Progress Report

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October 1, 2020, through

September 30, 2021

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) 2021 in carrying out this effort.

In–Vehicle Alcohol Detection Research

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Executive Summary

The Driver Alcohol Detection System for Safety program (DADSS), which began in 2008, was reauthorized in surface transportation legislation enacted in 2012, the Moving Ahead for Progress in the 21st Century Act, and was again reauthorized through Fiscal Year 2021 via the Fixing America's Surface Transportation Act. The statutorily authorized research is being implemented through a second Cooperative Agreement, established in 2013, between the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety. The research team under this agreement includes various technology companies that oversee the research, develop the sensors, and create processes and procedures to validate each step of development. Research efforts under the DADSS program align with the Safer Vehicles element of the Department's National Roadway Safety Strategy, leveraging technology to address behavioral issues and informing NHTSA's rulemaking effort to establish motor vehicle safety standards to require passenger motor vehicles manufactured to be equipped with advanced impaired driving prevention technology.

In the initial stages of the cooperative research partnership, exploratory research established the feasibility of two alcohol sensor approaches for in-vehicle use, breath and touch, which had the potential to measure a driver's alcohol concentration quickly, accurately, precisely, and with minimum inconvenience to the driver. In the current stage of development, the sensors have become increasingly refined, both in terms of hardware and software. For the sensors to effectively measure driver blood and breath alcohol across the passenger vehicle fleet many millions of times a day without inconveniencing a sober driver, or allowing a driver over the limit to drive, stringent performance specifications for accuracy and precision[1] were deemed critical. These specifications far surpass existing specifications for alcohol measurement and necessitated the development of innovative methodologies to verify that the technology can meet them. Specifically, verification and validation 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, in the laboratory and on-the-road. The accumulated data from these testing scenarios are used to determine whether the DADSS sensors are working as intended and identify areas for system improvement.

During the fiscal year ending September 30, 2021, progress was made in all program areas, including sensor development, calibration materials, processes and measurement procedures, and human subject testing both in the laboratory and in the vehicle. Although the COVID-19 pandemic has had some impacts, the DADSS team actively monitored potential risks and made necessary adjustments to protocols to continue to make progress during this period. This report summarizes the accomplishments during Fiscal Year 2021.

The breath sensor system uses infrared sensors to measure the concentrations of alcohol and carbon dioxide in exhaled breath. Carbon dioxide concentration, which is a

[1] Accuracy refers to the closeness of the measurements to a specific value, and precision is the closeness of the measurements to each other.

known quantity in expired breath, provides an indication of the degree of dilution of the breath, and hence alcohol dilution. Substantial progress was made in Fiscal Year 2021 in advancing both the Generation 3.3 sensor, intended for fleet vehicles which uses directed breath, and the Generation 4 sensors, intended for widespread use in passenger vehicles, which uses passive breath detection. The Automotive Coalition for Traffic Safety announced at the beginning of summer 2021 that the Generation 3.3 sensor would be available for open licensing by the end of the year and that goal was accomplished. Three product versions of the Generation 3.3 sensor are available, a vehicle–integrated solution, an aftermarket or accessory solution, and a stationary point–of–access solution. The driver will be required to direct a short puff of breath at the breath sensor from a distance of two to three inches which will then detect the presence of alcohol. This approach follows the SAE[2] J 3214 Standard for fleet vehicle use of breath-based alcohol detection systems, which received final approval from the SAE committee in January 2021.

Validation testing of the Generation 3.3 sensor was performed at different ambient temperatures, with a special emphasis on very cold temperatures. This resulted in full performance of a directed breath in the entire temperature range -40°C to +85°C. The Generation 3.3 device performed within accepted accuracy, precision, and start-up time as specified in the SAE J3214 standard. Progress also was made on the Generation 4 sensor with completion of the system level specifications. During the year, the most promising system concepts were evaluated. The chosen design was judged by the technology developers to have good assembly design, stable temperature control, and rapid measurement cell gas exchange with no strain on the optical assembly. A key emphasis during Fiscal Year 2021 has been on the components of the optical cell, including the detector, infrared emitter, and mirrors. The preferred emitter design demonstrated long term stability; an attribute critical to for use in an automotive environment. The preferred detector showed good performance during breath testing. The chosen mirror material had a smoother surface finish which has the potential to increase reflectivity. With this progress, the Generation 4 breath sensor could be ready for production in 2024.

The touch sensor allows estimation of blood alcohol concentration in the capillaries of a driver's finger tissue. The driver touches an optical module and a near-infrared light, generated by laser diodes, shines on the driver's skin and propagates into the tissue. A portion of the light is reflected back and is collected by the touch pad. Blood alcohol concentration can be estimated based on the properties of the light returned to the sensor. To produce accurate, precise, and reproduceable results, the laser signals need to be homogenized into a diffuse light source so that the light levels propagating through the tissue are always the same. In addition, levels of background noise need to be low and signal strength sufficiently strong so that the signal can be readily detected when reflected from the tissue.

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

Hardware and software research has led to significant accomplishments in the development of the touch sensor as well. Research has been conducted to assess the performance of the previous generation, Generation 4 stingray lasers (which comprise 20 laser chips in a single package, each interrogating two wavelengths to cover the 40 discrete wavelengths, thus reducing the packaging size and power requirements). A stingray package with a 3-inch integrating sphere[3] was assembled to measure ethanol/water samples. The touch system was able to detect ethanol samples with concentrations as low 0.022 g/dL with a standard deviation of approximately 0.003 g/dL. The latest generation of touch sensors (Generation 5) will incorporate tunable lasers, which can alter the wavelength of operation in a controlled manner, thus enabling the use of fewer lasers and a reduced package size. The first set of tunable lasers was received at the DADSS laboratory in January 2021. The DADSS team designed an effective tunable laser touch sensor for the bench top systems. Several rounds of simulations, including ray trace modeling,[4] have been completed to determine how laser light behaves within the bounds of the proposed opto-mechanical system designs, resulting in a recommended sensor design. The second generation of tunable lasers were delivered in August 2021. They are expected to have higher intensity and improved performance. Work is underway to characterize their performance. On the software/hardware front, upon receipt of the new generation of tunable lasers, upgrades and modifications were made on the photodetector and electronics boards.

As sensors evolve and improve, the new generations of the breath and touch sensor systems need to be evaluated. During Fiscal Year 2021 laboratory efforts have focused on research and testing of the Generation 3.3 fleet breath sensors, including verification and validation methodology, sensor characterization, and the exploration of different variables on sensor performance, such as, different breath strengths, inlet shape, distance from the sensors, and snorkel[5] design. The focus has been on understanding the effect of these variables on breath dilution. Researchers found only modest increases in dilution up to distances of 10-12 inches from the sensor even without snorkels. However, the use of snorkels helped to keep the dilution factor relatively low even at distances of up to 22 inches and resulted in less variability. Similar in-vehicle studies found that, at a dilution factor of 40 or below, no false positives were recorded. At a dilution factor of 60 or below, there were 0.02% false positives (1 in 538 samples). Additional areas of investigation conducted during the year include studies of best practices for snorkel design, such as snorkel length, width, and snorkel material. It was found that printed materials introduce a significant bias in ethanol readings when compared to commonly available plastic tubing. Because vehicle packaging space, such as the interior of the doors, can be very tight, additional investigations were undertaken to examine the effects of bending and kinking on snorkel performance. It was found that there is no discernable

[3] An integrating sphere is an optical component consisting of a hollow spherical cavity with its interior covered with a diffuse white reflective coating, with small holes for entrance and exit ports. Its relevant property is a uniform scattering or diffusing effect.

[4] Ray tracing is a method for calculating the path of waves or particles through a system with regions of varying propagation velocity, absorption characteristics, and reflecting surfaces.

[5] The snorkel is the delivery system that connects the breath inlet port to the breath sensors in the vehicle.

effect from bending or kinking the snorkel tubing. On the touch sensor front, to facilitate more cost-effective and expedient testing of touch sensors in the future, research continues into the use of tissue surrogates, that is, manmade materials that mimic the properties of human tissue and can be used for verification activities. Research, which is ongoing, examined various gelatin samples to determine which exhibited the best stability and durability during verification.

Human subject testing to evaluate the performance of the breath and touch sensors was conducted in controlled laboratory conditions at McLean Hospital, a Harvard Medical School Affiliate. Once ingested, alcohol is absorbed into and eliminated from the body. Subjects' alcohol absorption and elimination curves are plotted to determine the amount of alcohol in the body over time, including blood, breath, and tissue alcohol. These data are used to establish that alcohol measurements from diluted breath and in tissue are comparable to the standards of venous blood and deep-lung air widely used in traffic law enforcement of Driving Under the Influence laws. Previous research established that the alcohol measurements from breath and touch sensors are consistent, reproducible, and correlate very well with traditional blood and breath alcohol measurement.[6] Human subject testing was suspended in March 2020 when COVID-19 restrictions were put in place. McLean Hospital health coordinators worked diligently to develop safety procedures to protect participants and testing was resumed in September 2020.

Studies were focused primarily on exploring the role that wine, beer, non-alcoholic beer, and energy drinks play in the detection of alcohol on breath and blood samples. The evaluation of nonalcoholic beer consumption (i.e., beer containing < 0.5% ethanol) resulted in no positive blood alcohol concentrations in the participants blood samples, but measurable alcohol in the breath samples. The breath alcohol appeared during the consumption period which spans the first 19 minutes of the study and peaked between 0.01 – 0.03 g/dL. After that there were a few brief mini peaks of alcohol in the breath samples, likely due to gastric alcohol that results from belching and release of alcohol from the stomach. New procedures have been developed for future implementation of studies examining the effects of drinking alcohol while smoking traditional and electronic cigarettes, including modification of the test chamber with high performance air handling and filtering systems to evacuate tobacco smoke quickly and completely after testing.

The goal of human subject driving tests is to conduct basic and applied research to understand the performance of the sensors in the vehicle, across a range of environmental conditions. Such studies are undertaken in more controlled settings by the DADSS laboratory, and in naturalistic settings in cooperation with the states of Virginia and Maryland. Currently, only the breath sensor is being evaluated, but once the touch sensor is ready for real-world evaluation it will be installed in the research vehicles. Initially, routes were chosen to provide varying climactic conditions, such as low and high

[6] Lukas S E, Ryan E, McNeil J, Shepherd J, Bingham L, Davis K, Ozdemir 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.

temperatures, low and high humidity, varying elevations, and corrosive environments. In-vehicle integration of Generation 3.3 fleet sensors began in May 2021, after which significant time was spent testing the sensors in a variety of conditions, at different times, at various distances, and with a variety of breath types (e.g., passive, directed, strong versus lighter breaths). The goals of these studies were to evaluate differences between the performance of Generation 3.2 and 3.3 sensors and communication between the Generation 3.3 sensors, the data acquisition system, and the data viewer. Before the trials were suspended in March 2020 due to COVID-19, 114 Gen 3.2 test drives were completed and nearly 80,000 breath samples were collected. Data from sober passengers and drivers were used to compute the probability of a false positive (defined as a reading of BrAC $\geq$ 0.02 g/dL) given the person had no alcohol on board. Among the 579 sober samples with a dilution factor less than 60, ten were measured with a breath alcohol concentration $\geq$ 0.02 g/dL by the Generation 3.2 sensor, indicating a 1.73% false positive rate.

Efforts to expand consumer awareness of the technology through in-person opportunities to learn about the technology, have been limited because of the COVID-19 pandemic. As a result, there were significant efforts to share additional information digitally. This included maintaining and updating the DADSS website, adding new technology explainer videos and behind-the-scenes laboratory tours, and refreshing and expanding existing communications materials. Through the Driven to Protect TM partnership funded by the Commonwealth of Virginia, a new “Discovery Hub” also was launched on the DADSS website (https://www.dadss.org), which offers a suite of online resources to provide the public with an in-depth look at the technology and the development process.

Beginning in 2016, Virginia became the first state to partner with the DADSS program through the Department of Motor Vehicles. The partnership has two components. One is a pilot driving study in which the latest generations of the DADSS breath sensors were integrated into four James River Transportation commercial fleet vehicles in Richmond, Virginia. The data and feedback collected from the sensors, as well as from the drivers themselves, are used to modify and improve the technology as it continues to be developed. The second component of the partnership is to increase consumer awareness through community outreach events. Again, due to the pandemic, fewer events were scheduled during Fiscal Year 2021. Instead, the DADSS team has created educational opportunities for the public and high school students through the development of videos and online materials and the creation of Science, Technology, Engineering, and Mathematics modules. As discussed earlier, the Discovery Hub TM was launched on the DADSS website in November 2020, and on the Virginia Department of Education intranet site in March 2021 for use by educators. Both sites offer a suite of online resources to provide an in-depth look at the technology and the development process.

Another partnership between the State of Maryland Department of Transportation’s Motor Vehicle Administration and the Automotive Coalition for Traffic Safety began in 2019 with an agreement to test the latest breath sensors in state–owned vehicles. Along with the other on-road testing studies, data collected from the sensors and drivers will be used to modify and improve the technology as it continues to be developed. During a pause in testing due to COVID-19, operational tests and maintenance of the seven vehicles were conducted to ensure the vehicles were fully functional for resumption of testing. On-road testing of all the vehicles resumed in July, 2021. During Fiscal Year 2021, the vehicles were driven for 2,038 hours, over a distance of 15,869 miles, and 25,225 breath samples were collected.

While significant progress is being made on sensor development and performance in the laboratory and on the road, essential research is needed in several areas, including additional sensor development, verification and validation methodology, and human subject testing. The objective of this effort is to have a device or devices (i.e., breath, and/or touch sensors) that can be evaluated to assess suitability for commercialization for widespread passenger vehicle use. Once suitability can be established, automakers could take the next steps toward future product development and integration into motor vehicles.

Introduction

Alcohol-impaired driving continues to result in very large numbers of deaths among road users in the United States and around the world. Decades of research, focusing largely on modifying driver behavior through strong laws, enforcement, and public education, has identified ways in which alcohol-impaired driving can be reduced.[7] Significant progress has been made through these proven approaches, however, deaths from alcohol-impaired driving persist. An estimated 38,824 people died in motor vehicle traffic crashes in 2020 —the largest number of fatalities in 16 years.[8] In 2020 there were 11,654 fatalities in motor vehicle traffic crashes in which at least one driver was alcohol-impaired. This totaled 30 percent of all traffic fatalities in the United States for the year (National Highway Traffic Safety Administration, [NHTSA], 2022).[9] This finding is reinforced by the results of a recent survey in Canada and the United States, which reported that significant numbers of people surveyed say they are more likely to engage in risky driving, including after drinking than they were in prior years.[10]

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. This 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. A recent study from the Insurance

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[7] Ferguson S A. 2012. Alcohol-impaired driving in the United States: Contributors to the problem and effective countermeasures. Traffic Injury Prevention, 427-41.

[8] Newly Released Estimates Show Traffic Fatalities Reached a 16-Year High in 2021. 2022. The National Highway Traffic Safety Administration. https://www.nhtsa.gov/press-releases/early-estimate-2021-traffic-fatalities#:~:text=The%20National%20Highway%20Traffic%20Safety,the%2038%2C824%20fatalities%20in%202020.

[9] Alcohol Impaired Driving. 2020 data. Traffic Safety Facts. Research Note DOT HS 813 294. National Highway Traffic Safety Administration. Washington, DC.

[10] Vanlaar W G M, Woods-Fry H, Barrett H, Lyon C, Brown S, Wicklund C, Robertson R D. 2021. The impact of COVID-19 on road safety in Canada and the United States. Accident Analysis & Prevention, Vol. 160.

Institute for Highway Safety (IIHS) has estimated that alcohol detection systems that work perfectly in all vehicles to restrict driver's blood alcohol concentration (BAC) to less than 0.08 g/dL could prevent more than 9,000 deaths a year in the United States (Farmer 2020).[11]

In 2008, a public/private partnership began between NHTSA and the Automotive Coalition for Traffic Safety (ACTS)[12] to develop a technological solution or solutions to significantly reduce and ultimately end alcohol-impaired driving. This program, known as the Driver Alcohol Detection System for Safety (DADSS) is developing non–intrusive technologies that could prevent a vehicle from being driven when the device registers that the driver's BAC meets or exceeds the legal limit.[13] More recently, research has been underway to develop sensors that can be used in fleet vehicles to detect the presence of alcohol and prevent driving if alcohol is detected.

Early in the development process, DADSS researchers identified promising technologies that had the potential to prevent alcohol-impaired driving through instantaneous measurement of driver BAC or breath alcohol concentration (BrAC).[14, 15] After thorough review of the scientific and technical literature, two approaches were considered promising for quick and accurate measurement of BAC/BrAC. These were breath- and touch/tissue-based spectrometry systems. The breath 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 breath. Carbon dioxide is measured separately to determine 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-IR light reflected from within the skin tissue after an optical module is touched by the driver.

The 2008 cooperative agreement between NHTSA and ACTS 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

[11] Farmer C M. 2020. Potential lives saved by in-vehicle alcohol detection systems. Insurance Institute for Highway Safety, Ruckersville, VA.

[12] 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.

[13] From inception in 2008, the DADSS Research Project has been based on a BAC threshold of 0.08 g/dL or greater. NHTSA's statutory authorization for DADSS research explicitly specifies that this threshold be used. See 23 U.S.C. § 403(h).

[14] 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.

[15] 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.

in a vehicle environment as well as 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 cooperative agreement.[16] During this time, 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 physiologically and ergonomically in the laboratory and in the vehicle environment.

As required by the FAST Act, this report discusses these research programs in more detail and the progress achieved toward these goals in FY2021. 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, established in June 2017, consists of representatives from NHTSA, the automotive industry, participating State governments and public interest groups. The group 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 Working Group, managed by KEA Technologies Inc. (KEA), a research and technology company, consists of sensor developers and other program members, and carries out associated DADSS research.

[16] See section 403(h) of title 23 of the United States Code as amended by Public Law 112-41, July 6, 2012 and Public Law 114-94, December 4, 2015.

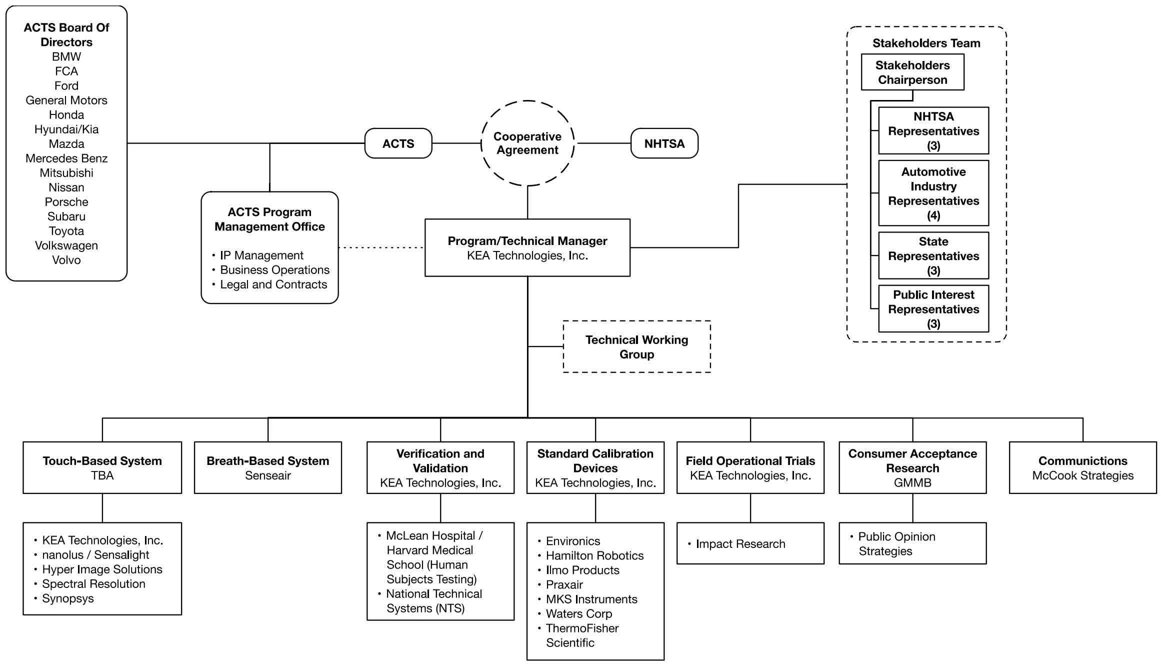


Figure 1. DADSS Research Program Organization

Research Plan with Technical Review Gates

From inception, the DADSS program has been structured to minimize risk by conducting the research with technical review gates. Initially, ACTS researched prototypes that could rapidly and accurately measure a driver's BAC or BrAC non-intrusively. The prototypes constructed (1st Generation) were designed to demonstrate proof of concept. The prototypes were delivered to and tested at the DADSS laboratory. Two of the technologies evaluated yielded favorable results. Thus, it was determined that development should continue for both the touch and breath sensors.

Beginning in late 2011, over a span of two years, technology providers made 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 will not be fully quantified until the completion of all required testing.

Beginning in 2013, the research focus has been 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.

Performance Specification Development

The purpose of the DADSS 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 automotive industry accepted level of reliability.[17] 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, performance specifications for the Gen 3.3 breath sensor were initiated in October 2019. This device is intended for motor vehicle fleet applications and will determine if the driver is registering any breath alcohol, otherwise known as zero tolerance. 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 (such as instructions for use), long-term reliability, and system maintenance requirements. Access to the data memory or the ability to set operational parameters, including the setting of BrAC concentration thresholds will be designed to deter unauthorized or inadvertent tampering. SAE International (SAE) led the development of a standard, SAE J3214, to provide the testing specifications adopted for such applications, which was finalized in January 2021. The standard has been published by SAE and is available through the sae.org website. The DADSS laboratory received ISO17025 accreditation to the SAE J3214 standard in September 2021 and is currently the only laboratory accredited to the standard. Unlike existing aftermarket alcohol ignition interlocks, this fleet device, operates without a mouthpiece and measures diluted breath samples. However, the SAE J3214 standard is applicable to systems with and without mouthpieces. The device is designed to meet international specifications and standards for alcohol measurement devices[18] currently in place in the United States, Canada, and Europe, but has more stringent requirements, especially with respect to the calibration curve and test gases.

DADSS Research Programs

The DADSS program of research and development began with the assumption that to be successful and acceptable to drivers, many of whom do not drink and drive, the technology must be seamless with the driving task. It must be speedy and unobtrusive, extremely reliable, durable, and highly accurate with precise measurements.

Research is ongoing to further develop the breath and touch sensor systems. 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 in-vehicle sensor

[17] Biondo, W, Zaouk, AK, Sundararajan, S. 2017. Driver Alcohol Detection System for Safety (DADSS) – Development of the subsystem performance specifications. Paper Number 17-0301. Proceedings of the 25th International Technical Conference on the Enhanced Safety of Vehicles.

[18] 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.

technology is the central focus of the DADSS research effort; however, the DADSS research program is multifaceted, including development of these sensor systems plus further testing and verification and validation of the 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. In addition, the vehicle integration laboratory is responsible for integrating the sensors in vehicles for on road studies.

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, or humidity, but as with other safety technologies, the systems must work reliably for the full operating life of the vehicle. These performance specifications are much more stringent than those for current in-vehicle alcohol ignition interlocks. This is because of the very large number of tests that would be performed daily if DADSS sensors are in widespread use across the passenger vehicle fleet. Thus, accuracy and precision must be sufficiently high to limit the number of misclassification errors, that is, false positives and negatives, and avoid inconveniencing drivers.

Accuracy and precision 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. 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. The progress achieved in each of these areas in FY2021 is detailed below.

The success of DADSS will require not only that the technologies successfully meet the performance criteria, but also achieve widespread implementation in the passenger vehicle fleet.

DADSS Subsystems Technological Research

The two technologies, breath and touch or tissue spectrometry, are being pursued for measuring driver BrAC and BAC non-invasively within the vehicle. As indicated in Table 1, progress has been made in the development of both technologies. Two different commercial devices are being pursued for each technology for use in vehicles - a fleet device (referred to as Gen 3.3 for the breath system) designed to prevent the vehicle from being driven if any alcohol is detected ($\geq$ 0.02 g/dL), and a passenger vehicle device (referred to as Gen 4 for the breath system), which is designed to measure alcohol precisely and accurately and prevent the vehicle from moving if the driver is at or above the state or country's legal limit for alcohol (typically 0.08 g/dL in the U.S.). The Gen 3.3 fleet/accessory device is the first to be brought to market in any capacity. ACTS announced at the beginning of summer 2021 that the Gen 3.3 sensor would be available for open licensing by the end of the year and that goal was accomplished. Senseair, the developer of the breath sensor, has obtained a license.

Table 1. Breath and touch device derivatives

DADSS DERIVATIVE		COMMERCIAL TARGET		OPERATING CHARACTERISTICS / VEHICLE INTEGRATION
Type	Generation	Licensing Date	Road Vehicle Market	
Breath	**GEN 3.2** Non-passive Operation	**2020**	Engineering Sample Only	For product research & development purposes only
	GEN 3.3 Non-passive Operation	**2021**	Fleets, Accessory Sales	"Yes/No" BrAC determination (0.02 BrAC set point), contactless, directed-breath, installed post series production
	GEN 4.0 Passive Operation	**2023 ~ 2024**	New Vehicle Safety Option	BrAC measurement against a specific set point (e.g., 0.08 BAC), contactless, passive-breath, installed during series production
Touch	**GEN 5.0** Passive Operation	**2023 ~ 2024**	Fleets, Accessory Sales	"Yes/No" BAC determination (0.02 BAC set point), 2-4 tunable lasers, single board electronics, installed post series production
	GEN 6.0 Passive Operation	**2024 ~ 2025**	New Vehicle Safety Option	BAC measurement against a specific set point (e.g., 0.08 BAC), 2 tunable lasers, ASIC-level electronics integration, installed during series production

Breath Sensor

The breath sensor approach uses sensors that simultaneously measure the concentrations of alcohol and carbon dioxide in the expired breath. The concentration of carbon dioxide in the breath sample can provide an indication of the degree of dilution of the alcohol concentration. A fan draws diluted breath into a chamber where detectors measure the concentrations of the alcohol and carbon dioxide in the sample.[19] BrAC is then calculated.

The ultimate 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 with windows closed, in the presence of heating and air conditioning (HVAC) as well as passengers, 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.

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

These positions minimized the impact of cabin air flow and the driver's position on alcohol measurements as well as optimized performance.

Since the technology's inception, sensors using passive breath have been under development for widespread in-vehicle deployment. More recently, sensors requiring a short puff of breath, directed at the sensor from a short distance, like blowing out a candle, have also been developed. The Gen 3.3 fleet device requires users to provide a directed breath to detect the presence of alcohol.

Major enhancements were undertaken during the Gen 3 sensor development to improve how the sensor detects alcohol. Ethanol detection now takes place over the full length of the optical cavity, and carbon dioxide is detected crosswise to eliminate systematic timing differences between the two signals.[20] The Gen 3.2 device saw sizeable improvements compared with the Gen 3.1 sensor. Gen 3.2 enabled passive in-cabin breath sampling through enhanced alcohol sensitivity, with precision markedly improved (See Figure 2). The Gen 3.3 device has been developed for fleet and accessory application with input from Gen 3.2 laboratory studies and human subject trials. There are three product versions available: a vehicle–integrated solution, an aftermarket or accessory solution and a stationary point–of–access solution. This fleet device will be set to detect the presence of alcohol but will also have the flexibility to set the limit up to a BrAC of 0.04 g/dL depending on the company fleet owner's preference. The Gen 4 sensor, which is targeted for licensing in 2024, is designed to be suited for wider deployment in passenger vehicles.

Tests of the Gen 3.2 sensor showed a significant reduction in background noise – down from 10.71% in the earliest Gen 3 sensor to only 1.64% relative to the previous sensor (see Figure 2). Background noise in sensors generally results from temperature variations, the air flowing through the sensor, and small fluctuations in the current drawn by the instruments themselves. This noise is generally small and has been significantly improved. Reducing the background noise enables the signal to be better detected, hence improving accuracy and precision measurements.[21] The Gen 4 sensor is under development with a design goal to reduce the noise even farther, to only 0.21% of the signal or better. The net result will be a significant enhancement of the alcohol signal.

[20] 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.
[21] 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.

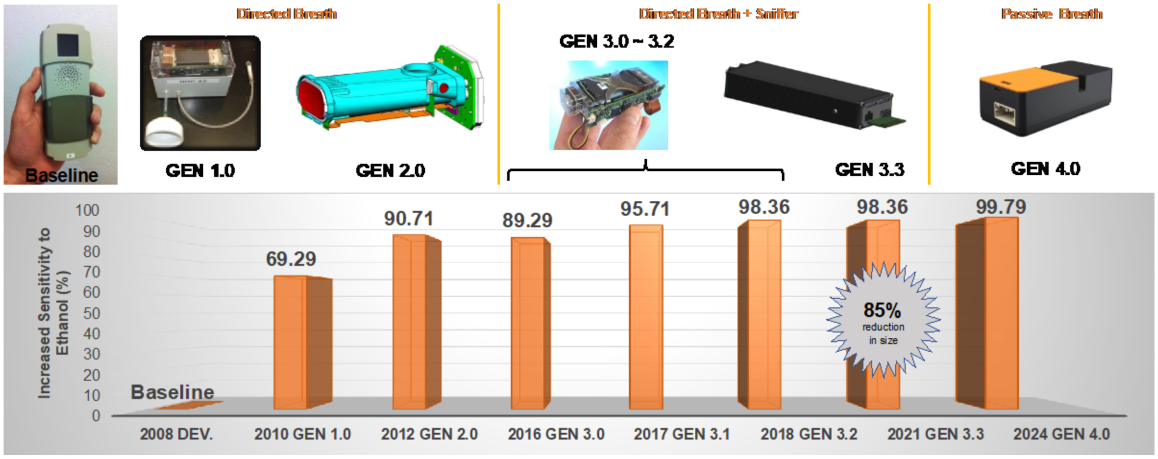


Figure 2. Sensor performance improvements and goals through increased sensitivity to ethanol.

Significant progress was made during FY2021 in both Gen 3.3 and Gen 4 sensor development and testing. Details are provided below.

Gen 3.3 sensor development

- During FY2021, the technology developer focused on optimizing the start-up sequence to meet sensor performance specifications for the Gen 3.3 sensor (see Figure 3). The testing was undertaken at different ambient temperatures, with a special emphasis on very cold temperatures. This resulted in an optimized parameter set-up, enabling full performance of a directed breath in the entire temperature range -40°C to +85°C. Test data indicated that the Gen 3.3 device performed within accepted accuracy, precision, and start-up time as laid out in the recently finalized SAE J3214 standard.

Figure 3. Gen 3.3 design

- Additional testing conducted in FY2021 included electrical tests, environmental tests, sensor performance tests, and durability tests.
- During 2021, 112 sensors were built and delivered to the DADSS program. The remaining 43 sensors are planned for delivery during the beginning of FY2022.

Gen 4 system development

- The initial system level specifications for the Gen 4 breath alcohol sensor system were completed by the technology developer. The completed document was available in the spring of 2021.
- During the year, the most promising system concepts were evaluated. In the evaluation, weight was given to mechanical parameters, for example size, and manufacturing complexity, electronics complexity, packaging, electromagnetic compatibility, and influence on optics, that is, sensor cell air flow, and temperature sensitivity. The main advantages of the chosen design were favorable design for assembly, good and stable temperature control, rapid measurement cell gas exchange and no strain on the optical assembly (see Figure 4). The dimensions of the Gen 4 prototype are 37 x 65 x 134 mm.

Figure 4. Gen 4 system design

- One emphasis during FY2021 was on the key components of the optical cell, including the detector, infrared emitter and mirrors. For the detector and the emitter, several alternative technologies identified during FY2020 were assessed using the optical assembly of the Gen 3.3 sensor to evaluate different components.
    - The preferred emitter design showed long term stability, a critical attribute for use in an automotive environment.
    - The preferred detector showed favorable performance during breath testing. However, the detector also showed a sensitivity to increasing temperature, resulting in more noise. To counteract the effect, a detector package was designed including a temperature stabilization component. The detector package is yet to be tested.
    - Alternative mirror materials were evaluated because rougher materials cause more scattering of light. The chosen material, which is different

than that used for the Gen. 3.3 sensor, has a smoother surface finish. Evaluations of the new material have shown a potential increase in the reflectivity of the mirrors, from 96% to 98%. In addition, the mirror materials were evaluated for heat propagation. Because the sensor design is being developed for use in an automotive application it needs to be fully operational in the entire temperature range of -40°C to +85°C. To avoid condensation at lower temperatures, the mirrors need to be heated. Thus, good heat propagation is essential to the system. Overall, the evaluations indicated favorable results for the new material.

- Another area of emphasis in FY2021 was the optical design of the sensor assembly. The main focus of the development effort is to develop a design with very high sensor resolution. This is necessary because the sensor must be able to detect and classify the alcohol content in highly diluted breath samples. At the end of the fiscal year, three different concept designs had been developed. Concept 1 utilized a lens solution rather than funnels to channel the light. Concept 2 focused on mirror redesign with a new light reflector solution. Concept 3 focused on a change to a different wavelength region for the alcohol measurement.

Generic development

- During previous development, validation of the sensors' performance was undertaken by the technology provider and the DADSS team with somewhat differing results due to the use of different gas pulse testing systems. In FY2021 the technology provider and the DADSS team collaborated on the testing systems. This resulted in similar results, regardless of the testing site.
- During FY2021 sensor diagnostics functions have been implemented in the alcohol sensor. The software functions include internal sensor status flags, such as signal stability and temperature checks, and also ambient environment monitoring, for example input voltage checks. The software is now capable of detecting 140 internal errors and can communicate them individually. The error handling functionality was grouped into fault types and documented accordingly. In the documentation, actions for each error are described, with the result that the user will receive information through the human-machine-interface about what needs to be done to address the error, for example, that the sensor needs to be restarted, or may need to be repaired.
- The first iteration of a carbon dioxide baseline correction algorithm was developed and implemented. The function is important for the long-term stability of the sensor, as it counteracts degradation of the cell over a longer time frame. The algorithm needs to be further adapted to suit the automotive environment.
- A pilot study was performed to investigate techniques that can be used to classify user circumvention attempts with machine learning algorithms.

The circumvention attempts studied were those listed in the new SAE J3214 standard. The investigated methods were able to accurately classify 98% of the samples and showed potential for being incorporated in the final product. The pilot study was undertaken using a computer, so additional studies are needed to examine how to achieve the same results with less computational power. Moreover, a higher sample size will be required before these techniques can be more fully proven.

- The breath sensor technology developer installed Gen 3.3 sensors in the DADSS research vehicle to perform a human subjects study on sensor ease-of-use. In the study, the subjects exhaled towards the sensors at various distances, ranging from 20cm up to 70cm (about 8-28 inches), in increments of 5cm. Using a dilution factor (DF) of 40 for the Gen 3.3. sensor, the results showed that at longer distances fewer successful breaths were collected by the sensor (see Figure 5). At 40cm roughly half of the samples were accepted by the sensor. No noticeable difference was noted between sober and intoxicated subjects.

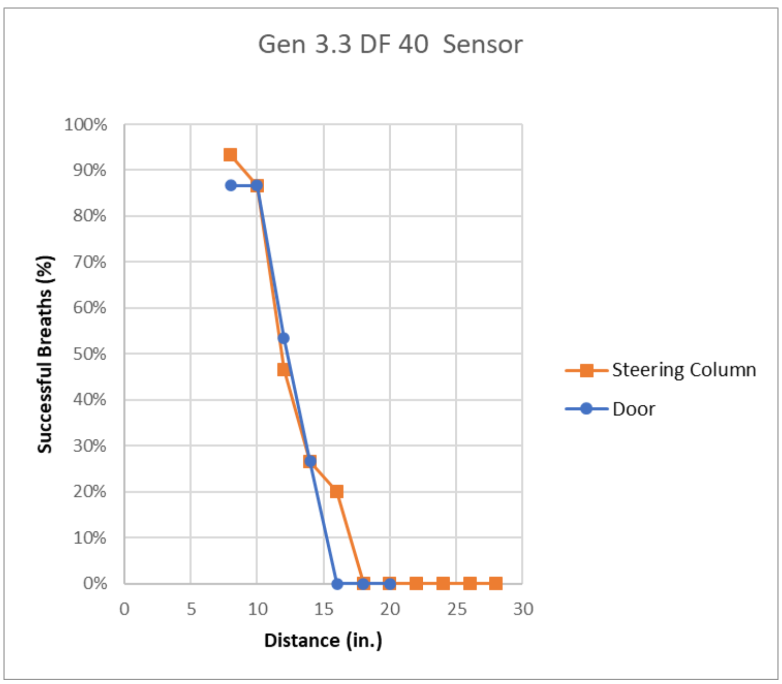


Figure 5. Effect of distance of breath on results

Touch Sensor

The touch sensor allows estimation of blood alcohol concentration in the capillaries of a driver's finger tissue. The driver touches an optical module and a near infrared light shines on the driver's skin and propagates into the tissue. A portion of the light is reflected from the skin's surface, where it is collected by the touch pad. Blood alcohol concentration can be estimated based on the properties of the light returned to the sensor.

The shift from an earlier touch sensor, which used a traditional Michelson interferometer[22] 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.[23] The key to such innovation was the definition of an optimized subset of optical wavelengths to enable high-quality, non-invasive alcohol measurement. Laser diodes[24] that are tuned for optimal alcohol measurements are used to generate 40 unique wavelengths of light. The laser diode specifications were derived from the comparison and analysis of human subject data and comparative reference data.

Extensive research was undertaken to develop the requisite laser diodes, many of which have not been previously manufactured, and assemble them in multi-laser packages. The individual laser signals are combined into a broader, diffuse light source in the optical module, which illuminates the finger and is reflected to the detector, where alcohol measurements are made. After initial work was completed to develop the laser diodes and packaging, a new supplier was selected with greater expertise in these areas. Each stage of the development process has required innovative research and has resulted in multiple patent applications.

The recent evolution of the touch sensor is depicted in Figure 6. Since February 2019, ACTS has taken over the development of the touch sensor (Gen 4) because of inadequate performance of the previous technology developer. Input has also been secured from semiconductor laser developers, and other experts in the spectroscopy and optics fields. In addition, in order to make faster progress, ACTS continues to look for partners to assist with touch sensor development.

The touch sensor consists 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 sensor aimed for use in privately-operated vehicles is targeted to be available during 2024-2025.

[22] The Michelson interferometer is a precision instrument that produces interference fringes by splitting a light beam into two parts and then recombining them after they have traveled different optical paths.

[23] 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.

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

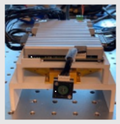
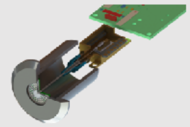
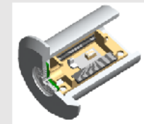
 2020	 Target 2023	 Target 2024-2025
GEN 4	**GEN 5**	**GEN 6**
• 20–laser (discrete laser architecture)	• 4 tunable lasers	• 2 tunable lasers
• Fiber coupled lasers	• Waveguide–coupled lasers	• Free space illumination
• Driver Optical Interface → Multi-Photo Diode Detectors	• Driver Optical Interface → 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 6. Future evolution of the DADSS touch sensor

Figure 7 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 with 10 in each. The subsequent design comprised 20 laser chips in a single package with each laser chip interrogating two wavelengths to cover the 40 discrete wavelengths (known as the stingray package, Gen 4SR), followed by a design in which 10 laser chips covered the 40 wavelengths (Gen 4DZ). The Gen 4 touch sensor resulted in a much-improved signal-to-noise ratio (SNR) compared to Gen 3. Recently, tunable lasers have been developed that are suitable for the touch sensor. Tunable lasers can alter the wavelength of operation in a controlled manner, thus enabling the use of fewer lasers. This development, engineered for use in the Gen 5 sensor, is expected to have higher sensitivity and perform faster than the stingray package. The first step will be four tunable lasers chips in a single package that can sweep the spectrum from approximately 1500-2500 nanometers. This modification will enable a smaller sensor footprint, use less power, have better temperature control to prevent measurement drift, and result in simplified optics and electronics. Ultimately, the plan is to use only two tunable laser chips to produce these same unique wavelengths (Gen 6).

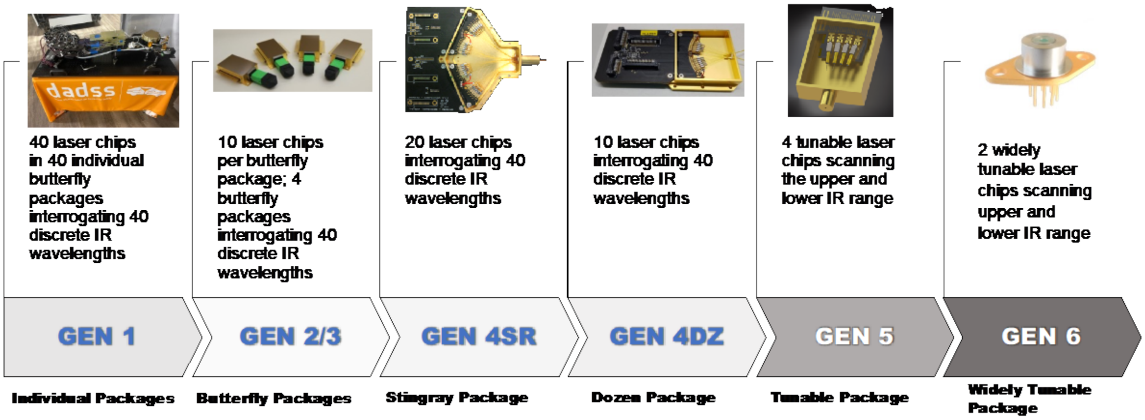


Figure 7. Evolution of laser development

The touch sensor function characteristics critical to accurate and repeatable performance are 1) the laser signal needs to be stable, not drifting or fluctuating; 2) the combined light source from the lasers needs to be homogenized so that the light levels propagating through the tissue are always the same; and 3) levels of background noise need to be low and signal strength sufficiently strong so that the signal can be readily detected when reflected from the tissue.

As with any new technology development, technical difficulties have been experienced along the way. It is to be expected that with each new generation of technology there is a learning curve. With the touch system, any time the light sources change, there are problems to be resolved. For example, research on the Gen 3 touch sensor revealed a problem with fluctuating laser intensity that could result in unreliable tissue alcohol measurements.[25] Researchers discovered that there was a lack of homogeneity in the combined light source causing the laser light 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 laser signals differ, the comparison, and hence alcohol measurement, cannot be effectively performed.

The integrating sphere, which is used to assist system design, is a hollow, spherical structure with an interior surface coated in a diffuse, white, reflective coating, designed to reflect all wavelengths of light equally (see Figure 8 for a graphic depiction of the integrating sphere). The sphere typically has 2-3 entrance or exit ports. The purpose of the integrating sphere it to allow non-uniform light to enter the sphere and undergo uniform scattering before the light leaves the exit port, resulting in one broad, diffuse light source that then shines into the finger. They come in many sizes, but this project utilizes 1” and 3” size integrating spheres.

[25] 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.

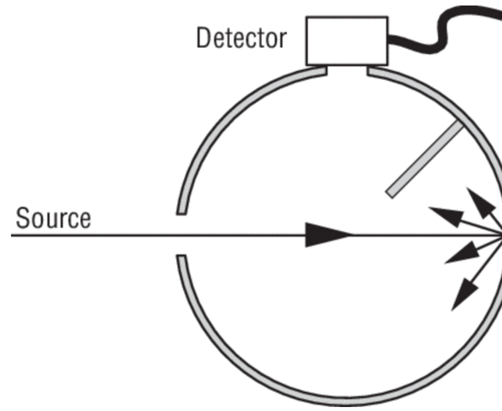


Figure 8. Integrating Sphere Internal Structure

During FY2021, there was continued research into the stingray laser performance, followed by the development of a new class of tunable lasers (Gen 5), which will be the basis for generating the necessary wavelengths for the touch sensors in the future. In addition, progress was made in critical electronics and software development.

Hardware

- Stingray lasers Research continued into assessing the performance of touch sensors using stingray lasers, named for the distinct triangular shape of the package (see Figure 9).

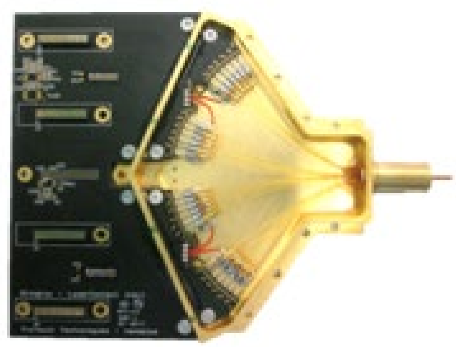


Figure 9. Stingray laser package

A stingray package with 3" integrating sphere setup was assembled and used to measure ethanol/water samples in transmission mode for evaluation of tissue surrogates (see Figures 10 and 11 for a schematic diagram and photograph of the experimental set up). Using the integrating sphere, it is possible to measure blood alcohol by passing light through the sample. A transmission model measurement requires splitting the diffused light in an integrating sphere into two paths. The first path takes the diffused light and passes it through the sample to be measured. Based on the sample's molecular properties, certain wavelengths of light are absorbed more than others. This light is then sampled using a photodetector. The second path involves sampling the unadulterated light in the integrating sphere with a photodetector, to generate a reference signal. By comparing the reference photodetector signal with the sample photodetector signal, the spectral profile of the sample can be determined. A two-component solution (water and ethanol) was used to build a calibration model. Ethanol concentrations as low as 0.025 g/dL were measured with a standard deviation of around 0.002-0.003 g/dL by the stingray laser 3” integrating sphere setup. Utilizing this setup in a transmission measurement configuration (light passing through an ethanol cuvette sample) was also successfully demonstrated for use with a prospective technology developer. The touch system as a whole was able to predict ethanol samples with concentrations as low as 0.022 g/dL with a standard deviation of approximately 0.003 g/dL.

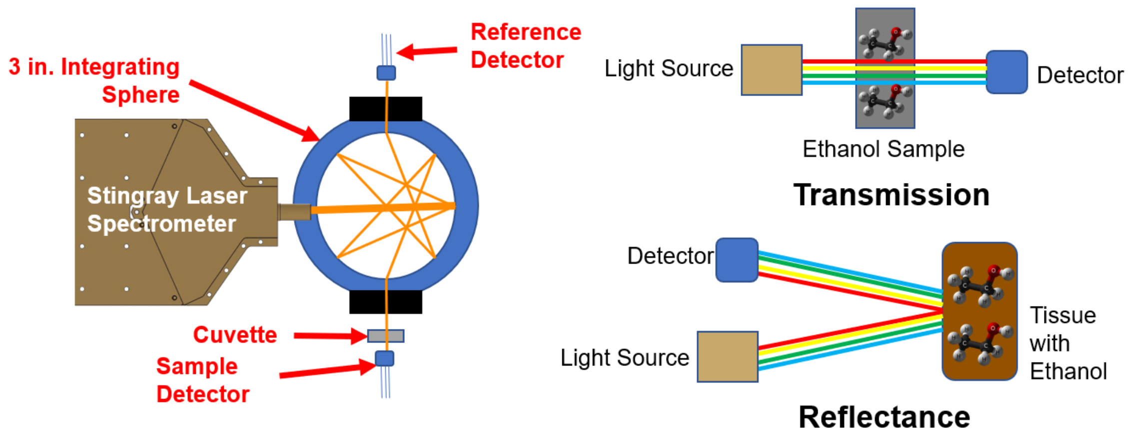


Figure 10. Setup for sample testing using the transmission method

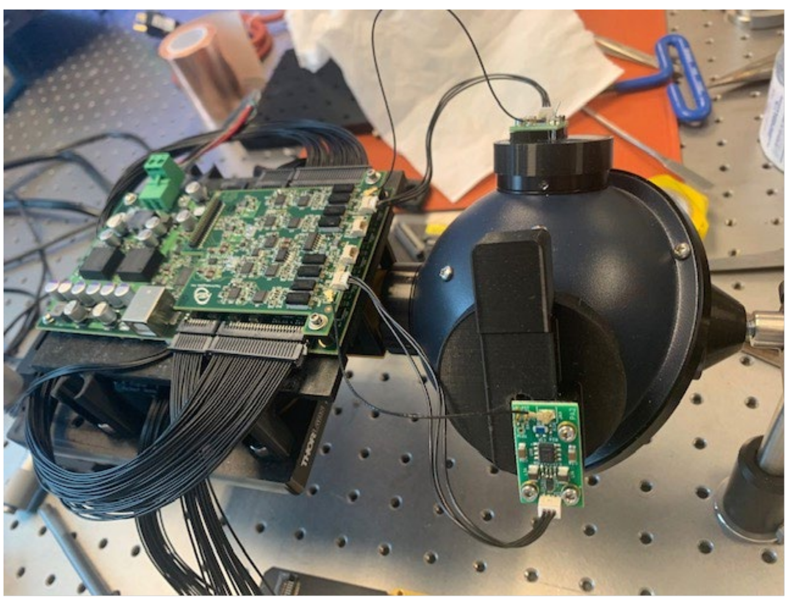


Figure 11. 3"integrating sphere/stingray lasers setup for measuring ethanol in transmission mode

- Utilizing custom laser control software, the DADSS team designed processes to verify lasers that are delivered to the DADSS team experienced no damage or changes in output during transit. In addition, experiments were designed to characterize the quality and performance of the lasers for making spectroscopic measurements.

Tunable lasers

- The first package of tunable lasers was received at the DADSS laboratory in January 2021. The transition to tunable lasers is necessary because of wavelength instabilities in the stingray laser packages. Tunable lasers have improved the temperature stability of the lasers, reduced the background noise, and reduced the size of the package.
- The DADSS team has now designed tunable laser touch sensor systems. The team has worked through several rounds of simulations, or ray trace models,[26] to determine how laser light behaves within the bounds of the opto-mechanical system designs that have been proposed (see Figure 12). This resulted in a recommended opto-mechanical design. The objective of the unit is to improve the homogenization of the light sources and improve the SNR. To develop the proposed design, different components were acquired, and others manufactured by the DADSS team, including optics components (e.g., beam splitters, lenses, etc.), mechanical hardware, electronics wires, cables, and 3D printed parts. In the first design, two 1” integrating spheres were incorporated as well as a cube beam splitter, and collimating lenses[27] to investigate the design and its performance. Currently, there are two units at the DADSS laboratory which researchers are using to investigate the design and performance, and to study the wavelength stability, temperature stability of the lasers, and SNR.

[26] Ray tracing is a method for calculating the path of waves or particles through a system with regions of varying propagation velocity, absorption characteristics, and reflecting surfaces.
[27] Collimating lenses are curved optical lenses that make the light rays that enter your spectrometer setup parallel. These lenses allow users to control the field of view, collection efficiency and spatial resolution of their setups, and to configure illumination and collection angles for sampling

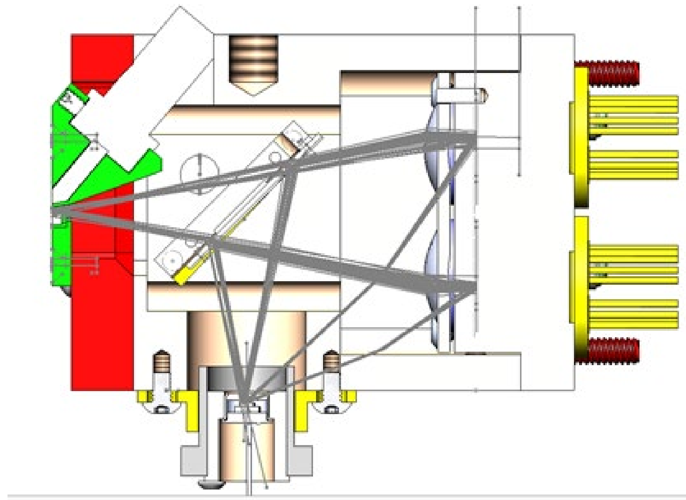


Figure 12. Example of a ray-trace model (grey lines) overlaid on a proposed mechanical design

- The first generation of tunable lasers was showing signal drift over time, causing a reduction in the SNR. The DADSS team is working on troubleshooting the issue. It was discovered that the firmware was causing the drifts, and that correcting for this led to enhancement of the stability of the lasers. Testing of the tunable lasers also indicated that the overall signal level appears to be lower than expected. Additional testing is needed to confirm these findings.
- The second unit with tunable lasers was used to collect spectral data across multiple sample targets and stray light was still detected. The unit was retested using the FLIR infrared imaging camera to identify sources of stray light. The ability to image light in this wavelength is critical as it allows the team to visualize the location of light within the opto-mechanical device. Using this technology, researchers are able to ensure that the optical lenses are correctly aligned, to identify areas of stray light leakage and poor focus of the laser beams. As a result of testing, potential sources of stray light were identified and mitigated.
- The second version of the tunable lasers were recently delivered with higher intensity and improved performance. The DADSS team has been working on characterizing the performance of the newly developed set of lasers, designed to operate in a faster measurement mode. The majority of the activity was focused on characterizing the lasers, which are mounted in the back-end assembly (heatsink and lenses), using the integrating sphere and 1mm photodetectors (See Figures 13 and 14). The lasers' temperature and wavelength stability, SNR performance, and system noise characteristics are all being investigated. This is being accomplished with the aid of custom software that is used to process and visualize the data collected. The goal is to collect data showing a stable baseline of performance of the lasers and

associated electronics, such that it can be integrated into the reflectance unit for further testing and data collection.

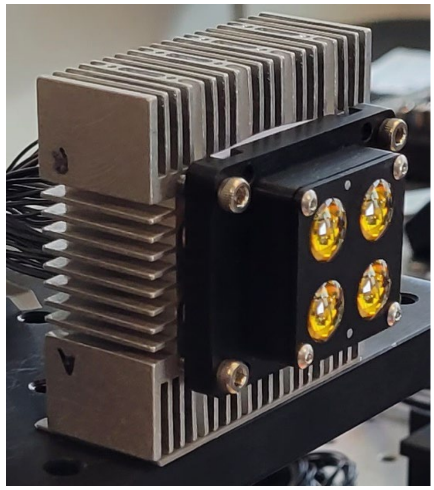


Figure 13. Back-end assembly (heatsink and lenses)

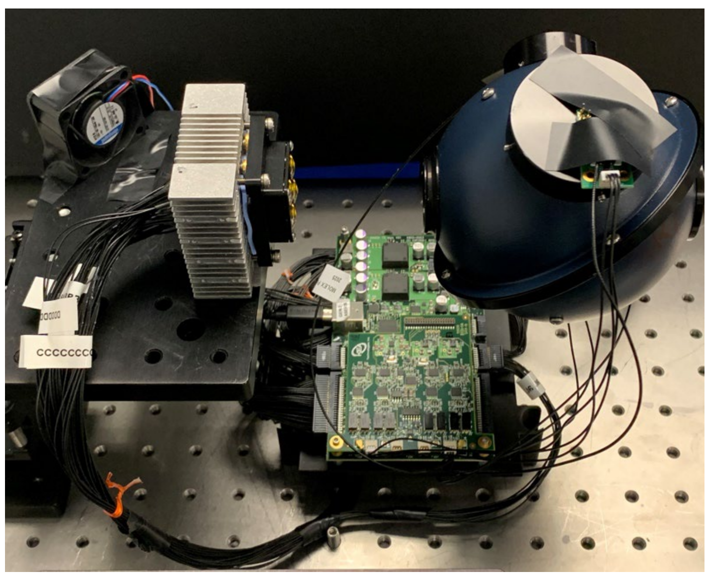


Figure 14. Optical benchtop laser characterization setup

- The research team has also made progress utilizing a spectrum analyzer to determine wavelength accuracy of the lasers. This is an instrument used to verify the wavelength of light generated by a laser over a given period (approximately 1 second). It is extremely precise, and if calibrated properly, can measure wavelengths to the nearest 0.001 nanometer. This instrument is critical as it allows the team to verify if a laser is operating at the wavelength to which it has been tuned. The relatively slow update rate of this instrument means that it is only able to characterize lasers operating in static (often referred to as continuous wavelength or CW) mode. In this mode, lasers are tuned to a specific setpoint and allowed to settle before a measurement is made. Although the analyzer is limited to a low sample rate, it provides a degree of confidence that the lasers are achieving the correct wavelengths. The team is transitioning to a faster measurement mode, where the lasers are dynamically and continuously ramped between several different setpoints, and a predetermined calibration profile allows the team to know what wavelength the laser is operating at, at a given point in time.

- The DADSS team is also working on testing, characterizing, and integrating a larger 2mm photodiode into the electronics system, using the integrating sphere. The goal is to integrate this larger photodiode into the reflectance unit to provide a higher SNR, through an improved signal. In addition, preamplifier boards are attached to the photodiodes to amplify the output signal to levels that are useable by the measurement board electronics.

Electronics accomplishments:

- Upon receipt of the Gen 2 tunable lasers, firmware and driver boards were upgraded and modifications were made on the photodetector and electronics boards. The current set of electronics includes the following; signal-conditioning circuitry that manipulates a signal to prepare it for the next stage of processing; filters used to reject unwanted signal in a specific frequency band; high-resolution analog-to-digital converters which are sub-systems that are able to precisely measure the very small signal from the sample and reference photodiodes, amplify them by an appropriate amount and convert it into a digital signal that can be processed by the system microprocessor; and power distribution capable of driving multiple lasers. The new electronics boards have demonstrated improvements in SNR compared with previous electronics.

Sensor Performance Research

As sensors evolve and improve, new generations of the breath and touch sensor systems must be tested to understand how well they perform. An important component of the testing process is to develop test methods that can demonstrate in a traceable manner that the breath and touch systems meet the requisite performance specifications. As part of this process the DADSS team must develop both test methods and traceable breath and tissue surrogates for use in the testing. The traceability of these test materials comes from the use of standard reference materials (SRMs) that are produced to a known value. Typically, with the implementation of such materials, researchers can use them with assurance that 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.

To fully address the many aspects of the testing process, the DADSS team has undertaken a multi-pronged program that is based around the research, development, and vetting of apparatus and methodology. The initial focus of these efforts was aimed at the development of the breath and tissue 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 Blending System (ABBS). The ABBS was developed to meet these needs by combining 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 ethanol gas. 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 with an extremely high level of precision.

Once developed, an SRMs composition, accuracy, and precision must be confirmed at the DADSS specifications. The instrumentation necessary for such verification must exceed the DADSS performance specifications by a significant order of magnitude. A 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. Various approaches and their methods, such as gas chromatography, liquid chromatography, and infrared spectroscopy were evaluated.

A Fourier Transform Infrared Spectroscopy (FTIR) device 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 SAE J3214 Standard, referred to above, there is a requirement that the test gas ethanol concentration has an uncertainty of less than 1.5%. To achieve this level of uncertainty, the gases are calibrated using the in-house FTIR device with the MKS Multi Gas 2030 Continuous Gas Analyzer using gases in which ethanol concentration is certified to a known concentration with very high accuracy. Gas standards that have enough accuracy to support this calibration are available from VSL, the National Metrology Institute of the Netherlands.

For in-vehicle breath sensor verification, a portable device was developed that permits controlled and uniform gas delivery to the breath sensors outside of the controlled laboratory conditions and utilizes gas tanks of ethanol mixed with carbon dioxide, oxygen, and nitrogen (see Figure 15). 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.

Figure 15. 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) to verify the accuracy and precision of breath sensors when they are first installed in vehicles. The test vehicle's Data Acquisition System (DAS) outputs sensor data to a dedicated website for analysis and the testing confirms that all acquisition systems are communicating. Review of the initial in-vehicle sensor results demonstrated comparable results across different sensors and accuracy levels that were comparable to similar testing regimens in the laboratory. Research is ongoing to improve the portable SCD for use in manufactured vehicles.

Also, in support of touch sensor validation, work is 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 being conducted 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.

For the tissue validation device, a Waters Acquity High-Performance Liquid Chromatography (HPLC) device with mass spectrometry, refractive index, and UV-Vis detectors was selected (see Figure 16). 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.

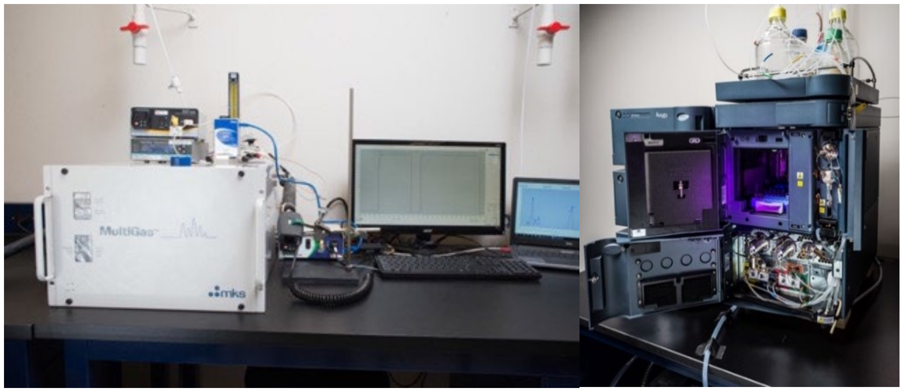


Figure 16. MKS Multigas 2030 FTIR and Waters Aquity HPLC in the DADSS research laboratory

With insight from the alcohol and environmental testing industries, new methods to improve the tissue 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.

Despite the pandemic, research and development has continued in FY2021 and has resulted in progress in many areas. During FY2021, laboratory efforts have focused on research and testing of the Gen 3.3 breath sensors. There are two main areas of emphasis; a) the development of methods for calibrating the sensors, and b) sensor testing, including formal sensor characterization, and research to explore the effects of many different variables on sensor performance. One area of interest has been to better understand applicable in-vehicle variations but in the more controlled environment of the laboratory. Factors of interest include, the effects of different breath strengths, mouth shape, distance from the sensors (for example, can people sitting normally in the vehicle get close enough to deliver a strong enough breath), and snorkel design. The results of this research will ultimately be shared with vehicle manufacturers who could then use the data to design implementation of the sensor systems for individual vehicle makes and models.

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- Through FY2021, 145 Gen 3.3 breath sensors were delivered to the DADSS laboratory for testing and evaluation. During that time, 68 Gen 3.3 sensors were characterized at various temperature, humidity, and ethanol levels (see Table 2).

Table 2. Gen 3.3 sensors characterization

Sensor Group	Number of Sensors	Number of Temperature Humidity conditions	Ethanol levels	Breaths	Data Points Analyzed in study
1	4	4	3	32	1536
2	8	4	3	32	3072
3	4	4	3	32	1536
4	8	4	3	32	3072
5	8	4	3	32	3072
8	4	4	3	32	1536
9	8	4	3	32	3072
10	8	4	3	32	3072
11	8	4	3	32	3072
12	8	4	3	32	3072
Total	68				26112

- Gen 3.3 sensors were installed in four research vehicles and data collection and analysis is underway.
- There were parallel investigations undertaken in the vehicle and in the laboratory to establish the relationship between distances from the sensor and DFs, system error, and BrAC measurements. Sober breaths were delivered to the sensor at a variety of distances to establish the relationship between distance from the gas source and the DF of the breath. Ten to twenty breaths were delivered at each distance. In addition, the relationship between DF and sensor error was studied to establish a baseline of the expected occurrence of false positive readings. Figure 17 illustrates the relationship between distance (in inches) from the sensor and the DF, with and without snorkels. The degree of variation is illustrated by the height of the vertical bars. A few findings emerged from the data. The DF sees only modest rises to distances of 10-12 inches from the sensor even without snorkels. However, in the absence of snorkels, the DF rises more quickly after that point and is more variable with the increase in distance from the sensors. By contrast, with the use of snorkels, the DF stays relatively low even at distances of up to 22 inches from the sensor and for the most part, variability is not as pronounced.

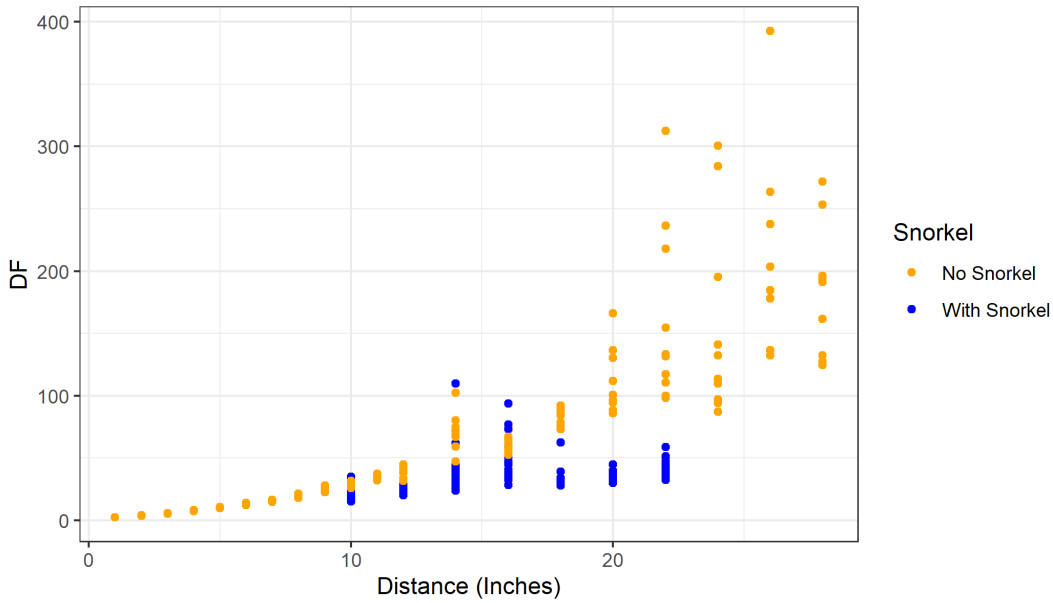

Figure 17. The relationship of distance from the sensor and dilution factor (DF), with and without snorkels

Figure 18 illustrates the relationship between various DFs and sensor error using gas with a BrAC of 0.00 g/dL (sober breath). At higher DFs there is more uncertainty in the BrAC measurement. This suggests that if a lower DF cut-off is adopted, it will be possible to successfully analyze a greater percentage of the breaths.

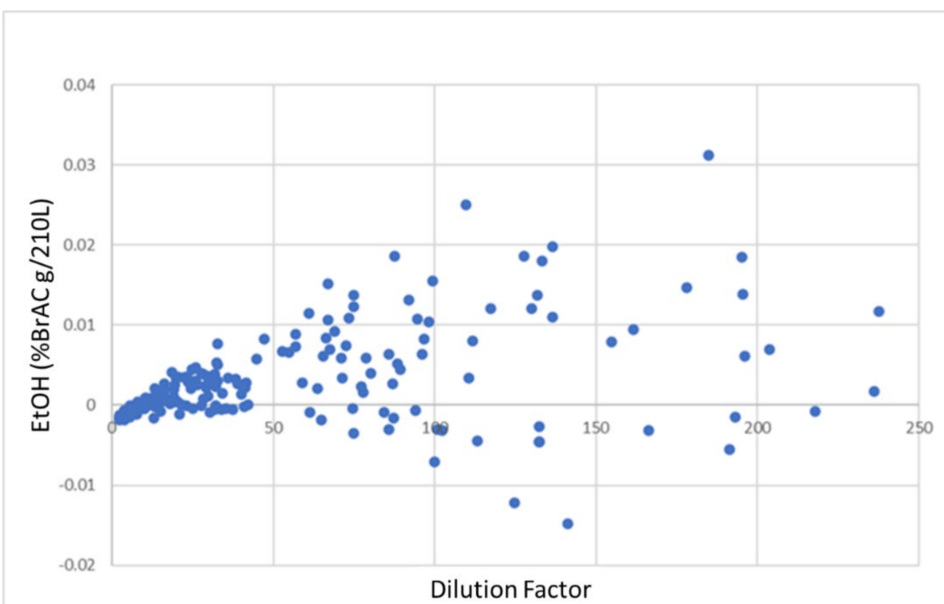

Figure 18. Variations in laboratory sensor BrAC measurements at 0.00 g/dL BrAC at different DFs

Figure 19 illustrates the variation in BrAC measurements for sober drivers at various DFs at the four sensor locations: driver door (dd), steering wheel (df), passenger door (pd) and passenger dashboard (pf). Subjects in the research vehicles delivered more than 1,000 sober breaths. At a DF of 40 or below, no false positives were recorded (defined as a measurement of greater than 0.02 g/dL indicated by the solid red line). In the real world, any measurements with a BrAC of less than 0.02g/dL would be reported to the driver as "Safe to Drive." At a DF of 60 or less, there were 0.02% false positives (1 in 538 samples). However, at a DF of greater than 40, only a third of the breaths were sufficient for system analysis.

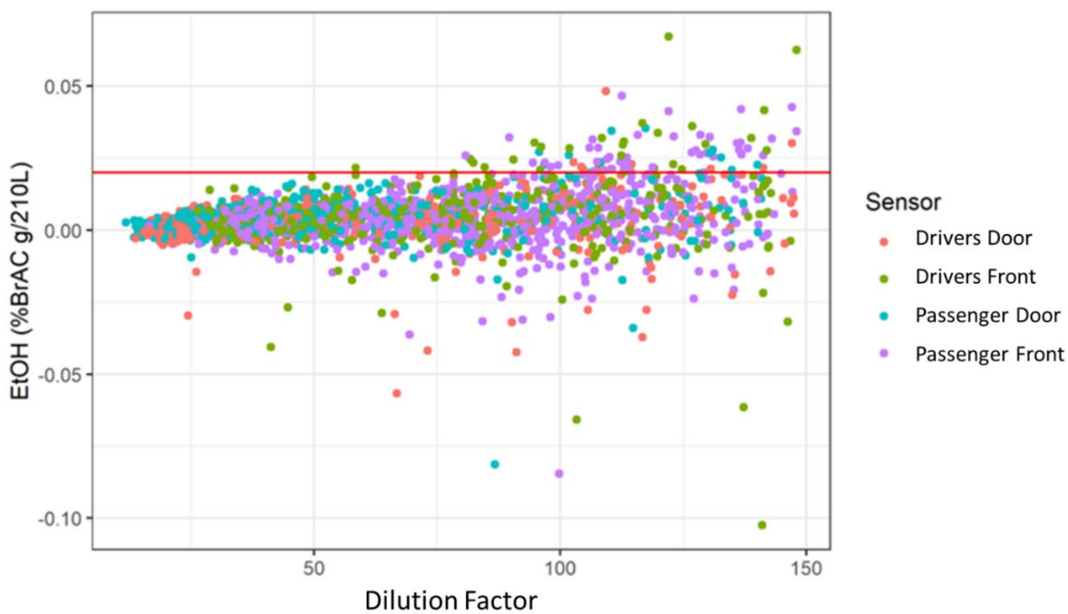

Figure 19. In-vehicle BrAC measurements at different breath dilutions

- Initial work is underway to quantitatively compare the accuracy and precision of the ABBS system to a traditional and less precise Automated Calibration Gas Dilution System using both the FTIR and the Gen 3.3 sensors as measuring devices.
- The DADSS laboratory is now accredited to the SAE J3214 specification and is currently the only laboratory accredited to the standard. To obtain accreditation new calibration gases were obtained for the MKS verification system to improve precision and reduce uncertainty in the measurement process.
- Investigations were undertaken in the laboratory into the design of snorkels to be used in vehicles. Initial studies examined snorkel length, width, and snorkel material. It was found that 3D printed materials introduce a significant bias in ethanol readings when compared to commonly available plastic tubing. Because vehicle interiors, such as the interior of the doors, can be very tight, additional investigations were undertaken to examine the effects of bending

and kinking on snorkel performance with regard to the flow of carbon dioxide and ethanol to the sensor. Snorkels were bent or kinked in a controlled manner to determine whether it was better to have a long, looping snorkel or to introduce a sharp corner when installed in a vehicle. Images of snorkel kinking tests are shown below in Figure 20. It was found that there is no discernable effect from bending or kinking the snorkel tubing.

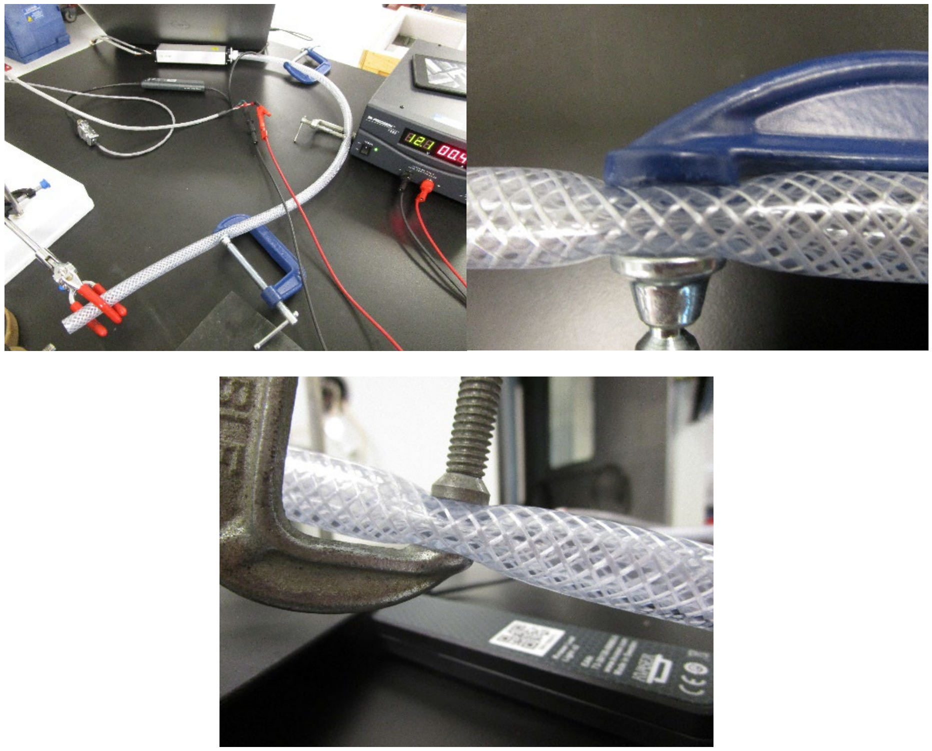

Figure 20. Images of snorkel kinking

- Design work currently is ongoing to update the portable SCD for use in research vehicles and ultimately by automakers to verify sensor performance in manufactured vehicles.
- An investigation into the laboratory characterization system was concluded in FY2021. Each sensor takes a period of four days to characterize because of the numerous variables investigated. Verification of full heating pathways was undertaken on the both 4-position and 8-position manifolds used for characterization testing, and their effects on the ethanol readings in the sensors was measured (see Figure 21). Aluminum foil was used to wrap the manifolds to prevent moisture accumulation and improve air quality. The challenge is to ensure consistent heating throughout the system to avoid condensation on colder spots. The studies confirmed that appropriate heating of the breath path reduces the bias caused when ethanol in the gas stream condenses on cold surfaces.

Figure 21. Insulated 4-position and 8-posion manifolds

- New batches of ethanol gel samples were prepared for touch sensor calibration using gelatin powder, ethanol and scattering components to replicate the scatter function of human tissue. The gels were characterized using the Nicolet iS50 FTIR instrument. A total of six samples with ethanol concentrations ranging from 0.10 to 3 g/dL were prepared. In the future, additional ethanol concentrations, various gel stiffness, and various calibration models using gel samples will be investigated.
- The DADSS laboratory has developed and tested various gelatin samples including agarose, porcine, alginate, collagen, alginate/collagen containing ethanol and scattering beads. One observation was that gel samples prepared from agarose and alginate change over time which makes it difficult to build a calibration model. However, promising results were achieved using porcine gels and polystyrene beads. Porcine gel samples demonstrate the highest stability and durability compared to other gel samples (see Figure 22).

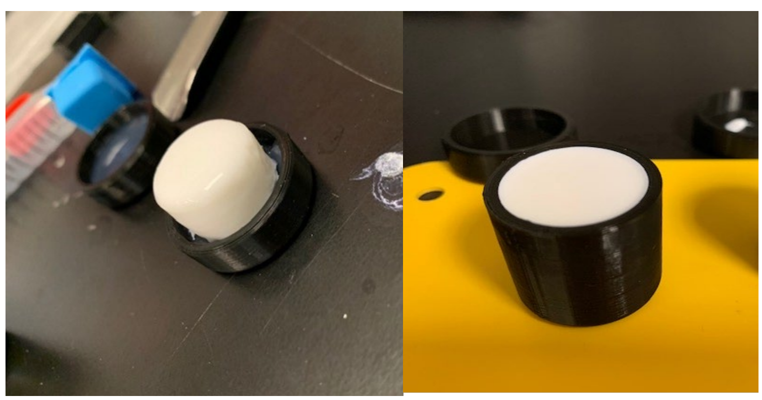

Figure 22. Tissue surrogates using 2% alginate gel (left) and 5% porcine gel (right)

Human Subject Testing

Calibrating DADSS sensors in the laboratory under highly controlled conditions is a key component in verifying sensor performance. However, researchers also need to verify sensor performance while considering human variability, such as age, sex, race/ethnicity, body mass, and medical conditions, as well as the effects of in-vehicle variability and environmental factors such as weather, humidity, temperature, road conditions to test the sensors in the environment in which they will be used. To investigate these variables, several research programs are underway, including human subject laboratory testing and human subject driving trials.

Human Subject Laboratory Testing (HST)

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 (i.e., blood, breath, tissue) and across the many factors that can affect alcohol concentration such as age, body mass, race/ethnicity, sex, medical conditions etc. 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 concentrations 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.

The purpose of human subject laboratory testing is:

- To quantify the rate of distribution of alcohol throughout the various compartments of the body (i.e., 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, both breath and blood, among a wide cross section of individuals of different ages, sex, body mass index, race/ ethnicity and in a variety of scenarios.

Many insights already 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 (i.e., 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 DADSS breath sensors), and tissue alcohol measurement (using the touch sensor) over a wide range of BACs (0.04-0.12 g/dL).[28]

Human subject testing protocol

Healthy adult male and female volunteers between the ages of 21-55 years are recruited via online advertisements to participate in the studies for which they are compensated. Most individuals participate in more than one experiment, providing within-subject comparisons. All participants are well matched by age, sex, ethnicity, body mass index (BMI), and current alcohol consumption levels. Participants are notified that they cannot drink alcohol for 24 hours prior to the scheduled study. The protocol and informed consents are approved by the Partners Healthcare Institutional Review Board (IRB). Individuals receive a full physical and psychiatric evaluation before being enrolled in the study. On each test day, they receive a breath alcohol test (Alco Sensor-FST®), a urine toxicology screen, and urine pregnancy test (women), all of which must be negative before the study can proceed.

Once the participants arrive at the laboratory, and are fully briefed, if they are comfortable with the study requirements and choose to participate, they sign the informed consent form. The participant is then given a standardized breakfast (juice and toast). All participants are dosed based on their body weight (0.3 g/kg or 0.7 g/kg), a total volume of 400 mL. Participants are given specific instructions about the rate and volume of the drinks that are consumed (either as a large bolus dose or as three drinks spread out over the course of 30-90 minutes).

Blood alcohol levels are analyzed in the McLean Hospital Clinical Chemistry Laboratory, with each sample collected at either 2- or 5-minute intervals. Breath samples also are collected both with the DADSS breath sensor and an Alco-Sensor FST®. Figure 23 provides an overview of the laboratory setting.

[28] 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.

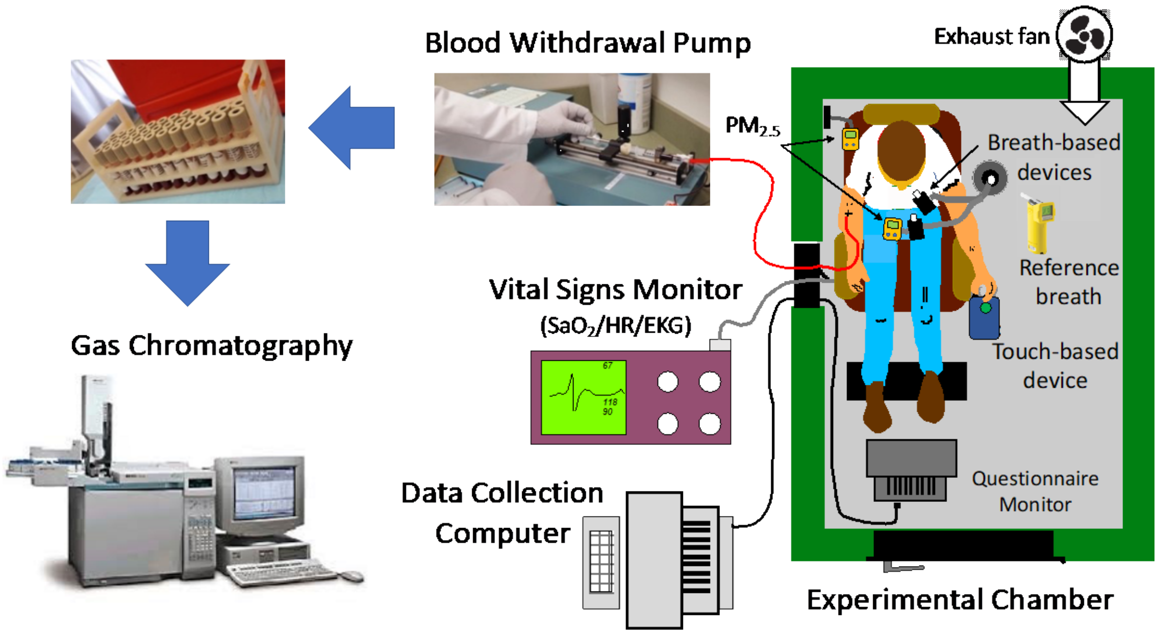

Figure 23. Test setup diagram for sensor verification using human subjects in a controlled laboratory setting at McLean Hospital

Although progress has been slower due to COVID-19, some progress was made during FY2021.

Laboratory testing

Human subject testing was suspended in March 2020 when COVID-19 restrictions were put in place. During the shut-down, McLean Hospital health coordinators worked diligently to develop safety procedures to protect participants. The restrictions were relaxed in August 2020 and testing was resumed in September 2020. However, data collection remained at lower rates until July 2021, when individuals became more willing to travel onsite to participate in studies again. The participation has begun to increase, although recruitment remains 10% below pre-COVID rates.

During FY2021, studies were focused primarily on exploring the role that wine, beer, near beer, and energy drinks play in the detection of alcohol on breath samples and in blood. The following scenarios were explored: 1) the effects of drinking low-dose beer (0.3 g/kg); 2) the effects of drinking standard-dose beer (0.5 g/kg); 3) the effects of drinking nonalcoholic or near beer (<0.5% alcohol); 4) the effects of drinking wine (0.7 g/kg); and 5) the effects of combining an energy drink with alcohol (0.3 g/kg). The studies continue to focus on the effective ranges of the DADSS breath sensors to ensure their performance at very low (e.g., 0.02 g/dL) to high (0.18 g/dL) alcohol concentrations, with a special emphasis on BAC/BrAC in the range of 0.08 g/dL concentration, which is the threshold for legal impairment in all but one U.S. state.[29] It should be noted that the touch sensor was withdrawn from testing during FY2019 and

[29] Ibid page 7

will be reintroduced once the development of the Gen 4 touch sensor has progressed to the point of being ready for human subject testing.

Methodology: New methods were developed to accommodate the new testing scenarios, details of which are provided below.

- The laboratory developed an "octopus-like" mounting system that can hold up to four breath sensors, as well as a meter to measure particulate matter ($PM_{2.5}$) in various positions around the participant's face. This meter can detect very fine particulate matter 2.5 micrometers and smaller, including from cigarette smoke. Using this system, it is possible to simulate the physical position and distance that the breath sensors would be from a driver when installed in the vehicle. This arrangement also allows direct comparison of the performance of multiple sensors when testing them simultaneously.
- New procedures have been developed for implementation of the study examining the effects of drinking alcohol while smoking traditional and electronic cigarettes. The test chamber was modified with high performance air handling and filtering systems to evacuate tobacco smoke quickly and completely from the room after testing the impact of smoking on the breath sensors. This was an important development to protect staff from tobacco smoke exposure.

Human subject studies

- During the fiscal year, 22 studies were conducted with 9 subjects (6 male, 3 female) participating in the new scenarios.
- Researchers analyzed 364 blood samples during FY2021, resulting in a total of 11,965 blood samples processed throughout the study period. The average number of samples per study remains lower due to shortened testing periods, averaging 25 samples/study. (Studies can be conducted for up to four hours, although most of the recent scenarios typically last 2 hours). The intra assay CV (a measure of variance) for these studies was 1.47% (range 0.90 - 2.04) and overall, for the past 239 studies it was 1.41%.
- Many study participants report that they drink a combined vodka and energy drink that contained caffeine. When alcohol is mixed with caffeine, the caffeine can mask the depressant effects of alcohol, making drinkers feel more alert than they would otherwise. As a result, they may drink more alcohol and become more impaired than they realize. Participants consumed a lower dose of alcohol (0.3 g/kg) either with or without 8 oz. of the energy drink. Once there is a sufficient sample size, analyses of the breath samples will be completed.
- The studies to examine the effects of drinking alcohol while smoking traditional and electronic cigarettes were delayed because of the need to verify whether the vapor from the electronic cigarette would interfere with the breath sensors. The flavored nicotine solution used in electronic cigarettes, was shown to contain the unlisted ingredient alcohol.[30] It is possible that they also contain ethanol.

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[30] Polkis, J L, Wolf, C E, Peace, M R. 2017. Ethanol concentration in 56 refillable electronic cigarettes liquid

Moreover, the nicotine juice in the electronic cigarettes is suspended in propylene glycol, and because it is very hard to distinguish ethylene glycol from ethanol, propylene glycol also may be detected due to the -OH groups and their locations in reference to carbon atoms. This issue will need to be resolved before exposing breath sensor systems units to the electronic cigarettes.

- Studies to examine the consumption of nonalcoholic beer (i.e., beverage grade beer containing < 0.5% ethanol) have been completed and the results are presented below for each of the Gen 3.1 and 3.2 breath sensors. Figure 24 shows the distribution of BrAC measured by the different breath sensors over time. BAC is indicated by the red dots along the x-axis. This is one of the few scenarios in which the breath samples did not match the blood. There were no positive BACs among the blood samples from any of the participants throughout the collection period. However, consumption of nonalcoholic beer resulted in measurable alcohol in the breath samples. The breath alcohol appeared during the consumption period which spans the first 19 minutes of the study and peaked between 0.01 – 0.03 g/dL (depending on the device). After the breath alcohol initially disappeared (at about 18 minutes post drinking) there were several brief mini peaks of alcohol in the breath samples. It is likely that these were the result of gastric alcohol that results from belching and release of alcohol from the stomach. Although this could potentially affect the ability to start the car if alcohol is detected when using a zero-tolerance device, impairment likely will not be present.

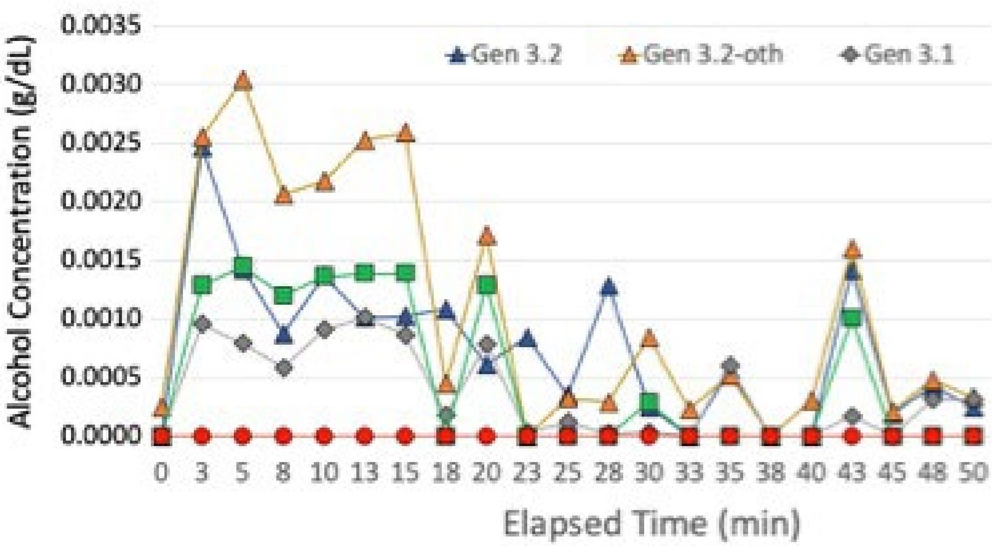

Figure 24. Time course of BAC and BrAC (g/dL) detected by various devices after consuming nonalcoholic beer

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formulations determined by headspace gas chromatography with flame ionization detector (HS-GC-FID). Drug Testing and Analysis, Vol. 9, 1637-1640.

Human Subject Driving Tests

The purpose of the human subject driving tests (HSD) is to conduct basic and applied research to understand the performance of the DADSS sensors in the vehicle physiologically and ergonomically. During the course of the HSD tests, in-vehicle testing has been undertaken in a diverse set of geographic/ environmental conditions, varying vehicle conditions, and with a large number of human subjects to assess the effects of human variability. Initially, 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. However, research has indicated that varying route conditions did not affect sensor performance, so having to utilize different routes is no longer a necessity.

Results from on-road testing is critical in determining the effectiveness of the DADSS sensors in a wide range of conditions 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 these devices in a vehicle environment, including driver behavior and user acceptance. The data will also be used to refine the DADSS Performance Specifications, and to improve system design and product development.

Once the breath sensors performed well in laboratory and human subject testing, vehicle trials in real-world driving environments began in June 2019 with the Gen 3.2 breath sensors (HSD1). The vehicles have the capability to accommodate one touch sensor when the technology is ready for real-world testing. In-vehicle testing utilizes fully-equipped Chevrolet Malibu vehicles, donated by General Motors.

The ultimate goal of the breath sensors is to passively detect drivers' breath alcohol within the ambient air of the vehicle cabin. For the purpose of this study, however, subjects are instructed to breathe towards the sensors to assist data collection. The subjects' directed breath has two types of variability, 1) subjects likely will breathe differently each time they give a sample, for example, the amount of breath, the strength of each breath, and the direction of the breath will vary; and 2) each person breathes slightly differently. One person's version of "provide a breath as if blowing out a candle" may be different than another's. When you factor in variations in subject height, distractibility during the drive, and other variables, these can all contribute to potential variations observed in sensor performance. As a result, a large amount of data are needed to fully understand how each of the sensors works across all conditions for every driver.

Vehicle data collection equipment

Both a reference sensor and DADSS breath sensors are integrated into each research vehicle to measure breath alcohol – two DADSS breath sensors on the driver side and two on the passenger side. On the driver's side the breath sensors are mounted in the steering wheel location and the driver's door. On the passenger side they are mounted in the passenger door and on the dashboard directly in front of the passenger (see Figure 25 orange inlet ports). The DADSS breath sensors can measure directed and passive breath. The reference sensor provides a comparison measurement and requires a deep lung sample of breath delivered through a plastic tube. The reference sensors provide information on sensor sensitivity (i.e., true positives), validity, and reliability.

Figure 25. 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 system (DAS), two video cameras, a web interface[31], data and video storage, and a user interface module for use by the passengers (Figure 26).

Figure 26. User interface module

[31] A web interface allows the user to interact with content or software running on a remote server through a web browser.

Human subject driving trials

Recruitment of the test subjects is being conducted at the DADSS laboratory and the McLean Hospital. Many of the test subjects have previously participated in DADSS human subject testing, affording researchers the opportunity to compare subjects' laboratory and in-vehicle data. Participants are brought into either of the laboratories prior to the study. The risks and benefits of the study are explained to them, and if they are comfortable with the study requirements and choose to participate, they sign the informed consent form. Subjects are screened for drug and alcohol presence, and they are familiarized with the vehicle set-up and protocol. After height and weight measurements are taken and the appropriate doses of alcohol are calculated, they are dosed with alcohol over a period of about 10 minutes. The subjects are passengers in the vehicle, and their alcohol measurements are collected frequently from the breath and reference sensors. They are instructed by a research assistant in the vehicle to direct their breath in a prescribed sequence toward the DADSS breath sensors in the vehicle. The current methodology permits collection of BrAC on up to four different sensors every 3.5-4 minutes for up to eight hours. The research assistant also monitors the subject's condition.

During vehicle testing the DADSS sensors passively sniff and analyze the vehicle cabin air for the presence of alcohol. In addition, drivers are asked to provide breath samples at the beginning and end of each study period. Additional vehicle instrumentation tracks environmental conditions and vehicle system data while providing participant videos. It should be noted that the vehicle windows are always in the closed position during driving trials.

Human subject driver testing began in June 2019 until being suspended on March 12, 2020 due to COVID-19. COVID-19 safety protocols and procedures were designed and approved by IRBs for both laboratories to resume studies with participants starting in August, 2021.

The field tests of the Gen 3.2 sensors in real-world settings and the demonstration projects in Virginia and Maryland (see the sections below for more information) are essential in understanding environmental and driver factors that might affect sensor performance. These projects are important in developing performance specifications, sensor placement in vehicles and the enhancement of the data acquisition systems. Information collected from these projects contributed to the development of several improvements in the next generation fleet device, Gen 3.3, including improved accuracy and precision, increased operational temperature range, a faster start-up, reduced cost, improved protection from electromagnetic interference (EMI), and improved start-up behavior. In addition, the trials have functioned as proof-of-concept studies to identify which variables need to continue to be investigated as new generations of sensors are evaluated.

During the driving trials of Gen 3.2 sensors, some outlying readings suggested that electromagnetic waves were interfering with the sensor function. When there is a strong transmitter near the sensor, like a cell phone, it was possible that the sensor experienced signal spikes that were incorrectly identified as alcohol. This was first noticed in demonstration cars. When someone was talking on a cell phone, the sensors would incorrectly report alcohol present when the driver was sober. Upon examining the HSD1 data, unexpected transient positive alcohol readings were noted even when there was no alcohol present. Careful control of EMI in the laboratory further confirmed that cell phone signals caused interference with the detector in the range of wavelengths where alcohol is reported. To test the effect of cell phone use, the team conducted a controlled trial of drives with and without cell phone use. The results suggested that the cell phone signal was likely the cause of the EMI. These findings led the team to develop a "wrap" to protect the sensors from EMI. After implementing the wrapped sensors, EMI was limited.

In-vehicle integration of Gen 3.3 sensors began in May 2021. The Gen 3.3 sensor has been under evaluation in the next round of trials, known as HSD2, since August 2021. As noted above, the Gen 3.3 sensor is designed for use in fleet vehicles to detect the presence of alcohol, thus, the focus of these studies is on testing the sensor with sober and low-dose alcohol participants.

HSD protocols, methods, and findings:

- After integration of Gen 3.3 breath sensors into five study vehicles, significant time was spent stress testing the sensors. That has involved testing over several weeks, in a variety of conditions, at different times, at various distances, and with a variety of breath types (e.g., passive, directed, strong versus lighter breaths). The goals of these studies was to evaluate:
    - Differences between the performance of Gen 3.2 and 3.3 sensors.
    - Communication between the Gen 3.3 sensors, the DAS, and the data viewer.
- New study protocols were developed for the Gen 3.3 sensor in-vehicle testing to evaluate the following questions:
    - Do the Gen 3.3 sensors perform better than the Gen 3.2 sensors in terms of sensitivity (i.e., true positives) and specificity (i.e., true negatives), accuracy, and precision?
    - Does performance change at different BrACs (i.e., sober vs higher BrACs)?
    - How often are false positives observed among sober drivers and false negatives among dosed passengers?
    - How do the sensors perform on start-up?
    - Are there sensor positions that adversely affect breath measurements?
    - Are there differences in sensor performance between stationary testing versus driving?
    - Is there sensor-to-sensor variability in performance?
    - How much interference is there from a drunk/non-sober passenger when measuring driver BrACs? Or how much interference is there on the passenger side from a sober driver.

- The results of the HSD1 studies, examining just the sober breaths, led to the identification of variables that do not significantly affect sensor readings, and therefore will not need to be included when testing new sensor generations. Given these were sober breaths, percent false positives (a BrAC reading by the breath sensor greater than 0.02g/dL) were used as the primary outcome to measure differences in performance.
- There were no clear differences in sensor performance between driving and stationary trials. Percent false positives among samples (DF less than 60) when the vehicle was stationary did not differ significantly from those in a moving vehicle; 1.18% (n=255) versus 1.54% (n=2848). To examine salt water/air exposure, distance to the shore was merged onto the location of each sample by GPS coordinate. The analysis compared the percent false positives for locations less than 10 miles versus more than 10 miles from the shore. No significant difference was found, with 1.34% false positives among breath sensor samples (DF less than 60) collected closer to the shore (n=372) versus 1.54% false positives among samples collected further from the shore (n=2731). As a result of these findings, the use of different driving routes is no longer deemed necessary.
- The role of environmental conditions, that is, temperature and barometric pressure, was examined with respect to potential effects on the agreement of the breath sensor with the reference sensor. The percent difference in breath sensor BrAC versus the reference BrAC was used as the measure of agreement and compared under different environmental conditions. Interior cabin temperature (°C) and barometric pressure (kilopascals), as measured by the vehicle, were extracted from vehicle data and merged onto each sample by date and time. There were no differences in agreement of the breath versus reference sensor BrAC by barometric pressure. However, differences were observed in the agreement by temperature. As the vehicle's interior temperature increased, the breath sensor reading was more likely to be higher than the reference sensor and vice versa. However, there were limited numbers of samples at these higher temperatures, 30-40°C, to draw any firm conclusions.
- In June 2021, KEA received IRB approval for significant changes to the study protocol. Under the new protocol, more driver breaths are collected, and more of the tests are undertaken in stationary vehicles, resulting in significantly less time spent driving. These changes allow more data to be collected daily, on a larger number of vehicles and sensors. In a typical study day, there is one hour of stationary testing with sober drivers and sober passengers, followed by one hour of stationary testing in which both the sober driver and the alcohol-dosed passenger provide directed breaths. This is followed by one hour of driving in which the dosed passenger is providing breath samples. The testing utilizes up to four vehicles.

Human subject driving trials:

- Until testing with outside participants could be resumed, more than 180 in-vehicle research and development study sessions were conducted from October 2020 until August 2021 using sober KEA staff as subjects. The goal was to capture more directed breaths from the driver-side sensors, given that the study currently focuses on alcohol-dosed passengers. The focus of these sessions was on performance of the breath sensors with sober drivers, including the effects at different distances from the sensors, spirometer testing to evaluate variations in breathing patterns, changes in altitude, and salt water/air exposure, and evaluation of different study designs. The effects of EMI with mobile phones turned off or in airplane mode, and in mobile service dead zones, was also investigated. Initially, Gen 3.2 sensors were used, and once integrated into research vehicles in May 2021 Gen 3.3 sensors were used.
- In FY2021, 11 HSD2 sessions were conducted to evaluate Gen 3.3 sensors; 6 from the DADSS laboratory, and 5 from McLean hospital.
- Since the HSD studies began in June 2019, there have been a total of 128 sessions; 117 of them during the proof of concept stage (HSD1) and 11 HSD2 sessions using the Gen 3.3 sensor.
- Driver and passenger data from the trials have been used to determine the sensor's performance in real-world driving conditions, including estimating how likely the sensor is to a) inconvenience drivers through a false positive reading, thus preventing the vehicle from moving when the driver is under the limit, and b) potentially miss a positive BrAC (false negative), thus allowing a driver to operate the vehicle when over the limit. The analysis compares the values measured by the DADSS sensor to those from the reference sensor. These measures are influenced by the defined measure of impairment and the "cut-off" used. The cut-off is the specified BrAC level where anything above it will be identified as positive (impaired) and anything below it negative (not impaired). DADSS breath samples with a DF less than 60 (n=11,821) were compared to the corresponding reference sensor BrAC measure. The DF varies by distance of the individual from the sensor. The driver-side DADSS breath sensors continuously collect breath samples from the ambient air and compute a BrAC.
- Before the trials were suspended in March 2020, the HSD trial completed 114 test drives and collected nearly 80,000 breath samples (43,311 from the DADSS passenger, 34,721 from the DADSS driver sensors, and 4,471 reference samples). Data from sober passengers and drivers were used to compute the probability of a false positive (defined as DADSS sensor reading of BrAC $\geq$ 0.02 g/dL) given the person had consumed no alcohol. In the real world, the majority of trips are by sober drivers. These sober drivers would be inconvenienced by a false positive. Among the 579 sober samples with a DF less than 60, ten were measured with a BrAC $\geq$ 0.02 g/dL by the Gen 3.2 sensor, indicating a 1.73% false positive rate.

- Testing of the Gen 3.3 sensor, began on August 26, 2021. Five cars have been equipped for testing, with a plan to equip ten vehicles in total.

Consumer Acceptance

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

Qualitative and quantitative research is undertaken on an ongoing basis to explore public perceptions about and receptivity to the DADSS in-vehicle technology. In the most recent public opinion survey, undertaken in January 2020, one of the questions asked was, "A new driver alcohol detection technology that will measure a driver's blood alcohol concentration (BAC) level when their vehicle is started. If a driver's BAC level is over the legal limit the vehicle will not shift into gear and will not move." In answer to this question, almost three quarters of drivers said they had a favorable opinion of the DADSS technology (73% percent), and this favorability reached 80% percent with young male drivers ages 21-34 and women ages 55 and older. Favorability also was high among drivers who had a conviction for drunk driving (75%) and who admitted they drove after drinking (74%). Reasons for favoring the technology included that the technology prevents drunk driving, is non-invasive and convenient, and is especially helpful for young drivers. Many of those surveyed also felt that it was an inevitable technology for vehicles.

During FY2021, the COVID-19 pandemic continued to affect in-person opportunities for consumers to learn about the technology. As a result, significant efforts were put into sharing information digitally. This included expanding the presence of DADSS on social media, maintaining and updating the DADSS website, adding new technology explainer videos and behind-the-scenes laboratory tours, leveraging opportunities for media coverage, and refreshing and expanding existing communications materials. In 2016, Virginia (VA) became the first state to use NHTSA highway safety grant funds to partner with the DADSS program through the Department of Motor Vehicles (DMV). The partnership is known as the Driven to Protect™ program. Through this partnership, a new "Discovery Hub" was launched on the DADSS website (https://www.dadss.org), which offers a suite of online resources to provide the public with an in-depth look at the technology and the development process.

DADSS Website

The DADSS website continues to be the central hub where key information about the program and the technology is housed, including updated videos that make the technology and its development accessible through straightforward explanations of the key concepts. A resources page provides an overview with an added navigation bar for ease of tracking the most recent DADSS news.

During FY2021, updates were made to the website to optimize search engine algorithms and to improve overall style, accessibility, navigation, and page load speed.

Although the overall design has remained the same, notable improvements include an updated navigation bar, which travels with the user for easier navigation, colored accents for improved style, and an announcement banner which features a link to more information about the technology being made available for open licensing in commercial vehicles.

State Programs

Currently, the DADSS program is partnering with two states, Virginia and Maryland, both to extend naturalistic, on-road experience with the breath sensors in a vehicle fleet setting with sober drivers and to increase consumer awareness of the technology. The accumulation of driver experience with the technology on a daily basis has enabled a better understanding of driver interactions with the technology, as well as providing insight into the sensor system and data transmission areas for improvement. The combination of human subject driving trials in a more controlled setting and naturalistic driving experience in the state programs has led to a better overall understanding of areas for improvement.

Virginia

As noted above, in 2016, Virginia (VA) first partner with the DADSS program through the Department of Motor Vehicles (DMV). The partnership is known as the Driven to Protect™ program. In September 2018, the Driven to Protect™ program partnered with James River Transportation (JRT), a transportation services company in Richmond, VA, to embark upon a naturalistic deployment project of DADSS breath sensors in some of their airport transportation vehicles. Data from the sensors, as well as from the drivers themselves, is being used to improve the technology, including sensor performance, power consumption/battery life, and data transmission.

Pilot DADSS Deployment Project

The pilot deployment project with JRT, has continued to run during the COVID-19 restrictions, although at a much slower rate due to reduction in customer travel, and has continued through FY2021. Initially, four fleet vehicles (2015 Ford Flex airport livery vehicles) were instrumented with Gen 3.1 sensors and underwent field tests. In late FY2020, the 2015 Ford Flex vehicles were decommissioned, and two 2019 Ford Flex vehicles were installed with the latest Gen 3.2 breath sensors and those on-road field tests continue today.

At start up, the JRT driver provides a breath sample toward the Gen 3.2 sensors located in the driver door and on top of the steering column (see Figure 27), and to the aftermarket commercially available interlock sensor which is used in part as a control reference for data assessment. If alcohol is detected in the sample breath, an alert is sent to authorized personnel including the ACTS Team program manager, ACTS Team project lead, JRT Operations Manager, and ACTS Team data analysists notifying them of the event. These personnel will quickly assess the alert, and other relevant data such as breath readings directly before and after to determine a potential course(s) of action for JRT consideration.

Figure 27. Sensor location in the driver door and at the top of the steering wheel.

The JRT pilot deployment project has provided valuable feedback on the driver's experience and interaction with the sensors and allowed troubleshooting of anomalous readings or problems with the sensors and data acquisition system. In the initial stages of the project (which included Gen 3.1 sensors), continuous video surveillance added information on driver's interaction with the sensor as well as visual cues the sensor provided during use. In addition, two small focus groups conducted in 2019 with JRT drivers were conducted to gain an understanding of driver receptiveness to the technology, their preference for sensor prompts, and other interactions with the sensors, and their feedback on the program training and driver test plan.

Driver feedback showed an initial learning and acclimation period in the use of the sensors. Around a quarter of post-drive feedback in the first two months indicated difficulties with the sensors that included items such as low breath volumes and indicator lights on the sensors that the drivers were not familiar with. These reported difficulties significantly declined in the following months. Feedback in the focus groups indicated that there was a small learning curve in providing a breath sample to the sensors, but after a short time they "got the hang of it." In addition, the post-drive surveys were important for feedback on the functioning of the sensors and data acquisition system. Several drivers reported problems with interference with in-vehicle GPS, radio, and keyless entry (such as EMI). This real-time reporting allowed technical modifications to be made to limit this interference. Ultimately, shielding was added to the sensors to control the interference with other vehicle systems.

Deployment details since the inception of the program through FY2021 include:

- During FY2021, test vehicles have been operational for 4,910 hours, and driven 15,922 miles, during which time 37,787 breath samples were collected. Since the beginning of the project, the test vehicles have been in operation a total of 12,602 hours and have been driven 67,706 miles. During that time 83,143 breath samples have been collected.

- Nineteen drivers operated the test fleet vehicles and provided feedback about the sensors, with 243 pre-drive, and 187 post-drive surveys.

Communications and Consumer Awareness

In addition to the naturalistic driving program, the Driven to Protect Program has conducted a series of outreach events each year. Due to the pandemic, however, in-person events were very few in FY2021.

- In October 2020, ACTS and the VA DMV participated on a panel for a virtual conference on transportation technology sponsored by the National Safety Council.
- An "Ask the Experts" webinar was conducted in March 2021 and focused on the benefits of the DADSS technology for fleet owners and operators, as well as the upcoming availability of the technology as an aftermarket product. Panelists were from KEA, Impact Research and JRT and the session was moderated by the VA DMV Deputy Commissioner, George Bishop.
- In June 2021, an "Ask the Experts" webinar was conducted for Virginia educators, which focused on building awareness of the Discovery Hub. Additionally, the webinar highlighted the partnership with the VA Department of Education to host the learning modules on Virtual Virginia.[32]
- The first in-person event since the onset of COVID-19 was conducted in August 2021, and sponsored by Volkswagen Group of America and the Greater Washington Urban League at the Volkswagen's headquarters in Herndon, VA. The Future Leaders in Mobility event was tailored for rising high school juniors and seniors from under-served communities in the Washington, DC metro area. It focused on educating students about the facts and figures associated with alcohol-impaired driving risks, and the range of career opportunities in the automotive industry, as well as specific careers that students could pursue in developing technologies such as DADSS.
- The ACTS Team attended the Neptune Festival in Virginia Beach, VA in late September 2021 and displayed the VP-1 demonstration vehicle to event goers. This event allowed the public to have direct, hands-on interaction with the technology, learn about the program history, and understand VA DMV's role in safety and their support for the Driven to Protect™ initiative.

Discovery Hub

The Discovery Hub, created in collaboration with the Driven to Protect™ Partnership, is a suite of online resources available on the DADSS website to provide an in-depth look at the technology and the development process (https://www.dadss.org/discovery-hub). It was also launched in 2021 on the Virginia Department of Education intranet site and is currently being used by educators. Both sites offer a suite of online resources to provide an in-depth look at the technology and the development process. The Discovery Hub includes educational modules and videos

[32] Virtual Virginia is a program of the Virginia Department of Education that provides flexible digital education opportunities to students and educators throughout the Commonwealth of Virginia.

designed to educate the public about the dangers of alcohol-impaired driving and the technology being developed to help prevent it. It also serves as a virtual education resource for the public to understand the role the DADSS technology could play in saving lives.

Components include:

- Five education modules:
    - *The Brain, Lungs, and BAC (What's their role in Driving)*, which provides the learner with some important knowledge of how alcohol is absorbed by the body and its effects on key body parts like the brain, nervous system, and lungs. In addition, information is provided on the effects of alcohol on BAC, and how those effects can increase the likelihood of alcohol-impaired crashes.
    - *The Alcohol Impaired Driving Informational*, which provides an introduction to the DADSS program and the Driven to Protect™ initiative, to combat impaired driving across Virginia and throughout the United States.
    - *Alcohol: Fact or Fiction* - a series of interactive questions which challenges the viewers to test their knowledge.
    - *Breath and Touch Alcohol Detection Systems*, which provides the learner with information regarding the history and development process of the DADSS technologies, the science behind them, and why developing these technologies is so challenging.
    - *Underage Alcohol Use and Zero Tolerance Law Informational*, which provides the learner with information and statistics on underage drinking, alcohol-impaired driving, and Virginia's zero-tolerance law for underage drivers. The module also includes information on risks and potential consequences associated with alcohol-impaired driving, along with information about the benefits that the Driven to Protect™ initiative and the DADSS program provide.

- A series of videos provide an overview of the technology, the road tests happening in Virginia, how the sensors are installed in vehicles, and more.
- Science, Technology, Engineering, and Mathematics (STEM) learning activities were created to complement Virginia's science and technology curriculum. These modules provide more information about the science of how the sensors work, the development and testing process, and the data collection and analysis. They will also give learners the opportunity to conduct some hands-on experiments at home.

Maryland

Beginning in March 2019, the State of Maryland (MD) partnered with the DADSS program and the Maryland Department of Transportation's Motor Vehicle Administration (MDOT MVA) to test alcohol detection breath sensors installed in state–owned and operated vehicles. One DADSS demonstration vehicle, a Ford Fusion, was instrumented and delivered in mid-July 2019 for use by MDOT MVA at vehicle and traffic safety events. The demonstration vehicle was prominently featured at the Maryland Association of Counties Events, held in August 2019, during which time Maryland Governor Hogan announced the Maryland partnership with DADSS.

Pilot Deployment Project

Ford Fusion vehicles were equipped with two Gen 3.2 sensors, one in the driver-side door and another on top of the steering wheel, one aftermarket commercially available interlock sensor which is used in part as a control reference for data assessment, as well as vehicle data collection equipment. A total of seven Ford Fusion state vehicles were prepared; two vehicles were fitted in November 2019, two in December 2019, and the final three vehicles in January 2020. Road tests were started in December 2019 and lasted until April 2020, before being paused due to the COVID-19 restrictions. All vehicles were reporting data by January 2020. During the pause in testing, operational tests and maintenance of the seven vehicles were conducted to ensure the vehicles were fully functional when testing was resumed. On-road testing of all the vehicles resumed in July 2021. During FY2021, the vehicles were driven for 2,038 hours, over 15,869 miles, and 25,225 breath samples were collected. Since the beginning of the project, the vehicles have been driven for a total of 2,411 hours, over 17,593 miles, with 35,253 samples collected.

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. In FY2021, seven patents were issued, thirteen new patents applications were filed and pending, and ten responses were prepared and sent to various countries in response to official action on pending applications.

ACTS continues to take a number of actions to ensure the commercial implementation of the DADSS technology. First, ACTS is prosecuting[33] 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. First, 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 public. Secondly, ownership by ACTS

[33] Patent prosecution is the process of writing and filing a patent application and pursuing protection for the patent application with the patent office.

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 3 summarizes the intellectual property generated to date under the DADSS program. Closed applications that are no longer being pursued are not listed.

Table 3. Patent Portfolio as of September 30, 2021

TITLE	COUNTRY	STATUS	APPLICATION #
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	Issued	10,099.554
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	Hong Kong	Pending	14109310.8
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	European Patent Office	Pending	20208476.0
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Japan	Pending	2021-63471
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	South Africa	Pending	2014/02304

SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	United States of America	Issued	10,710,455
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	3038865
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	Japan	Issued	6553614
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	South Africa	Pending	2016/00797
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	Canada	Pending	2,925,806
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	China	Issued	ZL201480055848.2
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	Japan	Issued	6656144
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	South Africa	Pending	2016/01639
BREATH TEST SYSTEM	United States of America	Pending	14/421,371
BREATH TEST SYSTEM	Canada	Pending	2,881,817
BREATH TEST SYSTEM	China	Pending	202110218823.1
BREATH TEST SYSTEM	European Patent Office	Issued	2888587
BREATH TEST SYSTEM	Japan	Issued	6496244
BREATH TEST SYSTEM	South Africa	Pending	2015/01246
BREATH TEST SYSTEM	Sweden	Issued	536784

HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Issued	10,151,744
HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Continuation Pending	16/215,830
HIGHLY ACCURATE BREATH TEST SYSTEM	Canada	Pending	2,881,814
HIGHLY ACCURATE BREATH TEST SYSTEM	China	Pending	202010449254.7
HIGHLY ACCURATE BREATH TEST SYSTEM	European Patent Office	Issued	2888588
HIGHLY ACCURATE BREATH TEST SYSTEM	Japan	Issued	6408001
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
HEATER-ON-HEATSPREADER	United States of America	Issued	10,826,270
HEATER-ON-HEATSPREADER	Canada	Pending	3.010,352
HEATER-ON-HEATSPREADER	China	Pending	Pending
HEATER-ON-HEATSPREADER	European Patent 0,826,270Office	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	Issued	11,104,227
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE	United States of America	Continuation Pending	17/462,318

BREATH ALCOHOL ESTIMATION			
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	Canada	Pending	3,018,315
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	China	Issued	ZL201680086043.3
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	Issued	678662
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	South Africa	Pending	2018/06358
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	United States of America	Issued	9,823,237
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	Preparing provisional application	Pending
METHOD AND APPARATUS FOR	United States of America	Pending	17/008,072

PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE			
METHOD AND APPARATUS FOR PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE	International (PCT)	Pending	PCT/US20/48792
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	United States of America	Issued	11,072,345
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	United States of America	Continuation Pending	17/386,245
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	Canada	Pending	3,112,181
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	China	Pending	201980073705.1
SYSTEM AND METHOD FOR CONTROLLING	European PCT Office	Pending	198602226.0

OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS			
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	Japan	Pending	2021-513285
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	Korea	Pending	2021-7010587
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	South Africa	Issued	2021-02340
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Pending	16/900,088
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	International (PCT)	Pending	PCT/US20/37455
WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	United States of America	Pending	63/004,816

WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	PCT	Pending	US2125771
SYSTEM AND METHOD FOR DISABLING A VEHICLE	United States of America	Issued	8,479,864
SYSTEM AND METHOD FOR DISABLING A VEHICLE	China	Issued	ZL20128019106
SYSTEM AND METHOD FOR DISABLING A VEHICLE	Europe	Issued	2683569
SYSTEM AND METHOD FOR DISABLING A VEHICLE	Japan	Issued	6121916

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 out of the Highway Trust Fund.[34] 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 out of the Highway Trust Fund through FY2020.[35]

For FY 2021, authorization for DADSS research was continued as part of a FAST Act extension.[36] In FY2021, Federal funding totaling $5,312,000 was authorized and appropriated (Table 4).

[34] 23 U.S.C. § 403(h) (as amended by Public Law 112–141, enacted July 6, 2012).
[35] 23 U.S.C. § 403(h) (as amended by Public Law 114–94, enacted December 4, 2015).
[36] 23 U.S.C. § 403(h) (as amended by Continuing Appropriations Act, 2021 and Other Extensions Act, Section 1103, Division B of Public Law 116-159, enacted October 1, 2021).

Table 4. FY2021 NHTSA Funding available for in-vehicle technology research to prevent alcohol-impaired driving

	Fiscal Year 2021
Funding for In–vehicle Technology Research	$5,312,000

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 planned 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 an extension of the FAST Act covering FY2021, the agreement was extended as well and additional research was planned for the extension period. Table 5 provides a general statement regarding the use of Federal funding for FY2020 to carry out the DADSS research effort.

Table 5. Funding Status

Automotive Coalition for Traffic Safety

Advanced Alcohol Detection Technologies (DADSS)
DTNH22-13-00433
Funding authorized, appropriated and expended

Funding Authorized & Appropriated – FY2021		**$ 5,312,000**
FY2021 Funding Expended		
Research & Development		$ 4,828,249
Indirect Rate		$ 471,751
	Total Expended	**$ 5,300,000**