Progress Report

DTNH22–13–H–00433

October 1, 2021
through
September 30, 2022

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) 2022 in carrying out this effort.

In–Vehicle Alcohol Detection Research

Table of Contents

Executive Summary

The Driver Alcohol Detection System for Safety (DADSS) program, which began in 2008, was authorized in the surface transportation reauthorization enacted in 2012, known as Moving Ahead for Progress in the 21st Century (MAP–21), and was again reauthorized through FY 2021 via the Fixing America's Surface Transportation Act. More recently, the program was authorized again through FY 2025 under the Bipartisan Infrastructure Law (BIL) (enacted as the Infrastructure Investment and Jobs Act (Pub. L. 117-58, Sec. 24103). The research program is implemented through a cooperative agreement, established between the National Highway Traffic Safety Administration and the Automotive Coalition for Traffic Safety. Research efforts under the DADSS program align with the Safer Vehicles element of the Department's National Roadway Safety Strategy (https://www.transportation.gov/NRSS), leveraging technology to address behavioral issues. The efforts also informs one of the National Highway Traffic Safety Administration's rulemaking efforts, mandated in BIL (Section 24220), to establish a Federal motor vehicle safety standard that requires new passenger motor vehicles to be equipped with advanced drunk and impaired driving prevention technology, provided the rulemaking can comply with the National Traffic and Motor Vehicle Safety Act (Safety Act).

The research team under this agreement includes technology companies that oversee the research, develop the sensors, and create processes and procedures to validate each step of development. In the initial stages of the cooperative partnership, exploratory research established the feasibility of two alcohol sensor approaches for in-vehicle use, breath and touch, which have the potential to measure a driver's alcohol concentration quickly, accurately, precisely, and with no inconvenience to the driver. In the current stage of development, the sensor hardware and software has become increasingly refined. 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 were deemed critical. These specifications far surpass existing specifications for alcohol measurement and necessitated the development of innovative methodologies to verify that the technology is able to meet them. Specifically, verification and validation processes, materials, methodologies, and instrumentation have been the subject of extensive 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 which ended September 30, 2022, progress was made in all program areas, including touch and breath sensor development, calibration materials, processes and measurement procedures, and human subject testing both in the laboratory and in the vehicle. In addition, consumer opinions and awareness of the DADSS technology were assessed. This report summarizes these accomplishments.

The breath sensor system uses infrared sensors to measure the breath alcohol and carbon dioxide concentrations in exhaled breath. Carbon dioxide concentration, a 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 FY 2022 in advancing the Generation 4 sensors, which will be designed to detect driver's breath passively and are intended for use in passenger vehicles. Researchers worked on the Generation 4 design, including investigation of critical parts of the sensor system. The chosen optical concept showed the highest alcohol resolution potential, was deemed the most cost-effective design, and was also the design most suitable for mass production. Investigations also were conducted on effective mirror materials and their resulting reflectivity. Mirrors were coated with a thin layer of metal, which resulted in higher reflectivity surfaces, providing less light loss and increased resolution. The team also implemented the architecture and component drivers throughout the year, enabling functional performance of the intermediate sensor samples, which were delivered to the DADSS laboratory for testing. Researchers also completed the development of an algorithm for compensation of long-term degradation effects. The algorithm is necessary for long term stability over the duration of a vehicle lifetime. Lifetime testing of critical components has been initiated, to ensure reliability of the design over the full lifetime of the car.

The touch sensor allows estimation of blood alcohol concentration in the capillaries of human 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 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. To produce accurate and reproduceable results, the laser signals are homogenized into a diffuse light source so that the light levels propagating through the tissue are consistent. 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. During FY 2022, research continued in a number of areas, including human testing of a new class of tunable lasers (Generation 5), that will be the basis for generating the necessary wavelengths for the touch sensors in the future. A significant improvement in the performance of the tunable laser resulted in generation of 27 unique wavelengths within the 2200 to 2400nm band range. This is about three times as many measured wavelengths, resulting in a more accurate representation of the ethanol absorbance curve for improved predictive modelling.

In addition, progress was made in critical electronics and software development as well as the initial conception of a smaller, automotive suitable, sensor system. Research has continued to address sensor performance challenges such as light illumination, assembly, alignment, and straylight. A single laser benchtop system was designed to provide enhanced flexibility for varying key optical parameters. The modular design of the system has allowed for multiple tests on the laser hardware and software as well as the system electronics. Improvements were made to better synchronize signals between the sample and reference channels and improved consistency with laser wavelength transitions between the reference and sample channels. This resulted both in an improved signal-to-noise ratio and greater stability.

As sensors evolve and improve, the new generations of the breath and touch sensor systems need to be evaluated. During FY 2022, areas of focus included the development of methods for in-house blood alcohol analysis, improvement of throughput in breath sensor characterization, assessment and quantification of breath sensor inlet performance, as well as optimization of standard calibration device performance. Researchers designed a new system for the automatic production of ethanol in a heated and humidified gas stream to reproduce the human breath. The new design has resulted in improved stability of the gas stream. To better optimize breath sensor integration into vehicles, numerous inlets, connectors, and sensor arrangements were designed and characterized. Ideally, the inlet minimizes the breath dilution factor so that most of the sensed gas is the breath sample. Results from a series of studies indicate that the larger inlet radius has the most significant impact on inlet performance. A key research finding is that inlet design should focus on the inlet pulling nearby gases into the sensor rather than a design which forces the breath into the system. The results of this sensor research will ultimately be shared with vehicle manufacturers and suppliers, who will design the implementation of the sensor systems for each individual vehicle make and model.

Human subject testing to evaluate the performance of the breath sensors was conducted in FY 2022 in controlled laboratory conditions. Once ingested, alcohol is absorbed into and eliminated from the body. Previous research has established that the alcohol measurements from breath and touch sensors are consistent, reproducible, and correlate very well with traditional blood and breath alcohol measurement.[1] 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 blood alcohol concentration - BAC) to high (0.18 g/dL) alcohol concentrations, with a special emphasis on BAC/breath alcohol concentration (BrAC) at

[1] 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.

0.08 g/dL concentration.[2] During FY 2022, researchers replicated time lag studies undertaken with the Generation 3.2 sensor using the Generation 3.3 breath sensor, they examined the effects of drinking different kinds of alcohol, and initiated a study protocol to compare BAC with blood obtained from the finger capillary bed via a finger prick.

The goal of human subject driving studies 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 DADSS researchers. In FY 2022, a number of key changes have occurred in human subject driving studies. Researchers are exploring the necessary steps to begin testing touch sensors in the vehicle once the sensors are ready for in-vehicle testing. The Generation 3.3 sensors were developed for fleet use, however, the trials collected data on occupants with positive BrACs (> 0.02 g/dL) as well as high BrACs (>0.08 g/dL) for analysis to inform sensor development for general consumer use. The driving studies of the Generation 3.3 breath sensors began in August 2022. By the end of FY 2022, the study had completed the equivalent of 77 drive days (multiple studies were conducted per day) and collected 21,773 breath samples. The results of the study are currently being assessed.

A key component to ensure a successful launch of DADSS alcohol detection devices in the marketplace is consumer acceptance of the technology. Ongoing efforts include assessing consumer understanding and acceptance of the DADSS technology through surveys and focus groups. In addition, public events are hosted to demonstrate the technology with key stakeholders and consumers and collect important feedback. Social media also is key, including the DADSS website, to distribute information to future consumers. The findings from these efforts will be incorporated into public messaging and the technology designs.

In FY 2022, focus groups were conducted inin Texas and Massachusetts to investigate consumer opinions about the DADSS technology. Overall, participants exhibited an openness to advanced safety technologies of all types. In response to the DADSS technology description, participants thought it would be good for parents with teen drivers, that it could provide insurance discounts, and that it would help curb drunk driving for those who are still resistant to ridesharing, leading to greater responsibility among drivers. Some participants said they did not need the technology because they do not drink and drive, and some thought there was no need for it because of ridesharing. Overall, respondents wanted assurance that the technologies would be accurate, fast, and

[2] For drivers 21 years or older, driving with a blood alcohol concentration (BAC) of 0.08 g/dL or higher is illegal. In Utah, the legal limit is .05 g/dL. For drivers under 21 years old, the legal limit is lower, with state limits ranging from 0.00 to 0.02 g/dL. Lower BAC limits apply when operating boats, airplanes, or commercial vehicles.

private (i.e., their data would not be shared). There was a baseline of trust that automakers would not install a system that was not fully tested and functional, but there was also concern about the possibility that the technology may prevent them from driving.

Beginning in 2016, Virginia became the first state to partner with the DADSS program through the Department of Motor Vehicles. The partnership – known as Driven to Protect – has two components. One includes pilot driving studies in which the latest generations of the DADSS breath sensors are integrated into commercial vehicles. In FY 2022 Generation 3.3 sensors, designed for fleet use, were integrated into trucks. The data and feedback collected from the sensors, as well as from the drivers themselves, will be used to modify and improve the technology through the development stage. The second component of the partnership is to increase consumer awareness through community outreach events.

Another partnership between the State of Maryland Department of Transportation's Motor Vehicle Administration and the DADSS program 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 FY 2022, test vehicles were operational for 2,819 hours and driven 23,363 miles, during which time sensors collected 58,305 breath samples.

While considerable progress is being made on sensor development and performance in the laboratory and on the road, essential research continues in a number of 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. At that stage, it is anticipated that 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 on modifying driver behavior through strong laws, enforcement, and public education, has identified ways in which alcohol-impaired driving can be reduced.[3] Significant progress has been made through these proven approaches, however, deaths from alcohol-impaired

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

driving are again on the rise. According to early estimates, the National Highway Traffic Safety Administration (NHTSA) projects that an estimated 42,915 people died in motor vehicle traffic crashes in 2021, a 10.5% increase from the 38,824 fatalities in 2020. The projection is the highest number of fatalities since 2005 and the largest annual percentage increase in the Fatality Analysis Reporting System's history.[4] In 2020, 11,654 people died in alcohol-impaired driving traffic deaths — a 14% increase from 2019.[5] This finding is supported 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.[6]

The deployment of in-vehicle technology that measures driver blood alcohol concentration (BAC) 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 drunk 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 Institute for Highway Safety (IIHS) has estimated that alcohol detection systems that work perfectly in all vehicles to restrict driver's BAC to less than 0.08 g/dL could prevent more than 9,000 deaths a year in the United States.[7]

In 2008, a public/private partnership began between NHTSA and the Automotive Coalition for Traffic Safety (ACTS)[8] to develop a technological solution or solutions to significantly reduce and eventually end alcohol-impaired driving. This program, known as the Driver Alcohol Detection System for Safety (DADSS) is developing non–intrusive technologies that can detect when a driver's BAC meets or exceeds the legal limit.[9] More recently, research has been underway to develop sensors that can be used in fleet vehicles

---

[4] National Highway Traffic Safety Administration. 2022. Newly Released Estimates Show Traffic Fatalities Reached a 16-Year High in 2021. https://www.nhtsa.gov/press-releases/early-estimate-2021-traffic-fatalities.

[5] National Highway Traffic Safety Administration. 2022. Drunk Driving. https://www.nhtsa.gov/risky-driving/drunk-driving#:~:text=Overview,These%20deaths%20were%20all%20preventable.

[6] 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.

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

[8] ACTS is a nonprofit safety organization funded by motor vehicle manufacturers, who make up its membership. ACTS' current members are BMW, Ford, General Motors, Honda, Hyundai/Kia, Mazda, Mercedes Benz, Mitsubishi, Nissan, Porsche, Stellantis, Subaru, Toyota, Volkswagen, and Volvo Cars. These ACTS members account for the majority of new light vehicle sales in the U.S. market.

[9] 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).

to detect the presence of alcohol with the ultimate goal of preventing driving if alcohol above the fleet's allowable limit is detected.[10]

Early in the development process, DADSS researchers identified promising technologies that had the potential to prevent alcohol-impaired driving through near instantaneous measurement of driver BAC or breath alcohol concentration (BrAC).[11] 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- or tissue-based spectrometry systems.[12] 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 exhaled 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 in a vehicle environment as well as development of the most promising approaches. From this initial review, the 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. The primary basis for the research relationship between the parties has been a succession of cooperative agreements issued under the specific authorizations for the DADSS program found in statute, and codified at Section 403(h) of Title 23, U.S. Code.[13]

---

[10] All U.S. states and the District of Columbia have per se laws prescribing BAC limits when driving of 0.08 g/dL, with the exception of Utah which has a BAC limit of 0.05 g/dL. For drivers under the age of 21, zero tolerance laws set a limit of 0.02 g/dL BAC or lower.

[11] 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.

[12] 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.

[13] See section 403(h) of title 23 of the United States Code as amended by Public Law 112-41, July 6, 2012, Public Law 114-94, December 4, 2015, and Public Law 117–58, November 15, 2021.

This report discusses the research program in more detail and the progress achieved in FY 2022. 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 ACTS team includes in–house staff, as well as multiple contractor organizations.

The stakeholder 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 team, managed by KEA Technologies Inc. (KEA), a research and technology company, consists of sensor developers and other program members, and conducts associated DADSS research.

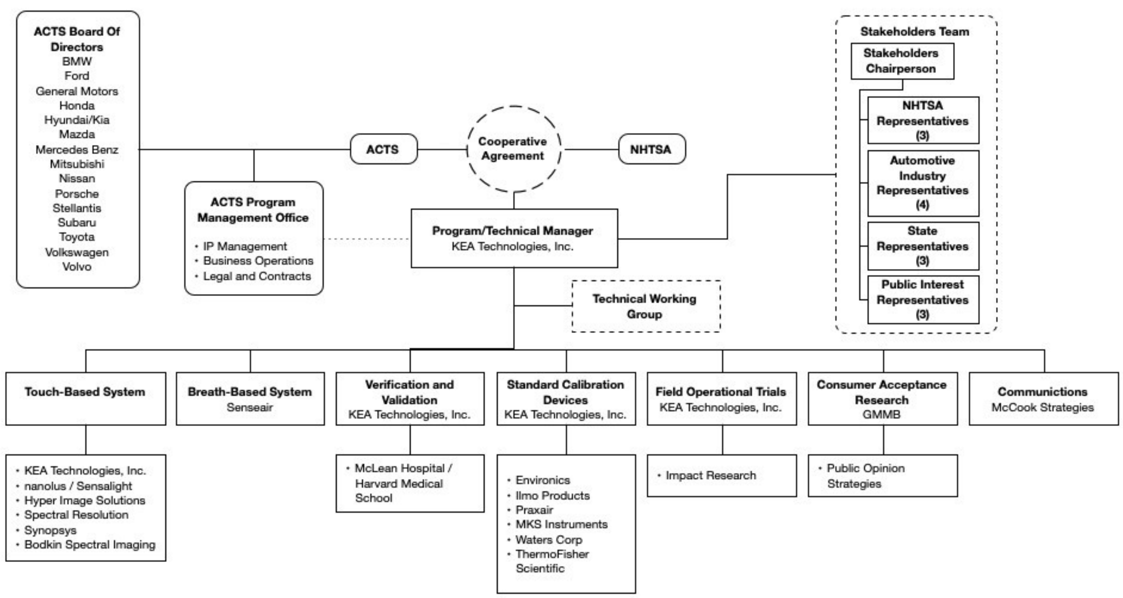

Figure 1. DADSS Research Program Organization

Research Plan with Technical Review Gates

The DADSS program is 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 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.

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 automobile industry accepted level of reliability, thus minimizing the potential for system failure.[14] 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 thresholds will be designed to deter unauthorized or inadvertent tampering. SAE International (SAE) led the development of the SAE J standard (SAE J3214) which was

[14] 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.

specifically developed to provide the testing specifications adopted for such applications and was approved in January 2021. SAE has published the standard and it 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 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[15] 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. Since its release there have been several changes to improve the document structure and flow, as well as to better define the testing requirements, including improvement of requirements for electrostatic discharge, electromagnetic compatibility, and interference.

In addition, SAE working committees have been established to create SAE standards for passive breath alcohol systems in consumer vehicles, and touch-based capillary blood alcohol measurement in-vehicle systems. It is anticipated that a draft of the passive breath standard should be released by the second half of 2023, and a draft of the touch-based standard by the second half of 2024.

DADSS Research Programs

The DADSS program of research and development began with the assumption that to be successful and acceptable to consumers the technology must be seamless with the driving task. It must be speedy and passive, reliable, durable, and measure alcohol accurately and precisely.

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 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

[15] 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.

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, often in conditions of high elevation, cold, heat, and humidity, but as with other safety technologies, the systems must work reliably for the full operating life of the vehicle. These performance specifications are 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 the driver.

Accuracy and precision are confirmed in the laboratory using breath and tissue surrogates, and with human subjects under controlled laboratory 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 FY 2022 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.

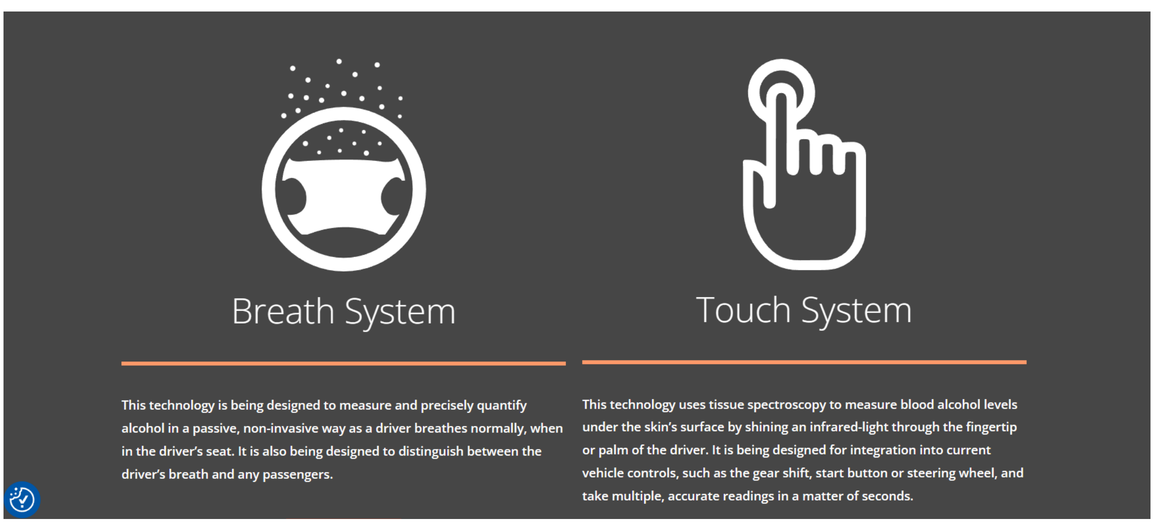

Figure 2. DADSS Research Programs: Breath System and Touch System

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 and 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 breath-based and Gen 5 touch-based) designed to prevent the vehicle from being driven if any alcohol is detected (<= 0.02 g/dL), and a passenger vehicle device (referred to as Gen 4 breath-based and Gen 6 touch-based), which is designed to measure alcohol precisely and accurately and prevent the vehicle from moving if the driver is at or above the legal limit for alcohol (generally 0.08 g/dL in the U.S. except for Utah that has a limit of 0.05 g/dL). The Gen 3.3 fleet/accessory device will be the first to be brought to market. 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.

CHARACTERISTIC	GEN 3.3 Breath	AGLOW Touch	GEN 4.0 Breath	RADIANT Touch
Estimated Commercialization*	**2021**	**2023**	**2024**	**2025**
Market Application	Fleet vehicles & accessory sales		Consumer vehicles	
Vehicle Integration	After mass production (Upfitter or dealer installed)		During mass production	
Alcohol (Ethanol) Set Point	0.02%		0.05 or 0.08%	
Operating Characteristics	Contactless, Directed–breath	Passive operation, up to 4 tunable lasers, single board electronics	Contactless, Passive–breath	Passive operation, up to 2 widely tunable lasers, ASIC–level electronics*

Figure 3. Breath and Touch Device Derivatives (*The time for integrating a DADSS sensor into a finished product will vary by the type of product and the product-level validation and verification necessary. In all instances, this is likely to be at least 18 to 24 months or longer)

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 to calculate BrAC.[16]

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

The goal of the DADSS sensors is to passively measure breath alcohol within the vehicle cabin without direct input from the driver. The challenge is to meet the 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 was focused on understanding the behavior and flow patterns of the expired breath plume within the vehicle cabin 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. These positions minimized the impact of cabin air flow and the driver's position on alcohol measurements as well as optimized performance.

Since the technologies' 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, similar to blowing out a candle, have also been developed. The Gen 3.3 fleet device will require users to provide a directed breath to detect the presence of alcohol.

Major enhancements were undertaken during the Gen 3 breath 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.[17] The Gen 3.3 breath device was developed for fleet and accessory application with knowledge gained 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 distribution in 2025, will be suited for wider deployment in passenger vehicles (see Figure 4).

[17] 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.

DADSS Breath Technology		
	First Generation System	**Next Generation System**
	GEN 3.3	**GEN 4.0**
Intended Use	Fleet Vehicles	Consumer Vehicles
Measurement Type	Directed Breath	Passive Breath
Hardware Details	Accessory product or vehicle–integrated	Fully integrated system
Alcohol Detection	Up to 0.04%	0.08% and above
Measurement Threshold	0.02%	0.08% (0.05% in Utah)
System Function	Can provide an alert if driver has a BrAC level at or above 0.02%	Will prevent a vehicle from moving if BAC level at or above 0.08% (0.05% in Utah)
Vehicle Implementation	Can provide a warning, prevent unlocking a vehicle's transmission, or prevent a vehicle from starting	Will prevent unlocking a vehicle's transmission, or prevent a vehicle from starting
Development Status	Reference Design completed; Open licensing available	In development
Commercial License Availability	Available now	2025

Figure 4. Recent evolution of DADSS breath sensors

Tests of the Gen 3.2 breath 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 5). 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 was significantly improved. Reducing the background noise enables the signal to be better detected, hence improving accuracy and precision measurements.[18] 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.

[18] 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.

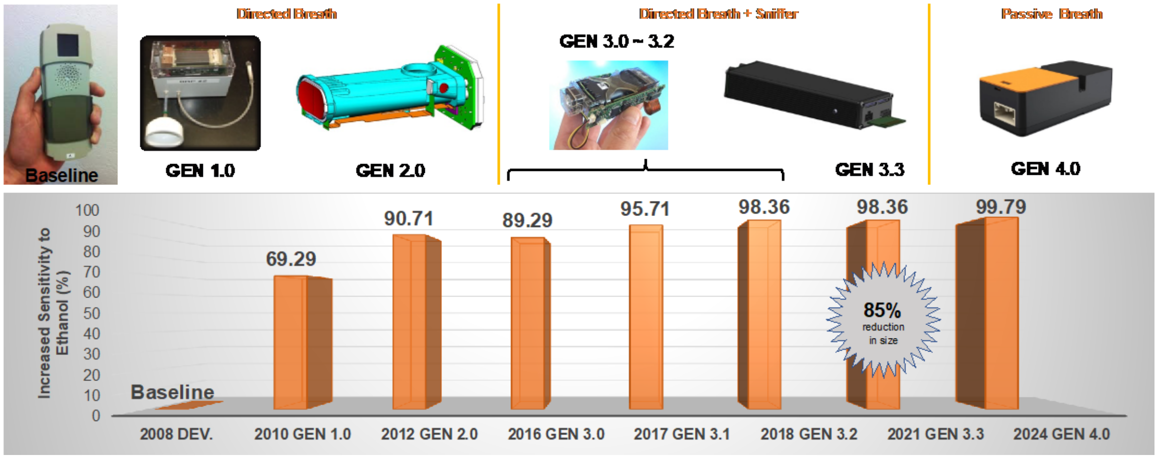

Figure 5. Sensor performance improvements and goals through increased sensitivity to ethanol

Significant progress was made during FY 2022 in the Gen 4 breath sensor development and testing as well as generic development research. Details are provided below.

Gen. 4 system development

- During the autumn of 2021, researchers worked on the optical concept selection for the Gen 4 design, including investigation of different critical parts of the sensor system. A prototype electronics board design was developed and completed to enable the evaluations, which was shared with the DADSS team. Three different optical concepts were under evaluation; 1) a Dome concept, 2) a Lens concept and 3) a Mid infrared (MIR) concept. For the selection, prototype bench-top assemblies of the different concepts were built and evaluated. Technical investigations on the different concepts included resolution, temperature dependence, and cross sensitivity. The Gen 4 optical concept evaluation and selection process was concluded in February 2022. Of the three remaining concepts, the MIR concept was selected. The selection was based on a Pugh matrix evaluation[19] including eighteen selection criteria. The MIR optical concept was selected as it showed the highest alcohol resolution potential, it was deemed as the most cost-effective design, and it was also the design most suitable for mass production.

- Investigations were conducted on the design of effective mirror materials. To evaluate the mirror material, engineers evaluated resulting reflectivity on mirrors that were coated with a thin layer of metal. The investigations of this new material

[19] A Pugh Analysis is a decision matrix where alternatives or solutions are listed on one axis, and evaluation criteria are listed on the other axis. The objective is to evaluate and prioritize the alternatives or solution.

resulted in higher reflectivity surfaces in the final design. For an assembled sensor, the increased reflectivity provides less light loss and therefore increased resolution.

- For the Gen 4 sensor, the sensor software will run on a single microprocessor unit. The architecture is based on a real time operating system, designed for use in automotive applications. During FY 2022, the software team developed a plan and path forward for the implementation of the sensor software. The team also implemented the architecture and component drivers throughout the year, enabling functional performance of the intermediate sensor samples, which were delivered to KEA in August.

- Following the selection of the optical concept, the project progressed into the realization phase. The project has been carefully planned with the goal to complete the Gen 4 sensor design in the fourth quarter (Q4) of 2024. The intermediate sample was completed in August 2022. The B-sample design is expected to be completed in Q4 2023 and the C-sample will be completed in Q4 2024. Once the C sample is released the design will be ready for mass production. Figure 6 illustrates the DADSS technology development time plan.

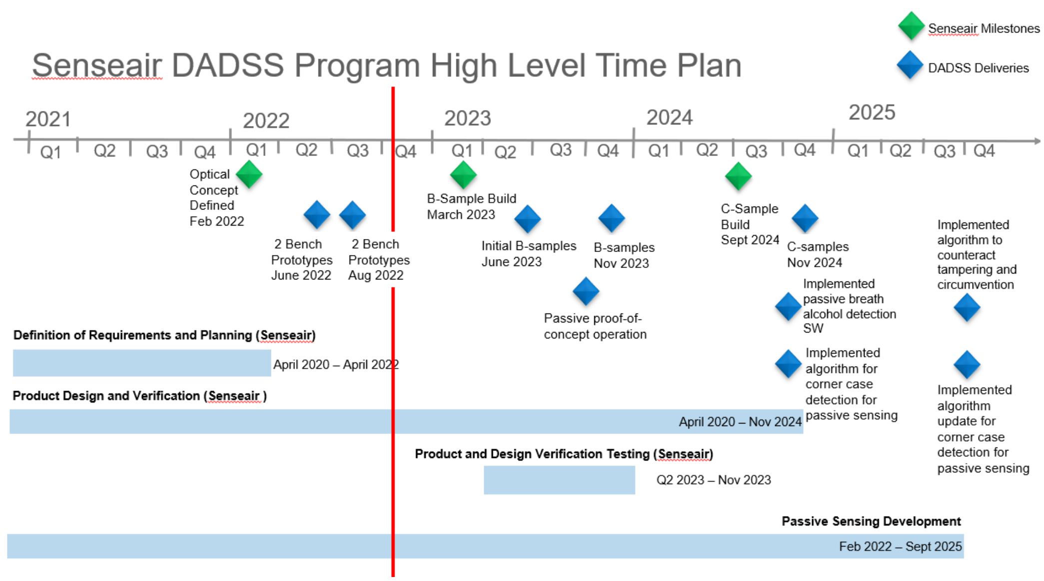

Figure 6. DADSS technology development time plan

- In the realization phase, the first step was to complete an intermediate sample design. During the spring/summer of 2022, the software, mechanical and hardware design of the intermediate sample prototypes were completed. Apart from vital mechanical, optical and hardware design, the intermediate sample also includes the first software release in the Gen 4 sensor development project. The intermediate sample enables measurement of all three infra-red optical measurement channels and provides a test bench for the continued development in the project. The research team assembled and delivered two intermediate samples to the DADSS program in August (Figure 7). The team also provided software that will enable sensor signal readout to the DADSS program.

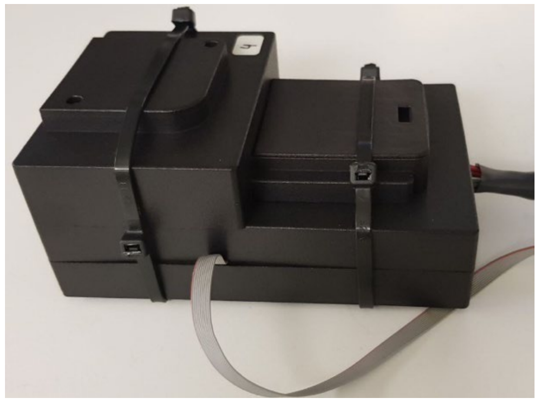

Figure 7. Gen 4 intermediate sample

- Upon completion of the intermediate sample design, the sensor design team switched focus to the B-sample design. The design freeze for the B-sample is planned for the 4th quarter of 2022, after which parts can be ordered and manufactured. During the final months of FY 2022, several key activities have been completed in the B-sample design cycle to meet that goal. An initial bill of materials and component specification requirements has been established for the design. Long lead time components were secured early in the design phase to ensure on-time prototype builds. Optical simulations have been completed for filter and lens material selection. The simulations have also included tolerance studies to ensure a suitable design for high volume production. A Design Failure Mode and Effect Analysis (D-FMEA) has been established, highlighting the design risks of the Gen 4 sensor. The D-FMEA is a living document that will be continuously updated throughout the project. Lifetime testing of critical components has been initiated, to ensure reliability of the design over the full lifetime of the car. The team has completed work on heating solutions for the various parts of the design, that is, the inlet heater, the mirrors, and the fan. The work has included several design options for the heaters, weighing pros and cons for the ultimate selection of the best solution. The different solutions will be evaluated before the B-sample design freeze. A framework for automated software testing has also been completed and implemented. The framework enables high volume testing of new code and code changes, without manual work, hence minimizing risk of human error.

Generic development

A team was formed to work on the development of passive alcohol detection of breath in a vehicle environment. First, the team completed an algorithm tool capable of adjusting sensor parameters through computer software. With the release of the tool a new algorithm was also released. The algorithm makes use of multiple exhalations accumulatively to perform the BrAC extraction calculation. To reach the goal of fully passive sensor operation, the team designed several studies to be performed for collection of key data for methodology development. One important study already undertaken involved both intoxicated and sober subjects performing a regular entry procedure into a car. During that period, the sensor signals from the installed breath sensors were recorded. The recording was then used to develop a sensor classification algorithm for passive operation. The lead targets in the algorithm development included two measures: correct classification of the driver's intoxication state, and time to detection. Performance studies for validation purposes will be conducted in FY2023.

- Researchers also completed the development of an algorithm for compensation of long-term degradation effects. The algorithm is necessary for long term stability over the duration of a vehicle lifetime.

- During FY 2022, the team upgraded the research vehicles by installing an updated version of the data acquisition system along with Gen 3.3 sensors (see Figure 8). The upgraded vehicles are dedicated to being used for passive alcohol sensing methodology development, robustness testing and anti- tampering protection development. In FY 2022, the vehicles were used for the passive entry study described above.

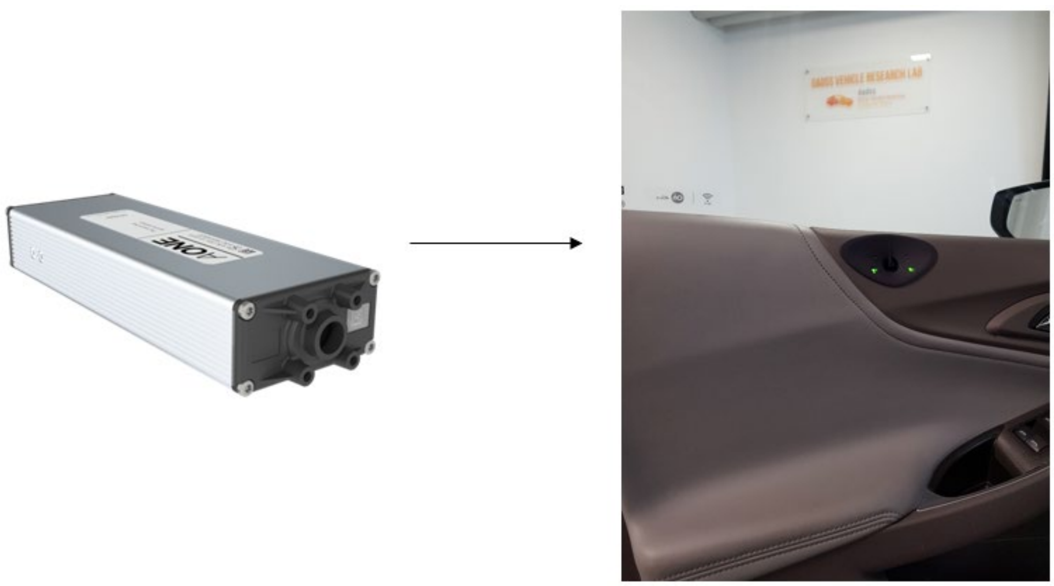

Figure 8. The research vehicle was updated with Gen 3.3 sensors

- The SAE J3214 standard includes a section that addresses tampering requirements. The team continued the work initiated in FY2021 on a classification-based method for tampering prevention. A preliminary version of the technique was completed in FY 2022. The technique makes use of the sensor signals available in the Gen 3.3 sensor and detects deviation from normal testing procedure. The current version operates in directed breath mode. Further work is required for robustness in an automotive environment.

- Forty Gen 3.3 sensors were delivered to the DADSS program during FY 2022.

Touch Sensor

The touch sensor allows estimation of BAC 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 from the skin's surface, where it is collected by the touch pad. BAC can be estimated based on the properties of the light returned to the sensor.

The shift from the Phase I proof-of-concept prototype, which used a traditional Michelson interferometer[20] 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.[21] The key to such innovation was the ability to define an optimized subset of optical wavelengths to enable high-quality, non-invasive alcohol measurement. Laser diodes[22] 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 back to the detector, where alcohol measurements are made. After initial work was completed to develop the laser diodes and packaging, a new technology provider was selected with greater expertise in these areas.

---

[20] 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.
[21] 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.
[22] A laser diode has the ability to directly convert electrical energy into light.

Each stage of the development process has required research and has resulted in multiple patent applications.

Since February 2019, ACTS has taken over the development of the touch sensor (Gen 4). Input also has 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. The Gen 5 sensor availability, suitable for fleet and accessory applications, is targeted for 2023. The consumer version Gen 6 sensor, for use in privately-operated vehicles is targeted to be available during 2025.

Figure 9 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 ten 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, thus, reducing the packaging size and power requirements (known as the stingray package). 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).

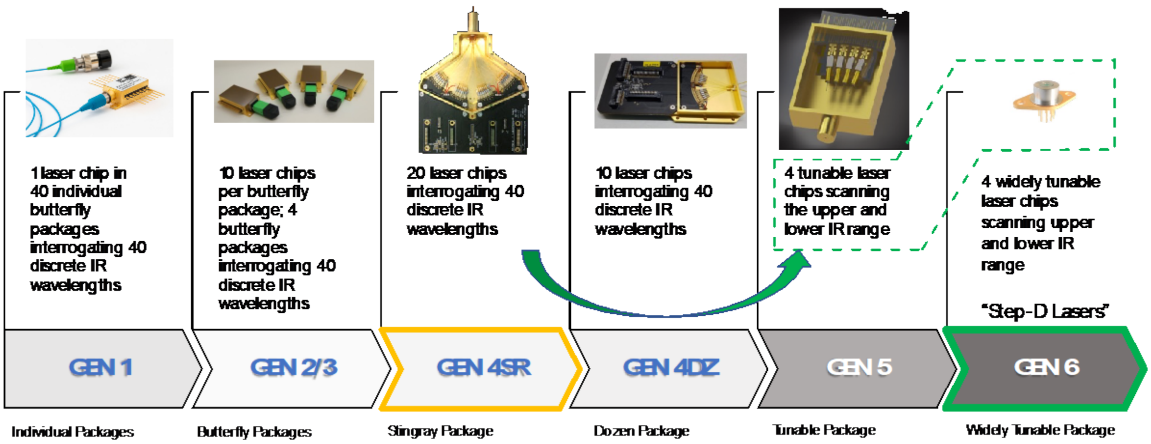

Figure 9. Evolution of laser development

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 4) signal strength sufficiently strong so that the signal can be readily detected when reflected from the tissue.

As with any innovative 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. Similarly, 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.[23] 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.

During FY 2022, there was additional research in a number of areas comprising development and testing, including human testing of a new class of tunable lasers (Gen 5). The tunable lasers 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 as well as the initial conception of a smaller, automotive suitable,

[23] 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.

sensor system. A more detailed summary of the research accomplishments is provided below.

At the beginning of FY 2022, research and development continued to focus on the compact sensor reflectance units which contain four tunable lasers each with desired near infrared wavelength bands within the 1500 to 2400 nm range (see Figure 10 and Figure 11 for a picture and schematic diagrams of the reflectance units). These units have a fixed optical path and a front-end tissue interface. Work has continued to address challenges related to sensor performance such as light illumination, assembly, alignment, and straylight.[24] During FY 2022, research focused on software development, specifically the ramp profiles for controlling the four lasers during measurements. The ramp profile contains the instructions for how the laser is powered in order to create the various wavelengths within its tunable band. The ramp profile provides multiple injection currents that accurately control temperature and the primary driving current that change rapidly to provide the discrete wavelengths.

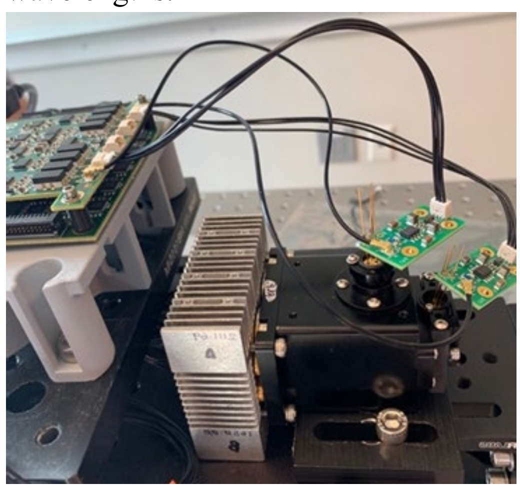

Figure 10. Compact reflectance unit

[24] Stray light is a broad term used to refer to any light within the optical system that cannot be used for the explicit purpose of making spectroscopic measurements.

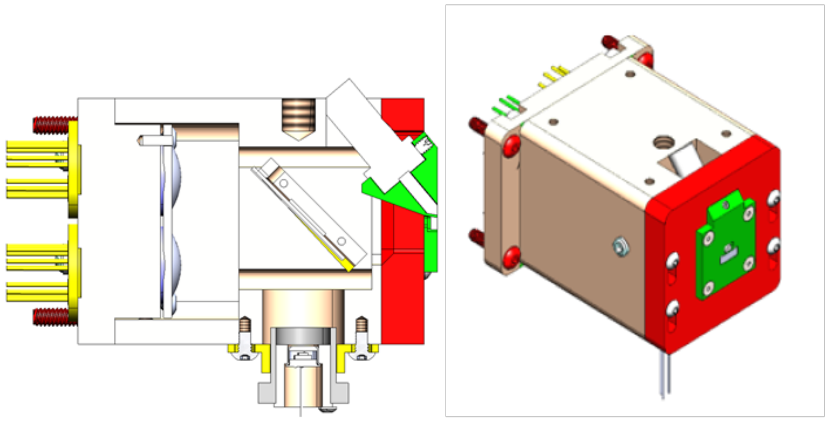

Figure 11. Schematics of the interior layout and exterior of the reflectance unit

During FY 2022, the research team identified difficulties with the units related to stray light, reduced tissue illumination, light intensity and the inability to easily make modifications to the units (e.g., change lasers, adjust laser beam focus, shape, and position). Based on these challenges, the reflectance unit was deconstructed and just one single tunable laser was utilized (detached from the main housing) and mounted into a separate heat sink cube, to obtain the desired beam focus and position on the frontend tissue interface (see Figure 12 for the initial modification to the touch system). The selected tunable laser has the largest ethanol absorbance signal in the 2200 to 2400nm band with multiple unique transitions.

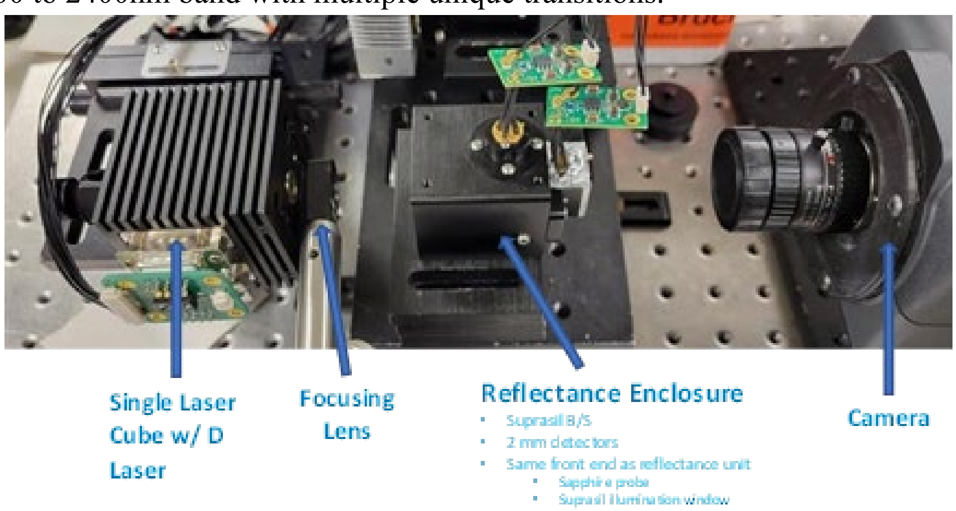

Figure 12. Deconstructed unit

Through FY 2022, the research team has continued to refine the deconstructed unit. A single laser optical reflectance benchtop system was developed, which is a highly flexible, modular test system with increased configurability and laser light control (see Figure 13). The system was designed with mainly off-the-shelf optical components to provide simplified and timely modifications and optical alignments.

This system was utilized for testing for the last nine months of FY 2022 and has undergone a large amount of debugging and numerous improvements. It also has allowed human subject testing (non-dosed and alcohol-dosed) to confirm that the unit can detect ethanol non-invasively in the tissue of a dosed human.

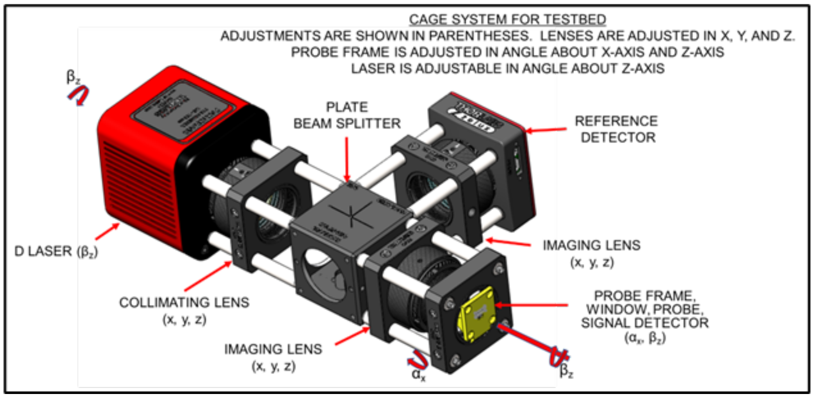

Figure 13. Modular touch-based sensor system

The single laser reflectance benchtop system was designed and constructed byDADSS contractors and delivered to KEA in December 2021 (see Figure 14). This benchtop system provides enhanced flexibility for varying key optical parameters and allows researchers to perform a matrix-based test plan for collecting optimum system settings and key tissue variable data for improved simulation-based analyses.

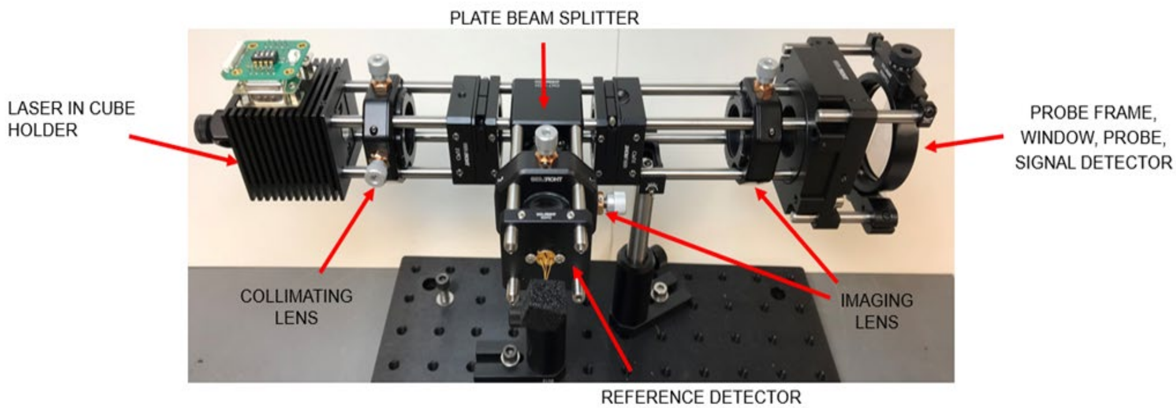

Figure 14. Single laser reflectance benchtop system

Utilizing the new benchtop system, testing initially focused on optical system alignment and laser beam positioning as well as tunable laser analyses (light output, temperature stability, wavelength generation) with the new setup. This was followed by system modifications to improve light intensity at the front-end interface window and updates to resolve sources of structured noise associated with the system design. One of the larger sources of variable structured noise was found to be associated with variable polarization states[25] emitted from the laser. This was resolved by adding a polarizer to the light path to create a single polarization state of the laser light itself. Another source of noise was due to back-reflected light from the front-end of the tissue interface window, travelling back into the laser cavity and destabilizing certain wavelengths. This was solved by rotating the interface window 20 degrees thus modifying the angle of incidence of the light and eliminating the back reflections.

The flexible, modular design of the system has allowed the team to perform multiple tests on the laser hardware and software as well as the system electronics. Improvements were made to temporal signal matching between the sample and reference channels (synchronization) via pre-amp board component updates and improved consistency with laser wavelength transitions between the reference and sample channels. This resulted both in an improved SNR and greater stability.

One of the advantages of the optical benchtop reflectance system is its ability to be reoriented without impacting optical performance. To improve ergonomic tissue insertions by human subjects, that is, placing of the specified portion of the hand on the optical sensor, the system was reoriented to a vertical structure and mounted on the side of the optical bench (see Figure 15). Once positioned and calibrated, the team initiated extended duration human tissue studies and performed the first dosed human subject study. The subject consumed a measured amount of alcohol targeted to achieve a 0.120 g/dL BAC. After the alcohol consumption, the subject placed his thenar palm[26] (see Figure 16) onto the front-end window sensor interface and kept it in place throughout the duration of the approximately five-hour study (with one exception for a restroom break). This was done to build an initial tissue model. Beginning one hour after alcohol consumption, intoximeter breathalyzer measurements were taken to obtain a BrAC reference for the subject. A review of the data confirmed that a dry lab[27] ethanol software analysis of the spectral data successfully predicted alcohol in the subject.

[25] An important feature of any laser beam is its state of polarization. This identifies the direction, which is always at right angles to the direction of propagation, in which the electric field is vibrating.
[26] The thenar palm, also known as thenar eminence is the mound formed at the base of the thumb on the palm of the hand.
[27] A dry lab is a type of laboratory that involves computational mathematical analyses for a wide array of different applications. These analyses are completed on a computer-generated model.

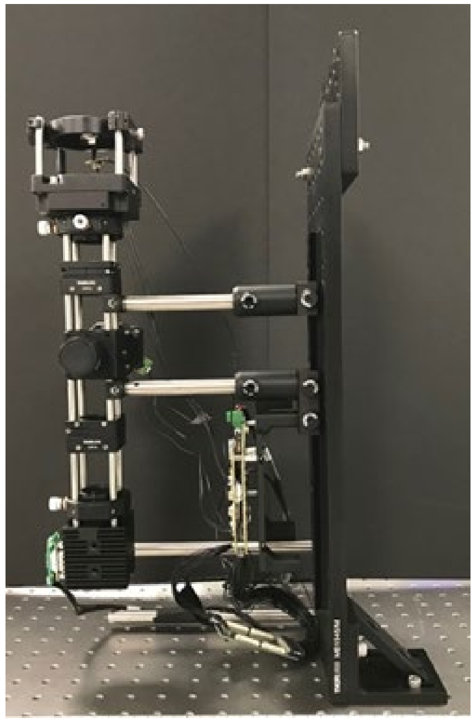

Figure 15. Vertical benchtop reflectance system

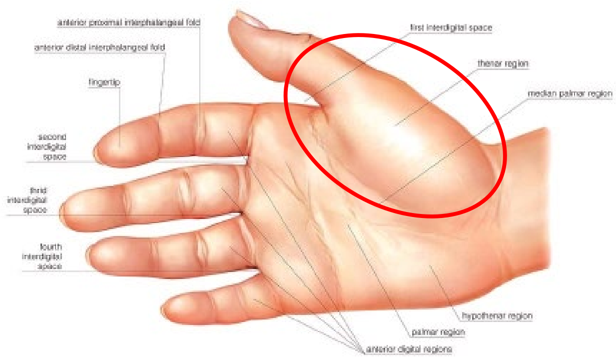

Figure 16. Thenar palm

After the initial testing, the technology's performance was assessed using a human subject who repeatedly inserted the thenar tissue onto the optical sensor interface. In order to help facilitate ergonomic testing and repeated positioning of the thenar palm tissue, a tissue support platform and insertion guide were designed, fabricated, and integrated onto the unit. Multiple sized insertion guides were created to accommodate different hand sizes (see Figure 17 below). During FY 2022, many additional human subject studies have been performed using dosed subjects, with the upgraded reflectance bench-top system providing confirmation that ethanol is being measured in thenar tissue across multiple subjects and studies. During ethanol measurement in dosed human subjects, it became apparent that insertion variance of the subject's tissue is potentially the largest source of measurement error. Areas for improvement include increased illumination interrogation of the tissue to decrease the variance due to tissue inhomogeneities and understanding systematic noise variances to remove and improve prediction results.

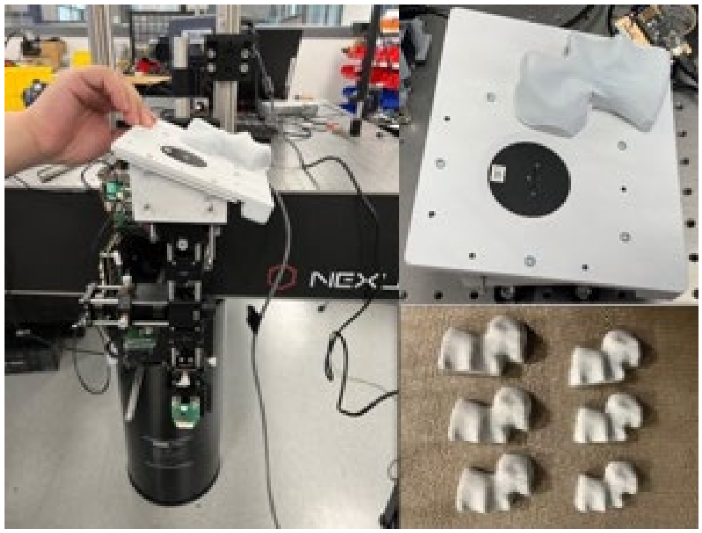

Figure 17. Configuration of thenar palm testing with molds for placing the palm in position

During FY 2022, there was a significant improvement in the performance of the tunable laser. The laser provider was able to enhance the performance of the laser such that 27 unique wavelengths can now be generated within the 2200 to 2400nm band range. This is about three times increase in measured wavelengths, resulting in a more accurate representation of the ethanol absorbance curve for improved predictive modeling.

In order to improve structural rigidity and reduce the potential for undesired system deflections during the tissue insertions, the cage post standoffs were removed, and the optical cage was mounted directly onto the base plate. An enclosure was designed and integrated onto the body of the sensor to prevent system noise associated with ambient light (Figure 18).

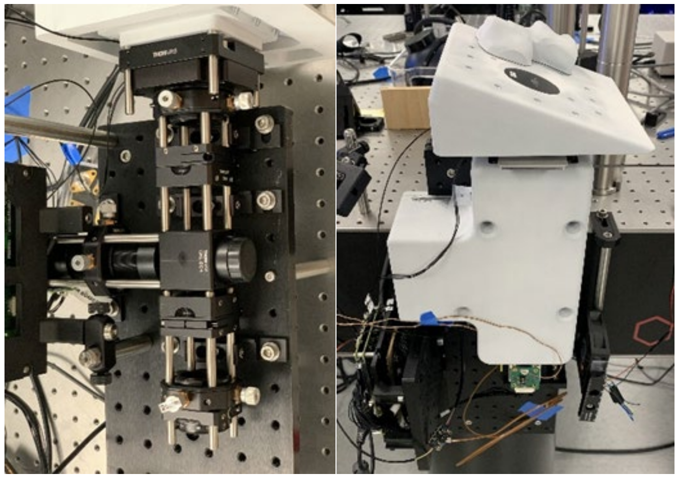

Figure 18. The benchtop reflectance system before and after enclosure

Graphical User Interface (GUI) software was developed that can display real time measurements during human subject testing (see Figure 19). The software utilizes a predictive model that was confirmed with non-insertion and insertion studies.

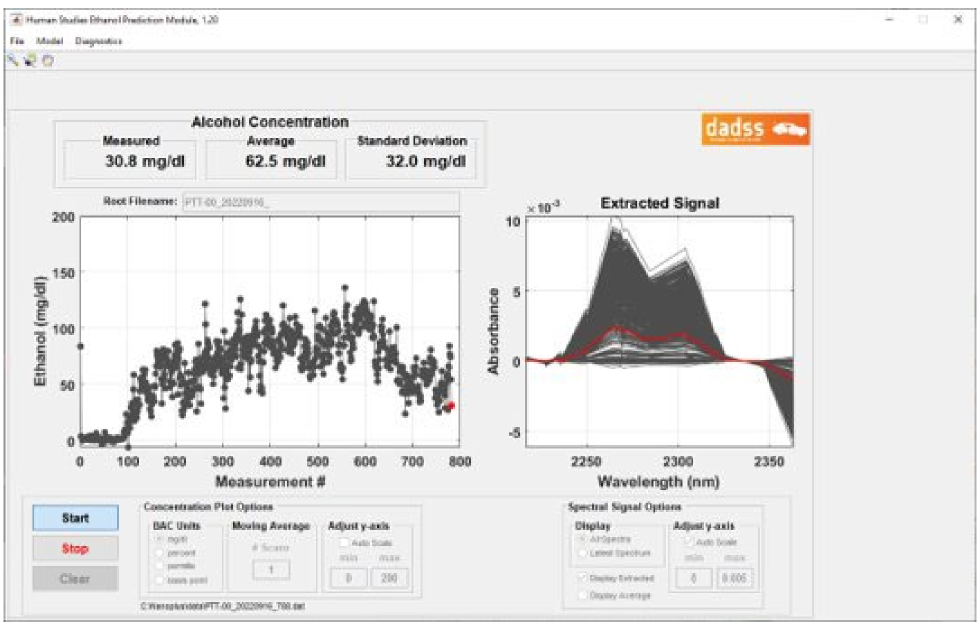

Figure 19. Graphical User Interface GUI

Additional efforts have focused on the redesign of the technology to create a smaller footprint to produce an automotive ready sensor that can be integrated into the vehicle cabin by leveraging the knowledge gained with the benchtop reflectance unit. The system consists of an aluminum housing in which the optical components are fixed and coupled with the single tunable laser. The primary 'sample channel' light path on the original benchtop is linear from the laser to the tissue interface and the 'reference channel' light path reflects 90 degrees at the beam splitter. In the new sensor design, the total laser light reflects 90 degrees at the reflective polarizer and then the 'reference channel' light path reflects another 90 degrees at the beam splitter. This allows for a more compact design. Light intensity is improved via a reduction in required optical components.

A multi-laser diode module can replace the single laser design for future expansion of desired wavelengths. The tissue interface will be decoupled from the laser and optomechanical components. In the original benchtop modular design, all of the components (laser, optics, front-end tissue interface) are connected to the mounting cage. When subjects apply their thenar palm to the sensor interface, they are potentially applying a pressure load to the entire system. This could result in micro deflections of the cage and components potentially producing an undesired movement of the laser beam, specifically at the tissue interface. The new design isolates the laser and optics assembly from these tissue loads.

DADSS Verification and Validation Overview

The DADSS sensors and subsystems undergo rigorous testing to insure they meet the requirements outlined in the DADSS Performance Specifications and the SAE J standard. The testing is separated into three categories:

1. Laboratory Standard Calibration Devices (SCD) - Understanding and measuring the performance of new sensors under tightly controlled laboratory conditions.
2. Human Subject Testing (HST) – Understanding the performance of sensors in a controlled setting while introducing humans and their variability.
3. Field Testing (HSD, Fleet) – Understanding the performance of the sensors in the real-world driving environment with human, sensor, and environmental variabilities. Field testing includes studies that are undertaken in more controlled settings by DADSS researchers, and in naturalistic settings in cooperation with the states of Virginia and Maryland as described below under state programs.

Laboratory - Standard Calibration Devices (SCD)

As sensors evolve and improve, new generations of the breath and touch sensor systems must be evaluated to understand how well they perform. A critical component of the testing process is to develop test methods that are able to demonstrate in a traceable manner that the breath and touch systems meet the requisite performance specifications. As part of this process the DADSS program 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, the researchers are able to 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 address the many aspects of the testing process, a multi-pronged program that is based around the research, development, and vetting of apparatus and methodology has been undertaken. 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.

The Alcoholic Breath Blending System (ABBS) was developed to meet these needs by combining the 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 evaluate the sensors. These variable parameters allow the ABBS unit to produce a simulated human breath to the sensors with a high level of precision. Recently, a second ABBS was developed to help improve testing throughput, with a significantly modified method to improve the output gas stream with an ideal distribution of gaseous ethanol (see the summary of accomplishments below for further details).

Once developed, the SRMs composition, accuracy, and precision has to be confirmed at the DADSS specifications. The instrumentation necessary for such verification has to exceed the DADSS performance specifications by an 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 in SCDs. 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 quantify accuracy and precision at the levels required. For the SAE J3214 Standard 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 (Figure 20) using gases in which ethanol concentration is certified to a known concentration accurately. Gas standards that have enough accuracy to support this calibration are available from VSL, the National Metrology Institute of the Netherlands.

For in-vehicle 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 20). 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 20. 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 similar results across different sensors and accuracy levels that were comparable to testing regimens in the laboratory.

Tissue surrogate

In support of touch sensor validation, work is ongoing on the development of tissue surrogates for the touch sensor as well as delivery systems to introduce the tissue sample to the sensor. The first touch SCD developed was a liquid solution which had a poor shelf life. Currently, research is being conducted to transfer the desired properties of the liquid solution to a different medium, such as a gel or solid. The tissue surrogate must closely represent the properties of a human tissue, 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. The DADSS Team is working to combine 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 21). 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.

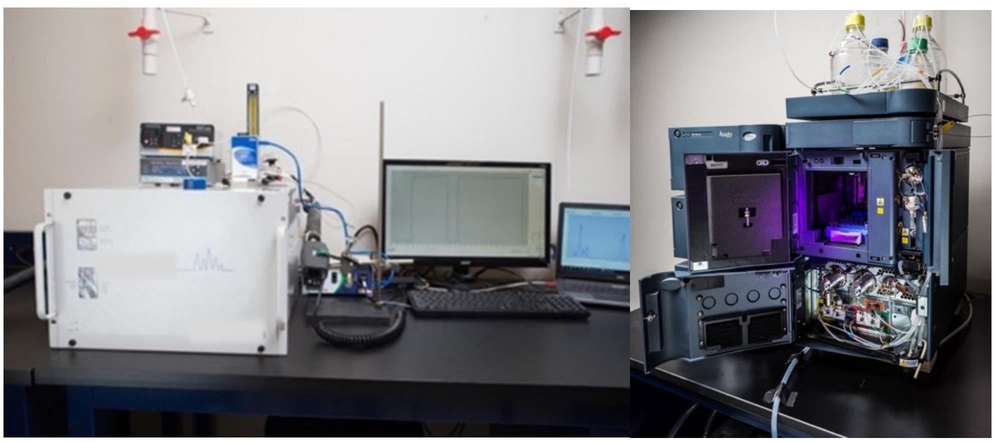

Figure 21. MKS Multigas 2030 FTIR and Waters Aquity HPLC in the DADSS research laboratory

During FY 2022, the areas of focus included the development of methods for in-house blood analysis, improvement of throughput in breath sensor characterization, assessment and quantification of breath sensor inlet performance, as well as optimization of SCD performance. The results of this research will ultimately be shared with vehicle manufacturers, who will need to design the implementation of the sensor systems for each individual vehicle make and model.

In-house blood analysis

To increase in-house capabilities for the evaluation of breath and touch sensors, a methodology was developed to collect whole blood samples and analyze their blood alcohol levels. The subject's blood is sampled using a finger-prick, which is then processed using a YSI 2900D biochemistry analyzer. A lancet is used to pierce the skin and a blood sample is drawn with a heparinized capillary tube (i.e., to prevent blood from coagulating) after which the blood is transferred into a 200 μL vial for short term storage and analysis (all three steps are illustrated in Figure 22). This low-cost method is accurate to within 3% of actual blood alcohol levels and can deliver results within 60 seconds after blood collection. Using this method, more than 140 blood samples have been analyzed. The ethanol-containing whole blood samples collected via a finger-prick can remain stable for over 48 hours, allowing for field collection prior to laboratory analysis. Biosafety standards have been instituted in the chemistry laboratory to allow for capillary blood collection and analysis methodology.

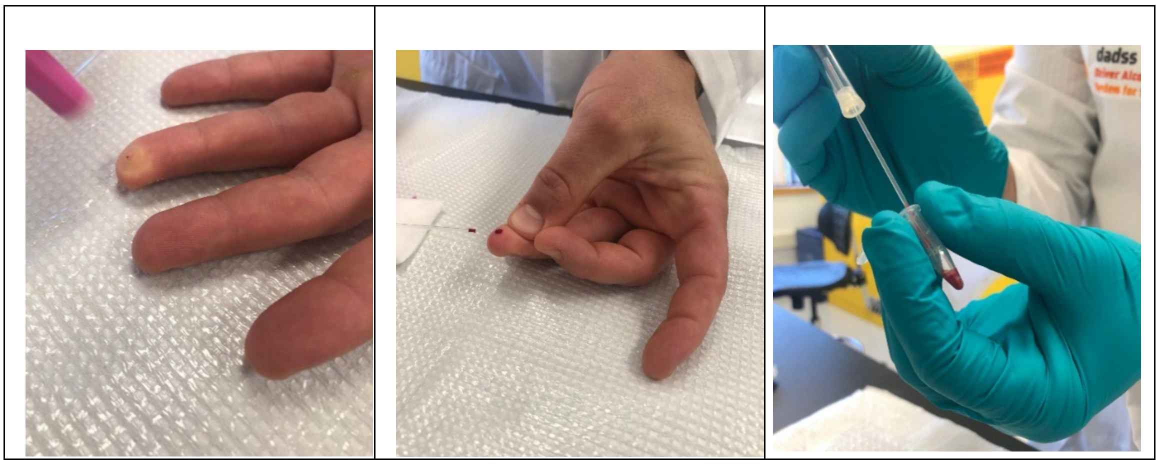

Figure 22. Blood sampling process

Improvements in breath testing

Researchers have designed a new system, known as ABBS 1.1, for the automatic production of ethanol in a heated and humidified gas stream to emulate the human breath. The new design has resulted in improved stability of the gas stream with decreased researcher involvement at a reduced cost. This is accomplished by using methodology to deliver humidity and ethanol into the vapor phase as well as custom hardware and software that is integrated with multiple detectors that provides improved system feedback. The custom software allows for the integration of multiple characterization systems for automation of the bulk of breath sensor characterization, including the detector, the sensor data collection system, and the environmental chamber while monitoring all temperature and pressure results. The current design will only require system setup and initiation prior to running a characterization study. As a result, sensor characterization can run on nights and weekends, cutting the time per eight sensor batch down from four working days to less than twenty hours.

Numerous inlets, connectors, and sensor arrangements were formulated and characterized to better optimize breath sensor integration into vehicles. Figure 23 illustrates the 3D printed inlets that were used in the studies in which the diameter and height of the inlets were varied systematically to allow analysis of each of these factors. The studies have generated design principles and guidelines to maximize sensor performance across a wide variety of vehicles and setups to enable improved sensor-vehicle integration. The performance of each sensor was assessed by evaluating the dilution factor (DF) of each breath. The DADSS sensors are continuously drawing in gaseous analytes for processing from the area surrounding the inlet such that they are always ready to accept a breath sample. As a by-product of this continuous sampling and remote breath delivery, any sample intended for the sensor will be diluted by the ambient air. An ideal inlet minimizes the DF such that most of the analyte at a given time is formulated from a maximum portion of the simulated breath sample relative to the ambient air. The key research finding from this work is that inlet design should focus on the inlet pulling nearby gases into the sensor rather than a design which forces the breath into the system.

Figure 23. Multiple inlets to evaluate the impact of inlet size and shape

To quantify the impact of inlet width and depth for directed breath collection, nine inlets were designed and evaluated with a circular face and various radius and height dimensions. These inlets were tested over the course of 3,956 breaths with varied inlet, distance, and angle from a directed breath source. As shown in the illustrated box plots that combine the results from 83 studies (see Figure 24 below), the larger inlet radius, (of the three 10, 20, and 30 mm dimensions), had the most significant impact on inlet performance with generally lower DFs at all angles and distances. The research also found that the height of the inlet and angle of the breath have no significant impact (figure not shown). The distance of the breath from the inlet 12, 18, and 24 inches is shown in different colors.

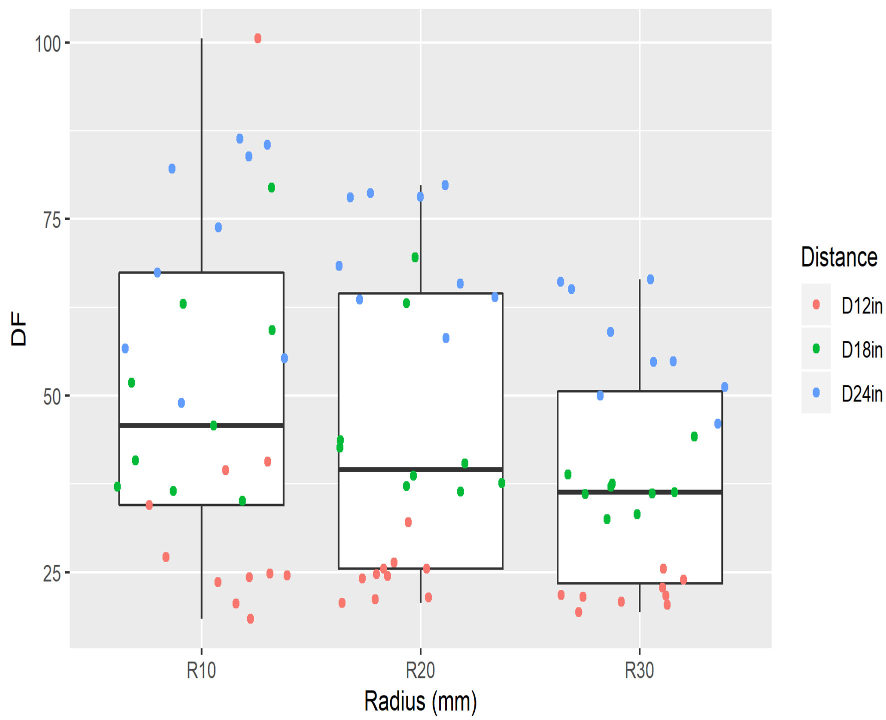

Figure 24. Box plots of the relationship between DF, inlet radius, and distance from the sensor

An additional study focused on the impact of the entire system on inlet performance using identical inlets with different positions and environments. Results are shown in Figure 25. This study helped researchers to understand how well sensors perform when the simulated breath is directed but not pointed directly at the inlet. Over 570 simulated breath samples were collected using various orientations of the breath input to the inlet. As expected, it was found that the inlet perpendicular to the air flow performed better than the inlet parallel to the airflow.

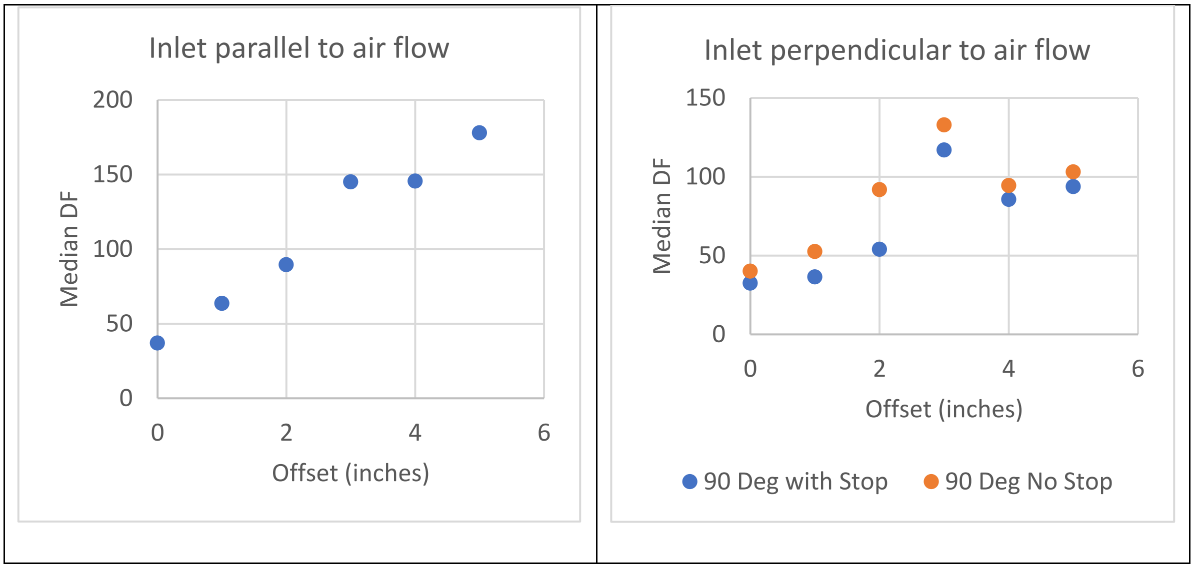

Figure 25. Results from testing with the inlet parallel and perpendicular to air flow

To improve integration into vehicles and based on previous snorkel studies, an initial study was performed to analyze the impact of length when using a plastic tube to connect an inlet to the sensor. Data was collected from more than 300 simulated breaths with four tube lengths at 0.1m, 0.3m, 1m, and 10m. The length change did not cause a statistically significant impact on the DF. The longer tube should increase the time between the breath sample being delivered and the sensor recording the breath and slightly decrease the flow rate at the face of the inlet. However, given the volume of air continuously moving though the tube neither of these factors impacted the DF for a given breath.

Characterization studies on the performance of both the wet-bath bubbler (a device for generating simulated alcohol-containing breaths) and breath blending techniques (ABBS 1.0) were performed to understand the advantages and shortcomings of each, with one sample of the results shown in Figure 26. Results demonstrated that the bubbler method, shown in blue, can achieve accuracy as low as 3% of actual blood alcohol levels for short durations, but rapidly decays by over 30% in 30 minutes. In identical experiments, the ABBS system achieved an accuracy as low as 0.5% and remained within 0.05% for 30 minutes. The minimal expense and ease-of-use of the bubbler allows for broad testing, but the results on the stability, accuracy, and precision of the methodology would suggest that the ABBS is the superior method. The ABBS method was shown to have superior performance across all metrics and is preferred for use in cases where longer-term testing or higher levels of precision are required.

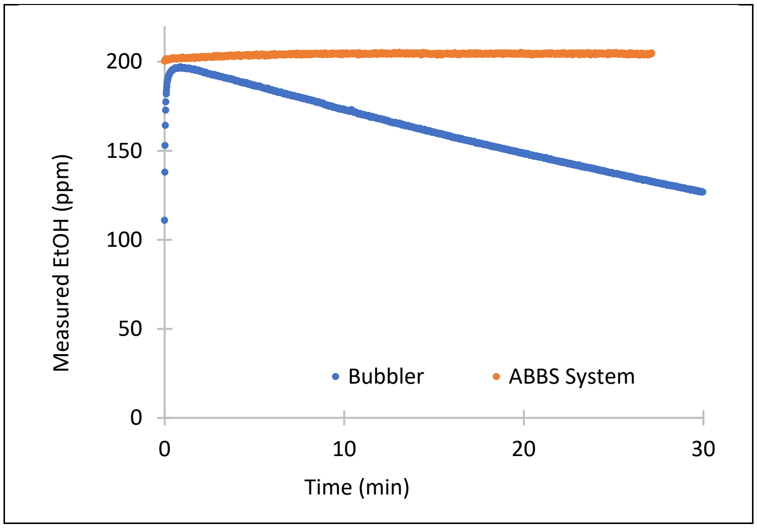

Figure 26. Measured ethanol concentration (EtOH = ethyl alcohol) vs. time for the ABBS system and the bubbler

KEA received a prototype of the next generation of breath alcohol sensors. The Gen 4 device is specifically designed for manufacture in sufficient quantities to be commercially implementable and is intended to be used with passive breaths. The DADSS lab will begin efforts to characterize the Gen 4 sensors in 2023.

When performing sensor characterization, the gas stream is directed into an environmental chamber and directed towards the sensors. During characterization, the environmental chamber temperature ranges from -40 to 85ºC and the manifold temperature must remain constant at all points. This is particularly challenging at ultra-cold temperatures, because if any site on the manifold is not sufficiently heated, ethanol will condense at this location causing false readings on the sensors. Figure 27 illustrates a recent rebuild of the eight-position manifold with different forms of and positions of insulation, temperature sensor location, and heater location. Figure A illustrates the original structure, B shows the first layer of insulation that prevents hot-spots, C shows heating tape which is applied evenly to cover all surfaces, and D shows additional insulation to ensure efficient and even heating and minimize cold spots, and aluminum tape provides additional insulation and water resistance. As a result of the investigations, the insulation was changed from fiberglass to a composite of fiberglass and felt which allowed for increased coverage and is safer and easier to work with allowing the team to further optimize the positioning of the insulation for improved performance. Minor modifications were made to the heating arrangement for the heater-tubing contact area and a different placement and material of temperature probes were used, allowing for temperature detection within the manifold.

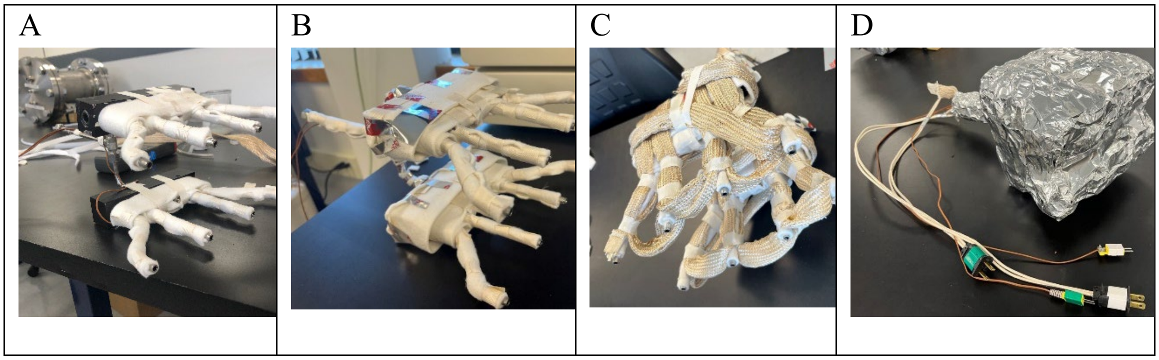

Figure 27. The initial eight position manifold with heated and insulated gas distribution lines, and subsequent adaptations (B,C,D)

The resulting design showed improved performance at ultra-cold temperatures but indicated further challenges at higher temperatures. A new manifold with both heating and cooling has been designed (see Figure 28) that is formed from aluminum in a single block with heating and cooling properties. The large thermal mass of the block will limit any temperature swings and circulating coolant will ensure the 34^{o}C temperature is maintained even when operating at 85^{o}C.

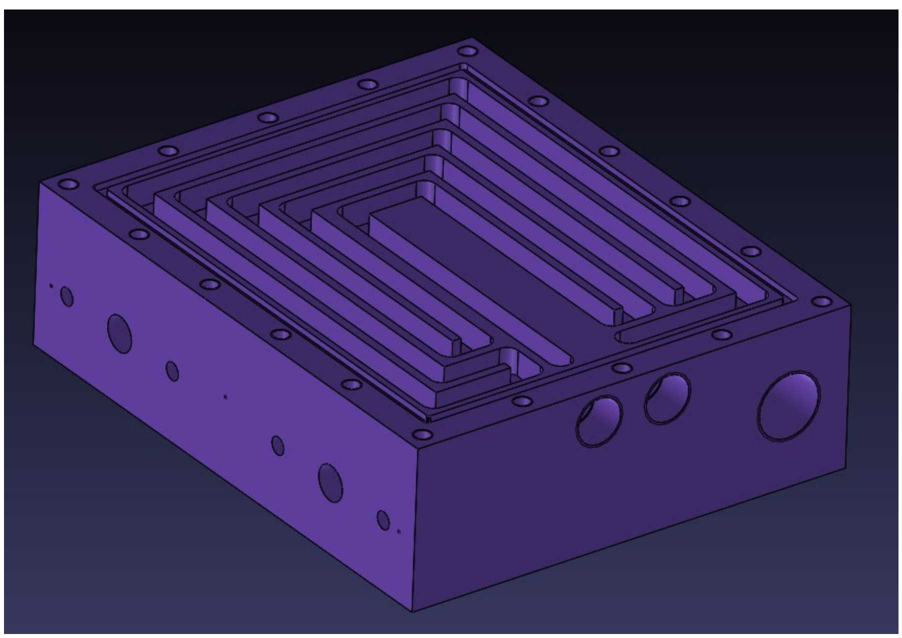

Figure 28. Next generation manifold

Human Subject Testing

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 real-world 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, a number of research programs are underway, that include 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 alcohol pharmacokinetics literature, intrinsic and extrinsic factors that can affect alcohol metabolism have been identified. Progress is being made in addressing these factors 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, and race/ethnicity in a variety of scenarios.

Many insights have been gained regarding the alcohol absorption and elimination curves and maximum BACs/BrACs reached by human subjects in a variety of real-world scenarios (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] Additional studies have begun to address additional factors that might affect alcohol measurements.

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. Most individuals participate in more than one experiment, providing within-subject comparisons. Subjects are matched by age, sex, ethnicity, body mass index (BMI), and current alcohol consumption levels. Subjects 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 have to be negative before the study can proceed.

After volunteers are fully briefed on, and agreed to, experimental procedures and requirements, subjects signed an informed consent form. The subject is then given a standardized breakfast (juice and toast). All subjects are dosed with various types of alcoholic beverages such as vodka, wine, or beer, and the amounts are based on their body weight. Subjects are given specific instructions about the rate and volume of the necessary beverages as they 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 29 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.

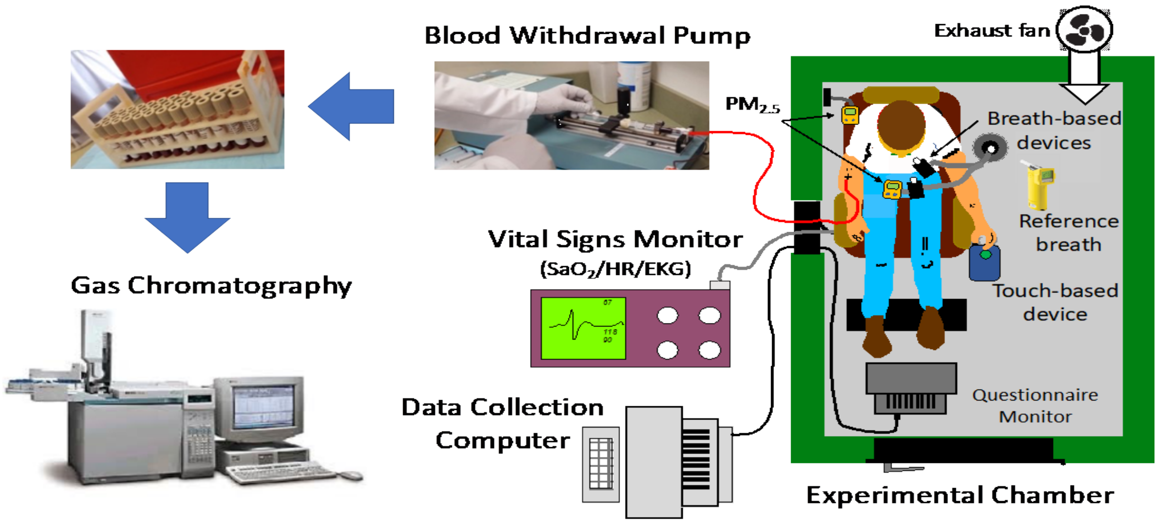

Figure 29. Sensor verification using human subjects in a controlled laboratory setting

During FY 2022 data collection remained lower than the pre-COVID rates. It is expected that these lower-than-expected response rates to advertisements was due to general public hesitancy to participate in non-essential activities out of the home. As a result, recruitment has remained at 10-20% below pre-COVID participation. Details regarding laboratory human subject testing during that time period are provided below.

The HST program continues to assist the HSD program by providing support for subject recruitment, subject safety verification (e.g., negative BrAC for all subjects and negative pregnancy test for women), beverage mixing, and administration and debriefing/safety testing at the end of the study. The current human testing paradigm permits the simultaneous collection of blood and breath using up to four different instruments at a frequency rate of every 2-10 minutes up to a period of 4 hours, although many of the more recent scenarios end in 2 hours. The intravenous catheter system with a continuous withdrawal approach allows the matching of the breath measurements with those of the blood samples collected.

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 subject's face. This meter can detect 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.

<u>Human Subject Studies</u>

During FY 2022, the following scenarios were explored:

a) The effects of drinking different kinds of alcohol,

b) Replications of the time lag studies undertaken with Gen 3.2 using the Gen 3.3 breath sensor,

c) Initiation of a study protocol to compare BAC with blood obtained from the finger capillary bed via a finger prick.

Studies continue to focus on the effective ranges of the DADSS breath sensors to ensure their performance at low (0.02 g/dL BAC) to high (0.18 g/dL BAC) 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, that is Utah, which has a BAC limit of 0.05 g/dL.

During FY 2022, twelve studies were conducted with six subjects (four male and two female). Analysis was conducted on 139 additional blood samples.

The intraassay CV, a measure of the variance between data points within an assay (procedure to measure the presence of a substance), remains low at 1.78% and overall, for the past 139 studies it was 1.41%. As of August 2022, 12,965 blood samples have been processed.

Drinking alcohol while vaping nicotine is a popular practice. Studies to examine the potentially interfering effects of electronic vaping cigarettes on the breath sensors are ongoing. However, studies have been limited with the removal of certain products from the market. Subjects are being surveyed to determine which e-cigarettes are commonly used by young adults and may proceed again in the future.

Another study examined whether ethanol concentrations in the capillary bed (i.e., via finger prick) is reflective of BAC. Two preliminary studies have been conducted during which blood samples were collected in mini vials and sent to the DADSS laboratory for processing.

Field Testing (HSD, Fleet)

The goal of human subject driving studies 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 DADSS researchers, and in naturalistic settings in cooperation with the states of Virginia and Maryland as described below.

Controlled Human Subjects On-Road Driving Studies

The purpose of the human subject driving studies (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 studies, in-vehicle testing was 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. Routes in New England were chosen to provide varying climactic conditions, such as low and high temperatures, low and high humidity, at varying elevations, and in corrosive environments.

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 (known as HSD1). In-vehicle testing utilizes 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 toward the sensors to assist data collection. The subjects' directed breath has two primary types of variability, 1) subjects likely will breathe differently each time they give a sample (e.g., the quantity, the strength, and the direction 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. Variations also arise with changing environmental conditions inside and outside the vehicles. 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 30 below). 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 to assess sensor sensitivity (i.e., true positives), validity, and reliability.

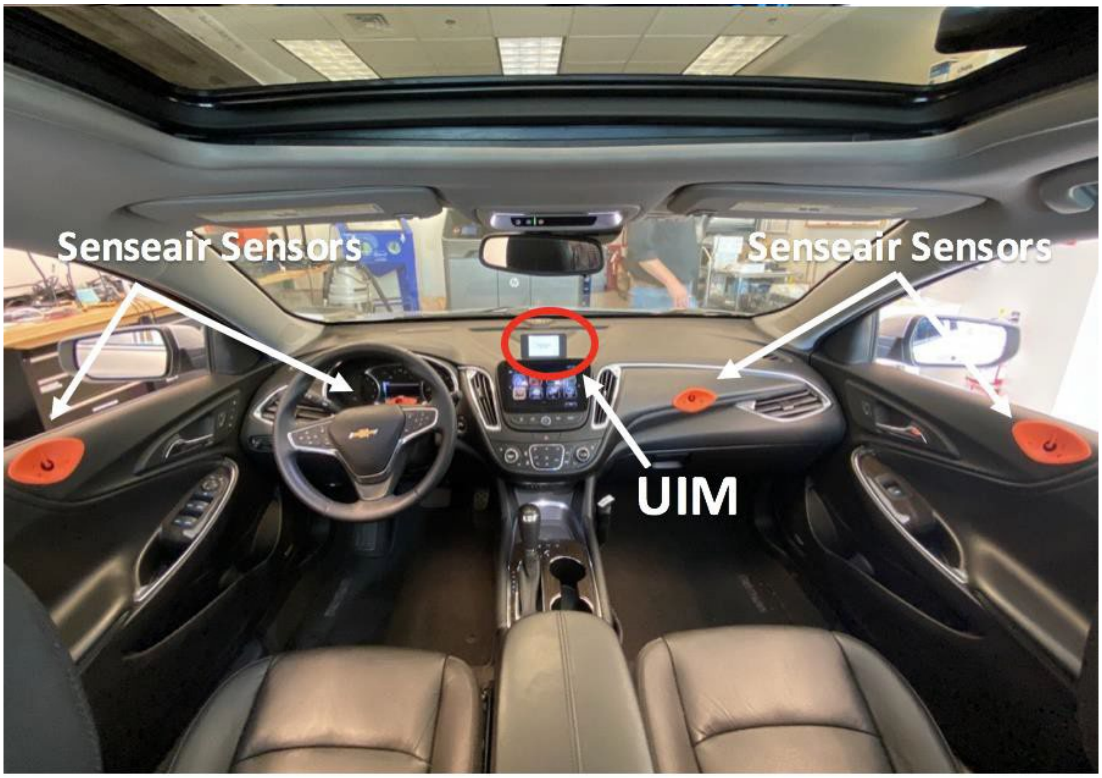

Figure 30. Position of the breath sensors on the driver (left) and passenger sides of the vehicle and user interface module (UIM)

Along with the alcohol sensors, the Chevrolet Malibu's are equipped with a comprehensive DAS, a video camera, a web interface[29], data and video storage, and a user interface module (UIM) for use by the passengers.

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. Once the subjects have been screened prior to testing (see above for details), they are dosed with the relevant quantities of alcohol over a period of about 10 minutes. The subjects' alcohol measurements are collected frequently from the

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

breath and reference sensors. A research assistant instructs them 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. Additional vehicle instrumentation tracks environmental conditions and vehicle system data while providing subject videos. It should be noted that the vehicle windows are always in the closed position during driving trials.

The phase I field studies (HSD1) were conducted with the Gen 3.2 sensors in real-world settings and the demonstration projects in Virginia and Maryland (see the sections below for more information). The HSD1 studies, in which dosed subjects were seated on the passenger side, were key in developing performance specifications, sensor placement in vehicles and the enhancement of the data acquisition systems. Drivers were asked to provide breath samples as the beginning and end of each study period. Information collected from these projects contributed to the development of 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) protection, 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 was a strong transmitter near the sensor, like a cell phone, the sensor experienced occasional signal spikes that were incorrectly identified as alcohol. When someone was talking on a cell phone, the sensors would incorrectly report alcohol present when the driver was sober. Upon examining the 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 assess 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 (see Figure 31 for sensor locations, and subject and research staff positions in the vehicle). The Gen 3.3 sensor is now being evaluated in the second round of trials, referred to as HSD2. As noted above, the Gen 3.3 sensor is designed for use in fleet vehicles to detect the presence of alcohol, thus, the initial focus of these studies was on evaluating sober and low-dose alcohol subjects. However, studies have also evaluated subjects who were dosed to moderate and high doses of alcohol. Overall evaluations were conducted with BrACs ranging from 0.0 – 0.12 g/dL.

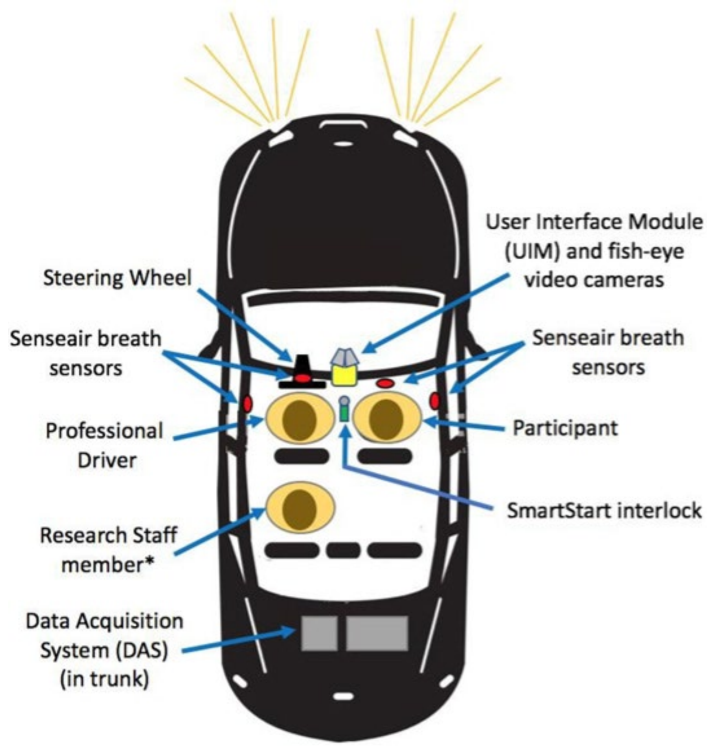

Figure 31. Vehicle sensor, subject, and staff locations

COVID safety protocols and procedures were designed and approved by IRBs to resume studies with subjects starting in August 2021. There was a pause in studies between December 2021 and February 2022 as a safety precaution in response to an increase in COVID rates.

Activities and findings for FY 2022 are described below. A number of key changes have occurred. Testing of dosed subjects was undertaken in a stationary vehicle. Gen 3.3 breathalyzers were integrated into study vehicles and time was spent stress testing study vehicles to evaluate differences between the performance of Gen 3.2 and 3.3 breathalyzers. In addition, software issues related to the Gen 3.3 sensors and the DAS were investigated along with communication between Gen 3.3 sensors, the DAS, and the data viewer.

In an effort to collect more sober breaths and to understand if there is drift observed between dosed and sober individuals in the study vehicles, all new study protocols have been amended to collect data from a sober research staff member seated on the passenger side of the study vehicle in parallel with a dosed research subject.

New protocols were designed, stress tested, and are currently underway to evaluate possible contaminants with sober human subjects to understand their effects and the rate of false positive readings on the Gen 3.3 sensors to support the fine tuning of sensor algorithms. An investigation of how long the effect of each contaminant lasts and possible mechanisms to reduce their effect are ongoing. Contaminants tested included different types of mouthwash, mouth spray, hand sanitizers, and cleaning products, such as alcohol wipes.

A protocol was designed to understand the impact of surgical masks on the Gen 3.3 breath sensors.

A comprehensive study dashboard was designed that is displayed on the DADSS data viewer (See Figure 32). Elements displayed on the dashboard during HSD2 include the number of reference (Smart Start) samples, the number of breath sensor samples collected, the number of protocols run, the total number of subjects, and the total study days. The dashboard also includes the above elements broken down by each protocol. The use of the dashboard will make the data more accessible to research and ACTS staff.

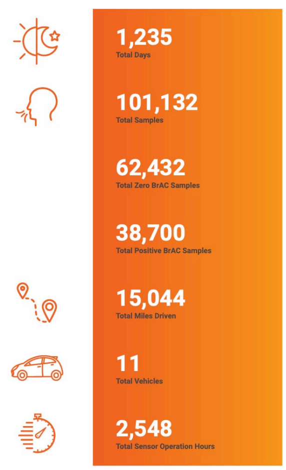

Figure 32. DADSS Data Viewer

In May 2022 new advertisements for recruiting subjects for HSD2 were created in an effort to improve the diversity of test subjects. Advertisements also included a schematic of the testing environment (see Figure 33) for prospective subjects to better understand the study. In addition, advertisements were designed to be used on social media.

Figure 33. Schematic of the test vehicle interior

Internal studies were conducted to measure Gen 3.3 sensor validity and reliability, investigation of windshield wiper fluid as a possible contaminant, understanding human behaviors and the associated time of getting into a personal vehicle, starting the vehicle, and moving the gear shift.

A new test vehicle, a compact SUV, was equipped with newly designed sensor inlets (see Figure 34). Researchers conducted internal studies with KEA staff to investigate the dilution factors associated with giving breaths at specific distances. These data were compared to data collected with the existing cars that utilized the previous sensor inlets (see Figure 27, above). Additional studies are ongoing.

Figure 34. Compact SUV with newly designed inlets in the instrument cluster

Researchers have begun to design potential HST (laboratory) studies using the touch sensor, including study protocols for stress testing the device, creating a unique data collection sheet, and creating a list of necessary questions and elements that need to be addressed by the touch team to develop an IRB package for study approval. Prior to beginning the external studies, internal studies will be conducted using KEA staff.

Studies with Alcohol-Dosed Subjects

Research vehicles will be used to gather data regarding breath sensor validity and reliability as well as to assess the real-world use of the sensors with human participants. Data collected from the study will be used to further refine the DADSS performance specifications and evaluate subsystem/sensor performance. In addition, researchers are exploring the necessary steps to begin testing touch sensors in the vehicle once the sensors are ready for in-vehicle testing.

- The HSD2 of the generation 3.3 breath sensors began August 26, 2022. Early study protocols involved the testing of sensors on the passenger side with sober subjects and subjects dosed to low BrACs in order to assess the accuracy, precision, sensitivity, and specificity of the breath sensors and inform the fleet application of the sensors.

- To further support future development of the breath sensors for consumer use, protocols that involved higher doses (>0.08 g/dL BrAC) were implemented later in the study. Overall, there were twenty-eight different protocols designed to answer different study questions.

Findings of the Gen 3.3 HSD2 studies

By the end of FY 2022, the HSD2 study had completed 77 drive days and collected 21,773 breath samples (6,846 from the DADSS driver and 12,274 from the DADSS driver sensors, and 2,653 reference samples). Within each drive day between two to seven protocols were conducted and at least two vehicles were tested. Overall, there were 11,695 matched pairs of BrAC measures (one breath sensor measure and one reference measure) that could be used in the performance evaluation.

Consumer Acceptance

A key component to ensure the success 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 automobile safety system, to desire and demand for the technology. If drivers do not fully accept it, the DADSS technology may never realize its full potential to save lives and deliver economic benefits to society as intended. For example, drivers may choose not to buy the technology, or even if they do, they may seek to disable the system or not use the system as intended.

Ongoing efforts include assessing consumer understanding and acceptance of the DADSS technology through surveys and focus groups. In addition, public events are hosted to demonstrate the technology with key stakeholders and consumers and collect important feedback. Social media also is key, including the DADSS website, to get the word out to consumers. The findings from these efforts will be incorporated into public messaging and the technology designs.

Qualitative and quantitative research is undertaken on an ongoing basis to explore public perceptions and receptivity to the DADSS in-vehicle technology. During the summer of 2022, four focus groups were conducted in Houston, TX and Waltham, MA with 34 drivers ages 21 and older, from various racial and ethnic backgrounds (Black/African American, Latinx, Hispanic, white). A number of key questions/areas regarding public perception of the DADSS technology were asked: 1) What is most acceptable to vehicle operators regarding how DADSS should function? 2) How do consumers view the design of the Driver-Vehicle Interface (DVI), 3) How do drivers perceive and define a passive system? and 4) To gain a better appreciation of when drivers might feel inconvenienced by the system and how much inconvenience they are willing to accept. Also, of interest was whether there are any differences in perceptions of the technology among different demographic groups.

Focus group participants were given a firsthand demonstration of the technology, using one of the recent breath sensor prototypes that requires a directed breath sample. In addition, each focus group included a series of individual written exercises and group discussion questions. The next step will be to continue the qualitative research with two online bulletin boards that involve moderated, online discussions among a group of 30 participants over the course of a few days. The purpose is to involve participants from all over the United States, as well as more rural residents. A primary focus will be how drivers feel about the speed of the sensor reading and analysis.

Focus Group Findings

Overall, participants exhibited an openness to advanced safety technologies of all types. Prior to testing the in-vehicle directed breath technology, respondents were given three written descriptions of new technologies and asked to rate their overall impression and their likelihood of wanting the technology in their next motor vehicle. These included a description of the DADSS technology, an in-vehicle camera system, and a head rest brain sensor technology. [30] The initial impressions of the respondents was that most reported having a favorable opinion of all three technologies, in particular 68 % had a favorable opinion of DADSS. More than half indicated they would be very or somewhat likely to want each of these new technologies in their next motor vehicle, with 58 % saying they would want the DADSS technology.

In response to the DADSS technology written description, participants thought it would be good for parents with teen drivers, that it could provide insurance discounts, and that it would help curb drunk driving for those who are still resistant to ridesharing, leading to greater responsibility among drivers. There were, however, some concerns about the DADSS technology as described. For example, some participants said they do not need it because they do not drink and drive, some who thought there was no need for it because of ridesharing, and also concerns about accuracy, privacy issues, and increased costs.

Experiencing the technology prototype raised more questions than it answered. After testing the technology, the questions increased about the need for the technology, about privacy issues, measurement accuracy and technology cost. Also, a number of questions arose about timing, speed, anticipated frequency of testing, and how the system would handle non-readings or mis-readings. Although participants generally used positive descriptions for the technology (e.g., safe, innovative, advanced technology, helping save lives lost to drunk driving), the overall impression and likelihood they would want it in their next vehicle dropped after seeing the prototype. The main reasons for not wanting it included that they do not personally see a need for it, and they were concerned that they might have to blow every time they got into their vehicle, and of the possible failure of the system (the idea that it would prevent you from driving was frequently referenced). In terms of timing, respondents reported that they would be comfortable if it took less than a second to capture, analyze, and produce the result, with more than half of respondents saying they were not comfortable with the time it took.

Regarding the DVI, respondents were more positive about DVIs that had more information. The top preference was for a screen that provided a readout of the BrAC, which would give them a sense of security knowing what level they are at, and a greater confidence in the system’s accuracy. For most respondents, less text was better. Drivers would also prefer the DVI in the dashboard area, where it is not as visible to passengers.

[30] A head rest sensor technology is designed to measure driver brain wave activity to determine if a driver is beginning to daydream or fall asleep while driving. If poor concentration levels are detected the steering wheel or pedals could vibrate, or the vehicle could display a warning icon or sound to alert the driver.

Regarding the touch technology, the in-depth discussions and questions led to a lessening of interest, with only 10 out of 34 respondents saying they would want it in their next vehicle. The touch system, however, was still preferred to the breath system, with 20 out of 34 respondents preferring the touch system versus 11 out of 34 preferring the directed breath system. Finally, the preferred locations for the sensors were the start button and/or steering wheel.

The overall conclusion was that the respondents wanted assurance that the technologies would be accurate, fast and private (that their data would not be shared), and they had trouble trusting that all three would be true. There was a baseline of trust that automakers would not install a system that was not fully tested and functional, but there was also a lot of hesitation about the idea that you would not be able to drive. Respondents did not understand what it meant to have a 0.08 g/dL BAC, with most people believing they would reach this level after a couple of drinks.[31]

The next research phase will continue the qualitative research with two online bulletin boards that involve moderated, online discussions among a group of thirty participants over the course of a few days. The purpose is to involve participants from all over the United States, as well as more rural residents. Participants will be asked to provide their personal opinions before they see the responses from the rest of the group, thus providing a more unbiased picture. A primary focus will be how drivers feel about the speed of the sensor reading and analysis.

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 for ease of tracking the most recent DADSS news.

During FY 2022, no major changes were made to the DADSS website. The Discovery Hub, which is housed on the website, is a suite of online resources that provide an in-depth look at the technology and the development process (https://www.dadss.org/discovery-hub). It includes educational modules and videos 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

[31] https://www.utoledo.edu/studentaffairs/counseling/selfhelp/substanceuse/bac.html. It is possible if body weight is 120 lbs. for women and 100 lbs. for men that BAC could reach 0.08 g/dL within an hour.

resource for the public to understand the role the DADSS technology will play in saving lives.

DADSS Media and Social Media

In FY 2022, the DADSS program received attention from national/top-tier, automotive and technology-focused media, driven by three key events:

The first was the signing of the federal, bipartisan infrastructure bill, a key provision of which is a mandate requiring automakers to install advanced drunk and impaired driving prevention systems in new vehicles no later than 2024 to identify and stop alcohol-impaired drivers. The DADSS program was mentioned or covered in several national news stories, including The Washington Post, USA Today, and the international news service Agency France-Presse. It also received coverage in automotive publications like Car and Driver and Motor Trend and technology-focused outlets like CNET, Fast Company and TechCrunch.

In December 2021, a joint announcement was made by ACTS, the Virginia Department of Motor Vehicles (DMV) and Schneider transportation that Schneider will become the first truckload carrier and major fleet provider to conduct a trial deployment of the DADSS technology. The collaboration will be carried out through the Driven to Protect Initiative with the Virginia DMV. At the event, speakers and guests were able to get a close-up look at the DADSS technology in the Schneider truck, as well as in other demonstration vehicles. Those in attendance were also given a chance to learn more about the technology development process and see videos and resources available for Virginia educators and the public at the Driven to Protect Discovery Hub. A reporter from National Public Radio attended the event, which resulted in a national story on the DADSS program and the Schneider partnership that aired in December 2021.

The third earned media event was in May 2022, when the DADSS program hosted reporters from NBC News for a behind-the-scenes look at the technology development. On Memorial Day Weekend in May 2022, NBC News aired a nationally televised story on the Today Show that featured the DADSS program (see Figure 35). This story aired on local NBC affiliates around the country and online via NBC News's online streaming platform NBC News Now.

Figure 35. NBC Today show featuring the DADSS program

DADSS social media continued in FY 2022, with content remaining focused on four key areas: 1) "technology 101" posts that explain how the technology works, 2) "frequently asked questions" that explain common answers about the program and technology, 3) technology updates from video shoots at the lab, and 4) news updates, announcements, and key milestones from the program. Four channels (Twitter, YouTube, Facebook and LinkedIn) remain active online with paid and organic/non-paid content published weekly. A summary of social media for FY 2022 are as follows:

- DADSS content promoted 5.9 million impressions across all social media channels – up from 3.3 million impressions in FY 2021. An impression is counted when any content is displayed to someone on social media.

- Engagement: DADSS content also received 234,191 engagements across all channels – up from 119,954 engagements in FY 2021. An engagement is any interaction with content from a user, such as a like, comment, or a share.

Using video continues to be a popular and necessary strategy to educate key audiences about the DADSS program and technology. In FY 2022, additional "behind-the-scenes" video clips were shared on social media using footage that was filmed at the DADSS laboratory to entice the public to watch longer "technology explainer" videos. The DADSS YouTube page, where all public video content is housed, received 15,811 video views in FY 2022 – up from the 10,685 in FY2021. These analytics do not count video views secured through social media advertising.

State Programs

In FY 2022 the DADSS program continued to partner with two states, Virginia and Maryland, to extend on-road experience with the breath sensors in a vehicle fleet setting with sober drivers. A second goal was 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 to suggest areas for improvement. The combination of human subject driving trials in a more controlled setting, described above, and the naturalistic driving experience in the state programs has led to a better overall understanding of areas for improvement.

Virginia

In 2016, Virginia (VA) became the first state to use NHTSA highway safety grant funds to partner with the DADSS program through the VA DMV and became known as the Driven to Protect initiative. In September 2018, the James River Transportation (JRT), a transportation services company in Richmond, VA, embarked upon a naturalistic deployment of DADSS breath sensors in some of their airport transportation vehicles. In FY2021, the initiative expanded its partnership to include Schneider, a commercial trucking company with 87 years in business and over nine million freight miles driven daily by 50,000 carriers. Data from these studies and the drivers input helps to improve the technology, including sensor performance, power consumption/battery life, and data transmission.

During FY 2022, JRT test vehicles were operational for 12,768 hours and driven 28,941 miles, during which time the system collected 56,410 breath samples.

During FY 2022, Schneider test vehicles were operational for 6,987 hours and driven 61,143 miles, during which time sensors collected 25,171 breath samples.

Communications and Consumer Awareness

In addition to the naturalistic driving program, the Driven to Protect initiative has conducted a series of outreach events each year. In-person events increased significantly in FY 2022 as pandemic restrictions were lifted in many places. At those events, awareness about the technology development process and saw videos and resources available for Virginia educators and the public at the Driven to Protect Discovery Hub.

Additional events were scheduled throughout the year for a number of organizations, some of which took place at the organization's meetings and conferences. DADSS technology was displayed at the VA Highway Safety Summit, Virginia Alcohol Safety Action Program, the Fort Belvoir Safety Day, Ford Driving Skills for Life Program for newly licensed and teen drivers, the Volkswagen Group of America & Greater Washington Urban League experiential program for rising high school, and the Virginia Black Business Expo.

Maryland

In August 2019, Maryland became the second state to join the Driven to Protect Initiative when its Governor formally announced the partnership between ACTS and the Maryland Department of Transportation Motor Vehicle Administration (MDOT MVA). Among other contributions to this initiative, Maryland was the first state to provide state government-owned vehicles for the on-road trial deployment. MDOT MVA plan to use the data and project experience to examine driver/sensor interaction, gauge overall driver acceptance (applicable to users, fleet owners, or managers) and assess the viability of the technology for potential future implementation. The Maryland project has been completed. During FY 2022, test vehicles were operational for 2,819 hours and driven 23,363 miles, during which time sensors collected 58,305 breath samples.

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 FY 2022, there were fourteen patents issued, eleven new patent applications were filed and are pending, and eight responses were prepared and sent to various countries in response to official action on applications pending.

ACTS continues to take a number of actions to ensure the commercial implementation of the DADSS technology. First, ACTS is prosecuting[32] 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 general public. Secondly, ownership by ACTS avoids hindering commercialization through blocking patents which might result if there were

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

multiple owners of the DADSS technology who could control the pace, scope, and price of commercialization.

Table 1 summarizes the intellectual property generated to date under the DADSS program. Closed applications that are no longer being pursued are not listed.

Table 1. Patent Portfolio as of September 30, 2022

TITLE	COUNTRY	STATUS	APPLICATION #
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	United States of America	Issued	11,001,142
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	South Africa	Pending	2014/02304

MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER			
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	Sweden	Issued	536784
BREATH TEST SYSTEM	United States of America	Issued	11,391,724

BREATH TEST SYSTEM	United States of America	Continuation Pending	14/421,371
BREATH TEST SYSTEM	Canada	Issued	2,881,817
BREATH TEST SYSTEM	China	Pending	202110218823.1
BREATH TEST SYSTEM	European Patent Office	Issued	2888587
BREATH TEST SYSTEM	Japan	Issued	6496244

HIGHLY ACCURATE BREATH TEST SYSTEM	South Africa	Pending	2015/01246
BREATH TEST SYSTEM	Sweden	Issued	536782
HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Issued	10,151,744
HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Continuation Issued	11,143,646
HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Continuation Two Pending	17/499,169
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	6408991
HIGHLY ACCURATE BREATH TEST SYSTEM	Japan	Issued	6954875

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 Office	Pending	16816457.2
HEATER-ON-HEATSPREADER	Japan	Issued	7138047
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 BREATH ALCOHOL ESTIMATION	United States of America	Continuation Pending	17/462,318
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 Application allowed	16826860.5
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE	Japan	Issued	678662

BREATH ALCOHOL ESTIMATION			
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 Responded	2.987,729
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	China	Issued	ZL201680046009.3
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	European Patent Office	Pending	16716787.3
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	Japan	Pending	2018-515758
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	South Africa	Pending	2017/08227
PASSIVE BREATH ALCOHOL DETECTION	United States of America	Inventors reviewing Provisional	Pending
METHOD AND APPARATUS FOR PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE	United States of America	Pending	17/008,072

METHOD AND APPARATUS FOR PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE	Canada	Pending	3,148,707
METHOD AND APPARATUS FOR PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE	China	Pending Filed Examination Request	202080075659.7
METHOD AND APPARATUS FOR PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE	European	Pending Fee Payment completed	208656310.6
METHOD AND APPARATUS FOR PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE	Japan	Pending	2022-513427
METHOD AND APPARATUS FOR PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE	Korea	Pending	2022-7010413

METHOD AND APPARATUS FOR PRODUCING A HIGH PRECISION BLENDED GAS MIXTURE COMPRISING A VOLATILE ANALYTE	South Africa	Pending	2022/03579
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	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 OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	European	Pending	198602226.0

SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	Japan	Pending Filed Examination Request	2021-513285
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	Korea	Pending Filed Examination Request	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	Notice of Allowance	16/900,088
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Canada	Pending	3,143,026
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	China	Pending Filed Examination Request	202080056975.X

SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Europe	Pending Fee Payment completed	20823461.7
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Japan	Pending	2021-573313
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Korea	Pending	2022-7000513
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	South Africa	Pending	2021/10881
WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	United States of America	Pending	17/222,493
WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	Canada	Pending	3,173,161
WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	China	To be filed by 12/3/22	N/A
WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	Europe	To be filed by 11/3/22	N/A

WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	Japan	To be filed by 10/3/22	N/A
WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	Korea	To be filed by 11/3/22	N/A
WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	South Africa	Pending	2021- awaiting #
PRESSURE PLATE FOR TOUCH-BASED SENSOR SYSTEM	United States of America	Inventors reviewing Provisional	Pending
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

Under 23 U.S.C. 403(h), NHTSA has specific authority to support the DADSS program. The statutory provision allows the agency to carry out a collaborative research effort on in–vehicle technology to prevent alcohol–impaired driving that includes authorization to spend sums from the highway trust fund for the research. The specific authority provision started in 2012 under the surface transportation authorization known as Moving Ahead for Progress in the 21st Century (MAP–21).[33] Currently, the program has been reauthorized for five additional years through 2025 under the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act.[34]

For FY 2022, authorization for DADSS research was continued under BIL. For the period covering FY 2022 through 2025, the statutory provision authorizes no more than $45,000,000 to be spent on the program. In FY 2022, Federal funding totaling $11,250,000 was authorized and appropriated.

Table 2. FY 2022 NHTSA Funding authorized for in-vehicle technology research to prevent alcohol-impaired driving

	Fiscal Year 2022
Funding Authorized for In–vehicle Technology Research	$11,250,000

The period of performance specified in the 2013 Cooperative Agreement, which was executed on September 23, 2013, initially covered a five–year period and research was planned for this entire period that concluded September 30, 2018 (FY 2018). In December 2017, ACTS and NHTSA agreed to extend the 2013 Agreement through September 30, 2020—the end of the Program's authorization in the FAST Act. Please note that a new cooperative agreement covering FY2024 and additional years under BIL has been entered into between the parties. Due to an extension of the FAST Act and the enactment of BIL occurring after the start of FY 2022, the 2013 Agreement was further extended through September 30, 2023.

Table 3. Funding Status

Automotive Coalition for Traffic Safety

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

[35]Funding Appropriated and Obligated – FY 2022	**$11,250,000**
Funding Expended – FY 2022	**$11,250,000**
Direct Cost	$ 6,480,718

[33] Public Law 112–141, enacted July 6, 2012.
[34] Public Law 117-58, enacted November 15, 2021.
[35] Figures have been rounded and may not total precisely as a result.

Indirect Cost	$ 643,408
Total Expended – FY 2022	**$ 7,124,126**
Carryforward balance for FY2023	$ 4,125,873