Progress Report

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October 1, 2019 through September 30, 2020

2020

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) 2020 in carrying out this effort.

In–Vehicle Alcohol Detection Research

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Executive Summary

The Driver Alcohol Detection System for Safety (DADSS) Program, which began in 2008, was reauthorized in the surface transportation reauthorization enacted in 2012, Moving Ahead for Progress in the 21st Century (MAP–21), and was again reauthorized through Fiscal Year (FY) 2020 via the Fixing America's Surface Transportation Act (FAST). The statutorily authorized research is being implemented through a Cooperative Agreement, established in 2013, between the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety. The research team operating under this agreement comprises various technology companies that oversee the research, develop the in-vehicle alcohol detection technology, and create processes and procedures to validate each step of development.

Research efforts under the DADSS program align with the Safer Vehicles element of the Department's National Roadway Safety Strategy, leveraging technology to address behavioral issues and informing NHTSA's rulemaking effort to establish motor vehicle safety standards to require passenger motor vehicles manufactured to be equipped with advanced impaired driving prevention technology.

In the initial stages of the cooperative research partnership, exploratory research established the feasibility of two alcohol sensor approaches for in-vehicle use, breath, and touch, that had the potential to measure driver alcohol quickly, accurately, precisely, and with minimum inconvenience to the driver. Since then, the sensors have become increasingly refined, both in terms of hardware and software. For DADSS sensors to effectively measure driver blood and breath alcohol across the passenger vehicle fleet many millions of times a day with minimal misclassification errors (i.e., false positives or false negatives), stringent performance specifications for accuracy and precision[1] were deemed critical. These specifications far surpass existing specifications for alcohol measurement and necessitated the development of innovative methodologies to verify that the technology is able to meet them. Specifically, calibration processes, materials, methodologies, and instrumentation have been the subject of extensive cutting-edge research to enable the requisite testing. In addition to bench testing of the sensor systems, research has focused on testing sensor performance on human subjects, both in the laboratory and on-the-road. The accumulated data from these testing scenarios will determine whether the DADSS sensors are working as anticipated and identify areas for system improvement.

During the fiscal year ending September 30, 2020, many accomplishments were realized in all areas of development, including sensor development, calibration materials, processes and measurement procedures, and human subject testing both in the laboratory and in the vehicle. Although the COVID-19 pandemic has had some impacts, the DADSS team actively monitored potential risks to the program and

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

continued to make progress on the work during this period. As of FY2020, continued progress has been made on both devices towards commercialization. However, neither device is at a point where it could be commercialized for widespread deployment in all consumer vehicles. Through the Program's research, the performance of the DADSS devices continues to evolve and improve for both the breath and touch sensors. This report summarizes the accomplishments during FY2020.

The breath sensor system uses infrared sensors to measure the concentrations of alcohol in exhaled breath. Substantial progress was made in FY2020 in advancing both the Generation (Gen) 3.3 sensor, intended for fleet vehicle use, and the Gen 4 sensors, intended for widespread use in passenger vehicles through passive breath detection. The program is working toward the release of the Gen 3.3 sensor during 2021. This sensor is the first derivative of the breath–based technology which will be suitable for deployment in fleet vehicles. The driver will be required to provide a short puff of breath directed at the sensor at a distance of two to three inches and will be set to detect the presence of alcohol. However, the sensor also has the flexibility to set the limit up to a blood alcohol concentration of 0.04 grams per deciliter.[2] This approach follows the SAE[3] J Standard for fleet vehicle use, which has been drafted and is close to final approval from the SAE committee. During the year, development work on the Gen 3.3 sensor was completed, and 45 sensors were sent to the DADSS laboratory for validation testing. The technology provider, Senseair, anticipates that the Gen 4 breath sensor could be ready for mass production in 2024. Based on data from previous generations, ten initial concepts for the Gen 4 sensor have been narrowed down to three and these three designs will be further evaluated to determine which one will become the final design. Prototypes for system-level testing are currently under construction. In addition to hardware design, algorithm development has resulted in improvements in sensor performance, including faster and more reliable measurement. Research also is underway to evaluate how the parameters of the breath snorkel system affect alcohol measurements. The snorkel is the means by which the breath inlet port in the vehicle is linked to the breath sensor. Parameters being investigated include the length, width, and material composition of the snorkel as well as breath flow rate, humidity, and test distance.

The touch sensors allow estimation of blood alcohol concentration by measuring alcohol concentrations in the driver's finger tissue (or more specifically the blood in the capillaries). The driver touches an optical module and a near-infrared light shines on the driver's skin and propagates into the tissue. A portion of the light is reflected back from the skin's surface, where it is collected by the touch pad. This light transmits information on the tissue's chemical properties, including

[2] The Federal Motor Carrier Safety Administration has established 0.04 grams per deciliter as the blood alcohol concentration at or above which a commercial motor vehicle operator is deemed to be driving under the influence of alcohol.

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

the concentration of alcohol. Twenty modulated laser diodes that are tuned for optimal alcohol measurements are used to generate 40 unique wavelengths of light. In order to produce accurate and repeatable results, the laser signals must be strong and stable as well as have effective homogenization so that the light levels propagating through the tissue are always the same. During FY2020, to accelerate progress on Gen 4 touch sensor development, the DADSS team was working on parallel studies to explore different hardware, and software designs to address these issues. On the hardware front, different types of optical modules are being studied to better understand the sources of laser signal instability, to improve signal homogenization, and to find solutions to these issues. A complete redesign of the system electronics is ongoing to improve laser temperature regulation, increase the strength of the received laser signal prior to measurement, and potentially eliminate background noise. Extensive modifications to the software have allowed greater flexibility for capturing, analyzing, and displaying data from the touch sensor to allow verification of test data and to study trends over time. Gen 5 availability, suitable for fleet and accessory applications, is targeted for 2023. The Gen 6 version aimed for use in privately-operated vehicles is anticipated to be available during 2024-2025.

As sensors evolve and improve, the new generations of the breath and touch sensor systems need to be evaluated. With respect to the breath sensors, research in FY2020 in the sensor calibration area has led to advances in sensor testing and to the sensors themselves. The Gen 3.2 breath sensors, an earlier version of the current Gen 3.3 fleet version, that were being used for human subject driver testing, were removed from test vehicles for recharacterization. It was confirmed that there was no degradation in performance over a six-month period. In addition, software improvements have allowed researchers to automate the calibration process more fully. During the year, further research was conducted to better understand and improve the performance and calibration of Gen 3.2 sensors. In-vehicle, human subject testing of the Gen 3.2 sensors indicated instances of electromagnetic interference from mobile phones, potentially affecting breath-alcohol measurements. The results of studies of this phenomenon indicated that the interference was mitigated with copper-wrapped sensors. In the future, all Gen 3.2 sensors will be installed with the copper wrapping. The electromagnetic interference has been separately addressed in the Gen 3.3 design and build. Beginning in April 2020 through the end of FY2020, 45 Gen 3.3 sensors were received from Senseair. These are the sensors that will be used for fleet applications.

To facilitate more cost-effective and expedient testing of touch sensors in the future, research continues into the use of alternate tissue surrogates. That is, tissue surrogates are manmade materials used for calibration that mimic the properties of human tissue. The laboratory has developed and tested gelatin samples containing up to 3000 mg/dL of ethanol. The gelatin samples have shown very good stability in alcohol concentration and the quality of the gel over a 3-month period.

Human subject testing to evaluate the performance of the breath sensors was conducted in FY2020 in controlled laboratory conditions at McLean Hospital, a

Harvard Medical School Affiliate in Massachusetts. Once ingested, alcohol is constantly absorbed into and eliminated from the body. Subjects' alcohol absorption and elimination curves are plotted to determine the amount of alcohol in the body over time, including blood, breath, and tissue alcohol. These data are used to establish that alcohol measurements made with diluted breath and in tissue are comparable to the well-accepted standards of venous blood and deep-lung air widely used in traffic law enforcement of Driving Under the Influence laws. Previous research has established that the alcohol measurements from breath and touch sensor prototypes are consistent, reproducible, and correlate very well with traditional blood and breath alcohol measurement.[4] Human subject testing was suspended in March 2020 when COVID-19 restrictions were put in place, but limited testing was resumed in September 2020 after initial restrictions were eased and additional safety procedures were developed. Substantial progress was made this year to measure the alcohol absorption and elimination curves of human subjects across a number of new scenarios, some of which are still ongoing. These include the effects of standard, low dose, and non-alcoholic beer on blood and breath alcohol concentrations; combining alcohol with energy drinks; and smoking standard and electronic (e.g., JUUL) cigarettes while drinking alcohol. During FY2020, 1,499 breath and blood samples were collected, contributing to a total of 11,968 breath, blood, and tissue samples collected from program inception to the end of FY2020.

The goal of human subject driving tests is to conduct basic and applied research to understand the performance of the sensors in the vehicle, across a range of environmental conditions. Currently, only the breath sensor is being evaluated, but once the touch sensor is ready for real-world evaluation it will be installed in the research vehicles. The chosen routes expose the system to a variety of temperatures, humidity levels, and elevations, among other factors, to ensure that the system will be operational across real-world conditions likely to be encountered. The test vehicles have registered temperatures from -9.5 to 53.5 degrees Celsius, or 14.9 to 128.3 degrees Fahrenheit. While traversing the planned routes, passengers who have previously been dosed with alcohol provide breath samples both to the DADSS breath sensors and a reference breath sensor. In FY2020, 77 studies were conducted from October 2019 until research was suspended in March 2020 as a result of the COVID-19 pandemic. A total of 177 studies have been conducted since the study began in June 2019. To date, 82,503 breath sensor samples have been provided. These are comprised of 43,311 breath sensor samples, of which 6,276 are directed breath, 34,721 breath sensor driver samples, and 4,471 reference sensor samples. Analyses are ongoing. The DADSS team currently is developing options to safely resume human subject driving trials to begin testing the Gen 3.3 sensors.

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[4] 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.

Qualitative and quantitative research to assess public perceptions about and receptivity to the DADSS in-vehicle technology was undertaken in the initial research stages. The most recent public opinion survey was conducted in January 2020. Almost three quarters of drivers said they had a favorable opinion of the DADSS technology, and this favorability reached 80 percent with young male drivers ages 21-34 and women ages 55 and older. Favorability also was high among drivers who had a Driving While Impaired conviction (75 percent) and who admitted they drove after drinking (74 percent). Reasons for favoring the technology included that the technology prevents drunk driving, is non-invasive and convenient, and is especially helpful for young drivers. Many of those surveyed also felt that it was an inevitable technology for vehicles.

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 is a pilot driving study in which the latest prototypes of the DADSS breath-based sensors were integrated into four James River Transportation commercial fleet vehicles in Richmond, Virginia. The data and feedback collected from the prototype sensors, as well as from the drivers themselves, will be used to modify and improve the technology as it continues to be developed. At the time of this report, the vehicles were inactive due to the COVID-19 pandemic. However, since the inception of the program through FY2020, the vehicles have been in operation 7,979 hours, 778 days, and have been driven 51,930 miles. During that time 46,664 breath samples had been collected by the in-vehicle DADSS breath sensors. The second component is to increase consumer awareness through community outreach events. Again, due to the pandemic, fewer events were scheduled this Fiscal Year. However, during the pandemic, the DADSS team has created educational opportunities for the general public and high school students through the development of videos and online materials and the creation of Science, Technology, Engineering, and Mathematics (STEM) modules. These materials became available to the public in November 2020 on a dedicated website (https://www.elearning.actsautosafety.org).

Another partnership between the State of Maryland Department of Transportation's Motor Vehicle Administration and the Automotive Coalition for Traffic Safety began in 2019 with an agreement to test the latest breath sensors in state–owned vehicles. Also, a DADSS Demonstration Vehicle was provided for use at safety events. To date, the seven vehicles have been in operation for 373 hours over 105 days, driven 1,724 miles, and 10,028 samples have been collected.

While significant progress is being made on sensor development and performance both in the laboratory and on the road, essential research is needed in a number of areas, including additional sensor development, calibration methodology, and human subject testing. The objective of this effort is to have a device or devices (i.e., breath, and/or touch-based) 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 both in the United States and around the world. Decades of research, focusing largely on modifying driver behavior through strong laws, enforcement, and public education, has identified ways in which alcohol-impaired driving can be reduced.[5] Significant progress has been made through these proven approaches, however, deaths from alcohol-impaired driving persist. In 2019 alone, crashes involving at least one driver with a blood alcohol concentration (BAC) of 0.08 grams per deciliter or higher (g/dL)[6] resulted in 10,142[7] deaths of U.S. road users.

The deployment of vehicle technology that measures driver BACs and prevents vehicle operation in an intoxicated state is seen as a potential solution to this continuing problem. This approach has the potential to prevent drinking and driving, reduce and ultimately eliminate those deaths, and free up current resources spent on drinking and driving prevention, punishment, and rehabilitation. A recent study from the Insurance 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 (Farmer 2020).[8]

In 2008, a public/private partnership began between the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS)[9] to develop a technological solution or solutions to significantly reduce and ultimately end alcohol-impaired driving. This program, known as the Driver Alcohol Detection System for Safety (DADSS) is developing non–intrusive technologies that could prevent a vehicle from being driven when the device registers that the driver's BAC meets or exceeds the legal limit.[10]

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[5] Ferguson S A. 2012. Alcohol-impaired driving in the United States: Contributors to the problem and effective countermeasures. Traffic Injury Prevention, 427-41.
[6] 0.08 g/dL is currently the legal limit in all of the United States except for Utah which has a BAC limit of 0.05 g/dL
[7] National Highway Traffic Safety Administration. 2020. Traffic Safety Facts. Research Note. DOT HS 813060. Washington, D.C.
[8] Farmer C M. 2020. Potential lives saved by in-vehicle alcohol detection systems. Insurance Institute for Highway Safety, Ruckersville, VA.
[9] ACTS is a nonprofit safety organization funded by motor vehicle manufacturers, who make up its membership. ACTS' current members are BMW Group, FCA US LLC, Ford Motor Company, General Motors Company, Honda Research & Development, Jaguar Land Rover, Mazda North America Operations, Hyundai America Technical Center Inc., Mercedes Benz USA, Mitsubishi Motors, Nissan North America, Inc., Porsche, Subaru of America, Inc., Toyota Motor Sales, U.S.A., Inc., Volkswagen of America, Inc., and Volvo Cars. These ACTS members account for the majority of new light vehicle sales in the U.S. market.
[10] 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).

Early in the development process, DADSS researchers identified promising technologies that had the potential to prevent alcohol-impaired driving through instantaneous measurement of driver BAC or breath alcohol concentration (BrAC).[11, 12] 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-based and touch- or tissue-based spectrometry systems. The breath-based approach uses an infrared (IR) beam to analyze BrAC. Expired breath is diluted with the vehicle cabin air and is drawn into an optical cavity where an IR beam is used to analyze the alcohol concentration in the subject's exhaled breath. Carbon dioxide is measured separately to determine breath dilution. The second approach, known as tissue spectrometry, estimates BAC through detection of light absorption at pre-selected wavelengths from a beam of near-infrared light reflected from within the 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 prototype development of the most promising approaches. Under specific authorizations for the DADSS program in the Moving Ahead for Progress in the 21st Century (MAP-21) Act and the Fixing America's Surface Transportation (FAST) Act, additional research has continued under a new cooperative agreement (covering Phase III of the research).[13] During Phase III, research has continued to advance the DADSS sensor technology. At the same time, a multi-pronged program of research has been undertaken to quantify sensor performance and understand human interaction with the DADSS sensors both physiologically and ergonomically in the laboratory and in the vehicle environment.

As required by the FAST Act, this report will discuss these research programs in more detail and the progress achieved towards these goals in FY2020. This report also includes a general accounting for the use of Federal funds obligated during this period.

DADSS Research Program Team

The DADSS Research Program is composed of several different elements that consider various aspects associated with the development and widespread deployment of DADSS technology (Figure 1). The Stakeholders Team, established in

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[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 and Public Law 114-94, December 4, 2015.

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., a research and technology company, consists of sensor developers and other program members, and carries out associated DADSS research.

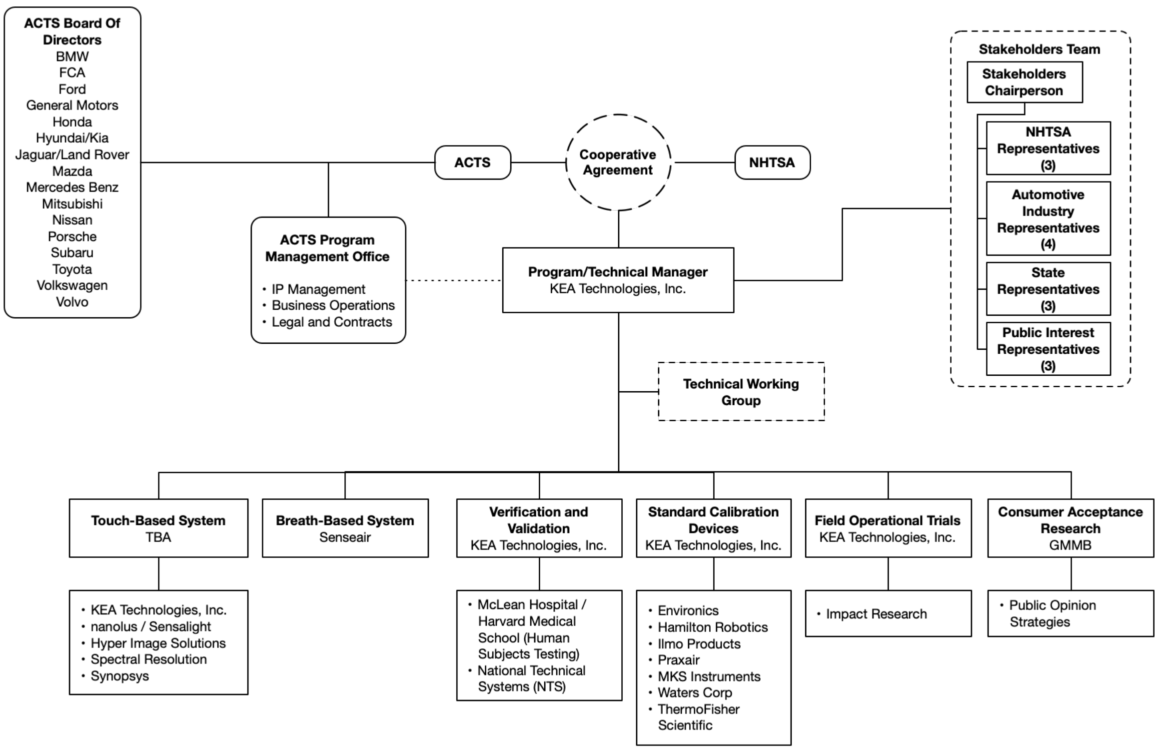

Figure 1. DADSS Research Program Organization

Phased Research Plan with Technical Review Gates

From inception, the DADSS program has been structured to minimize risk by conducting the research in phases with technical review gates between phases. The intent of Phase I was to research prototypes that could rapidly and accurately measure a driver's BAC or BrAC non-intrusively. The prototypes constructed during this Phase (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, at the conclusion of Phase I it was determined that development should continue for both the touch– and breath–based technologies.

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

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

DADSS Research Programs

The DADSS program of research and development began with the assumption that to be successful and acceptable to drivers, many of whom do not drink and drive, the technology must be seamless with the driving task. It must be speedy and unobtrusive, extremely reliable, durable, and highly accurate with precise measurements. To meet these challenging needs, performance specifications were developed at the outset that are unprecedented in the field of blood- and breath-alcohol measurement. These specifications, which are updated on an as needed basis, provide the performance goals for the research effort (the current version of which is set forth in the DADSS Performance Specifications).[14]

Research is ongoing in Phase III 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 calibration technologies being pursued simultaneously under the DADSS umbrella. The breadth of the research undertaken by the DADSS team necessitated the construction of a DADSS laboratory where in-house research is conducted by a team of highly trained professionals with expertise in numerous disciplines.

These additional research efforts are vital components to support and validate the approaches and technologies that are produced. Not only must the technology meet specifications to operate seamlessly with the vehicle start-up function, and be highly accurate and precise, often in conditions of high elevation, cold, heat, and humidity, but as with other safety technologies, the systems must work reliably for the full operating life of the vehicle. The accuracy and precision of the alcohol measurements are set at 0.0003 at a BAC of 0.08g/dL. These performance specifications are much more stringent than those for current in-

[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.

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 very high to limit the number of misclassification errors, that is, false positives and negatives, and avoid inconveniencing the driver.

Accuracy and precision must be confirmed in the laboratory using breath and tissue surrogates, and with human subjects under controlled conditions to establish the key variables that might affect measurement, and also in conditions that replicate those likely to be experienced in the vehicle environment. Success of DADSS will require not only that the technologies successfully meet the performance criteria, but also achieve wide-spread implementation that, absent a mandate, is dependent on the driving public adopting this optional technology when purchasing their future vehicles. To that end, a separate effort was launched to engage the driving public in discussions about the technologies so that their feedback could be incorporated into the DADSS specifications as early as possible in the development cycle. The progress achieved in each of these areas in FY2020 is detailed below.

DADSS Subsystems Technological Research

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

Breath sensor

The breath-based 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.[15] BrAC is then calculated.

The ultimate goal of the DADSS sensors is to passively measure breath alcohol within the vehicle cabin without direct input from the driver. The challenge is to meet the stringent accuracy and precision specifications while measuring this diluted breath. As a result, sensor location in the vehicle is key for effective breath alcohol detection. Thus, a significant component of the research has been focused on understanding the behavior and flow patterns of the expired breath plume within the vehicle cabin 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 improved analysis of the impact of cabin air

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

flow and the driver's position on alcohol measurements as well as optimized performance.

The breath sensor has been updated in Phase III with the goal of improving the ability to measure directed and passive breath more accurately and precisely. Although passive breath is the ultimate goal for widespread in-vehicle deployment, directed breath, which requires a short puff of breath directed at the sensor from a short distance, has also been investigated. The latest version, Generation (Gen) 3.3, which is intended for use as a fleet device, will require users to provide a directed breath to detect the presence of alcohol. Gen 3 underwent a complete re-design to increase sensitivity for measurements of passive samples, reduce the overall size, and improve performance over the full temperature range of -40°C to +85°C as specified by the DADSS Performance Specifications. A major improvement made during the Gen 3 sensor iteration is in detection of alcohol, whereby ethanol detection takes place over the full length of the cavity, whereas carbon dioxide is detected cross-wise to eliminate systematic timing differences between the two signals.[16] The Gen 3.2 device has seen sizeable improvements compared with the Gen 3.1 sensor. Gen 3.2 now enables passive in-cabin breath sampling through enhanced alcohol sensitivity, with precision markedly improved (See Figure 2). The Gen 3.3 device has been developed for fleet and accessory application with input from Gen 3.2 laboratory studies and human subject trials. The plan is to make it available as an accessory device for fleet vehicle use during 2021, assuming a successful demonstration of the sensors in the field and in the laboratory.

This fleet device will be set to detect the presence of any alcohol but will also have the flexibility to set the limit up to a BrAC of 0.04 g/dL. That is, at or below the commercial driver alcohol legal limit, depending on the company fleet owner's preference. A key feature will be the use of a directed breath, rather than the passive breath sample currently specified for the passenger vehicle market.

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

GEN 3.1 Engineering Prototype	**GEN 3.2** Limited Engineering Samples	**GEN 3.3** 2021 Fleet Derivative	**GEN 4.0** (Targeted for ~ 2024)
Directed BrAC measurement	Directed BrAC measurement	Directed BrAC measurement	Passive BrAC measurement
	Passive in–cabin alcohol "sniffing"	Passive in–cabin alcohol "sniffing"	Passive in–cabin alcohol "sniffing"
	Enhanced alcohol sensitivity	Enhanced alcohol sensitivity	Designed for scaled production
Suitable for fleet & accessory applications	Limited engineering samples for testing and evaluation	Suitable for fleet & accessory applications	Widely–deployable for POVs

[16] 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.

Figure 2. Evolution of DADSS breath-based sensor

Tests of the latest Gen 3.2 version have shown a significant reduction in background noise – down from 10.71 percent in the earliest Gen 3 prototype to only 1.64 percent relative to the initial version, which is considered to be 100 percent (see Figure 3). Background noise in sensors generally results from temperature variations, the air flowing through the sensor, and small fluctuations in the current drawn by the instruments themselves. This noise is generally small and has been significantly improved. Reducing the background noise enables the signal to be better detected, hence improving accuracy and precision measurements.[17] The Gen 4.0 version is under development with a design goal to reduce the noise even farther, to only 0.21 percent of the signal or better. The net result will be a significant enhancement of the alcohol signal.

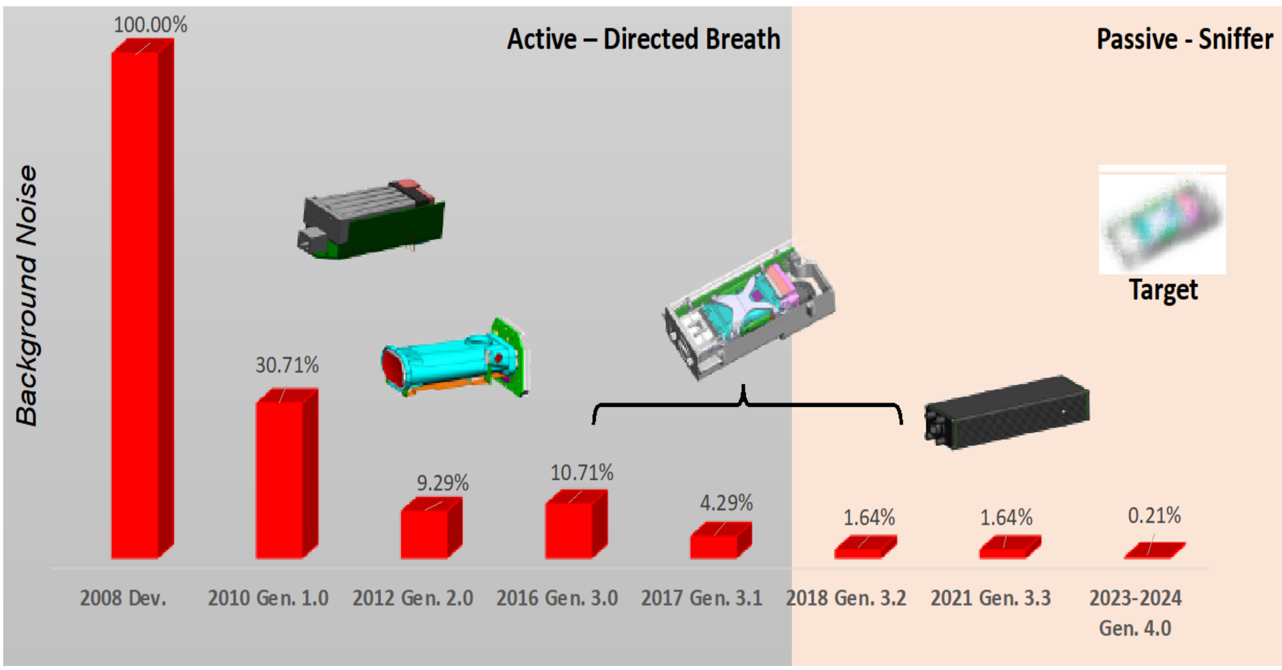

Figure 3. Sensor performance improvements and goals through reduction of background noise

Senseair has made significant progress in FY2020 in both Gen 3.3 and Gen 4 sensor development and testing. Details are provided below.

Generic development:

- An algorithm has been developed that enables data to be used from more than one breath sample to improve measurement. The algorithm can be applied to both directed breath and in the passive mode. In directed-

[17] 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.

breath mode, the algorithm allows the use of information from a failed first sample to carry over to subsequent samples. The fact that more than one sample can be included in the measurement lowers the threshold requirement. If two samples are given, it is less likely that both of them will result in an incorrect result. Therefore, the overall threshold for an acceptable breath can be lowered, making it easier for a user to deliver an acceptable breath sample to the unit. In the passive mode, the algorithm increases the validity of the measurement as more data are gathered over time.

- An algorithm has been developed that enables faster start-up times. The algorithm accounts for initial signal drift in the system. The implementation allows for reliable measurements earlier after powering the sensor system on.
- Senseair's automated functional test system has been evaluated and improved upon throughout the year. Among the updates, the test system now is able to systematically perform testing on Gen 3.3 sensors. The evaluation of the test system performance, using the MKS instrument, showed a performance level which met the precision requirements of the project, which as noted above is 0.0003 at a BAC of 0.08 g/dL.
- Senseair began an in-vehicle human subject driving study in Sweden after approval by the ethical review board in Uppsala, Sweden (Dnr 2019-05449). The Sweden Human Subject Driving, was designed to evaluate Gen 3.2 sensors using GM Malibu's. Testing was completed with four human subjects until testing came to a halt in March due to the COVID-19 pandemic.
- An algorithm was implemented to account for long-term sensor drift, which can be associated with aging of the sensor components. The goal is for the sensors to last for the life of the vehicle and not need continuing maintenance. The algorithm works by compensating the infrared signal baseline due to slow long-term adjustments of components within individual sensors. During the year, the algorithm has undergone laboratory testing, including gas pulse performance testing, accelerated adjustment testing, and long-term testing.
- Optical test benches have been built to perform methodological evaluations using experimental testing and human subjects. Again, full experimental tests to evaluate these ideas have been halted due to COVID-19. The use of water vapor as the tracer gas in addition to or instead of carbon dioxide may reduce the variability in diluted breath testing, hence increasing the reliability of the measured gas. Also, measuring in a different spectral region may allow for a broader selection of components, thereby allowing for a simpler design.
- The DADSS team is developing breath snorkel design rules. The snorkel is the delivery system that connects the breath inlet port to the breath sensors in the vehicle. Investigations were conducted that included snorkels of various lengths and shapes, as well as temperature-regulated

snorkels. The results of these investigations indicate that the snorkels should be kept short and heated at start up for improved performance at various operating temperatures.

- Copper shielding was developed for the Gen 3.2 sensor to provide an effective barrier against electromagnetic interference (EMI) (see the later section on Sensor Calibration Research for a more detailed account). The sensors base performance was improved compared to the Gen 3.2 sensor design. Self-diagnostics functions also have been implemented, including temperature measurement checks, memory checks, communication checks, fan control check, voltage checks, etc.

Gen 3.3 Development:

- During the year, development work on the Gen 3.3 sensor (see Figure 4) was completed, including improvements to the main electronics board, mechanical housing, sensor core firmware, optical elements, satellite board electronics and software. The development process was iterative with several versions of the board being developed, including changes to most of the components and sub-assemblies. The EMI shielding provided effective EMI protection for the sensor.
- The accuracy and precision of the Gen 3.3 sensor was improved compared to the Gen 3.2 sensor design. The Relative Standard Deviation, which is a measure of precision, was reduced from 3.73% for the Gen 3.2 sensor to 1.49% for the Gen 3.3 sensor. The average bias, which measures accuracy, was reduced from 11% for the Gen 3.2 sensor versus < 1% for the Gen 3.3 sensor.
- Self-diagnostics functions also have been implemented, including temperature measurement checks, memory checks, communication checks, fan control check, voltage checks, etc.

Figure 4. Latest Gen 3.3 design

- The Gen 3.3 sensor underwent algorithm tuning which addressed calibration, start-up sequence, and heater regulation, BrAC calculation during temperature gradients, compensation for ambient conditions and signal processing suitable for a dynamic condition. Initial testing has shown promising results.
- Senseair has started validation testing of the Gen 3.3 sensor based on the SAE J 3214 specifications. The testing includes electrical testing, accuracy, precision, durability, environmental and analytical specificity tests, focusing on life-time testing. To date, roughly half of the testing has been completed over a period of four months.
- Forty-five Gen 3.3 sensors have been delivered to the DADSS laboratory for testing and evaluation.

Gen 4 sensor development:

- During FY2020, specifications were developed for the Gen 4 sensor, which is intended for passenger vehicle use. The specifications focus on minimizing the total size of the sensor, maintaining, or improving the sensor measurement performance, reduced start-up time, a mechanical design suitable for high volume production, and enabling integration into personal vehicles.
- Based on previous sensor generations, ten initial concepts have been reduced to three, based on cross functional reviews weighing pros and cons for each concept. These three designs will be further evaluated to determine which one will be the final design of the Gen 4 sensor.
- Several suppliers have been identified as candidates for the Gen 4 design and the most promising components have undergone an initial evaluation. Based on these results, the decision was made to move ahead with system-level testing. Prototypes for system-level testing are currently under construction.

Touch Sensor

The touch sensors allow estimation of blood alcohol concentration by measuring alcohol concentrations in the driver's finger tissue (or more specifically the blood in the capillaries). The driver touches an optical module and a near infrared light shines on the driver's skin and propagates into the tissue. A portion of the light is reflected back from the skin's surface, where it is collected by the touch pad. This light transmits information on the tissue's chemical properties, including the concentration of alcohol.

The shift from the Phase I prototype, which used a traditional Michelson interferometer that utilizes moving parts, to a solid-state laser spectrometer, which is better suited to the automotive environment, has required extensive hardware and software research.[18] The key to such innovation was the ability to define an optimized subset of optical wavelengths to enable high-quality, non-invasive alcohol measurement. It was determined that the new spectrometer required the use of modulated laser diodes[19] 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 has been undertaken to develop the requisite laser diodes, many of which have not been previously manufactured, and assemble them in multi-laser packages. The individual lasers 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 supplier, Nanoplus, was selected with greater expertise in these areas. Each stage of the development process has required research and has resulted in multiple patent applications.

As with any new technology development, technical difficulties have been experienced along the way. For example, research on the Gen 3 touch sensor revealed a problem with fluctuating laser intensity that could result in unreliable tissue alcohol measurements.[20] Problems also were encountered with the integrating sphere[21] which combines the output from the individual lasers into one broader, diffuse light source that then shines into the finger. Researchers discovered that there was a lack of homogeneity in the combined light source causing the laser light to hit the sample and reference detectors differently. The reference sensor provides a baseline measurement against which the refracted signal from the finger is compared. Thus, if the two laser signals differ, the comparison, and hence alcohol measurement, cannot be effectively performed.

The recent evolution of the touch sensor is depicted in Figure 5. Since February 2019, ACTS has taken over the development of the new Gen 4 touch sensor with input from Nanoplus and other experts in the spectroscopy and optics fields. The touch sensors consist of the laser diodes, the laser guiding system to relay the laser signal into the skin in the prescribed fashion for optimal measurement, the detectors to receive the reflected signal, all of which reside in the driver optical interface, a reference sensor, and the electronics board that controls

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[18] 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.

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

[20] 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.

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

and guides the system. Each of these design elements will undergo significant enhancements from the current Gen 4 device. Gen 5 availability, suitable for fleet and accessory applications, is targeted for 2023. The Gen 6 version aimed for use in privately-operated vehicles is anticipated to be available during 2024-2025.

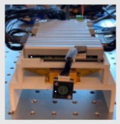
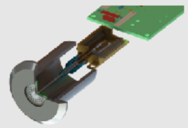
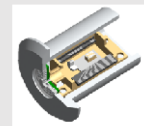
 2020	 Target 2023	 Target 2024-2025
GEN 4	**GEN 5**	**GEN 6**
• 20–laser (discrete laser architecture)	• 4 tunable lasers	• 2 tunable lasers
• Fiber coupled lasers	• Waveguide–coupled lasers	• Free space illumination
• Driver Optical Interface → Multi-Photo Diode Detectors	• Driver Optical Interface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

Figure 5. Future evolution of the DADSS touch-based sensor

Figure 6 depicts the recent evolution of laser diode development. As noted above, it was determined that 40 unique wavelengths would be the optimal number to differentiate the alcohol signal from other substances in the blood, such as water. In 2016, the 40 individual lasers were packaged into four discrete packages with 10 in each. The current design comprises 20 laser chips in a single package with each laser chip interrogating two wavelengths to cover the 40 discrete wavelengths. Recently, Nanoplus has been developing tunable lasers 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 current 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 (nm). 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).

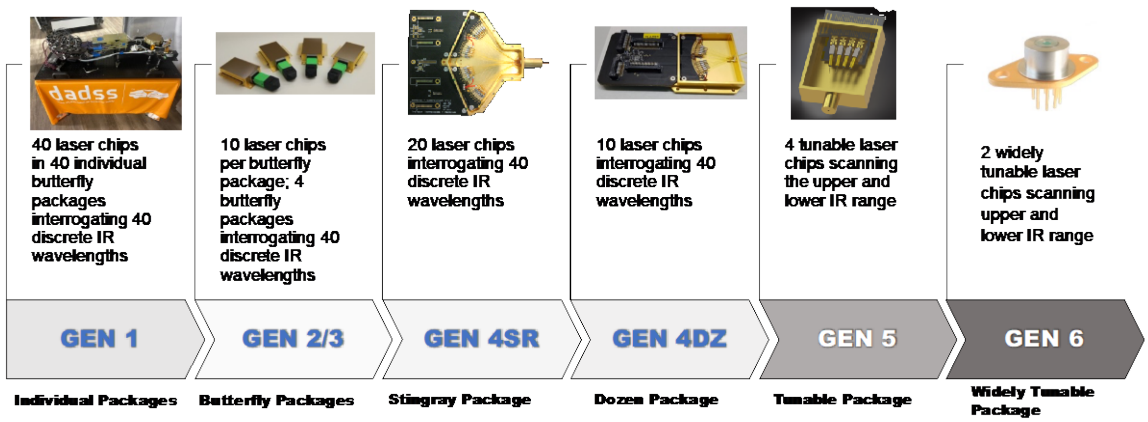


Figure 6. Evolution of laser development

The preliminary design of the Gen 4 prototype touch sensor resulted in a much-improved signal-to-noise ratio (SNR) compared to Gen 3. As can be seen in Figure 7, the Gen 4 sensor is considerably more compact than Gen 3, the components and overall structure of which are shown on the right. ACTS filed a patent on the new design – System for non-invasive measurement of an analyte in a vehicle driver (see Table 1).

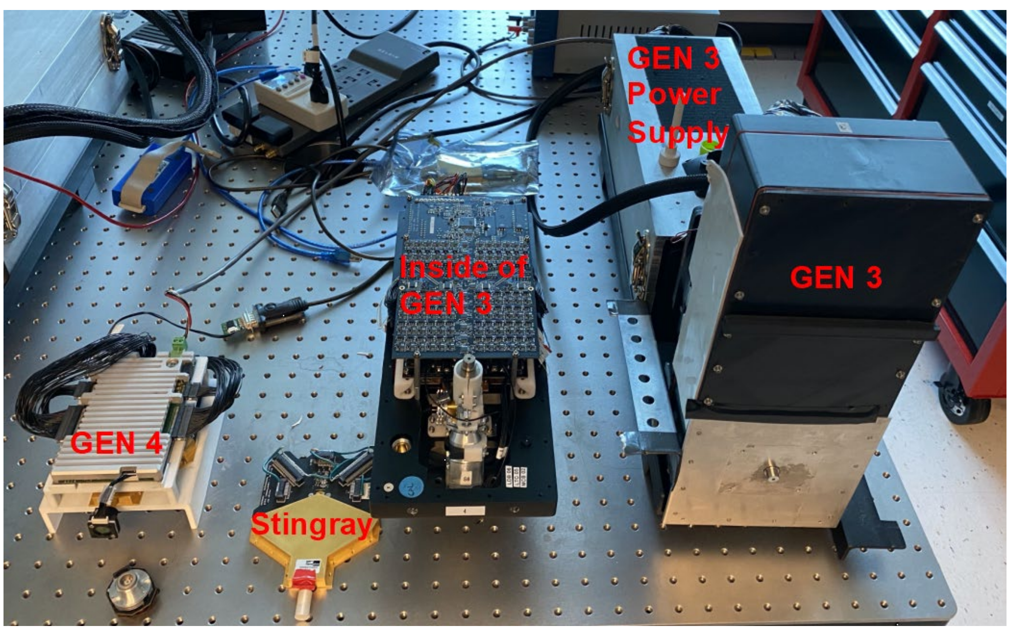


Figure 7. Comparison of Gen 3 prototype touch sensor (right) versus the new Gen 4 prototype

During FY2020, progress has been accomplished in critical hardware, electronics, and software development. Touch sensor function characteristics key 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 need to be homogenized so that the light levels propagating through the tissue are always the same; and 3) levels of background noise need to be low and signal strength sufficiently strong so that the signal can be readily detected when reflected from the tissue. To accelerate progress on sensor development, both KEA Technologies Inc. and Nanoplus, with input from experts in the field of spectroscopy, are working on parallel studies to explore different hardware and software changes to address these issues.

FY2020 accomplishments:

- New Gen 4 touch sensors have been designed to improve performance and address low signal levels, and signal drift, that is slow changes in the signal independent of the measured property. In this design, the integrating sphere was removed, and a new optical interface was designed that resulted in a smaller sensor with significantly improved SNR. In the new design, a waveguide[22] was used to mix the light more efficiently. Modifications also were made to the electronic board and software. The current hardware allows communication with the software so that modifications can be made to the laser parameters with the goal of optimizing studies of the new sensors. One of the advantages of the new sensors is that they have interchangeable parts which allows researchers to combine the components in optimal ways to assemble the best functioning sensor.
- ACTS has secured the services of an optical expert from Synopsys, an electronic design automation company, to work on analyzing and improving the optics of the touch design. The expert has developed a ray-tracing simulation model[23] of the new sensors, the data from which matches the data obtained from the hardware. This model allows simulations of different approaches and helps determine the most effective approach to be studied.
- Progress accelerated in September 2020 due to two new developments. The first development was the use of an off-the-shelf 3-inch integrating sphere for use in the Gen 4 optical interface (see Figure 8). The goal of the unit is to improve homogenization of the light sources and improve the SNR. This unit has been assembled at the DADSS laboratory and is currently being studied. Early results suggest that this new setup enables better detection of water troughs[24] and ethanol signals (500 mg/dL). Two of these setups have been assembled, one of which has been shipped to Nanoplus for parallel study of its performance. The second development was new software developed by the DADSS team that provides access and control over many more laser and measurement parameters. These two factors have allowed more in-depth analysis of how these parameters

[22] A waveguide is a structure that guides waves, such as electromagnetic waves or sound, with minimal loss of energy by restricting the transmission of energy to one direction.
[23] Ray tracing is a method for calculating the path of waves or particles through a system with regions of varying propagation velocity, absorption characteristics, and reflecting surfaces.
[24] A water trough is part of the tissue spectrum. The highest surface part of a wave (spectrum) is called the crest, and the lowest part is the trough.

interact (i.e., homogenization of the light source and SNR), and how to tune each laser for better SNR and more accurate spectroscopy which have greatly increased researchers' understanding of when to take a measurement after a laser fires.

Figure 8. The sensor setup includes a 3" integrating sphere, laser package, and electronic board

- Another avenue of investigation is being pursued to help isolate where in the system the SNR is being most affected. A Quartz Tungsten Halogen light source is being used in the DADSS laboratory that produces light in the visible and near infrared range. Recent tests with this light source show good agreement between the reference and touch sample detectors, suggesting that the lasers are the most likely source of the low SNR.
- Additional investigations have identified the most likely reason for the low SNR as the shifting polarization of the light while each laser is running. When each laser fires, there is a distinct pattern that it creates over time that is a function of the laser passing through the optical fiber. At first the waveforms are densely packed and over time the waves stretch out with increasing variability. This stretching causes measurements to be averaged over a slightly different part of the pattern each time, causing measurement instability that shows up in the touch and reference sensors slightly differently. If the light were completely homogenized this would not be a problem as both sensors would see the same pattern. This phenomenon may be due to temperature fluctuations in some part of the optical system and/or the lasers themselves. Future efforts will target this polarization from three fronts. The first approach will be new optical designs, which will attempt to neutralize the polarization such that both sensors see the same signal. The second approach will be more complex, involving a yet-to-be designed high-

speed data capture. This will allow the use of more complex data algorithms and pattern matching to ensure measurements are always made over the same part of each laser's firing pattern. The third approach will be eliminating the fibers that couple the lasers to the finger sampler with an open air, free space coupling. This is most likely the optimal approach as it appears the fibers are creating this issue.

- Studies are continuing to examine how alcohol measurements are affected by different factors such as temperature, laser intensity, averaging, etc.
- During FY2020, researchers successfully conducted Gen 4 touch sensor testing of the ethanol signal in two different samples - one with alcohol and one without.

Electronics accomplishments:

- Three boards are being designed to create a new measurement system, including a measurement board, a power supply and communications board, and a transimpedance amplifier[25] board that attaches directly to each diode. A large part of the SNR problem stems from low signal levels received from some of the laser photodiodes, as well as a wide variation of amplitudes over all 40 laser wavelengths that the current system cannot optimally handle. Sample signal amplitude varies from around 1 millivolt to above 1 volt. For the lower signal frequencies/amplitudes it is hard to distinguish the signal from the background noise with the fixed gain of the current measurement system. Thus, to improve the SNR, and hence improve the ability to measure the signal, a measurement interface will be needed with the ability to increase the amplitude of the lowest signals so that they measure closer to the highest amplitudes. The new measurement board can automatically increase the signal level sent from the photodiode before taking a measurement. The power supply and communication board features upgraded thermoelectric coolers that will improve regulation of the laser temperatures. It also has a much cleaner power supply that has non-fluctuating voltage. External photodiode amplifier boards will boost the very small photodiode signals locally before they travel down long cables to the measurement board, making the signals less sensitive to external noise compared with the prior design of having the signal boosters at the far end of the cables. This eliminates a major opportunity for noise to enter the signal chain

Software improvements:

- The software interface has been modified and updated with more features to control the different parameters on the laser.
- A new graphical user interface provides quicker analyses and creates more detailed data analysis reports, thus providing faster information on

[25] A transimpedance amplifier is a current-to-voltage converter used to process the current output of photodiodes.

how data tracks or changes over time. Another very useful feature is the ability to allow thousands of test results to be organized into trend graphs.

Performance Specification Development

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

In addition to the DADSS Performance Specifications, draft performance specifications for the Gen 3.3 breath sensor were initiated in October 2019 (FY2020). This device is intended for motor vehicle fleet applications and will determine if the driver is registering any breath alcohol. The draft specifications define the accessories' technology performance as it relates to accuracy, precision, speed of measurement, influence of the environment, issues related to user acceptance (such as instructions for use), long-term reliability, and system maintenance requirements. Access to the data memory or the ability to set operational parameters, including the setting of BrAC concentration thresholds will be designed to deter unauthorized or inadvertent tampering. The device will be designed to meet international specifications and standards for alcohol measurement devices[26] currently in place in the United States, Canada, and Europe. Efforts also are underway to establish an SAE J standard (SAE J3214) that will be specific to the zero-tolerance breath sensor. Unlike alcohol ignition interlocks, this fleet device, operates without a mouthpiece and measures diluted breath samples. It also has more stringent requirements, especially with respect to the calibration curve and test gases.

Sensor Calibration Device Research

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

[26] 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.

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

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

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

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

Once developed, the SRMs composition, accuracy, and precision has to be confirmed at the DADSS specifications. The instrumentation necessary for such verification has to exceed the DADSS performance specifications by a significant order of magnitude. The specified accuracy and precision of the DADSS sensors is 0.0003 at a BAC of 0.08g/dL. This requires the surrogates to be measured with instrumentation that can meet a precision target of 0.000075 and match the most accurate SRM. 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 identify or confirm the chemicals in the sample as well as quantify accuracy and precision at the levels required. For the tissue calibration device, a Waters Acquity High-Performance Liquid Chromatography (HPLC) device with mass spectrometry, refractive index, and UV-Vis detectors was selected (see Figure 9). 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.

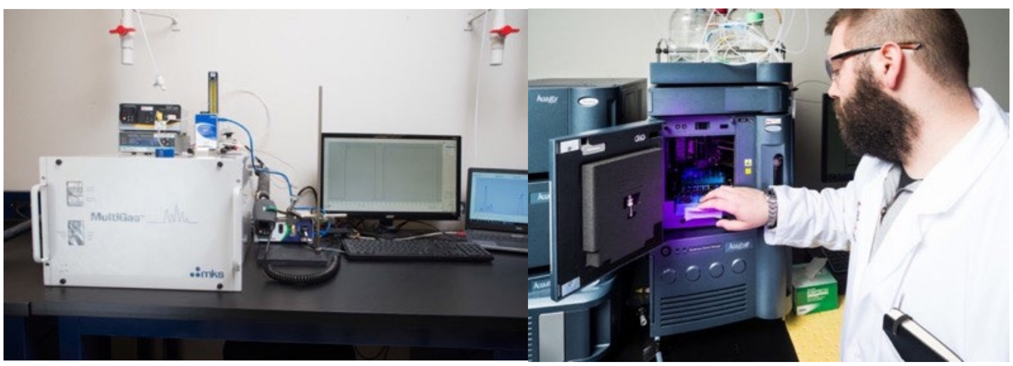


Figure 9. MKS Multigas 2030 FTIR and Waters Aquity HPLC in the DADSS Research Laboratory

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

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

An initial version of a portable device has been 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 10). 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 10. 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 similar testing regimens in the laboratory.

Despite the pandemic, research and development has continued in FY2020 and has resulted in progress in many areas:

- Improved testing methodology. The ABBS has previously relied on helium as a component gas. Due to helium shortages in recent years, a research program examined the possible replacement of helium with nitrogen gas, which is much more widely available. The DADSS team has been successful in making the change during this fiscal year.
- Sensor testing. Multiple sensors are tested at one time, although until now, a researcher had to be involved during the testing sequence. Recent software changes have been successful in improving testing efficiency by automating the testing process.
- Human subject driving trials breath snorkel design. Researchers have conducted preliminary testing on Gen 3.2 sensors to examine the effects on breath dilution and alcohol measurement of the design or shape of the delivery system (termed snorkel) that connects the breath inlet port to the breath sensors in the steering wheel, driver- and passenger-side

doors, and passenger dashboard (See Figure 11 for examples of snorkel designs). The initial results showed little effect on sensor performance from variations in gas flow rate, but some differences were seen comparing testing with and without the snorkels attached to the sensors. A follow up study is planned to investigate the effects of snorkel length, width, and material composition in conjunction with breath flow rate, percent humidity, and test distance using the latest Gen 3.3 sensors. Results from these tests will be used to inform future snorkel design.

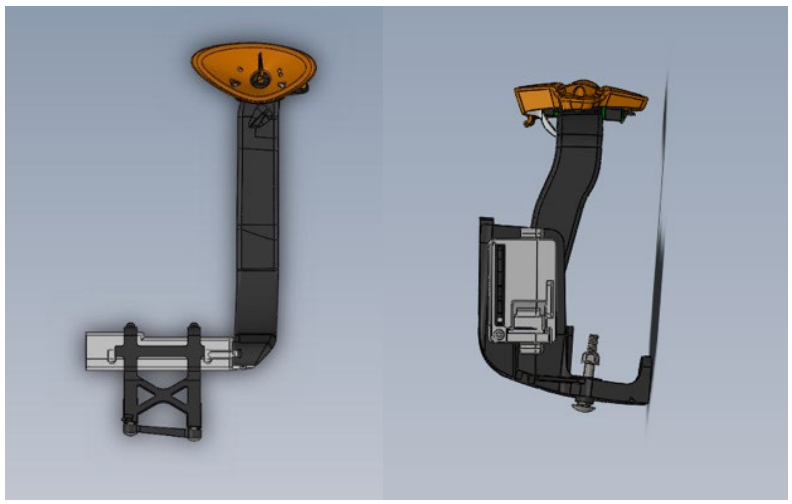


Figure 11. Design of breath sensor delivery systems (snorkels) from the breath inlet port to the sensor

- <u>Sensor improvements.</u> In-vehicle, human subject testing of the Gen 3.2 sensors indicated rare instances of EMI from cell phones, thereby potentially affecting breath-alcohol measurements. Two wraps, nickel, and copper were developed for the sensors in order to mitigate this interference. The new wraps were tested using regulated EMI exposure and characterization testing in the laboratory. An antenna was aimed at the sensors in a couple of different configurations and intensities (i.e., 75V/m or 50V/m) and although no alcohol was introduced to the sensors, the ethanol channel was measured. When the sensors were not wrapped or wrapped with nickel, the sensors were indicating the presence of alcohol. This effect was mitigated with the copper-wrapped sensors. In the future, all Gen 3.2 sensors will be installed with the copper wrap.
- <u>Sensor degradation testing</u>. After being installed in vehicles for six months, 12 Gen 3.2 sensors were removed and recharacterized in the laboratory to ensure that there was no notable change in sensor performance during the time of installation. Results showed no significant change in sensor performance during that time.
- <u>Sensor testing</u>. A total of 119 Gen 3.2 sensors (73,157 data points) have been tested to date.

- Gen 3.3 sensors. Beginning in April 2020 through the end of FY2020, 45 Gen 3.3 sensors were received from Senseair. These are the sensors that will be used for fleet applications. It is expected that by the end of 2020, 150 sensors will have been received. So far, 24 Gen 3.3 sensors (13,824 data points) have been characterized and data analysis is underway.
- Improvements to the testing system and methods. Improvements to the precision, accuracy, and efficiency of the test system and test methods are ongoing. Investigations are examining how junctures in the test system and heating throughout the delivery system affect the test results. These results are being used to redesign and improve the test system to ensure that no bias is affecting the sensor characterization results.
- Reference sensor testing. Testing of two different models of reference sensors used in human subject testing (Smart Start and Intoximeter) was undertaken to ensure that a reference bias was not present for the human subject test (HST) and human subject driving (HSD) results. The reference sensors were tested with traditional wet gas simulators, traditionally used when testing alcohol ignition devices, and a dry gas from the ABBS unit. Results showed some variation between individual sensor results, but all of the sensors in question passed Europe's CENELEC and NHTSA standards and specifications at their concentration ranges.
- New patent application. The chemistry laboratory filed a patent for the ABBS system titled Method and Apparatus for Producing a High Precision Blended Gas Mixture Comprising a Volatile Analyte (see Table 1).
- Development of a tissue surrogate. The laboratory has developed and tested gelatin samples containing up to 3000 mg/dL of ethanol using both the prototype touch sensor and the FTIR instrumentation. The results will be helpful in establishing a spectroscopic model for ethanol using the gelatin samples. The gelatin samples have shown very good stability in alcohol concentration and the quality of the gel over a 3-month period (Figure 12 shows samples of the gelatin tissue surrogate).

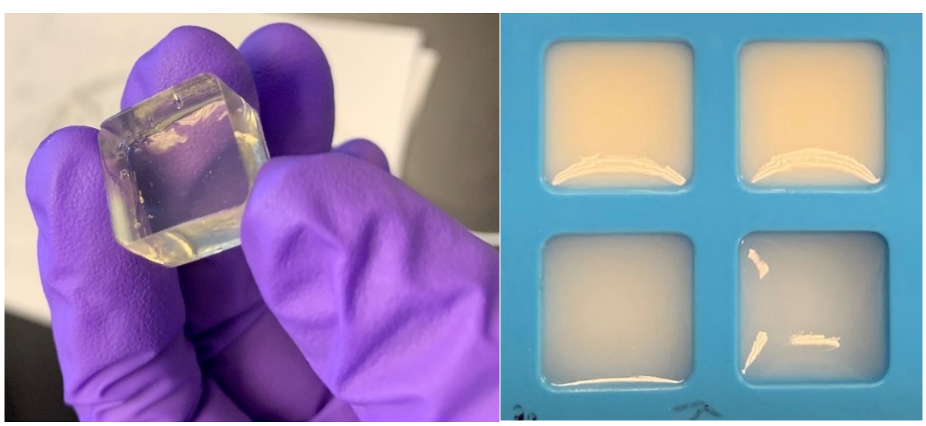


Figure 12. Gelatin tissue surrogates to simulate human tissue

Human Subject Testing

Human subject testing, also referred to as in vivo testing, is a critical part of understanding how the DADSS sensors will perform in the real world when confronted with large individual variations in the absorption, distribution, and elimination of alcohol within the human body (i.e., blood, breath, tissue) and across the many factors that can affect alcohol concentration. Past research has provided a clear understanding of these factors with respect to venous (blood) alcohol and breath-alcohol when samples of deep lung air are used. However, the new alcohol measurement methods being developed under the DADSS program, which determine alcohol levels from diluted breath samples and within human tissue, are not well understood. In particular, the rate of distribution of alcohol throughout the various compartments of the body under a variety of scenarios has been the subject of ongoing study.

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

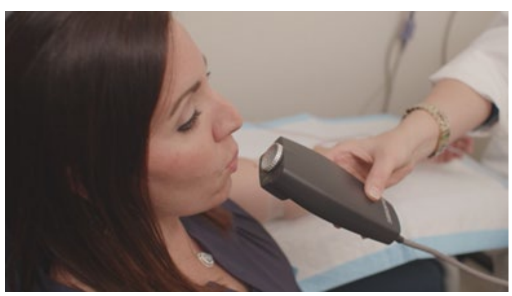


Figure 13. Human subject testing using the DADSS breath sensor

The purpose of human subject 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 among a wide cross section of individuals of different ages, gender, body mass index, race/ ethnicity, and using the different scenarios.

- To understand and analyze the performance of in-vehicle DADSS sensors through measurements of alcohol among dosed passengers across a range of real-world environmental driving conditions (i.e., differences in elevation, humidity, temperature, and presence of salt in the air).

Many insights already have been gained regarding the alcohol absorption and elimination curves and maximum BACs/BrACs reached by human subjects in a variety of real-world scenarios (i.e., length of time for alcohol to appear in each compartment, effects of snacking, dining, exercise, and "last call" on alcohol measurements). These studies have confirmed a solid linear relationship between blood, directed breath (using the DADSS breath sensors), and tissue alcohol measurement (using the Phase I tissue prototype device) over a wide range of BACs (0.04-0.12 g/dL).[27] Details regarding on-the-road subject testing during FY2020 are provided in a following section.

McLean Hospital laboratory testing:

Human subject testing was suspended in March 2020 when COVID-19 restrictions were put in place. The restrictions were relaxed in August 2020 and testing was resumed in September 2020. During the shut-down, McLean Hospital health coordinators worked diligently to develop safety procedures to protect participants. Moreover, the McLean Hospital laboratory has acquired an Abbotts Rapid COVID Test apparatus to test participants and staff prior to participating in studies to ensure they are COVID free. The touch sensor was withdrawn from testing during FY2019, and will resume testing when the Gen 4 touch sensor is considered ready for human subject testing, which is expected in late 2021 or early 2022. Details of FY2020 achievements in the laboratory are provided below.

- During the fiscal year, 33 subjects participated in new scenarios identified as potentially important in breath alcohol measurement, including the effects of drinking low dose beer (0.3 g/kg), standard dose beer (0.5 g/kg), and non-alcoholic or near beer (<0.005 g/kg alcohol). Also examined were the effects of drinking wine, the effects of combining an energy drink with vodka, and the effects of smoking tobacco while consuming vodka.
- Consuming beer at different doses causes the expected rise in BAC and BrAC, but the measurements from the breath sensors and Alcosensor-FST (reference sensor) consistently read higher than blood alcohol at the outset due to mouth alcohol (see Figure 14). The green line represents

[27] 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.

the Gen 3.2 breath sensor, and the blue line represents the reference sensor (labeled "intox"). Furthermore, breath samples collected between 60-90 minutes after consumption can have higher BrAC spikes. It is well known that alcoholic drinks with carbonation can play a role in altering BrAC because belching after drinking can cause a high breath alcohol concentration[28]. However, the source of the alcohol is from the stomach and not the lungs. This could explain the more variable increases in BrAC compared to BAC.

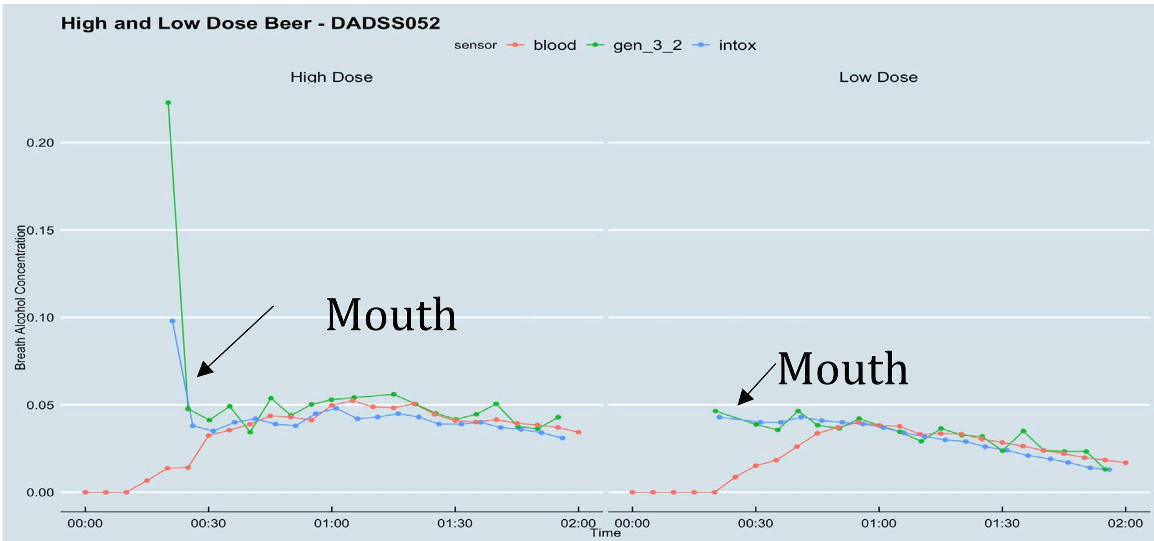


Figure 14. Breath and blood alcohol measured after drinking high and low dose beers

- The consumption of non-alcoholic beer, that is beer containing less than 0.5 g/dL alcohol, resulted in measurable amounts of alcohol in breath, but not blood samples. The BrAC appeared within two minutes, peaked within 0.01-0.03 g/dL, and persisted for 15-17 minutes after consumption. Non-alcoholic beer contains a small quantity of alcohol, which, when combined with carbonation can give rise to detectable amounts of breath alcohol. These measurements are below the DADSS 0.08 g/dL limit so would be unlikely to prevent driving. However, the Gen 3.3 fleet sensors that are set to detect any alcohol may initially register alcohol presence.
- 1,047 additional blood samples were analyzed, and the intra assay coefficient of variation was 1.41% (range 0.68-2.62%), which is considered very good in the blood testing field.

[28] New Scientist. 2001. Champagne does get you drunk faster. https://www.newscientist.com/article/dn1717-champagne-does-get-you-drunk-faster/

- Studies examining the effects of drinking alcohol while smoking traditional and electronic cigarettes are ongoing.

Methodology:

New methods that were developed to accommodate the new testing scenarios are provided below:

- The laboratory developed an “octopus-like” mounting system that can hold up to four breath sensors, as well as a meter to measure particulate matter ($PM_{2.5}$) in various positions around the participant’s face. This meter can detect very fine particulate matter 2.5 micrometers and smaller, including from cigarette smoke. Using this system, it is possible to simulate the physical position and distance that the breath sensors would be from a driver when installed in the vehicle. This arrangement also allows direct comparison of the performance of multiple sensors when testing them simultaneously.

Human Subject Driving Tests

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

Now that the breath sensors have performed well in extensive laboratory and human subject testing, the Gen 3.2 breath sensors have been utilized for testing in real-world driving environments. The vehicles also have the capability to accommodate one touch sensor when the technology is ready for real-world testing. Both a reference sensor (SmartStart’s alcohol ignition interlock device) and the Gen 3.2 breath sensors are integrated into each research vehicle to measure breath alcohol – two Gen 3.2 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 15 orange inlet ports). The Gen 3.2 sensors can measure both directed and passive breath. The reference sensor provides a comparison measurement and requires a deep lung sample of breath delivered through a plastic tube. The reference sensors provide information on sensor sensitivity (i.e., true positives), validity, and reliability.

Figure 15. Position of the breath sensors on the driver (left) and passenger sides of the vehicle

Along with the alcohol sensors, the Chevrolet Malibus are equipped with a comprehensive DAS, two video cameras, a web interface[29], data and video storage, and a user interface module for use by the passengers (Figures 16 and 17).

Figure 16. Equipment located in the trunk, from left to right, DAS, WIFI LTE, network switch, and DVR

Figure 17. User Interface Module (UIM)

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

Routes were chosen to provide varying climactic conditions, such as low and high temperatures, low and high humidity, at varying elevations, and in corrosive environments. The variety of conditions allows for a more in-depth analysis of the sensors performance in the operational context for which they are designed. Figure 18 provides a map of one of the driving routes being utilized in Massachusetts, including higher elevations and beach environments. A snapshot of the data viewer which can provide ongoing information about each of the trials is shown in Figure 19.

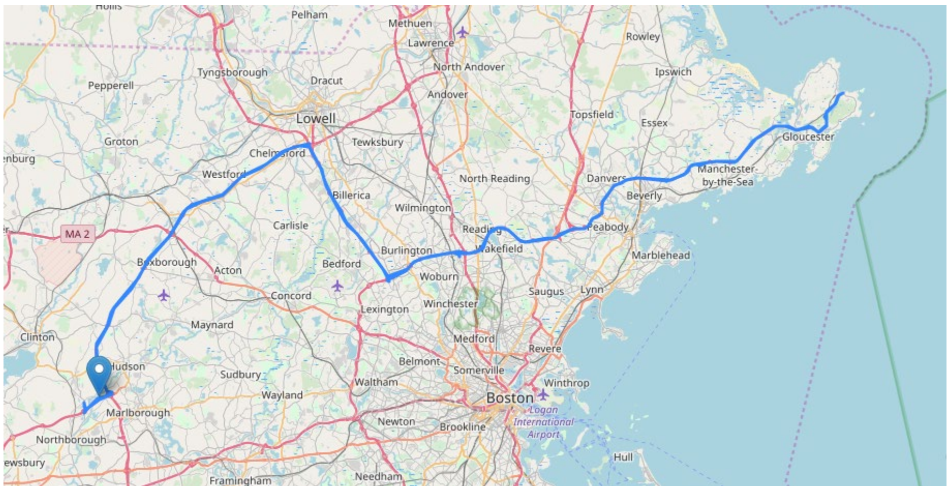


Figure 18. One of the planned Massachusetts driving routes

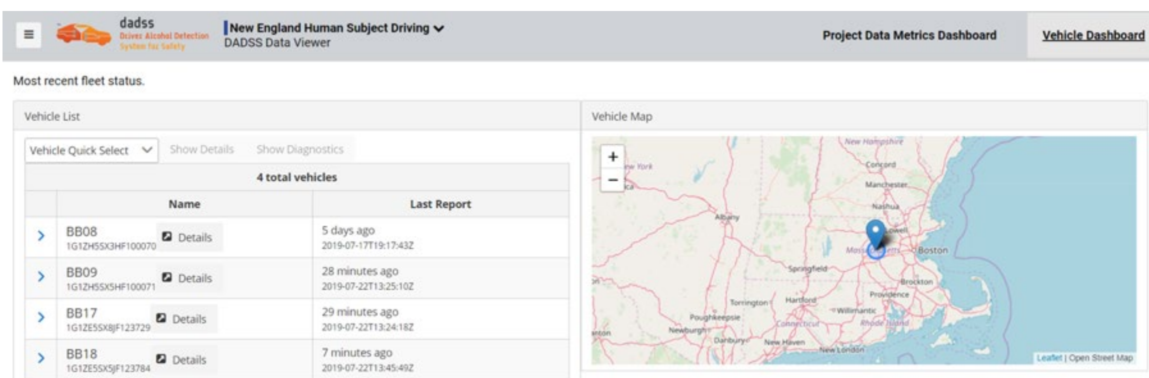


Figure 19. Data viewer

The HSDs commenced in June 2019. Recruitment of the test subjects is being conducted by KEA Technologies, Inc. and Mclean Hospital. Many of the test subjects have previously participated in DADSS human subject testing at the McLean Hospital laboratory, affording researchers the opportunity to compare subjects' laboratory and in-vehicle data. Results from these tests will be critical in determining the effectiveness of the DADSS sensors in a wide range of environments including the impact of environmental factors on sensor function over time, the impact of repeated use and vehicle mileage, the impact of vehicle vibration, and user interactions with prototype devices in a vehicle environment, including driver behavior and user acceptance.

Study participants are brought into either the DADSS or McLean laboratories prior to the study. The risks and benefits of the study are explained to them, and if they are comfortable with the study requirements and choose to participate, they sign the informed consent form. Subjects are screened for drug and alcohol presence, and they are familiarized with the vehicle set-up and protocol. After height and weight measurements are taken and the appropriate doses of alcohol are calculated, they are dosed 2-5 shots of vodka over a period of up to 20 minutes. The subjects are passengers in the vehicle, and their alcohol measurements are collected frequently from the breath and reference sensors. The passengers are instructed by a second research assistant in the vehicle to direct their breath in a prescribed sequence toward the DADSS breath sensors in the vehicle. The current methodology permits collection of BrAC on up to four different sensors every 3.5-4 minutes for up to eight hours. The research assistant also monitors the subject's condition.

During the driving phase, the DADSS sensors passively sniff and analyze the vehicle cabin air for the presence of alcohol. In addition, drivers are asked to provide breath samples at the beginning and end of each study period. Additional vehicle instrumentation tracks environmental conditions and vehicle system data while providing participant videos. It should be noted that the vehicle windows are always in the closed position during driving trials. Technical data gathered in these operational environments will also be used to refine the DADSS Performance Specifications, and to improve system design and product development.

Human subject driver testing was conducted from October 1, 2019 until being suspended on March 12, 2020 due to the COVID-19 pandemic. Once the testing resumes, the Gen 3.3 sensor will be installed in the test vehicles in the four existing locations: two on the driver-side and two on the passenger-side. Accomplishments for FY2020 are provided below:

HSD protocols and trials:

- Testing was continued in four research vehicles. Routes tested include beach/coastal and hill locations. Beach locations will determine the effects of high concentrations of salt and moisture in the air. Hill locations will provide data on the effects of high altitudes and thin, dry air on sensors' performance. Testing spans all four seasons, allowing testing in cold and hot weather, humidity, rain, and hail. Between August 2019 and March 2020, the vehicle registered outside temperatures from -9.5 to 53.5 °C; 14.9 – 128.3 °F, with an average temperature of 13.9 °C , 57 °F.
- In FY2020, 77 human subject studies were conducted (56 from the DADSS laboratory and 21 from the McLean Hospital). A total of 177 studies have been conducted since the study began in June 2019. To date, 82,503 breath sensor samples have been provided of which 43,311 were breath sensor passenger samples (6,276 directed breath samples), 34,721 breath sensor driver samples, and 4,471 reference sensor samples.
- Following the shut-down of field trials due to the pandemic, in June 2020 KEA Technologies Inc. personnel began to conduct in-vehicle testing

while sober and were sometimes accompanied by a sober family member. The aim was to gain a better understanding of how the driver-side sensors are performing with zero alcohol. This information, which is for internal use only, will be valuable when moving to testing the next generation of sensors, Gen 3.3. Fifty-five sober drives have been undertaken so far, 18 of which included a household member in the passenger seat.

Methodology:

- The DADSS team mounted a small, 3.5-inch screen on the dashboard, which displays real time BrAC values, and the breath dilution factors (see Figure 20). The display is only used for research purposes.

Figure 20. In-vehicle display of breath alcohol and breath dilution factors

- Procedures were developed to conduct in-vehicle evaluations of the effect of EMI within the vehicle. Researchers added a monitor of the four breath sensors to display graphs of carbon dioxide, and BrAC readings. They were able to observe, in real time, EMI from some electronic devices, such as cell phones. The following studies were conducted to better understand the EMI effects:
    - Subjects were tested sober for the first hour of testing prior to alcohol dosing.

- Drives were undertaken with mobile phones off, or in airplane mode.
- Testing was conducted in cell-service dead zones.

Sensor EMI mitigation

- Studies were conducted in the DADSS chemistry laboratory to develop sensor coatings that could mitigate the effects of EMI on alcohol measurements. It was found that copper coatings were the most effective (see section on Sensor Calibration Device Research above). Sensors from three of the HSD vehicles have been removed and recharacterized in the DADSS laboratory prior to wrapping and shielding the sensors and cables with copper. The vehicles were re-instrumented with the cables and test drives were conducted with KEA Technologies Inc. personnel to stress test the system and hardware to ensure that everything was in working order.

The Gen 3.2 trials have helped drive algorithm and sensor development of the Gen 3.3 fleet vehicle accessory device. Once human subject testing resumes, the Gen 3.3 sensor will begin in-vehicle testing. The Gen 3.3 device is being engineered to pass the SAE-J standard, which is more stringent that the CENELEC standard. Field studies will be resumed once it is safe to do so. Some issues that are pertinent to COVID-19 potential human transmission include the fact that participants need to be unmasked to provide breath samples and that social distancing is not possible in a vehicle between the driver and the passenger.

Consumer Acceptance Research Program

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

In Phases II and III, qualitative and quantitative research was undertaken to explore public perceptions about and receptivity to the DADSS in-vehicle technology. The most recent public opinion survey was undertaken in January 2020. Just over 1,000 drivers ages 21 and older completed an online survey, with a 95 percent credibility interval of $\pm$ 3.53 percent. Participants provided an opinion of the following statement "A new driver alcohol detection technology is under development that will measure a driver's blood alcohol concentration (BAC) level when their vehicle is started. If a driver's BAC level is over the legal limit the vehicle will not shift into gear and will not move." Almost three quarters of drivers said they had a favorable opinion of the DADSS technology (73 percent), and this favorability reached 80 percent with young male drivers ages 21-34 and women ages 55 and older. Favorability also was high among drivers who had a conviction for drunk driving (75 percent) and who admitted they drove after drinking (74 percent). Reasons for favoring the technology included that the technology prevents drunk driving, is non-invasive and convenient, and is especially helpful for young drivers. Many of those surveyed also felt that it was an inevitable technology for vehicles.

A key component of the public face of the technology has been the DADSS website which provides multiple resources, including updated videos that make the technology and its development accessible through straightforward explanations of the key concepts. The website can be found at https://www.dadss.org/.

FY2020 activities in this area consisted of:

- Updates for the DADSS website including, security updates, news and update pages, recent progress with the DADSS technology, and updates to various events in which the DADSS team has been involved.
- Elevating presence on social media including a Twitter account, which is used to highlight key events and accomplishments.

State Programs

Virginia

In 2016, Virginia became the first state to partner with the DADSS Program through the Department of Motor Vehicles (DMV). The partnership is known as the Driven to Protect™ Program. Prototypes of the DADSS breath sensors were integrated into four James River Transportation (JRT) commercial fleet vehicles in Richmond, Virginia. The data and feedback collected from the prototype sensors, as well as from the drivers themselves, will be used to improve the technology as it is prepared for commercialization.

Pilot DADSS Deployment Project:

Prior to the beginning of the integration into the JRT fleet, a DADSS-owned 2015 Ford Flex "Platform" Vehicle was equipped with the breath sensors and measurement equipment for system assessment and stress testing. The pilot deployment with JRT was initiated in FY2018 and has continued through FY2020. Four fleet Vehicles (2015 Ford Flex airport livery vehicles) were included in the original 2018 field tests. In FY2019, the latest Gen 3.2 sensors were installed in two of the 2015 Flex vehicles and data gathered for performance assessment and comparison across generations of sensors. In late FY2020, the 2015 Ford Flex vehicles were decommissioned, and two 2019 Ford Flex vehicles were installed with the latest alcohol detection software and equipment. Since April 15, 2020, the JTR vehicles have not been active due to the pandemic.

Deployment details since the inception of the program through FY2020 include:

- The vehicles have been in operation 7,979 hours, over the course of 778 days and have been driven 51,930 miles. During that time 46,664 samples have been collected.
- Nineteen different drivers operated the test fleet vehicles and provided feedback about the sensors.

Communications and Consumer Awareness:

In addition to the field studies, the Driven to Protect Program has conducted a series of outreach events each year. Due to the pandemic, in-person events were cancelled or postponed in 2020. An "Ask the Experts" Webinar event was conducted in August 2020 and was moderated by the Virginia DMV with DADSS leadership answering participant questions.

The following outreach events were conducted prior to the pandemic:

- The VP-1 Demonstration Vehicle was featured at the 37th annual Manassas Jubilee Festival in October 2019.
- The Neptune Festival in Virginia Beach in September 2019.

During the pandemic, the DADSS team has created educational opportunities for the general public and high school students through the development of online materials and the creation of Science, Technology, Engineering, and Mathematics (STEM) modules. The self-directed learning modules aimed at the general public cover a number of areas including modules on alcohol-impaired driving in Virginia and the United States; information about how alcohol is processed by the body and the effects of alcohol in relation to BAC; an on-line, game-based learning platform Kahoot, in which participants can undertake an individual challenge to determine whether a statement regarding alcohol is fact or fiction; and a technology module that provides an overview of the DADSS breath and touch alcohol detection technology development.

Four self-directed STEM modules have been prepared, primarily for 10th and 11th graders, that include: a module on the DADSS bench-top testing system; a spectroscopy experiment module, which explores the principles of spectroscopy, study of interaction between chemicals and electromagnetic radiation, and its real-world application in the DADSS Program; a basic data analysis module, which shows how data are collected in field trials and how statistics are used to understand the sensor's performance in real-world applications; and an advanced data analysis module, which shows how technical data are analyzed, describes the data using statistics, and teaches concepts such as false positives and negatives, and sensitivity and specificity as they relate to the DADSS sensors.

In addition to these learning modules, three on-line videos have been prepared that provide an overview of the breath-system vehicle installation process; a day in the life of a sensor that provides a first-hand look at the rigorous testing procedures that a breath sensor undergoes to ensure that it is ready for installation; and a video that showcases DADSS and the Driven to Protect demonstration vehicle that has been used at various events in Virginia.

Maryland

Beginning in March 2019, the State of Maryland entered into an agreement with ACTS and launched its partnership with the DADSS Program and the Maryland Department of Transportation’s Motor Vehicle Administration (MDOT MVA) to test advanced prototype driver alcohol detection sensors installed in state–owned vehicles. One DADSS-MD Demonstration Vehicle was instrumented and delivered to MVA Headquarters in mid-July 2019 for use by Maryland MVA at vehicle and traffic safety events. The demonstration vehicle was prominently featured at the Maryland Association of Counties Events, held 14-16 Aug 2019, during which time Maryland Governor Hogan announced the Maryland partnership with DADSS.

Pilot DADSS Deployment Project

The DADSS team completed the system architecture, design, development, installation, and test of seven Ford Fusion state vehicles. One Platform Ford Fusion (the "blueprint" for the six on-road test vehicles) was instrumented in late FY2019 and early FY2020. All seven instrumented vehicles were driven by MDOT MVA personnel in the normal course of business. Data was collected for 105 days beginning December 18, 2019 but was suspended in April 2020 due to the pandemic. During that time, the vehicles were operated for 373 hours, driven 1,724 miles, and 10,028 samples were collected. Once operation of the vehicles resumes, data collection will recommence.

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 FY2020, four patents were issued, six new patents applications were filed and pending, and nine 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[30] patent applications in the major automobile producing nations of the world to ensure production of any DADSS subsystem may proceed without threat of interruption. Specifically, applications are being prosecuted in China, the European Union, Canada, Hong Kong, Japan, South Africa, and the United States. Secondly, to further enhance the implementation of DADSS technology, the Board of Directors of ACTS has directed that the DADSS technology be made available on equal terms to anyone who, in good faith, wants to use the technology. Finally, ACTS, in coordination with NHTSA, has structured ownership of the intellectual property generated through this research so that it vests with ACTS (a 501(c)(4) nonprofit) and not the individual members of ACTS or the DADSS technology providers. This helps to facilitate commercialization as rapidly as possible in at least two ways. Firstly, the pooling of resources by NHTSA and ACTS provides a reliable and cost-effective basis to promote the standardization of the technology, its widespread deployment, and acceptance by the general public. And secondly, ownership by ACTS avoids hindering commercialization through blocking patents which might

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

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

Table 1 summarizes the intellectual property generated to date under the DADSS Program. One new technology innovation was developed with one provisional patent application filed. The bankruptcy court has ruled that four of the issued Takata patents for a system and method for disabling a vehicle are the property of ACTS and are listed at the end of Table 1.

Table 1. Patent applications to date

TITLE	COUNTRY	STATUS	APPLICATION #
MOLECULAR DETECTION SYSTEM AND METHODS OF USE	United States of America	Closed[31]	13/838,361
SYSTEM FOR NONINVASIVE DETERMINATION OF ALCOHOL IN TISSUE	United States of America	Closed	61/528,658
SYSTEM FOR NONINVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Closed	13/596,827
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Issued	15/090,809
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Pending	16/161.857
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	China	Issued	ZL201280042179.6

[31] The term closed means that the patent no longer is being pursued.

SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Germany	Closed	NOT ASSIGNED
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	European Patent Office	Pending	12827669.8
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Hong Kong	Pending	14109310.8
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Japan	Closed	2014-528520
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Japan	Pending	2016-176239
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Japan	Pending	**2018-235318**
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	South Africa	Pending	2014/02304
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	PCT	Closed	PCT/US12/52673
SINGLE/MULTIPLE CAPACITIVE SENSORS "PUSH TO START" WITH LED/HAPTIC NOTIFICATION AND MEASUREMENT WINDOW	United States of America	Closed	61/870,384

SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	United States of America	Issued	14/315,631
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	United States of America	Pending	16/928,500
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	Canada	Pending	2,920,796
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	China	Issued	ZL201480047728.8
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	European Patent Office	Issued	3 038 865
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	Japan	Issued	2016-538915
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	South Africa	Pending	2016/00797
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	PCT	Closed	PCT/US14/44350
SEMICONDUCTOR LASER THERMAL CONTROL METHOD FOR COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	United States of America	Closed	61/889,320
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	United States of America	Issued	9,281,658

SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	United States of America	Closed	15/058,650
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	Canada	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	European Patent Office	Pending	14755950.4
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
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	PCT	Closed	PCT/US14/50575
BREATH TEST SYSTEM	United States of America	Pending	14/421,371
BREATH TEST SYSTEM	Canada	Pending	2,881,817
BREATH TEST SYSTEM	China	Pending	201380054912.0
BREATH TEST SYSTEM	European Patent Office	Pending	13830956.2
BREATH TEST SYSTEM	Japan	Issued	2015-528442
BREATH TEST SYSTEM	Japan	Closed	2018-216391
BREATH TEST SYSTEM	South Africa	Pending	2015/01246
BREATH TEST SYSTEM	Sweden	Issued	536784

BREATH TEST SYSTEM	PCT	Closed	PCT/SE13/50991
HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Issued	14/421,376
HIGHLY ACCURATE BREATH TEST SYSTEM	United States of America	Pending	16/215,830
HIGHLY ACCURATE BREATH TEST SYSTEM	Canada	Pending	2,881,814
HIGHLY ACCURATE BREATH TEST SYSTEM	China	Closed	201380054007.5
HIGHLY ACCURATE BREATH TEST SYSTEM	European Patent Office	Pending	13831692.2
HIGHLY ACCURATE BREATH TEST SYSTEM	Japan	Issued	2015-528441
HIGHLY ACCURATE BREATH TEST SYSTEM	Japan	Pending	2018-177686
HIGHLY ACCURATE BREATH TEST SYSTEM	South Africa	Pending	2015/01247
HIGHLY ACCURATE BREATH TEST SYSTEM	Sweden	Issued	536782
HIGHLY ACCURATE BREATH TEST SYSTEM	PCT	Closed	PCT/SE13/50990
HEATER ON HEATSPREADER (HOH) LASER WAVELENGTH MODULATION CONTROL	United States of America	Closed	62/274,543
HEATER-ON-HEATSPREADER	United States of America	Pending	15/343,513
HEATER-ON-HEATSPREADER	PCT	Closed	PCT/US2016/060622
HEATER-ON-HEATSPREADER	Canada	Pending	3.010,352
HEATER-ON-HEATSPREADER	China	Pending	Pending
HEATER-ON-HEATSPREADER	European Patent Office	Pending	16816457.2
HEATER-ON-HEATSPREADER	Japan	Pending	2018-534915
HEATER-ON-HEATSPREADER	South Africa	Pending	2018/05421
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE	United States of America	Closed	62/312,476

BREATH ALCOHOL ESTIMATION			
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	United States of America	Pending	15/389,724
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	PCT	Pending	PCT/US16/68789
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	Canada	Pending	3,018,315
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	China	Pending	201680086043.0
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	European Patent Office	Pending	16826860.5
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	Japan	Pending	2018-549525
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	South Africa	Pending	2018/06358
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	United States of America	Closed	62/171,566
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	United States of America	Issued	15/090,948
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	PCT	Closed	PCT/US2016/026024
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	Canada	Pending	2.987,729
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	China	Pending	201680046009.3

INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	European Patent Office	Pending	16716787.3
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	Japan	Pending	2018-515758
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	South Africa	Pending	2017/08227
PASSIVE BREATH ALCOHOL DETECTION	United States of America	Preparing provisional application	Pending
METHOD AND APPARATUS FOR PRODUCING HUMIDIFIED, CONTROLLED VOLATILE EFFLUENTS USING REAL-TIME FEEDBACK CONTROLS	United States of America	Closed	62/894,038
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	International (PCT)	Pending	PCT/US20/48792
VOICE ACTIVATED START	United States of America	Closed	62/728,898
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	United States of America	Pending	16/566,415
SYSTEM AND METHOD FOR CONTROLLING OPERATION OF A VEHICLE USING AN ALCOHOL DETECTION APPARATUS	International (PCT)	Pending	PCT/US19/50421

SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Closed	62/860,413
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	United States of America	Pending	16/900,088
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	International (PCT)	Pending	PCT/US20/37455
WIDELY TUNABLE, SINGLE MODE EMISSION SEMICONDUCTOR LASER	United States of America	Pending	63/004,816
OCCUPANT SENSOR SYSTEM	United States of America	Expired	61/451,082
SYSTEM AND METHOD FOR DISABLING A VEHICLE	United States of America	Issued	13/415,767
SYSTEM AND METHOD FOR DISABLING A VEHICLE	China	Issued	20128019106
SYSTEM AND METHOD FOR DISABLING A VEHICLE	Europe	Issued	12754647.1
SYSTEM AND METHOD FOR DISABLING A VEHICLE	Japan	Issued	2013-0557868
SYSTEM AND METHOD FOR DISABLING A VEHICLE	PCT	Closed	PCT/US12/28295

Accounting of Federal Funds

Surface transportation reauthorization enacted in 2012, Moving Ahead for Progress in the 21st Century (MAP–21), amended section 403 of title 23 of the United States Code to authorize NHTSA to carry out a collaborative research effort on in–vehicle technology to prevent alcohol–impaired driving.[32] Surface transportation reauthorization enacted in December 2015, Fixing America's Surface

[32] 23 U.S.C. § 403(h) (as amended by Public Law 112–141, enacted July 6, 2012).

Transportation (FAST) Act, amended section 403 of title 23 of the United States Code, continuing the authorization for DADSS research through FY2020.[33]

Funding for DADSS research was provided under the highway trust fund as part of the appropriations legislation enacted for FY2020. Federal funding totaling $4,766,000 was authorized and ultimately appropriated (Table 2).[34]

Table 2. FY2020 NHTSA Funding available for in-vehicle technology research to prevent alcohol-impaired driving

	Fiscal Year 2020
Funding for In–vehicle Technology Research	$4,766,000

The period of performance specified in the 2013 Cooperative Agreement initially covered a five–year period (September 30, 2013 to September 29, 2018) and research was planned for the entire five–year period through FY2018.). In December 2017, ACTS and NHTSA agreed to extend the award to September 2020 – the end of the program's express authorization in the FAST Act. Consistent with the extension, research was planned for the entire agreement period. Table 3 provides a general statement regarding the use of Federal funding for FY2020 to carry out the DADSS research effort.

Table 3. Funding Status

Automotive Coalition for Traffic Safety

Advanced Alcohol Detection Technologies (DADSS)

DTNH22-13-00433

Funding authorized, appropriated and obligated, expended

Funding Authorized & Appropriated – FY2020		**$ 4,766,000**
FY2020 Funding Expended		
Research & Development		$ 4,332,727
Indirect Rate		$ 433,273
	Total Expended	**$ 4,766,000**

[33] 23 U.S.C. § 403(h) (as amended by Public Law 114–94, enacted December 4, 2015).
[34] Further Consolidated Appropriations Act, 2020, Public Law No. 116–94, enacted Dec 20, 2019.