BACtrack

KHN SOLUTIONS, Inc.

November 30, 2015

M. Katherine Jung, Ph.D.
Program Director, NIAAA Division of Metabolism and Health Effects
National Institute on Alcohol Abuse and Alcoholism
5635 Fishers Lane, MSC 9304
Bethesda, MD 20892-9304

BACtrack's Entry for "A Wearable Alcohol Biosensor Challenge"

Dear Dr. Jung:

Enclosed herein is KHN Solutions, Inc.'s official entry for the NIAAA Challenge: A Wearable Alcohol Biosensor.

Our entry consists of the following:

1) This PDF document describing our solution;
2) An unlisted YouTube link with a video of our solution: https://youtu.be/SRZifNHD18k
3) A prototype that will be sent to the judges upon receipt of shipping instructions, per the Challenge FAQ section.

We have reviewed the eligibility criteria required to win a prize; I confirm that KHN Solutions, Inc., and the innovations contained herein, meet all of the eligibility criteria.

Our team has spent considerable resources pursuing this challenge, and we are proud of the final result. We believe our solution is a great step forward in creating the next generation of alcohol safety devices.

I can be reached at keith.nothacker@bactrack.com or 415.693.9756 x113 with any questions regarding our entry.

Sincerely,

Keith Nothacker
CEO, KHN Solutions, Inc., DBA BACtrack®

About BACtrack

KHN Solutions, Inc., DBA BACtrack, designs and sells portable breath alcohol testers under the brand name **BACtrack®**. BACtrack is used by consumers for self-testing, as well as by businesses, schools, treatment clinics, law enforcement, and militaries. BACtrack products are available in over 10,000 retail store locations including Costco, Best Buy, Walgreens, and Target, as well as through online retailers like amazon.com. BACtrack is a privately held company with 13 employees based in San Francisco, California.

In 2001, BACtrack was the first company to market a handheld breath alcohol tester as a consumer-friendly device. In 2004, BACtrack was the first company to receive FDA 510(k) pre-marketing clearance for a breath alcohol tester. BACtrack has several models approved by the U.S. Department of Transportation as Preliminary Alcohol Screening Devices.

Current BACtrack products employ two main types of sensor technologies: Xtend® fuel cell sensor technology, and MicroCheck™ semiconductor sensor technology. Two BACtrack products can connect to a user's smartphone via Bluetooth using BACtrack's free companion app. BACtrack Mobile, our first smartphone device, won Popular Science's Best of What's New award in the Health Category in 2013.

BACtrack Mobile
--Xtend Fuel Cell Technology
--Connects to iOS and Android devices

Specific Aims

✓ **Aim 1. Accuracy, Reliability, and Frequency of Blood Alcohol Measurement**

BACtrack has successfully integrated transdermal alcohol sensor technology into a sleek, miniaturized prototype called *BACtrack Skyn* that offers continuous and non-invasive monitoring of a user's BAC. The prototype is able to sample transdermal alcohol every second, and it offers the most accurate and reliable transdermal sensing technology currently available on the market.

✓ **Aim 2. Functionality, Accuracy, and Integration of Data Collection, Data Transmission and Data Storage**

BACtrack Skyn connects via Bluetooth to a user's smartphone. BACtrack already has a platform in use that seamlessly and securely transfers data from the point of collection to a cloud based storage and retrieval system. A proprietary algorithm processes multiple user datasets. The potential study of large amounts of networked user data could dramatically advance the understanding and performance of transdermal monitoring.

✓ **Aim 3. Safeguards for Privacy Protection and Data Integrity**

Data security and privacy will be strictly enforced through industry-standard technologies. Data is secure from the point of acquisition, through the Bluetooth connection, on the user's phone, and to and from a secure cloud environment. Safeguards are in place to protect against lost or stolen devices, smartphones, and passwords. A HIPAA-compliant, medical-focused version is planned.

✓ **Aim 4. Plans for Process of Manufacture**

BACtrack has more than 10 years experience manufacturing professional and consumer alcohol testers. BACtrack Skyn can be manufactured in BACtrack's existing facilities. Significant cost savings can be achieved with an automated sensor manufacturing system.

✓ **Aim 5. Marketability and Likelihood of Bringing the Product to Market**

BACtrack Skyn is appealing to several different markets. Researchers and treatment providers can use Skyn with patients. At the same time, the enormous growth of the consumer wearables market makes Skyn appealing to consumers as a discretionary safety device. BACtrack currently has breath alcohol testers placed at some of the largest retail chains in the world, including Walgreens, Target, and Costco, and BACtrack can leverage these relationships for placement. BACtrack sees huge market opportunities, as there are no other low cost, reliable, continuous alcohol monitoring devices available.

✓ **Aim 6. Appeal and Acceptability to Wearers**

BACtrack carefully considered size, body location, industrial design, and user experience in creating Skyn. Skyn's attractive design enables it to be sold as a mass market consumer item, and its high accuracy and reliability make it equally suitable for serious clinical applications.

✓ **Aim 7. Feasibility**

Prototype fabrication and test data have provided promising results. The transdermal hardware has been miniaturized and works as intended; the smartphone app receives continuous data in real time; and BAC can be estimated through real time analysis of Raw Alcohol Count data.

Design Considerations

BACtrack reviewed a variety of existing and promising alcohol measurement technologies for the Challenge. The technology that we ultimately selected and developed most closely matched the Challenge criteria: a non-invasive technology, in contact with the human body, inconspicuous, continuously monitoring, and most closely approximating real time monitoring.

These criteria eliminated existing breath testing technologies, as current embodiments are not inconspicuous and are do not monitor continuously.

We considered near-infrared spectroscopy, but due to size, cost, and other factors, we determined current technologies were not suitable for the Challenge requirements.

As we investigated transdermal sensing, we saw that currently available devices were large, bulky, and designed specifically for the criminal justice segment. The devices were not at all "appealing to the wearer" as stated in the Challenge. A white paper funded by a transdermal manufacturer says exactly this:

> *"There are also punitive qualities associated with continuous transdermal alcohol monitoring. In addition to inconvenience and financial costs, it provides a constant deterrent and reminder to offenders of the problem behavior that needs correction."*

However, we saw promise in transdermal technology, as it can truly allow for non-invasive, continuous monitoring. Further, we believed that if we could significantly shrink the form factor down, and rethink the user experience and industrial design, ***we could create a product that people would want to wear.***

With breath alcohol testing, BACtrack took a law enforcement technology, reduced the size and cost, and radically changed the industrial design to make it appealing for both personal *and* professional use. By doing so, BACtrack pioneered the consumer breathalyzer industry. We believe that our entry for this Challenge also has the same potential for radical industry change.

Medical Significance

Alcohol use remains the third leading cause of death both in the USA (85,000 deaths annually) and worldwide (up to 2.5 million deaths annually) (Mokdad et al 2000; and NCADD Report 2009). The economic costs associated with excessive drinking exceed $223 billion annually in the USA alone (Bouchery et al 2006).

To effectively study alcohol kinetics, metabolism, the effects of therapeutic drugs on alcohol use, alcohol treatment techniques, and other important factors in understanding the disease, clinical researchers need continuous, real-time monitoring of alcohol (Stahl et al 2002; Chaurasia et al 2007). However, many clinical studies rely on self-report, which suffers from substantial limitations, including the inability to accurately quantitate blood alcohol levels, intentional or unintentional misrepresentation, reporting biases, and memory artifacts (Leffingwell et al 2013).

Some of the objective methods for measuring alcohol in clinical studies, such as breathalyzers and biological assays, also have significant drawbacks, including invasiveness, constant user interaction, and/or the inability to provide real-time quantitative measurements of alcohol (as opposed to metabolites) (Leffingwell et al 2013). **By contrast, transdermal alcohol detection, which measures alcohol permeating through the skin and correlates that measurement to the blood alcohol concentration, offers the distinct capacity to provide a noninvasive, continuous, and quantitative measurement of bodily alcohol.**

Sensor Background

The BACtrack Skyn sensor senses ethanol vapor at the surface of the skin, using an electrochemical cell that produces a continuous current signal proportional to ethanol concentration. Our transdermal sensor development partner possesses significant experience and scientific knowledge in this field, and this partner supplies 10,000 transdermal sensors per year to the criminal justice market.

Transdermal Alcohol Sensing Background

Using the sensing element, the sensing electrode measures the transdermal alcohol by oxidizing it at the sensing electrode (Equation [1]), which is held at a constant potential (0.0V vs. Pt/air reference electrode). As the ethanol is oxidized at the sensing electrode, the resulting current is measured at the counter electrode (Equation [2]), and the current is directly proportional to the transdermal alcohol diffusing through the skin.

[1] $CH_3CH_2OH + H_2O \rightarrow CH_3COOH + 4e^- + 4H^+$ Sensing Electrode Reaction

[2] O_2 (Air) $+ 4H^+ + 4e^- \rightarrow 2H_2O$ CounterElectrode Reaction

current

proton

This three-electrode sensing element design and electrochemical measurement technique not only enables a passive, noninvasive, and continuous measurement of transdermal alcohol, but also provides signal stability and longevity not achievable by devices currently commercially available.

The only competing noninvasive transdermal alcohol sensing device is an ankle unit (SCRAM® device) used in law enforcement and manufactured by Alcohol Monitoring Systems, Inc. (Littleton, CO). However, the SCRAM® device uses a two-electrode fuel cell to measure the transdermal alcohol, which requires a pump to deliver the sample. Not only is the unit power-hungry and unsuitable for a miniaturized device due to the pump requirements, the device also requires the sample to be fully consumed by the fuel cell. As a result, the SCRAM® device is only able to sample every 30 minutes. By contrast, the BACtrack Skyn sensing element has a dedicated reference electrode that keeps the device in a ready-state to continuously oxidize any alcohol reaching the sensing electrode, and therefore is able to sample as low as every one (1) second. Indeed, this more stable sensing mechanism has shown greater reliability during clinical research, as a three electrode sensing device very similar to BACtrack Skyn detected up to 86.1% of self-reported drinking events, while the SCRAM® device was only able to detect up to 75.9% of self-reported drinking events (Wray et al 2012; Barnett et al 2011).

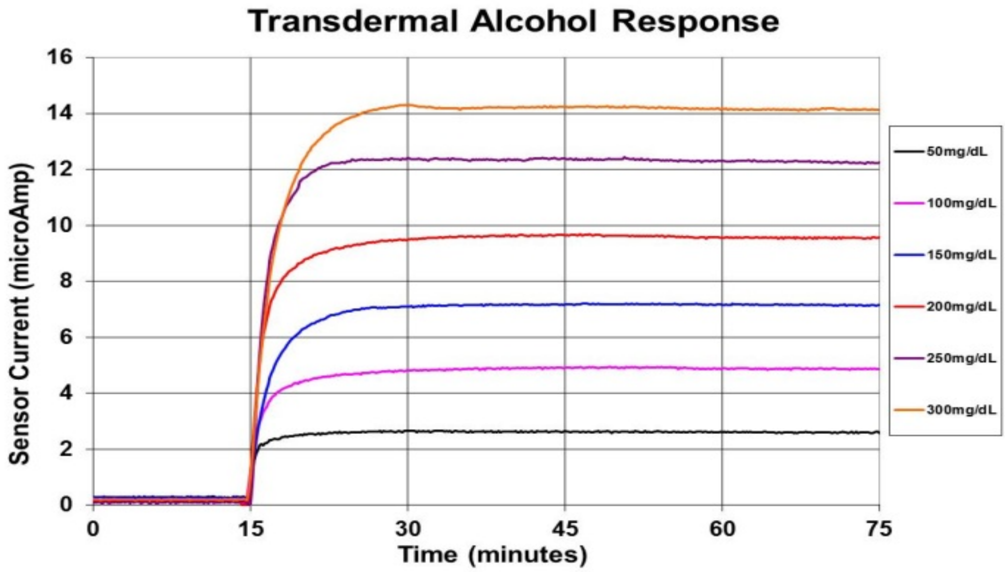


Figure 1 – Transdermal Alcohol Sensor response over a concentration range of 0-300mg/dL wherein the alcohol is introduced at the 15 minute mark.

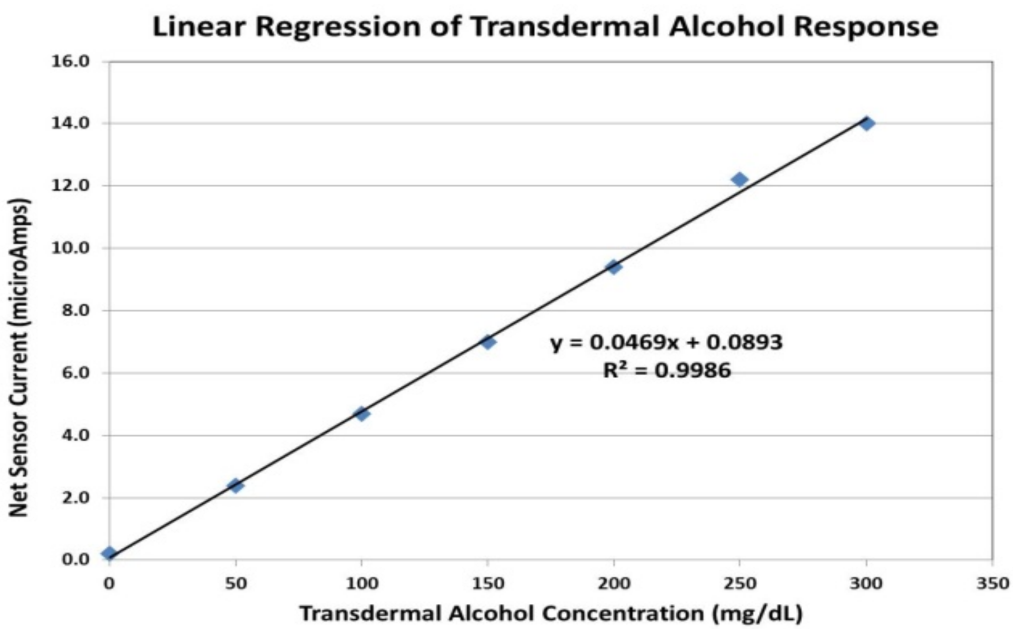


Figure 2 – Linear regression of the transdermal alcohol response for the concentrations tested and shown in Figure 2.

To illustrate the inherent accuracy of the three electrode sensing element, Figure 1 demonstrates typical responses curves over an alcohol vapor concentration range of 0 – 300 mg/dL, and Figure 2 provides a linear regression of the response curves in Figure 3a.

As shown in the graphs above, the accuracy of the three electrode sensing element is sub-1mg/dL (0.01%) over an alcohol bath of known concentration. When measuring transdermal alcohol on a human, however, a multitude of physiological factors limits the accuracy due to person-to-person variability. For instance, variability in body water, body fat, skin thickness, skin temperature, relative humidity, and perspiration will all affect the amount of alcohol diffusing through the skin.

Currently, a correlation factor is used that relates the transdermal alcohol signal to a BAC value similar to the partition coefficient used by breathalyzer devices. During the 2-point calibration, the sensor measures a background value (i.e. 0mg/dL) and the response over a known alcohol concentration to provide a linear calibration curve. A correlation factor then relates this calibration curve to BAC, which is a proprietary value established by clinical studies. This correlation factor is similar to the partition coefficient used in breathalyzer values that establishes a relationship between the deep lung vapor ethanol sample and BAC, except the correlation factor relates the transdermal vapor ethanol concentration to BAC.

BACtrack plans to examine a number of techniques that provide a more personalized calibration. In future clinical studies, KHN will model a number of the physiological factors affected the transdermal alcohol response, such as body water, body fat, skin temperature, perspiration, etc. If this modeling demonstrates greater accuracy versus blood-gas measurements or breathalyzer readings, then the mobile application will query the user to enter these parameters into the application, which will then be used to adjust the correlation factor.

Another alternative BACtrack will examine for a more personalized calibration will be to have the user drink a known amount of alcohol (i.e. a bolus drink), and use the response from that bolus drink to adjust the correlation factor.

Calibration data is currently being acquired, tested, and implemented for the new Skyn prototype devices, and %BAC results will be displayed in the next prototype App update.

The Product

We have invented a low cost, wearable, non-invasive alcohol monitoring device. This prototype is code-named BACtrack® Skyn™.

BACtrack Skyn sends Transdermal Alcohol Content (TAC) results via Bluetooth to an iOS device. TAC samples can be taken as frequently as every second, can be sent from the wrist device to a smartphone, and if desired, to a cloud server.

Render 1: Full View

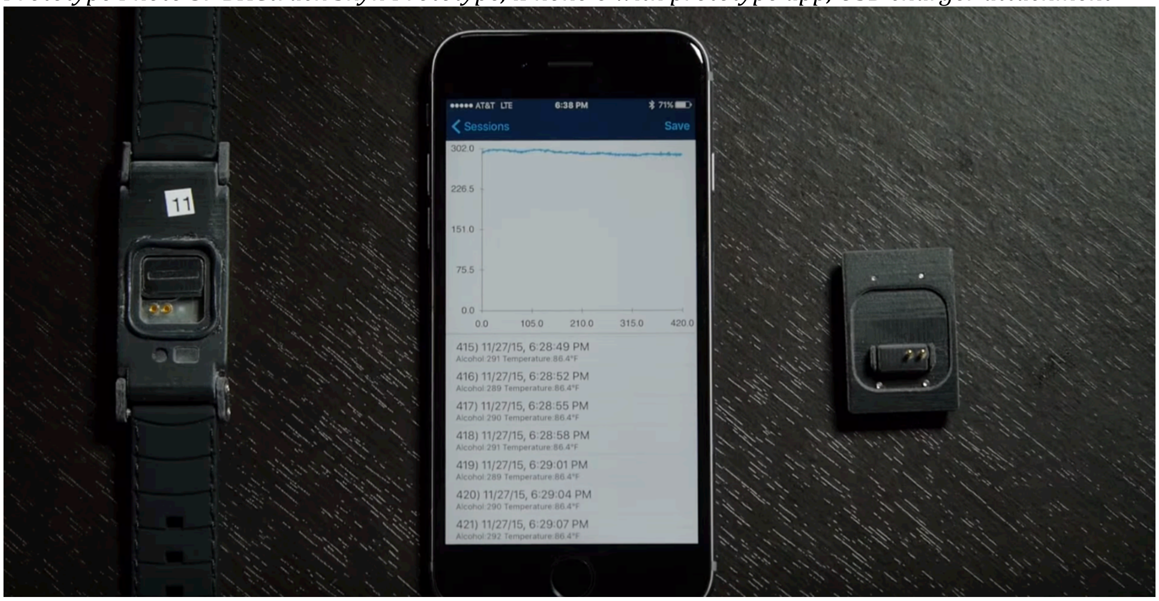
Render 2: Zoomed View

Render 3: Sliding Door Open, Sensor Exposed

Prototype Photo 1: Worn on wrist

Prototype Photo 2: Wrist band

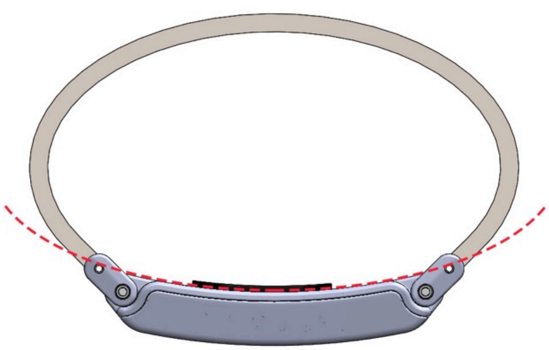
Prototype Photo 3: BACtrack Skyn Prototype, iPhone 6 with prototype app, USB charger attachment



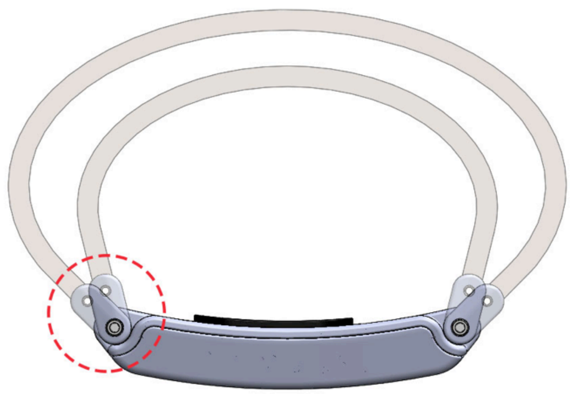
Mechanical & Hardware Features

The following hardware features have been incorporated to maximize performance, size, and comfort.

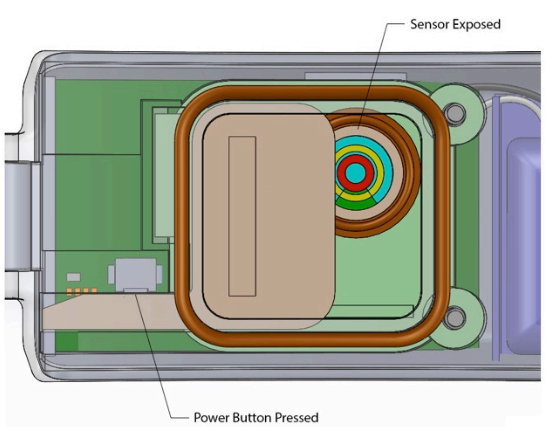
Arch of Device: Device is slightly curved to closely match the curvature of the wrist

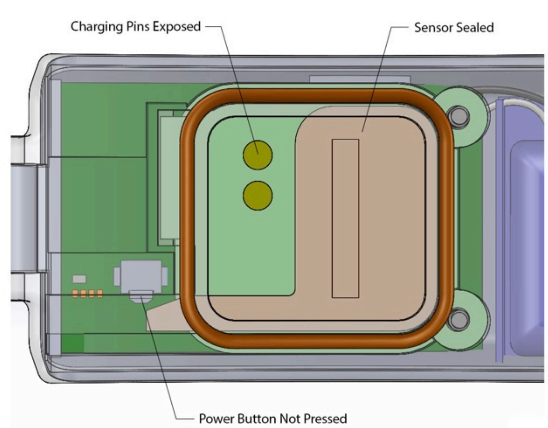


Wrist-Band Attachment: Because the device is longer than a typical watch, we needed to think about how to attach the wrist band so that it could fit both large and small wrists equally well. The 4 links between the device and strap rotate so that they are more horizontal for a larger wrist and more vertical for a smaller wrist.

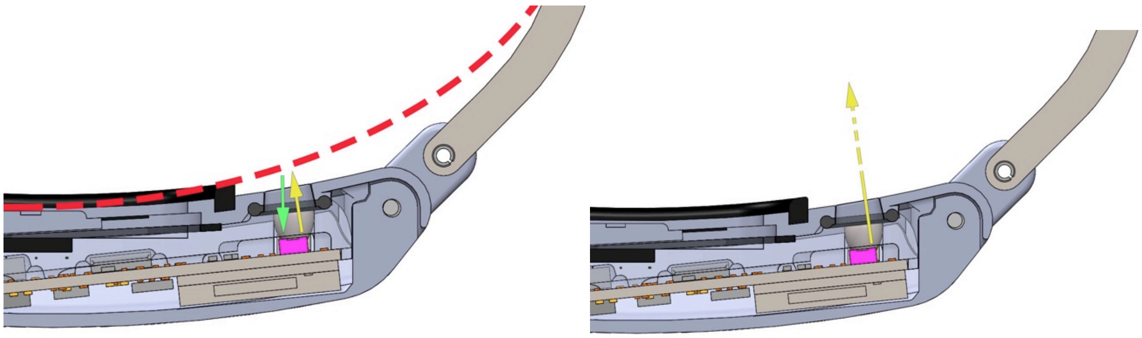


Sliding Door: Combines all the necessary shut-down features into a single motion: (1) seal off chamber so that water in chamber doesn't evaporate (2) turn off electronics in device to save battery life and (3) expose charging pins. Device cannot be charged without closing the door, which makes it less likely that the device will run dry since it will always be sealed when taken off the body to charge. Future versions may have an automatically actuated door that will close when not in use.





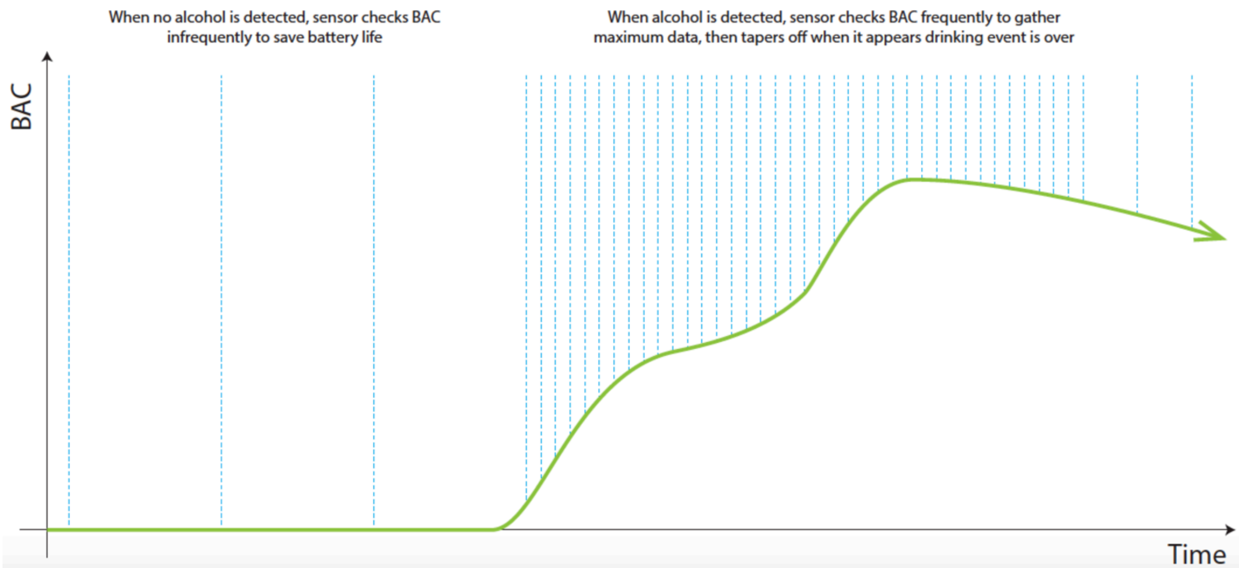
Optical Sensor: Saves battery life by only taking readings when the device is being worn. Also can be used to notify user that they need to close the sliding door if they took off the device but forgot to close the door.



Rechargeable Battery: Easily recharge the battery with a micro USB connector.

Reduced Size Transdermal Sensor: Sensor is custom-designed for BACtrack Skyn, allowing the device size to be appropriate for a wrist.

Sampling Algorithm: Saves battery life by adjusting sampling rate based on current activity. If device is reading no alcohol, slow sampling rates to several minutes apart, but if reading alcohol, speed up sampling rates to gather as much real-time data as possible. Current BACtrack Skyn prototypes can **sample the skin as frequently as every second.**



Note: Several of these features are planned and are incorporated into current hardware design, but are not yet active in the prototype.

Smartphone Connectivity & Features

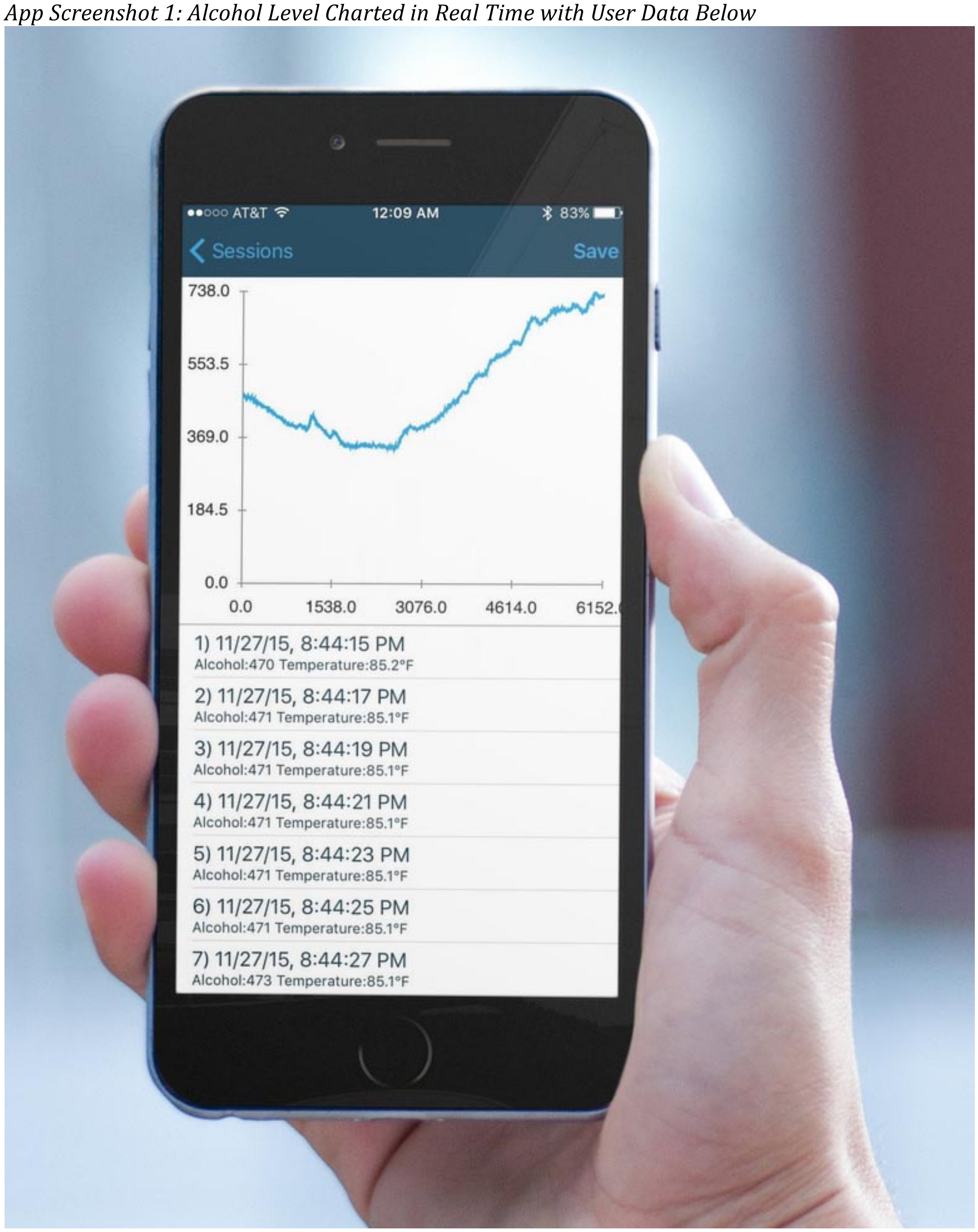
The BACtrack Skyn app acquires real time transdermal alcohol data from Skyn via Bluetooth. The current BACtrack Skyn app allows users to view a continuously-updating graph of their Raw Alcohol Count, see each data point, start, stop and save sessions, control sampling frequency, and export data.

Our conversion from Raw Alcohol Count to BAC leverages previous research performed in testing a three-electrode, non-pumping, transdermal sensor. See **Prototype Test Data** section to understand how BACtrack Skyn will convert Raw Alcohol Count to Blood Alcohol Content.

(app screenshots on following pages)

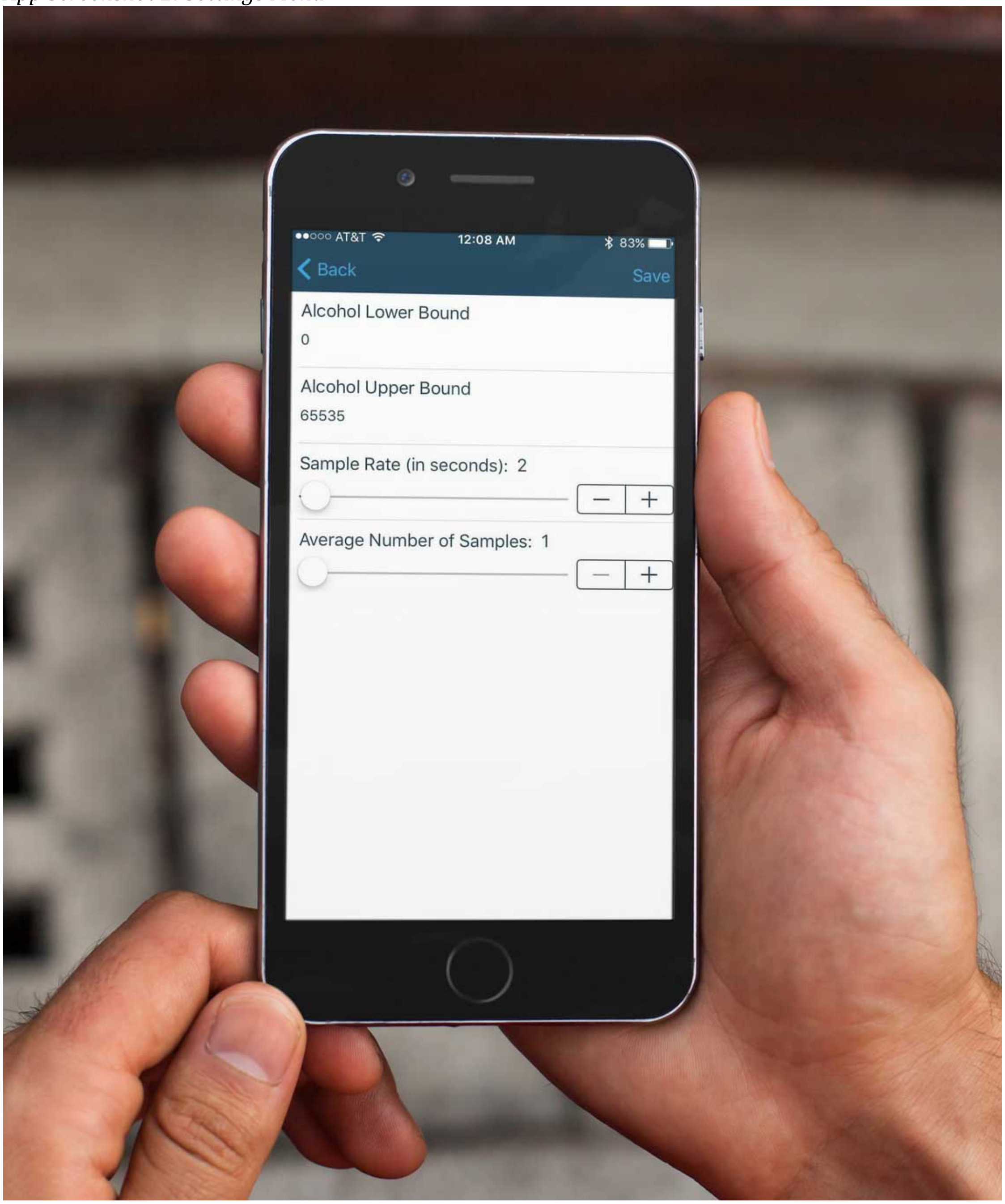
View real-time Raw Alcohol Count, Temperature, Date and Time.

App Screenshot 1: Alcohol Level Charted in Real Time with User Data Below



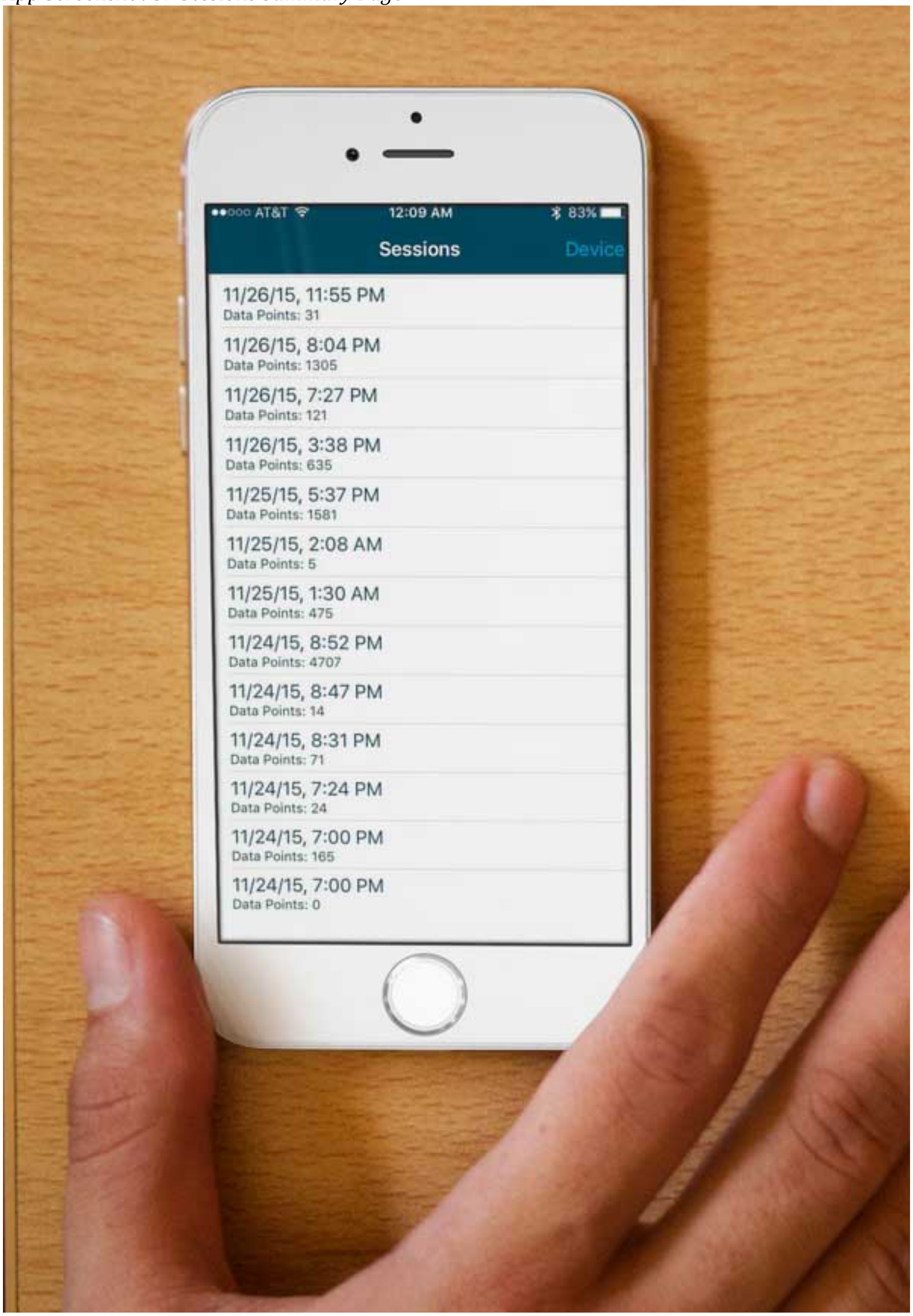
Adjust Sample Rate, adjust Sample Averaging and Review Blood Alcohol Content conversion factors (Upper & Lower Bounds)

App Screenshot 2: Settings Menu



Save, Access, and Review Session Data

App Screenshot 3: Sessions Summary Page



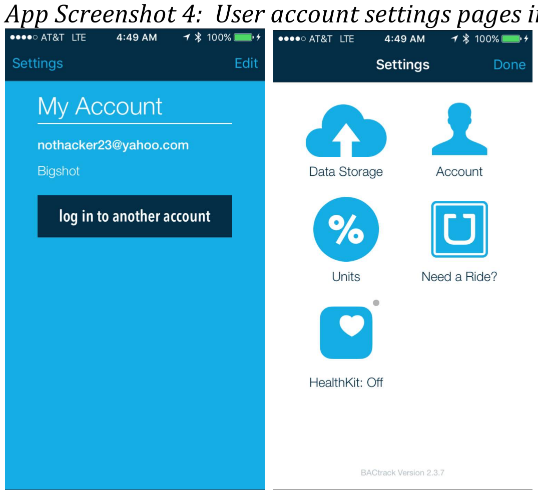
Software features planned for future release:

1) User accounts with secure cloud-based storage of user data.

BACtrack already securely maintains a large number of BACtrack breath alcohol tester user accounts. Users of the BACtrack app have the option of creating a username and password and saving their breath alcohol test results, location, date/time, notes, and photos.

BACtrack already runs this data management platform, and we can integrate BACtrack Skyn into this platform quickly and reliably.

App Screenshot 4: User account settings pages in BACtrack's existing app

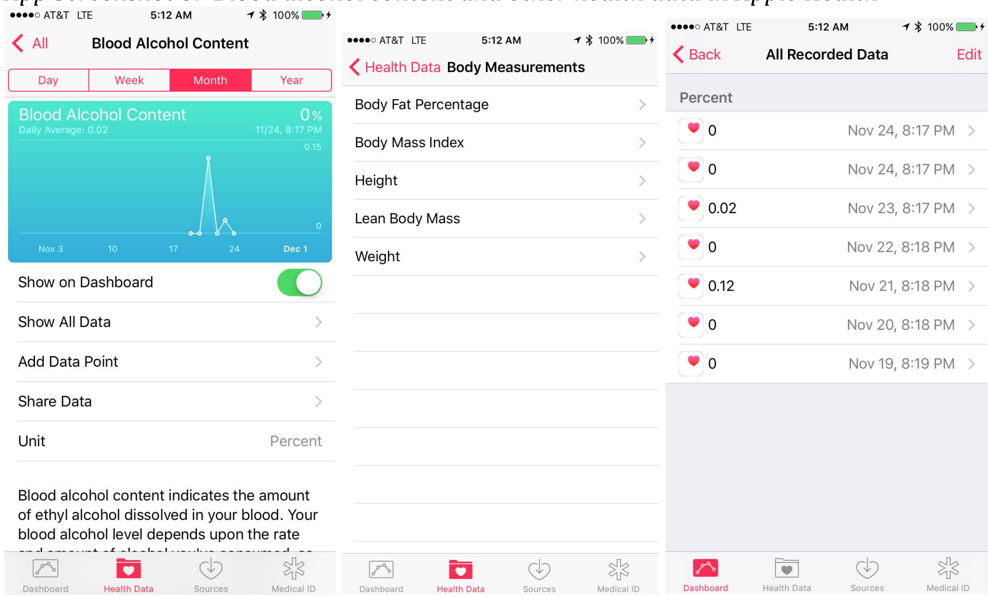


2) Integration with Apple Health and HealthKit.

BACtrack's smartphone breath alcohol testers integrate with Apple's Health app. BACtrack users can save their BAC data to the Health App and view it together with the rest of their health data.

A BACtrack Skyn integration with Apple Health could have enormous benefits for users and for the overall pursuit of accurate continuous alcohol monitoring. Users frequently save their height, weight, BMI, exercise data, and other data into Apple Health, and HealthKit allows developers like BACtrack to access that data with a user's permission. Having access to a user's weight, BMI, or other physiological data would allow BACtrack to customize the Skyn algorithm to each specific user.

App Screenshot 5: Blood alcohol content and other health data in Apple Health



3) A HIPAA-compliant version tailored for medical use.

BACtrack Skyn would be handling Protected Health Information (PHI) in the case of sending results to a covered entity such as a doctor. BACtrack would have an app that is HIPAA compliant.

Battery Life

An optical sensor and a temperature sensor let the Skyn know if it's being worn; when it is not being worn, the Skyn is in a low power mode. The baseline sample rate of the BACtrack Skyn can be easily adjusted by using the Skyn's iOS application. Increasing the sample rate will yield more BAC readings, but will decrease the battery life. The sample rate is also automatically adjusted with respect to the rate of change of the wearer's BAC. After taking a sample, the BAC data is stored in flash memory and is streamed to an iOS device, using Bluetooth Low Energy (BLE), when the iOS app is open.

If a ***production*** BACtrack Skyn (with final firmware optimized for battery life) averages a sample once every 60 seconds, the battery life will be approximately 9.82 days until it needing to be recharged with the embedded 60mAh battery.

If the Skyn device averages a sample once every 10 seconds, the battery life will be approximately 6.02 days before needing to be recharged. A 60mAh battery was chosen so that it could fit inside of the aggressively small prototype, making it a more viable wearable for a larger audience. However, a larger battery could be used to increase battery life in applications where a larger form factor is acceptable. For example, if a 2000mAh battery is used instead, and the Skyn was sampling once every 60 seconds, the battery life would be approximately **327.29 days**.

The current BACtrack Skyn prototype is configured in a demo mode, which continuously captures transdermal measurements after a session is started in the iOS prototype app. The period between samples, in seconds, can be configured from the app. The number of averaged samples per recorded data point can also be configured. The iOS application is configured to poll recorded data from the BACtrack Skyn device every 30 seconds in demo mode.

The rechargeable Lithium Polymer (LiPo) battery life is affected by the sample rate. As the sample period decreases, the battery life decreases proportionally. Battery life is also affected by the frequency of BLE communication and the amount of data that is transferred. A greater frequency and duration of BLE communication will proportionally decrease battery life. Demo mode is designed to streamline data collection; these interactions are *not* configured to optimize battery life.

A ***factory production*** operating mode will feature significant power optimizations. Proximity sensing and temperature readings will be used to determine whether a BACtrack Skyn device is on the wrist of a user. When the device is not being worn, it will enter a low power sleep mode where it will check every 20-30 minutes to determine whether a user has attached the device to a wrist. The device will also feature an algorithm to automatically increase sample rate when a drinking event is detected, and decrease sample rate when a user is at 0.00% BAC. This will allow the Skyn to provide better resolution when it matters, while simultaneously extending battery life. These settings are adjustable by the user and/or a monitoring party.

The prototype device hardware will benefit from significant power optimizations. The existing prototype hardware features a switching buck-boost power supply with a "power-save mode" which skips pulses to conserve power. The power supply has a very large quiescent current draw when "power-save mode" is disabled. Power-save mode must be disabled during Bluetooth communication events in order to prevent disruption of communication due to a slow response to transient power supply loads. The current prototypes activate power-save mode while the device remains in sleep mode—that is, while samples are not being recorded. Efforts are underway to optimize power-save mode to be active at all times between Bluetooth communication events. The efficiency of the power supply at low load in power-save mode ranges from 70~90%, whereas the efficiency at low load with power-save mode disabled ranges from 0~10%. <u>Optimizing a power-save mode algorithm will increase battery life in the existing prototypes by a multiple of approximately 7x.</u>

Careful and thorough calculations have been made to calculate battery life, taking every component and operating mode in the BACtrack Skyn device into consideration. These calculations include sample rate, battery and power supply inefficiencies, leakage current, power consumption of all individual components and circuits, hardware states, and the time spent performing all system tasks. The outcome of the extensive calculations can be seen in Exhibit A.

Market Potential

There is an enormous potential market for a wearable transdermal alcohol sensor with smartphone connectivity. Wrist-based health tracking products like Fitbit, Jawbone, and Apple Watch have created excitement, broad awareness, and a large retail sales market for wearables – now a multibillion dollar market.

On the clinical side, one of the significant barriers for current clinical research and expanding into new markets has been the relatively high cost of a transdermal device ($1000+) due to the devices being customized for the law enforcement market. A number of clinical researchers studying important behavioral and physiological mechanisms associated with alcohol use do not have the funding to support the high cost of the current transdermal alcohol detection devices, and have to rely on less accurate methods, such as self-report. **With the potential low cost (~$99) of BACtrack Skyn, transdermal alcohol sensing would be accessible to more researchers and larger studies thereby improving clinical knowledge of alcoholism and the impacts of alcohol consumption on overall health.**

Because we have designed the product with comfort, size, and aesthetics in mind, we expect significant "voluntary-use" demand. These groups could include:

-Early gadget adopters
-Anyone curious about their alcohol level
-People who want to make sure they stay below the legal driving limit

There likely would also be more serious voluntary-use consumers:

-Families with an alcoholic family member who want to a solution for accountability and/or positive reinforcement.

We would also expect a robust market for "voluntary recovery" patients who are under the care of a treatment provider. These individuals could also wear the device for accountability and/or incentive-based behavioral treatment. The product could also assist the voluntary research study market.

In all of these cases, the user is wearing the device voluntarily. Although there could be unique user tracking in the latter cases to help verify compliance with a medical professional, in no cases is the device "locked" on the subject as in a criminal-justice use case.

There would be enormous benefits in building up an active, voluntary user base. First, aggregated user data could be analyzed and used to improve the transdermal to BAC algorithm. Currently only a very limited number of studies and datasets exist for testing and analyzing transdermal alcohol testing.

Again, BACtrack is uniquely positioned to bring a wearable, continuous-monitoring alcohol sensor to multiple markets. We already sell our handheld alcohol screening devices to alcohol treatment centers, researchers, and other health service providers across the country, and we could immediately offer BACtrack Skyn to these same customers and others. And we have existing relationships with national retailers, including drug retailing chains like Walgreens and Rite Aid, who stock a variety of other diagnostic and drug testing devices.

Finally, there is the potential to integrate BACtrack Skyn directly into other wearable devices or products. A single product could send alcohol data, together with a variety of other biosensor data, to a smartphone for analysis.

Data Security

Bluetooth Security

BACtrack Skyn uses Bluetooth Low Energy (BLE) v4.0 to communicate with mobile devices. The Bluetooth Core Specification provides several features to protect privacy and data integrity. These features include passkey protection for pairing, frequency hopping, 128-bit AES encryption, and AES-CMAC signed data protection.

Bluetooth Low Energy defines three pairing models (Just Works, Passkey Entry, and Out of Band). The Passkey Entry and Out of Band paring methods can be used to protect a BLE device from a Man-in-the-Middle attack. After establishing a connection using one of the pairing models, data exchange is protected by the industry-standard 128-bit AES encryption. A pseudo-random frequency hopping pattern, used over 40 channels in the 2.4GHz unlicensed ISM band with a channel spacing of 2MHz, is agreed upon in advance by the sender and receiver. This frequency hopping is used for data transmission and helps complicated sniffing attacks. BLE also has the capability to sign unencrypted data packets using AES-CMAC. This is useful when the device must have a method to maintain data authentication with an unencrypted communication channel.

Added security enhancements will be made possible when embedded software stack support for BLE v4.2 is released in Q2 2016. In addition to the security protection that is currently implemented, BLE v4.2 will support further privacy protection against identity tracking by frequently changing private addresses of communicating devices. This will prevent some of the most sophisticated methods for correlating BLE communications to specific devices, and therefore specific users, as devices are no longer tied to one address.

Furthermore, the Elliptical Curve Hellman-Diffie (ECHD) algorithm will be introduced to protect the key exchange process during device pairing. This will protect against sniffing BLE communications with sophisticated equipment during the pairing process, which could otherwise allow a security offender to gain access to the encryption keys that will be used to protect subsequent communication.

BACtrack Skyn Device Security

The current Skyn prototype stores user data in memory locally on the device. A production version could delete data from the Skyn immediately after it is transferred to or through a smartphone. If a user loses the device, there is not personally identifying data stored on the Skyn (like name, account, or GPS address) just sensor data results and time.

Smartphone Device Security

The prototype Skyn app stores data on the user's smartphone. A final production device + app might not store data on the smartphone, and instead have all data securely stored on the cloud. (The current BACtrack app for our smartphone breath alcohol testers stores data only in the cloud, not on the smartphone or alcohol test device.) There are satisfactory security safeguards available under both scenarios.

If some or all user data is stored locally on a smartphone: 1) the phone itself can be password protected with a security code or fingerprint; 2) the app can request a password to open; 3) the content can be encrypted on the phone; 4) if lost or stolen, all iOS devices and most Android devices can be remotely wiped of all content. There are many apps that store sensitive user data on a smartphone, and BACtrack would meet or exceed all industry standards for data security.

Cloud Server Security

If data is stored in the cloud with an industry-leading service provider like Amazon Web Services, communication with the server would be done over **encrypted https**, which is the web standard for encrypted communication. It is the same encryption used for banking data transfer and other highly sensitive information.

On the server we would use SELinux, Linux's security module, to provide enhanced security and auditability. We would also have the ability to store the data encrypted on the server.

BACtrack already uses Amazon Web Services and SELinux for our smartphone users' data storage. We would be able to integrate BACtrack Skyn into our existing platform, and make any security improvements, as needed.

BACtrack's current cloud storage system also has secure API data access. API allows one party to securely delegate access to data to another party. OAuth is the security protocol for the API. **Secure API access could, for example, allow hundreds of researchers to security view BACtrack Skyn user data in real time or anytime.** This could dramatically increase the pace of research and treatment. Again, BACtrack already has this API capability live with our other breath alcohol testing products.

Unique User Identification

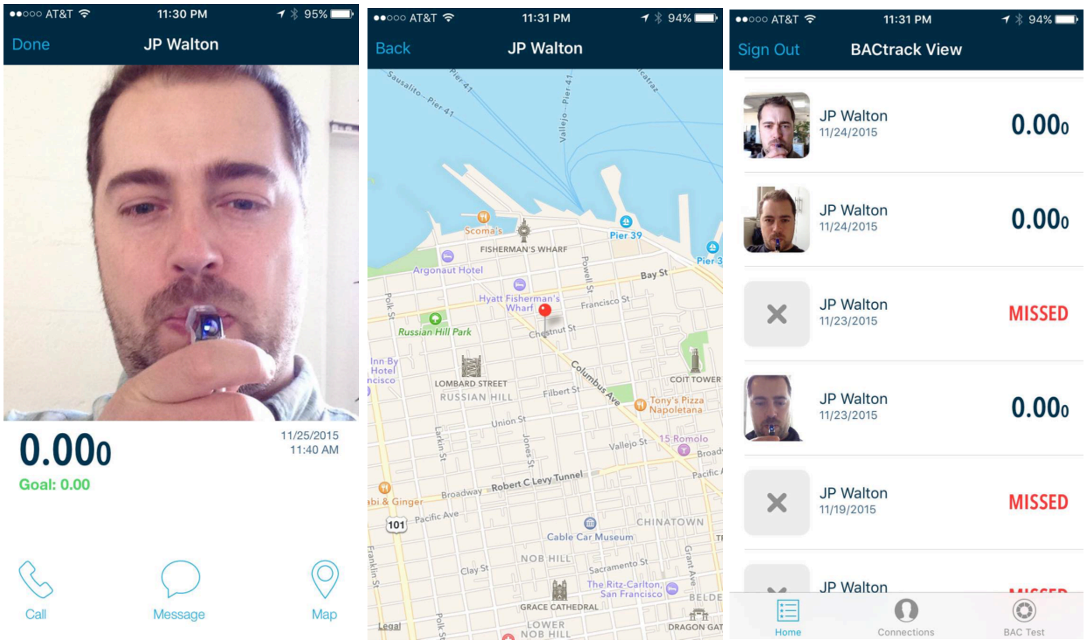
There are a number of ways to confirm the identity of a BACtrack Skyn user.

First, all Bluetooth devices have a unique MAC address. The MAC of a specific Skyn device can be recorded prior to subject use, and it can be matched continuously during testing with the MAC address of the user's smartphone, and verified at the server level. This would confirm that the appropriate Skyn device is being used with the appropriate smart device, either the user's smartphone or perhaps a device supplied by a treatment provider.

Next, if Location Services is enabled on an iOS device for the Skyn app (production version), the exact GPS location of the user can be recorded and saved. So a unique Skyn device ID, unique smartphone ID, and GPS coordinates can together confirm where the device is being used, and sensor data from BACtrack Skyn can confirm whether the device is being used.

If a user tries to have another person wear their Skyn, the intended user's smartphone would need to constantly be in range to transmit results. If Skyn connects to an unapproved or unknown smartphone, this could trigger a User Identification flag.

Finally, BACtrack already has built a Remote Monitoring smartphone system to visually identify users. The system, currently in private Beta testing, allows a Monitor to initiate a Check-in Request from another user. The Monitor initiates a Check-in; the Subject gets a push notification on their phone; the Subject uses the smartphone camera to record a video or photo of themselves blowing into a BACtrack breathalyzer. In the case of BACtrack Skyn, it could be that the video requirement is simply to show the Skyn properly attached to the subject's wrist. This recorded video is then immediately available to the Monitor for viewing and confirmation.



Screenshots from BACtrack's Remote Monitoring app, currently in private Beta testing.

Manufacturing

BACtrack has extensive experience in the manufacturing of breath alcohol test devices. Our experience includes component sourcing, raw material planning, factory design and setup, lead time planning, production runs, quality assurance, and regulatory compliance. Our manufacturing facilities have been audited by our national retail partners including Costco and Best Buy, and are regularly visited and audited by BACtrack.

We possess extensive experience with alcohol simulation equipment, factory calibration, and post-sale recalibration and verification. We perform calibration and/or recalibration in the United States, in Asia, and in a handful of countries throughout the world through trained BACtrack partners.

Our transdermal sensor development partner currently manufactures and sells approximately 10,000 transdermal sensors per year for the criminal justice segment. In order to reduce costs and significantly scale up production capabilities, BACtrack would implement an automated manufacturing process at the sensor level.

BACtrack's specific alcohol tester experience, developed over the last 14 years, makes BACtrack uniquely situated to bring a transdermal alcohol tester to market on a mass scale.

Prototype Test Data

BACtrack has hand-assembled several prototype units for preliminary data collection. The prototypes include 3D printed SLA parts, and electronic circuitry that is not yet optimized for final production. Still, despite the incomplete nature of the prototypes, valuable and very promising data has already been acquired, and the data is being used to create TAC to BAC conversion factors custom to the product.

In the charts below, Raw Alcohol Counts are the raw data points acquired by the Skyn sensor. The BAC data points are self-administered on a fuel cell-based breath alcohol tester, either BACtrack Mobile or a Lifeloc FC10.

We are encouraged by the following observations:

1) BACtrack Skyn has demonstrated the ability to identify alcohol consumption as quickly as 20 minutes after alcohol has been consumed. This could be due to placement on the wrist, the unique capabilities of the sensor, the mechanical design, or other factors. This is faster than many other transdermal studies have reported initial detection.

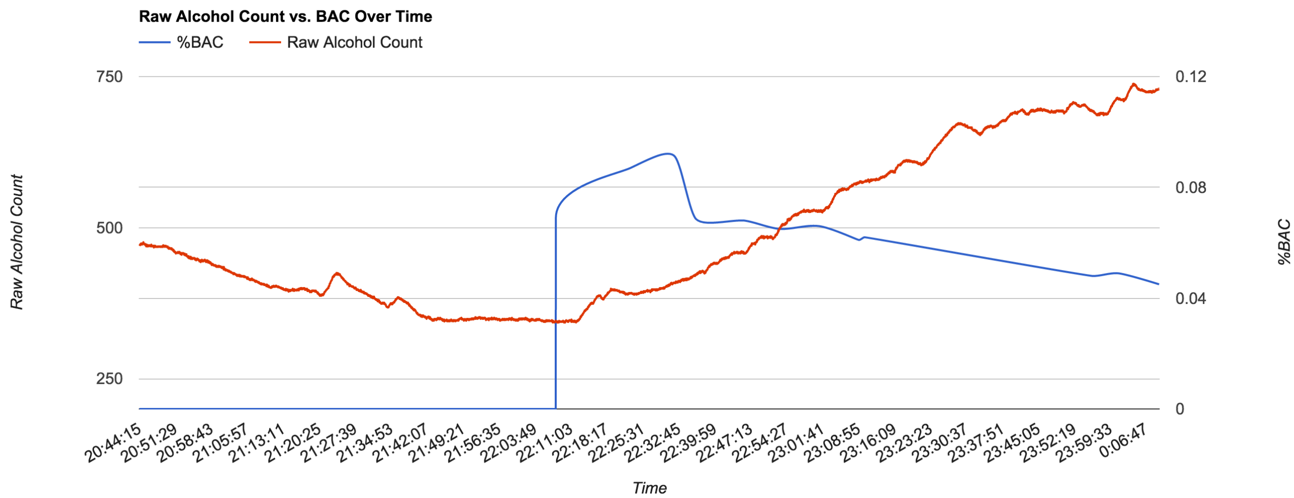
2) Despite testing with hand-assembled SLA prototypes, the overall rise and fall patterns of BACtrack Skyn transdermal alcohol results are in line with previous transdermal studies, confirming the technology.

3) Using our very preliminary calibration conversion factor for the prototype devices of 1105 Raw Alcohol Count = 200 mg/dL, it looks like we can accurately estimate a subject's peak BAC by taking the difference between peak Raw Alcohol Count and baseline Raw Alcohol Count.

4) We are successfully able to sample transdermal alcohol content as frequently as every second. Soon we expect to be able to accurately estimate BAC based on small changes in the curve – for example, determining the speed of alcohol consumption, based on the initial slope of the Raw Alcohol Count curve, and then subsequent small plateaus and slopes.

Chart 1: Subject Consumes Alcohol Rapidly

Raw Alcohol Count vs. BAC Over Time
One Test Subject
November 27-28 2015
BACtrack Skyn Prototype #8
Sensor Sampling Every 2 Seconds



Raw Data and Interactive Chart:
https://docs.google.com/spreadsheets/d/1trXrQ4sW6almc5gdlp6O1DqEdftA7giTyBLtrzNxVGw/edit?usp=sharing

In the above graph, the subject starts drinking 3 shots of 80 proof alcohol rapidly at 21:51 (9:51 PM) and finishes them at 21:52. The subject also starts drinking a beer at 22:01 and finishes the beer at 22:15.

The subject's BAC is 0.00 at 21:50, hits a peak of 0.091 at 22:32, and starts to show regular, continuous reduction of BAC at 22:36, when the BAC moves from 0.069 to 0.061 to 0.048 over an 80 minute period. The final BAC test taken is 0.042 at 00:14 (12:14 AM).

BACtrack Skyn accurately identifies this drinking episode. The Raw Alcohol Count changes from a consistent baseline in the 340's to a rapid jump to 350's, 360's and higher starting at 22:12.

Conversion from Raw Alcohol Count to BAC using subject's actual BAC data

> The peak Raw Alcohol Count is 738, the baseline Raw Alcohol Count established prior to consuming alcohol is 345, and the difference is 393.
>
> The peak BAC is 0.091 and the starting BAC is 0.00.
>
> If we divide the change in BAC by the change in Raw Alcohol Count, we get 0.00023. Multiplying by 100 gives us 0.023 %BAC.
>
> So our ***data-observed conversion factor*** is ***0.023 %BAC = 100 Raw Alcohol Count.***

Estimate of BAC using only Raw Alcohol Count and Manufacturing Calibration Data

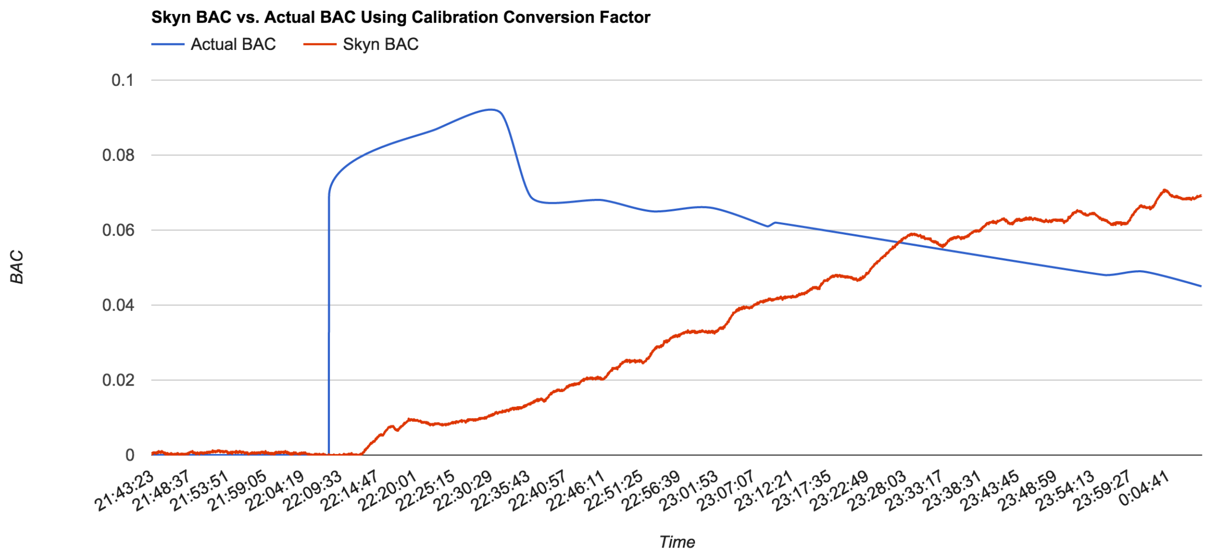
> Shortly after product assembly, we acquire laboratory calibration data for the sensors by placing them just above a specific mg/dL ethanol concentration, simulating skin contact, and recording Raw Alcohol Count.
>
> For Skyn Prototype #8, the ***laboratory-observed conversion factor*** is
>
> ***18 mg/dL = 0.018 %BAC = 100 Raw Alcohol Count***

Given that we were calibrating a first-ever hand-assembled prototype, we are pleased that the laboratory-observed conversion factor is relatively close to the actual data-observed conversion factor. Slight inherent differences in response to the same alcohol concentrations occur with the electrochemical sensing elements; software will correct for this when generating the calibration curve.

Using the laboratory-observed conversion factor, the following chart shows actual BAC vs. Skyn BAC. It does not yet make any adjustments for time lag of transdermal, sensor temperature adjustments, or use any predictive algorithmic adjustments.

Chart 2: Skyn BAC vs. Actual BAC Using Calibration Conversion Factor

Raw Alcohol Count Baseline = 345
Conversion Factor = 0.00018



Raw Data and Interactive Chart:
https://docs.google.com/spreadsheets/d/1HOK-eo8Ynakrj6OS5FKntDSnWvL98mDgLGKHENDC2AQ/edit?usp=sharing

The subject's data collection most likely ends before the Skyn BAC reaches peak value. In previous clinical studies of the electrochemical sensing element used in the Skyn device, the transdermal alcohol signal has been accurate to ~1 standard drink (+/- 20mg/dL) in the range of 0.0 – 0.10% BAC (0 – 100 mg/dL). Future clinical studies will evaluate more personalized calibration schemes, as discussed in **Sensor Background** section.

It is also possible to set the Skyn BAC ***equal to*** the BAC measurement. This is another type of calibration we are considering. A person would take a bolus drink, and the transdermal correlation factor would be tagged to a standard BAC measurement from a breath alcohol tester.

Continuous BAC Estimates in Near Real Time

Our prototype data shows that we can measure transdermal alcohol as soon as 20 minutes after alcohol has been consumed. We may possibly reduce this period even further with improvements to our hardware.

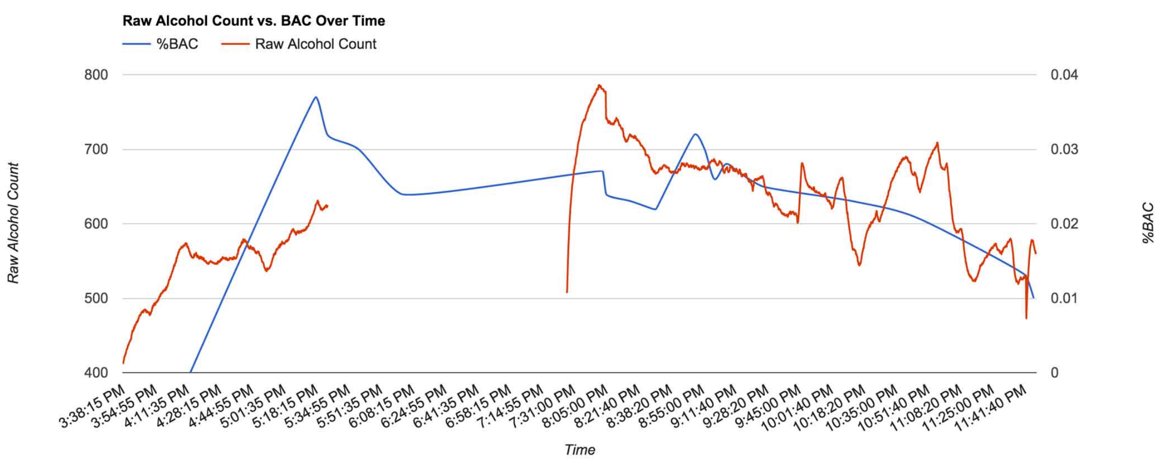
Once transdermal data is acquired, and because Skyn has the capability to take readings as frequently as every second, we will be able to immediately measure the slope of the Skyn BAC curve. We believe that this slope data will be immensely valuable in making near real time predictions of actual BAC.

- The slope of the curve could possibly signal whether the alcohol content of the drink being consumed is high or low.

- The slope may signal the speed of alcohol ingestion by the subject.

Below is additional test data in Chart 3. The prototype device used, #12, was one of the earliest assembled devices, and calibration conversion data was not collected. Still, the results of the Raw Alcohol Count compared to BAC follow expectations.

Chart 3: Subject Consumes Alcohol at Normal Pace
Raw Alcohol Count vs. BAC Over Time
One Subject
BACtrack Skyn Prototype 12
November 26, 2015



Raw Data and Interactive Chart:
https://docs.google.com/spreadsheets/d/1tNlrKGYAgmr3_2jV3gkXDzntuhbdztgHlDgJUcUUCUo/edit?usp=sharing

In Chart 3, the subject starts drinking wine at 4:13 PM. The wine is consumed at a leisurely rate with food for several hours. At 8:36 PM, ¾ of a glass of wine is consumed quickly and is finished at 8:39 PM.

The subject removes Skyn at 5:24 PM and puts it back on at 7:27 PM. The lower initial Raw Alcohol Count and skin temperature data reflects this at 7:27. Then, once the device is back on, the Raw Alcohol Count rises to a peak of 786 at 7:44 PM.

The subject's BAC hits a peak of 0.037 at 5:18 PM, drops to 0.022 by 8:31, rises to 0.032 at 8:51 PM, and then shows a regular, continuous reduction down to 0.010 at 11:59 PM.

This data collection period is a less controlled study as compared to the Chart 1 data. Still, even with a non-production prototype, and not having corrective features in the algorithm yet, the Raw Alcohol Data roughly reflects the rise and fall of the subject's BAC. We are encouraged by all of our preliminary test data.

Video Demonstration

A demonstration of BACtrack Skyn can be viewed at this unlisted YouTube link:

https://www.youtube.com/watch?v=SRZifNHD18k

Exhibit A – Battery Life Calculations

Inputs / Assumptions	Value	Units	Notes
Sample Intervals			
Device on, user not wearing.	1200	Seconds	
Device on, user wearing, no drinking detected.	30	Seconds	
Device on, user wearing, drinking detected.	10	Seconds	
Bytes written to memory per minute	14	bytes/minute	
Bytes read from memory per day	10000	bytes/day	
Proximity and Ambient Light Sensor			
LED current setting	50	mA	
Duty Cycle	0.003125	ratio	
BLE Activity			
Time spent transmitting per day	4	seconds	2.5kB /second transfer rate

Battery	Value	Units	Notes
Battery Capacity	60	mAh	
Battery Voltage	3.7	Volts	
Battery efficiency	80%	Percent	

Constants	Value	Units	Notes
LED Current	5	mA	Assumes 5mA per channel with only a single color displayed at any given time
TPS63030 Voltage	3.3	V	Regulated voltage from the TPS63030 buck-boost converter
TPS63030 Efficiency	80.00%	Percent	Including inductor selection
Seconds in a day	86400	seconds	This is a frequently used constant in the spreadsheet

Time to perform tasks	Value	Units	Notes
Flash byte program time	0.000007	Seconds	
Flash block erase time			We are using a circular buffer and will hardly ever erase
Flash read rate	4000000	Bytes/Second	
Take a proximity reading	0.16	Seconds	Depends on the integration time
Take a BAC reading	0.002	Seconds	Conversion time for the CC2541's ADC in 12-bit mode is 132 uS
Take a temperature reading	0.002	Seconds	Conversion time for the CC2541's ADC in 12-bit mode is 132 uS

Calculated Values	Value	Units	Notes
Samples taken per day	8640	Samples	Currently set at taking a sample every 10 seconds, with device on, user wearing, drinking detected

Hardware State	Average Current (mA)	Average Voltage (V)	Average Power (mW)	Time spent in state (Sec per Day)	Average Power (mW per Sec in day)
Full sleep mode	0.21624	3.3	0.713592	84978.89638	60640.26063
CC2541 Active + BLE Active	10.23264	3.3	33.767712	4	135.070848
CC2541 Active + writing flash	45.04464	3.3	148.647312	0.14112	20.97710867
CC2541 Active + reading flash	21.04464	3.3	69.447312	0.0025	0.17361828
CC2541 Active + taking proximity reading	9.2559	3.3	30.54447	1382.4	42224.67533
CC2541 Active + taking BAC reading	10.55064	3.3	34.817112	17.28	601.6396954
CC2541 Active + taking temperature reading	10.50864	3.3	34.678512	17.28	599.2446874
LED On	5	3.3	16.5	120	1980

Power of individual parts	Average Current (mA)	Average Voltage (V)	Average Power (mW)
BLE Soc			
CC2541 Active	7.4	3.3	24.42
CC2541 BLE Advertising	0.023	3.3	0.0759
CC2541 Sleep	0.001	3.3	0.0033
CC2541 Transmit	8.37	3.3	27.621
CC2541 ADC Power Consumption	1.2	3.3	3.96
BAC Transdermal Sensor			
Sensor On	0.07	3.3	0.231
Sensor Off	0.035	3.3	0.1155
Optical Sensor			
VCNL4040 Standby	0.0002	3.3	0.00066
VCNL4040 Proximity Mode	0.15625	3.3	0.515625
Temperature Sensor			
MF52A1104H4150 current at 25°C.	0.017	3.3	0.0561
Memory			
SST25VF040B Standby	0.02	3.3	0.066
SST25VF040B Read	10	3.3	33
SST25VF040B Write	30	3.3	99
SST25VF040B Erase	30	3.3	99
Operational Amplifiers			
OP481 Supply Current/Amplifier	0.004	3.3	0.0132
LiPo Charger			
ISL9301IRZ Supply Current, VBAT	0.01	3.7	0.037
ISL9301IRZ Supply Current, VIN	1	5	5
ISL9301IRZ Standby Current, VBAT	0.001	3.7	0.0037
3.3V Buck-Boost Conveter			
TPS63030 Quiescent Current, VOUT	0.004	3.3	0.0132
TPS63030 Quiescent Current, VIN and VINA	0.025	3.7	0.0925
TPS63030 Shutdown Current	0.0001	3.7	0.00037
-3.3V Linear Regulator			
MAX1044 Supply Current	0.03	3.3	0.099

Calculated Results	Value	Units
Percent awake	1.64%	Percent
Percent Asleep	98.36%	Percent
Max Current	45.04464	mA
Average Power	1.2291903	mW
Battery Life	144.4853576	Hours
	6.020223232	Days

Exhibit B – Bibliography and References Cited

Barnett, NP, J Tidey, JG Murphy, R Swift, SM Colby, "Contingency management for alcohol use reduction: A pilot study using a transdermal alcohol sensor," *Drug and Alcohol Dependence*, **118**, 391– 399 (2011); doi:10.1016/j.drugalcdep.2011.04.023.

Bouchery, EE, MS Henrick, J Harwood, JJ Sacks, CJ Simon, RD Brewer, "Economic Costs of Excessive Alcohol Consumption in the U.S., 2006," *Am J Prev Med* **41**(5), 516–524 (2011).

Chaurasia, CS, M Müller, ED Bashaw, E Benfeldt, J Bolinder, R Bullock, PM Bungay, ECM DeLange, H Derendorf, WF Elmquist, M Hammarlund-Udenaes, C Joukhadar, DL Kellogg Jr., CE Lunte, CH Nordstrom, H Rollema, RJ Sawchuk, BWY Cheung, VP Shah, L Stahle, U Ungerstedt, DF Welty, H Yeo, "AAPS-FDA Workshop White Paper: Microdialysis Principles, Application and Regulatory Perspectives," *Pharmaceutical Research*, **24**(5), 1014-1025 (2007).

Leffingwell, TR, NJ Cooney, JG Murphy, S Luczak, G Rosen, DM Dougherty, and NP Barnett, "Continuous objective monitoring of alcohol use: Twenty-first century measurement using transdermal sensors," *Alcohol Clin Exp Res*, **37**(1), 16–22 (2013) DOI: 10.1111/j.1530-0277.2012.01869.x.

Mokdad, AH, JS Marks, DF Stroup, JL Gerberding, "Actual causes of death in the United States, 2000," *JAMA,* **291**(10), 1238-1245 (2004).

NCADD (National Council on Alcoholism and Drug Dependence, Inc.), "2.5 million alcohol related deaths worldwide annually," In the News, http://ncadd.org/in-the-news/155-25-million-alcohol-related-deaths-worldwide-annually [Accessed Aug 4, 2014].

Stahl, M, R Bouw , A Jackson, V Pay "Human microdialysis," Current Pharmaceutical Biotechnology, **3**, 165-178 (2002).

Wray, TB, RN, Reed, R Hunsaker, JR Finn, and JS Simons, "How much did you drink on Friday?" Comparisons of three self-report measures of alcohol use with transdermal alcohol assessment, The University of South Dakota, 2012.