a gas cylinder at a defined pressure and with a controlled flow rate and pulse duration. Initial versions utilize mixed gas ILMO tanks of ethanol with CO_2, O_2, and N_2 (see Figure 17). At his stage of development, the precision and accuracy of the device is limited by the gas cylinder's accuracy and precision.

Figure 17. Portable Gas SCD

<u>Tissue-based calibration</u> An Ultra Performance Liquid Chromatography (UPLC) with three detectors was chosen for characterization of the tissue-based SCD. The Refractive Index (RI) detector quantitates ethanol, the Photo Diode Array (PDA) quantitates non-ethanol reagents, and a mass spectrometer is used for identification of the non-ethanol reagents. Identification of the liquid ethanol in the tissue SCD is performed by a benchtop ThermoFisher Scientific Nicolet FTIR. Figure 18 shows the Waters Acquity UPLC and ThermoFisher Scientific Nicolet FTIR. The RI detector has demonstrated its ability to precisely quantitate NIST certified ethanol in water at the DADSS performance specification.

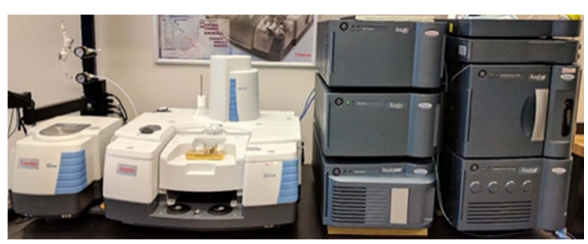

Figure 18. FTIR and UPLC used for verification of the tissue-based SCDs

The initial tissue-based SCDs included ethanol, saline, creatinine, urea, glucose, triton and polymeric beads. However, more recently the formula has been changed to exclude the organic components (glucose, creatinine, and urea). The simplification of the tissue-based SCD was done to remove the potential for cross-reactivity of the components and potential bacterial contamination, resulting in an improved shelf life. The initial version of the tissue-based SCD proved to be unstable, with a fermentation or polymerization process evident from residue noted in the bottom of the vials. Moreover, there was an issue with potential volatility of the ethanol in the solution that needs to be addressed.

Going forward, the goal is to map the new tissue SCD, referred to as the Liquid Alcohol Test SCD (LATS), to determine which individual components are responsible for different parts of the spectra. Such mapping techniques have been used previously to understand many complex chemical systems and develop methods for tuning the specific output concentrations (Privman et al., 2013). The SCD solutions will be created using highly accurate scales, along with a densitometer that will provide accurate ethanol concentration measurements in water solutions. The aim is to build a library of the individual components to determine how they react with one another. With this understanding it will be possible to further tailor the SCD to either include or exclude components that interfere with the long-term storage, accuracy, precision of the standard.

Human Subject Testing

Human subject testing is a critical part of understanding how the DADSS sensors will perform in the real world when confronted with large individual variations in the absorption, distribution, and elimination of alcohol in the various compartments within the human body (blood, breath, tissue) over the myriad factors that can affect BAC. There has been extensive research to understand these relationships with respect to venous (blood) alcohol and breath alcohol when samples of deep lung air are used. However, the new measurement methods being researched as part of the DADSS program that determine alcohol levels from diluted breath samples and within human tissue are not well understood. In particular, the rate of distribution of alcohol throughout the various compartments of the body under a variety of scenarios requires further study.

The purpose of human subject testing is:

- To quantify the rate of distribution of alcohol throughout the various compartments of the body (blood, breath, tissue) under a variety of scenarios.
- To quantify alcohol absorption and elimination curves among a wide cross section of individuals of different ages, body mass index (BMI), race/ethnicity, and sex using a wide range of scenarios.

Significant progress has been achieved in conducting human subject testing at the DADSS Satellite Lab at McLean Hospital in Belmont, MA (See Figure 18). The initial scenarios explore a variety of conditions that are designed to mimic real-life situations (see Lukas et al., 2019 for further details). They include the lag time of the appearance of alcohol in bodily compartments (blood, breath or tissue) after subjects consume alcohol, social drinking while snacking, social drinking with a full meal, last call, where drinkers have a last drink before the bar closes, and dancing and drinking.

Figure 19. Human Subject Testing at DADSS Satellite Lab at McLean Hospital in Belmont MA using the breath- and tissue-based sensors

Significant progress has been made in a number of critical areas, including method development and human subject testing. Many insights have been gained regarding the alcohol absorption and elimination curves and maximum BAC/BrACs reached by the subjects in the scenarios outlined above. In addition, human subject research has begun on new scenarios identified as potentially important in breath and touch alcohol measurement, including the effects of smoking on breath alcohol measurements and the effects of hand sanitizer gel and skin temperature on tissue alcohol measurement.

Across the range of scenarios, a solid linear relationship between blood, breath-based and tissue-based BAC/BrACs has been established. These results indicate that the measurements produced by the various generations of breath-based and touch-based (tissue-based) prototypes is consistent, reproducible, and correlates very well with the "gold-standard" method of measuring alcohol in the body, which is accomplished by measuring blood via gas chromatography. Moreover, the breath and touch sensors responded to the various environmental conditions in the same way that blood alcohol did, providing justification that they serve as a valid alternative for BAC and BrAC measurements.

TECHNOLOGY & MANUFACTURING READINESS LEVELS

The DADSS Program adopted a set of automotive metrics derived from the methodology used by the Department of Defense to quantify a technology's commercial feasibility. The Technology Readiness Level (TRL) provides an objective measure for assessing the maturity of a particular technology. TRL metrics facilitate informed decisions regarding investment and risk associated with technology development and transition to commercialization. Similarly, the Manufacturing Readiness Level (MRL) assesses the maturity of manufacturing readiness. These two sets of readiness levels assist all those engaging with the automotive sector, by providing specific, identifiable stages of maturity, from early stages of research all the way through to supply chain entry. Both the TRL and the MRL are comprised of 9 levels, 1 – 9, although the MRL is offset (delayed) from the TRL. Transfer to the private sector for applied research and development leading potentially to commercialization and mass production is targeted to occur at a TRL equal to eight (8) and an MRL equal to seven (7). Figure 20 shows the DADSS technology and manufacturing readiness levels.

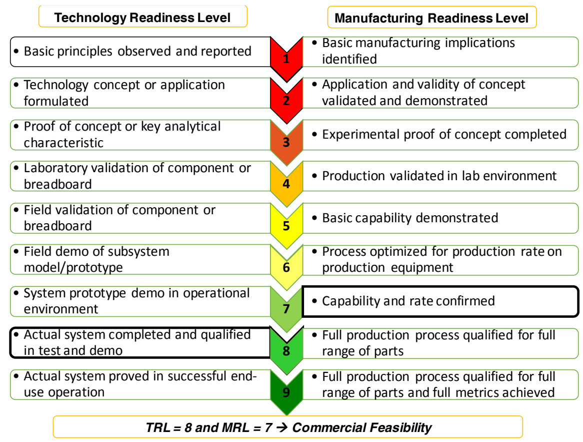

Figure 20. TRL/MRL Demonstrated Commercial Feasibility

Figure 21 summarizes a preliminary evaluation of the "readiness" of the breath–based and touch–based technologies determined by the DADSS team.

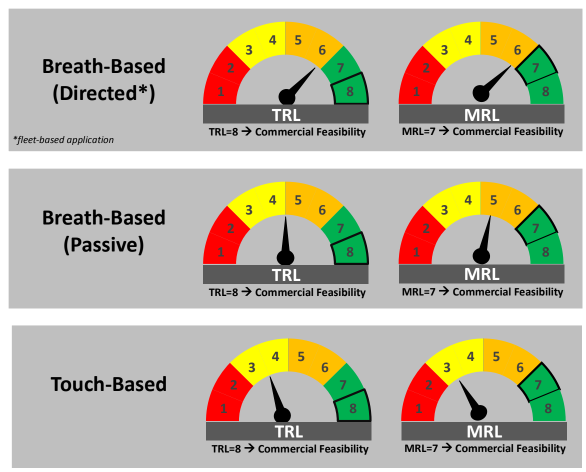

Figure 21. Technology and Manufacturing Readiness Levels by Technology Type

These rating indicate that the breath–based technology research is ahead, but the touch–based technology lags expectations due to challenges with the development of the laser diodes and its associated supply chain, which are in the process of being resolved.

CONCLUSIONS

Since its inception in 2008, the DADSS Program has made tremendous progress in the development of in-vehicle technologies that will prevent impaired drivers from driving their vehicles. The breath- and touch-based sensors have become increasingly refined, both in terms of hardware and software, as headway is made in meeting the high standards required for unobtrusive and reliable alcohol measurement. At the same time, additional research and development is paralleling the sensors' development to allow the characterization of sensor performance in the laboratory, on the road, and among human subjects.

Significant progress has been made in the development of breath and touch-based calibration processes, materials and methodologies making the testing of multiple sensors at a time a reality. Moreover, instrumentation has been identified that can enable the requisite testing across the range of specified environmental conditions.

As sensor development has progressed, research vehicles have been readied for Field Operational Testing (FOT) with the latest versions of the breath sensors seamlessly integrated within the vehicle interiors. Vehicle instrumentation packages have been developed and installed and pilot testing trials now are beginning to provide data on sensor performance under real-world driving conditions. The accumulated data from an extended program of FOTs under diverse conditions will determine whether the DADSS sensors are working as anticipated and allow the identification of areas for system improvement.

Also, a comprehensive program of human subject research also is well underway, starting with the laboratory environment where better control of conditions can be exerted, and continuing in the vehicle where the sensors can be tested in the environment in which they will be used. This research has quantified alcohol absorption and elimination across a wide range of conditions that are anticipated to affect BAC and BrAC as well as some new scenarios specific to the breath and touch-based approaches. Testing showed that the data collected from the various generations of breath-based and touch-based prototypes was consistent, reproducible, and correlates very well with the "gold-standard" method of measuring alcohol in the body, which is accomplished by measuring blood via gas chromatography.

In summary, great progress has been made on a number of fronts to develop in-vehicle sensors that will seamlessly measure driver's blood and breath alcohol and prevent them from driving while impaired. Moreover, additional research is ongoing to continue the progress toward meeting the exacting performance specifications to ensure acceptance and longevity in the vehicle environment.

REFERENCES

Ferguson, S. A. 2012. Alcohol-impaired driving in the United States: Contributors to the problem and effective countermeasures. Traffic Injury Prevention, 13, 427-441.

Ferguson, S.A., Traube, E, Zaouk, A, Strassburger, R. 2009. Driver Alcohol Detection System For Safety (DADSS) – A non-regulatory approach in the development and deployment of vehicle safety technology to reduce alcohol-impaired driving. Paper Number 09-0464. Proceedings of the 21st International Technical Conference on the Enhanced Safety of Vehicles.

Ferguson, S.A., Zaouk, A., Strohl, C. 2010. Driver Alcohol Detection System for Safety (DADSS). Background and Rationale for Technology Approaches. Society for Automotive Engineers Technical Paper, Paper No. 2010-01-1580, Warrendale, PA: Society of Automotive Engineers.

Ferguson, S.A.; Traube, E; Zaouk, A; Strassburger, R. 2011. Driver Alcohol Detection System For Safety (DADSS) – Phase I Prototype Testing And Finding. Paper Number 11-0230. Proceedings of the 22nd International Technical Conference on the Enhanced Safety of Vehicles.

Fournier, R, Zaouk, A.K., Willis, M., Strassburger, R. 2019. Assessing system implementation readiness of the Driver Alcohol Detection System for Safety (DADSS) to reduce alcohol-impaired driving in a real-world driving pilot deployment project. Paper Number 19-0263. Proceedings of the 26th International Technical Conference on the Enhanced Safety of Vehicles.

Fratto, B.E. & Katz, E. Utilization of a fluidic infrastructure for the realization of enzyme-based Boolean logic operations. *Int. J. Parallel Emergent Distrib. Syst.* In Press. (DOI: 10.1080/17445760.2016.1213250.

Fratto, B.E. & Katz, E. Reversible Logic Gates Based on Enzyme-Biocatalyzed Reactions and Realized in Flow Cells: A modular Approach. *ChemPhysChem.,* 2015, 16, 1405 –1415 DOI: 10.1002/cphc.201500042

Hök, B., Pettersson, H., Andersson, G. 2006. Contactless measurement of breath alcohol. Proceedings of the Micro Structure Workshop. May, 2006, Västerås, Sweden.

Jones, A.W. 2008 Biochemical and Physiological Research on the Disposition and Fate of Ethanol in the Body. Garriott's Medicological Aspects of Alcohol (Fifth Edition), 47.

Katz, E. & Fratto, B.E. Enzyme-based reversible logic gates operated in flow cells. In: *Advances in*

Unconventional Computing, A. Adamatzky (ED.), Springer, 2016, Volume 2, Chapter 2, pp 29-59.

Lindberg, L., Brauer, S, Wollmer, P., Goldberg, L., Jones, A.W., Olsson, S.G. 2007. Breath alcohol concentration determined with a new analyzer using free exhalation predicts almost precisely the arterial blood concentration. Forensic Science International. 168: 200-207.

Ljungblad, J., Hök, B., Allalou, A., Pettersson, H. 2017. Passive in-vehicle driver breath alcohol detection using advanced sensor signal acquisition and fusion. Traffic Injury Prevention, Vol 18, 31-36.

Lukas, S.E., Ryan, E., McNeil, J., Shepherd, J., Bingham, L.,Davis, K., Ozdemir, K., Dalal, N., Pirooz, K., Willis, M., Zaouk, A. K. 2019. Driver Alcohol Detection System for Safety (DADSS) – Human Testing of Two Passive Methods of Detecting Alcohol in Tissue and Breath Compared to Venous Blood. Paper Number 19-0268. Proceedings of the 26th International Technical Conference on the Enhanced Safety of Vehicles.

Privman, V., Fratto, B.E., Zavalov, O., Halámek, J., Katz, E. Enzymatic AND Logic Gate with Sigmoid Response Induced by Photochemically Controlled Oxidation of the Output. *J. Phys. Chem. B*, 2013, *117* (25), pp 7559–7568

Ridder, T.D., Hendee, S.P., Brown, C.D. 2005. Noninvasive alcohol testing using diffuse reflectance near-infrared spectroscopy. Applied Spectroscopy, 59, 181-189.

Verma, A., Fratto, B.E., Privman, V., Katz, E. Design of Flow Systems for Improved Networking and Reduced Noise in Biomolecular Signal Processing in Biocomputing and Biosensing Applications. *Sensors (MDPI)* 2016, 16, 1042; doi: 10.3390/s16071042

Willis, M., Zaouk, A.K., Bowers, K., Chaggaris, C., Spicer, R., Bahouth, G., Strassburger, R., Traube, E. Driver Alcohol Detection System for Safety (DADSS) – pilot Field Operational Tests (PFOT) vehicle instrumentation and integration of DADSS technology. Paper Number 19-0262 Proceedings of the 26th International Technical Conference on the Enhanced Safety of Vehicles.

Zaouk AK, Willis M, Traube E, & Strassburger R. 2015. Driver Alcohol Detection System for Safety (DADSS) – A Status Update. Paper Number 15-0276. Proceedings of the 24th International Technical Conference on the Enhanced Safety of Vehicles.

Zaouk A. K, Willis, M., Dalal, N., Traube, E., Strassburger, R. 2017. Driver Alcohol Detection System for Safety (DADSS) – A Status Update. Paper Number 17-0271. Proceedings of the 25th International Technical Conference on the Enhanced Safety of Vehicles.

Biondo, W., Zaouk A. K, Sundararajan, S. 2017. Driver Alcohol Detection System for Safety (DADSS) – Development of the Sybsystem Performance Specifications. Paper Number 17-0301. Proceedings of the 25th International Technical Conference on the Enhanced Safety of Vehicles.