Progress Report

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2019

This report describes the progress made in a cooperative research program, known as the Driver Alcohol Detection System for Safety (DADSS), which is exploring the feasibility, the potential benefits of, and the public policy challenges associated with a more widespread use of non–invasive technology to prevent alcohol–impaired driving. This report includes a general accounting for the use of Federal funds obligated or expended in Fiscal Year (FY) 2019 in carrying out this effort.

In–Vehicle Alcohol Detection Research

Executive Summary

In-vehicle alcohol sensors that will effectively prevent alcohol-impaired driving from occurring, are a promising future technology that could significantly improve highway safety. As outlined in this report, during FY2019, on-going research into unobtrusive alcohol detection to passively measure driver blood alcohol concentration (BAC) quickly, accurately, precisely, and with minimum inconvenience to the driver, has made significant progress toward achieving that goal. The Driver Alcohol Detection System for Safety, known as the DADSS Program, began in 2008, was reauthorized in the surface transportation reauthorization enacted in 2012, Moving Ahead for Progress in the 21st Century (MAP–21), and was reauthorized through FY2020 via the FAST Act. The statutorily-authorized research is being implemented through a Cooperative Agreement between the National Highway Traffic Safety Administration and the Automotive Coalition for Traffic Safety, which was entered into in October 2013 (the "2013 Cooperative Agreement"). The research team being utilized under this agreement comprises technology companies that oversee the research, that develop the sensors, and create processes and procedures to validate each generation of sensors.

In Phases I and II of this cooperative research partnership, exploratory research established the feasibility of two alcohol sensor approaches, breath- and touch-based, for in-vehicle use. In the current phase, Phase III, the sensors have become increasingly refined, both in terms of hardware and software, as the DADSS program strives to meet the very stringent Performance Specifications developed by the team, which are necessary for unobtrusive and reliable alcohol measurement to ultimately be implemented in passenger vehicles. At the same time, additional research and development is paralleling the sensors' development to allow the characterization of sensor performance in the laboratory, and human subject testing in the laboratory and in the vehicle.

Research began with the assumption that for DADSS sensors to effectively measure driver blood and breath alcohol across the vehicle fleet many millions of times a day with minimal misclassification errors, stringent performance specifications for accuracy and precision were critical. These specifications far surpass existing specifications for alcohol measurement and, as a result, necessitated the development of innovative methodologies to verify that the technology is meeting these elevated specifications. Specifically, calibration processes, materials, methodologies, and instrumentation have been the subject of extensive cutting-edge research to enable the requisite testing. In addition to bench testing of the sensor systems, research has focused on testing sensor performance on human subjects, both in the laboratory and on-the-road. The accumulated data from these testing scenarios will determine whether the DADSS sensors are working as anticipated

and identify areas for system improvement. To prepare for the launch of the technology in the future, media coverage continues to be assessed to better understand the tone and quality of the DADSS news articles to which consumers are exposed. Assessment of consumer sentiment and outreach efforts will be increased as the technology is refined for potential commercialization.

During FY2019, many accomplishments were realized across a number of fronts, including sensor development, calibration materials, processes and measurement procedures, and human subject testing both in the laboratory and in the vehicle.

The breath-based system uses infrared sensors to measure the concentrations of alcohol in exhaled breath. Substantial progress was made in FY2019 in advancing the system to passively measure in-vehicle breath with the completion of a study to examine the necessary vehicle parameters and development of an algorithm. At the same time, new components are being researched that would provide higher sensitivity, faster response, and lower power consumption. The technology provider anticipates that the Generation 4 breath-based sensor could be ready for mass production in 2024, or even 2023 if the program can be accelerated. Notably, the program is working toward the release of the first derivative of the breath–based technology by the end of 2020, which will be suitable for limited deployment in fleet vehicles. This device will require the user/driver to provide a short puff of breath directed at the sensor at a distance of two to three inches. The device will be engineered and validated to conform with performance specifications suitable for motor vehicle fleet applications. Vehicle fleets typically have a zero BAC standard for drivers (often 0.02 g/dL), requiring the ability to detect the presence of alcohol with a directed breath sample rather than meeting the performance specifications. To that end updated Performance Specifications[1] have been drafted and work has begun to create an SAE J standard for fleet vehicle use.

During FY2019, progress was made in the development of the latest generation, Generation 4, touch-based sensor system. The touch-based sensors allow estimation of blood alcohol concentration by measuring alcohol concentrations in the driver's fingertip tissue (or more specifically the blood in the capillaries). Since February of 2019, the DADSS team at KEA Technologies has taken over the development of the touch-based system with input from Nanoplus, a world leader in laser technology, and other experts in the spectroscopy and optics fields. Researchers have developed innovative improvements to the technology, software, and electronics and significantly reduced the size of the prototype

[1] Biondo, W., Zaouk, A.K., Sundararajan, S. 2017. Driver alcohol detection system for safety (DADSS) – development of the subsystem performance specifications. Paper No. 17-0301. Proceedings of the 25th International Technical Conference on the Enhanced Safety of Vehicles.

system. Specifically, a new optical interface was designed that removed the integrating sphere and optical fibers, resulting in reduced size, significantly improved signal levels, and reduced thermal- and mechanical-related signal drift. A complete redesign of the system electronics is ongoing, which will improve the system in many ways, including size reduction, lower power consumption, complete control of firmware to fine-tune measurement and data collection systems, and increased communications speed. Finally, extensive modifications to the software have allowed greater flexibility for capturing, analyzing, and displaying data from the touch-based sensor system to allow for speedy verification of test data and study trends over time.

As sensors evolve and improve, the new generations of the breath-and touch-based systems need to be evaluated. During FY2019, progress in calibration and testing of the two systems has been made on a number of fronts, including improvements in calibration samples, measurement procedures, design, and characterization of delivery systems, as well as the characterization of the latest generation 3.2 breath sensors. Improvements have focused on improving the efficiency and reliability of surrogate breath production, including changes to the Liquid Ethanol Gas Generation System and Automated Breath Based System that supply gases to the sensors for testing. Also, the environmental test chamber, which allows control of the ambient conditions for testing, has undergone modifications to improve environmental stability. The Gen-1 portable breath-based Standard Calibration Device (SCD), developed during FY2018, has been used to perform repeatable testing on sensors integrated in vehicles. This testing assists in evaluation of degradation in the sensor performance over time and with environmental exposures.

On the touch-based front, research continues into the use of alternate tissue surrogates. This resulted in the identification of gelatinous materials which may be further explored as the basis for the next generation of tissue-based SCD. Procedural improvements in the fabrication of the tissue-based SCD were successful, including the use of the Waters Acquity High Performance Liquid Chromatography to control the quality of starting materials and initial dilutions when producing the liquid SCD.

Human subject testing was conducted throughout FY2019 in controlled laboratory conditions at McLean Hospital, in Massachusetts, to evaluate the performance of the breath and touch-based sensors. Once ingested, alcohol is constantly absorbed into and eliminated from the body. Subjects' alcohol absorption and elimination curves are plotted to determine the amount of alcohol in the body (including blood, breath, and tissue alcohol) over time to establish that alcohol measurements made with diluted breath and in tissue are comparable to the well-accepted standards widely used in traffic law enforcement of Driving Under the Influence (DUI) laws. Previous research has established that the alcohol measurements from breath-based and touch-based prototypes are consistent, reproducible, and correlate very well with traditional blood and breath alcohol measurement.[2] Substantial progress was made in fiscal year 2019 to measure the alcohol absorption and elimination curves of human subjects across many new scenarios. A number of new scenarios were ongoing during FY2019 using the breath and touch sensors to examine the effects of hand sanitizer, varying hand temperature, electronic cigarettes, energy drinks, breath holding, and hyperventilation. Data from these studies currently are being analyzed. Through FY2019, 10,469 samples have been collected; of which 1,417 samples from 49 subjects were added during FY2019 to investigate the new scenarios outlined above.

The Office of Management and Budget approved the Information Collection Request (ICR) for Human Subject Driving on March 20, 2019. After the Institutional Review Board approval of the human subject driving study, in June 2019 human subject driving tests were initiated along planned routes in Massachusetts to test the breath-based sensor performance under real-world conditions. The goal of the human subject driving tests is to conduct basic and applied research to understand the performance of the sensors in the vehicle, and across a range of environmental conditions. These routes exposed the system to a variety of temperatures, humidities, and elevations (among other factors) to ensure that the system will be operational across real-world conditions likely to be encountered. While traversing the planned routes, passengers who had been dosed with alcohol provide breath samples both to the breath-based sensors and a reference sensor (SmartStart alcohol ignition interlock). By the end of FY2019, 45 drives were completed with 30 unique passenger subjects having provided 17,460 directed-breath samples.

While significant progress is being made across the board on sensor development and performance both in the laboratory and on the road, essential research remains needed in a number of areas, including further sensor development, calibration methodology, and human subject testing. The objective of this effort is to have a device or devices (breath, and/or touch-based) that can be evaluated to assess suitability for commercialization for in-vehicle use. At that stage, it is anticipated that automakers could take the next steps toward future product development and integration into motor vehicles.

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[2] Lukas, S.E., Ryan, E., McNeil, J., Shepherd, J., Bingham, L., Davis, K., Ozedmir, K., Dalal, N., Pirooz, K., Willis, M., Zaouk, A. 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.

Introduction

Alcohol-impaired driving continues to result in a large number of deaths among road users both in the United States and around the world. Decades of research, focusing largely on modifying driver behavior through strong laws and enforcement, has identified ways in which alcohol-impaired driving can be reduced.[3] Significant progress has been made through these proven approaches, however, deaths from alcohol-impaired driving remain stubbornly high. In 2018 alone, crashes involving at least one driver with a blood alcohol concentration (BAC) of 0.08 grams per deciliter or higher (g/dL)[4] resulted in 10,511[5] deaths of U.S. road users.

The deployment of vehicle technology that measures driver BACs and prevents vehicle operation in an intoxicated state is seen as a potential solution to this continuing problem. Such an approach has the potential to prevent drinking and driving, reduce and ultimately eliminate those deaths, and free up current resources spent on drinking and driving prevention, punishment, and rehabilitation. The Insurance Institute for Highway Safety research estimated that 7,082 deaths could have been prevented in 2010 if all drivers with BACs of 0.08 g/dL or higher were kept off the roads.[6] Applying the same methods for 2017 fatality data yields an estimate of 7,426 preventable deaths.[7]

A vehicle-based, preventative approach has the potential, over the longer term, to permanently address the problem of alcohol-impaired driving. In 2008, a public/private partnership was begun in the United States between the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS)[8] to design a technological solution or solutions to end alcohol-impaired driving. This program, known as the Driver Alcohol Detection System for Safety (DADSS) is developing non–intrusive

[3] Ferguson, S.A. 2012. Alcohol-impaired driving in the United States: Contributors to the problem and effective countermeasures. Traffic Injury Prevention, 427-41.
[4] 0.08 g/dL is currently the legal limit in the all of the United States except for Utah which has a BAC limit of 0.05 g/dL.
[5] National Highway Traffic Safety Administration. 2019. Traffic Safety Facts. Alcohol-Impaired Driving. DOT HS 812826. Washington DC.
[6] Lund, A.K; McCartt, A.T.; and Farmer, C.M. 2012. Contribution of alcohol-impaired driving to motor-vehicle crash deaths in 2010. Arlington, VA. Insurance Institute for Highway Safety.
[7] Insurance Institute for Highway Safety. Accessed 10/23/2019 https://www.iihs.org/topics/alcohol-and-drugs.
[8] ACTS is a nonprofit safety organization funded by motor vehicle manufacturers, who make up its membership. ACTS' current members are: BMW Group, FCA US LLC, Ford Motor Company, General Motors Company, Honda Research & Development, Jaguar Land Rover, Mazda North America Operations, Hyundai America Technical Center Inc., Mercedes Benz USA, Mitsubishi Motors, Nissan North America, Inc., Porsche, Subaru of America, Inc., Toyota Motor Sales, U.S.A., Inc., Volkswagen of America, Inc., and Volvo Cars. These ACTS members account for the majority of new light vehicle sales in the U.S. market.

technologies that could prevent the vehicle from being driven when the device registers that the driver's BAC meets or exceeds the legal limit.[9]

Early in the development process, DADSS researchers identified promising technologies which had the potential to prevent alcohol-impaired driving through instantaneous measurement of driver breath- or tissue-alcohol concentration.[10, 11] After a thorough review of the scientific and technical literature, two approaches were considered promising for quick and accurate measurement of driver breath alcohol concentration (BrAC) or BAC. These were breath-based and touch- or tissue-based spectrometry systems. The breath-based approach uses an infrared (IR) beam to analyze BrAC. Expired breath is diluted with the vehicle cabin air and is drawn into an optical cavity where an IR beam is used to analyze the alcohol concentration in the subject's exhaled breath. Carbon dioxide is measured separately to determine the degree of breath dilution. The second approach, known as tissue spectrometry, estimates BAC through detection of light absorption at pre-selected wavelengths from a beam of near-infrared light reflected from within the subject's skin tissue after an optical module is touched by the driver.

The 2008 cooperative agreement between NHTSA and ACTS (covering Phases I and II of the research) began with a comprehensive review of emerging and existing state–of–the–art technologies for alcohol detection to identify promising technologies that are capable of measuring BAC or BrAC in a vehicle environment as well as prototype development of the most promising approaches. Under specific authorizations for the DADSS program in the Moving Ahead for Progress in the 21st Century (MAP-21) Act and the Fixing America's Surface Transportation (FAST) Act additional research has continued under a new cooperate agreement (covering Phase III of the research).[12] During Phase III, research has continued to advance the DADSS sensor technology. At the same time, a multi-pronged program of research has been undertaken to quantify sensor performance and understand human interaction with the DADSS sensors both physiologically and ergonomically in the laboratory and in the vehicle environment. In addition, to prepare for the future launch of the technology, media coverage of the DADSS research program

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[9] From inception in 2008, the DADSS Research Project has been based on a BAC threshold of 0.08 g/dL or greater. The MAP-21 authorization to continue the DADSS research explicitly specifies that this threshold be used. See section 403(h) of title 23 of the United States Code.

[10] 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. Washington, D.C., USA.

[11] Zaouk A. K, Willis, M., Traube, E., Strassburger, R. 2019. 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 - Status Update. Paper Number 19-0260. Proceedings of the 26th International Technical Conference on the Enhanced Safety of Vehicles.

[12] See section 403(h) of title 23 of the United States Code as amended by Public Law 112-141, December 4, 2015.

continues to be assessed. Assessment of consumer sentiments and outreach efforts will be increased as the technology is refined and readied for commercialization.

As required by the FAST Act, this report will discuss these research programs in more detail and the progress achieved towards these goals in FY2019. This report also includes a general accounting for the use of Federal funds obligated during this period.

DADSS Research Program Team

The DADSS Research Program is composed of several different elements that consider various aspects associated with the development and widespread deployment of DADSS technology (Figure 1). The Stakeholders Team, consisting of representatives from NHTSA, the automotive industry, participating State governments and public interest groups, meets on a regular basis to discuss progress to date and issues affecting future use such as public policy, vehicle deployment, and state law. The Technical Team, managed by KEA Technologies, a research and technology company, consists of sensor developers and other program members, and carries out associated DADSS research.

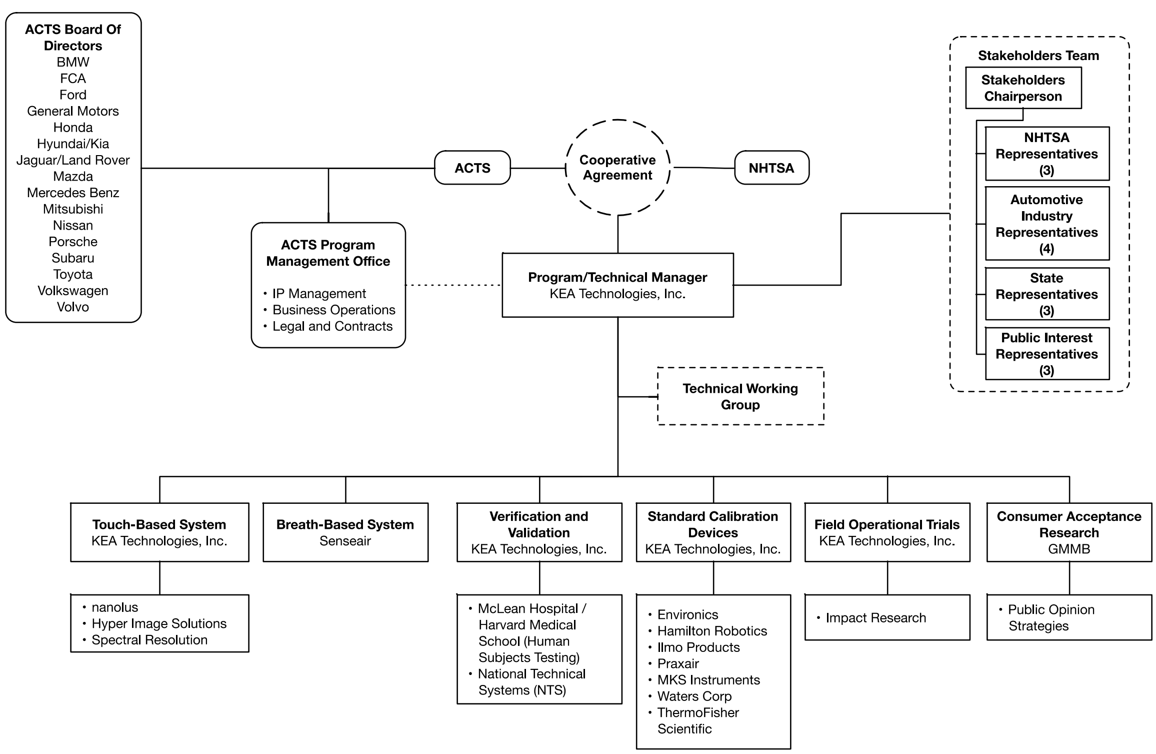

Figure 1. DADSS Research Program Organization

Phased Research Plan with Technical Review Gates

From inception, the DADSS program has been structured to minimize risk by conducting the research in phases with technical review gates between phases. The intent of Phase I was to research prototypes that could rapidly and accurately measure a driver's BAC non-intrusively. The prototypes constructed during this Phase (1st Generation) were designed to demonstrate proof of concept. Three prototypes were delivered and tested at the DADSS laboratory. Two of the three technologies evaluated yielded favorable results. Thus, at the conclusion of Phase I it was determined that development should continue for both the touch– and breath–based technologies.

The Phase II effort, began in late 2011, spanned two years and required technology providers to make significant improvements to device accuracy, precision, reliability, and speed of measurement. The effort also examined an extensive array of performance specifications common in the automotive industry to address the wide range of environmental conditions experienced when technology is integrated into a vehicle. However, the devices' accuracy, precision, and speed of measurement could not be fully quantified until the completion of all required testing.

Phase III, which began in 2013, is ongoing and focuses on further refinement of the technology and test instruments as well as basic and applied research to understand human interaction with the sensors both physiologically and ergonomically.

DADSS Research Programs

The DADSS program of research and development began with the assumption that to be successful and acceptable to the driver, many of whom do not drink and drive, the technology must be seamless with the driving task. It must be quick and unobtrusive, extremely reliable, durable, and highly accurate with precise measurements. To meet these challenging needs, performance specifications were developed at the outset that are unprecedented in the field of blood-alcohol measurement. These specifications, which are updated on an ongoing basis, provide the performance goals for the research effort (the current version of which is set forth in the DADSS Performance Specifications).

Research is ongoing in Phase III to further develop the breath- and touch-based sensor subsystems. Progress is being made in meeting the rigorous performance specifications necessary to conduct driver alcohol measurements in a vehicle environment subject to a myriad of challenging conditions. The development of the breath and touch-based in-vehicle sensors is the central focus of the DADSS research effort. However, the DADSS research program is multifaceted, with the research and development of multiple technologies being pursued simultaneously under the DADSS umbrella. The breadth of the research undertaken by the DADSS team necessitated the construction of a DADSS laboratory where in-house research is conducted by a team of highly-trained professionals with expertise in numerous disciplines.

These additional research efforts are vital components to support and validate the approaches and technologies that are produced. Not only must the technology meet specifications to operate seamlessly with the vehicle start-up function, and be highly accurate and precise, often in conditions of high elevation, cold, heat, and humidity, but as with other safety technologies, the systems must work reliably for the full operating life of the vehicle. The accuracy and precision of the alcohol measurements, which are set at 0.0003% at a BAC of 0.08%, must be confirmed in the laboratory using breath and tissue surrogates, with human subjects under controlled conditions to establish the key variables that might affect measurement, and also in conditions that replicate those likely to be experienced in the vehicle environment. Success of DADSS will require not only that the technologies successfully meet the performance criteria, but also achieve wide-spread implementation that is dependent on the driving public adopting this optional technology when purchasing their future vehicles. To that end, a separate effort was launched to engage the driving public in discussions about the technologies so that their feedback could be incorporated into the DADSS Specifications as early as possible in the development cycle.

DADSS Subsystems Technological Research

The two approaches that are being pursued for measuring driver BrAC and BAC non-invasively within the vehicle are a breath-based approach, and a touch-based (tissue) spectrometry approach.

Breath–based sensor

The breath-based approach uses sensors that simultaneously measure the concentrations of alcohol and carbon dioxide in the breath. The known quantity of carbon dioxide in the human breath is an indicator of the degree of dilution of the alcohol concentration in expired air. A fan draws diluted breath into a chamber where detectors measure the concentrations of the alcohol and carbon dioxide in the sample.[13] BrAC is then calculated.

[13] Hök B, Pettersson, H, Andersson G, Contactless measurement of breath alcohol. Paper presented at the Micro Structure Workshop 2006, MSW2006; Västerås, Sweden.

The goal of the DADSS sensors is to passively measure breath alcohol within the vehicle cabin without direct input from the driver. The challenge is to meet the stringent accuracy and precision specifications while measuring this diluted breath. As a result, sensor location in the vehicle is key for effective breath alcohol detection. Thus, a significant component of the research has been focused on understanding the behavior and flow patterns of the expired breath plume within the vehicle cabin and identifying effective locations for the sensors. After comprehensive research that investigated optimal sensor placement in numerous locations within the vehicle, the sensor was adapted for installation in the DADSS research vehicles in two different positions: above the steering column in front of the driver and in the driver's door panel. These positions improved analysis of the impact of cabin air flow and the driver's position on alcohol measurements as well as optimized performance.

The breath-based sensor has been updated in Phase III with the goal of improving the ability to measure directed and passive breath more accurately and precisely. The latest, 3rd Generation version (Gen 3), underwent a complete re-design to increase sensitivity for measurements of passive samples, 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. 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 carbon dioxide is detected cross-wise to eliminate systematic timing differences between the two signals.[14] The Gen 3.2 device has seen sizeable improvements compared with the Gen 3.1 sensor. Gen 3.2 now enables passive in-cabin sniffing through enhanced alcohol sensitivity, with precision markedly improved. (See Figure 2).

Research is under way to quantify the impact made to accuracy and precision. The Gen 3.2/3.3 device is anticipated to be made available for fleet and accessory application during 2020. This fleet device will be set to detect/non detect for the presence of any alcohol but will also have the flexibility to set the limit up to a BAC of 0.04 g/dL. That is, at or below the commercial driver alcohol legal limit, depending on the company fleet owner's preference. Another feature will be the use of a directed breath, rather than the passive breath sample currently specified for the passenger vehicle market.

The Gen 4.0, which is targeted for distribution in 2023 – 2024, will be suited for wider deployment in passenger vehicles.

[14] 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.

GEN 3.1 (Engineering Samples)	GEN 3.2 / GEN 3.3 (Limited Engineering Samples/2020 Fleet Der.)	GEN 4.0 (Targeted for 2023 ~ 2024)
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

Figure 2. Evolution of DADSS breath-based sensor

There has been a significant reduction in background noise – down from 10.71 percent in the earliest Gen 3 prototype to only 1.64 percent in the latest Gen 3.2 version (see Figure 3). Reducing the background noise enables the signal to be better detected, hence improving accuracy and precision measurements.[15] The Gen 4.0 version is under development with a design goal to reduce the noise even farther, to only 0.21 percent of the signal. The net result will be a significant enhancement of the alcohol signal.

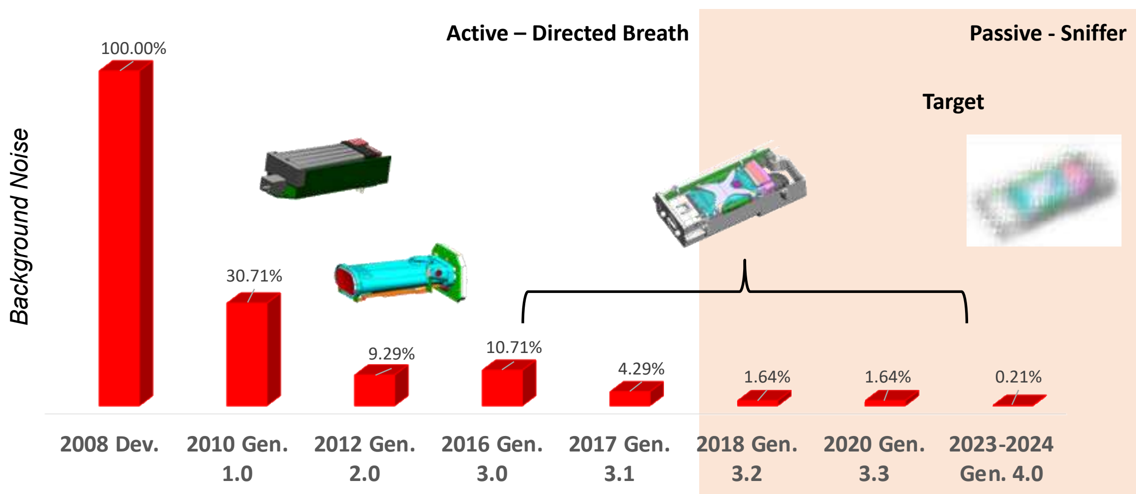

Figure 3. Sensor performance improvements and goals through reduction of background noise

Significant progress has been made in FY2019 on a number of fronts including hardware and software and is detailed below.

[15] Signal detection theory refers to the ability to differentiate between information-bearing patterns (called the signal) and random patterns that distract from the information (called noise) consisting of background stimuli and random activity of the detection machine).The separation of such patterns from a disguising background is referred to as signal recovery.

- Senseair, the sensor developers, conducted an in-vehicle human subject study to investigate different modes of operation in a vehicle environment to allow for unobtrusive alcohol testing: 1) directed breath while leaning towards the sensor, 2) directed breath while seated in a relaxed position and 3) monitoring the exhaled breath without active assistance from the subject (passive measurement).[16] The directed breath modes required only a light exhalation for an acceptable sample, but the passive mode required a longer monitoring time before a reliable reading could be taken. Based on these results, a methodology for passive alcohol detection was developed that includes control of the heating, ventilation, and air conditioning system (HVAC) to build elevated levels of exhaled target gas, and thus, better breath alcohol detection. A patent describing this methodology was submitted during the year.
- A study is underway at Senseair for the design and implementation of the Gen 4 breath sensor, which will be the first truly passive sensor. The Gen 4 version is targeted for mass production no later than 2024. Among the new components being researched are various pyroelectric sensors that might enable greater sensitivity, faster response, and lower power consumption. Initial results are promising.
- The Senseair laboratories in Sweden (Delsbo and Västerås facilities) have continued to update their sensor calibration techniques to bring them more in line with those used at the KEA Technologies laboratory in Marlborough, MA, resulting in better agreement of sensor performance across the sites.
- An algorithm was developed that increases the usability of the sensor in terms of allowable distance to the sensor and provides feedback to the user. This methodology is currently going through the patent submission process.
- An algorithm was developed that continuously measures and adjusts for variation in background carbon dioxide levels minimizing the variation in signal measurement.
- A baseline algorithm correction has been implemented that will counteract any long-term intensity degradation of the sensor core, which potentially could occur due to environmental pollution. The IR signal is measured each time the sensor is used in the vehicle and the algorithm corrects signal variance, either up or down.

[16] Ljungblad, J., Hök, B., Åhlenius, M., Eriksson, G. 2019. Vehicle integrated non-dispersive infrared sensor system for passive breath alcohol determination. Paper Number 19-0296. Proceedings of the 26th International Technical Conference on the Enhanced Safety of Vehicles.

The DADSS program is working to release the first derivative of the breath–based technology by the end of 2020, which will be suitable for limited deployment in fleet vehicles, which typically have a driver BAC limit of 0.02 g/dL, also known as zero tolerance. This derivative device will be engineered and validated to conform with performance specifications suitable for zero tolerance fleet applications which are, in some instances, less stringent than those suitable for widespread deployment in privately–owned vehicles. The device is a directed breath-based sensor whereby the user/driver must provide a breath sample directed at the sensor at a distance of two to three inches. Revised Performance Specifications for zero tolerance fleet applications for a device that does not use a mouthpiece have been drafted for potential inclusion as part of the CENELEC EN 50436 or SAE-J requirements, which are being developed (see also the section on Performance Specifications).

Touch-Based Sensor

The touch-based approach analyzes alcohol found in the driver's fingertip tissue (or more specifically, the blood alcohol concentration detected in the capillaries). The driver touches an optical module and a near infrared light shines on the driver's skin, similar to a low power flashlight, which propagates into the tissue. A portion of the light is reflected back to the skin's surface, where it is collected by the touch pad. This light transmits information on the skin's chemical properties, including the concentration of alcohol.

The shift from the Phase I 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.[17] The key to such innovation is the ability to define an optimized subset of optical wavelengths to enable high-quality non-invasive alcohol measurement. 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.

The highest technical risk of the touch-based system is fabrication of an in-specification laser diode.[18] Extensive research has been undertaken to develop the requisite lasers, many of which have not been previously manufactured, and assemble them in multi-laser packages. The individual lasers are combined into a broader, diffuse

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[17] Ver Steeg, B., Treese, T., Adelante, R., Kraintz, A, Laaksonen, B., Ridder, T., Legge, M., Koslowski, N., Zeller, S., Hildebrandt, L., Koeth, J., Cech, L., Rumps, D., Nagolu, M., Cox, D. 2017. Development of a solid state, non-invasive, human touch-based blood alcohol sensor. Paper Number 17-0036. Proceedings of the 25th International Technical Conference on the Enhanced Safety of Vehicles.

[18] A laser diode has the ability to directly convert electrical energy into light.

light source in the optical module, which illuminates the finger and is reflected back to the detector where alcohol measurements are made. After initial work was completed to develop the laser diodes and packaging, a new supplier, Nanoplus, was selected with greater expertise in these areas. Each stage of the development process has required painstaking research which has resulted in multiple patent applications.

As with any new technology development, technical difficulties have been experienced along the way. For example, research on the Gen 3 sensor revealed a problem with fluctuating laser intensity that could result in unreliable tissue alcohol measurements.[19] Problems also were encountered with the integrating sphere which combines the output from the individual laser into one broader, diffuse light source that then shines into the finger. Researchers discovered that there was a lack of homogeneity in the combined light source causing light peaks to hit the sample and reference detectors differently. The reference sensor provides a baseline measurement against which the refracted signal from the finger is compared. Thus, if the two signals differ, the comparison, and hence alcohol measurement, cannot be effectively performed.

The recent evolution of the touch-based sensor is depicted in Figure 4. Touch-based sensors consist of the laser diodes, the laser guiding system to relay the laser signal into the skin in the prescribed fashion for optimal measurement, the detectors to receive the reflected signal, all of which reside in the driver optical interface, a reference sensor, and the electronics board that controls and guides the system. Each of these design elements will undergo significant enhancements from the current Gen 4 device. Gen 5 availability, suitable for fleet and accessory applications, is targeted for 2023. The Gen 6 version aimed for use in privately-operated vehicles is anticipated to be available during 2024-2025.

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[19] Zaouk A. K, Willis, M., Traube, E., Strassburger, R. 2019. 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 - Status Update. Paper Number 19-0260. Proceedings of the 26th International Technical Conference on the Enhanced Safety of Vehicles.

 2020	 Target 2023	 Target 2024-2025
GEN 4	**GEN 5**	**GEN 6**
• 20–laser (discrete laser architecture)	• 4 tunable lasers	• 2 tunable lasers
• Fiber coupled lasers	• Waveguide–coupled lasers	• Free space illumination
• Driver Optical Interface → Multi-Photo Diode Detectors	• Driver Optical Interface → Monolithic sensor array	• Driver Optical Interface → TBD
• Single board electronics design	• Single board electronics designed for low volume manufacturing	• ASIC–level electronic integration
• Proof of concept architecture	• Potential for fleet & accessory applications	• Widely–deployable for privately–operated vehicles (POVs)

Figure 4. Recent evolution of touch-based sensor

Figure 5 depicts the recent evolution of laser diode development. As noted above, it was determined that 40 unique wavelengths would be the optimal number to differentiate the alcohol signal from other substances in the blood, such as water. In 2016, the 40 individual lasers were packaged into four discrete packages that make up the alcohol detection system (ADS); 10 in each. The current stingray design comprises 20 laser chips in a single package with each laser chip interrogating 2 wavelength to cover the 40 discrete wavelengths. Recently, Nanoplus was successful in developing tunable lasers suitable for the touch-based sensor. Tunable lasers are able to alter the wavelength of operation in a controlled manner, thus enabling the use of fewer lasers. The first step will be four tunable lasers chips in a single package that can sweep the spectrum from approximately 1500-2500 nanometers (nm) which will enable a smaller sensor footprint, use less power, have better temperature control to prevent measurement drift, and result in simplified optics and electronics. It is anticipated that they will be ready for testing in FY2020. Ultimately, the plan is to use only two tunable laser chips to produce these same unique wavelengths.

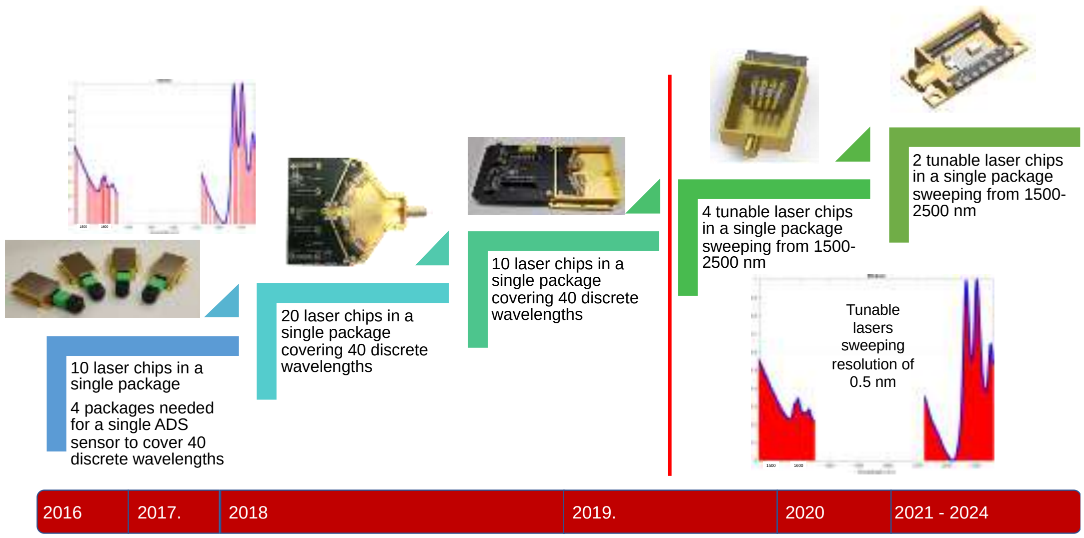

Figure 5. Evolution of Laser Development

Since February 2019, progress has been achieved in critical hardware, electronics, and software development.

Hardware accomplishments:

- During FY 2019, significant improvements were made to the Gen 3 touch-based sensor system. The Gen 4 version now includes a new optical interface that was designed by the DADSS team in concert with Nanoplus. The new optical interface comprises multi-channel photodiode detectors with arrays of square-shaped photosensors arranged in concentric circles (see Figure 6, second figure from the left). This development allowed removal of the integrating sphere and optical fibers (shown in Figure 6 on the far left).

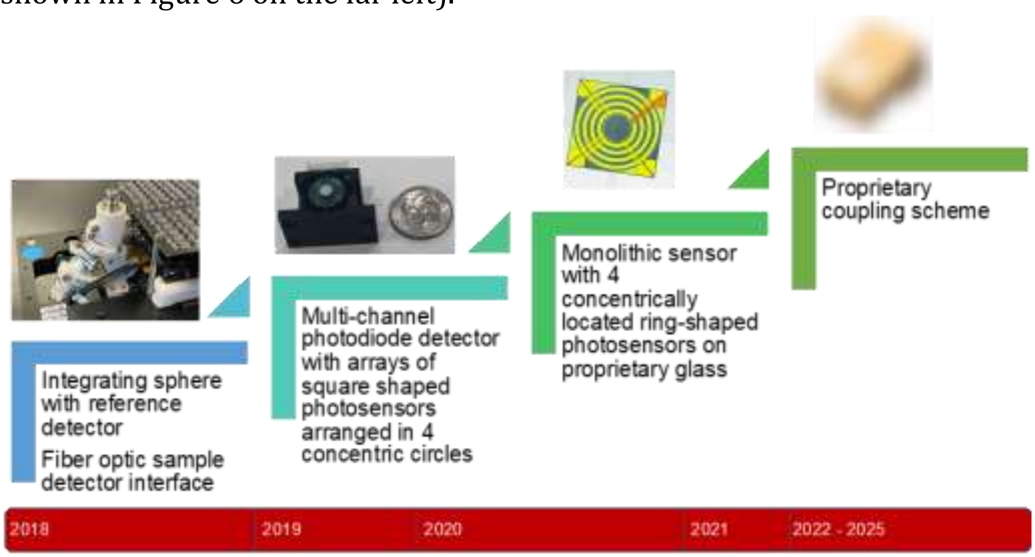

Figure 6. Evolution of the touch-based optical module

Figure 7 shows a schematic representation of the Gen 4 components along with a picture of the Gen 4 prototype, including the layout of the new multi-channel photodiode detector, stingray laser package, and single board electronics. Elimination of the original components has several positive impacts on the system. Not only does it reduce the size needed for these optical components, but greatly reduces the loss of signal throughput, significantly improving signal levels. Removal of the integrating sphere and optical bundles also reduces thermal- and mechanical-related signal drift. The new interface has multiple sample detector rings which will allow for new analyses of the signal. This new optical interface was tested using surrogate tissue gel samples at high alcohol concentrations and confirmed that it is possible to see the ethanol signal with the new design.

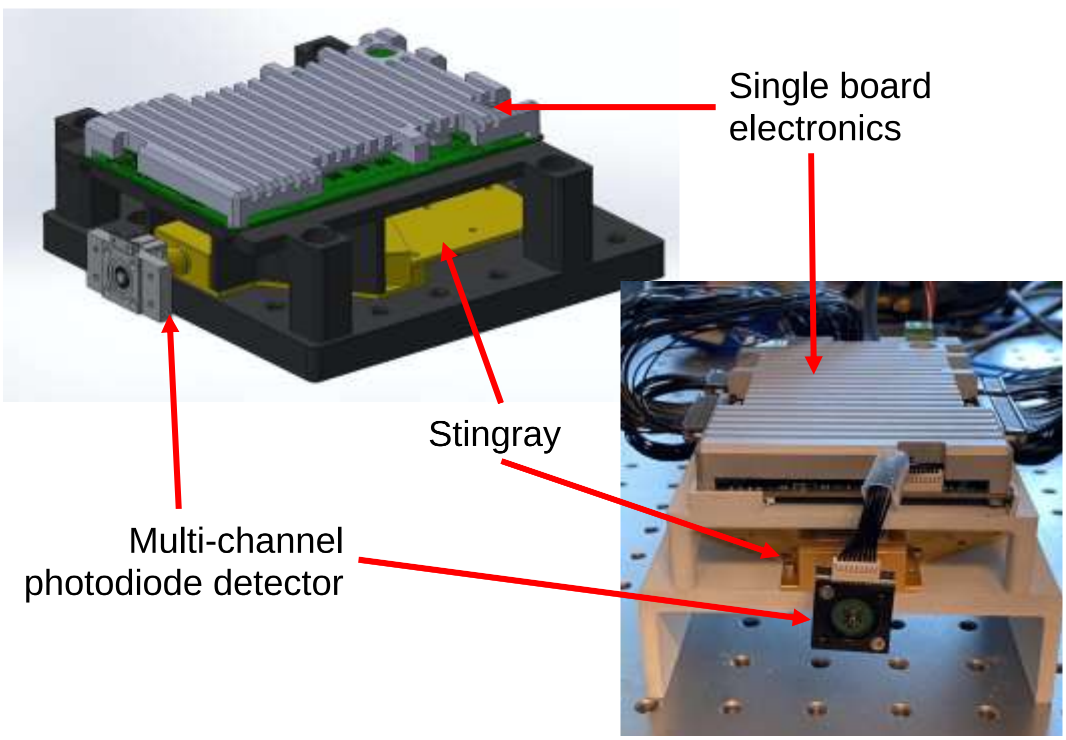

Figure 7. Schematic representation of the Gen 4 prototype (left) and the Gen 4 device (right)

- The preliminary design of the Gen 4 prototype touch-based sensor resulted in a much-improved signal-to-noise ratio (SNR) compared to Gen 3. As can be seen in Figure 8, the Gen 4 is considerably more compact than Gen 3, the components and overall structure of which are shown on the right. The inside of the Gen 3 sensor included a heat sink that was needed because of substantial thermal signal drift (see Figure 9). Various components have been replaced, including the optical integrating sphere, heat sink, and existing electronics board, resulting in a much smaller footprint. A Patent was filed on the new design – System and Method for Controlling the Operation of a Vehicle Using an Alcohol Detection Apparatus.

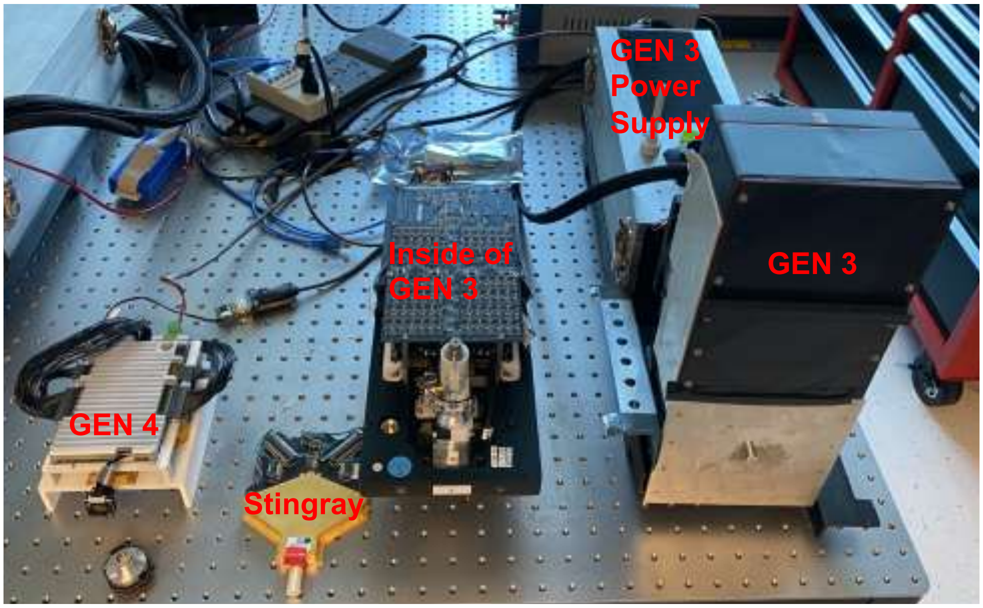

Figure 8. Comparison of Gen 3 prototype sensor (right) versus the new Gen 4 prototype

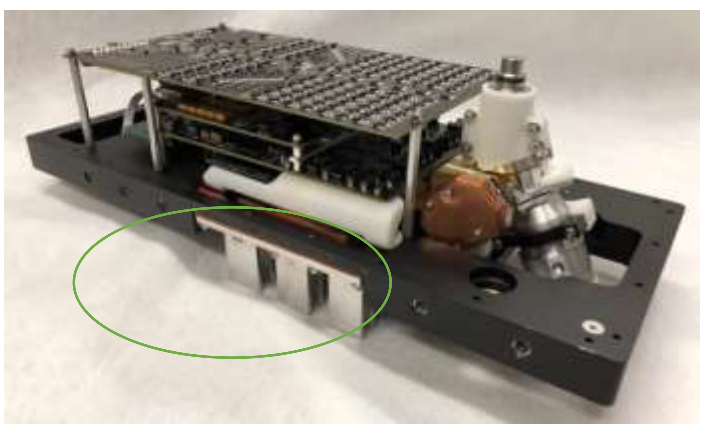

Figure 9. Gen 3 Sensor showing three pillar heat sink (Bottom center)

Electronics accomplishments:

- A complete redesign of the system electronics is ongoing (see Figure 7 Gen 4 sensor above). There are several benefits to the new approach including size reduction, lower power consumption, complete control of firmware to fine-tune measurement and data collection systems, and communications speed.

Testing software improvements:

- New software has been designed in the form of advanced Excel macros that allow greater flexibility for designing studies and capturing data from the touch-based sensor system.
- A graphical interface has been developed that is capable of displaying and analyzing data and creating spreadsheets in the form of Excel reports.
- Enhanced interface software has improved communication between the original software and the touch-based system.
- Special test functions were added to help analyze the warm-up behavior of the touch system and the behavior of system variables on test outcomes.
- A graph display was added for quick verification of test data and improved consumer demonstrations.
- A new graphing interface provides quicker analyses and creates more detailed data analysis reports, thus providing faster information on how data tracks or changes over time (see Figure 10). Another very useful feature is the ability to allow thousands of test results to be organized into trend graphs.

Figure 10. Graphing Interface

Because of the wide range of absorbance across the 40 lasers, sample signal amplitude measured across the 40 wavelengths by the Mark 4 varies from around 1 millivolt to above 1 volt. For the lower signal frequencies/amplitudes it is harder to distinguish the signal from the background noise with the fixed gain of the current measurement system. Thus, to improve the SNR and hence, improve the ability to measure the signal, a measurement interface will be needed with the ability to increase the amplitude of the lowest signals closer to the highest amplitudes.

Performance Specification Development

The purpose of the Performance Specifications document is to establish the DADSS Subsystem Performance Specifications for passenger motor vehicles. The document is based on input from the Technical Working Group. In addition to specifications that detail the sensor's speed of measurement, accuracy and precision, reliability specifications have been identified that conform to the automobile industry accepted 6σ (six sigma) level of reliability, thus minimizing the potential for system failure. International Organization for Standardization (ISO) standards also are followed to ensure that materials, products, and processes developed within the DADSS Performance Specifications are acceptable for their purpose.

In addition to the DADSS Performance Specifications, draft performance specifications have been prepared for the zero-tolerance directed breath-based alcohol measurement device mentioned above. This device is intended for motor vehicle fleet applications and will determine if the driver is registering any breath alcohol. The draft specifications define the accessories' technology performance as it relates to accuracy, precision, speed of measurement, influence of the environment, issues related to user acceptance, long-term reliability, and system maintenance requirements. Access to the data memory or the ability to set operational parameters, including the setting of BrAC concentrations will be designed to deter unauthorized or inadvertent tampering. The device will be designed to meet international standards for alcohol measurement devices[20] currently in place in the United States, Canada, and Europe. Efforts also are underway to establish an SAE J[21] standard that will be specific to the zero-tolerance directed breath device, which unlike alcohol ignition interlock devices, operates without a mouthpiece.

Sensor Calibration Device Research

As sensors evolve and improve, the new generations of the breath-and touch-based systems must be evaluated. An important component of the calibration process is to develop a qualification and verification process that is able to demonstrate in a traceable manner that the breath-based and tissue surrogates meet the requisite performance specifications. The traceability of these calibration standards comes from the use of standard reference materials (SRMs) that are produced to a known value. With the implementation of such materials, the researchers are able to use them with assurance that

[20] International standards for existing breath-based alcohol measurement devices: United States, NHTSA Standards for Devices to Measure Breath Alcohol (38 FR 30459); Europe, CENELEC standard EN 50436-1; Canadian standard, CAN/ CSA Z627-16.

[21] SAE International is a professional association and standards development organization for the engineering industry, with a special focus on transport sectors including automotive.

they meet the stated specifications. In the United States, such materials are usually traceable to a national standard that is held by the National Institute of Standards and Technology (NIST) or certified by another nation's national laboratory which holds a letter of agreement with NIST regarding the specific material.

Because the accuracy and precision specifications for DADSS alcohol sensors exceed those established for commercially available alcohol measurement devices, such as alcohol ignition interlocks, it has not been possible to find certified sources of gas and/or liquid(s) with the requisite levels of accuracy and/or precision. DADSS researchers have worked with various manufacturers in the specialty gas industry to develop the SRMs, but, over time, a limitation in the availability of these gases has required in-house development.

To fully address the many aspects of the calibration process, the DADSS team has undertaken a multi-pronged program that is based around the research, development, and vetting of both apparatus and methodology. As noted above, the initial focus of these efforts was aimed at the development of the breath and tissue-based surrogates that have the potential to meet the DADSS accuracy and precision specifications. At the same time, research efforts focused on the development of standard calibration devices (SCDs) and methodologies for delivery of the samples to the verification instrumentation and the sensors for analysis. For example, because the breath SCD is designed to represent a human breath, parameters such as volume, pressure, humidity, temperature, and chemical makeup have to be specifically tailored to represent human physiological conditions. This was made possible by the development of the Alcohol Breath-Based Simulator (ABBS). The ABBS was developed in cooperation with Environics to meet the needs mentioned above by combining the DADSS produced ethanol gas with stock diluent gases in specific ratios. The ethanol ratio is monitored in real time and automatically adjusted based on a feed-back loop to adjust for variation in the DADSS produced ethanol. The goal of ABBS is to allow flexibility in flow rate, ethanol concentration, carbon dioxide concentration, temperature, pressure, and humidity as needed to test the sensors. These variable parameters allow the ABBS unit to produce a simulated human breath to the sensors with a level of precision that exceeds the DADSS specification.

Work is also ongoing in the development of a new tissue surrogate for the tissue sensor as well as delivery systems to introduce the sample to the unit. Although initially developed as a solution, research is ongoing to transfer the desired properties of the solution to a different medium, such as a gel or solid. The tissue surrogate must closely represent the properties of a human finger, so temperature, optical properties, chemical composition, density, hydration levels, elasticity and conductivity are just some of the parameters that must be considered. Both the aqueous base and gelatinous base have their respective advantages and challenges, so the DADSS team is working to amalgamate these two approaches either into a hybrid system or develop a methodology which utilizes the advantages of each material.

Once developed, the SRMs composition, accuracy, and precision has to be confirmed at the elevated DADSS specifications. The instrumentation necessary for such verification has to exceed the DADSS performance specifications by a significant order of magnitude. 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%. A comprehensive worldwide search was conducted for suitable technological approaches and instrumentation that could meet these goals. A comprehensive evaluation of forensic toxicology instrumentation revealed emerging technologies with improved ability to quantify and identify ethanol in SCDs. Various approaches and their methods, such as gas chromatography, liquid chromatography, and infrared spectroscopy were evaluated. The instrumentation must quantify the chemical components within the samples with better precision and accuracy than the touch and breath-based surrogates.

A Fourier Transform Infrared Spectroscopy (FTIR) with the MKS Multi Gas 2030 Continuous Gas Analyzer was selected for the breath samples because of its ability to identify or confirm the chemicals in the sample as well as quantify accuracy and precision at the levels required. For the tissue-based calibration device, a Waters Acquity High-Performance Liquid Chromatography (HPLC) with mass spectrometry, refractive index, and UV-Vis detectors was selected (see Figure 11). The pairing of this unit with an FTIR provides extremely precise measurement and identification of ethanol as well as the other components in the tissue surrogate.

Figure 11. MKS Multigas 2030 FTIR for breath –based samples and Waters Acquity HPLC for touch-based samples in the DADSS Research Laboratory

With insight from the alcohol and environmental testing industries, new methods to improve the tissue-based calibration solution's accuracy were adopted, including best techniques to weigh, portion, and quantify the ethanol when manufacturing the solutions. In addition, properties of other chemicals were used to quantify the ethanol in the solutions with extreme confidence. A similar approach to manufacture breath-based SRMs is being developed.

Once reliable methodologies were available, measurement of accuracy and precision of the SRMs became the focus through development of calibration curves for both the breath and touch systems. Precision targets have been met for breath-based gases. Efforts are ongoing to try to meet the precision targets for the touch-based solutions. With respect to accuracy, the DADSS team continues to investigate and research SRMs and methods that may be further developed to meet the accuracy specifications.

An initial version of a portable device utilizing mixed gas ILMO tanks of ethanol with carbon dioxide, oxygen, and nitrogen has been developed that permits controlled and uniform gas delivery to the breath sensors outside of the controlled laboratory conditions (see Figure 12). The initial concept for the portable SCD is to deliver dry compressed gas from a gas cylinder at a defined pressure and with a controlled flow rate and pulse duration. At this stage of development, the precision and accuracy of the device is limited by the gas cylinder's accuracy and precision. Research is underway to develop a new version of the SCD that would produce a test gas in real time similar to the Automated Breath Based System (ABBS).

Figure 12. Portable Gas SCD

The portable gas SCD uses dry, compressed gas cylinders at two ethanol concentrations (0.040 g/dL and 0.080 g/dL BrAC) to verify the accuracy and precision of breath-based sensors installed in vehicles. The vehicle's Data Acquisition System (DAS) outputs sensor data to a dedicated website for analysis. Utilizing the portable SCD, it was possible to collect data from sensors outfitted in several different vehicles. Within a 15-minute window, four vehicles were tested using four pulses each at two different concentrations. The ability to quickly spot-check vehicles after sensor installation allows for further experimental control and the ability to verify the performance of the installed sensors. Data was also collected from similar sensors on the laboratory bench for comparison purposes. Review of the initial in-vehicle sensor results demonstrated adequate grouping and accuracy levels that were comparable to similar testing regimens in the laboratory. Prior to these tests, it was assumed that the sensors would need to be removed from the test vehicles to determine their performance after in-vehicle testing. The addition of the portable SCD now allows the sensors to be spot-checked at any time without their removal from the vehicle.

The research and development conducted in FY2019 has resulted in substantial progress on numerous fronts, including improvements in calibration samples, measurement procedures, design, and characterization of delivery systems, as well as the characterization of the latest generation sensors. Specifically, progress has been achieved in the following areas:

- Improved testing methodology. The ABBS has been updated to operate at a higher flow rate to allow for a wider range of testing conditions. In addition, nitrogen gas is being investigated as the ethanol vaporization gas instead of helium due to wider availability of nitrogen gas. Initial results show no change in accuracy or precision of the test gas produced by the SCD while using nitrogen, but further research is ongoing to confirm this.
- Design and construction of a pressure testing apparatus. An apparatus was designed and constructed to allow the breath-based sensors to be tested in a manner that represents both high and low altitude conditions. This device has been designed to work in conjunction with the ABBS system to provide a sample to the sensor while maintaining the desired internal pressure/ vacuum.
- Environmental test chamber. A baffling system was created to decrease the turbulence of circulated air within the environmental chamber while maintaining extreme temperatures during testing. This ensures environmental stability while mitigating effects on the test gas stream prior to reaching the sensors.
- Liquid Ethanol Gas Generation System (LEGGS). This DADSS-designed system, which is capable of creating a highly accurate and precise alcohol dry gas in real-time, has been refined to produce a higher concentration of ethanol gas (16,000ppm) which is then diluted as needed to produce the desired %BrAC sample in ABBS. The higher concentration of the source ethanol gas leads to a greater precision of ethanol in the test gas once diluted.

- Design and construction of analytical specificity test rig. A rig has been designed and constructed that allows the sensors to be tested for the analytical specificity[22] requirements that are found in the U.S. Federal Register notice on this issue,[23] CENELEC, SCA,[24] and DADSS specifications for breath alcohol measurement devices. That is, other substances are required to be tested that might be present in the breath or tissue, that might interfere with the measurement of alcohol and affect its accuracy.
- Test Methodology Feedback Loop. The DADSS laboratory collaborated with Senseair to ensure that the laboratories understand their respective testing methodologies and to provide feedback for improvements to the sensors based on the results of testing.
- Improved testing platforms. Upgraded testing platforms were produced to further minimize sources of lab induced error. These improvements were in the form of tunable testing manifolds and mitigation of internal pressure waves in the system prior to delivery of the test gas to the sensors.
- Test Throughput Improvement. Research is underway to develop a method to test up to 16 breath sensors at once. Currently, no more than 8 sensors can be tested at one time, so this development will double sensor throughput while ensuring testing parameters do not influence the sensors performance.
- Sensor Degradation Testing. The Gen-1 portable breath-based SCD, developed during FY 2018, has been used to perform repeatable testing on sensors integrated in vehicles. This testing assists in evaluation of degradation in the sensor performance over time and with environmental exposures.
- Alternate tissue surrogates. Research continues into the use of alternate tissue surrogates. This resulted in the identification of gelatinous materials which may be further explored as the basis for the next generation of tissue-based SCD.
- Improved tissue-based SCD. Procedural improvements in the fabrication of the tissue-based SCD were successful, including the use of densitometry and the Waters Acquity HPLC to control the quality of starting materials and initial dilutions when producing the liquid SCD.

Before the breath alcohol sensors are ready for commercial implementation, additional research is needed to determine their ability to perform as anticipated. In terms of calibration requirements, air movement mapping of the environmental chamber is needed due to potential variations as the result of high gas flow rates into the chamber during a gas

[22] Analytical specificity refers to the ability of an assay to measure a particular organism or substance, e.g., alcohol, rather than others, in a sample.
[23] Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs), 78 FR 26849, (May 8, 2013)
[24] Ibid.

pulse and the effects of exhaust fans prior to the pulse. There is also a need to better understand the effects of test gas humidity and pressure at the sensor inlet on performance.

Human Subject Laboratory Testing

Human subject testing, also referred to as "in vivo 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 within the human body (blood, breath, tissue) and across the many factors that can affect alcohol concentration. Past research has provided a clear understanding of these factors with respect to venous (blood) alcohol and breath-alcohol when samples of deep lung air are used. However, the new alcohol measurement methods being developed under the DADSS program, which 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 has been the subject of ongoing study.

From the outset, a comprehensive program of human subject research has been carried out to establish that alcohol measurements made with diluted breath and tissue samples are comparable to the well-accepted standards of venous blood and deep-lung air widely used in today's alcohol detection systems. Based on an extensive review of the extant alcohol pharmacokinetics literature, intrinsic and extrinsic factors that can affect alcohol metabolism have been identified. Progress is being made in answering those questions with an ongoing, comprehensive program of human subject research being undertaken by Mclean Hospital, a Harvard Medical School affiliate (see Figure 13). Studies first started in the laboratory environment where conditions can be better controlled, followed more recently by in-vehicle studies where the sensors can be tested in the environment in which they will be used. In FY 2019, real-world driving trials were begun with alcohol-dosed passengers using both a reference breath-alcohol sensor and the Senseair breath-based sensor using directed breath samples.

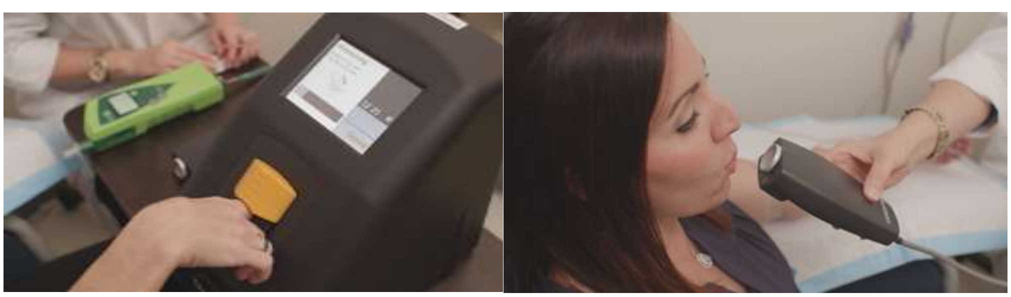

Figure 13. Human Subject Testing at DADSS Satellite Lab at McLean Hospital in Belmont, MA

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 real-world scenarios, and across a range of factors that could potentially affect measurement. The key question is whether these various factors have differential effects on the distribution of alcohol within the different compartments.
- To quantify alcohol absorption and elimination curves among a wide cross section of individuals of different ages, sex, body mass index (BMI), race/ethnicity, and using the different scenarios.
- To understand and analyze the performance of in-vehicle DADSS sensors through measurements of alcohol among dosed passengers across a range of real-world environmental driving conditions (i.e., differences in elevation, humidity, temperature, and presence of salt in the air).

Significant progress has been made in FY2019 in method development and human subject testing. Many insights have been gained regarding the alcohol absorption and elimination curves and maximum BACs/BrACs reached by human subjects in a variety of real-world scenarios (length of time for alcohol to appear in each compartment, effects of snacking, dining, exercise, and "last call" on alcohol measurements). These studies have confirmed a solid linear relationship between blood, directed breath (using the Senseair breath sensors), and tissue alcohol measurement (using the Phase I tissue prototype device) over a wide range of BACs (0.04-0.12 g/Dl).[25]

During FY2019, laboratory research has focused on new scenarios identified as potentially important in breath and touch alcohol measurement, including the effects of combining alcohol with high caffeine energy drinks, breath holding and hyperventilation, as well as smoking on breath-alcohol measurements, and hand sanitizer gel and varying skin temperatures on tissue-alcohol measurements. Progress during FY2019 has been achieved in the following specific areas in the laboratory. Details about on-the-road subject testing during FY2019 are provided in the next section.

McLean Hospital Laboratory Human Subject Research:

- The most advanced breath sensor (Gen 3.2) is being used for testing.

[25] 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.

- 1,417 samples for 49 subjects were collected during FY2019, contributing to a total of 10,469 samples collected from program inception to the end of FY2019.
- New methods were developed to accommodate the new testing scenarios outlined above:
  - The testing chamber was equipped with high performance air handling and filtering systems to evacuate tobacco smoke from the room after testing the impact of smoking on the breath sensors in order to minimize tobacco smoke exposure to subjects and researchers.
  - A set of skin-based thermocouples were developed to precisely monitor skin temperature during the cold and warm hand scenarios.
  - A method was developed to hold frozen gel packs on the test hand of the participants to reduce skin temperature by 8-10° C.
  - A method was developed to hold a heating pad on the test hand of the participants in order to increase skin temperature by 4-6°C.
  - A methodology was developed to standardize the skin exposure to hand sanitizer gel containing 60% ethanol.
- A number of new scenarios were ongoing during FY2019; the effects of hand sanitizer, varying hand temperature, energy drinks, electronic cigarettes, breath holding and hyperventilation. Data currently are being analyzed.

Other scenarios have been identified that have the potential to affect breath and touch alcohol measurement. These scenarios that will be tested include the effects of vaping, consumption of aspartame (to control for sugar free mixers), consumption of non-alcoholic beer and wine, and alcohol in combination with marijuana.

Human Subject Driving Tests

The goal of the Human Subject Driving (HSD) tests is to conduct basic and applied research to understand the performance of the DADSS sensors, both physiologically and ergonomically, in the vehicle in a diverse set of geographic/environmental conditions and with a large number of human subjects. The HSD will utilize fully-equipped Chevrolet Malibu vehicles, donated by General Motors.

Now that the Senseair breath-based sensors have performed well in extensive laboratory and human subject testing, the latest generation breath sensors (Gen 3.2) are being utilized for testing in real-world driving environments. Vehicles also have the capability to accommodate one touch sensor when the technology is ready for real-world testing. Both a reference sensor (SmartStart's alcohol ignition interlock device) and Senseair Gen 3.2 breath sensors are integrated into each research vehicle to measure breath alcohol – two on the driver-side and two on the passenger-side. On the driver's side, the Senseair sensors are mounted in the steering wheel location and the driver's door. On the passenger's side they are mounted in the passenger door and on the dashboard directly in front of the passenger (see Figure 14). The Gen 3.2 sensors can measure both directed and passive breath. The reference sensor provides a comparison measurement and requires a deep lung sample of breath. The reference devices will provide information on sensor sensitivity, validity, and reliability.

Figure 14. Position of the breath sensors on the driver (left) and passenger sides of the vehicle

Along with the alcohol sensors, the Chevrolet Malibus are equipped with a comprehensive Data Acquisition Systems (DAS), two video cameras, a Web interface, data and video storage, and a user interface module (UIM) (Figures 15 and 16). The UIM is the small black box affixed to the dash for use by passengers that instructs them when they need to provide breath samples to the breath-based and reference sensors.

Figure 15. Equipment located in the trunk, from left to right, DAS, WIFI LTE, network switch, and DVR

Figure 16. User Interface Module (UIM)

Prior to the HSD tests, initial testing was undertaken in Marlborough, MA and Sterling, VA to ensure that the sensors, DAS, cameras, and communications systems etc. were fully operational. These initial tests provided a detailed insight in the development of the test plan (test routes, number of starts/stops, number of samples required, etc.). Routes were chosen to provide varying climactic conditions, such as low and high temperatures, low and high humidity, at varying elevations and in corrosive environments, etc. to ensure that the sensors will be operational for the real-world conditions they are likely to encounter. This variety of conditions allows for a more in-depth analysis of the sensor's performance in the operational context for which they were designed. Figure 17 provides a map of one of the driving routes being utilized in Massachusetts, including higher elevations and beach environments. A snapshot of the data viewer which can provide ongoing information about each of the trials is shown in Figure 18.

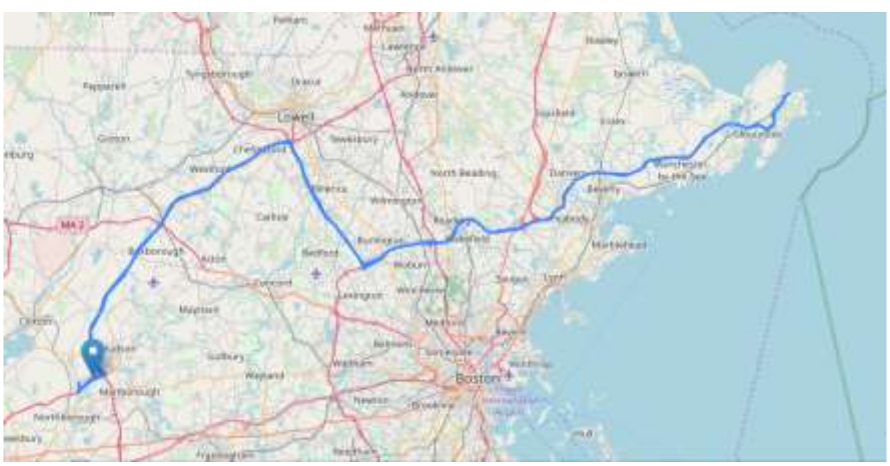

Figure 17. One of the Planned Massachusetts Driving Routes

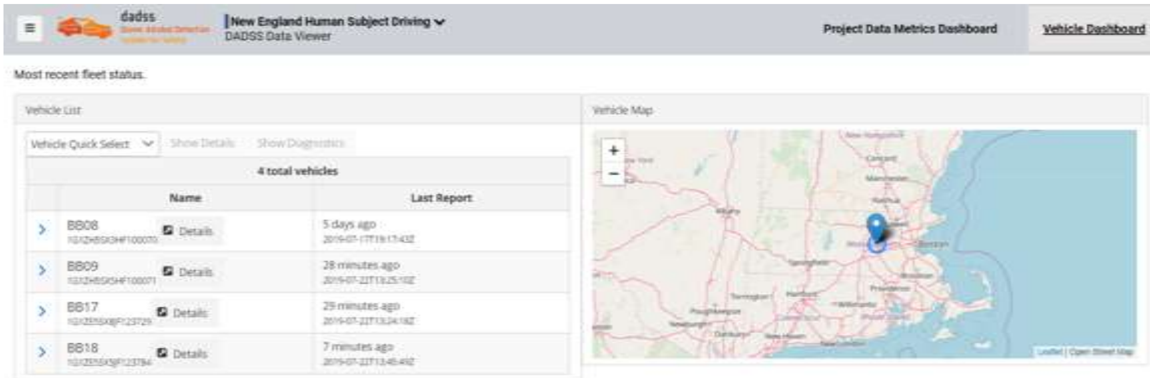

Figure 18. Data viewer

OMB approval was given to proceed with the human subject driving tests on March 20, 2019. Institutional Review Board approval to run driving studies from headquarters in Marlborough, MA and the satellite office in Sterling, VA and McLean Hospital in Belmont, MA also have been granted. These more extensive and comprehensive HSDs commenced in June 2019. Recruitment and alcohol dosing of the test subjects, who will be passengers in the vehicle, is conducted at KEA Technologies, Inc. and with Mclean Hospital. Many of the test subjects had previously participated in DADSS human subject testing at the McLean hospital laboratory, affording researchers the opportunity to compare subjects' laboratory and in-vehicle data. Results from these tests will be critical in determining the effectiveness of the DADSS sensors in a wide range of environments including the impact of environmental factors on sensor function over time, the impact of repeated use and vehicle mileage, the impact of vehicle vibration, and user interactions with prototype devices in a vehicle environment, including driver behavior and user acceptance.

Passenger alcohol measurements are collected frequently from the breath and reference sensors. The passengers are asked to direct their breath in a prescribed sequence toward the DADSS breath sensors in the vehicle. Drivers are asked to provide breath samples at the beginning and end of each study period. During the driving phase, the DADSS sensors will be passively sniffing and analyzing the vehicle cabin air for the presence of alcohol. Additional vehicle instrumentation tracks environmental conditions and vehicle system data while providing participant videos. Technical data gathered in these operational environments will also be used to refine the DADSS Performance Specifications, and to improve system design and product development.

Accomplishments during FY2019 in HSD testing are provided below:

Engineering:

- Hardware and software design of research vehicles used for HSD testing was completed.
- Design was completed on the third-generation data acquisition system and incorporated in several vehicles.
- Software was successfully moved from QNX to a Linux operating system to reduce research costs.
- Over-the-air updates for Gen 3.1 and Gen 3.2 breath sensor firmware were completed.
- Testing of Gen 3.2 sensors that are integrated into research vehicles was completed.
- A user interface module was developed to maximize testing (see Figure 15). The module is mounted in the center of the dashboard and provides written commands to the participant regarding when to provide breath samples into the Senseair and SmartStart devices. The UIM also displays BrAC values after the participant has administered a breath, which will also indicate whether a successful sample was received.

HST protocols and trials:

- Initial routes tested include beach/coastal and hill locations. Beach locations will determine the effects of high concentrations of salt and moisture in the air. Hill locations will provide data on the effects of high altitudes and thin, dry air on sensors' performance.
- Breath sensors have been tested in multiple research vehicles. The testing paradigm permits the collection of breath alcohol measurements every 3.5-4.0 minutes for up to eight hours.
- Procedures were developed to evaluate test conditions such as distance from the subject's mouth and the door and dashboard sensors.
- Stationary tests in the vehicles are being conducted to compare performance in moving vehicles to assess the effect of vibration and movement on sensor performance.
- As of September 30, 2019, 45 drives have been completed with 30 unique subjects having provided breath alcohol data in the HSD trials. A total of 17,460 directed-breath samples have been provided to the DADSS breath sensors and 1,869 samples to the reference sensor.

There are several critical areas in which additional research is required to ensure that the sensors are performing as expected in a vehicle environment. As experience is gained from evaluation of the breath sensors both in the laboratory and on-road driving tests, additional laboratory and in-vehicle research is needed to better understand some of the variables that can affect alcohol measurement in a vehicle environment. Some of the factors that have the potential to affect breath alcohol measurement in the vehicle include:

- The design or shape of the delivery system (termed snorkel) that connects the breath inlet port (in the dash or steering wheel) with the breath sensor and its effects on breath dilution and alcohol measurement (See Figure 19 for examples of snorkel designs).

Figure 19. Design of breath sensor delivery systems (snorkels) from the breath inlet port to the sensor

- The effect of vehicle vibration, to be tested both in the laboratory on a shaker table and in the vehicle.
- The effect of varying distances between the driver and the sensor inlet port.
- The effect of varying humidity, temperature, and air conditioning (HVAC) on breath measurement.
- The role of other intoxicated passengers in the vehicle on driver breath alcohol measurement.
- The role of smoking (cigarettes, e-cigarettes, marijuana) in the vehicle.

Consumer Acceptance Research Program

A key component to ensure a successful launch of in-vehicle alcohol detection devices in the marketplace is consumer acceptance of the DADSS technology. This process encompasses several phases, beginning with awareness of the technology and how it works, to acceptance of the technology as a valuable automobile safety system worth buying, to desire and demand for the technology.

In Phases II and III, qualitative and quantitative research was undertaken to explore public perceptions about and receptivity to new, optional in-vehicle alcohol-detection technologies. Baseline measurements of attitudes toward this new technology were established that can be tracked as efforts to increase awareness are accelerated. In addition, messaging and language were researched to identify the most impactful approaches to capture and increase public acceptance of this new technology. Ongoing media monitoring and analyses were performed to assess the media landscape, to include the tone and quality of the news articles to which consumers are exposed. Outreach also has been initiated to potential partners and stakeholders, who will help to engage the public and the media to increase awareness and acceptance. A key component of the public face of the technology has been the redesign of the DADSS website which provides multiple resources, including updated videos that make the technology and its development accessible through straightforward explanations of the key concepts. The website can be found at https://www.dadss.org/.

FY2019 activities in this area consisted of:

- Updates for the DADSS website including, news and update pages, recent progress with the DADSS technology, and updates to various events in which the DADSS team has been involved.
- Media support, monitoring and analyses to assess the media landscape; that is, the tone and quality of the news articles concerning DADSS to which consumers are exposed.
- Support for meetings attended by DADSS personnel, including conference materials, presentations, and exhibits. Events/Meetings included:
    - GHSA 2019 Annual Meeting | August 24 - 28, 2019 | Anaheim, California
    - 26th International Technical Conference on The Enhanced Safety of Vehicles (ESV) | June 10 - 13, 2019 | Eindhoven, Netherlands
    - NAFA's 2019 Institute & Expo | April 15 - 17, 2019 | Louisville, Kentucky
    - 2019 Lifesavers National Conference on Highway Safety Priorities | March 31 - April 2, 2019 | Louisville, Kentucky

    - Subcommittee Hearing on "Enhancing Vehicle Technology to Prevent Drunk Driving" | March 14, 2019 | Washington, D.C.
- Outreach to potential partners and stakeholders, who will help to engage the public and the media to increase awareness and acceptance once the DADSS technology is sufficiently developed.
- Elevating presence on social media including a Twitter account, which is used to highlight key events and accomplishments.

State Programs

<u>Virginia</u>

Recognizing the potential of the DADSS technology to save lives by preventing drunk driving, Virginia became the first state to use NHTSA highway safety grant funds to partner with the DADSS Program through the Department of Motor Vehicles. The partnership – Driven to Protect – is another example of the technological innovation happening in Virginia and the ongoing leadership the state is showing in the fight against drunk driving. Technology integrators installed prototypes of the breath-based sensors into four vehicles in the James River Transportation (JRT) commercial fleet. The data and feedback collected from the prototype sensors, as well as from the drivers themselves, are going to be used to improve the technology as it is prepared for widespread commercialization.
Pilot Deployment Project Summary - Using a DADSS-owned 2015 Ford Flex "Platform" Vehicle, all equipment was installed, and integration tested prior to installation in the pilot test vehicles. The Pilot Deployment with JRT was initiated in FY2018 and extended into FY2019. High level metrics from October 1, 2018 through September 30, 2019 include:

- 360 days in operation;
- 4 Fleet Vehicles (2015 Ford Flex Airport livery vehicles) included in the naturalistic test;
- 4,778 hours in operation through September 30, 2019;
- Generation 3.1 sensors installed through early July 2019. Replaced with Generation 3.2 sensors in mid-July 2019;
- 34,431 samples through September 30, 2019 (24,965 samples with Gen 3.1 sensors; 9,466 with Gen 3.3);
- 49,069 miles driven on DADSS-equipped fleet vehicles through September 30, 2019; and
- 19 different drivers operating test fleet vehicles.

Events attended during the fiscal year:

- 14 Virginia-local events held in FY2019;

- In September 2018 Governor Ralph Northam announced the Virginia partnership with DADSS, and a video of the event was released in October 2018;
- Impairment Meeting - Combating alcohol- and drug-impaired driving: How do we move the needle? October 2018;
- Virginia Governor's Transportation Innovation Summit November 2018
- Virginia Office for Substance Abuse Prevention (VOSAP) Collaborative Meeting February 2019;
- DADSS and DADSS-VA Stakeholder Meeting February 2019;
- Mid Atlantic DUI Conference April 2019;
- Virginia Department of Motor Vehicles (VA DMV) Donate Life Event April 2019;
- 2019 Virginia Highway Safety Summit May 2019;
- Ft. Belvoir Safety Day Trade Show Event June 2019;
- 2019 Youth of Virginia Speak Out (YOVASO) Summer Leadership Retreat June 2019;
- 2019 Salem Virginia Fair July 2019;
- 2019 Judicial Transportation Safety Conference August 2019;
- Potomac Nationals Baseball Game August 2019;
- 46th Annual Neptune Festival September 2019; and
- Herndon Labor Day Festival Event September 2019

<u>Maryland</u>
In March 2019, the state of Maryland formally entered into an agreement and launched its partnership between the Automotive Coalition for Traffic Safety's DADSS Program and the Maryland Department of Transportation's Motor Vehicle Administration (MDOT MVA) to test advanced prototype driver alcohol detection sensors installed in state–owned vehicles. One DADSS-MD Demonstration Vehicle was instrumented for use by MD MVA at Safety Events and was completed in mid-July 2019 and delivered to MVA Headquarters. The Demonstration Vehicle was prominently featured at the Maryland Association of Counties (MACo) Events, held August 14-16, 2019. In addition, Maryland Governor Hogan announced the Maryland partnership with DADSS on August 15, 2019.

The DADSS team completed the system architecture, design, development, and procurement of equipment for six vehicle Maryland State vehicle fleet in which the DADSS system would be incorporated. One Platform Ford Fusion (the "blueprint" for the remaining six on-road test vehicles) began instrumentation in mid-September 2019.

Patent Prosecution

As a result of the innovative research that is being undertaken under the DADSS Program, ground-breaking technologies and procedures are being developed that are the subject of Patent Applications. ACTS continues to take a number of actions to ensure the commercial implementation of the DADSS technology. First, ACTS is prosecuting[26] patent applications in the major automobile producing nations of the world to ensure production of any DADSS subsystem may proceed without threat of interruption. Specifically, applications are being prosecuted in China, the European Union, Canada, Hong Kong, Japan, South Africa, and the United States. Secondly, to further enhance the implementation of DADSS technology, the Board of Directors of ACTS has directed that the DADSS technology be made available on equal terms to anyone who, in good faith, wants to use the technology.

Finally, ACTS, in coordination with NHTSA, has structured ownership of the intellectual property generated through this research so that it vests with ACTS (a 501(c)(4) nonprofit) and not the individual members of ACTS or the DADSS technology providers. This helps to facilitate commercialization as rapidly as possible in at least two ways. Firstly, the pooling of resources by NHTSA and ACTS provides a reliable and cost-effective basis to promote the standardization of the technology, its widespread deployment, and acceptance by the general public. And secondly, ownership by ACTS avoids hindering commercialization through blocking patents which might result if there were multiple owners of the DADSS technology who could control the pace, scope, and price of commercialization. Table 1 summarizes the intellectual property generated to date under the DADSS Program. In FY2019, six (6) patents were issued and seven (7) new patent applications were filed. Three new technology innovations were developed with two provisional patent applications filed and one disclosure received for filing.

Table 1. Patent Applications Through FY2019

TITLE	COUNTRY	STATUS	APPLICATION #
MOLECULAR DETECTION SYSTEM AND METHODS OF USE	United States of America	Closed[27]	13/838,361
SYSTEM FOR NONINVASIVE DETERMINATION OF ALCOHOL IN TISSUE	United States of America	Closed	61/528,658
SYSTEM FOR NONINVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Closed	13/596,827

[26] Patent prosecution is the process of writing and filing a patent application and pursuing protection for the patent application with the patent office.
[27] The term closed means that the patent no longer is being pursued.

SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Issued	15/090,809
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Pending	16/161.857
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	China	Issued	ZL201280042179.6
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Germany	Closed	NOT ASSIGNED
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	European Patent Office	Pending	12827669.8
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Hong Kong	Pending	14109310.8
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Japan	Closed	2014-528520
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Japan	Pending	2016-176239
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Japan	Pending	2018-235318
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN	South Africa	Pending	2014/02304

ANALYTE IN A VEHICLE DRIVER			
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	PCT†	Closed	PCT/US12/52673
SINGLE/MULTIPLE CAPACITIVE SENSORS "PUSH TO START" WITH LED/HAPTIC NOTIFICATION AND MEASUREMENT WINDOW	United States of America	Closed	61/870,384
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	United States of America	Pending	14/315,631
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	Canada	Pending	2,920,796
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	China	Issued	ZL201480047728.8
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	European Patent Office	Issued	3 038 865
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	Japan	Issued	2016-538915
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	South Africa	Pending	2016/00797
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE	PCT†	Closed	PCT/US14/44350

IGNITION USING BIOMETRIC DATA			
SEMICONDUCTOR LASER THERMAL CONTROL METHOD FOR COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	United States of America	Closed	61/889,320
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	United States of America	Issued	9,281,658
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	United States of America	Closed	15/058,650
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	Canada	Issued	2,925,806
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	China	Pending	201480055848.2
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	European Patent Office	Pending	14755950.4
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	Japan	Pending	2016-516589
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	South Africa	Pending	2016/01639
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	PCT†	Closed	PCT/US14/50575

BREATH TEST SYSTEM	United States of America	Pending	14/421,371
BREATH TEST SYSTEM	Canada	Pending	2,881,817
BREATH TEST SYSTEM	China	Pending	201380054912.0
BREATH TEST SYSTEM	European Patent Office	Pending	13830956.2
BREATH TEST SYSTEM	Japan	Issued	2015-528442
BREATH TEST SYSTEM	Japan	Pending	2018-216391
BREATH TEST SYSTEM	South Africa	Pending	2015/01246
BREATH TEST SYSTEM	Sweden	Issued	536784
BREATH TEST SYSTEM	PCT†	Closed	PCT/SE13/50991
HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Issued	14/421,376
HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Pending	16/215,830
HIGHLY ACCURATE BREATH TEST SYSTEM	Canada	Pending	2,881,814
HIGHLY ACCURATE BREATH TEST SYSTEM	China	Pending	201380054007.5
HIGHLY ACCURATE BREATH TEST SYSTEM	European Patent Office	Pending	13831692.2
HIGHLY ACCURATE BREATH TEST SYSTEM	Japan	Issued	2015-528441
HIGHLY ACCURATE BREATH TEST SYSTEM	Japan	Pending	2018-177686
HIGHLY ACCURATE BREATH TEST SYSTEM	South Africa	Pending	2015/01247
HIGHLY ACCURATE BREATH TEST SYSTEM	Sweden	Issued	536782
HIGHLY ACCURATE BREATH TEST SYSTEM	PCT†	Closed	PCT/SE13/50990
HEATER ON HEATSPREADER (HOH) LASER WAVELENGTH MODULATION CONTROL	United States of America	Closed	62/274,543
HEATER-ON-HEATSPREADER	United States of America	Pending	15/343,513
HEATER-ON-HEATSPREADER	PCT†	Closed	PCT/US2016/060622

HEATER-ON-HEATSPREADER	Canada	Pending	3.010,352
HEATER-ON-HEATSPREADER	China	Pending	Pending
HEATER-ON-HEATSPREADER	European Patent Office	Pending	16816457.2
HEATER-ON-HEATSPREADER	Japan	Pending	2018-534915
HEATER-ON-HEATSPREADER	South Africa	Pending	2018/05421
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	United States of America	Closed	62/312,476
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	United States of America	Pending	15/389,724
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	PCT†	Pending	PCT/US16/68789
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	Canada	Pending	3,018,315
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	China	Pending	201680086043.0
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	European Patent Office	Pending	16826860.5
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	Japan	Pending	2018-549525
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE	South Africa	Pending	2018/06358

BREATH ALCOHOL ESTIMATION			
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	United States of America	Closed	62/171,566
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	United States of America	Issued	15/090,948
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	PCT†	Closed	PCT/US2016/026024
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	Canada	Pending	2.987,729
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	China	Pending	201680046009.3
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	European Patent Office	Pending	16716787.3
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	Japan	Pending	2018-515758
INTEGRATED BREATH ALCOHO SENSOR SYSTEM	South Africa	Pending	2017/08227
PASSIVE BREATH ALCOHOL DETECTION	United States of America	Disclosure received	Pending
METHOD AND APPARATUS OR PRODUCING HUMIDIFIED, CONTROLLED VOLATILE EFFLUENTS USING REAL-TIME FEEDBACK CONTROLS	United States of America	Provisional patent application pending	62/894,038
VOICE ACTIVATED START	United States of America	Closed	62/728,898
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	United States of America	Pending	16/566,415
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	International (PCT†)	Pending	PCT/US19/50421

SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Provisional patent application pending	62/860,413

†PCT means Patent Cooperation Treaty

Accounting of Federal Funds

Surface transportation reauthorization enacted in 2012, Moving Ahead for Progress in the 21st Century (MAP–21), amended section 403 of title 23 of the United States Code to authorize NHTSA to carry out a collaborative research effort on in–vehicle technology to prevent alcohol–impaired driving.[28] Funding for the DADSS Research Program for FY2013 - FY2016 was made under the MAP-21 authorization. Surface transportation reauthorization enacted in December 2015, Fixing America's Surface Transportation (FAST) Act, amended section 403 of title 23 of the United States Code, continuing the authorization for DADSS research through FY2020.[29]

Funding for DADSS research was provided under the Highway Trust Fund (HTF) as part of the appropriations legislation enacted for FY2019. Federal funding totaling $5,494,000 was authorized and ultimately appropriated (Table 2).[30]

Table 2. FY2019 NHTSA Funding Available for In-Vehicle Technology Research to Prevent Alcohol-Impaired Driving

	Fiscal Year 2019
Funding for In–vehicle Technology Research	$5,494,000

The period of performance specified in the 2013 Cooperative Agreement initially covered a five–year period (September 30, 2013 to September 29, 2018) and research was conducted for the entire five–year period through FY2018.). In December 2017, ACTS and NHTSA agreed to extend the award to September 2020 – the end of the program's express authorization in the FAST Act. Consistent with the extension, research has been planned for the entire agreement period. Table 3 provides a general statement regarding the use of Federal funding for FY2019 to carry out the DADSS research effort.

[28] 23 U.S.C. § 403(h) (as amended by Public Law 112–141, enacted July 6, 2012).
[29] 23 U.S.C. § 403(h) (as amended by Public Law 114–94, enacted December 4, 2015).
[30] Further Consolidated Appropriations Act, 2019, Public Law No. 116–94, enacted Dec 20, 2019.

Table 3. Funding Status

Automotive Coalition for Traffic Safety

Advanced Alcohol Detection Technologies

DTNH22-13-00433

Funding Authorized, Appropriated and Obligated, Expended

Funding Authorized & Appropriated – FY2019	**$ 5,494,000**
FY2019 Funding Expended	
Research & Development	$ 4,994,545
Indirect Rate	$ 499,455
Total Expended	**$ 5,494,000**