# Quantac

Wearable Alcohol Biosensor Platform



NIH Wearable Alcohol Biosensor Challenge Submission | May 2017 Catherine Ziac, Lukas Schulte, Ben Lieber, Jack Sattell Quantac | 47 Iroquois St. | No. 1 | Boston, MA 02120



### Overview

Quantac provides an easy, automatic, and accessible method of continuous alcohol tracking. The Company's first wearable product, the Tally is currently available for research use and devices are being deployed in research studies beginning May 2017.

# Solution

Quantac is answering the need for a tool that gives accurate data about a person's drinking in a user-friendly and continuous way. Quantac recognizes the limitations to using current alcohol detection technologies, which are generally not user-friendly, sometimes require manual user input, frequently bulky, and often stigmatized.

The Quantac Tally is a standalone wearable alcohol biosensor platform that uses miniaturized, unobtrusive, patent-pending hardware paired with proprietary software to easily and automatically track alcohol consumption for a user.

Quantac hopes to make gathering data about alcohol consumption reliable and simple. Beyond providing innovative solutions in the research space, Quantac's mission is to empower intelligent drinking for everyone. This has informed the Company's decision to invest in developing a fuel cell-based technology that is low power, low cost, and has the potential to be commercialized quickly. Fuel cells, even with their drawbacks, are the most viable solution for a mass-market wearable alcohol product because of their prevalence in existing breathalyzer and gas-sensing technologies.

The Quantac team acknowledges this Challenge's focus on non-gaseous alcohol sensing technologies. The team believes that Quantac's market readiness, unique multi-sensor approach, heavy focus on research collaborations, and fast commercialization timeframe make the Company well positioned to address the needs of this Challenge, alcohol researchers, and the alcohol monitoring space at large.



# **Approach**

Quantac owns every layer of its wearable technology stack, including the hardware, sensor, electronics, software, firmware, mobile application, backend, cloud infrastructure, and data analytics. Quantac's agility in the alcohol monitoring space owes to this approach; by designing the full stack, the Company has deep control over the user experience, analytics, and technological direction. This has enabled rapid exploration and iteration using numerous technologies throughout the stack. Several key advancements, including temperature and humidity sensing, as well as the high-performance time-series database began as rapid prototyped concepts. With Quantac's full stack approach these ideas could quickly be incorporated into the hardware and software stacks of current and future designs.

For users, the Tally platform includes the standalone Tally device as well as the accompanying Tally mobile application, which is currently available for iOS with plans to expand to Android this summer.

# Hardware

### Sensor

Quantac's biosensor is a fuel cell-based technology, with a provisional patent on the wearable fuel cell sensor system. The biosensor is a two-lead amperometric cell that sits on a user's wrist and detects transdermal alcohol content (TAC).

The current alcohol sensor dimensions are 3.4mm in height by 7.3mm in width by 7.3mm in length. The sensor consists of two plastic housing pieces that contain the active sensor material and two electrodes for current transmission. The sensing orifice is protected by a selective polyimide membrane that rejects moisture and debris while allowing gaseous ethanol to pass through. The polypropylene housings have been designed to be machinable for low volume manufacturing and injection moldable at higher volumes.

### Wearable Hardware

Currently, all hardware components are contained within a small acrylic puck, which is then inserted into a flexible urethane band. The band is secured on a user's wrist by threading the end of the band with the metal pin through the plastic loop on the other end of the band and inserting the metal pin into the appropriate notch. Please see Figure 1 below for a diagram of this mechanism. A user must remove the puck to charge his or her Tally. The device is splash-proof, but not water-proof.

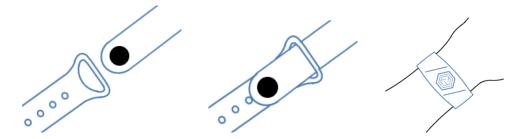


Figure 1: Band wearing guidelines

For an overview of the Quantac Tally specifications, please see <u>Appendix I: Quantac Tally Specs</u>. For an overview of how to use the Quantac Tally, please see <u>Appendix II: Quantac Tally User Guide</u>.

### **Electronics**

The hardware layer also includes sensors for temperature, humidity, and capacitive touch. Quantac has discovered the importance of incorporating measurements of other environmental factors when estimating alcohol consumption. Capacitive touch enables monitoring of when the Tally is being worn and when it is taken off a user's wrist. This feature could be leveraged in applications where an administrator, like a lead researcher on a study, for example, needs to understand whether a specific user is still wearing the Tally or has removed it.

The Tally is charged via micro-USB and battery level can be monitored externally. The Tally has 7day+ battery life while actively collecting data and includes onboard flash storage to allow for multiday offline storage of data for scenarios in which users are not near their paired mobile devices.

### Software

Quantac's software design is highly modular; the focus is to do minimal processing on the user's device or smartphone and instead transmit data to the backend for more extensive processing. This enables more granular data capture, easier algorithm updates, and less code duplication between the iOS and future Android applications. Please see Figure 2 below for a diagram of this software architecture.

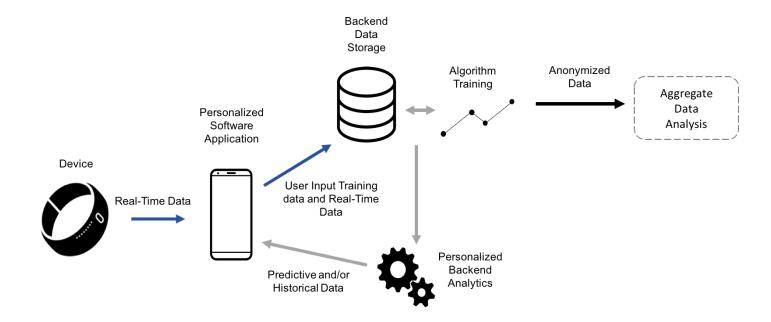


Figure 2: Quantac software architecture

# **Firmware**

The Tally device firmware does minimal data processing. Instead, it acts as a data relay, capturing and communicating with the device's sensors that store that data, and opportunistically transmitting that data to a paired mobile device via Bluetooth Low Energy (BLE). Minimal on-device data processing enables longer device battery life, as high-power consumption components like the processor can be put to sleep for longer periods of time.

The Tally includes capability for over-the-air (OTA) updates, which allows firmware updates to be pushed to any Tally device from a paired smartphone when improvements are available. This allows devices to stay up-to-date even after they have been shipped and are no longer physically accessible to Quantac.

# Mobile Application

The Tally application allows the smartphone to connect to the device, manages user authentication, enables notifications, and transmits device and user data to the backend. The Tally application currently has four pages – "New Drink," "Data," "Sensors," and "Settings." More details on each of these pages are provided in <u>Appendix III: Quantac Tally Application</u>.

The Tally application is currently supported for iOS and development for Android is scheduled for this summer.

# Backend

The Tally application opportunistically uploads sensor data to the cloud, where processing and analysis take place. Quantac stores data and analyses in an open source time-series database hosted on Amazon Web Services (AWS). Once data is processed in the cloud, this information is viewable on an administrator's dashboard and sent back to the iOS device, where users can visualize their alcohol consumption and related statistics.



# Accuracy, reliability, and frequency of blood alcohol levels as validated by NIAAA

# **Detection and Accuracy**

The Tally measures TAC through a user's skin in a non-invasive, continuous, and near real-time manner. Quantac's biosensor sits on a user's wrist and measures the alcohol diffusing through his or her skin. The sensor is completely non-invasive. Technologies which involve light, chemicals, microneedles, or other substances/instruments to aid in real time estimations were dismissed due to unique drawbacks which the team concluded would prevent rapid commercialization. Infrared spectrometry requires relatively high power for wearable applications, sweat stimulation has thus far required topical stimulants, and micro-needles have a high development cost (Jayoung Kim, 2016). Fuel cell detection is essentially continuous, the Quantac Tally providing a one second sampling frequency of alcohol, temperature, and humidity.

As this technology is still under development and requires significant real-world validation, Quantac does not yet make specific claims about the accuracy of its algorithmic drink count, backward looking blood alcohol content (BAC) inferences, or other estimations.

Quantac's first technological milestone is automatic drink count detection. The target sensitivity for this estimation is down to one standard drink consumed over a period of 20 minutes, with an accuracy of ±0.5 standard drinks. To aid in estimation, Quantac collects physiological information (gender, height, weight) and environmental data (temperature, humidity).

The team strongly believes that understanding alcohol consumption in standard drink units is a meaningful metric to consumers and researchers. Standard drink units are often cited in research publications in studies that use self-reporting (Thad R. Leffingwell, 2012). The NIH guidelines provide recommendations for individual maximum alcohol consumption per week in standard drink units (NIH National Institute on Alcohol Abuse and Alcoholism, 2017). For consumers, "one drink" is often easier to understand for the average consumer than given BAC values, except in the context of driving while intoxicated. By developing algorithms to estimate the number of standard drinks consumed, Quantac's aim is to provide technological synergies with the well understood concept of total drink consumption.

The next step will be to use the validated fuel cell and device design and a better understanding of environmental impacts on the technology to develop robust BAC estimates from TAC. This solution will use predictive analytics to project a TAC curve into the future. Quantac continues to invest in developing BAC estimates from TAC.

# Innovation

# Skin temperature and humidity sensing

Temperature and humidity are two factors critical to gaseous alcohol sensor designs, but ones that Quantac competitors have not yet addressed. Humidity affects the fuel cell itself, particularly in environments with extremely high relative humidity. Figure 3 below shows one sensor's baseline response when the user was not drinking, but perspiring for a sensor design which was particularly susceptible to rapid changes in humidity. Notably, the sensor recovers quickly and returns to baseline quickly.

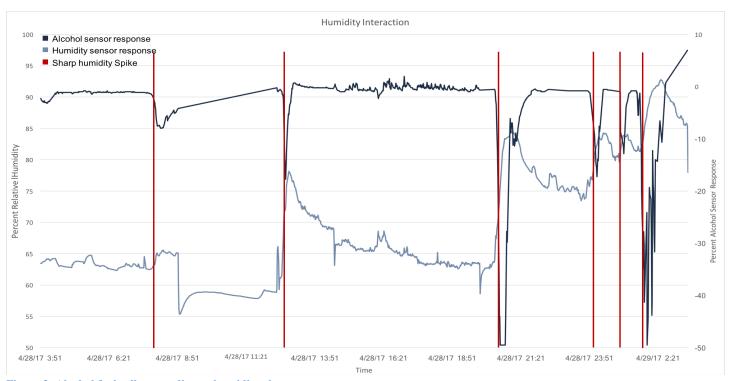


Figure 3: Alcohol fuel cell responding to humidity changes

Increased temperature and humidity is often linked with greater perspiration. Perspiration affects how quickly and how much ethanol is diffused through the skin's surface. The magnitude of the alcohol sensor response depends not just on how much alcohol is consumed, but also how much the user is perspiring. Temperature and humidity sensors monitor these environmental conditions and provide information and tools to compensate for their impact on the alcohol sensor response.

### Research Focus

Before addressing other markets, Quantac is focusing on providing better alcohol sensing tools to researchers. The hope is to work with the research community to vet Quantac's technology while providing them with new tools and capabilities. The team is in ongoing conversations with alcohol researchers across the country including at the University of Florida, Ohio State, the University of Chicago, Brown University, and others.

A common theme in these talks has been a strong interest in ecological momentary assessment (EMA) and intervention-based studies using sensor information as a trigger. Quantac is designing its software platform so that researchers may send push notifications to study subjects based on algorithmic detection of alcohol consumption, geolocation, and other factors.

# Administrator dashboard

All device and user data are uploaded to the cloud backend. This information is then available to individual users, or, in certain settings, research study administrators.

Quantac currently uses an open-source time-series database and visualization tool. This allows instant recall of any data and structured query language (SQL)-like querying. Critically, this means elegant dashboards can be built for any administrator, with access to alcohol sensor values, temperature, humidity, battery life, and capacitive touch for any deployed device under that administrator's jurisdiction. Data can also be easily downloaded in common Comma Separated Values (CSV) and JavaScript Object Notation (JSON) formats.

# Sensor module development for integration

Quantac is sensitive to the limited wrist space of ordinary wearable consumers; a standalone Tally device might have a difficult time competing for wrist space with popular smart watches and fitness wearables on the market. Additionally, alcohol data is more valuable to an average consumer when married with other health and wellness metrics such as heart rate, activity, and sleep.

To the best of the Company's knowledge, Quantac is unique among its direct competitors in it's plan to democratize alcohol sensing technology and make it available to other wearable manufacturers. The long-term goal is to manufacture uniquely identifiable alcohol sensor modules and develop a cloud-based Application Program Interface (API) to allow any wearable or smart device manufacturer to incorporate Quantac technology. To achieve this, Quantac will be working to further shrink the sensor design to target dimensions of approximately 2.0mm in height by 4.0mm in width by 4.0mm in length and to develop a surface-mount printed circuit board (PCB) module that contains a unique sensor ID as well as the necessary amplification components. This work is targeted for the first half of 2018.

### **Obstacles**

Quantac is confident in its choice of sensing technology, but aware of the drawbacks to the solution, including the inherent time delay, potential sensor cross-sensitivity to other materials, and the effects of temperature and humidity on the system. More details on each of these obstacles are provided below.

# Time delay

Non-invasive transdermal alcohol detection methodologies have an associated time-delay due to the amount of time it takes for alcohol to diffuse from the blood stream to the skin's surface, with the stratum corneum of the skin presenting the most significant barrier (Joseph C. Anderson, 2005). Robust data collection and analysis could allow for the development of non-real-time BAC estimates in the short-term and real-time predictive analytics-based estimates in the long-term.

# Sensor cross-sensitivity

Fuel cell-based sensors have cross-sensitivity to other chemicals, especially to those with a hydroxyl functional group (-OH). For example, methanol and formaldehyde have a strong cross-sensitivity to the Quantac sensors. Fortunately, these chemicals are generally not naturally occurring in concentrations similar to those of alcohol occurring on skin when one is drinking. Additionally, it is unlikely that over time exposure to an interfering substance would misinterpreted as that of alcohol diffusing through skin.

# Temperature and humidity

Quantac understands that temperature and humidity have unique effects on both the fuel cell sensor itself as well as the mechanism by which alcohol evaporates off the skin's surface. Increased temperatures and humidity levels affect the internal workings of the sensor, impacting sensor readings. Increased levels also often indicate increased perspiration, which naturally increases the amount of alcohol detected on a user's skin (Joseph C. Anderson, 2005). Quantac tries to adjust for these environmental changes by incorporating temperature and humidity sensors into the Tally device and calibrating its algorithms behind drink detection accordingly.



# Data collection, transmission, and interpretation

# Data Collection, Storage, and Transmission

Please see Quantac's hardware and software section.

# **Data Interpretation**

Quantac's foundational work involved demonstrating the relationship between TAC measurements versus breathalyzer estimated blood alcohol content (BrAC) versus self-reported standard drink consumption. Figure 5 below is from a recorded drinking session while a user consumed three standard drinks, wore a Quantac device, and used a standard breathalyzer at regular intervals. The user's sensor response to TAC is shown in the top plot, followed by the user's BrAC values as measured by a breathalyzer shown in the middle plot, followed by the user's aggregate self-reported alcohol consumption shown in the bottom plot.

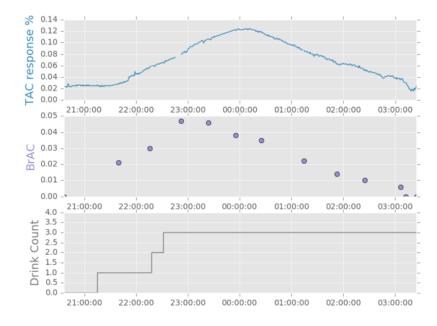


Figure 4: TAC vs. BrAC vs. self-reported drinks

The sensor response is correlated with both the user's BrAC levels and self-reported alcohol consumption. However, there is a ~20 minute time delay between when a user first drinks and BrAC is first detectable and there is a ~45 minute time delay between when a user first drinks and TAC is

first detectable (Joseph C. Anderson, 2005). Both time delays are comparable to values reported in literature.

# Estimating standard drink consumption from signal peak, duration, and area under the curve

While the results of this basic foundational work are promising, it is much more challenging to develop robust models to account for the variability observed across drinking sessions. Existing literature explains that peak BrAC or BAC and the TAC response are not linearly correlated. Additionally, the area under the curve (AUC) of the TAC response can be used to estimate total drink consumption. This estimate can be further improved by accounting for physiological effects such as gender (Nathalie Hill-Kapturczak S. L., 2014), (Donald M. Dougherty, 2014), (Webster, 2008).

However, this literature examines drinking in highly controlled laboratory settings (Donald M. Dougherty, 2014), (Nathalie Hill-Kapturczak J. D., 2015). Beyond the physiological differences of users and the sensor-to-sensor manufacturing variations between devices, real-life situations show further variability in TAC response due to many additional factors. Quantac has discovered additional factors which affect sensor response such as differences in how the band is worn and consequentially how the sensor makes contact with the skin, the activity and perspiration of the user, and environmental factors like temperature and humidity. These have not been studied extensively in existing literature due to a lack of existing environmental monitoring tools.

Given these challenges, the intermediate steps on which Quantac is actively focused are to develop models to correlate alcohol consumption to standard drink units using historical data and to be able to predict when the user is actively drinking versus when he or she is sober.

Quantac correlated AUC to consumed standard drink units using some of its own data, shown below in Figure 6. These drinking sessions were recorded in real-life environments as opposed to controlled laboratory settings. AUC was calculated by manually cropping the raw sensor response graph of each drinking session and setting a static baseline at a predetermined threshold value. The number of standard drinks consumed was determined using self-reporting through a Quantac mobile application. Despite the real-life setting and a more informal process overall, the analysis yielded an R-squared value of 0.75, similar to those values reported in the literature in models that do not account for physiology (Donald M. Dougherty, 2014).

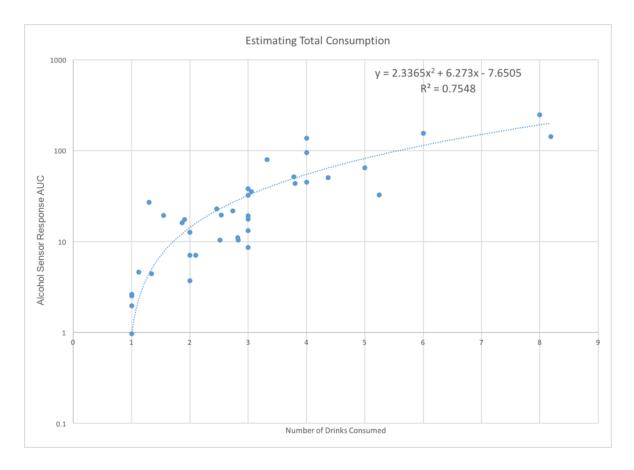


Figure 5: Number of Drinks Consumed vs. AUC

Since this initial AUC graph was produced, Quantac has refined its backend and analytics pipeline and tools to drive improved, automatic data analytics. The results shown below in Figure 6 show a strong linear correlation between standard drinks consumed from 41 drink sessions and the time duration of the Quantac sensor response. Results are all from the same user, but different devices and again in uncontrolled, real-life scenarios.

Critically, these drinking sessions were automatically detected over a 90 day period with Quantac's algorithms and subsequently verified using self reported data provided by the user through the Tally mobile application. Standard drink units consumed in each session were approximated using the same self-reported data.

Each drink session and its duration was detected automatically by filtering the signal, correcting against baseline drift, and then applying a moving average against a predetermined threshold. Detected sessions were compared against the time window where drinks were self-reported. Excluded from this plot are:

- False positive detected sessions when a drink session was detected that was not reported
- False negative detected sessions when a drink session that was reported was not detected

"Near misses" – when a drink session was detected within a reported window, but clearly outside the expected bounds of the duration of the response (<0.75 hours per standard drink unit or >3.0 hours per standard drink unit), likely due to a degenerate sensor or an incomplete or corrupted signal

# Drink Session Duration in Hours by Std. Drinks Consumed

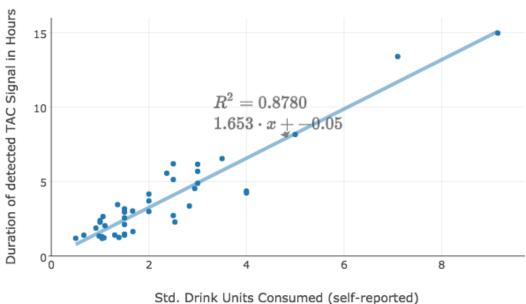


Figure 6: Number of Drinks Consumed vs. Signal Time Duration

This is an incredible result given the real-life setting and informal procedure and demonstrates that a clear correlation can be obtained even with all real-life variation. It also crudely estimates that every 100 minutes of positive sensor signal response corresponds to one standard drink unit consumed for this user.

Sensor signal duration varies by number of standard drinks consumed. Figure 7 below shows the comparative Quantac sensor response to TAC for various amounts of alcohol consumed, including one standard drink-, three standard drink-, and seven standard drink-sessions. The peak magnitude and total time duration of the Quantac sensor response increases as more alcohol is consumed. although "the congruence between peak TAC and BrAC increas[es] as a function of the beers consumed" (Tara E. Karns-Wright, 2017).

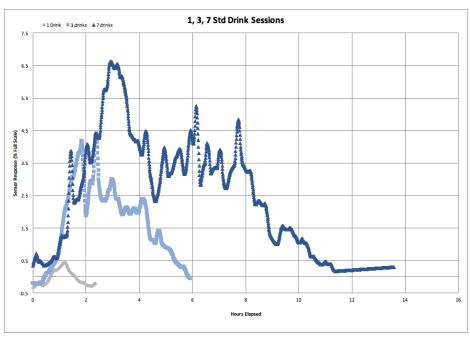


Figure 7: Varying Drinks Consumed

An example of raw TAC sensor signal response smoothing is shown in Figure 8. The blue trace indicates the raw sensor response, while the red trace indicates the filtered response.

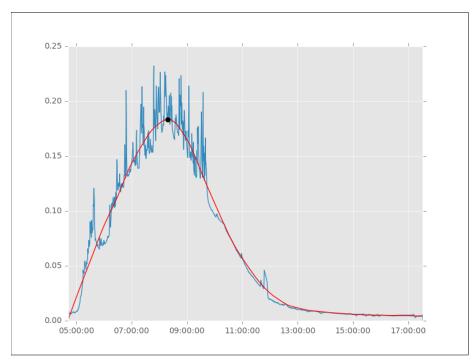


Figure 8: Signal Smoothing

Quantac is actively working on improving its analytical techniques, data collection, and automation to better estimate standard drinks consumed using the TAC sensor response. Prototypes for automating real-time detection of user drinking are in development.



# Safeguards for data integrity and privacy protection for the user

# **Data Security**

The Tally is considered a low-risk general wellness product and therefore does not require Federal approval. For more information, please see the U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health's *General Wellness: Policy for Low Risk Devices* here.

Quantac collects users' names, email addresses, heights, weights, and genders. None of this information is shared with people outside of qualified Quantac employees or the user, except in the case of research study applications. Quantac does not collect any personally identifying numbers, credit card information, addresses, or other personal health information.

In pilot research study applications Personally Identifiable Information (PII), including users' names and email addresses is not shared with Quantac, but instead shared with the research study administrator. Quantac collects only de-identified data, including heights, weights, and genders, which are necessary for sensor response understanding and the basic functionality of the Tally platform. The burden of PII safeguarding in these cases falls on the research study administrators.

# **Privacy Policy**

When a user creates a Quantac account, he or she agrees to the Quantac Privacy Policy. The most current version of the Quantac Privacy Policy can be found on the Quantac website <a href="https://example.com/here/">here</a>.

### Terms of Use

When a user creates a Quantac account, he or she agrees to the Quantac Terms of Use. The most current version the Quantac Terms of Use can be found on the Quantac website <a href="here">here</a>.



# Plans for process of manufacture

# Sensor Module

The Quantac alcohol sensing module was designed with scaled manufacturing in mind. It consists of two off-the-shelf components, two lengths of wire, two custom molded housing halves, and one diecut membrane. The custom components can be manufactured with traditional injection molding methods. The lengths of wire and die-cut membrane are easily sourced from a number of vendors. The off-the-shelf components are currently sourced from a single supplier, who has capabilities to produce 10,000 units per week. Quantac is pursuing additional sources, with the goal of obtaining two backup sources by the start of 2018.

The assembly of components into the module takes approximately two minutes with no automation. The housing halves are then glued together and the sensor must cure for 15 minutes at room temperature.

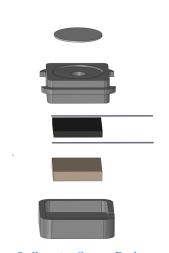


Figure 9: Quantac Sensor Design

While this process is acceptable for prototype assembly, there are several simple opportunities to increase the speed of production. With minor modifications to the injection molded housings, the housing halves can be connected with thermal bonding, eliminating the need for the 15 minute cure time. Additionally, locating features and robust physical properties of the components will allow for easy automation.

Quantac is currently discussing manufacturing plans with several contract manufacturers with intentions of beginning manufacturing by Q1 2018. All contract manufacturers being explored have the capability of assembling components in an International Standards Organization (ISO) class 8 or higher clean environment. The sensors will initially be manufactured by hand in batches of 20 that will require less than 30 seconds per sensor. The first 100 sensors produced will be extensively tested to ensure that they meet quality requirements of dimension,

sensitivity, accuracy and precision, and appearance. They will then be subjected to a series of accelerated aging studies to ensure performance over time. The following 1000 units will undergo 100% testing to ensure quality of the assembly process. Subsequent batches will have 10% of units tested to ensure continued quality. As volumes increase above 10,000 per week, all processes will be automated and performed in sequence, requiring little to no human interaction.

# Tally Standalone Device

The Tally standalone device is a combination of custom and off-the-shelf components. The majority of the components and sensors are off-the-shelf and contained on one circuit board per device. Additional components include a lithium polymer battery, two injection molded housing halves, one injection molded elastomeric band, a custom metal clasp, and two off-the-shelf metal pins. Quantac devices are currently generation 3, with generation 4 slated to begin design in late Q2 2017.

The clasp pin is a radially symmetric part that is lathed from stainless steel rod stock and tumbled to achieve the desired surface finish.

The two housing halves are easily produced using traditional injection molding. One of the housing halves will be overmolded with two metal pins used to determine whether the device is touching skin.

Production costs are kept down by incorporating all internal electronics on one circuit board. This component has a custom shape and size, but other than the Quantac sensor module described above, all electrical components are standard. First, the circuit board must be programmed with the device firmware. Then the battery and the Quantac sensor module are soldered to the circuit board. This is a standard procedure that takes seconds.

The assembly of circuit board and housing must be done by hand, but because there are only three components, the assembly can be done in less than one minute. The circuit board is placed in one of the housing halves, a silicon adhesive is applied to the other housing half, and the two halves are pressed together, holding the circuit board in place.

Assembling the band only requires inserting the metal clasp into a hole of the band.

The testing schedule of assembled Tally devices will be similar to that of the sensors themselves. The first 100 devices will be thoroughly tested for physical defects and electrical abnormalities. They will then be tested in accelerated aging studies to determine effects of temperature, humidity, light, water, and pressure. The next 1,000 units will be examined for physical and electrical defects before they are shipped. After that, 10% of devices produced will undergo inspection.

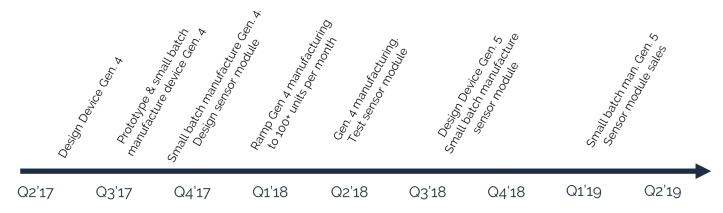


Figure 10: Manufacturing timeline for device and sensor module

# Accessories, Packaging, and Shipping

The Tally puck will be contained within a moisture and static-proof bag for shipping and storage. The Tally charges with a standard micro-USB cable and charger which is included with every Tally sold. Additionally, a small instruction card will be included that describes how to charge and set up the device and download the Tally application. Prototype packaging has been produced, but will continue to be refined. Because Quantac intends to sell exclusively to institutions and not individuals, shipping will be done in bulk. The one exception is replacing an individual's damaged Tally device, in which case we will ship directly to that person.



# Marketability and likelihood of bringing the product to market

# Research deployment

Tally devices are being deployed in external research studies beginning this month. While Quantac does not yet consider the Tally to be "consumer ready," successful completion of these initial research pilots will help to validate the technology and bring the product to the broader market.

Quantac's first pilot includes the University of Florida Southern HIV and Alcohol Research Consortium (SHARC). Quantac is also in discussions with Dr. John Clapp of Ohio State University, Dr. Andrea King and Dr. Daniel Friedberg of the University of Chicago, Dr. Nancy Barnett of Brown University, and others to gather requirements and feedback about the technological capabilities researchers would need before integrating these types of wearables in their studies.

# Go-to-market strategy

Quantac's go-to-market strategy is clear: begin with device sales to research, then to enterprises, gauge consumer interest through preliminary consumer sales, then finally module sales to other wearable manufacturers.

Research is a natural and strategic market to address first as researchers are tolerant of using devices still in development, have unique needs in the alcohol monitoring space that are unable to be met by current devices on the market, and can vet Quantac's technology in a strict research setting. Deploying Tally devices in a these setting also helps Quantac expand its user testing to a more diverse demographic set. This is crucial as it allows Quantac to better personalize its algorithms based on a user's unique physiology.

Once more extensive user testing through research partnerships is complete, Quantac will expand to enterprise sales. Enterprise sales are comprised of multiple segments, including, but not limited to colleges, corporate social responsibility (CSR), corporate wellness, resorts, taxi/delivery drivers, machine operators, medical patients, and driving under the influence (DUI) offenders. Additional enterprise segments include commercial truck drivers, pilots, captain, pipeline operators, railroad workers, military, bus drivers, and hospital employees. These later segments would likely require the Tally to be approved by the Food and Drug Administration (FDA) and are thus further out in terms of addressability.

Finally, Quantac is planning on development for module sales to other wearable manufacturers. Quantac is in early conversations with smart clothing manufacturers and large smartphone and wearable device manufacturers about potentially incorporating Quantac technology into existing wearable devices.

# Marketability

The Tally platform provides multiple benefits to each of the aforementioned addressable markets.

### Research

The Tally platform allows researchers to explore current alcohol-related research questions in a more robust way and address new research questions that were previously unanswerable due to technological limitations.

For example, researchers have discussed with Quantac leveraging the BLE functionality of the Tally to explore research questions related to group drinking behavior. BLE enabled devices can "communicate" with one another and can detect the relative proximities of devices and therefore drinkers. Does group drinking behavior exhibit a "pack" mentality? Is there always a drinking "leader" in any group of drinkers? Does someone always assume the role of "responsible caretaker" in a group drinking setting? These are the types of questions that alcohol researchers can investigate in more detail using the Tally platform.

# Enterprises and safety-sensitive employees

Many industries employ "safety-sensitive" employees, who are federally mandated to be subject to regular alcohol and drug testing. Companies in these industries have a real interest in being able to monitor their employees in these safety-sensitive job functions. Should Quantac seek federal approval for its technology, its devices could be used in these mandated tests.

However, even if Quantac does not seek federal approval for its technology, devices are of interest to enterprises. Owners and operators want to make sure their employees and equipment are safe.

### Consumers

Individuals receive personalized and actionable feedback on their drinking patterns from the Quantac platform. When the Quantac sensor is integrated into a multi-function wearable, individuals receive even more insights, helping them lead healthier and safer lives.

### Wearable manufacturers

Wearable companies are able to incorporate a unique sensor into their devices, helping them to differentiate their products in an increasingly competitive market. Wearable incorporation allows for greater consumer adoption of this drink tracking technology.

Quantac has focused on developing a sensor design with the features necessary to be integrated into wearable devices: small size, low cost, and low power consumption.



# Appeal and acceptability to users

# Acceptability

Quantac's Tally design is sleek and unobtrusive, with a design similar to that of popular wearables in the health and wellness space. A small plastic puck containing the sensor array fits inside of a flexible wristband with a simple clasp that can easily be put on by a single individual.

The acceptability of this design has already been vetted and validated by the largest wearable companies in the market, proving appealing to both mass consumers as well as user in enterprise or corporate settings.

# **Appeal**

Tally allows users to better understand alcohol consumption as it relates to other health and productivity metrics. Because Tally collects data continuously, users can see how many standard drinks they have consumed, for how long they have been drinking, and estimates of when they will reach sobriety.

Tally is vastly more appealing than current solutions available in the research space. Most subjects who have participated in alcohol research studies are familiar with using ankle monitors for testing. Ankle monitors are bulky, uncomfortable, and socially stigmatized. Tally is small, sleek, discreet, and very comfortable to wear. Ankle monitors require power-intensive pumps to blow air across a user's skin and often use a dial-up modem to relay data. Tally technology does not require any pumps and uses Bluetooth to upload data.

The acceptability of the Tally design makes the platform appealing to enterprises and corporates, as employees are more likely to wear the device.

The Tally platform is appealing to other wearable manufacturers, as the technology can be integrated into a variety of existing third-party wearables, including bands, smart watches, patches, and smart clothing. Quantac is the only known alcohol sensor company developing a platform specifically for integration.

# Appendix I: Quantac Tally Specs



# Sensors

- Transdermal Alcohol (TAC)
- On-Skin Temperature
- On-Skin Humidity
- Capacitive Touch

# **Battery**

- Rechargeable Lithium-Ion
- 7 day battery life
- 90 minutes charge time
- Micro-USB charging

# Connectivity

- Bluetooth low energy (BLE)
- Automatic app-pairing

# In the Box

- Tally puck & band
- Micro-USB Cable
- USB Power Adapter

# **Materials**

- Acrylic housing
- Urethane Band

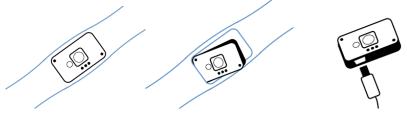


# Appendix II: Quantac Tally User Guide

# **Battery & Charging**

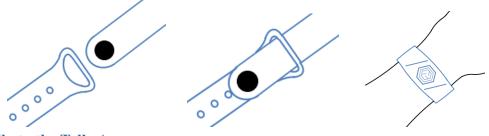
• The battery icon on the home screen of your Tally app tells you the current battery remaining of your Tally.

- Your Tally battery should last about 7 days.
- In order to recharge your Tally, remove the puck from the band, connect to the micro-USB charger, and plug into a standard outlet. Charging should take about 1 hour.



# **Wearing your Tally**

- Your Tally should be worn snugly against your wrist, with the sensor side of the puck touching the top side of your wrist.
- In order to secure your Tally on your wrist, thread the side of the band with the metal pin through the loop on the other side from bottom to top, then insert the metal pin downwards into a hole so the band fits comfortably, but snugly against your wrist.



# **Connecting your Tally to the Tally App**

• Your Tally connects to your iOS device through Bluetooth. Make sure Bluetooth is enabled on your iOS device, secure your Tally on your wrist, and hold it close to your iOS device until you see the word "Connected" appear on the home screen of your Tally app.

# **Updating your Tally App**

- Your Tally app updates through the TestFlight app on your iOS device.
- In order to update your Tally app to the latest version, open TestFlight, click "Update" in blue next to the Tally listing, and reopen your Tally app.

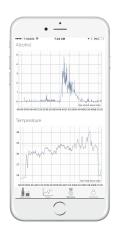
# **Best Practices**

• You should check periodically that your Tally is charged and that your Tally is connected to your Tally app. At least once a day, open your Tally app to check the remaining battery on your Tally and to check that your Tally is still listed as "Connected." Follow the "Battery & Charging" or "Connecting your Tally to the Tally App" steps above if necessary.

# Appendix III: Quantac Tally Application









### **New Drink**

The "New Drink" page prompts users to manually input their drinks as Quantac continues to use this data to train the proprietary algorithms on the backend. Preset drink types (mixed drink, liquor, wine, beer) and amounts (single, double, half glass, glass, large glass, 12oz, 16oz, 22oz) appear after a user hits the "Add Drink" button to easily enter information, or the user can choose "Manual Input" to enter the specific alcohol percentage, ounces, and description of his or her drink.

Manual input in no way affects the raw sensor readings that are displayed to users and this manual input page will eventually fall away as Quantac's proprietary algorithms are sufficiently trained. However, this technology around feedback collection will be leveraged in the future to perform other types of studies and utilize user interaction. Future feedback collection could include breathalyzer readings or EMA features.

# Data

The "Data" page displays a bar graph of a user's standard drink consumption over the past month or week. The page also shares an approximation of a user's average daily calories, average daily drinks, and total drinks for the selected time frame. Calorie consumption estimates are the first steps towards incorporating alcohol data into a user's larger health and wellness picture. Future information could include the effects of alcohol consumption on a user's sleeping patterns, mile times, exercising habits, and more.

### Sensors

The "Sensors" page includes graphs of the raw alcohol sensor readings over time, as well as temperature and humidity readings. These graphs are dynamic, meaning users can zoom in and out and scroll through the graphs using standard pinching and swiping motions with their fingers.

# Settings

Finally, the "Settings" page is where the device information (remaining battery, connection status, name, firmware version) and user account information (email, first name, last name, gender, height, weight) is displayed. Users can also submit feedback to the Quantac team using the "Feedback" button at the top of this page.

Because Quantac has complete ownership over the Tally application, certain aspects of the user interface can be revealed or concealed depending on the application. For instance, in Quantac's first research partnership pilot study (detailed in the "Marketability and likelihood of bringing the product to market" section below), study subjects will not be able to access information in the Tally application beyond the basic device information on battery life and connectivity.

# Appendix IV: Team

The Quantac team has expertise in hardware, software, product development, and finance, with shared experience across enterprise software development, medical device product development, microelectronics prototyping, and market analysis. The team is formerly from Microsoft, Nomura, and medical device product development firm, Sage Product Development, and are passionate about delivering innovative solutions to hard problems. Quantac recently graduated from the *Techstars Connection program in partnership with AB-Inbev*, demonstrating institutional support for this technology.

For more, please see the Quantac website, <u>here</u>.

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