2015 In-Vehicle Alcohol Detection Research

DTNH22-13-H-00433

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 under MAP-21 in carrying out this effort.

September 30, 2013 through September 30, 2015

2015

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 (the "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.

Surface transportation reauthorization enacted in 2012, known as 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 begun in October 2013 (the "2013 Cooperative Agreement"). The 2013 Cooperative Agreement covers Phase III and any subsequent phases of 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 currently anticipated that the private sector will engage in further product development and integration into motor vehicles.

During the fiscal year ending September 30, 2015, the following accomplishments were realized:

- Breath-based DADSS Subsystem Research
 - \circ $\,$ Completed validation testing of 2^{nd} Generation DADSS sensor
 - Redesigned and developed a 3rd Generation DADSS sensor that is smaller and more compact for eventual vehicle integration; added water vapor sensor to sensing package
 - $\circ~$ Manufactured the 3^{rd} Generation sensor and initiated its performance evaluation process
 - Continued sensing system algorithm development, testing, and validation

- Completed research, build, and validation testing of prototype breathing manikin for vehicle cabin aerodynamic studies
- Initiated vehicle integration effort focused on developing assisted air flow to guide the breath plume to the sensor as well as investigating the integration of the sensor into the seat belt



Figure 1. 3rd Generation breath-based sensor

- Touch-based DADSS Subsystem Research
 - Identified and validated new laser diode supplier
 - Completed development of solid state DADSS sensing system
 - Initiated redesign of DADSS subsystem to facilitate eventual vehicle integration with focus on scalability and automotive application
 - Initiated the development of the Human Machine Interface (HMI) for the ignition start/stop button in which the sensors touch pad will be integrated
 - Developed and tested an anti-circumvention concept that insures the driver is the only occupant that can press the ignition start/stop button
 - Initiated the long term development of the swept laser system that will allow for a significant reduction in the number of required lasers and therefore in overall sensor size



Figure 2. Ignition Start/Stop anti-circumvention concept with 4th Generation touchbased mockup

- Standard Calibration Test Device Research
 - Completed research, build, and validation testing of Standard Calibration Device for the breath-based DADSS subsystem capable of analyzing 15 breaths per minute over a BAC range of 0.00 to 0.12 BAC
 - Continued research, build, and validation testing of robotic assembly system for manufacturing "fingers" with the same optical properties as human fingers for use as Standard Calibration Device for the touch – based DADSS subsystem
- Human Subject Testing
 - Began research on social drinking dosing protocol
 - Began work to secure Institutional Review Board (IRB) approval
- Patent Prosecution
 - Intellectual property developed under the DADSS Research Program will be licensed on equal terms to all requesters competent to manufacture original equipment level DADSS subsystems
 - Initiated efforts to prepare and prosecute patent applications in the main auto-producing regions of the world, i.e., the United States, Europe, Japan, China, and South Africa

- Consumer Acceptance Research
 - Initiated the planning and development of consumer acceptance research

For the first half of fiscal year 2013, no funding was appropriated. Full funding of nearly \$5.3 million was appropriated the second half of fiscal year 2013, and the funding was obligated by the National Highway Traffic Safety Administration September 30, 2013 after a cooperative agreement was signed. Research on DADSS continued during fiscal year 2013 using funding remaining under the 2008 Cooperative Agreement, funding provided by ACTS, and funding provided by the DADSS technology providers. Total expenditures in fiscal year 2013 prior to the effective date of the 2013 Cooperative Agreement totaled approximately \$2,638,883.

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 2013, 10,076 lives were lost in alcohol–impaired driving crashes (i.e., fatality in a crash involving a driver with a blood alcohol concentration (BAC) of 0.08 percent or greater), or 31 percent of all the people who died in motor vehicle crashes that year. This percentage has remained unchanged for the prior 10 years. 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 legal limit in all 50 states –6,904 deaths could have been prevented.¹ This is the number of deaths directly attributable to BACs at or above 0.08 percent, i.e., the number of deaths that could have been prevented via specific deterrence, according to the IIHS analysis. The actual number of lives saved could be higher due to the added effects of general deterrence.²

Another IIHS study shows 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

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 It is generally accepted that driver behavior can influenced by both general deterrence and specific deterrence. In the instance of DADSS, general deterrence results from the public's perception that traffic laws are enforced and that there is a risk of detection and punishment when traffic laws are violated. Specific deterrence may result from, among other things, the implementation of a DADSS in motor vehicles.

good" idea, and more than 40 percent said they would want the technology in their own cars.³ More detailed research into how consumers would respond to DADSS is planned as part of this cooperative research effort.

Surface transportation reauthorization enacted in 2012, known as Moving Ahead for Progress in the 21st Century (MAP–21), amended section 403 of title 23 of the United States Code to authorize additional DADSS research.⁴ As required by MAP-21, this report describes the progress made by this cooperative research program, 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 under MAP-21 in carrying out this effort.

Background

Alcohol-impaired driving is one of the primary contributing factors in motor vehicle fatalities on U.S. roads every year and in 2013 alone resulted in more than 13,000 deaths. There are a variety of countermeasures that have been effective in reducing this excessive toll, many of which center around strong laws and visible enforcement.

Separate from these successful countermeasures, NHTSA and ACTS⁵ 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

³ McCartt, A.T., Wells, J.K, and Teoh, E.R., *"Attitudes toward in-vehicle advanced alcohol detection technology,"* Traffic Injury Prevention, March 2010.

⁴ See section 403(h) of title 23 of the United States Code as amended by Public Law 112–141, July 6, 2012. ⁵ 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 represent the majority of automotive companies that develop and build new vehicles for the U.S. market.

(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 legal limit (currently at or above of 0.08 grams per deciliter (g/dL) or 0.08 percent).⁶

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. A parallel 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 meet 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 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, etc.) 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

⁶ 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.

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 tissue or 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 will be installed allowing a first look at how such technology might work within the vehicle environment.

The 2013 Cooperative Agreement covers Phase III and any subsequent phases of 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. 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 currently anticipated that the private sector will engage in further product development and integration into motor vehicles. A preliminary 5-year road map for Phase III is shown in Figure 3.

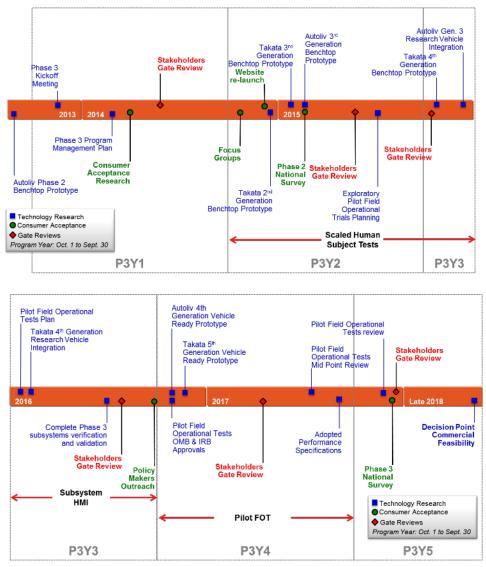


Figure 3. Overview of 5-Year Research Plan for the DADSS Program

Note: In Figure 3 P3 means Phase III, and Y# is the year number. For example, Y1 is Year One.

The organization of the Cooperative Research Agreement program team is shown in Figure 4. ACTS formed a Stakeholders Working Group of Experts, including representatives from domestic and international automotive manufacturers and DOT representatives in order to consider the views of industry and other stakeholders.

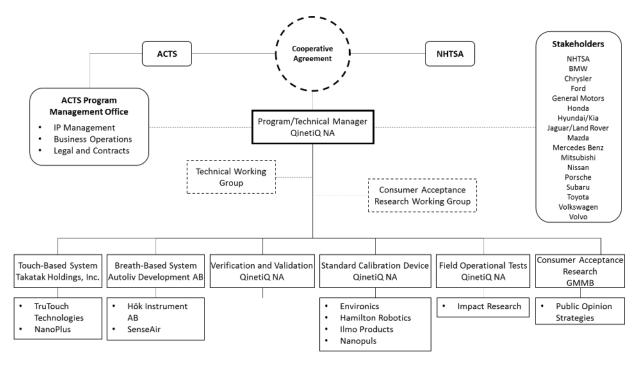


Figure 4. DADSS Research Program Organization

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 2008 Cooperative Agreement covers Phases I and II. The 2013 Cooperative Agreement covers Phase III and any phases to be subsequently defined.

The intent of Phase I was to research prototypes capable of rapidly and accurately measuring a driver's BAC non-intrusively. 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 time, accuracy, and precision in future iterations.

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 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 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 in Waltham, MA that yielded promising results for two of the three technologies (Figure 5).



Figure 5. DADSS BioSafety Lab in Waltham, MA.

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 within the needs 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. These prototypes will be integrated into a research vehicle (DADSS X1 Research Concept Vehicle shown in Figure 6, and DADSS X2 Research Concept Vehicle show in Figure 7).



Figure 6. DADSS X1 Research Concept Vehicle



Figure 7. DADSS X2 Research Concept Vehicle

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 2018 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.

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 at the same point. 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. This approach is being developed by Autoliv Development AB.
- **Tissue Spectrometry, a touch-based approach** that analyzes alcohol found in the driver's fingertip tissue (or more specifically, the blood alcohol content 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. This approach is being developed by Takata-TruTouch, a partnership between TK Holdings, Inc. and TruTouch Technology.

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.

Autoliv Breath-based Subsystem

The breath-based sensor achieved incremental improvement in Phase II that primarily involved a change in material composition of the sensor optical housing as well as significant improvements in mirror fabrication, coating, and integrated heaters designed to improve startup time, accuracy and precision. The focus of research in Phase III is to design, test, and validate a smaller, more robust optical sensor cavity that may be more easily packaged into a motor vehicle, with the objective remaining that the devices meet or exceed the DADSS Performance Specifications. Figure 8 shows the evolution of the Autoliv sensors.

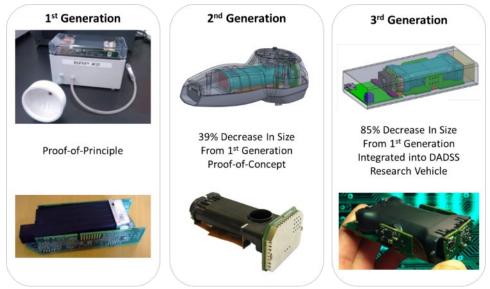


Figure 8. Evolution of Breath-based DADSS Sensor

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:

- Research designed to improve sensor's accuracy and precision to resolve identified non-compliances from the Phase II target
- Research to improve sensor's robustness to resolve identified non-compliances from the Phase II environmental simulation
- In-depth research of the human breath aerodynamics within the occupant compartment of various sized vehicles under a variety of environmental conditions
- Research the optimal placement parameters for breath-based sensors within the varying geometry of vehicle cabins
- Research air inlet design parameters for optimal sensor performance
- Evaluate potential of and design strategy intended to prevent user manipulation of device

Takata TruTouch Touch-based Subsystem

In Phase II, a fundamental change in the touch–based device sensor was initiated in system architecture from Phase I - a shift from a bulky spectrometer engine (an instrument used to measure properties of light over a specific portion of the electromagnetic

spectrum) with moving parts to a fully solid-state electronics spectrometer sensor with no moving parts. This new approach requires extensive hardware and software research, the aims of which are to transform the touch-based sensor to improve suitability for long-term in-vehicle use and to improve the signal to noise ratio for better accuracy, precision, and shorter measurement times. The new system architecture is much more suited to a vehicle environment and is intended to offer better reliability, durability, and cost basis for in-vehicle use.

The focus of current efforts is to complete the design, test, and validation of the solid state architecture to be used by this system, This involves developing new "recipes" for the solid state wafers to be used for the laser diodes – each diode the size of a grain of rice – that make up this system. Forty laser diodes that interrogate 40 different slices of the infrared light spectrum are needed. These diodes must work with extremely high – and unprecedented – precision and accuracy in the infrared light spectrum used to measure ethanol (alcohol). Research of the touch-based system architecture has been the most impacted by the resource constraints of the DADSS Program. Under the 2008 Cooperative Agreement, the supply chain used to make the experimental laser diodes stretched from China through Ireland to Germany. This complicated research significantly. The DADSS Program has now been able to streamline the supply chain under the 2013 Cooperative Agreement and the pace of research accelerated. In September 2014, a fully working prototype of the solid state touch-based system was demonstrated at the technology provider's laboratory in Riverside, California. Figure 9 shows the evolution of the touch-based sensor and Figure 10 shows the 2nd generation solid state touch-based prototype.



Figure 9. Evolution of Solid State Touch-Based DADSS Subsystem

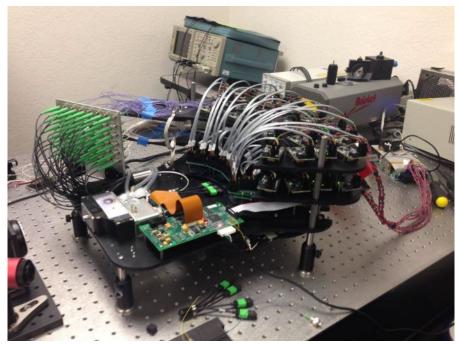


Figure 10. Solid State Touch-Based 2nd Generation Prototype Undergoing Testing at the Technology Provider's Laboratory in Riverside, California

In Phase III, additional research is being pursued to improve functionality and invehicle 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 sensors include:

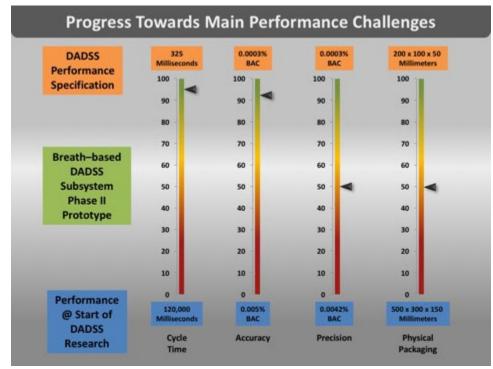
- Research designed to improve sensor's accuracy and precision to resolve identified non-compliances from the Phase II target
- Research designed to improve sensor's robustness to resolve identified noncompliances from the Phase II environmental simulation
- Scale up supplier processes in an effort to meet potential high volume demand, specifically as it relates to wafer processing of the laser diodes which are currently needed on less prominent high 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 and 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 others who might attempt to circumvent the system
- Protection of data (cybersecurity)
- Integrity and security of communication between DADSS sensor and vehicle.

Figure 11 and Figure 12 illustrate the progress made through Phase II for the critical performance specifications of speed, accuracy, precision and physical size.





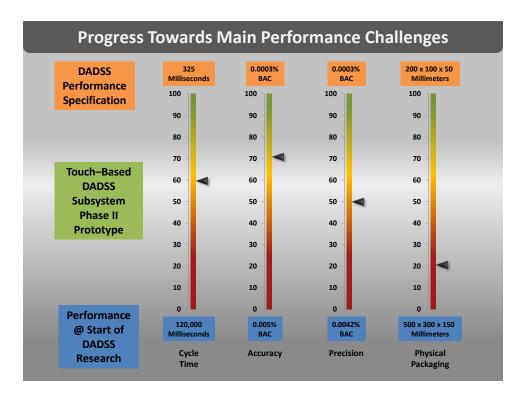


Figure 12. Progress Towards Main Performance Specifications (Touch-based DADSS Subsystem)

Technology & Manufacturing Readiness Levels

The DADSS Program adopted a set of automotive metrics derived from the methodology used by the Department of Defense to quantify a technology's commercial feasibility.⁷ The Government Accountability Office (GAO) has described it as a best practice for improving acquisition outcomes.⁸ The Technology Readiness Level (TRL) provides an objective measure for assessing the maturity of a particular technology. TRL metrics facilitate informed decisions regarding investment and risk associated with technology development and transition to commercialization. Similarly, the Manufacturing Readiness Level (MRL) assesses the maturity of manufacturing readiness. These two sets of readiness levels assist all those engaging with the automotive sector, by providing specific, identifiable stages of maturity, from early stages of research all the way through to supply chain entry. Both the TRL and the MRL are comprised of 9 levels, 1 – 9, although the MRL is offset (delayed) from the TRL. Transfer to the private sector for applied research and development leading potentially to commercialization and mass production is targeted to occur at a TRL equal to eight (8) and an MRL equal to seven (7). Figure 13 shows the DADSS technology and manufacturing readiness levels.

⁷ See section 403(h) of title 23 of the United States Code as amended by Public Law 112–141, July 6, 2012.

⁸ See section 403(h) of title 23 of the United States Code as amended by Public Law 112–141, July 6, 2012.

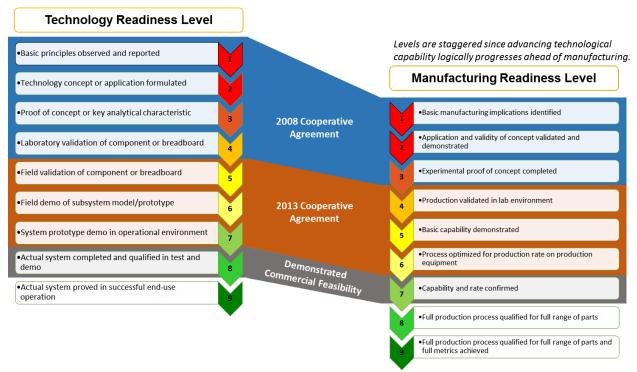


Figure 13. Technology and Manufacturing Readiness Scales

Table 1 summarizes a preliminary evaluation of the "readiness" of the breath-based and touch-based technologies at the end of Phase II as determined by ACTS.

Table 1. Technology and	Manufacturing Readiness	Levels by Technology Type
	0	

Technology	Technology Readiness Level (TRL)	Manufacturing Readiness Level (MRL)
Breath-based	4	4
Touch-based	3	2

These rating indicate that the breath-based technology research is ahead of where Program Management expected it would be at the end of Phase II, but the touch-based technology lags expectations due to challenges with the development of the laser diodes and its associated supply chain. However, a number of technological challenges are ahead for the breath-based system relating to sampling in a vehicle cabin with the windows open or the air conditioning or heater on, which are not expected to be challenges that the touch-based system will need to surmount. Work to research in-cabin sampling techniques was initiated as part of Phase III. See Figure 11.



Figure 11 Anthropomorphic Manikin with Simulated Breathing Developed to test Breath-based DADSS Technology in DADSS X1 Research Concept Vehicle

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.

Limited human subject testing was performed during Phases I and II (Figure 14), but more research will be conducted under the 2013 Cooperative Agreement to better understand how these new technologies perform in BAC measurement relative to the benchmarks of blood and (deep lung) breath and over a wide range of drinking scenarios. 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 following scenarios:
 - fast (bolus) drinking; and
 - social drinking scenarios including food ingestion.



Figure 14. Human Subject Testing at DADSS BioSafety Lab in Waltham, MA

Standard Calibration Test Device Research

As part of the prior Cooperative Agreement effort, Standard Calibration Devices (SCDs) were researched and constructed to assess and document the accuracy and precision of the device prototypes created. Two different SCDs have been built for prototype testing; one for use with breath-based technologies and one for use with touchbased technologies. Two aspects essential to accurate detection were investigated. First, samples of simulated "breath" and "tissue" were created to provide a calibrated (known) and consistent ethanol concentration delivered to the prototype in vapor and/or liquid form. These samples also were created to provide reasonable facsimiles of human breath and tissue. As noted previously, the DADSS Performance Specifications require a significantly higher degree of accuracy and precision than the specifications for current evidential breath alcohol measurement calibration instruments, thus the samples of breath and tissue had to exceed the DADSS Performance Specifications by an order of magnitude. Second, delivery methods were developed so that the targeted samples could be effectively delivered to the prototypes. In the case of touch-based testing, research is needed to support the development of non-liquid samples that will mimic human tissue to streamline and simplify sensor evaluation and calibration.

Additional research planned in Phase III is designed to create SCDs for in-vehicle testing, including optimization of breath and touch samples, and delivery system miniaturization. To that end, continued research involving the Gas Chromatograph (GC) SCD verification system created in Phase II will be critical for Phase III and for meeting the DADSS Performance Specifications. This will include researching higher tolerance temperature controllers to maintain temperature stabilization across the GC system, decreasing the temperature and pressure fluctuation in the environment of the GC system in an effort to further stabilize the measurements, and developing a headspace auto–sampler with high repeatability and reproducibility.

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 Prosecution

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

First, ACTS is prosecuting patent applications in the auto producing regions 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, 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. One, 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 two, 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 2 summarizes the intellectual property generated to date under the DADSS Program.

TITLE	COUNTRY	STATUS	APPLICATION #
MOLECULAR DETECTION SYSTEM AND METHODS OF USE	United States of America	Pending	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	Pending	13/596,827
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	PCT†	Closed	PCT/US12/52673
SYSTEM FOR NON-INVASIVE MEASUREMENT OF AN ANALYTE IN A VEHICLE DRIVER	South Africa	Pending	2014/02304
SINGLE/MULTIPLE CAPACITIVE SENSORS "PUSH TO START" WITH LED/HAPTIC NOTIFICATION AND MEASUREMENT WINDOW	United States of America	Closed	61/870,384

Table 2. Patent Applications to Date

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	РСТ	Pending	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	Pending	14/456,738
SYSTEM AND METHOD FOR CONTROLLING COLLOCATED MULTIPLE WAVELENGTH TUNED LASERS	РСТ	Pending	PCT/US14/50575
BREATH TEST SYSTEM	Sweden	Issued	SE1250954-3
BREATH TEST SYSTEM	РСТ	Pending	PCT/SE13/50991
HIGHLY ACCURATE BREATH TEST SYSTEM	Sweden	Issued	SE1250953-5
HIGHLY ACCURATE BREATH TEST SYSTEM	РСТ	Pending	PCT/SE13/50990

†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 DADSS meets all of the requirements for in–vehicle use but drivers are not motivated to choose DADSS as an option in their new vehicle it will 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. The research will include the following:

- Pre-research discovery Conduct pre-research into audiences, their attitudes, the messages they are currently being given on vehicle safety technology, and anything else that will help make the best use of focus groups.
- Qualitative research Conduct eight focus groups as follows:
 - Three focus groups among parents who have children ages 14 to 22 years old (one group among mothers, one group among fathers, and one mixed gender group among married parents).
 - Two focus groups among social drinkers or people who acknowledge they have driven after drinking an alcoholic beverage (one group among women and one group among men)
 - Three focus groups among new car buyers (two groups among early technology adopters and one group among moderate to low technology adopters
- Quantitative research Conduct a national survey of drivers to quantify the learnings from groups and provide quantitative data that helps establish a baseline data of consumers attitude towards DADSS.

Accounting of Federal Funds

Two-year 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.⁹

Full funding for DADSS research was provided in appropriations legislation enacted for fiscal years 2013 and 2014. ^{10, 11} Federal funding totaling \$10,729,400 was authorized and ultimately appropriated (**Table 3**).

For fiscal year 2013, the agency obligated the full funding amount of approximately \$5.3 million after completing negotiations with ACTS for a new five year cooperative agreement. These negotiations concluded in September 2013 and the funds were obligated shortly thereafter. During this process, research on DADSS continued under the prior agreement with previously obligated funding from NHTSA and funding provided by ACTS and the DADSS technology providers. Total expenditures in fiscal year 2013 prior to the establishment of a new cooperative agreement totaled approximately \$2,638,883.

⁹ 23 U.S.C. § 403(h)(1) (as amended by Public Law 112–141, enacted July 6, 2012).

¹⁰ Consolidated and Further Continuing Appropriations Act, 2013, Public Law No. 113–6, enacted March 26, 2013.

¹¹ Consolidated Appropriations Act, 2014, Public Law No. 113–76, enacted January 17, 2014.

Table 3. NHTSA funding available for in-vehicle technology research to preventalcohol-impaired driving

	Fiscal Year 2013	Fiscal Year 2014
Funding for In-vehicle Technology	\$5,289,400	\$5,440,000
Research		

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. Adjustments to the five-year research plan may need to be made depending upon the funds ultimately available in future fiscal years. MAP-21 reauthorized surface transportation programs through fiscal year 2014. Table 4 provides a general statement regarding the use of Federal funding for FY 13 & FY 14 provided under MAP-21 to carry out the DADSS research effort. Although there were some initial delays in expending funds to allow ACTS to undertake subcontract negotiations with technology providers, to date, the research effort has now expended all of these funds.

Table 4. Funding Status

Automotive Coalition for Traffic Safety Advanced Alcohol Detection Technologies (DADSS) DTNH22-13-00433 Funding Authorized, Appropriated and Expanded

Funding Authorized & Appropriated -	FY13 & FY14	\$ 10,729,400
FY 13 & FY14 Funding Expended to Da	ite	
Research & Development		\$ 10,480,685
Indirect Rate		\$ 248,715
	Total Expended	\$ 10,729,400

*Funding not spent or obligated is due to delays in subcontract negotiations with technology providers

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 is designed to measure alcohol in the driver's finger tissue through placement of a finger on the sensor.

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.

In summary, the DADSS Program so far has accomplished the goals set at the onset of the program. Prototype testing has indicated that there are potential technologies that ultimately could function non-invasively in a vehicle environment to measure a driver's BAC.