Detailed Description of Sensor Diagnostics, Inc.'s Wearable Alcohol Biosensor

Submitted by SENSOR DIAGNOSTICS, INC.
in response to NIH / NIAAA Challenge:
A Wearable Alcohol Biosensor: A Second Challenge

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I. Submission Letter

Sensor Diagnostics, Inc. ("SDI") is a US company that researches and develops transdermal biosensors. SDI was founded, is funded, and operates in the United States. SDI previously developed Sober Steering, a steering wheel based alcohol sensor for automotive applications. SDI developed Sober Steering from concept into a commercially viable product with growing sales. We have invested a significant amount of time and resources developing a new, novel sensor design for an unobtrusive wearable alcohol biosensor. We believe a sleek wearable alcohol sensor represents a significant market opportunity, and we look forward to successfully commercializing it as we have our previous product.

Sensor Diagnostics, Inc. has developed an ***innovative*** polymer based biosensor that enables transdermal detection of alcohol in the bloodstream. Unlike previous transdermal sensors, within 5 minutes of initial ingestion, our sensor's superior sensitivity can accurately detect blood alcohol levels below 0.02% as it is distributed through the bloodstream, ensuring no meaningful biological delays in alcohol detection and monitoring.

Sensor Diagnostics, Inc.'s proposed Solution is a Fitbit style wearable device. Our sensors are located on the inside of the wearable band and are in close proximity with the skin on the underside of the wrist. Our Fitbit style wearable seamlessly integrates with a smartphone. Our proposed prototype collects, interprets and securely transmits sensor data wirelessly to a smartphone via a secure Bluetooth connection, also ensuring no device related delays. A detailed description of the proposed Solution – including images with dimensions – are included as part of this written submission.

Sensor Diagnostics, Inc. has ***validated*** its sensor's capabilities with continuous in-vivo testing in over 100 tests over hundreds of hours in preparation for this application. Evidence of successful data storage and retrieval, of consistent function, reliability and robust reproducibility of alcohol are included as part of this written submission. Moreover – with the superior alcohol sensitivity of our novel biosensor design – our testing shows there is no meaningful delay – biological or otherwise – between transdermal and breath based alcohol detection. Specifically, our testing shows that our transdermal alcohol sensors are suitable for the real-time alcohol detection and monitoring expected of a wearable device.

Also included in our submission today is a short video demonstrating our prototype's required capabilities. The video can be viewed at the following URL:

https://drive.google.com/open?id=0B0uNUNj2uN6OdmRYNWJFd1hveVE

We are pleased to submit our wearable alcohol biosensor prototype and having our ***verifiable technique*** for real-time quantification and monitoring of blood alcohol levels reviewed by NIAAA as part of this NIH Challenge.

Sincerely,

Catherine Carroll, CEO
Sensor Diagnostics, Inc.

II. AN INNOVATIVE WEARABLE ALCOHOL BIOSENSOR

SDI's proposed Solution is a novel transdermal sensing technique that enables non-invasive, real-time monitoring of blood alcohol levels as alcohol enters into the bloodstream with minimal biological delay.

Our chip based biosensor design is small, connected and easy to manufacture making it ideal for a wearable application. We've built an unobtrusive, wrist-watch style wearable that is ideal for research purposes. It transmits sensor data wirelessly via Bluetooth to a paired smartphone app.

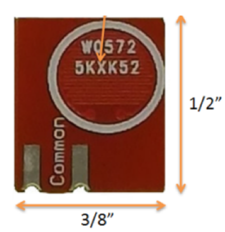
Functionally speaking, our existing prototype provides the necessary data for both studying alcohol related health outcomes and providing consumers with valuable data. However, in our next form factor iteration – which is illustrated here – we will manufacture a more commercially appealing Fitbit style watch/wearable that is more discrete than our existing prototype.

A. Method of Alcohol Detection

After years of iterative research and development, SDI has developed a breakthrough transdermal biosensor capable of detecting and quantifing blood alcohol levels well below 0.02% BAC within minutes of initial ingestion of alcohol. With superior alcohol sensitivity, our biosensor eliminates the delay – biological or device related – between transdermal and breath based alcohol detection.

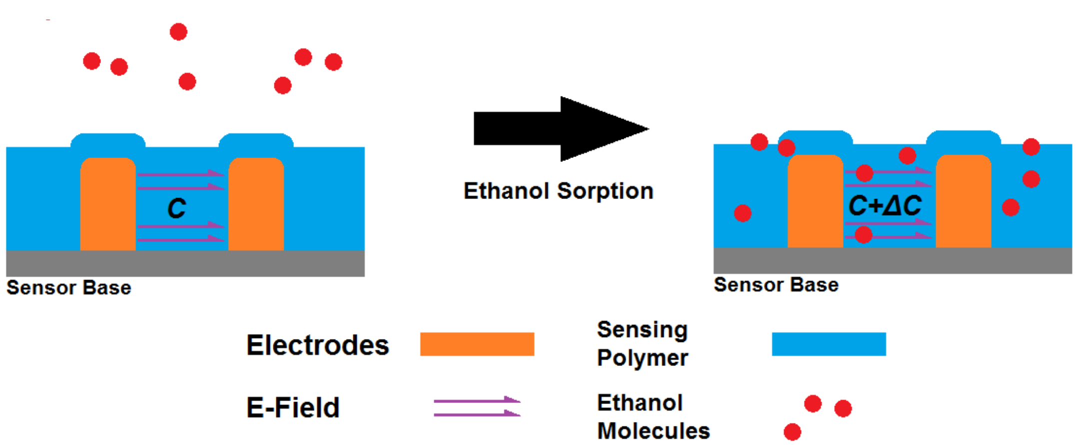
Our capacitive sensor design employs proprietary sensing materials customized by SDI to specifically detect ethanol while remaining relatively inert to other chemical compounds found on the surface of the skin. When our biosensors are in proximity to the skin, ethanol sorption changes the electrical and physical properties of the polymeric sensor material. These changes are proportional with the amount of ethanol absorbed by the material. Electrical and physical changes are effectively captured by the electrical field of the sensor. Capacitance changes are converted into proportional voltage levels reflecting the amount of ethanol detected.

Figure 1: SDI's proprietary sensor design



The figure below illustrates the side view of the sensor setup, and the operation principle of our proprietary sensing polymer as the transdermal alcohol content (TAC) detection agent.

Figure 2: Ethanol sorption response of the sensing polymeric material measured in capacitance (C) variation.



Our novel sensor design has multiple benefits:

Fast response time:	Real-time detection can quantify alcohol in bloodstream within minutes of initial ingestion, minimizing biological delay
Accurate:	Can quantify blood alcohol levels, including well below the equivalent of 0.02% BAC
Small:	Enables flexible form factor design
Modular design:	Enables easy and inexpensive manufacturing process
Connectivity:	Seamlessly integrates with smartphones and other electronics

Accordingly, SDI's core sensor technology is well suited for development of commercially viable wearable alcohol biosensor.

B. Proposed Wearable Design

For research purposes, we've designed a wristwatch style wearable device that complies with necessary functionality as described by the challenge. However, we're already designing a new form factor – around our existing sensor design - that we believe will be more appealing to consumers.

1. *Detailed Description of Wearable Alcohol Biosensor*

Existing Prototype. Our wristwatch style wearable device is worn with the face of the watch on the inside of the wrist, as shown below, to ensure our sensor is in proximity to the skin.

Figure 3: Face of wearable worn on inside of wrist

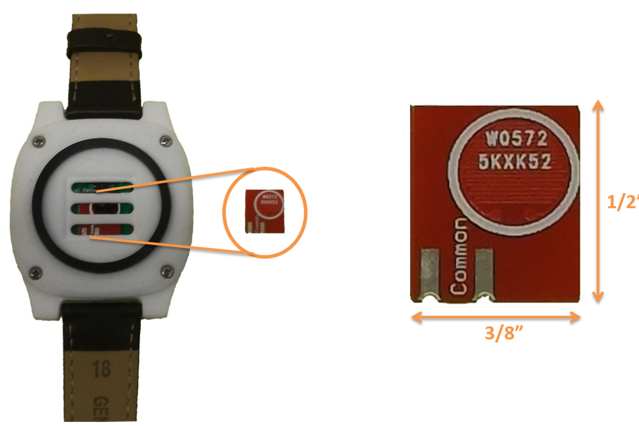
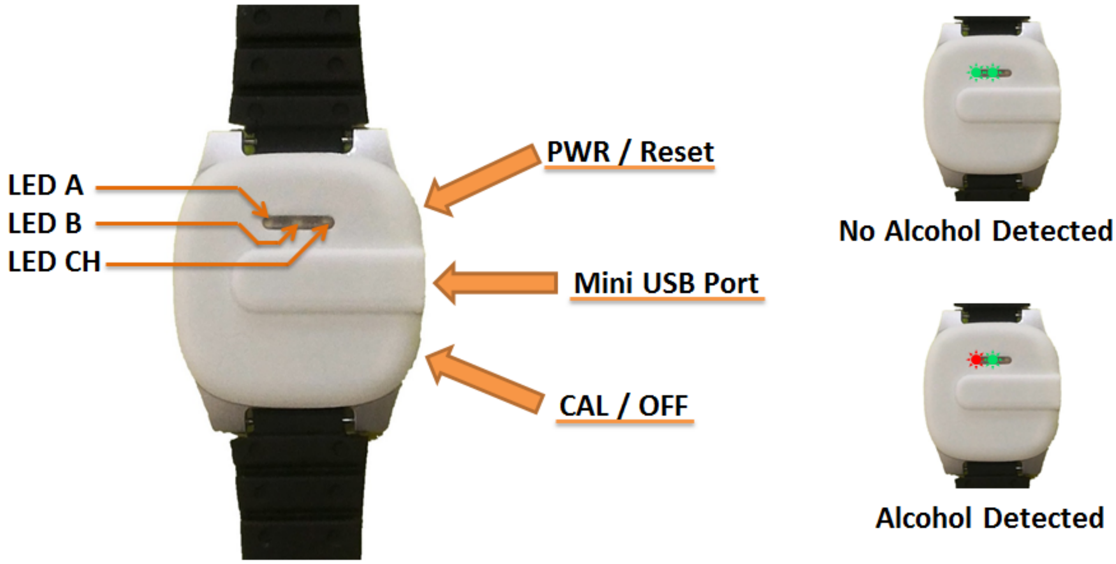


Figure 4: Back side of wearable, highlighting sensor chip

The sensor chip is protected by the plastic shield to prevent any form of physical tampering. A rubberized O-ring attached on the outside of the plastic shield is the only part in direct contact with the skin surface of the subject, and the skin circumscribed by the O-ring is the sampling area from which the transdermal alcohol content is collected into the sensing chamber.

Easy Operation. We've kept operation of the wearable as simple as possible. With the current two-button interface, users can easily power-up, calibrate, and power-down the prototype. Powering-up the wearable takes 3 seconds, after which it auto calibrates for approximately 5 minutes, then begins monitoring blood alcohol levels.

Figure 5: Sober Steering wearable transdermal alcohol sensor control interface.



LED lights indicate 1) alcohol detection, 2) Bluetooth connectivity, 3) calibration status, and 4) sensor health and 5) a loss of system functionality. If alcohol is detected above a preprogrammed threshold, LED indicators will blink red; meanwhile, more detailed sensor data is wireless transmitted to a smartphone app via Bluetooth. A more complete Operations Manual will be included with the prototype submission.

Interval of Data Sampling. The prototype is currently programmed to continuously test once it is calibrated upon power-up. The wearable tests twice per second for a two-hour test period; in that time, it collects and wirelessly transmits (in real-time) 14,400 data points. The prototype can be programmed for more specific interval data sampling. For instance, if desired, it could test once every twenty minutes.

The interval of data sampling directly impacts the battery life of the wearable. More specifically, Bluetooth data transmission that is the primary drain of battery life. If interval data sampling were modified to test once per second, the wearable's battery life would support 8-10 hours of continuous data sampling. Sampling once per minute extends battery life beyond 24 hours.

Rechargeable Power Source. The wearable is charged using a mini-USB connector that plugs directly into the face of the watch. LED lights on the watch face indicate when charging is required, when charging is in process, and when charging is complete. The wearable fully charges within an hour. The number of charging cycles does not impact the sensor capabilities.

Modified Form Factor. SDI has already begun the design and manufacturing process for the next iteration of its wearable form factor. As shown in the figure below, our next wearable design is a Fitbit style wearable that is more discrete about its alcohol detection capabilities. This would enable users to benefit from alcohol monitoring data without raising questions from casual observers. Alternate "modes" will include the time of day and, possibly, heart rate and pedometer readings.

Figure 6: Design for SDI's next wearable device

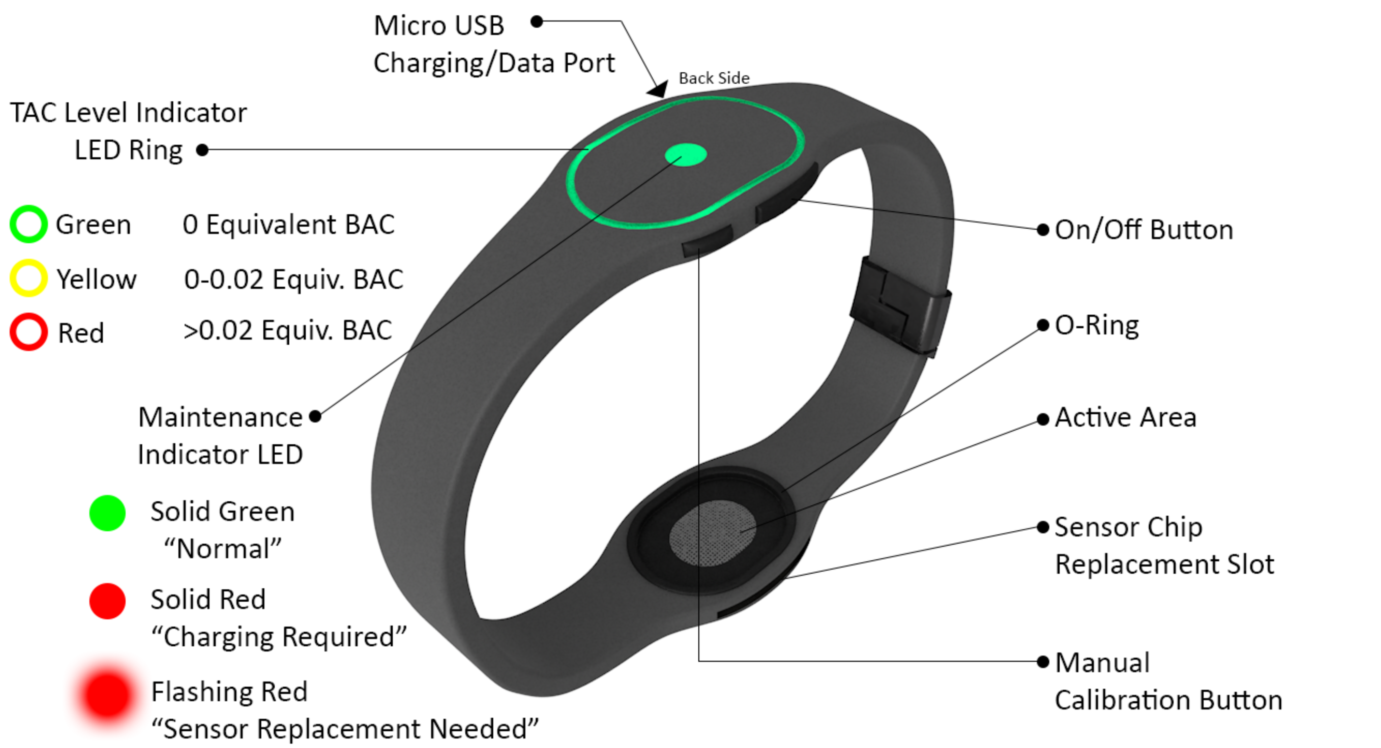


Figure 7: Design for SDI's next wearable device in a discrete "time of day" mode

Our sensor's compact chip size enables it to be embedded with a simple readout circuit within the wrist band of the wearable, thereby allowing the digital electronics portion of the wearable sensor to be placed on the outside of the wrist, while enabling the TAC sampling from inside of the wrist. More importantly, this design also enables simpler sensor chip replacement as well as larger battery pack without incurring further size increase.

However, given our sensor's small size and modular design, we are not limited to this type of wearable form factor. We could easily integrate our sensor capabilities into other form factors. Potential integrations include an actual Fitbit, an Apple iWatch, other luxury watch designs, or even a key fob. SDI is open to integration partnerships as a way of expanding our commercial appeal and making consumers more comfortable with monitoring their own alcohol levels as a means of making healthy decisions.

2. Collecting and Transmitting Data

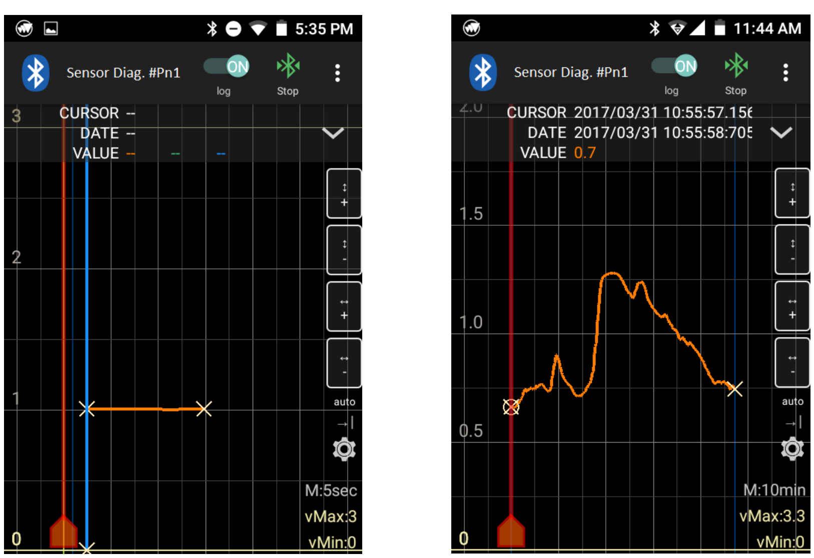
SDI's wearable prototype enables both wired and real-time wireless data collection, transmission and storage. In both cases, the wearable device transmits sensor readings in both voltage levels and equivalent BrAC levels.

Figure 8: Graphic illustration of both wired and wireless data communication

As shown in the figure above, wired transmissions use a mini-USB connector interfaces to a basic communication application (HyperTerminal, etc.) and other compatible desktop programmable applications (LabView, etc.). For real-time wireless transmissions, the wearable establishes a Bluetooth connection to a password paired mobile device.

Internally, SDI has almost exclusively used wireless data collection and transmission in its sensor research and testing. The figures below are actual photos of our smartphone app used for successful transmission, storage and retrieval of wearable test data.

Figure 9: Wireless transmission alcohol monitoring data using smartphone app

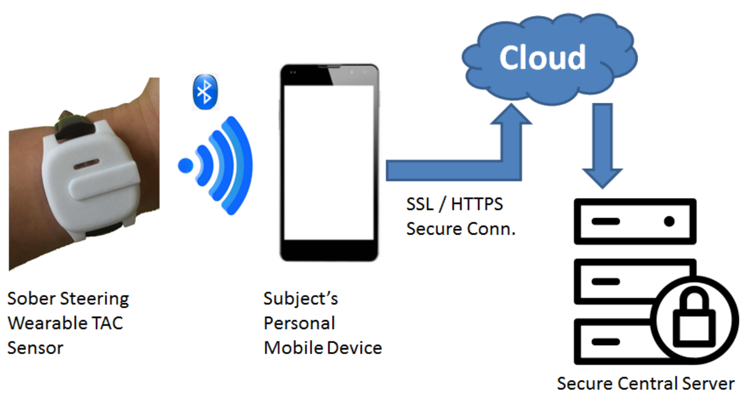


Local and cloud data collection is currently done using a 3rd party smartphone app (Visual Logger) which has been modified for our specific use. We are currently developing a proprietary smartphone app (that also works with local computers) that will replace 3rd party functionality both for wired and wireless data transmissions.

We are currently using password paired wireless connections to ensure the integrity of our research data. This ensures a known connection between a specific sensor – which has a 6-digit unique identifier – and the subject's smartphone being used to collect data. To this point – for our internal research purposes – we have been more concerned with ensuring the integrity of data collection than the digital security of that information. **However, we recognize that, as we offer our wearable device for NIAAA research or as a consumer product, we must enhance our data security to ensure the integrity of the data on a broader scale and the privacy of the user.**

In the next iteration of our prototype (illustrated in Figures 6 and 7 above), we will include encrypted data transmission, SSL/HTTPS connection with cloud servers via our proprietary mobile app, and a secure central server for data storage. The next prototype wearable sensor will utilize the companion app on the mobile device to collect and store its alcohol sensor readings securely with encryption on the subject's mobile device. When the app is configured for reporting the sensor reading histories to law authorities, the alcohol readings as well as the subject's identification information will be automatically transmitted to the designated cloud server via encrypted communications (SSL or HTTPS). The subject's readings will then be kept securely on the data server, from which the authorized parties can retrieve the data for analyzing the drinking habits of any selected subject. Fig. 3.4 indicates the system block diagram for the sensor data transmission and storage.

Figure 10: Data transmission and storage architecture of SDI's proposed wearable alcohol sensor



As a company, SDI has both expertise and experience in securing wireless data. Our subsidiary company, Sober Steering, has a commercially available automotive product and already incorporates this level of data security features. We will be able to port over many of Sober Steering's security features to our wearable.

3. Standardization of Measurements

SDI verifies the standardization of measurements at regular intervals. We have developed robust software to intelligently detect and compensate for variations in changes in sensor sensitivity and environmental factors.

If environmental factors – or system functionality – exceeds the thresholds for proper alcohol monitoring, LEDs indicate a loss of functionality. If the sensor degrades beyond usability, the LEDS indicate that it is time to replace the sensor chip. Sensor chips are easy and inexpensive to replace, taking less than 30 seconds to complete and costing only a few dollars.

C. Subject Identification

Our current wearable prototype uses password pairing between the prototype and the user's smartphone to as a means of subject identification. For the purpose of our internal testing, this was intended to ensure that the integrity of the data being wireless collected by automatically specifying the specific sensor from which data was being collected during testing. For willing subjects of a voluntary research project, this may be sufficient.

For offenders, however, it is not. While not specifically mentioned as part of this challenge, DUI offenders are often a key part of research examining the health impact of alcohol. Also, DUI offenders will certainly be part of SDI's strategy for bringing our wearable device to market. As shown in the illustration of our next wearable form factor iteration (Figures 6 and 7 above), the device has a metal clasp that can identify when a user takes off the wearable. For offender use, we can make this clasp secure to ensure the offender cannot remove the wearable (much like the existing SCRAM bracelet). Otherwise, each time the clasp is opened, we can send an alert indicating that the wearable was removed. Removing the wearable will require it to be re-paired using password protection and re-collaborated ensuring there it was in no way tampered with while off the wrist.

Unfortunately, there are currently no good alternatives for passive subject identification that can be integrated into a wearable. While IR vein pattern and heartbeat pattern monitors can uniquely (and passively) identify a user, both these technologies are early stage. IR vein pattern devices are too big to be incorporated into a wearable device. Heartbeat pattern monitors can be integrated into a wearable like ours, but the technology is still too early in its development to be considered reliable and is prohibitively expensive to add as a feature to our device. Regardless, we will continue to explore these, and other technologies, as potential add-on features to our device in the future.

III. Verified Monitoring of Blood Alcohol Levels

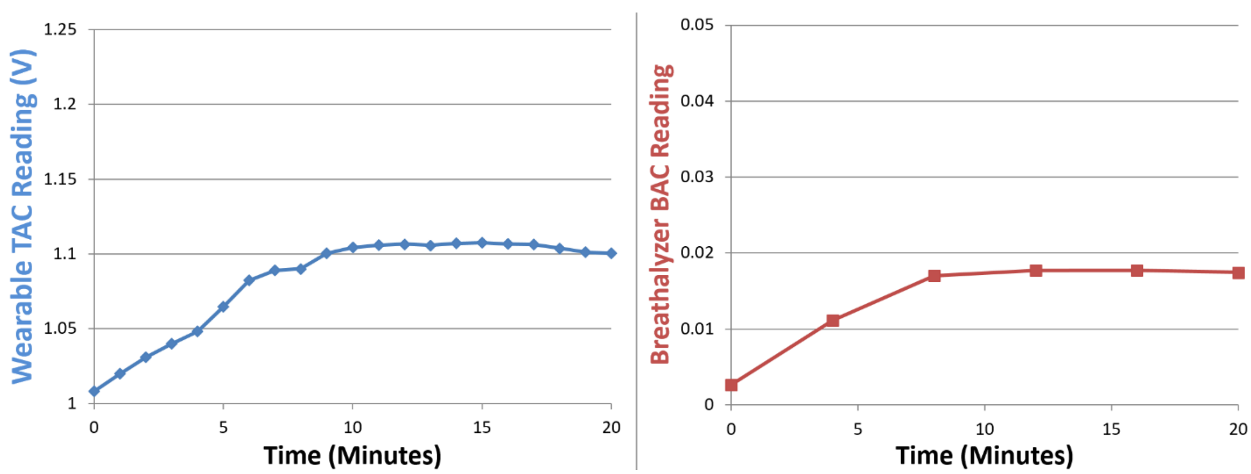
SDI has been refining our transdermal sensor and wearable prototype system design for the past 18 months. After each modification, the prototype is subjected to multiple rounds of performance evaluations. The following written evidence demonstrates our prototype's robust reproducibility of alcohol quantification, reliability, and consistent functioning.

Moreover, the following disproves a decades-long misconception that there is a meaningful delay, biological or device related, between transdermal and breath based monitoring of blood alcohol levels. If anything, our transdermal sensor design has a more rapid detection response time than the breathalyzer, and TAC levels are consistently measurable below the equivalent of 0.005%. Through written evidence here – and hopefully through NIH/NIAAA validation resulting form this Challenge – we will advance the state of transdermal alcohol detection in published literature.

A. Accuracy: quantifying BAC, including levels below 0.02%

For this application, SDI conducted 100 trials of simultaneous TAC and BrAC collection on selected subjects with different test conditions – 25 controls (No EtOH intake) and 75 experiments (EtOH intake with different food intake instructions). All experimental subjects other than controls have ingested 1.5 oz of alcohol (40 w.t.%) prior to the start of the designated tests.

Figure 11: Averaged values of TAC (left) and its high correlation with BrAC collected by breathalyzer (right).



The results clearly indicate a correlation between our transdermal sensor response and breathalyzer response. More specifically, the Figures 11 and 12 show that there is no meaningful delay – biological or otherwise – between transdermal and breathalyzer readings.

This evidence makes it clear that our innovative transdermal sensor is suitable for real-time monitoring of blood alcohol levels as part of a wearable device. Furthermore, more detailed individual testing, shown in the figure below (Figure 12), shows that our transdermal sensor is capable of detecting alcohol faster than a breathalyzer and quantifying at levels well below the equivalent of 0.02% BAC.

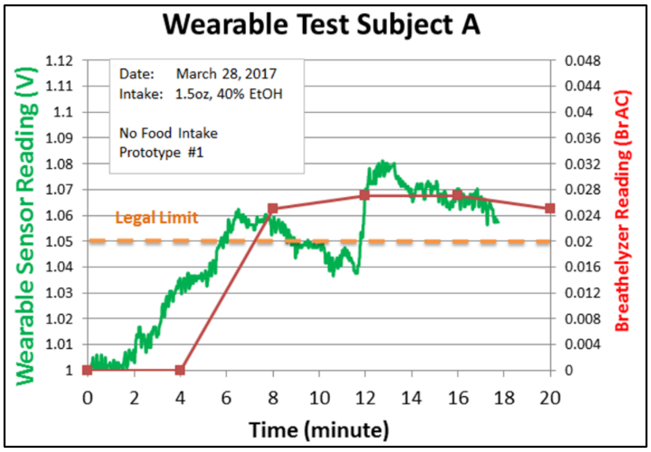


Figure 12: TAC detection prior to BrAC detection

B. Reliability: robust reproducibility of alcohol quantification

Using our proprietary polymeric material, our wearable device is highly selective towards ethanol, and is insensitive to most of the chemical compounds found on human skin. As a result, the SDI wearable alcohol sensor can consistently deliver stable and ethanol-specific readings with minimal interference. Our testing has shown minimal inter-device performance variations. The figure below (Figure 13) shows a high correlation between sensors on the same individual. Variance in TAC readings are accounted for during the initial calibration process.

Additionally, individual sensors produce repeatable results across individual subjects. The sensors in the figure below (Figure 14) were characterized by at least 40 different trials.

Significant additional testing over the past 18 months has produced a reliable wearable that delivers reproducible results.

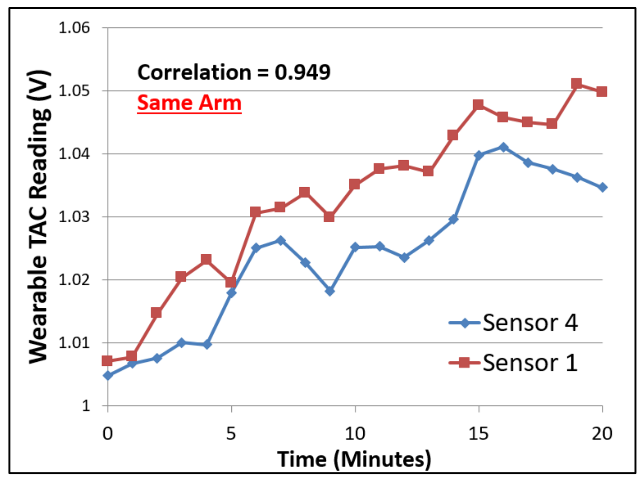
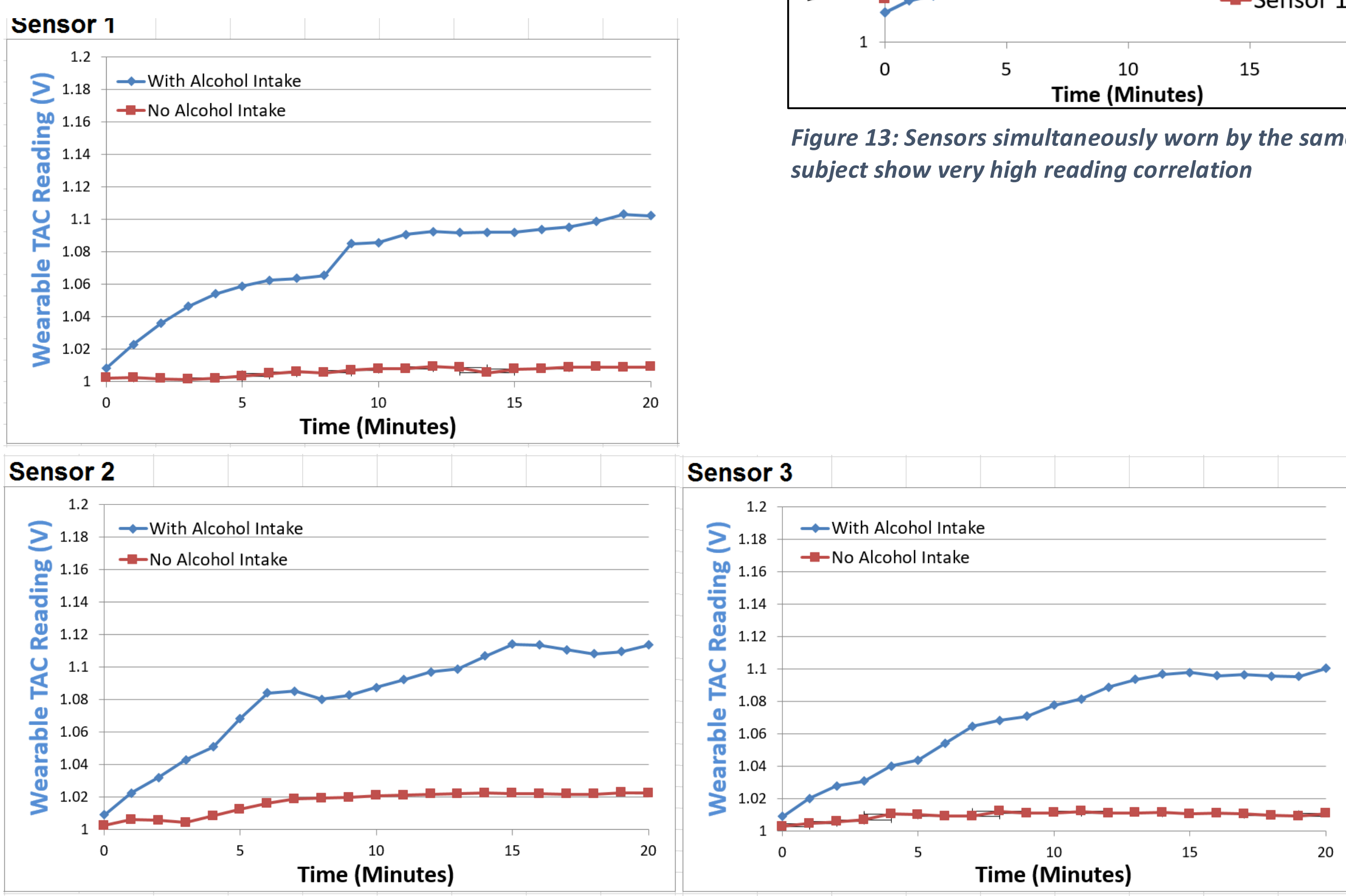


Figure 13: Sensors simultaneously worn by the same subject show very high reading correlation

Figure 14: TAC response patterns of selected sensors



C. Frequency of blood alcohol monitoring: consistent functionality

As shown in the figures above, SDI's wearable tests for alcohol levels 2x per second. We conduct continuous testing for approximately two hours, which is the life of the battery at that testing frequency. The primary draw on the battery isn't the testing itself, but rather the real-time data transmission of 14,400 data points to a smartphone via Bluetooth during that time.

Our devices can be reliably programmed to test at less frequent intervals, resulting in a dramatic improvement in battery life. For instance, if we were to reduce testing for blood alcohol levels to 1x per second, the battery life would extend to approximately 8-10 hours. By testing every 10 minutes, we could extend the battery life to well over 24 hours. With 18 months of sensor and system testing, we believe we have achieved a consistently functioning wearable that can be easily programmed for monitoring frequency as use cases dictate.

IV. MARKETABILITY AND MANUFACTURING

Sensor Diagnostics, Inc. has invested significant resources to the research and development of a unobtrusive, wearable transdermal sensor. We strongly believe that there is a significant market opportunity for such a device. After several years and significant investment dollars, we believe we’re very close to achieving a commercially viable wearable biosensor fro real-time alcohol detection and monitoring.

A. Appeal and acceptability to wearers

Our current prototype was designed for research and rigorous sensor testing. While we believe it does prove the technology is viable as intended, it is not sleek enough for the consumer market. The proposed design below focuses not only on functionality, but also an appealing form factor.

Figure 15: Design for SDI's next wearable device in a discrete “time of day” mode

We believe the above form factor will be more acceptable to wearers because its multi-mode functionality makes the device a more discrete wearable alcohol sensor. To the casual observer, the device looks like any other Fitbit style fitness tracker. The sleek design, combined with the privacy of a user’s own smartphone based data interface, makes this proposed device suitable for alcohol related health research and appealing to consumer users.

Ultimately, however, we would like to see a person’s alcohol levels become an important piece of trackable health data. As alcohol monitoring becomes more acceptable in the mainstream, we hope to partner with existing, branded wearables like Fitbit or Apple iWatch and integrate our chip based alcohol sensors into their existing form factors.

B. Marketability and likelihood of bringing product to market

We believe that there is a strong market opportunity developing for wearable alcohol biosensors. The combination of effective alcohol detection, sleek wearable design, and an affordable price make an wearable alcohol sensor a compelling product in multiple markets.

Specifically, we would target the following markets:

1. *Research and rehab centers.* As pointed out in this challenge, there is an existing need for an effective wearable alcohol biosensor for studying the effects of alcohol. Besides the study of these effects, rehab centers can use these devices to help monitor and rehabilitate those with alcohol related

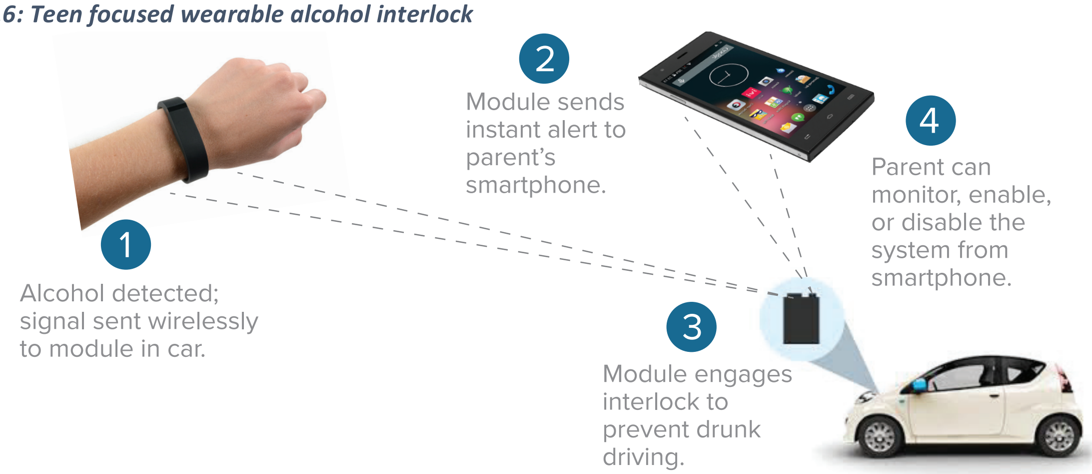
illnesses. These are ideal first markets to pilot our prototype. If we are chosen as a winner of this challenge, we look forward to designing a product to meet the specific needs of this market vertical.

2. *Alcohol related offenders.* There is currently only one device – the SCRAM bracelet that offers wearable alcohol monitoring of alcohol related offenders. Approximately 30,000 SCRAM bracelets are leased each year to offenders, and this existing market is growing by double digits each year. The SCRAM bracelet is obtrusive, inefficient, difficult for users to charge and use, and expensive. By contrast, our sleek wearable device would offer superior alcohol monitoring and a user friendly design at a significantly lower price.

   We believe we would be able to quickly penetrate the existing market for wearable alcohol sensors for alcohol related offenders and absorb a significant market share quickly. The financial benefit associated with this market alone justifies SDI's investment and commitment to commercializing its wearable alcohol biosensor prototype.

3. *Teen drivers.* Drunk driving is the #1 killer of people under 25. Based on our experience in the automotive market, a wearable alcohol interlock targeting teen drivers is an interesting product for big name auto manufacturers. It combines the growing trends of 1) monitoring, and mitigating, the erratic behavior of human drivers, 2) teen safety, and 3) connected technologies that can 'sync' with the vehicle post production. An example of an alcohol interlock using the wearable prototype is illustrated in the following figure:

Figure 16: Teen focused wearable alcohol interlock



4. *Concerned drivers.* There is an existing market for drivers that simple interested in ensuring that they are not driving drunk. For this group, we may consider modifying the form factor from a wearable to a key fob. While the form factor will change, the fundamental technology validated through the development and validation of the wearable device proposed here is the same.

C. Proposed process for manufacturing

As a company, we have both the expertise and experience necessary to transition from a prototype to a market ready product. From the beginning, we've designed our wearable prototype with an eye toward large scale manufacturing. Our scalable sensor system design will help reduce the cost of the wearable sensor and the disposable sensor chips periodically required for replacement.

The PCBs for the main sensor unit are panelized for volume production and will be loaded with components using a standard surface mount (SMT) line and solder reflow at a contract manufacturer experienced with our existing sensor and telematics products. Once loaded with components, the individual boards will be removed from the panel using a standard router process. The routed PCBs are then assembled into the main housing, followed by placing the soft buttons and the top cover before production validation test.

Production testing will be conducted via a USB connection from a mobile computer to the device fitted to a small bench top fixture with a known reference capacitor connected to the readout circuit board of the main sensor unit. The device will be programmed and calibrated at this point, and the calibration results are subsequently compared to the defined Pass and Fail limits. Finally, the reference capacitor is removed from the sensor, and the lower housing cover is screwed in place to complete the mechanical assembly of the main sensor unit.

This manufacturing process will be undertaken by contract manufacturers – to be clear, we will not be manufacturing these devices ourselves as hardware manufacturing does not make financial sense for small companies like ours. The benefit of working with contract manufacturers is that they source the components required for the build and – given their size – they can pass along benefit of scale to small companies like ours even in small quantity builds. Furthermore, contract manufacturers handle all aspects of the manufacturing process. Once we provide the necessary designs and testing instructions, we simply order the number devices we need and provide the customer information, and the contract manufacturer will “drop ship” completed, packaged products to our clients. This enables us to focus on what we do best – transdermal sensor design and development.

V. IN CONCLUSION

We believe that our innovative transdermal sensor design is ideal for a sleek, unobtrusive wearable device capable of monitoring blood alcohol, non-invasively, and in real-time. We’ve validated this belief with months of prototype testing. We hope that we will be chosen as a winner in this challenge. Specifically, we look forward to working with NIH / NIAAA to verify our transdermal monitoring of alcohol levels using blood tests. To date, we have not been able – logistically or financially – to do broad scale blood testing to validate our sensor data. Through a working relationship with NIH / NIAAA – or simply using the financial award from this challenge – we look forward to demonstrating, once and for all, that our innovative transdermal sensor is suitable for real-time detection and monitoring of blood alcohol levels.