

Driver Alcohol Detection System for Safety: Field Operational Test

Orientation

Submitted by:



Technologies, Inc.

KEA Technologies, Inc.
400 Donald Lynch Blvd, Suite 102
Marlborough, MA 01752
(508) 658 - 9416

Principal Investigator

Kelly Ozdemir, PhD.
Director of Applied Sciences
KEA Technologies, Inc.
400 Donald Lynch Blvd, Suite 102
Marlborough, MA 01752
(508) 658 – 9425
Kelly.Ozdemir@keatechinc.com

Paperwork Reduction Act Statement: A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2127-0734. The purpose of the information collection is to collect information to provide a greater understanding of the performance of both breath- and touch-based sensors with actual dosed passengers using the technology under varying environmental conditions. The primary component of this information collection is the collection of sensor data during a Field Operational Test (FOT) involving human subjects; however, demographic information about participants and post-test information will be collected as well. The objectives of the FOT are to: (1) Determine the effectiveness of the DADSS sensors in a real-world driving environment; (2) Analyze DADSS breath- and touch-based sensors in real-world driving scenarios; and (3) Obtain technical data to further refine the DADSS Performance Specifications that will ultimately be used for system design and product development. We estimate that it will take approximately 30 minutes to one hour to complete the orientation and up to 5 hours to complete the FOT. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Room W45-205, Washington, DC, 20590.

HSD Study Day Checklist

Participant ID: HSD-_____ **Date:** _____ **Arrival time:** _____

MINIMUM 1 WEEK BEFORE STUDY

- Confirm date of study
- Confirm scenario/protocol being run (Staff Responsible: _____)
- Confirm address to send BinaxNOW™ COVID-19 Self-Test
- Conduct Health Screening Questionnaire (Staff responsible: _____)
- Notify and schedule staff for study

TWO DAYS BEFORE STUDY

- Confirm with subject and discuss Uber or Cab transportation
- Confirm receipt of BinaxNOW™ COVID-19 Self-Test and arrange Teams video call with staff and participant anytime within 24 hours of study. (Date and Time of Test: _____)
- Remind subject of restrictions for study day
- Remind them to bring their own source of entertainment for the day- phone, laptop, books, etc.
- Make sure screening room will be free
- Confirm protocol and route (Protocol: _____, Route: _____)
- Assign driver (Staff responsible ID #: _____)
- Assign research assistant (Staff responsible ID #: _____)

DAY BEFORE STUDY

- Obtain Subject ID #: _____
- Conduct Health Screening Questionnaire (Staff responsible: _____); script below
- Conduct BinaxNOW™ COVID-19 Self-Test with participant via Teams video call

Staff responsible: _____, Test Result: _____

- Qualified to proceed? Y N Staff Signature: _____

If NO, read positive antigen test script and inform PI and Sub-investigator of a positive result

- Print Informed Consent, lunch menu, in car measurements sheet, study day BrAC form, W-9
 - Decide who will be performing informed consent (Staff responsible: _____)
- Confirm route (Staff responsible: _____, Route: _____)
- Make sure that graduated cylinders for measuring vodka and that dosing cups are clean
- Check dose from rough weight estimate and check to make sure we have enough vodka
- Ensure that we have toast, butter, jam, and OJ for breakfast
- Car
 - Water bottles
 - Crackers
 - Barf bags
 - Clean biohazard bucket
 - Gloves
 - Mouthpieces for Smart Start
 - First-aid kit
 - Paper towels
 - Disinfectant wipes or spray
 - Phone chargers
 - LED Flashing lights
 - Fix-a-flat
 - ACTS Letter

- BRANY IRB Approval letter

STUDY DAY

BEFORE SUBJECT ARRIVES

- Set-up scale and height measurement tools in screening room
- Prepare biohazard bucket with new drug test cup and pregnancy test (if female)
- Two slices bread (2 butter, 2 jam) and OJ - put in refrigerator
- Make sure screening room and HS bathroom are clean
- Place blank Informed Consent Form into the room
- Place W-9 Form into the room
- Place study-day/set-up Panera menu in the room
- Place blank in car measurements sheet in room
- Ensure pack of gloves, paper towels, and short trash barrel are in the room
- Confirm study staff BinaxNOW™ COVID-19 Self-Test result
(Staff Responsible _____, Driver (init: _____), Result: _____, RA (init: _____), Result: _____)
- Check Health Screening Questionnaire's for research staff & for participant (Staff responsible: _____)
- Breathalyze driving team (Staff responsible: _____)
- Ensure that driver/proper personnel completed the Vehicle Inspection Checklist form on Microsoft Forms by 9:30 AM.

WHEN SUBJECT ARRIVES

Human Subject Screening Room:

- Check for Uber/Lyft receipt (Staff responsible: _____)
- Check for valid form of ID.
 - Confirm identity and age (Birth Year: _____) (Staff responsible: _____)
 - Form of ID Provided: _____
- Check for CDC COVID-19 Vaccine Card (if first study/first study back) (Staff responsible: _____)
- Informed Consent Form (Staff responsible: _____)
- Collect spare COVID-19 Self-Test test kit (if applicable). (Staff responsible: _____)
- Go over current study protocol (route for the day, what they will be expected to do)

Protocol Description: Today we will be completing the _____ route(s) (SHOW MAP). In a couple minutes, we will be doing an orientation in the vehicle to make sure you are comfortable and understand what is being asked of you, but as an overview, you will be in the passenger seat of the car for the duration of the study and you will be expected to administer breaths to three alcohol breath sensors. The testing sessions will be about 2 minutes, followed by a 2 minute break where you will not need to administer breaths. The User Interface Module, located on the dash of the car, will provide written instructions of what you need to be doing. The research assistant in the car will also be available to prompt you and give instruction or help throughout the study. Please let us know throughout the study day if you have any questions or concerns.

- Reference breathalyzer: _____
- Last Food (no food after 8pm): _____
- Last Alcohol (nothing for 36 hours): _____
- Last Nicotine (no smoking after 8pm): _____
- Last Caffeine (nothing for 12 hours): _____
- Last Drug Use (nothing for 2 days): _____
- Last Medication Use (nothing for 12 hours) _____
- First day of last menstrual cycle: _____

- Urine Sample:
 - Drug Test (Results: _____)
 - Pregnancy Test (Results: _____)
- Height: _____
- Weight: _____ BMI: _____
- Temperature (F): _____

- Qualified to proceed? Y N Staff Signature: _____
- Lunch Order
 - Staff member to pick up lunch: _____
- Breakfast (2 pieces of toast, 2 butter/jam, and 1 clear glass of OJ) Staff Responsible: _____

- Orientation with the car
 - Driver: _____ RA(s): _____
 - Introduce driving team
 - Show the participant where the User Interface Module is and familiarize with prompts
 - Complete in car measurements sheet
 - Run through two complete cycles with the participant and ensure they are able to follow the directions and understand what data collection will require

- Alcohol preparation:
 - Staff Member 1 Responsible: _____ Staff Member 2 Responsible: _____
 - Drink master (print 1 and save a digital copy) Alcohol Dose: _____ Mixer Dose: _____
 - Need: Completed drink master, Vodka, 3 tumblers, 4 solo cups, beakers
 - Lock Vodka back in study fridge Staff Member Responsible: _____

- Bathroom break if necessary **BEFORE** drinks**

- Explain room:
 - U** *This is where you will be for the duration of the study when you are not in the car. After you return from the driving route, you will return to this room where you will be able to eat lunch, relax, and keep yourself entertained with your phone, laptop, books, or whatever you have brought. We will try to make sure that you are comfortable, please let us know if there is anything we can get you or do to make you feel more comfortable.*

Alcohol Administration:

- Bring tray into Chamber
- U** *You will be given three drinks of vodka OR a mixed drink (clarify which one it will be for the day) and will have 10 minutes to finish the drink(s).*
- If Shots:** *We will also ask you to swish and rinse with water after each drink (signal showing that water is in the solo cups). Please do not swallow the water. The purpose of this is to eliminate any residual mouth alcohol.*
- If Mixed Drink or Chaser:** *We will also ask you to swish and rinse at the very end with water (signal showing that water is in the solo cup). Please do not swallow the water. The purpose of this is to eliminate any residual mouth alcohol.*



Technologies, Inc.

U *I will be handing you the drinks of vodka, which you will drink when I say go. You have 10 minutes to finish the drinks. After 10 minutes, we will take you out to the car and you will be driven on a pre-mapped route to _____(location). In case you are not feeling well in anyway during this process, please let me know. Please let us know as soon as possible if you are ever feeling ill during the drive as well. Do you have any questions?*

- Drink: Time 00:00:00 (“GO!”) Real Time Start Time: _____
 - Subject begin drinking
 - Start clocks (Staff responsible: _____)
 - Finish drink (00:10:00) Real Time End Time: _____

- Time of departure with driving team: _____

POST STUDY

- Monitor BrAC every 15 minutes
- Given them signed copies of their ICF
- Cleared to go?
 - BrAC: _____ Staff Sign off: _____
- Call Uber/Lyft and ensure that they safely enter the correct vehicle (Staff responsible: _____)
- Clean HS screening room
- Ensure that KEA study personnel check-in with Kelly or Kianna regarding the study
- Ensure that KEA study personnel have filled out all required forms for the day
- Check Request Submitted (\$30 + Uber compensation)
- Log study into data viewer
- Put together data sheet and upload to sharepoint

Health Screen

1. Are you experiencing any of the following symptoms:
 - a) Fever or feeling feverish
 - b) Sore throat
 - c) New cough
 - d) Nasal congestion or new runny nose
 - e) Muscle aches
 - f) New loss of smell or taste
 - g) Shortness of breath
 - h) Diarrhea, nausea, or other GI symptoms
 - i) No Symptoms

2. Have you traveled outside of Massachusetts in the last 14 days?
 - a) Yes. Where: _____*
 - b) No (SKIP TO QUESTION 4)

*If yes:

International travel: wait minimally two weeks to schedule.

Domestic travel:

3. Did you take a plane?
 - a) Yes*
 - b) No**

*Wait a week to schedule study post plane travel

- **Did you drive a personal vehicle?
- a) Yes*
 - b) No**

*yes: fine to proceed with scheduling

**no: how did you travel to this location?

4. Have you had contact in the last 2 weeks with anyone who has had the above symptoms or who has suspected or known positive COVID-19
 - a) Yes*
 - b) No

*Ask if they have been or are planning to get tested and verify vaccination status. Wait two weeks to schedule.

5. Do you wear a face mask or covering according to state guidelines/requirements?
 - a) Yes
 - b) No

Script for Positive Antigen Test

Your test for COVID-19 is positive. However, this test is not 100% definitive. The golden standard for tests is PCR tests and this test is an antigen test. We advise you to visit <https://www.mass.gov/covid-19-testing> to find the nearest COVID-19 testing site and to contact your doctor or visit an urgent care center if you develop symptoms and feel unwell. Until you have a PCR test, you should do the following:

- **Monitor your symptoms.** If symptoms develop or worsen, call your doctor's office. If you have a medical emergency and need to call 911.
- **Stay home except to get medical care.** Call ahead before visiting the doctor to let the office know you had a positive antigen test. When leaving home for essential medical care, avoid public transportation, including buses, trains, ride-sharing services, and taxis.
- **Separate from other people and animals in your home.** This includes staying in a single room away from other people and using a separate bathroom if available. If there isn't, the bathroom should be cleaned and disinfected after you use it. Please do not allow visitors who do not have an essential need to be in the home.
- **Wear a covering or mask around other people and pets, even at home.** Wear a face covering or mask around other people and pets, including at home and in vehicles. If you have trouble breathing with a face covering or mask on, other people in the household should wear a face covering or mask when in the same room as you.