Progress Report

DTNH22–13–H–00433

October 1, 2015 through
September 30, 2016

2016

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 also includes a general accounting for the use of Federal funds obligated or expended in FY 2016 in carrying out this effort.

In–Vehicle Alcohol Detection Research

Executive Summary

The National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS) began research in February 2008 to try to find potential in–vehicle approaches to the problem of alcohol-impaired driving. Members of ACTS comprise motor vehicle manufacturers representing approximately 99 percent of light vehicle sales in the U.S. This cooperative research partnership, known as the Driver Alcohol Detection System for Safety (DADSS) Program, is exploring the feasibility, the potential benefits, and the public policy challenges of more widespread use of non-invasive technology to prevent alcohol-impaired driving. The 2008 Cooperative Agreement between NHTSA and ACTS (2008 Cooperative Agreement) for Phases I and II outlined a program of research to assess the state of detection technologies that are capable of measuring blood alcohol concentration (BAC) or breath alcohol concentration (BrAC) and to support the creation and testing of prototypes and subsequent hardware that could be installed in vehicles.

Moving Ahead for Progress in the 21st Century (MAP–21) authorized additional research into the DADSS technology. This additional research is being implemented through a new cooperative agreement between NHTSA and ACTS that began in October 2013 (2013 Cooperative Agreement). The 2013 Cooperative Agreement covers Phase III of the research. It involves continued research into the DADSS technology and test instruments as well as basic and applied research to understand human interaction with the DADSS sensors both physiologically and ergonomically – that is, how these technologies might operate in a vehicle environment. At the culmination of this effort will be a device or devices that will allow a determination to be made regarding whether the DADSS technologies can ultimately be commercialized. If it is determined that one or more of these technologies can be commercialized, it is anticipated that the private sector will engage in further product development and integration into motor vehicles.

During the fiscal year ending September 30, 2016, the following accomplishments were realized:

- Breath–based DADSS Subsystem Research
    - Completed the design, development, and manufacturing of the 3rd Generation DADSS sensor
        - Improvement to the startup time, dynamic accuracy and measurement performance at very low temperatures
    - Completed an initial series of verification and validation tests as per the DADSS Performance Specification
        - Initial tests were favorable; however, additional work remains in sensor operation at low temperatures and passive detection

        - Further improvements required on accuracy and precision to meet the DADSS Performance Specification
    - Performed in-vehicle experiments, both simulated and with human subjects, that showed that passive breath alcohol detection is feasible, where adequate signal levels can be reached under favorable circumstances
    - Integrated the 3rd Generation DADSS sensor into the DADSS X1 and X2 Research Vehicles for use with a directed breath
    - Continue to improve manufacturing process of the 3rd Generation sensor through improved quality control of key components
    - Completed research, build, and validation testing of prototype breathing manikin capable of passive breathing and directed breath for vehicle cabin aerodynamic studies
    - Continued sensing system algorithm development, testing, and validation with focus on passive alcohol detection

Figure 1. Third Generation breath-based sensor integrated into DADSS X2 research vehicle steering column (left) and driver door panel (right)

- Touch–based DADSS Subsystem Research
    - Completed the design, development, and manufacturing of the multi-laser butterfly packages that interrogate the 40 wavelengths required for the touch-based sensors
        - 4 multi-laser butterfly packages are required to interrogate all 40 wavelengths
        - Each multi-laser butterfly package includes 10 laser diodes at 10 unique wavelengths
    - Integrated the 4th Generation DADSS touch-based sensor into the DADSS X2 Research Vehicle (Figure 2)
    - Initiated a clinical calibration trial with 100 subjects to support the development of the mathematical model

- Initiated the development of the tunable laser system that will allow for a significant reduction in the number of required lasers and therefore in overall sensor size
- Initiated redesign of touch-based sensor, with emphasis on the multi-laser package, focused on scalability and cost for automotive application

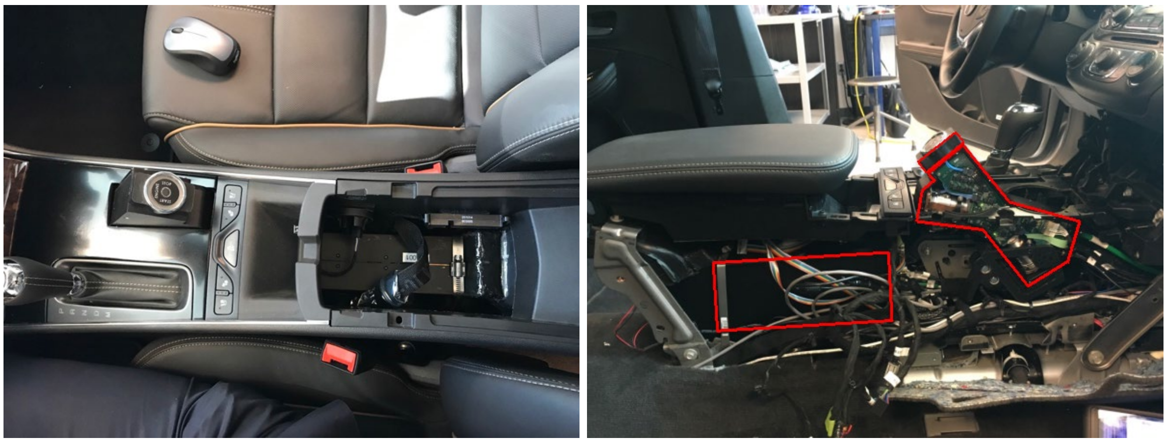

Figure 2. Fourth Generation touch-based sensor integrated in the DADSS X2 research vehicle center stack

- Standard Calibration Devices Research
  - Breath-based Standard Calibration Device (SCD) validated with testing against new, state-of-the-art Fourier transform infrared (FTIR) spectroscopy instrumentation packages for accuracy and precision.
    - Researched processes to accurately mix dry gases for calibration of new FTIR instrumentation
    - Dry gas delivery system optimized to minimize impact of physical and chemical variables on precision
    - Humidified gas mixing and delivery system tested over range of breath alcohol concentrations (0.020 %BrAC – 0.120 %BrAC) using new FTIR instrumentation
  - Updated programming of Touch-based SCD using robotic pipetting system that mixes tissue-based SCD
  - Researched and created precise calibration curve on High Performance Liquid Chromatography (HPLC) to quantify ethanol in tissue-based SCD

- Human Subject Testing
  - Secured Institutional Review Board (IRB) approval
  - Initiated alcohol dosing scenario protocols
    - Continued collection of data for lag time alcohol dosing protocol
    - Continued collection of data for social alcohol dosing protocol

        - Continued collection of data for social brunching alcohol dosing protocol
        - Continued collection of data for exercise and alcohol dosing protocol
        - Continued collection of data for “last call” alcohol dosing protocol

- Patent Prosecution
    - One patent issued in the United States of America; System and Method for Controlling Collated Multiple Wavelength Tuned Lasers (US 9,281,658).
    - Submitted provisional patents applications for the following three patents:
        - Highly Accurate Breath Test System
        - Heater-On-Heatspreader
        - Integrated Breath Alcohol Sensor System
    - Intellectual property developed under the DADSS Research Program will be licensed on equal terms to all requesters with ability to manufacture original equipment level DADSS subsystems
    - Initiated efforts to prepare and prosecute patent applications in the main auto–producing regions of the world, that is, the United States, Europe, Japan, Canada, Hong Kong, China, and South Africa

- Consumer Acceptance Research
    - Tracking relevant studies
    - Planning for future research

- In September 2016, Virginia became the first state to enter into a voluntary partnership with the DADSS program to help further develop and deploy DADSS in Virginia.

  Total NHTSA expenditures in fiscal year 2016 totaled $5,493,906 for this research.

Introduction

Since 2008, researchers have been working under an auto industry partnership with the U.S. Department of Transportation’s National Highway Traffic Safety Administration (NHTSA) known as the Driver Alcohol Detection System for Safety Program or simply, the DADSS Program. The goal of the DADSS Program is to research in–vehicle technology aimed at preventing drunk driving.

In 2015, 10,265 lives were lost to an alcohol–impaired driver (i.e., fatality involving a driver with a blood alcohol concentration (BAC) of 0.08 percent or greater), or 29 percent of all the people who died in motor vehicle crashes that year. An analysis prepared by the Insurance Institute for Highway Safety (IIHS) has shown that in that year, had driver BACs been limited by a device like DADSS to no more than 0.08 percent – the illegal *per se* limit in all 50 states – 6,904 deaths could have been prevented.[1] This is the number of deaths involving drivers with BACs at or above 0.08 percent, i.e., the number of deaths that could have been prevented via specific deterrence.

Another IIHS study showed that the public is receptive to in–vehicle alcohol–detection technology like DADSS. Two-thirds of those surveyed by the Institute considered the use of advanced technology to keep drunk drivers off the roads to be a "good" or "very good" idea, and more than 40 percent said they would want the technology in their own cars.[2] More detailed research into how consumers would respond to DADSS is planned as part of this cooperative research effort.

The surface transportation reauthorization enacted in 2015, known as Fixing America's Surface Transportation (FAST) Act, amended section 403 of title 23 of the United States Code to authorize additional DADSS research.[3] As required by the FAST Act, this report describes the progress made from Oct 1, 2015 to Sept 30, 2016 by this cooperative research program, which is exploring the feasibility, potential benefits, and public policy challenges associated with a more widespread use of non–invasive technology to prevent alcohol–impaired driving. This report also includes a general accounting for the use of Federal funds obligated or expended in fiscal year 2016 in carrying out this effort.

Background

Alcohol-impaired driving is one of the primary causes of motor vehicle fatalities on U.S. roads every year and in 2015 alone resulted in more than 10,000 deaths. There are a variety of countermeasures that have been effective in reducing this excessive toll, many of which center around strong laws, visible enforcement, and appropriate consequences.

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[1] Lund, A.K., McCartt, A.T., and Farmer, C.M., *"Contribution of Alcohol–Impaired Driving to Motor Vehicle Crash Deaths in 2010,"* Insurance Institute for Highway Safety, May 2012, updated April 2015.
[2] McCartt, A.T., Wells, J.K, and Teoh, E.R., *"Attitudes toward in–vehicle advanced alcohol detection technology,"* Traffic Injury Prevention, March 2010.
[3] See section 403(h) of title 23 of the United States Code as amended by Public Law 112–141, December 4, 2015.

Separate from these successful countermeasures, NHTSA and ACTS[4] began research in February 2008 to try to find potential in–vehicle approaches to the problem of alcohol–impaired driving.

The 2008 cooperative agreement between NHTSA and ACTS covering Phases I and II of the research outlined a program to assess the state of detection technologies that are capable of measuring BAC or BrAC and to support the creation and testing of prototypes and subsequent hardware that could be installed in vehicles.

Since the program's inception it has been clearly understood that for in–vehicle alcohol detection technologies to be acceptable for use among drivers, many of whom do not drink and drive, they must be both seamless with the driving task and non–intrusive (that is, accurate, fast, reliable, durable, and require little or no maintenance). To that end, 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 illegal limit (currently at or above 0.08 grams per deciliter (g/dL) or 0.08 percent).[5]

To achieve these challenging technology goals, very stringent performance specifications (the current version of which is set forth in the DADSS Performance Specifications) have been established that provide the template for the research effort. Another important challenge will be to ensure that the driving public accepts in–vehicle alcohol detection technology that meets the stringent criteria for in-vehicle use. An effort is underway to engage the driving public in discussions about the technologies being researched so that their feedback can be incorporated into the DADSS Performance Specifications as early as possible. The challenges to meeting these requirements are considerable, but the potential life-saving benefits are significant.

The three year initial effort began with a comprehensive review of emerging and existing state–of–the–art technologies for alcohol detection in order to identify promising technologies. Phase I, completed in early 2011, focused on the creation of proof–of–principle prototypes. The objective of Phase I was to determine whether there were any

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[4] 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.

[5] From inception in 2008, the DADSS research project has been based on a BAC threshold of 0.08 percent or greater. The MAP–21 authorization to continue the DADSS research explicitly specified that this threshold be used. Please see section 403(h) of title 23 of the United States Code.

promising technologies on the horizon. Three prototypes were delivered and tested at the DADSS laboratory, and two yielded promising results.

The technological approaches that were chosen for DADSS 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 from it. Not only must technologies under consideration quickly and accurately measure BAC, but the medium through which it is measured (e.g., breath, tissue, sweat) must provide a valid and reliable estimation of actual BAC levels. Based on an understanding of the way in which the human body processes alcohol, ACTS formulated a typology of four potential technological approaches:

1. electrochemical systems,
2. tissue spectrometry systems,
3. distant/offset spectrometry systems, and
4. behavioral systems.

However, after a thorough review of the literature and technical approaches, it was determined that only two of the approaches held merit at the time for quick and accurate measurement of driver BAC. These were tissue spectrometry and distant, breath-based spectrometry systems. In essence, tissue spectroscopy 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 (NIR) light reflected from within the subject's tissue. Distant spectrometry systems use a similar approach, in that an Infrared (IR) beam is used to analyze Breath Alcohol Concentration (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 Phase II effort, begun in late 2011, continued research on technology needed to narrow gaps in performance between the DADSS prototypes and the DADSS Performance Specifications. The Phase II effort also produced a research vehicle into which the DADSS technologies were installed to allow first look at how such technology might work within the vehicle environment.

Phase III involves continued research into the DADSS technology and test instruments as well as basic and applied research to understand human interaction with the DADSS sensors both physiologically and ergonomically – that is, how these technologies might operate in a vehicle environment. The culmination of this effort (currently authorized through 2020) will be a device or devices that will allow a determination to be made regarding whether the DADSS technologies can ultimately be commercialized. If it is determined that one or more of these technologies can be commercialized, it is currently anticipated that the private sector will engage in further product development and integration into motor vehicles.[6]

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 2008 Cooperative Agreement covers Phases I and II. The 2013 Cooperative Agreement covers Phase III of the research.

The intent of Phase I was to research prototypes capable of rapidly and accurately measuring a driver's BAC in a non-intrusive manner. The prototypes constructed during this Phase, were designed to address accuracy, precision, and speed of measurement specifications only. The prototypes did not attempt to address repeatability and reliability. Phase I results indicated that both touch– and breath–based technologies showed sufficient promise to suggest they may ultimately be capable of meeting the DADSS Performance Specifications with respect to measurement speed, accuracy, and precision in future iterations. The research effort that comprised the 2008 Cooperative Agreement began with a comprehensive review of emerging and existing state–of–the–art technologies for alcohol detection in order to identify promising technologies. This first phase, completed in early 2011, focused on the creation of proof–of–principle prototypes (1st Generation). During this phase, device prototypes of the candidate technologies were evaluated for measurement speed, accuracy, and precision to see if the devices showed promise for ultimately meeting the DADSS Program's stringent performance requirements. Three prototypes were delivered and tested at the DADSS laboratory that yielded promising results for two of the three technologies (Figure 3).

For Phase II, the DADSS technology providers were required to work to resolve the performance gaps identified in Phase I and research a BAC sensor/subsystem with the intent to meet all sections of the DADSS Performance Specifications. The second phase, begun in late 2011, continued the research of the DADSS technologies to narrow gaps in performance against the DADSS Performance Specifications and meet the DADSS Performance Specifications of an in–vehicle environment. Device prototypes constructed as a result of this phase (2nd Generation) allow a practical demonstration of one or more alcohol detection subsystems suitable for installation in one or more research vehicles and continued development.

[6] Associated technical papers and updates on DADSS research can be found at www.dadss.org.

Figure 3. DADSS Research Laboratory

The third phase, begun in 2013, continued research into the DADSS technologies and test instruments as well as basic and applied research to understand human interaction with the DADSS sensors both physiologically and ergonomically – that is, how these technologies might operate in a vehicle environment. Prototypes from this phase were integrated into two research concept vehicles, the DADSS X1 shown in Figure 4, and DADSS X2 shown in Figure 5 and Figure 6. These vehicles were used as development and verification platforms of the Pilot Field Operational Tests (PFOT) of vehicles intended to evaluate the DADSS prototypes long term performance and understand the driver's behavior in a naturalistic setting.

During this period, the DADSS team developed an instrumentation package for the DADSS X2 research concept vehicle (Figure 7). The instrumentation package is being used to assess whether the DADSS sensors and instrumentation perform as intended when they're integrated into vehicles and to identify areas for system improvement with the objective to ensure system repeatability, robustness and readiness for field operational testing.

Figure 4. DADSS X1 Research Concept Vehicle

Figure 5. DADSS X2 Research Concept Vehicle

Figure 6. DADSS X2 interior with steering column breath-based sensor (top left), touch-based sensor (bottom right), and control monitor (top right)

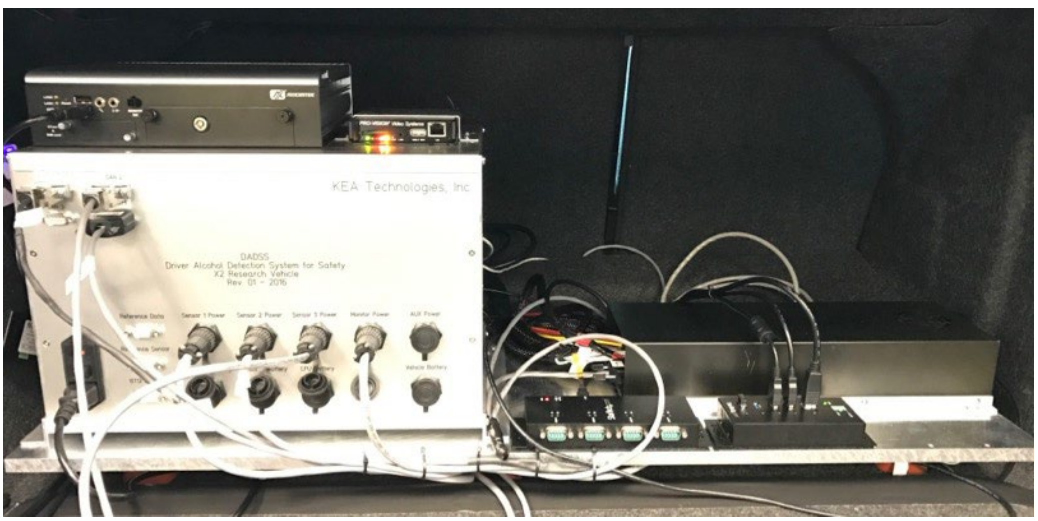

Figure 7. DADSS X2 Instrumentation located in the vehicle trunk

Additional phases of research – the focus of a new Cooperative Agreement begun in September 2013 – will 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. At the culmination of the 2013 Agreement, in September 2020, a determination will be made regarding whether the DADSS technologies can ultimately be commercialized. If it is determined that one or more of these technologies can be commercialized, it is currently anticipated that the private sector will engage in further product development and integration into motor vehicles.

DADSS Subsystem Technological Approaches

Two DADSS approaches are being pursued that have considerable promise in measuring driver BAC non-invasively within the time and accuracy constraints established:

- **Distant/Offset Spectrometry, a breath-based approach** that measures the concentrations of alcohol and carbon dioxide in the breath simultaneously. The known quantity of carbon dioxide in human breath is an indicator of the degree of dilution of the alcohol concentration in expired air. Molecules of alcohol and those of tracers such carbon dioxide absorb infrared radiation at specific wavelengths. The device directs infrared light beams on the breath sample and analyzes the wavelengths returned to quickly and accurately calculate the alcohol concentration.

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

The Phase II effort begun in late 2011, spanned two years, and required technology providers to make significant improvements to device accuracy, reliability, and speed of measurement. The effort also examined an extensive array of performance requirements common in the automotive industry over a wide range of environmental conditions. The devices' accuracy, precision, and speed of measurement will not be fully quantified until the completion of all required testing. Phase III is focusing on fast–tracking the DADSS sensors research with the objective that the devices ultimately meet or exceed the DADSS Performance Specifications.

Breath–based Subsystem

The third generation (Figure 8) of the breath-based sensor has been updated in Phase III. The sensor has been adapted for installation in two research vehicles in two different positions: above the steering column and in the driver's door panel. The different positions improved understanding of the impact of cabin air flow and the driver's position on alcohol measurements. The current implementation of the sensors requires a directed breath. Current effort is focused on implementing algorithm updates to support a "sniffer function” that provides the capability for the sensor to passively detect the presence of alcohol.

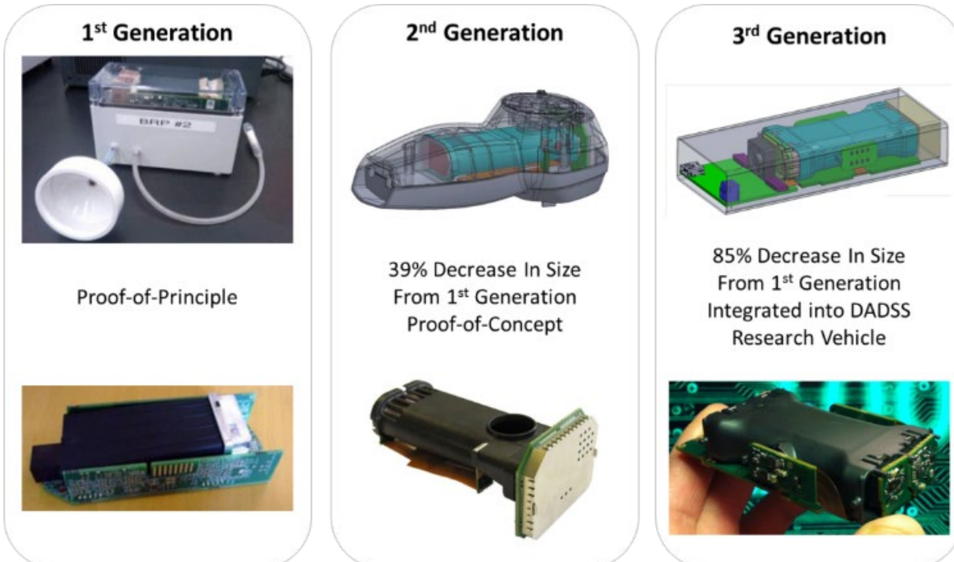

Figure 8. Evolution of breath-based DADSS Sensor

Additional sensors were bench-tested in laboratory conditions with the current standard calibration devices to establish accuracy and precision performance benchmarks of the latest sensor iteration.

Specific tasks that may be needed (based on the results of testing) to accelerate the current state of the breath-based sensor technology include the following:

- Continue to improve the sensor’s accuracy and precision to resolve identified non-compliances to the DADSS Performance Specifications
- Continue to improve the sensor’s robustness to resolve identified non-compliances to the DADSS Performance Specifications
- Continue the in-depth research of the human breath aerodynamics within the occupant compartment of various sized vehicles under a variety of environmental conditions
- Continue to research the optimal placement parameters for breath-based sensors within the carrying geometry of vehicle cabins
- Research air inlet design parameters for optical sensor performance
- Evaluate potential of and design strategy intended to prevent user manipulation of device

Touch–based Subsystem

The initial implementation of the solid-state architecture of the touch-based sensor has been completed. A new supplier, Nanoplus, was selected to continue the developmental work and manufacturing previously started; this greatly improved the rate of progress. A Mark 2B system has been developed for implementation in one research vehicle (Figure 9).

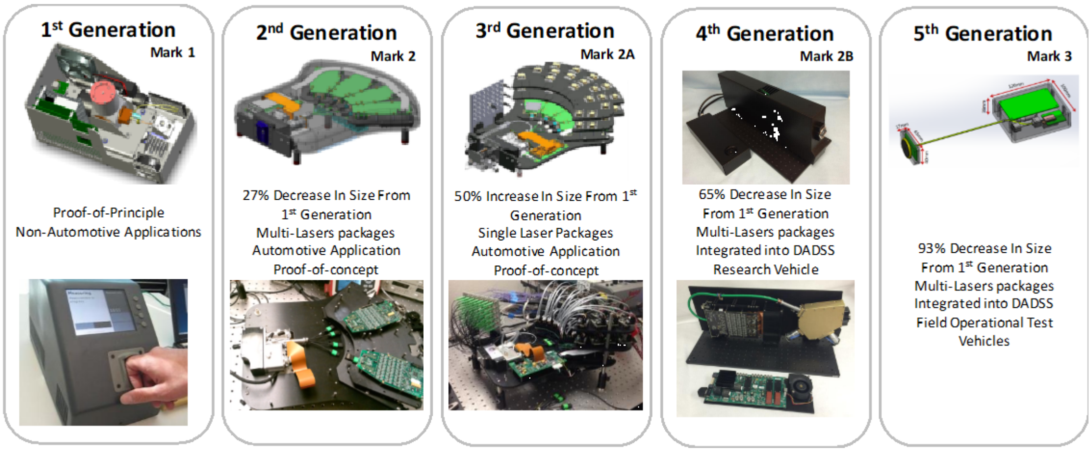

Figure 9. Evolution of touch-based DADSS Sensor

The next iteration of the solid-state architecture will reduce the number of laser diodes required, which has significant impact on the power consumption, size, and eventually, cost.

In Phase III, additional research is being pursued to improve functionality and in–vehicle performance. Specific tasks that may be needed (based on the results of testing) to accelerate the current state of technology development of the touch–based sensor include:

- Research designed to improve sensor's accuracy and precision to resolve identified non-compliances from the Phase II target
- Research designed to improve sensor's robustness to resolve identified non-compliances from the Phase II environmental simulation
- Scale up supplier processes in an effort to meet potential high volume demand, specifically as it relates to wafer processing of the laser diodes which are currently needed in lower volume applications
- Optimize Phase II integrated sensor package (size and shape) for standardization and high volume applications
- Redesign main processing system for standardization and high volume applications.
- Research sensor serviceability techniques
- Evaluate potential of design strategy intended to prevent user manipulation of device
- Research an Application Specific Integrated Circuit (ASIC) specification for the laser drive/receive system

DADSS Performance Specifications

A significant part of this effort has been the establishment of DADSS Performance Specifications which set the bar high by existing alcohol measurement standards for breath alcohol measurement. Such stringent standards are intended to allow driver BAC measurements to be performed unobtrusively. The DADSS Performance Specifications document is continuously reviewed and updated based on research findings. As Phase III and later phases progress, 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 driver sample as well as differentiation of driver sample from all vehicle passengers' samples, interfering substances, and other ways to attempt to circumvent the system
- Protection of data (cybersecurity)
- Integrity and security of communication between DADSS sensor and vehicle.

Figure 10 illustrates the progress made on the breath-based sensor for both passive and directed breath (driver provides a directed breath at a short distance from the sensor) alcohol detection for the critical performance specifications of speed, accuracy, precision and physical size. It should be noted that the directed breath based sensor, a necessary stepping stone in the development of the passive sensor, is not for automotive application and is more suitable for workplace enforcement.

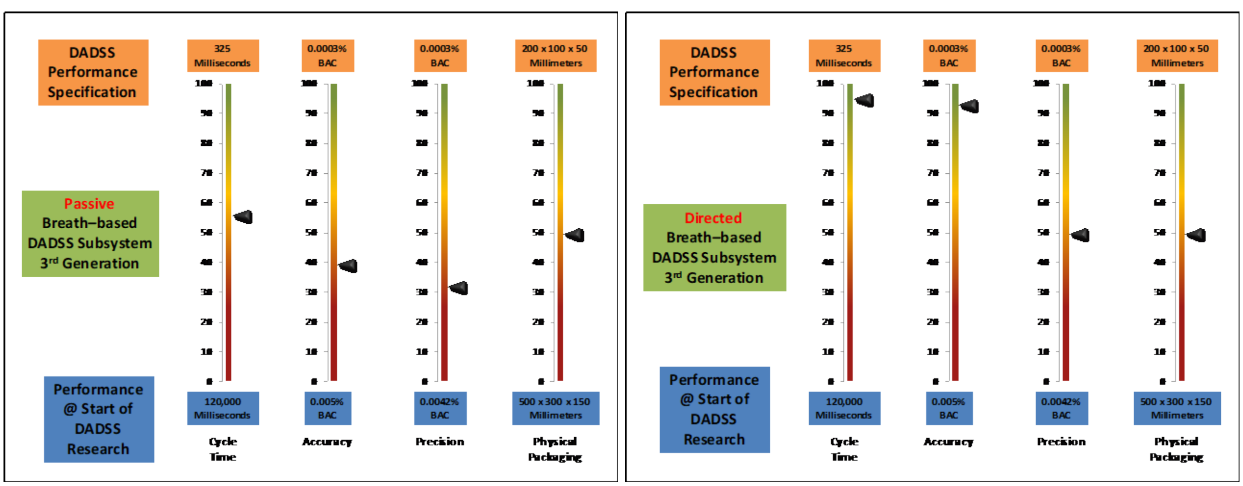

Figure 10. Progress towards main Performance Specifications on the breath-based sensor for Passive (left) and directed breath (right) alcohol detection

Figure 11 illustrates the progress made on the touch-based sensor for both laser spectrometer (suitable for automotive application) and interferometer (initial prototype developed to show feasibility of touch-based system, but not suitable for automotive application) alcohol detection for the critical performance specifications of speed, accuracy, precision and physical size.

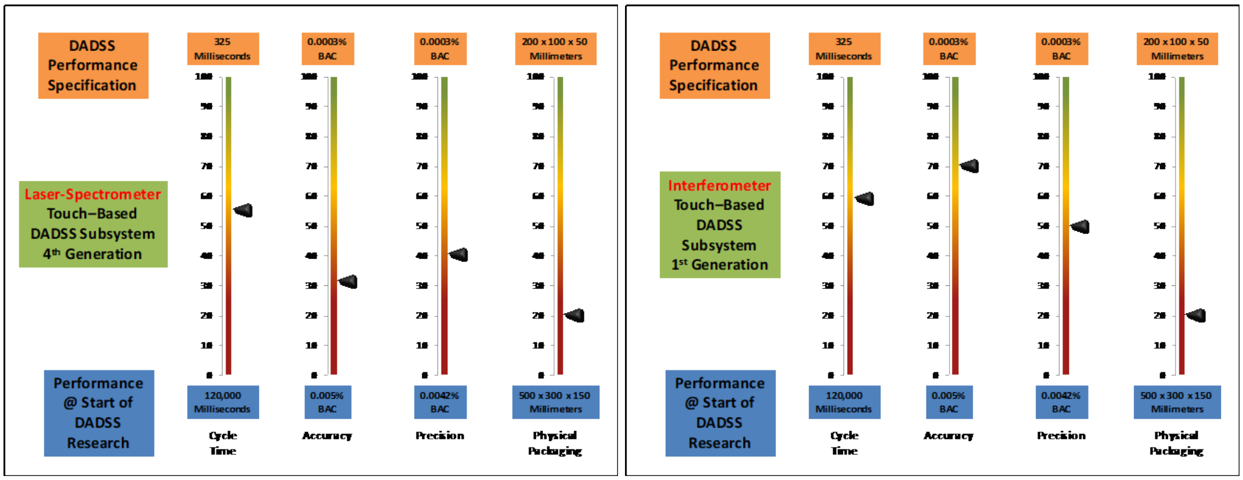

Figure 11. Progress towards main Performance Specifications on the touch-based sensor for the laser spectrometer (left) and interferometer (right) alcohol detection

Human Subject Testing

Human subject 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 in the various compartments within the human body (blood, breath, tissue) over the myriad factors that can affect BAC. There has been extensive research to understand these relationships with respect to venous (blood) alcohol and breath alcohol when samples of deep lung air are used. However, the new measurement methods being researched as part of 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 requires further study.

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. Particular attention will be paid to the less well-known kinetics of tissue alcohol.
- To quantify alcohol absorption and elimination curves among a wide cross section of individuals of different ages, body mass index (BMI), race/ethnicity, and sex using the different scenarios

Significant progress was achieved in conducting human subject testing at the DADSS Satellite Lab at McLean Hospital in Belmont, Massachusetts (See Figure 12). Data was collected during five developed scenarios in an effort to quantify alcohol absorption and elimination. The set scenarios explore a variety of conditions that are designed to mimic real-life situations. The five scenarios are as follows:

- Lag time to appearance of alcohol in three compartments: blood, breath, or tissue. The aim of this scenario is to determine the lag time to first appearance of alcohol in each of the three compartments. One of the most basic question to answer is in which compartment (blood, breath or tissue) will alcohol first appear after consuming a single large dose of 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 over extended period of time. The aim of this scenario is to determine the profile of alcohol pharmacokinetics during a very common pattern of drinking, steady drinking over an extended time, while eating only a small amount of snack-type food.
- Social drinking with a full meal. The aim of this scenario is to quantify the time course of alcohol pharmacokinetics under a variety of conditions that include the consumption of food along with alcohol. Participants will be exposed to a routine that is present in most restaurants where they will be first served alcohol (on an empty stomach), followed by appetizers and then full meal that is served with additional alcohol.
- A single large dose of alcohol at the end of a continuous, steady drinking session. This scenario is designed to simulate "Last Call" and will be conducted by having participants drink several drinks at a programmed rate for a set period of time. When "Last Call" is made, the participant consumes additional drinks.
- Drinking during exercise. The effects of different intensities of exercise will be programmed while participants drink alcohol over a period of 3-4 hours. The exercise conditions will be manipulated to include light, moderate and heavy physical activity. This scenario will simulate dancing and drinking scenarios in which individuals consume alcoholic beverages while engaged in episodic bouts of physical activity.

Figure 12. Human Subject Testing at DADSS Satelite Lab at McLean Hospital in Belmont MA

Standard Calibration Test Device Research

New research into forensic toxicology has revealed emerging technologies with improved ability to both quantify and identify ethanol in SCDs. Initially, a Gas Chromatograph (GC) with a Flame Ionization Detector (FID) was used to precisely quantify ethanol in the breath-based SCD. Unfortunately, the GC-FID provides good quantification but is unable to identify the chemical it is quantifying. It became clear that two different technologies would be required—one for the breath-based SCD and another for the tissue-based SCD. The Fourier Transform Infrared Spectroscopy (FTIR) was selected over other technologies due to its ability to both identify and precisely measure the ethanol in a breath-based SCD (Figure 13, left side). A High-Performance Liquid Chromatography (HPLC), with numerous detectors and interfacing with an FTIR, can provide extremely precise measurements and identification of ethanol as well as the other reagents in the tissue-based SCD (Figure 13, right side).

Figure 13. Thermo Fisher iS50 FTIR, Waters Aquity UPLC and MKS Multigas 2030 FTIR in the DADSS Research Laboratory

Accuracy is limited by the calibration solution used with all of these technologies. The advanced capabilities of the new instrumentation packages revealed deficiencies in the current calibration solutions. New contaminants were identified that were previously undetected. The accuracy of the breath-based SCDs 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 solutions available, alternative ways to produce the calibration solutions were researched and pursued. To improve tissue-based calibration solution accuracies, the 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 solutions is being pursued.

Specific tasks in the DADSS sensor calibration methods research include:

- Research designed to improve performance of current SCD accuracy, precision and stability.
- Research designed to improve performance of current Wet Gas Breath Alcohol Simulator, a system used to simulate a human breath.
- Modify and optimize SCDs for in-vehicle testing to evaluate sensors performance and quality control.
- Investigate a non–liquid-based, touch–based SCD for use as diagnostics and quality control of the DADSS Sensor.

Patent Activity

ACTS has taken a number of actions to ensure the commercial implementation of the DADSS technology if it is demonstrated that the technology is commercially viable.

First, ACTS is pursuing 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 pursued 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, working with NHTSA, has structured ownership of the intellectual property generated through this research so that it vests with ACTS, a 501(c)(4) nonprofit, and not the individual members of ACTS or the DADSS technology providers. This helps to facilitate commercialization as rapidly as possible in at least two ways. First, the pooling of resources by NHTSA and ACTS provides a reliable and cost effective basis to promote the standardization of the technology, its widespread deployment, and acceptance by the general public. Second, 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	Pending	201280042179.6
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	Germany	Closed	NOT YET 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	Pending	2014-528520
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	United States of America	Closed	61/870,384

TO START" WITH LED/HAPTIC NOTIFICATION AND MEASUREMENT WINDOW			
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	Pending	201480047728.8
SYSTEMS AND METHODS FOR CONTROLLING VEHICLE IGNITION USING BIOMETRIC DATA	European Patent Office	Pending	EP14744677.7
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	United States of America	Closed	61/889,320

FOR COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS			
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	United States of America	Issued 9,281,658	14/456,738
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	United States of America	Pending	15/058,650
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	Canada	Pending	201480055848.2
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	China	Pending	201480055848.2
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	European Patent Office	Pending	14755950.4
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	Japan	Pending	2016-516589
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	South Africa	Pending	2016/01639
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED	PCT	Closed	PCT/US14/50575

MULTIPLE WAVELENGTH TUNED LASERS			
BREATH TEST SYSTEM	United States of America	Pending	14/421,371
BREATH TEST SYSTEM	Canada	Pending	2,881,817
BREATH TEST SYSTEM	China	Pending	201380054912.2
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	SE1250954-3
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	SE1250953-5

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	Pending	PCT/US2016/060622
SENSOR SYSTEM FOR PASSIVE IN-VEHICLE BREATH ALCOHOL ESTIMATION	United States of America	To Be Filed	Unfiled
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	United States of America	Closed	62/171.566
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	United States of America	Pending	15/090.048
INTEGRATED BREATH ALCOHOL SENSOR SYSTEM	PCT	Pending	PCT/US2016/026024

†PCT means Patent Cooperation Treaty.

Consumer Acceptance Research

ACTS and NHTSA have recognized from the outset that consumer acceptance of, and demand for, the DADSS technology is important. If at the end of this program (currently authorized through 2020) DADSS meets all of the performance requirements for in–vehicle use but drivers do not choose DADSS as an option in their new vehicle, it may not be possible to realize the potential life–saving benefits of the technology. Under the 2013 Cooperative Agreement, research has been initiated to understand public opinions about DADSS and the use of advanced safety technology to address alcohol–impaired driving, raise public awareness, and understand how the technology should operate in motor vehicles to achieve high levels of acceptability for the technology.

In 2016, the DADSS Research Program focused on advancing the technology; answering questions from partners, supporters and key members of the media to keep them well-informed on progress; and planning for increased outreach in the year ahead. Because there was minimal public exposure for the DADSS program in 2016, follow-up research to measure shifts in public perception during that period were not conducted. Activities were limited and included the following:

- Tracking related studies on impaired driving and public opinion, such as the release of 2016 Traffic Injury Research Foundation (TIRF) U.S. research
- Planning a second round of qualitative and quantitative research to measure shifts in public awareness and acceptance of the DADSS technology, and to address questions that came up in policy discussions about technology use and limitations.

State Participation

In September 2016, Virginia became the first state to partner with the DADSS Program through an independent agreement with the Virginia Department of Motor Vehicles' Highway Safety Office.

Virginia will be involved at various levels: from initial manufacturing and vehicle integration, to field operational tests, to helping raise public awareness and gauging the public's acceptance of the technology. As the testing of the DADSS technology advances in the laboratory, Virginia will get an early look at the progress that has been made, provide input about the technology's convenience and operational features, and help refine and improve the technology before it becomes widely available.

Accounting of Federal Funds

The surface transportation reauthorization enacted in 2012, known as 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.[7] The authorization covered fiscal years 2013 through 2016. Subsequent reauthorization for DADSS research occurred in December 2015 under the Fixing America's Surface Transportation (FAST) Act. The FAST Act provides specific authority for DADSS research through fiscal year 2020.[8]

The agency received appropriated amounts from the highway trust fund for this research program in fiscal year 2016. Specifically, funding was provided under NHTSA's highway traffic safety grants account consistent with the identified funding authority provisions in both Sections 403 and 405 of Title 23 of the United States Code.[9] For fiscal

[7] 23 U.S.C. § 403(h) (as amended by Public Law 112–141, enacted July 6, 2012).
[8] 23 U.S.C. § 403(h) (as amended by Public Law 114–94, enacted December 4, 2015).
[9] Public Law 112-141, Sections 31103(h)(2) and 31105(a)(2).

year 2016, the agency made funding available in the amount of $5,493,906 for the research program (Table 2).[10]

Table 2. FY16 NHTSA funding provided for in-vehicle technology research to prevent alcohol-impaired driving

	Fiscal Year 2016
Funding for In–vehicle Technology Research	$5,493,906

The period of performance specified in the 2013 Cooperative Agreement covers a five–year period (September 30, 2013 to September 29, 2018) and research has been planned for the entire five–year period, that is, through fiscal year 2018. Table 4 provides a general statement regarding the use of Federal funding for fiscal year 2016 to carry out the DADSS research effort.

Table 4. Funding Status

Automotive Coalition for Traffic Safety
Advanced Alcohol Detection Technologies (DADSS)
Cooperative Agreement # DTNH22-13-00433
Funding Amount Provided

Funding Amount Provided – FY16		**$ 5,493,906**
FY16 Funding Expended		
Research & Development		$ 5,363,700
Indirect Rate		$ 130,206
	Total Expended	**$ 5,493,906**

Conclusion

Significant progress has been made to identify DADSS technologies that have the potential to be used on a more widespread basis in passenger vehicles. Two specific approaches have been chosen for further investigation; tissue spectrometry, or touch-based sensors, and distant/offset spectrometry, or breath-based sensors. Proof-of-principle prototype DADSS sensors have been developed, one designed to remotely measure alcohol concentration in drivers' breath from the ambient air in the vehicle cabin, and the other designed to measure alcohol in the driver's finger tissue through placement

[10] Consolidated Appropriations Act, 2016, Public Law No. 114–113, enacted December 18, 2015.

of a finger on the sensor. Both sensors have been integrated into a research vehicle for testing and evaluation.

Progress also has been made to develop calibration devices for both breath- and touch-based bench testing in order to measure whether the DADSS devices can meet the stringent criteria for accuracy and precision. Unique standard calibration devices have been developed for both the breath- and touch-based systems that go well beyond current alcohol-testing specifications.