U.S. Department
of Transportation
**National Highway
Traffic Safety
Administration**

1200 New Jersey Avenue SE.
Washington, DC 20590

May 8, 2020

The Honorable Sam Graves
Ranking Member, Committee on Transportation
and Infrastructure
United States Senate
Washington, DC 20515

Dear Congressman Graves:

Enclosed is the Report to Congress, 2018 In-Vehicle Alcohol Detection Research, prepared by the National Highway Traffic Safety Administration (NHTSA) in response to Section 403(h) of Title 23, United States Code. NHTSA publishes an annual report that describes the progress made in carrying out the collaborative research effort on in-vehicle technology to prevent alcohol impaired driving, including an accounting of the use of Federal funds obligated or expended in carrying out this effort.

Since 2008, the Driver Alcohol Detection System for Safety (DADSS) program has focused on the research, development, and assessment of detection technologies capable of measuring a driver's blood or breath alcohol concentration. In this regard, the research has resulted in the development and testing of prototype technology that could be installed in vehicles to prevent the vehicle from being moved if driver BAC exceeds a blood alcohol concentration of 0.08 g/dL, the legal limit in all U.S. States except Utah, which recently adopted a 0.05 g/dL limit. The purpose of this report is to outline the progress accomplished under the program in fiscal year 2018.

Significant progress continues to be made in developing prototype DADSS sensors. One sensor being developed measures alcohol concentration in a driver's breath from the ambient air in the vehicle cabin (breath-based), and the other sensor measures alcohol in the driver's finger tissue (touch-based). Substantial progress was made in FY 2018 in the breath-based sensors' hardware and software that significantly reduced background noise and resulted in a marked improvement in the resolution of alcohol measurement. Improvements were also made to the detector itself and airflow through the system. The current generation of breath sensors now are sufficiently advanced for on-road testing.

Additional progress was made in the assembly of the touch-based sensor system. Progress was made in developing laser packages that effectively measure the alcohol spectrum. In addition, mechanical enclosures and electronic subsystems were designed, fabricated, and tested; firmware and software were updated; and a custom, automated laser calibration system was developed.

Planning for field operational tests in FY18 continued with "shakedown" testing in which DADSS Program researchers drove daily five fully-equipped test Chevrolet Malibu vehicles to ensure that the sensors, Data Acquisition Systems, cameras, and communications systems, etc., were fully operational. These initial tests provided detailed insight into the necessary parameters of test-site set up and will be used to complete the development of a required test plan.

Extensive research was conducted in materials and procedures for the measurement of breath- and touch-based sensors' performance. This included making progress on the development of more accurate and precise calibration samples, measurement procedures, and delivery systems as well as verification of the performance of the latest sensors. An Automated Breath-Based Standard Calibration Device was developed that allows improved control for sensor testing. Additionally, a portable testing device was developed that will be used for the Field Operational Tests.

In summary, the DADSS Program continues to make significant progress towards the goal of developing in-vehicle technologies that could reduce or eliminate alcohol-impaired crashes, improving upon both existing technologies and exploring new technologies.

A similar letter has been sent to the Chairman of the House Committee on Transportation and Infrastructure; the Chairman and Ranking Member of the Senate Committee on Commerce, Science, and Transportation; and to the Chairwoman and Ranking Member of the House Committee on Science, Space, and Technology.

Sincerely,

James C. Owens
Deputy Administrator

Enclosure

U.S. Department
of Transportation
**National Highway
Traffic Safety
Administration**

1200 New Jersey Avenue SE.
Washington, DC 20590

May 8, 2020

The Honorable Peter A. DeFazio
Chairman, Committee on Transportation
and Infrastructure
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Enclosed is the Report to Congress, 2018 In-Vehicle Alcohol Detection Research, prepared by the National Highway Traffic Safety Administration (NHTSA) in response to Section 403(h) of Title 23, United States Code. NHTSA publishes an annual report that describes the progress made in carrying out the collaborative research effort on in-vehicle technology to prevent alcohol impaired driving, including an accounting of the use of Federal funds obligated or expended in carrying out this effort.

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Sincerely,

James C. Owens
Deputy Administrator

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U.S. Department
of Transportation
**National Highway
Traffic Safety
Administration**

1200 New Jersey Avenue SE.
Washington, DC 20590

May 8, 2020

The Honorable Frank D. Lucas
Ranking Member, Committee on Science, Space,
and Technology
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Lucas:

Enclosed is the Report to Congress, 2018 In-Vehicle Alcohol Detection Research, prepared by the National Highway Traffic Safety Administration (NHTSA) in response to Section 403(h) of Title 23, United States Code. NHTSA publishes an annual report that describes the progress made in carrying out the collaborative research effort on in-vehicle technology to prevent alcohol impaired driving, including an accounting of the use of Federal funds obligated or expended in carrying out this effort.

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Sincerely,

James C. Owens
Deputy Administrator

Enclosure

U.S. Department
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**National Highway
Traffic Safety
Administration**

1200 New Jersey Avenue SE.
Washington, DC 20590

May 8, 2020

The Honorable Eddie Bernice Johnson
Chairwoman, Committee on Science, Space,
and Technology
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

Enclosed is the Report to Congress, 2018 In-Vehicle Alcohol Detection Research, prepared by the National Highway Traffic Safety Administration (NHTSA) in response to Section 403(h) of Title 23, United States Code. NHTSA publishes an annual report that describes the progress made in carrying out the collaborative research effort on in-vehicle technology to prevent alcohol impaired driving, including an accounting of the use of Federal funds obligated or expended in carrying out this effort.

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Sincerely,

James C. Owens
Deputy Administrator

Enclosure

U.S. Department
of Transportation
**National Highway
Traffic Safety
Administration**

1200 New Jersey Avenue SE.
Washington, DC 20590

May 8, 2020

The Honorable Maria Cantwell
Ranking Member, Committee on Commerce, Science,
and Transportation
United States Senate
Washington, DC 20510

Dear Senator Cantwell:

Enclosed is the Report to Congress, 2018 In-Vehicle Alcohol Detection Research, prepared by the National Highway Traffic Safety Administration (NHTSA) in response to Section 403(h) of Title 23, United States Code. NHTSA publishes an annual report that describes the progress made in carrying out the collaborative research effort on in-vehicle technology to prevent alcohol impaired driving, including an accounting of the use of Federal funds obligated or expended in carrying out this effort.

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Sincerely,

James C. Owens
Deputy Administrator

Enclosure

U.S. Department of Transportation
National Highway Traffic Safety Administration

1200 New Jersey Avenue SE.
Washington, DC 20590

May 8, 2020

The Honorable Roger F. Wicker
Chairman, Committee on Commerce, Science,
and Transportation
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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James C. Owens
Deputy Administrator

Enclosure

# Progress Report

DTNH22–13–H–00433

October 1, 2017 through
September 30, 2018

# 2018

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) 2018 in carrying out this effort.

## In–Vehicle Alcohol Detection Research

## Executive Summary

Since its inception in 2008, the Driver Alcohol Detection System for Safety (DADSS) program has made tremendous progress in the development of in-vehicle technologies that will prevent impaired drivers from driving their vehicles. Recognizing the continued importance of these efforts, Congress included a provision in the Moving Ahead for Progress in the 21st Century (MAP-21) Act that specifically authorized DADSS research. Congress continued the provision in the Fixing America's Surface Transportation (FAST) Act. As part of the provision, NHTSA is required to report on progress under the DADSS program each year. This report describes the progress for Fiscal Year (FY) 2018.

In the early stages of this cooperative research partnership between the National Highway Traffic Safety Administration and the Automotive Coalition for Traffic Safety, exploratory research established the feasibility of two alcohol sensor approaches, breath- and touch-based, for in-vehicle use. In the current phase, Phase III, the sensors have become increasingly refined, both in terms of hardware and software, as the DADSS program strives to meet the very high specifications required for unobtrusive and reliable alcohol measurement. At the same time, additional research and development is paralleling the sensors' development to allow the characterization of sensor performance in the laboratory, on the road, and among human subjects.

To effectively measure driver blood and breath alcohol in the vehicle with little inconvenience and negligible misclassification errors, stringent performance specifications for accuracy and precision were established which far surpass existing specifications for alcohol measurement. This necessitated the development of innovative approaches that will verify the technology is meeting these elevated specifications. Specifically, calibration processes, materials, methodologies and instrumentation have been the subject of extensive cutting-edge research to enable the requisite testing. As sensor development has progressed, research vehicles have been readied for Field Operational Testing with the latest versions of the breath sensors seamlessly integrated within research vehicle interiors. Vehicle instrumentation packages have been developed and installed and pilot testing trials now are providing data on sensor performance under real-world driving conditions. The accumulated data from an extended program of on-the-road trials under diverse conditions will determine whether the DADSS sensors are working as anticipated and allow the identification of areas for system improvement. A comprehensive program of human subject research also is being 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 traffic law enforcement. At the same time, media coverage and consumer sentiments continue to be assessed. Associated outreach efforts will be increased as the technology is refined and improved and readied for further commercialization with the goal of widespread implementation.

During the Fiscal Year ending September 30, 2018, many accomplishments were realized across a number of fronts, including sensor development, calibration materials, processes and measurement procedures, human subject testing, and Field Operational Trials. The breath-based approach uses infrared sensors to measure the concentrations of alcohol in exhaled breath. During Fiscal Year 2018, substantial progress was made in the breath sensors' hardware and software that significantly reduced background noise and resulted in a marked improvement in the resolution of alcohol measurement. Improvements were made to the detector itself and the sensor fan that draws diluted breath into the sensor was modified to allow more homogeneous airflow through the system, resulting in increased peak gas levels when measuring breath exhalations at the same distance. These are critical steps for passive breath measurement. Sensor calibration procedures in place in both the Swedish laboratories where the breath sensor is being developed and in the U.S. at the DADSS laboratory, have been upgraded in laboratories in Sweden and are now in-line with those used in the U.S. In addition, software algorithms for passive detection of breath alcohol were enhanced this year, such that consecutive data collected can be accumulated to improve reliable measurement. Further investigations of critical components, including detectors, emitters and mirrors, have identified noteworthy options for more production friendly choices which may be integrated in the future. These additions have increased the calibration accuracy over the entire concentration span. The latest breath sensors have undergone rigorous environmental testing aimed to simulate a sensor lifetime of fifteen years. As a result of all these advances, the breath sensors now are sufficiently advanced for on-the-road testing and have been readied for efficient vehicle installation with the first 8 sensors delivered by the end of October 2018 and additional units scheduled for delivery in FY2019.

The program is working to release the first derivative of the breath–based technology by the end of 2020 suitable for limited deployment in fleet applications. This device, referred to as the Compact Alcohol Reader to Inform (CARI) will be engineered and validated to conform with performance specifications suitable for motor vehicle fleet applications which are separate and distinct from, and in some instances, less stringent than those required for deployment in privately–owned vehicles. To that end, updated Performance Specifications have been drafted for fleet vehicles. The fleet vehicle device is a directed breath-based sensor whereby the user/driver must provide a breath sample directed at the sensor at a distance of three to five inches.

During Fiscal Year 2018, progress was made in the assembly of the latest generation touch sensor system. The tissue-based sensors allow estimation of blood alcohol concentration by measuring alcohol concentrations in tissue. This is achieved through detection of light absorption at chosen wavelengths from a beam of near-infrared light reflected from within the subject's finger tissue. In anticipation of the delivery of functioning laser packages that effectively measure the alcohol spectrum, mechanical enclosures and electronic subsystems were designed, fabricated and tested. Firmware and software were updated that oversee and control the touch system operation. A custom, automated laser calibration system also was built to test the power and wavelengths of the incoming laser packages. Improvements to the optical subsystem mixing and delivery are underway.

Extensive research has been conducted in materials and procedures for the measurement of breath and touch-based sensors' performance. During the year, progress was made on a number of fronts, including development of more accurate and precise calibration samples, measurement procedures, and delivery systems as well as verification of the performance of the latest Generation 3.2 sensors. An upgraded gas blender, referred to as the Automated Breath Based Standard Calibration Device, was developed that allows improved control over each of the gases for sensor testing. Separate sources of gas (e.g., ethanol, oxygen, carbon dioxide, nitrogen) are combined by the gas blender to better control the concentrations of the gases for delivery to the sensors. Another improvement to testing methods includes the ability to test eight sensors concurrently - a critical need as sensor production ramps up. As Field Operational Trials begin, all sensors are required to be characterized for accuracy and precision at various alcohol concentrations prior to and after installation in the research vehicles. To aid this effort, a portable testing device was developed that is being used in the field.

Human subject testing was conducted throughout the year to evaluate the breath and touch-based sensors. Substantial progress was made in measuring the alcohol absorption and elimination curves of human subjects across many of the scenarios identified by a comprehensive literature search, including the lag time when alcohol is first measured by the sensors, the effects of social drinking, food ingestion, last call drinks, and exercise on the absorption and elimination of alcohol. Across the range of scenarios, a solid linear relationship between blood, breath and tissue-based blood and breath alcohol concentrations has been established. This indicates that the measurements produced by the various generations of breath-based and touch-based prototypes are consistent, reproducible, and correlate very well with the gold-standard method of measuring blood alcohol in the body. Moreover, the breath and touch sensors responded to the various environmental conditions in the same way that blood alcohol did, providing justification that they serve as a valid surrogate for blood measurement.

Field operational tests planning continued throughout Fiscal Year 2018. Initial testing was performed in which DADSS Program researchers are driving five fully-equipped test Chevrolet Malibu vehicles to ensure that the sensors, Data Acquisition Systems (DAS), cameras, and communications systems etc. are fully operational. These initial tests provided a detailed insight into the necessary parameters of test site set up and will be used to complete the development of a required test plan (test routes, number of starts/stops, number of samples required, etc.).

## Introduction

Alcohol-impaired driving continues to exact a significant toll among road users both in the United States and around the world. Decades of research, focusing mainly on modifying driver behavior through strong laws and enforcement, has identified ways in which alcohol-impaired driving can be reduced (Ferguson et al. 2012).[1] Significant progress has been made based on these approaches through the 1980s, 1990s, and early 2000s. Nonetheless, in 2017 alone, crashes involving at least one driver with a blood alcohol concentration (BAC) of 0.08 grams per deciliter (g/dL) resulted in almost 11,000 deaths of U.S. road users – a number that is little different than in 2009.[2]

Due to the intractable nature of this problem, there is a clear need to identify a sustainable solution that no longer leaves the decision to drive impaired in the hands of the driver. In 2008, a public/private partnership was begun between the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS)[3] to develop a technological solution to end alcohol-impaired driving on U.S. roads. The Insurance Institute for Highway Safety research has estimated that 6,973 deaths could have been prevented in 2015 if all drivers with blood alcohol concentrations (BACs) of 0.08 g/dL or higher were kept off the roads (Lund et al., 2012).[4]. Applying the same methods for 2016 fatality data yields an estimate of 7,152 preventable deaths.

This cooperative research partnership, known as the Driver Alcohol Detection System for Safety (DADSS), has identified technologies capable of preventing alcohol-impaired driving through instantaneous measurement of driver breath- or tissue-alcohol.

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

[2] National Highway Traffic Safety Administration. 2018. Traffic Safety Facts. Alcohol-Impaired Driving. DOT HS 8124450. Washington DC.

[3] ACTS is classified as a 501(c)(4) nonprofit corporation by the U.S. Internal Revenue Service. Funding for ACTS is provided 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.

[4] Lund, A.K; McCartt, A.T.; and Farmer, C.M. 2012. Contribution of alcohol-impaired driving to motor-vehicle crash deaths in 2010. Arlington, V. Insurance Institute for Highway Safety.

The DADSS program is developing non–intrusive technologies that could prevent the vehicle from being driven when the device registers that the driver's BAC meets or exceeds the legal limit (currently at or above 0.08 g/dL in all states except Utah which has a BAC limit of 0.05 g/dL).[5] The selected technological approaches are founded on a clear understanding of the processes by which alcohol is absorbed into the blood stream, distributed within the human body, and eliminated (Ferguson et al., 2010).[6] Not only must the technologies quickly measure BAC or breath alcohol concentration (BrAC), but the medium through which it is measured (e.g., breath, tissue) must provide a valid and reliable estimation of actual BAC/BrAC.

After a thorough review of the literature and technical approaches, two approaches were deemed promising for quick and accurate measurement of driver BAC or BrAC. These were tissue and breath-based spectrometry systems. Tissue spectrometry systems allow estimation of BAC by measuring alcohol concentrations in tissue. This is achieved through detection of light absorption at a particular wavelength from a beam of Near-Infrared light reflected from within the subject's tissue. The breath-based approach is similar, in that an Infrared (IR) beam is used to analyze BrAC. Expired breath, mixed with the vehicle cabin air is drawn into an optical cavity where an IR beam is used to analyze the alcohol concentration in the subject's exhaled breath.

The 2008 cooperative agreement between NHTSA and ACTS (covering Phases I and II of the research) began with a comprehensive review of emerging and existing state–of–the–art technologies for alcohol detection to identify promising technologies that are capable of measuring BAC or BrAC in a vehicle environment. Under specific authorizations for the DADSS program in the Moving Ahead for Progress in the 21st Century (MAP-21) Act and the Fixing America's Surface Transportation (FAST) Act additional research has continued under a new cooperate agreement (covering Phase III of the research).[7] During Phase III, the research program has continued to advance the DADSS technology and test instruments as well as conduct basic and applied research to understand human interaction with the DADSS sensors both physiologically and ergonomically as well as how these technologies might operate in a vehicle environment.

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

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

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

As required by the FAST Act, the remainder of this report will discuss these research programs in more detail and the progress achieved towards these goals in Fiscal Year (FY) 2018. This report also includes a general accounting for the use of Federal funds obligated during this period.

## DADSS Research Program Organization

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

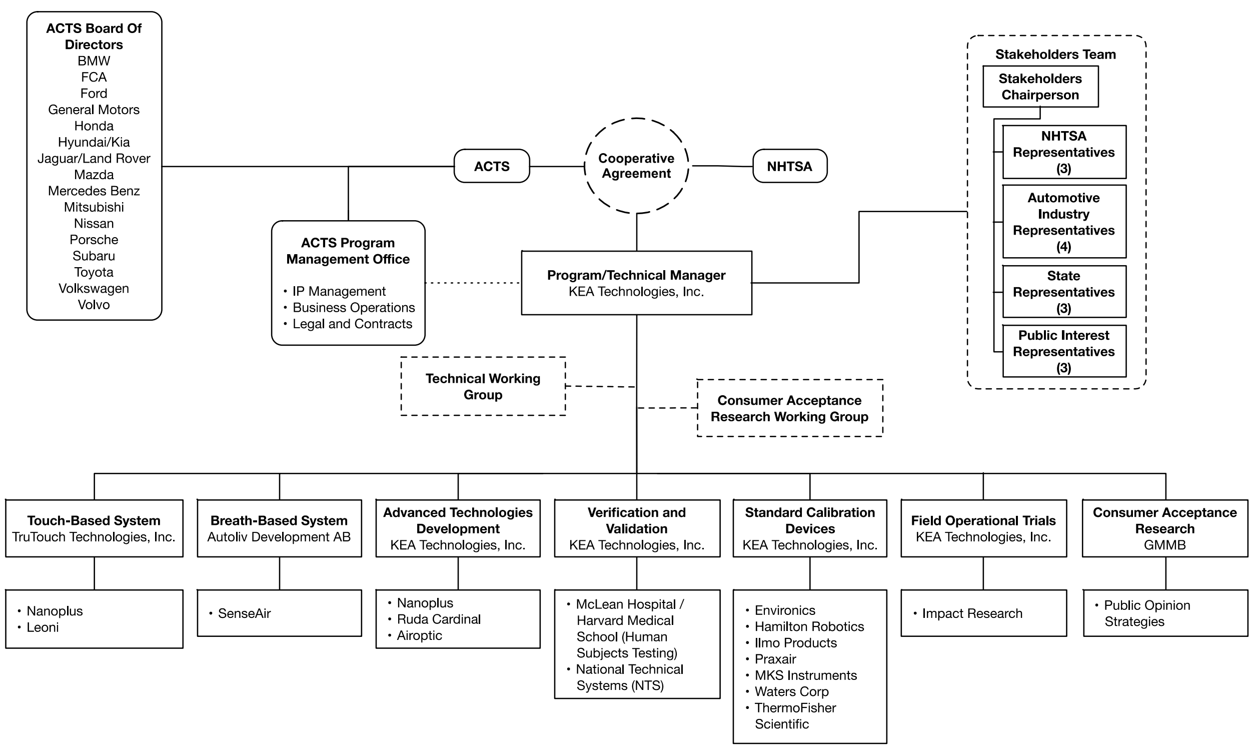


**Figure 1. DADSS Research Program Organization**

## Phased Research Plan with Technical Review Gates

From inception, the DADSS program has been structured to minimize risk by separating the research into phases with technical review gates between phases. The intent of Phase I was to research prototypes that could rapidly and accurately measure a driver's BAC non-intrusively. The prototypes constructed during this Phase (1st Generation) were designed to demonstrate the proof of concept prototypes. Three prototypes were delivered and tested at the DADSS laboratory (Figure 2) that yielded favorable results for two of the three technologies. Thus, at the conclusion of Phase I it was determined that development should continue for the two 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 over a wide range of environmental conditions. However, the devices' accuracy, precision, and speed of measurement will not be fully quantified until the completion of all required testing.

**Figure 2. DADSS Research Laboratory**

Additional phases of research are ongoing to permit 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. Phase III is focusing on optimizing and improving the DADSS sensors with the objective that the devices ultimately meet or exceed the DADSS Performance Specification that provide a template for the technology development.

## DADSS Research Programs

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

Research is ongoing in Phase III to further the development of these two sensor subsystems. Progress is being made in meeting the rigorous performance specifications necessary to conduct driver alcohol measurements in a vehicle environment subject to a myriad of challenging conditions. The development of the breath and tissue-based in-vehicle sensors is the central focus of the DADSS research effort. However, the DADSS research program is multifaceted, with many programs of research and development being pursued simultaneously under the DADSS umbrella. The breadth of the research undertaken by the DADSS team (as outlined in Figure 1) 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 extreme 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 must be confirmed in the laboratory using breath and tissue surrogates, and also with human subjects in conditions that replicate those likely to be experienced in the real world, including the vehicle environment. When the technologies have successfully met all these exacting criteria, the driving public must be on-board with this optional technology and be willing to purchase it for their vehicle. 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. When the technology is validated for real world use, it must be accepted by the public in order for it to be successful and widely implemented. The progress achieved in each of these areas in FY2018 is detailed below.

## DADSS Subsystems Technological Research

Two approaches are being pursued that have considerable promise in measuring driver BrAC and BAC non-invasively within the time and accuracy constraints established**:** a breath-based spectrometry approach and, a touch-based tissue spectrometry approach.

## Breath–Based Subsystem

The breath-based approach uses sensors to measure the concentrations of alcohol and carbon dioxide in the breath simultaneously. The use of carbon dioxide in human breath as a tracer chemical allows it to be used as an indicator for the degree of breath dilution, and thus the dilution of the alcohol concentration in the expired breath. A fan draws diluted breath into a chamber where a detector measures the concentrations of the alcohol and carbon dioxide in the sample.[8] BrAC is then quickly and accurately calculated.

The goal of the DADSS sensors is to passively measure breath alcohol within the vehicle cabin without directed input from the driver. The challenge is to meet the stringent performance specifications while measuring highly diluted breath. Thus, a significant component of the research is focused on understanding the behavior and flow patterns of the expired breath plume within the vehicle cabin and identifying effective locations for the sensors. The breath-based sensor has been updated in Phase III with the goal of improving this capability. The latest, 3rd Generation version (Gen. 3), underwent a complete re-design to increase sensitivity for measurements of passive samples, reduce the overall size, and improve performance over the full temperature range of -40°C to +85°C as specified by the DADSS Performance Specifications. A major improvement of the Gen. 3 sensor is the optical module configuration (See Figure 4 below). 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.[9] The Gen 3.2 device has seen sizeable improvements compared with the Gen 3.1 sensor. Gen 3.2 now enables passive in-cabin sniffing through enhanced alcohol sensitivity, with precision markedly improved. (See Figure 3. Recent Breath-based DADSS Sensor Development.)

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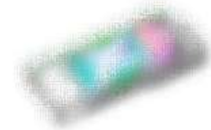
[8] Hök B, Pettersson, H, Andersson G, Contactless measurement of breath alcohol. Paper presented at the Micro Structure Workshop 2006, MSW2006; Västerås, Sweden.

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



| GEN 3.1 (Engineering Samples) | | | | GEN 3.2 / GEN 3.3 (Limited Engineering Samples) | | | | GEN 4.0 (targeted 2022) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Directed BrAC measurement | | | | Directed BrAC measurement | | | | Passive BrAC measurement | | | |
| | | | | Passive in–cabin alcohol “sniffing” | | | | Passive in–cabin alcohol “sniffing” | | | |
| | | | | Enhanced alcohol sensitivity | | | | Designed for scaled production | | | |
| Suitable for fleet & accessory applications | | | | Suitable for fleet & accessory applications | | | | Widely–deployable for POVs | | | |
| **Key Performance Specifications Targeted** | | | | | | | | | | | |
| **Speed** | **Accuracy** | **Precision** | **Size** | **Speed** | **Accuracy** | **Precision** | **Size** | **Speed** | **Accuracy** | **Precision** | **Size** |
| < 1 sec | +/- 0.002 | +/- 0.0008 | 76 x 140 x 38 mm | < 1 sec | TBA | +/- 0.0004 | 76 x 140 x 38 mm | 325 ms | +/- 0.0003 | +/- 0.0003 | 51 x 25 x 19 mm |

**Figure 3. Evolution of breath-based DADSS Sensor**

As shown in Figure 4, there has been a significant reduction in background noise[10] – down from 10.71 percent in the earliest Gen 3 prototype to only 1.64 percent in the latest Gen 3.2 version. The Gen 4.0 version, under development is anticipated to reduce the noise even farther, to only 0.21 percent of the signal. The net result is a significant enhancement of the alcohol signal.

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

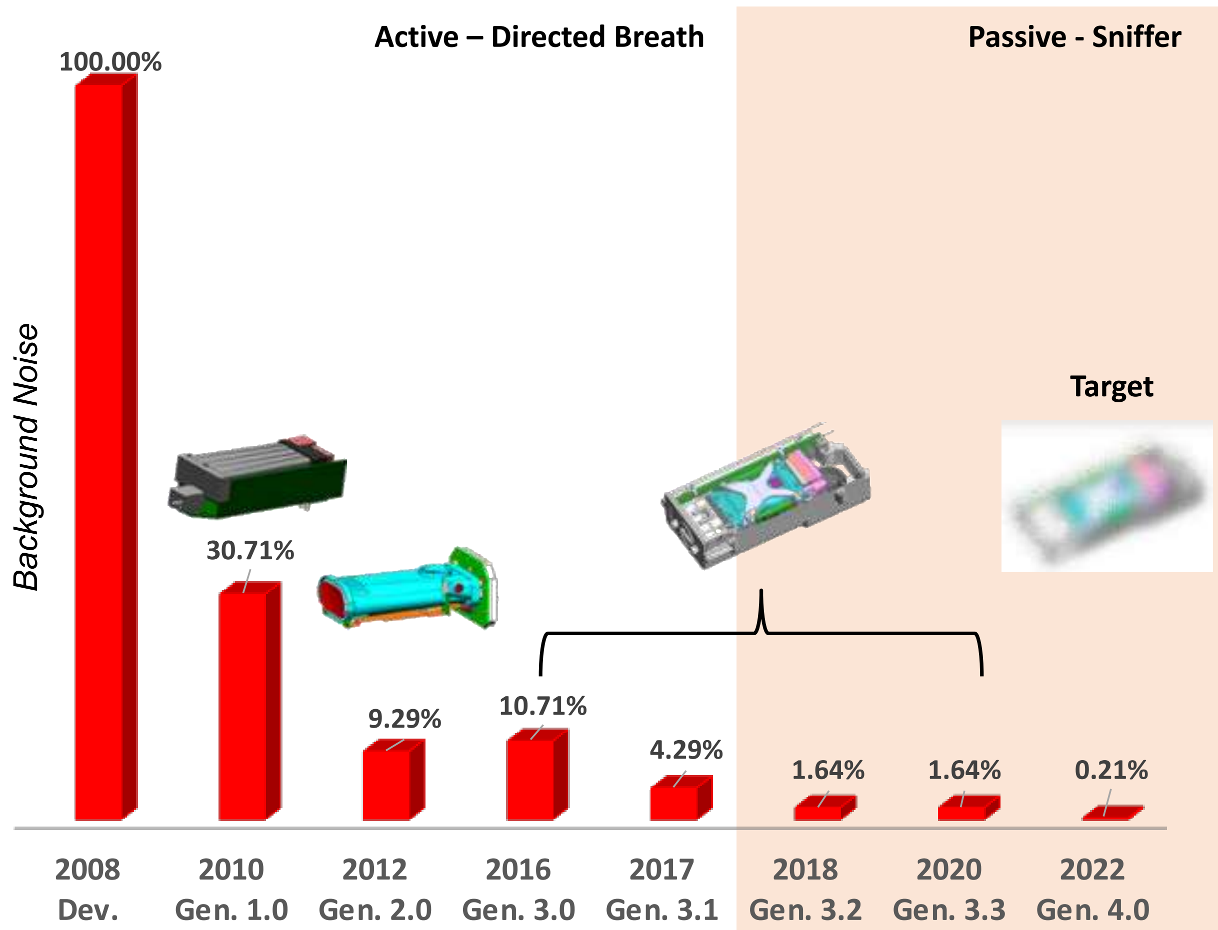



**Figure 4. Sensor performance improvements through reduction of background noise**

After comprehensive research that investigated optimal sensor placement in numerous locations within the vehicle, the sensor was adapted for installation in the DADSS research vehicles in two different positions: above the steering column in front of the driver and in the driver's door panel. These positions improved analysis of the impact of cabin air flow and the driver's position on alcohol measurements as well as optimized performance. The Generation 3.1 sensors required a directed breath sample although modifications recently undertaken in Gen 3.2 support a "sniffer function" that provide the capability for the sensor to passively detect the presence of alcohol.

Significant progress has been made in FY2018 on a number of fronts including hardware and software.

- The next generation, Gen. 3.2, sensor development focused on increasing the resolution of alcohol measurement. This resulted in an increase in the signal to noise ratio by a sizeable amount. The new detector is the main contributor to this increase.

- Improvements were made to the sensor fan, which provides a more homogenous airflow through the system. This modification resulted in increased amounts of alcohol and carbon dioxide gases when measuring breath exhalations from the same distance, compared to previous sensor generations. This contributes to enhanced ease-of-use of the sensor system as well as improved passive sensing.
- A new algorithm for passive detection of breath alcohol was developed during the year. The basic operation of the algorithm is to accumulate information from several consecutive signal features measured over time, thus improving the sensors ability to detect the alcohol in diluted breath. When sufficient information has been gathered, the sensor system provides an output describing the state of intoxication of the driver. A patent application has been submitted describing this methodology.
- Further investigations of critical components, including detectors, emitters and mirrors, has identified potential new options for more production friendly choices. More investigation will be undertaken before implementation.
- A new 9-point calibration procedure and superior measurement instrumentation (MKS Fourier Transform Infrared [FTIR]Spectroscopy instrument) were adopted in the two facilities in Sweden where the breath sensor is being developed and calibrated. This brings testing protocols in line with procedures used in the DADSS laboratory in the United States. These additions have increased the calibration accuracy over the entire concentration span.
- The updated Gen. 3.2 sensors have undergone rigorous environmental testing aimed to simulate a sensor lifetime of fifteen years. The information gathered during testing is vital for continuing sensor development and in the ongoing product development of the Gen. 3.2 sensors.
- In preparation for fitment of the new Gen. 3.2 sensors in the Field Operational Test (FOT) vehicles, the outer housing remained unchanged from the Gen. 3.1 version to facilitate rapid exchange of in-vehicle installed sensors. To facilitate exchangeability, a connector printed circuit board was developed to avoid the removal of the Human Machine Interface (HMI) board with every disassembly/reassembly.
- Material for 130 Gen. 3.2 FOT and application sensors was stockpiled, and fabrication is underway. The first 8 sensors intended for FOT integration were delivered in September of 2018.
- The first platform vehicle has been completed and system testing is in progress.

Research is continuing to improve the sensors' performance. Furthermore, the program is working to release the first derivative of the breath–based technology by the end of 2020 suitable for limited deployment in fleet applications (referred to as Generation 3.3). This derivative device will be engineered and validated to conform with performance specifications suitable for fleet applications which are separate and distinct from, and in some instances, less stringent than those required for the technology derivative for widespread deployment in privately–owned vehicles. To that end, the modified Performance Specifications for fleet applications have been drafted. The Compact Alcohol Reader to Inform (CARI) device is a directed breath-based sensor whereby the user/driver must provide a breath sample directed at the sensor at a distance of two to three inches.

## Touch-Based Subsystem

The tissue-based approach analyzes alcohol found in the driver's fingertip tissue (or more specifically, the blood alcohol concentration detected in the capillaries). The driver touches an optical module and a near infrared light shines on the driver's skin (typically a finger), similar to a low power flashlight, which propagates into the tissue. A portion of the light is reflected back to the skin's surface, where it is collected by the touch pad. This light transmits information on the skin's unique 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 (Ver Steeg et al., 2017).[11] The key to enabling such innovation is the ability to define an optimized subset of optical wavelengths which will provide the high-quality non-invasive alcohol measurement in humans that is needed (see Figure 5 for a schematic representation of this approach). It was determined that the new spectrometer requires the use of modulated laser diodes to generate 40 unique wavelengths of light that are physically configured for optimal alcohol measurements. The laser diode specifications were derived from the comparison and analysis of human subject data and comparative reference data.

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[11] 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.

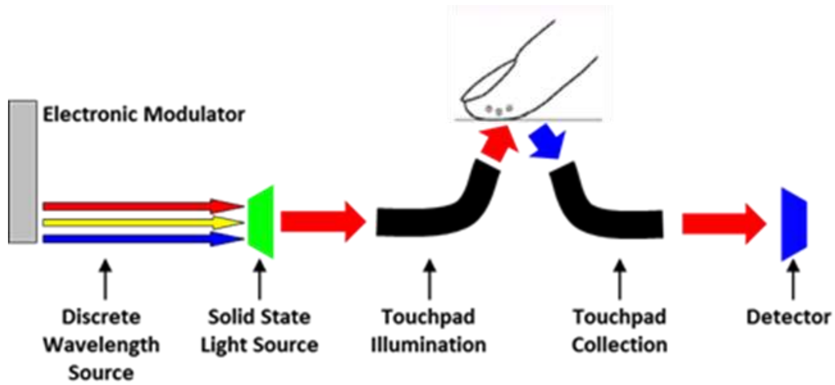


**Figure 5. Touch-based solid-state laser spectrometer approach**

The highest risk technical element of the touch-based system is the laser device fabrication which meets target specifications. Extensive, cutting-edge research has been undertaken to develop the requisite lasers, many of which have not been manufactured before, and assemble them in multi-laser packages. The individual lasers pinpoints of light 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 to develop the laser diodes and packaging, a new supplier, Nanoplus, was selected with greater expertise in these areas. Each stage of the development process has required painstaking research which has been the subject of multiple patent applications. As with any new technology development, complications have arisen along the way. For example, research on the Generation 3 sensor (see Figure 6, Recent Touch-Based DADSS Sensor Development), revealed a problem with fluctuating laser intensity that could result in unreliable tissue alcohol measurements.

|  |  |  |
|---|---|---|
| **GEN 3** (Q4–2018) | **GEN 4** (targeted for 2021) | **GEN 5** (targeted for 2022 ~ 2023) |
| • 20–laser diode system (discrete laser architecture) | • 10–laser diode system (optimized discrete laser architecture) | • 2–laser diode system (tunable architecture) |
| • Reflective cavity optics | • Waveguide–coupled lasers | • On–chip waveguides |
| • Fiber–coupled lasers | • Reduced fiber couplings | • No fiber couplings |
| • Modular electronic design | • Manufacturable design (low volumes) | • ASIC–level electronic integration |
| • *In vivo* performance demonstration | • Suitable for fleet & accessory applications | • Widely–deployable for privately–operated vehicles (POVs) |

| **Key Performance Specifications Targeted** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Speed | Accuracy | Precision | Size | Speed | Accuracy | Precision | Size | Speed | Accuracy | Precision | Size |
| 2000 ms | TBD | TBD | 152x305x76 mm | 1000 ms | 0.0003 | 0.0003 | 76x127x51 mm | 325 ms | 0.0003 | 0.0003 | 51x25x19 mm |

**Figure 6. Recent touch-based DADSS Sensor Development**

During FY2018, progress was made in the assembly of the Gen. 3 touch sensor system, including modifications to laser packages, optical subsystems, electronics, as well as calibration systems and software and firmware updates.

- In preparation for delivery of the Gen. 3 laser packages, the mechanical enclosures and electronic subsystems were designed, fabricated and tested.
- Gen. 3 package firmware and software that oversee and control the touch system operation were updated.
- A custom, automated laser calibration system was built to test the power and wavelengths of the incoming laser packages.
- The touch-based sensor requires the use of modulated laser diodes to generate 40 unique wavelengths of light that are physically configured for optimal alcohol measurements. In FY 2017, it was discovered that lasers were not delivering the required wavelength, rather they were fluctuating, thus, affecting the ability to measure the tissue alcohol effectively. Steps were taken to correct for that through redesign of the optical subsystems. During FY 2018, multiple optical laser mixing and delivery systems were evaluated via simulations and modelling and four of the best candidates were fabricated and bench tested. The best performing combinations were incorporated into the Gen. 3 system.
- Thirteen Gen. 3 laser packages were delivered and tested to ensure they were performing at  the required power and wavelengths.
- Of the 13, eight laser packages were considered to be performing well enough to be incorporated into the Gen. 3 touch-based system, which also includes the system enclosures, electronic subsystems, and optical interface.
- The eight Gen. 3 systems were tested, including in vitro (bench) testing. These tests identified an elevated error rate due to laser dynamic behavior and optical system throughput. Improvements to the optical subsystem mixing and delivery are underway.
- In preparation for in vivo (human subject) testing, which will be undertaken once bench tests confirm sensors are measuring alcohol as predicted, a search was conducted of potential sites for clinical testing. A preferred candidate was chosen, testing protocols were agreed upon, and preliminary training has been conducted.

## Performance Specification Development

The Performance Specifications document is the primary tool for evaluating in-vehicle advanced alcohol detection technologies. The purpose of the document is to establish the DADSS Subsystem Performance Specifications for passenger motor vehicles. The document is based on input from the Technical Working Group, which is made up of representatives from the automotive industry with relevant expertise in vehicle design, as well as representatives from ACTS and NHTSA. In addition to specifications that specify the sensor's speed of measurement, accuracy and precision, reliability specifications have been identified that conform to the automobile industry accepted 6σ (six sigma) level of reliability thus minimizing the potential for system failure. International Organization for Standardization (ISO) principles also are followed to ensure that materials, products, and processes developed within the DADSS Program are acceptable for their purpose.

As Phase III research progresses, the DADSS Performance Specifications will require continued updating. In particular, the specifications will be revised to include new research findings and technology updates that are designed to address the following:

- Prevent manipulation (tamper resistance) and circumvention.
- Clear identification of the driver sample as well as differentiation of the driver sample from all passengers' samples and other interfering substances.
- Protection of data (cybersecurity).
- Ensuring integrity of communications between DADSS sensor and vehicle.

In addition to the DADSS Performance Specifications, draft performance specifications have been prepared for a potential breath-based derivative alcohol measurement device mentioned above. This device is intended for motor vehicle fleet applications. The driver or user will be required to provide a directed breath at a distance of about 3-5 inches from the sensor (without a mouthpiece) before the vehicle can be moved. The draft specifications define the accessories' technology performance as it relates to accuracy, precision, speed of measurement, influence of the environment, issues related to user acceptance, long-term reliability, and system maintenance requirements. In addition, CARI will be designed and manufactured so that it cannot be put out of service, rendered ineffective or destroyed without visible changes to the device. Access to the data memory or the ability to set operation parameters including the setting of BrAC concentrations will be designed to deter unauthorized or inadvertent interference.

## Sensor Calibration Device Research

As each new generation of the breath-and touch-based sensors are developed, researchers must evaluate the sensors' performance. Instrument and/or sensor calibration is one of the primary processes used to confirm and maintain a sensor's accuracy and precision. An important component of the calibration process is to develop a qualification and verification process that is able to illustrate in a traceable manner that the breath-based and tissue-based Standard Calibration Devices (SCDs) meet the requisite performance specifications. This involves using standard reference materials (SRMs) or certified reference materials (CRMs) that are produced to a known value. The calibration standards used in the United States are traditionally traceable to a national standard held by the National Institute of Standards and Technology (NIST). Considering that the accuracy and precision specifications for DADSS alcohol sensors exceed those established for commercially available alcohol measurement, it has not been possible to find certified sources of gas and/or liquid(s) with the requisite accuracy and precision. Initially, the DADSS researchers worked with specialty gas manufacturers to develop the gases, but going forward, reference materials for the specified levels of accuracy and precision have begun to be developed by the DADSS team. The sample materials,  or SRMs, when combined with the delivery methods are considered to be the SCD.

A multi-pronged program of research and development is being undertaken to address the various aspects of the calibration process. The initial efforts focused on the development of the breath and tissue surrogates that could meet the DADSS accuracy and precision specifications. This ongoing research is conducted in-house at the DADSS laboratory and in concert with outside providers of necessary materials. Once the initial breath and touch surrogates were synthesized, delivery systems were developed to deliver the samples to the instrumentation and the sensors for measurement purposes. For the breath SCD that meant simulating human breath volume, pressure, temperature and humidity. The Wet Gas Breath Alcohol Simulator (WGBAS) was developed in cooperation with Environics to meet those needs. The goal of the WGBAS is to combine the gas blends with the required level of humidity to provide an output that simulates a human breath that can be delivered to the sensors. Similarly, for the tissue sensors, updated tissue surrogates and delivery systems continue to be developed.

Once developed, the SRMs composition, accuracy, and precision has to be confirmed at these elevated specifications. The instrumentation necessary for such verification has to exceed the DADSS performance specifications by a significant order of magnitude. To meet those needs a comprehensive worldwide search was conducted for suitable technological approaches and instrumentation that could exceed the already stringent DADSS specifications. A comprehensive evaluation of forensic toxicology instrumentation revealed emerging technologies with improved ability to quantify and identify ethanol in SCDs. Various approaches and their methods, such as gas chromatography, liquid chromatography, and infrared spectroscopy were evaluated. The chosen instrumentation must quantify the chemical components within the samples with better precision and accuracy than the touch and breath-based surrogates. The specified accuracy and precision of the DADSS sensors is 0.0003% at a BAC of 0.08%. This requires the surrogates to be measured with instrumentation that can meet a precision and accuracy target of 0.000075%.

The instruments not only quantify accuracy and precision but also identify substances in the tissue and breath samples. For the breath-based sample, the Fourier

Transform Infrared Spectroscopy (FTIR) was selected due to its ability to identify and precisely measure the intrinsic ethanol. For the tissue-based calibration, a High-Performance Liquid Chromatography (HPLC), with numerous detectors and interfacing with an FTIR, provides extremely precise measurements and identification of ethanol as well as the other compounds in the tissue surrogate. Today, compounds in trace concentrations as low as parts per trillion may easily be identified (see Figure 7, MKS Multi-gas 2030 FTIR for Breath–Based Samples and Waters Aquity HPLC for Touch-Based Samples in the DADSS Research Laboratory).

**Figure 7. MKS Multigas 2030 FTIR for breath –based samples and Waters Aquity HPLC for touch-based samples in the DADSS Research Laboratory**

The advanced capabilities of the new instrumentation packages revealed deficiencies in the current calibration solutions. Contaminants were identified that previously went undetected. The accuracy of the breath-based samples from the same manufacturing lot were found to vary despite optimization of the systems to reduce errors beyond current industrial practices. Thus, to improve accuracy beyond the commercial off-the-shelf materials available, alternative ways to produce the calibration samples were researched and pursued. To improve tissue-based calibration solution accuracy, alcohol industry practices were studied, and systems were designed to precisely weigh and use other chemical properties to quantify the ethanol in a solution with extreme confidence. A similar approach to breath-based calibration samples is being developed.

Once the instrumentation had been identified that could meet the very exacting specifications required, research was undertaken to develop highly accurate and precise calibration curves for the breath- and touch-based SCDs. Precision targets have been met for breath-based gases. Efforts continue on meeting precision targets for touch-based solutions. With respect to accuracy, the DADSS team continues to investigate SRMs and methods which can be developed that can meet the accuracy specifications.

Research has been conducted in FY2018 that has resulted in substantial progress on a number of fronts, including development of calibration samples, measurement procedures, and delivery systems as well as characterization of the latest generation sensors. Progress has been achieved in the following specific areas:

- Testing now is implemented in two different settings; the ambient laboratory environment and a controlled environmental chamber which allows measurement across the full temperature range (-40°C, +22°C, and +85°C).
- Improvement of testing methods. An upgraded gas blender replaced the WGBAS that allows for an improved range of alcohol concentrations as well as improved control of the concentrations of each of the independent gases (e.g., ethanol, oxygen, carbon dioxide, nitrogen) that are delivered to the sensors. An added advantage of this system is the facilitation of multiple sensor testing.
- An Automated Breath Based System (ABBS) was developed to produce gaseous ethanol from liquid ethanol to improve the precision of the SCD's and reduce costs.
- The DADSS laboratory collaborated with Senseair to ensure that their laboratories were aligned in their calibration procedures and in their use of the latest Fourier Transform Infrared (FT IR) spectroscopy instrument produced by MKS Instruments, Inc.
    - A comparison was made of Senseair and DADSS breath-based SCD reference instruments using the same ethanol bubbler system with solutions from the same lot. As expected, the reference instruments performance was very similar.
- A portable breath-based SCD using dry gases was developed for testing in field operational trials. This device permits controlled and uniform gas delivery to the breath sensors outside of the laboratory.
    - Using this device, continuous verification of FOT Senseair Gen. 3.1 and Gen. 3.2 breath-based sensors is being performed after installation in the research vehicles to validate the continued operation within tolerances.
- Improvements of tissue solutions for touch-based SCDs. Research has begun to develop alternatives to existing liquid tissue surrogates using the ThermoFisher FTIR.
- Using the Waters Aquity HPLC, the DADSS laboratory verified ethanol concentrations in liquid tissue surrogates created by TruTouch.
- Improvement of testing procedures. Researchers developed a setup to test 8 sensors at once, resulting in drastically increased sensor testing throughput.

- Testing of the breath-based alcohol sensor. The Gen. 3.1 and 3.2 sensors were plumbed inline after passing through the MKS FTIR to confirm the precision of the gas sample prior to measurement with the breath-based alcohol sensor.
    - Breath sensors were tested to verify performance at temperatures of -40°C, 22°C, and 85°C and concentrations of 0.02, 0.05, 0.08, and 0.10 g/dL BrAC. More than 2,800 data points were collected in total.
- The DADSS Specifications require that accuracy and precision be confirmed at lower alcohol concentrations – not normally a concern of alcohol testing. Using the Thermo Fisher FTIR liquid flow through cell, researchers were able to quantify ethanol at low concentrations.
- The DADSS laboratory was equipped to perform testing according to an adapted CENELEC standard (CENELEC is responsible for European standardization of breath alcohol measurement)

## Human Subject Testing

Human subject testing, referred to as in vivo testing, is a critical part of understanding how the DADSS sensors will perform in the real world when confronted with large individual variations in the absorption, distribution, and elimination of alcohol within the human body (blood, breath, tissue) over the myriad of factors that can affect alcohol concentration. Extensive 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 measurement methods being researched under the DADSS program that determine alcohol levels from diluted breath samples and within human tissue, are not well understood. In particular, the rate of distribution of alcohol, throughout the various compartments of the body under a variety of scenarios, has been the subject of ongoing study.

The fundamental challenge is to ensure that the levels of alcohol that are detected by the breath- and touch-based sensors do, in fact, reflect the concentration in venous blood, which is the gold standard of measurement. Based on an extensive review of the extant alcohol pharmacokinetics literature, intrinsic and extrinsic factors that can affect alcohol metabolism have been identified. Consequently, a comprehensive program of human subject research is underway, starting with the laboratory environment where better control of conditions can be exerted, followed by the in-vehicle environment where the sensors can be tested *in situ.*

The purpose of human subject testing is:

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

Significant progress has been achieved in conducting human subject testing at the DADSS Satellite Laboratory at McLean Hospital in Belmont, Massachusetts (See Figure 8). Data were collected during five developed scenarios in an effort to quantify alcohol absorption and elimination and various generations of breath-based sensors were used to collect data. The scenarios explore a variety of conditions that are designed to mimic real-life situations. The five scenarios are as follows:

- Lag time. This will address in which compartment alcohol first appears (blood, breath or tissue) after subjects consume alcohol. This information is critical to calibrating any temporal offsets and setting the timing of how the two prototypes will be implemented in the vehicle.
- Social drinking. The aim is to determine the profile of alcohol absorption and elimination during steady drinking over an extended time while eating only a small amount of snack-type food.
- Social drinking with a full meal. The aim is to quantify the profile of alcohol absorption and elimination with the consumption of dinner along with alcohol.
- Last call. This scenario is designed to simulate "Last Call" at the end of the evening wherein participants drink several drinks at a programmed rate for a set period of time.
- Drinking during exercise. This scenario will simulate dancing and drinking in which individuals drink alcohol while engaging in episodes of physical activity.

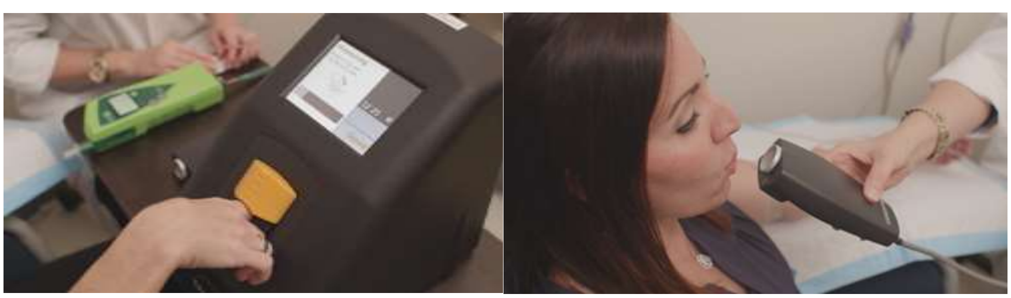

**Figure 8. Human Subject Testing at DADSS Satellite Lab at McLean Hospital in Belmont MA**

Significant progress has been made in Fiscal Year 2018 in a number of areas, including method development and human subject testing. Many insights have been gained regarding the alcohol absorption and elimination curves and maximum BACs/BrACs reached by the subjects in a variety of different scenarios. In addition, research focused on new scenarios identified as potentially important in breath and touch alcohol measurement, including the effects of smoking on breath alcohol measurements and hand sanitizer gel and skin temperature on tissue alcohol measurement. Progress has been achieved in the following specific areas:

- The Phase I testing scenarios data collection outlined earlier was finalized and testing was begun on Phase II scenarios.
- The testing chamber was modified with high performance air handling and filtering systems to quickly and completely evacuate tobacco smoke from the room after testing the impact of smoking on the breath-based devices. This was a crucial development to protect McLean Hospital and KEA Technologies staff from tobacco smoke exposure.
- Methods were devised to reduce skin temperature by 8°C to 10°C and increase skin temperature by 4°C to 6°C. In addition, a set of skin-based thermocouples was developed to precisely monitor skin temperature during the cold and warm hand scenarios.
- A method was devised to standardize the skin exposure to hand sanitizer gel containing 60% ethanol.
- Substantial progress has been made in measuring the alcohol absorption and elimination curves across all of the scenarios outlined above, with a total of 137 subjects (more than 9,000 blood samples).
- The results of testing to date indicate that each of the scenarios has an effect on the alcohol pharmacokinetic curves.
- Across the range of scenarios, a solid linear relationship between blood, breath- and tissue-based BAC/BrACs has been established. These findings are based on linear regressions of more than 4,000 data points for each of the tissue and breath samples. his indicates that the measurements produced by the various generations of breath-based and touch-based prototypes is consistent, reproducible, and correlates very well with the gold-standard method of measuring alcohol in the body—blood via gas chromatography.
- The breath and touch sensors responded to the various environmental conditions in the same way that blood alcohol did, providing justification that they serve as a valid surrogate for BAC.

## DADSS - Field Operational Test

The specific aim of the DADSS – Field Operational Test (DADSS-FOT)[12] is to conduct basic and applied research to understand the performance of the DADSS sensors, both physiologically and ergonomically, in the vehicle in a diverse set of geographic environments and with a large number of human subjects. In support of the DADSS-FOT, General Motors donated 40 2017 Chevrolet Malibus (valued at $1,332,500) to the DADSS Program (Figure 9).

**Figure 9. 15 DADSS-FOT 2017 Chevrolet Malibus**

The Chevrolet Malibus have been fitted with the latest Gen. 3.2 breath-based alcohol sensors and comprehensive Data Acquisition Systems (DAS). Touch-based sensors will be integrated once they have completed the requisite test protocols. As an initial step, the vehicles have undergone a "shakedown" stage, in which DADSS Program researchers drove five fully-equipped test Chevrolet Malibu vehicles on a daily basis to ensure that the sensors, DAS, cameras, and communications systems etc. are fully operational. These initial tests provided detailed insight into the necessary parameters of the test site set up and will be used to complete the development of the Test Plan (test routes, number of starts/stops, number of samples required, etc.).

Under the research, the sensors will be tested in extreme real-world environmental conditions, including high heat, cold, varying humidity, corrosive environments, etc. to ensure that they will be operational for the harshest real-world conditions that they are likely to encounter. Data will be collected from the DADSS breath alcohol sensors as well as from breath-alcohol reference sensors. The research protocol prescribes that passengers who have been drinking direct their breath toward sensors in the vehicle. At the same time, the sensors will be passively sniffing or analyzing the vehicle cabin environment for the presence of alcohol. Additional instrumentation tracks environmental conditions, vehicle system data, and test participant video. These data will be critical in determining the

[12] The DADSS-FOT has been previously referred to as Pilot Field Operational Testing (PFOT). To avoid confusion with other testing and future FOTs, we will use DADSS-FOT to refer to the initial test of the technology involving 40 vehicles in this report.

effectiveness (accuracy, precision) of the DADSS sensors in real-world driving environments. The data also will be used to evaluate the effects of repeated use and vehicle mileage on sensor function and in diverse environments, analyze driver behavior and user acceptance, analyze and assess the impact of the DADSS sensors using real-world data, improve awareness of in-vehicle alcohol detection systems and assess potential impact of the sensors on alcohol-impaired driving. Technical data gathered in these operational environments will also be used to refine the DADSS Performance Specifications and will be used for system design and product development.

**Figure 10. Platform development 2017 Chevrolet Malibu integrated with the breath-based sensors**

The DADSS-FOT will focus initially on using vehicles in Massachusetts and Virginia. However, efforts will be made to test the vehicles in other areas around the country with the goal to expose the technology to different environmental conditions that involve low and high temperatures, low and high humidity and at varying elevations. Information collected during the DADSS-FOT will be critical to refining the technology as the development process moves from a research-oriented focus.

As detailed below, significant progress has been made in FY2018:

- Installed test equipment into the test Chevrolet Malibu's (Figure 10).
- Performed "Shakedown" testing in which DADSS Program researchers are driving five fully-equipped test Chevrolet Malibu vehicles on a daily basis, to and from work, to ensure that the sensors, Data Acquisition Systems (DAS), cameras, and communications systems etc. are fully operational.
- Initial tests provided detailed insight and identified areas in which modifications were required in the vehicles and at the test site to allow for smoother operation and data collection.
- Development of the Test Plan (test routes, number of starts/stops, number of samples required, etc.) is ongoing as the initial vehicle tests are being conducted in Marlborough, MA, and Sterling, VA.

## 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 and proceeding to acceptance of the technology as a good auto safety system worth buying.

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

Activities in this area in FY2018 consisted of:

- Updating of resources for the DADSS website included updates to a new video that highlights the coalition of organizations behind DADSS, and updates to various events in which the DADSS team has been involved.
- Media support and ongoing media monitoring and analyses to assess the media landscape; that is, the tone and quality of the news articles to which consumers are exposed.
- Continued outreach to potential partners and stakeholders, who, once the DADSS technology is sufficiently developed for increased consumer and media scrutiny, will help to engage the public and the media to increase awareness and acceptance.

## Patent Prosecution

As a result of the innovative research that is being undertaken under the DADSS Program, ground-breaking technologies and procedures are being developed that are the subject of Patent Applications. ACTS continues to take a number of actions to ensure the commercial implementation of the DADSS technology. First, ACTS is prosecuting 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. Second, to further enhance the implementation of DADSS technology, the Board of Directors of ACTS has directed that the DADSS technology be made available on equal terms to anyone who, in good faith, wants to use the technology.

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

**Table 1. Patent Applications to Date**

| TITLE | COUNTRY | STATUS | APPLICATION # |
|---|---|---|---|
| **MOLECULAR DETECTION SYSTEM AND METHODS OF USE** | United States of America | Closed | 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 | Pending | 15/090,809 |
| **SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER** | China | Issued | ZL201280042179.6 |
| **SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN** | Germany | Closed | NOT YET ASSIGNED |

| TITLE | COUNTRY | STATUS | APPLICATION # |
|---|---|---|---|
| **ANALYTE IN A VEHICLE DRIVER** | | | |
| **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** | 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 | Pending | 14/315,631 |
| **SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA** | Canada | Pending | 2,920,796 |
| **SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA** | China | Issued | ZL201480047728.8 |

| TITLE | COUNTRY | STATUS | APPLICATION # |
|---|---|---|---|
| **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 | Pending | 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 | Issued | 2,925,806 |
| **SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS** | China | Pending | 201480055848.2 |
| **SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS** | European Patent Office | Pending | 14755950.4 |
| **SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS** | Japan | Pending | 2016-516589 |

| TITLE | COUNTRY | STATUS | APPLICATION # |
|---|---|---|---|
| **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 | Pending | 2015-528442 |
| **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 | Pending | 14/421,376 |
| **HIGHLY ACCURATE BREATH TEST SYSTEM** | Canada | Pending | 2,881,814 |
| **HIGHLY ACCURATE BREATH TEST SYSTEM** | China | Pending | 201380054007.5 |
| **HIGHLY ACCURATE BREATH TEST SYSTEM** | European Patent Office | Pending | 13831692.2 |
| **HIGHLY ACCURATE BREATH TEST SYSTEM** | Japan | Pending | 2015-528441 |
| **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 |

| TITLE | COUNTRY | STATUS | APPLICATION # |
|---|---|---|---|
| | | | |
| **HEATER-ON-HEATSPREADER** | China | Pending | Pending |
| **HEATER-ON-HEATSPREADER** | European Patent Office | Pending | 16816457.2 |
| **HEATER-ON-HEATSPREADER** | Japan | Pending | 2018-534915 |
| **HEATER-ON-HEATSPREADER** | South Africa | Pending | 2018/05421 |
| **SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION** | United States of America | Closed | 62/312,476 |
| **SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION** | United States of America | Pending | 15/389,724 |
| **SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION** | PCT | Pending | PCT/US16/68789 |
| **SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION** | Canada | Pending | Pending |
| **SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION** | China | Pending | Pending |
| **SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION** | European Patent Office | Pending | Pending |
| **SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION** | Japan | Pending | Pending |
| **SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION** | South Africa | Pending | Pending |
| **INTEGRATED BREATH ALCOHOL SENSOR SYSTEM** | United States of America | Closed | 62/171,566 |
| **INTEGRATED BREATH ALCOHOL SENSOR SYSTEM** | United States of America | Pending | 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 |

| TITLE | COUNTRY | STATUS | APPLICATION # |
| --- | --- | --- | --- |
| **INTEGRATED BREATH ALCOHO SENSOR SYSTEM** | South Africa | Pending | 2017/08227 |
| **VOICE ACTIVATED START** | United States of America | Pending | 62/728,898 |

†PCT means Patent Cooperation Treaty.

## State Participation

In 2016, Virginia became the first state to partner with the DADSS Program through the Virginia Department of Motor Vehicles Highway Safety Office. Virginia will be involved at various levels, from pilot manufacturing and vehicle integration, to field operational tests, to helping raise public awareness and gauging the public's acceptance of the technology. As part of these efforts, in 2018, Virginia announced a partnership with James River Transportation (JRT) to conduct in-vehicle, on-road test trials using the alcohol detection technology. Integrators installed prototypes of the breath-based sensors on four vehicles of the JRT commercial fleet. Data and feedback collected from the prototype sensors, as well as the drivers, have helped to improve the technology.

## 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.[13] Funding for the DADSS Research Program for fiscal years 2013 through 2016 were made under the MAP-21 authorization. Surface transportation reauthorization enacted in December 2015, Fixing America's Surface Transportation (FAST) Act, amended section 403 of title 23 of the United States Code, continuing the authorization for DADSS research through FY 2020.[14]

Funding for DADSS research was provided under the highway trust fund as part of the appropriations legislation enacted for FY 2018. Federal funding totaling $5,494,000 was authorized and ultimately appropriated (Table 2).[15]

[13] 23 U.S.C. § 403(h) (as amended by Public Law 112–141, enacted July 6, 2012).
[14] 23 U.S.C. § 403(h) (as amended by Public Law 114–94, enacted December 4, 2015).
[15] Consolidated Appropriations Act, 2018, Public Law No. 115–141, enacted March 23, 2018; Joint Explanatory Statement, 142 Cong. Rec. H2876 (2018).

**Table 2. FY2018 NHTSA funding available for in-vehicle technology research to prevent alcohol-impaired driving**

| | Fiscal Year 2018 |
|---|---|
| **Funding for In–vehicle Technology Research** | $5,494,000 |

The period of performance specified in the 2013 Cooperative Agreement initially covered a five–year period (September 30, 2013 to September 29, 2018) and research has been planned for the entire five–year period through Fiscal Year 2018. ). In December 2017, ACTS and NHTSA agreed to extend the award to September 2020 – the end of the program's express authorization in the FAST Act. Consistent with the extension, research has been planned for the entire agreement period. Table 3 provides a general statement regarding the use of Federal funding for Fiscal Year 2018 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 – FY2018** | | **$ 5,494,000** |
| **FY2018 Funding Expended** | | |
| Research & Development | | $ 4,994,545 |
| Indirect Rate | | $ 499,455 |
| | **Total Obligated/Expended** | **$ 5,494,000** |