DRIVER ALCOHOL DETECTION SYSTEM FOR SAFETY (DADSS) – A VEHICLE SAFETY TECHNOLOGY APPROACH TO REDUCING ALCOHOL-IMPAIRED DRIVING – A STATUS UPDATE.

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ABSTRACT

Alcohol-impaired driving continues to take a significant toll among road users both in the United States and around the world. In 2021, an estimated 42,915 people died in motor vehicle traffic crashes, a 10.5% increase from 2020. The projection is the highest number of fatalities since 2005 and the largest annual percentage increase in the Fatality Analysis Reporting System's (FARS) history. In 2020, in the U.S. alone, motor vehicle fatalities from crashes involving alcohol totaled 11,654, a 14% increase over 2019, which accounts for approximately 30% of all traffic fatalities in the US for the year. To better address this ongoing problem, in 2008 the National Highway Traffic Safety Administration (NHTSA) and the Automotive Coalition for Traffic Safety (ACTS) formed a cooperative research partnership to explore the feasibility, the potential benefits of, and the public policy challenges associated with the widespread use of non-invasive technologies to prevent alcohol-impaired driving. This partnership, known as the Driver Alcohol Detection System for Safety (DADSS) Program has made great strides forward in the development of in-vehicle technologies that will measure blood or breath alcohol and may prevent alcohol-impaired drivers from driving their vehicles. Exploratory research in earlier phases of the program established the feasibility of two sensor approaches, breath- and touch-based, for in-vehicle use. The sensors have since been refined, in terms of both hardware and software, as the program strives to meet the performance specifications required for unobtrusive and reliable alcohol measurement.

In late 2021 the program announced that the first zero-tolerance breath alcohol sensor product equipped with new alcohol detection technology will be available for open licensing in commercial vehicles. "Open licensing" means that the technology, which measures a driver's breath alcohol concentration, will be made available to any product integrator for preparation into fleet vehicles. The breath sensor is designed for fleet operators implementing a zero-tolerance alcohol policy for their drivers, staff or employees. It requires a directed puff of breath and provides a "pass/fail" reading of the driver's breath alcohol concentration.

Currently the DADSS program is focused on transitioning the latest generations of consumer breath and touch sensors from research to product development. Numerous parallel research programs continue including sensor development, development of calibration processes, materials and instrumentation that will verify the technologies are meeting these elevated performance specifications, human subject testing in conditions that replicate those likely to be experienced in the real world, and real-world field trials in diverse settings. The goal for DADSS technologies is commercialization. This paper will outline the technological approaches and the status of the various DADSS research programs.

INTRODUCTION

Alcohol-impaired driving (defined as driving at or above the legal per se limit of 0.08 grams per deciliter (g/dL) or 0.08 percent in all U.S. States except in Utah where the limit is 0.05 g/dl) is one of the primary factors in motor vehicle fatalities on U.S. roads every year. Although strong laws and enforcement have led to fewer alcohol-impaired deaths on the roadways (Ferguson, 2012), in 2020 alone, crashes involving at least one driver with a blood alcohol concentration (BAC) of 0.08 g/dl resulted in 11,654 deaths of U.S. road users (National Highway Traffic Safety Administration (NHTSA), 2020). In 2008, the NHTSA and the Automotive Coalition for Traffic Safety (ACTS)[1] began research to develop in-vehicle solutions to address alcohol-impaired driving. The alcohol sensors under development are required to be seamless with the driving task, that is, passive, accurate, fast, reliable, durable, and require little or no maintenance. Ultimately, DADSS technology seeks to restrict the motive power when the device registers that the driver's blood alcohol concentration (BAC) exceeds the legal per se limit, although other limits could be programmable. This cooperative research partnership, known as the Driver Alcohol Detection System for Safety (DADSS) Program, has been developing both breath-based and touch-based non-invasive technologies that will be able to prevent alcohol-impaired driving, (Ferguson et al., 2009, Ferguson et al., 2010, Ferguson et al., 2011, Zaouk et al., 2015, Zaouk et al., 2017).

To effectively measure blood and breath alcohol in real time with negligible misclassification errors, stringent performance specifications have been developed that provide a template to guide the overall research effort. The ability to calibrate the performance of each generation of sensor prototypes is a critical component of the development process. In addition, SAE led the development of the SAE J3214 standard, Breath-Based Alcohol Detection System, finalized in January 2021, which was specifically developed to provide the testing specifications adopted for breath sensors in fleet vehicles. The standard has been published by SAE International and is available through the sae.org website. Additional standards are in development, as outlined later in this paper. These elevated standards, especially those for accuracy and precision, have necessitated the development of innovative approaches that will enable measurement of the technologies' performance on an ongoing basis. Specifically, calibration processes, materials, methodologies and instrumentation have been the subject of extensive cutting-edge research to enable the requisite testing.

Research vehicles have been equipped for Field Operational Testing (FOT) with the latest versions of the breath sensors seamlessly integrated within the vehicle interiors. Instrumentation packages also have been developed that will provide a myriad of data on sensor performance under challenging real-world driving conditions. Along with determining whether the DADSS sensors are working as anticipated, the FOT data collection effort will allow the identification of areas for system improvement.

A comprehensive program of human subject research is being carried out, starting with the laboratory environment where better control of conditions can be exerted, and in the vehicle where the sensors can be tested in the environment in which they will be used. This research aims to establish that alcohol measurements made with diluted breath as well as capilary blood and interstitial fluid (in the tissue of the finger and thenar region of the hand) exceed or are comparable to the well-accepted standards of venous blood and deep-lung air widely used in traffic law enforcement.

At the same time, media coverage and consumer sentiments are being monitored in anticipation of a future launch of the technology. Consumer acceptance is an ongoing consideration and is a critical element and factor in realizing full implementation.

The purpose of this paper is to provide a status update on the following key DADSS program areas:

- Performance Specification Development
- DADSS Sensor Development and Subsystem Technological Research
  - Breath Sensor
  - Touch Sensor
- DADSS Verification and Validation
  - Laboratory - Standard Calibration Devices (SCD)
  - Human Subject Laboratory Testing (HST)
    - In-House Bood Ethanol Analysis

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[1] Members of ACTS comprise motor vehicle manufacturers representing approximately 99 percent of light vehicle sales in the U.S.

- o Field Testing
  - ▪ Controlled Human Subjects On-Road Driving Tests
  - ▪ Naturalistic Human Subjects On-Road Driving Tests
    - • James River Transportaion
    - • Schneider National

PROGRAM PROGRESS

Performance Specification Development, SAE J3214, and Future Standards

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

In addition to the DADSS Performance Specifications, performance specifications for the zero-tolerance breath sensor (referred to as Gen 3.3) were initiated in October 2019. This device is intended for use-in motor vehicle fleet applications and will determine if the driver is registering any breath alcohol, otherwise known as zero-tolerance. The draft specifications define the accessories' technology performance as it relates to accuracy, precision, speed of measurement, influence of the environment, issues related to user acceptance (such as instructions for use), long-term reliability, and system maintenance requirements. Access to the data memory or the ability to set operational parameters, including the setting of Breath Alcohol Concentration (BrAC) thresholds will be designed to deter unauthorized or inadvertent tampering.

SAE led the development of the SAE J3214 standard which was specifically developed to provide the testing specifications adopted for fleet vehicle breath sensors and was approved in January 2021. SAE International has published the standard and it is available through the sae.org website. The DADSS laboratory received ISO17025 accreditation to the SAE J3214 standard in September 2021 and is currently the only laboratory accredited to the standard. Unlike alcohol ignition interlocks, this fleet device operates without a mouthpiece and measures diluted breath samples. However, the SAE J3214 standard is applicable to systems with and without mouthpieces. The fleet device is designed to meet international specifications and standards for alcohol measurement devices currently in place in the United States, Canada, and Europe, but has more stringent requirements, especially with respect to the calibration curve and test gases. Since its release there have been several changes to improve the document structure and flow, as well as better define the testing requirements, including improvement of requirements for electrostatic discharge, electromagnetic compatibility, and interference. The updated version is expected to be released in the fourth quarter of 2022.

In addition, an SAE working committee has been established to create SAE standards for passive breath alcohol systems in consumer vehicles, and touch-based capillary blood alcohol measurement in-vehicle systems. This committee published the SAE J3214 (Breath Alcohol Detection System Standard) in January of 2021. It is anticipated that the passive breath standard should be released by the second half of 2023, and the touch-based standard by the second half of 2024.

DADSS Sensor Development & Subsystems Technological Research

The two technologies, breath and touch are being pursued for measuring driver BrAC and Blood Alcohol Content (BAC) non-invasively within the vehicle. Progress has been made in the development of both technologies. Two different devices are being pursued for each technology for use in vehicles – the Gen 3.3 breath sensor and Aglow touch sensor devices designed to prevent the vehicle from being driven if any alcohol is detected ($<= 0.02$ g/dL), and passenger vehicles devices, Gen 4.0 breath sensor and Radiant touch sensor, designed to prevent the vehicle from moving if the driver is at or above the legal per se limit for alcohol (typically 0.08 g/dL in the U.S.). Table 1 shows the target dates by which the DADSS sensors will be ready to license to product integrators. The length of time required to integrate a DADSS sensor into a motor vehicle will vary depending upon the type of product and the length of time needed to conduct validation and verification testing at the vehicle level.

Table 1. Breath and Touch Sensors Derivative.

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

* Gen 3.3 Breath Sensor Reference Design released for open licensing for use in commercial vehicle in December 2021

Breath Sensor

The sensor technology under development by Senseair and its partners uses infrared (IR) spectroscopy, which is stable over the full product lifetime, eliminating the need for recurrent calibrations. The challenge in measuring breath alcohol within the vehicle cabin is that the breath is diluted with the cabin air. The breath-based approach uses sensors to measure the concentration of alcohol and carbon dioxide (CO_2) in diluted breath simultaneously. The use of CO_2 in human breath as a tracer chemical allows it to be used as an indicator for the degree of breath dilution, and thus the dilution of the alcohol concentration in the expired breath. A fan draws diluted breath into a chamber where a detector measures the interaction with the alcohol and CO_2 in the sample (Hök et al., 2006). BrAC is then quickly and accurately calculated (Figure 1).
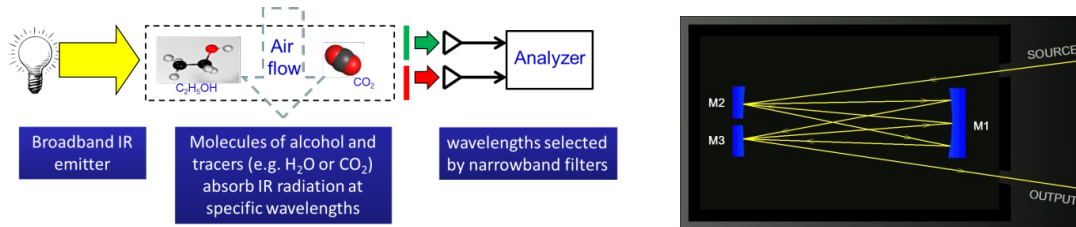

Figure 1. Breath-based sensor block diagram

The goal of the DADSS sensors is to passively measure breath alcohol within the vehicle cabin without directed input from the driver. The challenge is to meet the stringent performance requirements while measuring highly diluted breath. Thus, a significant component of the research is focused on understanding the behavior and flow patterns of the expired breath plume within the vehicle cabin and identifying effective locations for the sensors.

The breath-based sensor was updated with the goal of improving the ability to accurately and passively detect breath alcohol levels. The latest, 3rd Generation version (currently Gen 3.3), underwent a complete re-design to increase sensitivity for measurements of passive samples through improvements in the overall signal-to-noise ratio (SNR), reduce the overall size, and improve performance over the full temperature range of -40°C to +85°C as specified by the DADSS Performance Specifications (Biondo et. al. 2017). A major improvement of the Gen 3.3 sensor is the optical module configuration. Major enhancements were undertaken during the Gen 3.3 sensor development to improve how the sensor detects alcohol. Ethanol detection takes place over the full length of the cavity, whereas CO_2 is detected cross-wise to eliminate systematic timing differences between the two signals. This enables the possibility of passive in-vehicle sensing (Ljungblad, 2017). The Gen 3.3 device has been developed for fleet and accessory application with knowledge gained from Gen 3.2 laboratory studies and human subject trials. There are three product versions available: a vehicle–integrated solution, an aftermarket or accessory solution and a stationary point–of–access solution. This fleet device will be set to detect the presence of alcohol but will also have the flexibility to set the limit up to a BrAC of 0.04 g/dL depending on the company fleet owner's preference. The Gen 4.0 sensor will be suited for wider deployment in passenger vehicles (Figure 2) for a graphic representation of the sensor evolution and SNR improvements. The detector and sensor fan were modified to allow more homogeneous

airflow through the system. This resulted in improved sensitivity and increased peak gas levels when measuring breath exhalations at the same distance. This is a critical step for passive breath measurement. Software algorithms for passive detection of breath alcohol levels also have been enhanced, whereby several consecutive signal features can be accumulated to provide sufficient data for reliable measurement.
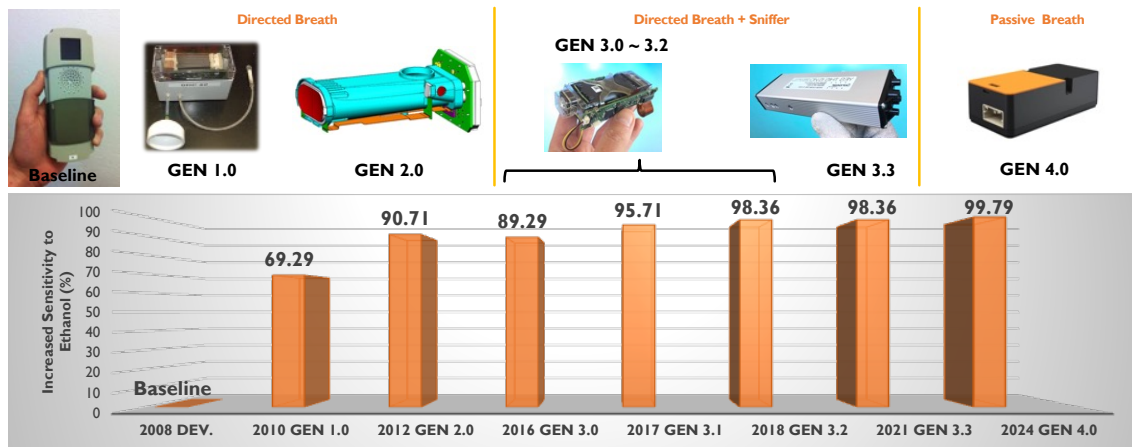

Figure 2. Breath-based DADSS Sensor Evolution and SNR improvements

Further investigations of critical components, including detectors, emitters and mirrors, have identified noteworthy options for more production friendly choices which are intended to be integrated in Gen 4.0. The latest generation 3.3 sensors have undergone rigorous operational and environmental testing aimed to simulate a sensor lifetime of fifteen years.

Touch Sensor

The touch sensor uses near-infrared (NIR) spectrometry - a noninvasive approach that utilizes the near infrared region of the electromagnetic spectrum (from about 0.7 μm to 2.5 μm) to measure substances of interest in bodily tissue (Ferguson et. al., 2010, Ridder et al., 2005). It has been determined that the 1.25-2.5 μm portion of the spectrum provides the highest sensitivity and selectivity for alcohol measurement because the alcohol signal is hundreds of times stronger than the signal in the 0.7-1.25 μm part of the NIR.

As depicted in Figure 3, the measurement begins by illuminating the user's skin with NIR light (like a low power flashlight). The light propagates into the tissue (the skin must be in contact with the device) and a portion of it is diffusely reflected back to the skin's surface where it is collected by an optical touch pad. The light contains information on the unique chemical information and tissue structure of the user. This light is analyzed to determine the alcohol concentration. The challenge is to measure the concentration of alcohol (sensitivity) while ignoring all the other interfering analytes or signals within the skin (selectivity).
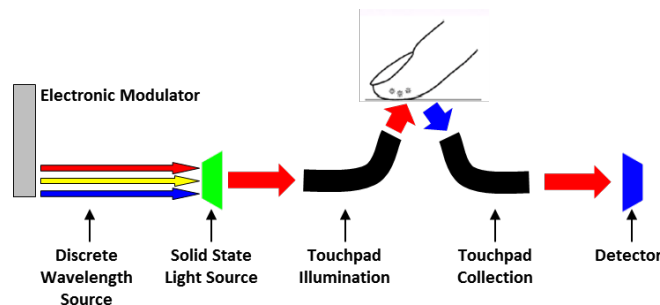

Figure 3. Touch-based subsystem solid-state laser spectrometer approach

The shift from the Proof–of–Concept prototype, which used a traditional Michelson interferometer that utilizes moving parts, to a solid-state laser spectrometer (which is better suited to the automotive environment) has required extensive hardware and software research (Ver Steeg et al., 2017). The key to enabling such innovation is the ability to define an optimized subset of optical wavelengths which will provide the high quality non-invasive alcohol

measurement in human tissue. Laser diodes that are tuned for optimal alcohol measurements are used to generate 40 unique wavelengths of light. The laser diode specifications were derived from the comparison and analysis of human subject data and comparative reference data.

Extensive research has been undertaken to develop the requisite laser diodes, many of which have not been previously manufactured, and assemble them in multi-laser packages. The individual laser signals are combined into a broader, diffuse light source in the optical module, which illuminates the finger or palm, and is reflected back to the touch pad's detector, where alcohol measurements are made. After initial work was completed to develop the laser diodes and packaging, a new supplier was selected with greater expertise in these areas. Each stage of the development process has required research and has resulted in multiple patent applications.

Recently, tunable lasers have been developed that are suitable for the touch sensor. Tunable lasers can alter the wavelength of operation in a controlled manner, thus enabling the use of fewer lasers to interrogate the NIR spectrum of interest. This development is expected to have higher measurement sensitivity and perform faster than the prior laser packages. It will enable a smaller sensor footprint, use less power, have better temperature control to prevent measurement drift, and result in simplified optics and electronics. Ultimately, the goal is to use only one to two tunable laser chips to produce these same unique wavelengths. depicts the recent evolution of laser diode development (Figure 4).
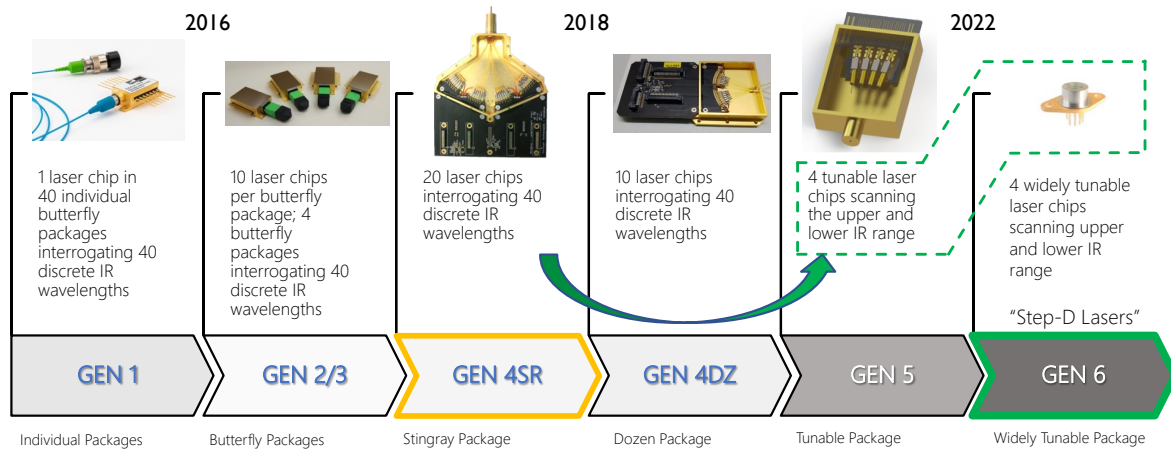

Figure 4. Evolution of laser development.

The touch sensor consists of the laser diodes, the laser guiding system to relay the laser signal into the skin in the prescribed fashion for optimal measurement, the detectors to receive the reflected signal (all of which reside in the driver optical interface), a reference sensor, and the electronics board that controls and guides the system. Each of these design elements will undergo significant enhancements from the current benchtop device. The Aglow sensor availability, suitable for fleet and accessory applications, is targeted for 2023. The consumer version, Radiant sensor, for use in privately-operated vehicles is targeted to be available during 2025.
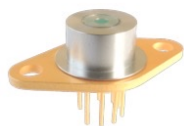

Figure 5. TO66 Tunable Near Infrared Laser

Research and development activity on the touch sensor is currently focused on optimizing the hardware and software for the benchtop optical system used in the laboratory and the development of a compact benchtop systems for field trials. All systems leverage tunable NIR lasers in a TO66 package size (Figure 5) and are primarily designed for in-vivo analysis, more specifically, the illumination and capture of reflected light from the dermal tissue on the thenar palm (Figure 6). The thenar has been selected for initial measurements due to consistency in skin tissue thickness and reduced light scatter compared to the pad of the finger.

The touch sensor functional characteristics critical to accurate and repeatable performance are 1) the laser signal needs to be stable, not drifting or fluctuating; 2) the combined light source from the lasers needs to be homogenized so that the light levels propagating through the tissue are always the same; and 3) levels of background noise need to be low and signal strength sufficiently strong so that the signal can be readily detected when reflected from the tissue.

As with any innovative technology development, technical difficulties have been experienced along the way. It is to be expected that with each new generation of technology there is a learning curve. Similarly, with the touch system, any time the light sources change, there are new challenges to be addressed. Work continued to address challenges related to sensor performance such as light illumination, assembly, alignment, and straylight.[2] Furthermore, research focused on software development, specifically, ramp

Figure 6. Thenar Palm

profiles for controlling the lasers during measurements. The ramp profile contains the instructions for how the laser is powered in order to create the various wavelengths within its tunable band.
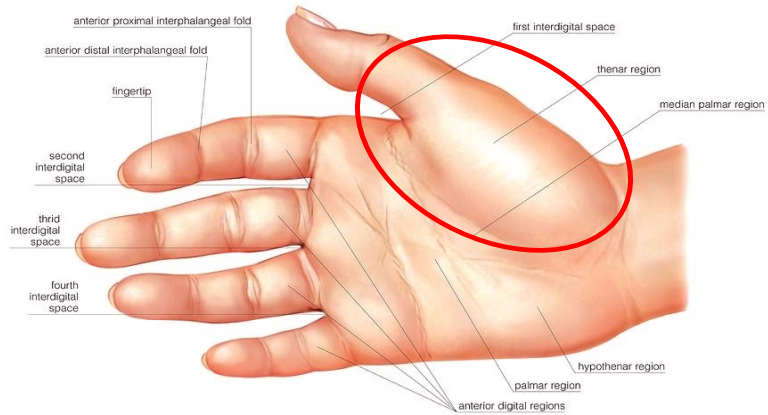
A single laser optical reflectance benchtop system was developed, which is a highly flexible, modular test system with increased configurability and laser light control (see Figure 7). The benchtop system provides enhanced flexibility for varying key optical parameters and allows researchers to perform a matrix-based test plan for collecting optimum system settings and key tissue variable data for improved simulation-based analyses. Utilizing the new benchtop system, testing initially focused on optical system alignment and laser beam positioning as well as tunable laser analyses (light output, temperature stability, wavelength generation). This was followed by system modifications to improve light intensity at the front-end interface window and updates to resolve sources of structured noise associated with the system design.
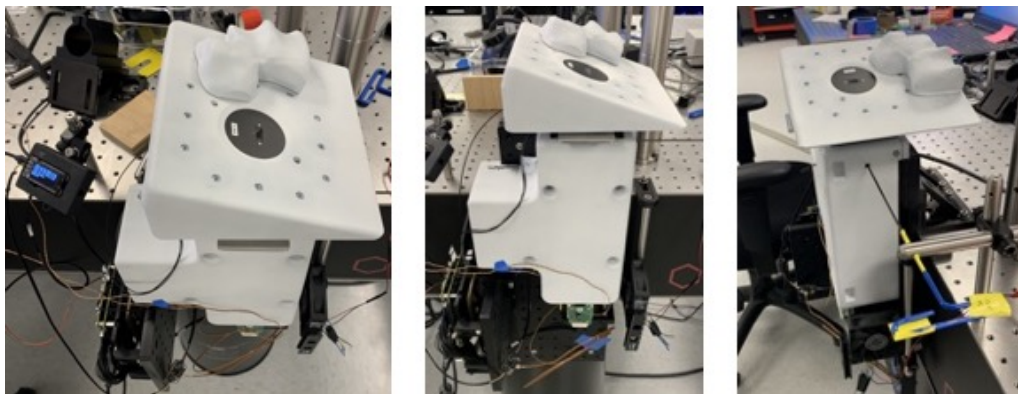
Figure 7. Single Laser Reflectance Benchtop System

The benchtop system is undergoing continuous improvement and is being used to conduct human subject testing (non-dosed and alcohol dosed) to confirm that the unit can detect ethanol non-invasively in the tissue of a dosed human. Lessons learned from this unit are currently being applied to the development of a compact portable unit with improved performance for use in vehicle application.

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

DADSS Verification and Validation Overview

The DADSS sensors and subsystems undergo rigorous testing to insure they meet the requirements outlined in the DADSS Performance Specifications and SAE J3214 standard. The testing is separated into three categories (Figure 8):

1) Laboratory – Understanding and measuring the performance of new sensors under tightly controlled laboratory conditions.
2) Human Subject Testing – Understanding the performance of sensors in a controlled setting while introducing humans and their variability.
3) Field Testing (Human Subject Driving (HSD), Fleet) – Understanding the performance of the sensors in the real world driving environment with human, sensor, and environmental variability's.
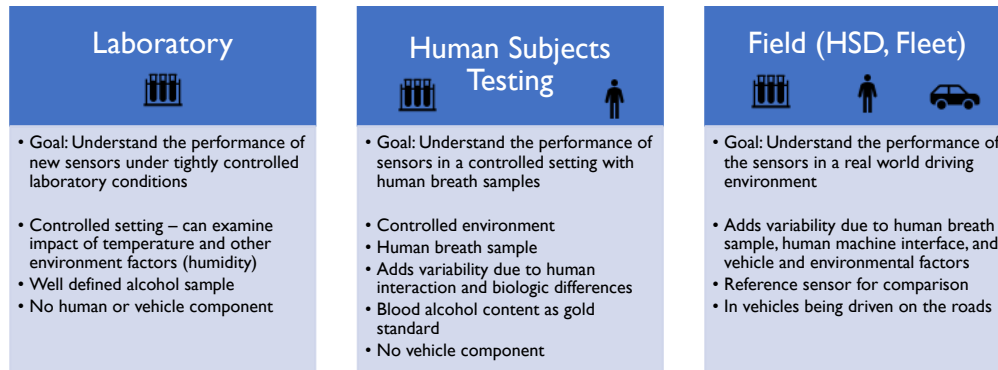

Laboratory	Human Subjects Testing	Field (HSD, Fleet)
• Goal: Understand the performance of new sensors under tightly controlled laboratory conditions	• Goal: Understand the performance of sensors in a controlled setting with human breath samples	• Goal: Understand the performance of the sensors in a real world driving environment
• Controlled setting – can examine impact of temperature and other environment factors (humidity) • Well defined alcohol sample • No human or vehicle component	• Controlled environment • Human breath sample • Adds variability due to human interaction and biologic differences • Blood alcohol content as gold standard • No vehicle component	• Adds variability due to human breath sample, human machine interface, and vehicle and environmental factors • Reference sensor for comparison • In vehicles being driven on the roads

Figure 8. DADSS Verification and Validation Overview

Laboratory - Standard Calibration Devices (SCD)

As sensors evolve and improve, new generations of the breath and touch sensor systems must be evaluated to understand how well they perform. A critical component of the testing process is to develop test methods that can demonstrate in a traceable manner that the breath and touch systems meet the requisite performance specifications. As part of this process the DADSS team must develop both test methods and traceable breath and tissue surrogates for use in the testing. The traceability of these test materials comes from the use of standard reference materials (SRMs) that are produced to a known value. Typically, with the implementation of such materials, the researchers can use them to confirm that they meet the stated specifications. In the United States, such materials are usually traceable to a national standard that is held by the National Institute of Standards and Technology (NIST) or certified by another nation's national laboratory which holds a letter of agreement with NIST regarding the specific material.

To fully address the many aspects of testing, the DADSS Team has undertaken a comprehensive protocol that is based around the research, development, and vetting of apparatus and methodology. The focus of this effort is the development of breath and tissue surrogates capable of evaluating the performance of DADSS sensors against the accuracy and precision specifications. Research efforts are focused on the development of SCD's and methodologies for delivery of the samples to the verification instrumentation and the sensors for analysis. The research and development that has been conducted thus far has resulted in substantial progress, including improvements in calibration samples, measurement procedures, design, and characterization of delivery systems, as well as the characterization of the latest generation sensors.

The breath SCD has been designed to represent a naturally exhaled human breath. Parameters such as volume, pressure, humidity, temperature, and chemical composition must be specifically tailored to represent human physiological conditions. This is made possible by the development of the Alcohol Breath–Based Simulator (ABBS). ABBS, shown in Figure 9, was developed to meet these needs by combining the ethanol gas with stock diluent gases in specific ratios. The ethanol ratio is monitored in real time and automatically adjusted based on a feedback loop to adjust for variation in the ethanol gas. The design intent of ABBS is to allow flexibility in flow rate, ethanol concentration, carbon dioxide concentration, temperature, pressure, and humidity as needed to evaluate the sensors. These variable parameters allow the ABBS unit to produce a simulated human breath to the sensors with a high level of precision. Recently, a second ABBS has been developed to help improve testing throughput, with a significantly modified method to improve the output gas stream with an ideal distribution of gaseous ethanol.
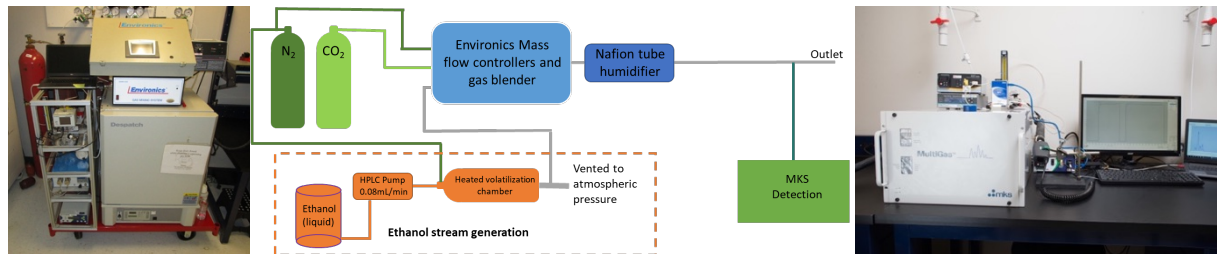
Figure 9. ABBS with the MKS Multigas 2030 FTIR

Once developed, the SRMs composition, accuracy, and precision must be confirmed based on the DADSS specifications. The instrumentation necessary for such verification must meet or exceed the DADSS performance specifications. A worldwide search was conducted for suitable technological approaches and instrumentation that could meet these goals. A comprehensive evaluation of forensic toxicology instrumentation revealed emerging technologies with improved ability to quantify and identify ethanol in SCDs. Various approaches and their methods, such as gas chromatography, liquid chromatography, and infrared spectroscopy were evaluated. A Fourier Transform Infrared Spectroscopy (FTIR) device with the MKS Multi Gas 2030 Continuous Gas Analyzer was selected for the breath samples because of its ability to identify or confirm the chemicals in the sample as well as quantify accuracy and precision at the levels required. For the SAE J3214 Standard, referred to above, there is a requirement that the test gas ethanol concentration has an uncertainty of less than 1.5 percent. In order to achieve this level of uncertainty, the gases are calibrated using the in-house FTIR device with the MKS Multi Gas 2030 Continuous Gas Analyzer using gases in which ethanol concentration is certified to a known concentration with very high accuracy. Gas standards that have enough accuracy to support this calibration are available from VSL and the National Metrology Institute of the Netherlands.

In support of touch sensor validation, work is ongoing on the development of tissue surrogates as a standard reference material, for the Touch sensor as well as delivery systems to introduce a tissue equivalent sample to the sensor. The first Touch SCD developed was as a liquid solution which had a poor shelf life. Currently, research is being conducted to transfer the desired properties of the liquid solution to a different medium, such as a gel or solid. The tissue surrogate must closely represent the properties of a human tissue, so temperature, optical properties, chemical composition, density, hydration levels, elasticity, and conductivity all must be considered. Both the aqueous base and gelatinous base have their respective advantages and challenges. The DADSS Team is working to combine these two approaches either into a hybrid system or develop a methodology which utilizes the advantages of each material.

Figure 10. Waters Acquity HPLC in the DADSS research laboratory.

With insight from the alcohol and environmental testing industries, new methods to improve the tissue solution's accuracy were adopted, including best techniques to weigh, portion, and quantify the ethanol when manufacturing the solutions. In addition, properties of other chemicals were used to quantify the ethanol in the solutions with extreme confidence.

For the tissue surrogate validation device, a Waters Acquity High-Performance Liquid Chromatography (HPLC) device with mass spectrometry, refractive index, and UV-Vis detectors was selected (see Figure 10). The pairing of this unit with an FTIR provides extremely precise measurement and identification of ethanol as well as the other components in the tissue surrogate.
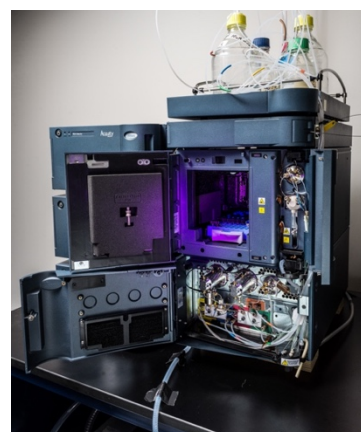
Human Subject Laboratory Testing (HST)

HST, also referred to as in vivo testing, is a critical part of understanding how the DADSS sensors will perform in the real world when confronted with large individual variations in the absorption, distribution, and elimination of alcohol within the human body (i.e., blood, breath, tissue) and across the many factors that can affect alcohol concentration such as age, body mass, race/ethnicity, gender, and medical conditions. Past research has provided a clear understanding of these factors with respect to venous (blood) alcohol and breath-alcohol when samples of deep lung air are used. However, the new alcohol measurement methods being developed under the DADSS program, which determine alcohol concentrations from diluted breath samples and within human tissue, are not well

understood. In particular, the rate of distribution of alcohol throughout the various compartments of the body under a variety of scenarios has been the subject of ongoing study.

From the outset, a comprehensive program of human subject research has been carried out to establish that alcohol measurements made with diluted breath and tissue samples are comparable to the well-accepted standards of venous blood and deep-lung air widely used in today's alcohol detection systems. Based on an extensive review of the extant alcohol pharmacokinetics literature, intrinsic and extrinsic factors that can affect alcohol metabolism have been identified. Progress is being made in answering those questions with an ongoing, comprehensive program of human subject research being undertaken by McLean Hospital, a Harvard Medical School affiliate (Lukas et al 2019).

The purpose of human subject laboratory testing is:

- To quantify the rate of distribution of alcohol throughout the various compartments of the body (i.e., blood, breath, tissue) under a variety of real-world scenarios, and across a range of factors that could potentially affect measurement. The key question is whether these various factors have differential effects on the distribution of alcohol within the different compartments.
- To quantify alcohol absorption and elimination curves, both breath and blood, among a wide cross section of individuals of different ages, sex, body mass index and race/ ethnicity and in a variety of scenarios.

Table 2. Clinical Human Subjects Testing Study Protocols Conducted.

Protocol	No. of Studies
Exercise	17
Social Snack	15
Social Brunch	14
LagTime	49
Last Call	18
Cigarette	6
Hand Sanitizer	9
Temperature	30
Energy Drink	29
JUUL	5
Breath	10
Non-Alcohol	10
Beer	20
Wine	11
Marijuana	1
Total Studies	244

Many insights already have been gained regarding the alcohol absorption and elimination curves and maximum BACs/BrACs reached by human subjects in a variety of real-world scenarios (i.e., length of time for alcohol to appear in each compartment, effects of snacking, dining, exercise, and "last call" on alcohol measurements). These studies have confirmed a solid linear relationship between blood, directed breath (using the DADSS breath sensors), and tissue alcohol measurement (using the touch sensor) over a wide range of BACs (0.04-0.12 g/dL) (Lukas et al 2019).

To date, more than 244 clinical human subject studies have been conducted involving more than 15 protocols (see Table 2), generating more than 12,107 blood samples, 15,701 DADSS breath sensor sample, 7,627 comparative breath samples, and 8,212 DADSS touch sensor samples.

In-house Blood-Ethanol Analysis

To increase in-house capabilities for the evaluation of breath and touch sensors, a methodology was developed to

Figure 11. YSI 2900D Analyzer

collect whole blood samples and analyze test subjects blood alcohol levels. The subject's blood is sampled using a finger-prick, which is then processed using a YSI 2900D Biochemistry Analyzer (Figure 11). A lancet is used to pierce the skin and a blood sample is drawn with a heparinized capillary tube (i.e., to prevent blood from coagulating) after which the blood is transferred into a 200 µL vial for analysis (all three steps are illustrated in Figure 12). This low-cost method is accurate to within 3 % of actual blood alcohol levels and can deliver results within 60 seconds after blood collection. Using this method, more than 140 blood samples have been analyzed. The ethanol-containing whole blood samples collected via a finger-prick can remain stable for over 48 hours, allowing for field collection prior to laboratory analysis. Biosafety standards have been instituted in the chemistry laboratory to allow for capillary blood collection and analysis methodology.

The HST program continues to assist the HSD program by providing support for subject recruitment, subject safety verification (e.g., negative BrAC for all participants and negative pregnancy test for women), beverage mixing and administration and debriefing/safety testing at the end of the study

Figure 12. Blood Sampling Process

Field Testing

The goal of human subject driving tests is to conduct basic and applied research to understand the performance of the sensors in the vehicle, across a range of environmental conditions. Such studies are undertaken in more controlled settings by DADSS researchers, and in naturalistic settings in cooperation with the states of Virginia and Maryland as described below.

Controlled Human Subjects On-Road Driving Tests

The purpose of the controlled human subject on-road driving tests (HSD) tests is to conduct basic and applied research to understand the performance of the DADSS sensors in the vehicle physiologically and ergonomically. During the HSD tests, in-vehicle testing is undertaken in a diverse set of geographic and environmental conditions, varying vehicle conditions, and with diverse human subjects to assess the effects of human variability. Routes in New England were chosen to provide varying climactic conditions, such as low and high temperatures, low and high humidity, at varying elevations, and in corrosive environments.

Results from on-road testing is critical in determining the effectiveness of the DADSS sensors in a wide range of conditions including the impact of environmental factors on sensor function over time, the impact of repeated use and vehicle mileage, the impact of vehicle vibration, and user interactions with these devices in a vehicle environment, including driver behavior and user acceptance. The data will also be used to refine the DADSS Performance Specifications, and to improve system design and product development.

Once the breath sensors performed well in laboratory and human subject testing, vehicle trials in real-world driving environments began with the Gen 3.2 breath sensors (known as HSD1) and are currently on-going using the Gen 3.3 breath sensors (knows as HSD2). Once Gen 4.0 breath sensors become available, HSD3 studies will commence. The ultimate goal of the breath sensors is to passively detect drivers' breath alcohol within the ambient air of the vehicle cabin. For the HSD1 and HSD2 studies, subjects are instructed to breathe towards the sensors to assist in data collection. The subjects' directed breath has two types of variability: 1) subjects likely will breathe differently each time they give a sample, for example, the amount of breath, the strength of each breath, and the direction of the breath will vary; and 2) each person breathes slightly differently. One person's version of "provide a breath as if blowing out a candle" may be different than another's. When you factor in variations in subject height, distractibility during the drive, and other variables, these can all contribute to potential variations observed in sensor performance. Variations also arise with changing environmental conditions inside and outside the vehicles. As a result, a large amount of data is needed to fully understand how each of the sensors works across all conditions for every driver.

The controlled HSD tests utilize fully instrumented DADSS Program vehicles equipped with four (4) DADSS breath sensors integrated into the vehicle to measure breath alcohol – two DADSS breath sensors on the driver side and two on the passenger side. On the driver's side the breath sensors are mounted in the steering wheel location and the driver's door. On the passenger side they are mounted in the passenger door and on the dashboard directly in front of the passenger (Figure 13). The DADSS breath sensors can measure directed and passive breath. A comparative sensor, installed on the passenger side, provides a comparison measurement, and requires a deep lung sample of breath delivered through a plastic tube. This sensor is used to assess the DADSS breath sensor's sensitivity (i.e., true positives), validity, and reliability.

Along with the alcohol sensors, the vehicles are equipped with a comprehensive data acquisition system (DAS) with real time data upload to the DADSS data view, a video camera, a web interface[3], data and video storage, and a user interface module (UIM) for use by the test subject and research associate.

Figure 13. Position of the breath sensors and user interface module on the driver (left) and passenger sides of the vehicle.

A comprehensive data view dashboard provides real time data from all sensors as well as vehicle parameters (Figure 14). Elements displayed on the dashboard include the number of reference samples, the number of breath sensor samples collected, the number of protocols run, the total number of subjects, the total study days, and total miles driven. The dashboard also includes the above elements broken down by each protocol.
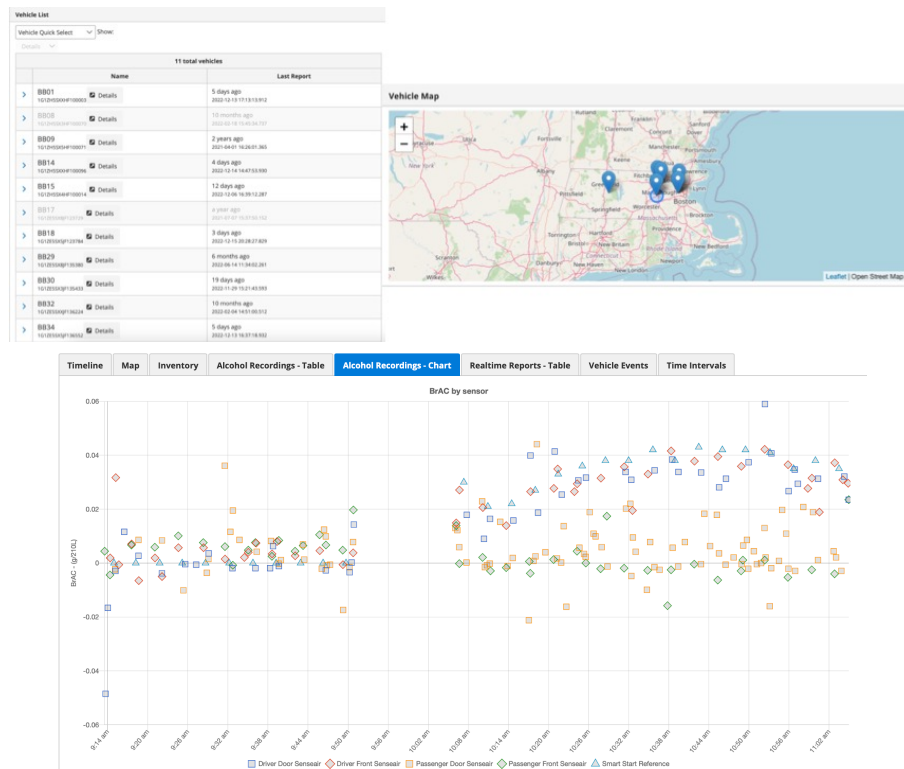

Figure 14. DADSS Data Viewer.

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

Recruitment of the test subjects is being conducted at the DADSS laboratory and the McLean Hospital. Many of the test subjects have previously participated in DADSS human subject testing, affording researchers the opportunity to compare subjects' laboratory and in-vehicle data. Participants are brought into either of the laboratories prior to the study. The risks and benefits of the study are explained to them, and if they are comfortable with the study requirements and choose to participate, they sign the informed consent form. Subjects are screened for drug and alcohol presence, and they are familiarized with the vehicle set-up and protocol. After height and weight measurements are taken, they are dosed with the relevant quantities of alcohol over a period of about 10 minutes. The subjects alcohol measurements are collected frequently from the breath and reference sensors. The subjects are instructed by a research assistant in the vehicle to direct their breath in a prescribed sequence toward the DADSS breath sensors in the vehicle. The current methodology permits collection of BrAC on up to four different sensors every 3.5-4 minutes for up to eight hours. The research assistant also monitors the subject's condition.

During vehicle testing the DADSS sensors passively sniff and analyze the vehicle cabin air for the presence of alcohol. Additional vehicle instrumentation tracks environmental conditions and vehicle system data while providing participant videos.

Information collected from HSD1 tests contributed to the development Gen 3.3 breath sensor, including improved accuracy and precision, increased operational temperature range, a faster start-up, reduced cost, improved protection from electromagnetic interference (EMI) protection, and improved start-up behavior. In addition, the trials have functioned as proof of concept studies to identify which variables need to continue to be investigated as new generations of sensors are evaluated.

The Gen 3.3 sensor is now being evaluated in the second round of trials, referred to as HSD2. As noted above, the Gen 3.3 sensor is designed for use in fleet vehicles to detect the presence of alcohol, thus, the initial focus of these studies was on evaluating sober and low-dose alcohol participants. However, studies have also evaluated participants who were dosed to moderate and high doses of alcohol. Overall evaluations were conducted with BrACs ranging from 0.0 – 0.12%.

Table 3 provides a sample count of the DADSS breath sensors and comparative sensor, number of subjects and number of study protocols. Table 4 provides a samples count by sensor for HSD1 and HSD2.

Table 3. HSD1 and HSD2 Metrics.

Study	Total Study Protocols	Total Breath Sensor Samples	Total Comparative Samples	Total Unique Subjects	Total No. of Study Protocols
HSD 1 using Gen 3.2 Sensor	1	78,032	51,368	61	117
HSD 2 using Gen 3.3 Sensor	1	16,179	14,604	17*	245
TOTAL	18	94,211	65,972	67*	362

*11 Unique Subjects participated in both HSD 1 and HSD 2, therefore the total Unique Subjects is 67

Table 4. HSD Samples Count by Sensor.

Study Protocol	Breath Sensor Sample Count	Comparative Sample Count	Subject Count	Protocol Count
Passenger Side Sober Stationary	3,395	398	17	25
Sober Stationary with Mask	352	118	10	10
Passenger Side Low dose (0.3 g/kg) Stationary	1274	178	12	12
Passenger Side Moderate Dose (0.5 g/kg) Stationary	1070	138	9	9
Low dose (0.3 g/kg) drive	509	131	11	13
Moderate dose (0.5 g/kg) drive	1,049	176	11	15
Sober drive	1,197	201	11	19
Moderate-High Dose (0.7g/kg) Drive	257	69	7	7
High Dose (0.9g/kg) Drive	244	60	5	5
Driver Side Sober Stationary	303	49	4	6
Low Dose Driver Side Stationary	341	61	3	3
Moderate Dose Driver Side Stationary	1,099	188	6	6
Hand Sanitizer - Blowing Across hands	317	0	10	10
Hand Sanitizer - Waving hands	242	28	10	10
Mouthwash	349	0	10	10
Mouthwash with water rinse	331	0	10	10
Mouthwash following UIM	172	26	10	10
Mouth Spray	216	0	10	10
Mouth Spray with water rinse	188	0	10	10
Mouth Spray following UIM	168	28	10	10
Lysol Disinfecting Spray	196	0	5	5
Individually Wrapped Hand Sanitizer Wipes	459	0	7	7
Isopropyl Alcohol Medical Pads	95	0	6	6
Hand Sanitizing Honest Wipes	276	0	5	5
Moderate-High Dose (0.7g/kg) Stationary	1786	278	7	7
High Dose (0.9 g/kg) Stationary	1479	221	5	5

Naturalistic Human Subjects On-Road Driving Tests

In 2018, The Driven to Protect, Powered by DADSS initiative, a partnership with the Virginia Department of Motor Vehicles, Highway Safety Office and the DADSS Program, partnered with James River Transportation (JRT), a transportation company with offices in Richmond and Norfolk, VA, to conduct the first in-vehicle, on-road naturalistic test trials with prototype breath-based alcohol sensors in their vehicles. The partnership was expanded in 2021 to include Schneider National, Inc. to conduct a pilot deployment out of its Virginia-based operations in South Boston, Virginia.

James River Transportation

Initially, four fleet vehicles (2015 Ford Flex airport livery vehicles) were instrumented with Gen 3.1 sensors and underwent field tests. In late 2020, JRT decommissioned the 2015 Ford Flex vehicles and commissioned two 2019 Ford Flex vehicles with the Gen 3.2 breath sensors, and those on-road field tests continue today.

At start-up, the JRT driver provides a breath sample toward the Gen 3.2 sensors located in the driver door and on top of the steering column (see Figure 15) and to the aftermarket commercially available interlock sensor used as a reference sensor. If the sensor detects alcohol in the sample breath, an alert goes to authorized personnel. Personnel quickly assess the alert and other relevant data, such as breath readings, directly before and after to determine a potential course(s) of action for JRT consideration.

The JRT pilot deployment project has provided valuable feedback on the driver's experience and interaction with the sensors and allowed troubleshooting anomalous readings or problems with the sensors and data acquisition system. In the initial stages of the project, continuous video surveillance added information on the driver's interaction with the sensor. In addition, two small focus groups were conducted in 2019 with JRT drivers to understand driver receptiveness to the technology, their preference for sensor prompts and other sensor interactions, and their feedback on the program training and driver test plan. Driver feedback

Figure 15. JRT Sensors Location.

showed an initial acclimation period in using the sensors. About a quarter of post-drive surveys in the first two months indicated difficulties with the sensors, including low breath volumes and unfamiliarity with indicator lights on the sensors. These difficulties declined significantly in the following months. Feedback indicated a slight learning curve in providing a breath sample to the sensors, but after a short time, they "got the hang of it." In addition, the post-drive surveys were important for feedback on the functioning of the sensors and data acquisition system. Several drivers reported problems with interference with in-vehicle GPS, radio, and keyless entry (such as EMI). This real-time reporting allowed technical modifications to be made to limit this interference with the addition of sensor shielding.

To date, test vehicles were operational for 29,996 hours and driven 97,746 miles, during which time the system collected 142,388 breath samples.

Schneider National, Inc

The Schneider pilot deployment began with equipping a Freightliner Cascadia heavy-duty semi-trailer truck (Figure 16) with two (2) Gen 3.3 breath sensors, a data acquisition system (DAS), a driver display (Figure 17). The initial truck was used as a platform truck for the

Figure 16. Schneider Freightliner Cascadia Truck.

DADSS engineering team to design, develop and test the sensors and instrumentation. The platform truck was extensively road tested by a Schneider operator, in collaboration with the DADSS program, prior to integrating the system into 7 additional trial vehicles. Schneider stipulated that the installation should not be distracting to the driver and should not include permanent modifications to the trim package or cab interior or interfere with the vehicle's

Figure 17. Overhead Sensor Above Driver's Head and Dashboard Unit.

safety features and equipment. In addition, efforts were made to minimize driver and supervisor actions (e.g., responding to false alarms).

Engineers developed the operating software for the Schneider truck, with a goal to mitigate the likelihood of a false positive. A collaborative working group agreed upon a threshold of above 0.025% BrAC from both sensors to generate an initial on-screen notification to the driver while concurrently sending a message to key program

personnel. Prior to moving the vehicle, the system prompts the driver to provide additional verification breaths to the sensors immediately. If the follow-on breaths are also above the threshold, the system would generate an alert via email and text message to the Schneider regulatory team as well as key program personnel monitoring notifications and alerts. The display also prompts the driver to contact their immediate supervisor or manager via on-screen messaging.

The on-road deployment of the platform truck allowed researchers to assess the value of the fleet sensor system and collect data for future technology improvements. In May 2022, the DADSS Team installed the sensors into seven (7) additional Schneider trucks and performed system updates to the platform vehicle in preparation for integration into the overall fleet pilot environment. After installation and testing of the systems, the team met with each volunteer driver to provide hands-on training in system operation and answer any questions about the technology or system operation. They were also provided with some basic troubleshooting techniques and briefed on contacting the team to resolve any problems, including an online fillable form to record any issues or concerns. Initially, a few concerns arose, including a few drivers who were too short to see the right front mirror over the dashboard unit. The

resolution required disassembling the components of the all-in-one dashboard unit and segregating the components into alternate mounting locations (Figure 18). The engineering team also needed to redesign a new housing, inlet, and snorkel to reposition the dashboard sensor to an alternate area. The trucks now have three trucks with the initial system installation on the dash and three trucks with the revised alternative system for a total of six active Schneider trucks gathering project data.
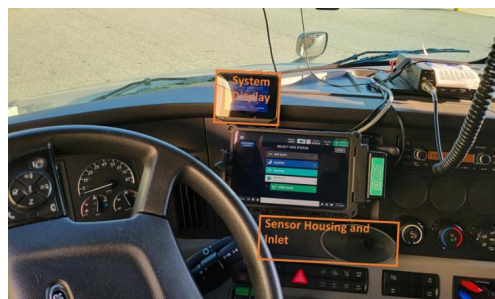
As of October 1, 2022, test vehicles were operational for 6,987 hours and driven 61,143 miles, during which time sensors collected 25,171 breath samples.

Figure 18. Alternate DADSS Installation – System Display and Sensor.

CONCLUSIONS

Since its inception in 2008, the DADSS Program has made tremendous progress in the development of in-vehicle technologies that will prevent impaired drivers from driving their vehicles. The breath- and touch-based sensors have become increasingly refined, both in terms of hardware and software, as headway is made in meeting the high standards required for unobtrusive and reliable alcohol measurement. At the same time, additional research and development is paralleling the sensors' development to allow the characterization of sensor performance in the laboratory, on the road, and among human subjects.

Substantial progress has been made in the development of breath and touch-based calibration processes, materials and methodologies making the testing of multiple sensors at a time a reality. Moreover, instrumentation is being used that can enable the requisite testing across the range of specified environmental conditions.

As sensor development has progressed, research vehicles have been readied for on road testing with the latest versions of the breath sensors seamlessly integrated within the vehicle interiors. Vehicle instrumentation packages have been developed and installed and pilot testing trials are providing data on sensor performance under real-world driving conditions. The accumulated data from an extended program of on road driving trials under diverse conditions will determine whether the DADSS sensors are working as anticipated and allow the identification of areas for system improvement.

A comprehensive program of human subject research also is well underway, starting with the laboratory environment where better control of conditions can be exerted, and continuing in the vehicle where the sensors can be tested in the environment in which they will be used. This research has quantified alcohol absorption and elimination across a wide range of conditions that are anticipated to affect BAC and BrAC as well as some new scenarios specific to the breath and touch-based approaches. Testing showed that the data collected from the various generations of breath-based and touch-based prototypes were consistent, reproducible, and correlates very well with the "gold-standard" method of measuring alcohol in the body, which is accomplished by measuring blood via gas chromatography.

In summary, great progress has been made on a number of fronts to develop in-vehicle sensors that will seamlessly measure driver's blood and breath alcohol and prevent them from driving while impaired. Moreover, additional research is ongoing to continue the progress toward meeting the exacting performance specifications to ensure acceptance and longevity in the vehicle environment.

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