Transdermal Alcohol Monitoring System

TAMS

Index

1. Overview

Drunk driving costs the United States $199 billion a year, and 50 to 75% of convicted drunk drivers continue to drink and drive on a suspended license. Every two minutes a person is injured in a drunk driving crash [1,2]. According to the National Highway Traffic Safety Administration (NHTSA) 32,719 people died in traffic crashes in 2013 in the United States, including an estimated 10,076 people who died in drunk driving crashes, accounting for 31% of all traffic deaths that year [1,3]. Similarly, in 2012 about 29.1 million people admitted to driving under the influence of alcohol [4]. According to the Center for Disease Control an average drunk driver has driven drunk 80 times before first arrest, and the rate of drunk driving is highest among 21 to 25 year olds, which is about 23.4% [5]. The statistics also shows that about one-third of all drivers arrested or convicted of drunk driving are repeated offenders [6]. These adversaries can be significantly avoided by implementing adequate equipment to continuously monitor blood alcohol level (BAC) in driving under the influence (DUI), driving while intoxicated (DWI) offenders and preventing them from driving while intoxicated.

Transdermal alcohol monitoring system (TAMS) aims to provide (i) law enforcement and judiciary agencies the real time BAC data of the DUI offenders, and (ii) an alert system and real time BAC monitor for the user while they indulge themselves in social drinking. Measurements will be taken in the form of electrical signals via a newly developed fuel-cell type alcohol sensor and will subsequently be correlated to Blood Alcohol Concentration (BAC) and displayed to the intended user continuously and in real time via an Android application and an LCD screen. Power consumption is kept to a minimum as to ensure longer lasting service life. TAMS will be appealing in design and worn on the wrist similar to a standard wristwatch. In a law enforcement setting TAMS will incorporate a series of anti-tampering techniques to ensure dependability. TAMS will be available to a wide range of general and law enforcement users. We strongly believe this technology creates a way for safer roads, better health and self-awareness towards intoxication.

The technology behind the existing DUI offender monitoring system includes breathalyzers with spectrophotometers [7,8], and semiconductor sensors [9-12]. These breathalyzers or the sensor in the breathalyzer cannot be implemented as device or a part of the device for continuous transdermal monitoring of BAC, because (i) they were calibrated to measure BAC in breath, (ii) the relationship between BAC, transdermal ethanol diffusion and the sensor response are unknown. Further, the alcohol content in the blood will be excreted in about 8 hours, where the offender can use this time window to get intoxicated and sober before next breath sampling. To prevent this behavior of the offender, wearable alcohol sensors such as SCRAM bracelet and WristTAS were developed with fuel cell technology for continuously monitor alcohol in the offenders sweat. Both these system has limitations due to signal interference by humidity.

Our device has the potential to separate and eliminate the interfering humidity signal from the ethanol signal. This has been achieved by using suitable catalyst and measurement techniques. The research and development of our device revealed that the formal potential of ethanol oxidation is more positive than the interfering humidity signal. Utilizing this phenomenon, the amperometric experiments were forged to reflect only the signal of ethanol and to completely eliminate the humidity signal. Identifying the solutions for the existing problems and designing the sensor alone is not enough, through our goals we (i) constructed highly sensitive ethanol fuel cell, and (ii) implemented and constructed wearable device. The relationship between constructed sensor and the ethanol pharmacokinetics is still under development due to the deviation in ethanol diffusion in various skin type.

In this work, a complete wearable platform has been developed capable of providing a comprehensive low power, high accuracy and easily sustainable electrochemical sensor solution. The ability of the platform to recalibrate based on humidity presence makes it an adaptable, general purpose wearable device. The platform is able to provide real-time statistical analysis of different vapor and liquid footprints, including alcohol and can be calibrated the needs of the user. This low powered platform has long lasting rechargeable battery and has a user interface that gives instant feedback of the data gathered to the individual user. It also contains the ability to connect to external devices, such as mobile devices or computers, for even further in depth analysis of the data gathered. All of these features are placed in a condensed and custom made printed circuit board (PCB) that can be fitted in a wearable device such as a watch for a natural feel to the user.

The wearable sensor platform has been optimized to operate with electrochemical type sensors arranged in a unique and novel manner. There are various aspects that make the platform unique, they include the specific arrangement of pre-existing components from various vendors such as Texas Instruments and Microchip and Sharp that have been optimized to provide a fully software controllable electrochemical type sensor wearable platform. A customized PCB has been designed to accommodate all the components in a condensed fashion making the platform suitable for wearable use. It is fitted in such a way that the core components are tightly interconnected in order to minimize the total volume and is sufficiently small in size to fit on a wearable platform comparable in size to a common wristwatch. The individual components chosen for the platform are miniature in size, provide excellent interfacing capabilities with the electrochemical type sensor, and are arranged in a manner that provides full software control of important parameters to developers. The platform has an auto-calibration feature that will provide the best real-time output to the user. Briefly, our proposed technology composed of a fuel cell type alcohol sensor, and the electronic circuitry with miniaturized potentiostat to support the measurements. The developed fuel cell sensor addresses the existing limitations mentioned above, and its properties enabled continuous monitoring of transdermal ethanol vapor of the wearer by in-vitro method.

The existing SCRAM or WristTAS bracelet cost \$50-\$100 for installation, \$10-\$15 for daily monitoring fee, so the total monthly costs are as high as \$450. The first time DUI offender has possible probation of 6 to 9 months, the second time offenders have up to 5 years, which leads to total of about \$27000. The high monitoring cost in the existing systems are due to the requirement and expense of analysts to interpret the data.

Our technology aims to reduce the cost by an order of magnitude while providing immediate data with alert system to the agencies. The expected cost of the device will be about \$50 to \$100 with installation, and the monitoring fee can be significantly reduced because the data will be better calibrated, intuitive, and more user friendly, thereby minimizing the need for analyst. Further, our system can integrate with the offenders' mobile phone for transmitting encrypted data to the server. The expected server maintenance cost will be less than \$200 per month per user. This technology has the potential to revolutionize the wearable alcohol monitoring market and provide more user friendly support to law enforcement, judiciary agencies and the offenders to show their improvement in their drinking behavior.

2. Proposed Solution

2.1. Method of alcohol detection

2.1.1. Concept and mechanism

In the fuel cell sensor technology, monitoring the potential change in anode with high accuracy is important for constructing a reliable ethanol sensor. In principle, ethanol diffusing from the skin epidermis interacts with the fuel cell sensor anode which is present in the close proximity (embedded in wearable device). The humid ethanol vapor gets oxidized on the anode to form protons with six electrons and carbon dioxide. During this electrochemical reaction the protons are exchanged to cathode through proton exchange membrane (PEM). Simultaneously, the atmospheric oxygen gets reduced to water in presence of protons and four electrons. The reaction schematic and mechanism of the fuel cell type ethanol sensor for continuous monitoring is given in Figure 1 and equations (1 and 2). The anode and cathode in the same figure represents working and counter electrode. As mentioned earlier, contrary to the two electrode system in a traditional fuel cell setup, three electrode setup was developed in this work. The two electrode system also have the same electrochemical reaction mechanism as mentioned above, however the potential measured for two electrode system will be full cell reaction as given in equation (3). The problem in measuring full cell reaction is the interference from the cathode, where the byproduct water and humidity will affect both the current and potential output of the sensor. So to eliminate the signal interference, in this work three electrode system has been adapted. The advantage of the three electrode system is that it helps monitor only the anode (half-cell) reaction as given in equation (1). This can be achieved by measuring the potential between anode and reference electrode, and letting the current pass between anode and cathode. This mechanism gives very stable signal of the ethanol oxidation in the anode.

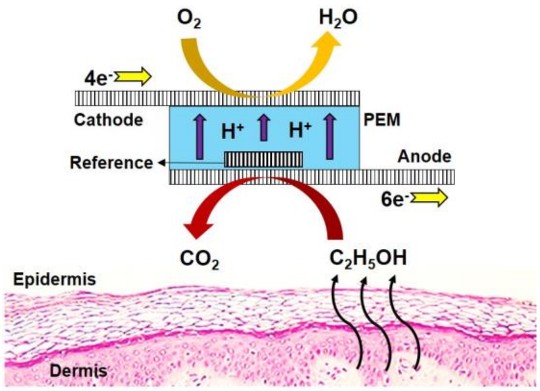


Figure 1. Schematic of fuel cell based sensor for continuous monitoring of ethanol in close proximity with the epidermal layer.

$$C_2H_5OH + 3H_2O \rightarrow 12H^+ + 12e^- + 2CO_2 \qquad \rightarrow (1)$$

$$3O_2 + 12H^+ + 12e^- \rightarrow 6H_2O \qquad \rightarrow (2)$$

$$C_2H_5OH + 3O_2 \rightarrow 3H_2O + 2CO_2 \qquad \rightarrow (3)$$

2.1.2. Fuel-cell sensor design and function

The sensor has been designed in such a way that the working electrode is on the anode side of the membrane, and the counter and reference electrodes on the cathode side of the membrane (Figure 2). The working electrode area has been kept (1.2 cm^2) smaller than the counter electrode area (1.5 cm^2) to avoid the effect of limitation of the oxygen reduction reaction (compared to ethanol oxidation on anode). The other advantages of this electrode design includes (i) alignment of anode to the close proximity to the reference electrode, which enables exchange of H^+ ions easily, (ii) atmospheric oxygen reduction reaction will be the reference voltage across the reference and working electrode (oxygen is abundantly available in the atmosphere), which provides a stable reference voltage, (iii) avoid short circuit voltage between working and the reference electrode, (iv) the electron flow limitation due to limited counter electrode area has been eliminated. The sensor is at the size of the working electrode 1.5x0.8 cm, counter electrode 1.5x1 cm and reference electrode 1.5x0.2 cm. The thickness of the Nafion membrane is 0.03 cm and the thickness of the micro-perforated metal electrodes is 0.02 cm.

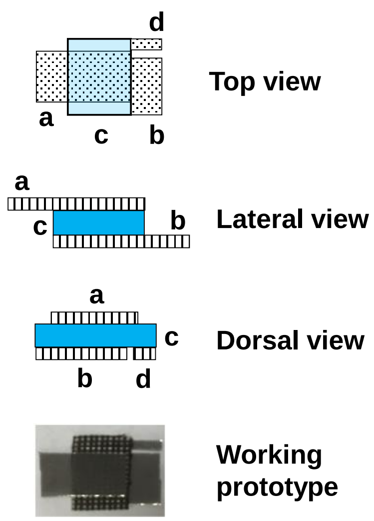


Figure 2. Fuel cell ethanol sensor and its design, (a) working electrode, (b) counter electrode, (c) Nafion membrane and (d) reference electrode.

As mentioned earlier, the three electrode system can maintain constant potential between the electrodes, and can provide the voltage of the working electrode alone (half-cell voltage). The half-cell voltage is important to identify the reaction at the anode accurately. In this work the working electrode is the anode (ethanol oxidation), counter electrode is cathode (oxygen reduction). The open circuit potential (OCP) of the cell in presence of ethanol is at 0.6 V, whereas the humidity is at 0.2 V. This OCP generated in presence of humidity is related to the catalyst oxidation reaction at the anode, and not by the humidity itself. Similarly, the OCP mentioned in these experiments were for stainless steel electrodes, the OCP varies depends on the catalyst used. For accurate ethanol detection, it is necessary to measure the anode signal instead of whole cell potential. This can be achieved by a three electrode system. This concept has been demonstrated using OCP experiments as shown in Figure 3, where three electrode system shows 0.6 V in presence of ethanol. The same figures show there is a significant lower in OCP voltage of two electrode system when compared to three electrode system. This lower in OCP can be attributed to the influence of oxygen reduction reaction signal from the cathode side. Three electrode system also provides wide potential window between ethanol and humidity signal compared to that of two electrode system.

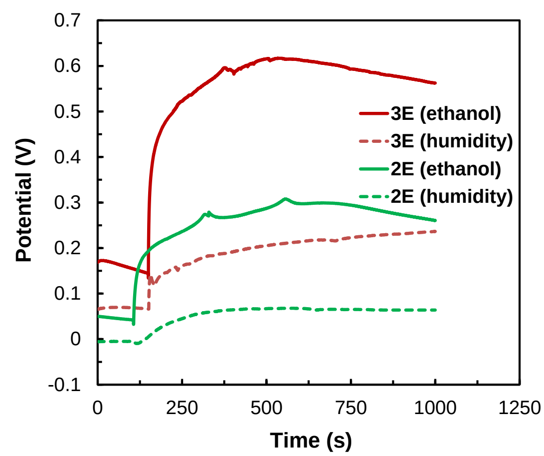


Figure 3. Comparison between two (2E) and three (3E) electrode systems made of stainless steel electrodes. (OCP technique).

2.1.3. Cancelling humidity by multi-step technique

As discussed above, the constructed fuel cell electrode can split the humidity signal from the ethanol signal. However, the observation has been made that the ethanol curves from OCP deviates in presence of humidity. So obtaining an accurate linear range (calibration curve) for the sensor will be impossible. The humidity gradient affects (i) rate of H^+ transfer through the membrane, which in turns affects the pH, (ii) amount of catalyst get oxidized on anode, and (iii) the amount of oxygen gets reduce on the cathode. These mentioned factors affect both the full cell potential (E_{cell}) value and the current signal generated. Deriving the accurate relationship between humidity and the signal generation is practically impossible, because in a sandwiched fuel cell setup there will be a humidity gradient between the outer layers and the middle layer. So attaching a humidity sensor and calibrating the fuel cell sensor will not provide accurate results. To eliminate this limitation and humidity interference, amperometric technique has been introduced in this device for the ethanol signal measurement. In general, the amperometric technique provides the signal of current generated between the working (anode) and counter (cathode) electrodes during the fuel cell reaction, where a potential is applied between working and reference electrode (ethanol oxidizes in anode, oxygen reduces in cathode). In this device, by keeping the electrode potential exactly at the full cell potential (E_{cell}) at any

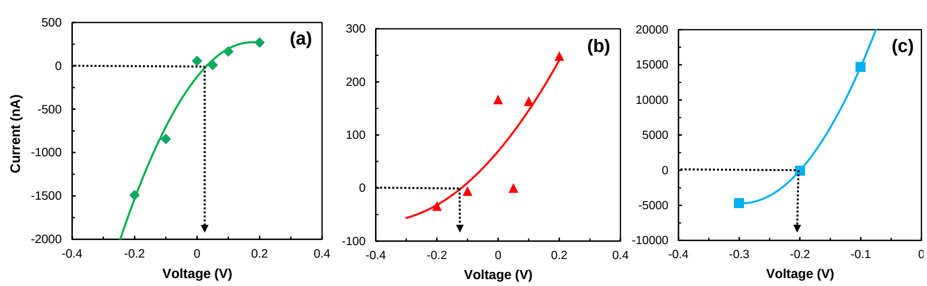


Figure 4. Amperometric measurements of (a) stainless steel, (b) gold and (c) nickel electrode fuel cell setups at various applied potentials to obtain the E_{cell} value for zero current in presence of 50% humidity.

given humidity level, the current flow due to humidity has been eliminated.

2.1.4. Subject identification

In the fuel cell setup, in the presence of humidity, the catalyst gets oxidized at the anode and oxygen get reduced at the cathode. Due to the fact that formal potential ($E^{0'}$) of ethanol is much higher than the $E^{0'}$ of catalyst, during amperometric measurements (applied potential: E_{cell}) in presence of ethanol the current flows between the anode and cathode. To identify the E_{cell} for each metal catalyst used, series of amperometric measurements were made and the current was plotted vs. applied potential (Figure 4) at 50% humidity. The results show that the E_{cell} values depends on the metal type. These results also revealed that the E_{cell} has floating values with respect to humidity even if it is a single catalyst. To demonstrate the reduction and elimination of humidity signal, amperometric experiments were carried out at various potentials for stainless steel electrodes as given in Figure 5. In these experiments humidity was introduced at 50 s, and ethanol was introduced in 100 s. The potentials tested were 0, 0.35 and 0.55 V. From the same figure it is evident that there was a flip in polarization of the humidity signal if the applied potential for measurements were below the E_{cell} (0.15 V). Based on these experimental observations, a flow chart (Figure 6) was constructed for the accurate measurement of ethanol even in the presence of high humidity level. The concept behind this flow chart involves the nullification of current produced by humidity by two following functions,

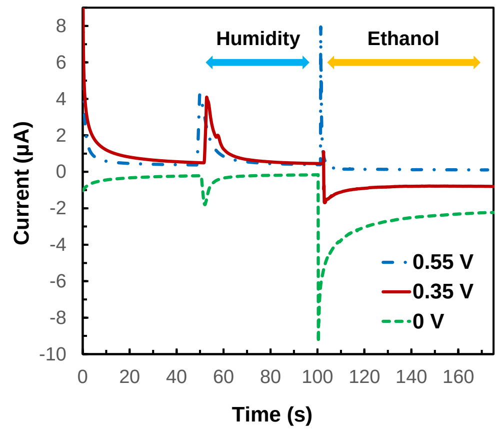


Figure 5. Amperometric signals of fuel cell constructed with stainless steel at different potentials.

1st function: Automatically calibrate fuel cell sensor in certain intervals (intervals changes depends on the needs based on the material used for construction).

2nd function: Measurement of ethanol using amperometric measurement.

The calibration (1st function) is necessary to know the humidity level and nullify the humidity signal in the second function. The 1st function involves OCP measurement, the 2nd function involves amperometric measurements. In the 1st function if the value is lower than the threshold value, it indicates no ethanol present, where it stores the value in the device. This stored value will be the bias voltage for amperometric measurements in the 2nd function, where the current is measured and fitted against a pre-determined calibration curve. This process will nullify the humidity signal in the existing environment. In this OCP is otherwise called E_{cell}.

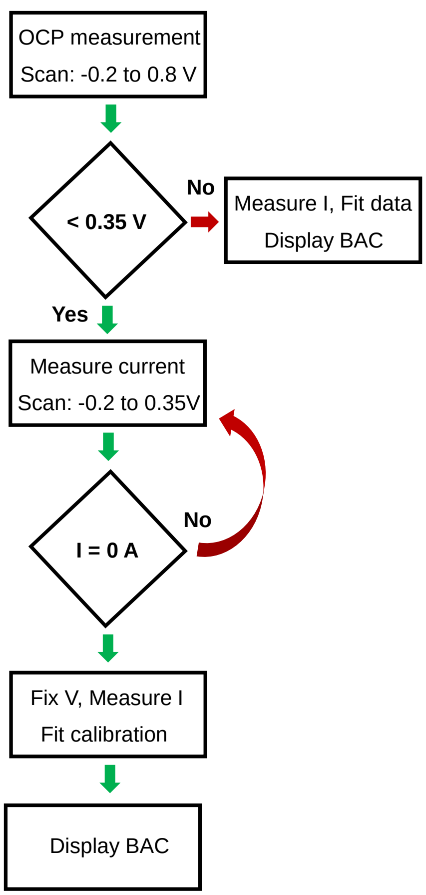


Figure 6. Flow chart representing ethanol sensing steps needed for accurate measurement of BAC.

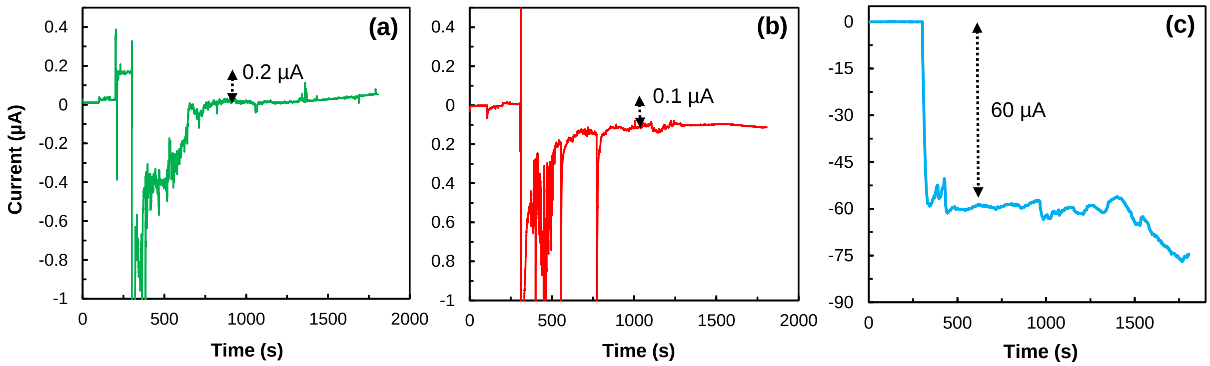


Figure 7. Amperometric signals of 95% ethanol at the fuel cell sensor containing (a) stainless steel, (b) gold and (c) nickel as catalyst.

In the 1st function, if the value is higher than the threshold value, i.e., >0.35V (for stainless steel), it indicates there is a presence of ethanol, and the device will start measuring ethanol using amperometric method (2nd function), and the bias used for this measurement will be last stored bias value from the 1st function. Above >0.35 V calibration should not be done because it will nullify the ethanol signal. Here our aim is only to nullify the humidity signal and keep the ethanol signal.

In the device there will be multiple pre-determined calibration curves stored for each bias voltage. Based on the bias voltage obtained in 1st function the calibration curve will be selected for fitting. This is due to the reason that the current signal magnitude in 2nd function changes based on the applied bias. The final step is to display BAC from the calibration curve fit, which is work in progress for this device.

2.1.5. Nickel as catalyst for ethanol fuel cell sensor

The electrodes, stainless steel, gold and nickel has been studied under amperometric technique to understand the effect of catalytic activity on ethanol oxidation current signal. For these experiments 95% ethanol was used to obtain highest current possible. The amperometric results revealed that among these three catalysts, nickel provided higher current (Figure 7). This higher current can be attributed to the higher catalytic activity of nickel towards the oxygen reduction reaction (refer previous section on OCP results), where more than 3 electron transfer involved per oxygen molecule. Higher the rate of reduction, higher the amperometric current. The current obtained at stainless steel sensor was 0.2 µA, for gold it was 0.1 µA, and for nickel it was 60 µA. It is evident from this that catalyst plays an important role in determining the current.

2.2. Consistent function, reliability and robust reproducibility

Standardization of measurements and reproducibility: The standardization of the measurements was achieved through step by step evaluation. The steps involved were (i) study of the sensor response for various concentration of ethanol, (ii) constructing calibration plots and understating the sensitivity and (iii) studying the sensor response for the low concentrations of ethanol. As mentioned in the previous sections, the amperometric method was implemented to study the properties of the developed fuel cell sensor itself. The experimental setup consists of a chamber with liquid ethanol at the bottom and a closed headspace at the top. The sensor was housed at the top of the chamber to receive the ethanol vapor. The ethanol solution concentration was varied to obtained the various concentrations of ethanol vapor. The experimental conditions are the room temperature and pressure. As given in Figure 8a, there was a linear response in the current with respect to voltage. The label ‘control’ in the same figure is measured in the absence of ethanol and in the presence of 95% humid air flow. The other curves in the Figure 8a are the current signal for

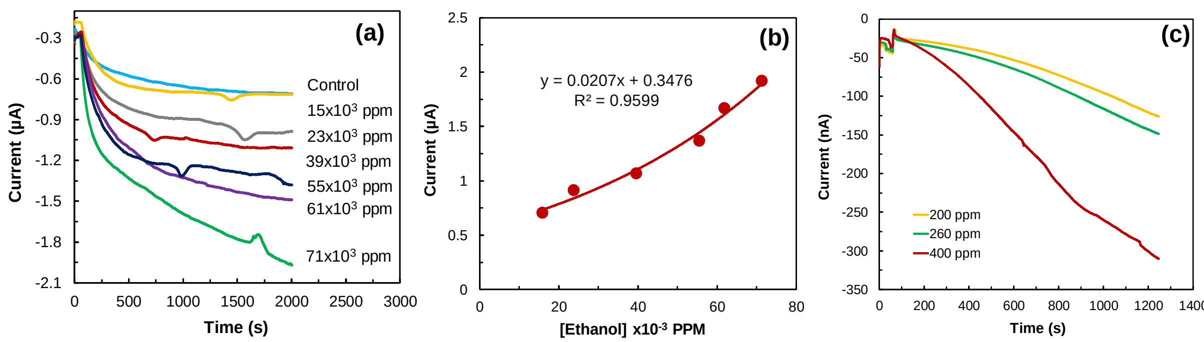


Figure 8. (a) Amperometric signals of the fuel cell sensor at various ethanol concentration (b) plot of ethanol concentration vs. current, (c) amperometric signals of the fuel cell sensor at lower ethanol concentrations.

different concentration of ethanol. The linear plot in Figure 8b is the plot of current vs. ethanol concentration obtained from Figure 8a at the time interval of 1200s. The experiments were repeated several times to obtain the deviation in current, which is ±20 nA. Similarly, the Figure 8c is the study of sensor signal at low concentrations (200, 260 and 400 ppm) of ethanol. These low ppm concentrations were generated from ethanol pressurized cylinders.

Stability and reliability: The curves in Figure 8a indicates that the signal of the fuel cell sensor gradually increased till 1000s then attains steady state current. Once attaining the steady state current, it never went down as long as the ethanol vapor was present on the anode surface of the sensor (Figure not shown). This indicates that the sensor is stable and reliable for prolonged measurements. The sensitivity of the sensor stays same in both high and low concentrations of ethanol vapor exposure.

3. Data Collection, Transmission and Operation

The system will operate from a 3.7 VDC Lithium-Ion (Li-ion) battery capable of providing up to 1000mAh. This voltage will be regulated to provide a constant 3.3 VDC source to the system in Figure 9 through a battery voltage range of $1.7\ VDC \leq V_{DC} \leq 3.7\ VDC$ using the power management unit (TPS63030). This will ensure a minimum battery life of six months. The Li-ion battery can be recharged on the wearable platform through a micro-USB device connected directly to a Li-ion battery charging circuit which allows simultaneous system operation and charging functions. The analog front end (AFE) sensing device (LMP91000) was chosen as the signal path solution between the microprocessor (MSP430F5529LP) and the ethanol fuel cell sensor due to its ability to detect current in the nanoampere (nA) range and provide an output voltage proportional to fuel cell current times a gain factor. The AFE sensing device is fully configurable through software. In order to ensure reliable AFE sensing operation, and for calibration purposes, a digital-to-analog converter (DAC) is employed. The device (MCP4725) will provide fully software configurable reference voltage to the AFE sensing device, of which a fixed percentage will be applied across the ethanol fuel cell sensor for biasing purposes as determined during calibration time.

The sensor monitoring system consists of two very important components responsible for the electrochemical sensing capabilities and the establishment of a sensor bias voltage of an electrochemical type sensor for zero current calibration and sensor operation purposes. Electrochemical sensing for an electrochemical sensor is provided by the LMP91000 analog front end sensing device [13]. The voltage reference to the analog front end sensing device is provided by the digital to analog converter (MCP4724) and is fully adjustable through software in order to meet a wide range of supply voltages to the LMP91000 in order to specify bias voltages with accuracy [14]. The software controllable voltage reference to the

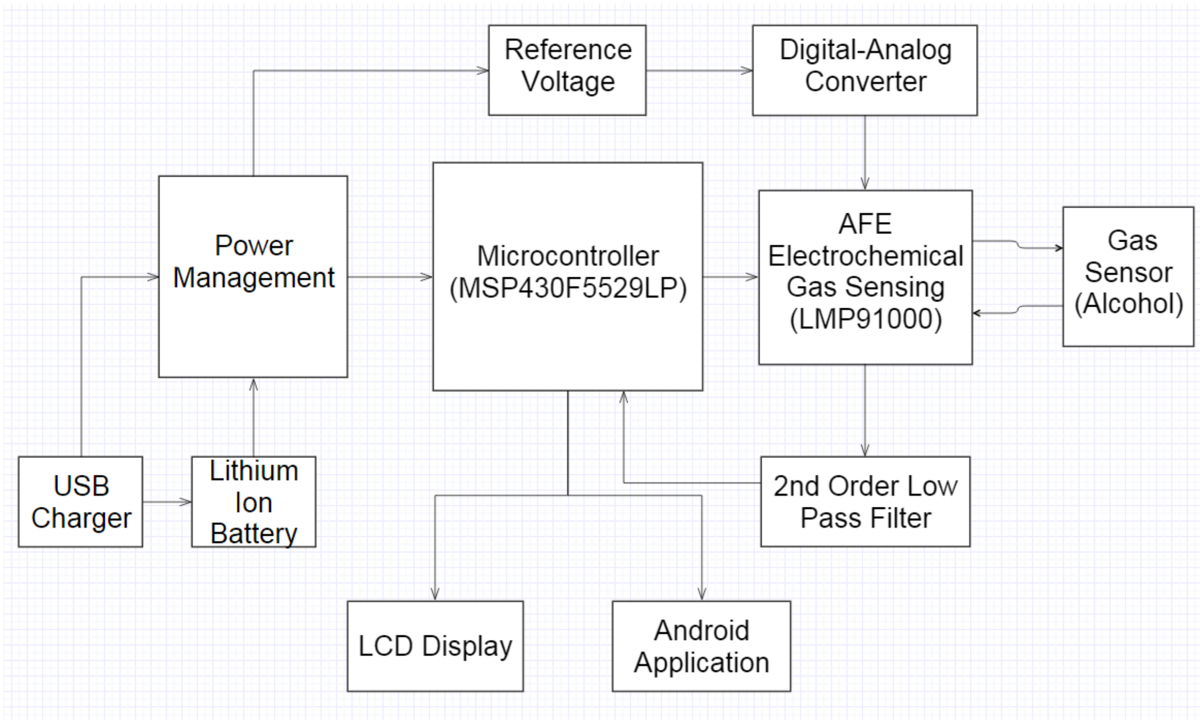


Figure 9. Overview of transdermal alcohol monitoring system.

LMP91000 also provides the ability of performing cyclic voltammetry through a wide range of voltages. In the Figure 9 an overview of the system is presented.

The component responsible for electrochemical sensing is a Texas Instruments LMP91000 configurable AFE potentiostat for low-power chemical sensing applications, available in a small 4mm x 4mm, 14 pin WSON package [13]. The purposes of the AFE device in this particular application are to establish a software-configurable sensor bias voltage across a two or three electrode sensor. The analog front end sensing device generates an output voltage that can be collected on the *Vout* pin and is proportional to the cell current, made available by a trans-impedance amplifier whose voltage is dependent on a feedback resistor, either internally or externally available, connected to the feedback path of the trans-impedance amplifier [13]. The schematic representation in Figure 9 was derived from the 3-lead amperometric cell in potentionstat configuration found in the datasheet of the LMP91000 [13]. Under this configuration the circuit in Figure 9 is conceived, where the external three electrode sensor is connected to the counter, reference and working electrodes respectively. The output voltage available at the *Vout* pin of the LMP91000 is then routed to the microcontroller unit and connected to general purpose input/ouput (GPIO), where it is conditioned by an analog-to-digital converter for interpretation. The trans-impedance amplifier gain is adjusted to provide a voltage proportional to cell current, it can be internally programmed via software for a range of $2.5\,K\,\Omega \leq R_{tia} \leq 350\,K\,\Omega$ and externally configured if necessary [13]. The algorithm for interpreting sensor data has been derived from [13], under this configuration two additional cables are routed from the LMP91000 *C1* and *C2* pins to the MSP430F5529LP GPIO pins. The data from *C1* and *C2* consists of the analog output voltage *Vout* of the LMP91000 and the analog voltage present at the inverting input of the TIA, who is directly connected to the working electrode of the three-electrode sensor and is the same voltage at the non-inverting input of the TIA who is a fixed percentage of the Reference Voltage (V_{REF}) or Divided Reference Voltage ($V_{REF_{DIV}}$), and is chosen dependent on electron current flow to the WE. Through this procedure we then derive the current flowing at the working electrode of the three electrode system (I_{WE}) as follows $I_{WE} = (V_{out} - V_{REF_{DIV}})/R_{tia}$, once $V_{REF_{DIV}}$ has been established using the aforementioned procedure, R_{tia} is chosen depending on the sensitivity of the sensor given in parts-per-million *(ppm)*, the current of the sensor is then calibrated via software as a function of all described parameters.

3.1. Verification of data security and integrity

Data security and integrity is assured by performing all the processing on the platform itself without relying on any external device, such as a phone application, to process data. Future versions of TAMS will include an encryption algorithm before data is sent out via Bluetooth. A security feature included in TAMS now is the requirement for a password to connect to the Bluetooth itself. The requirement of a password ensures that no person other than the intended user can connect to the platform and intercept data. It is important to note that for simplicity, this specific TAMS unit has shipped out with no password protection, although one can be effortlessly added through software. The authentication protocol for the device once the user selects a password is as given in Figure 10.

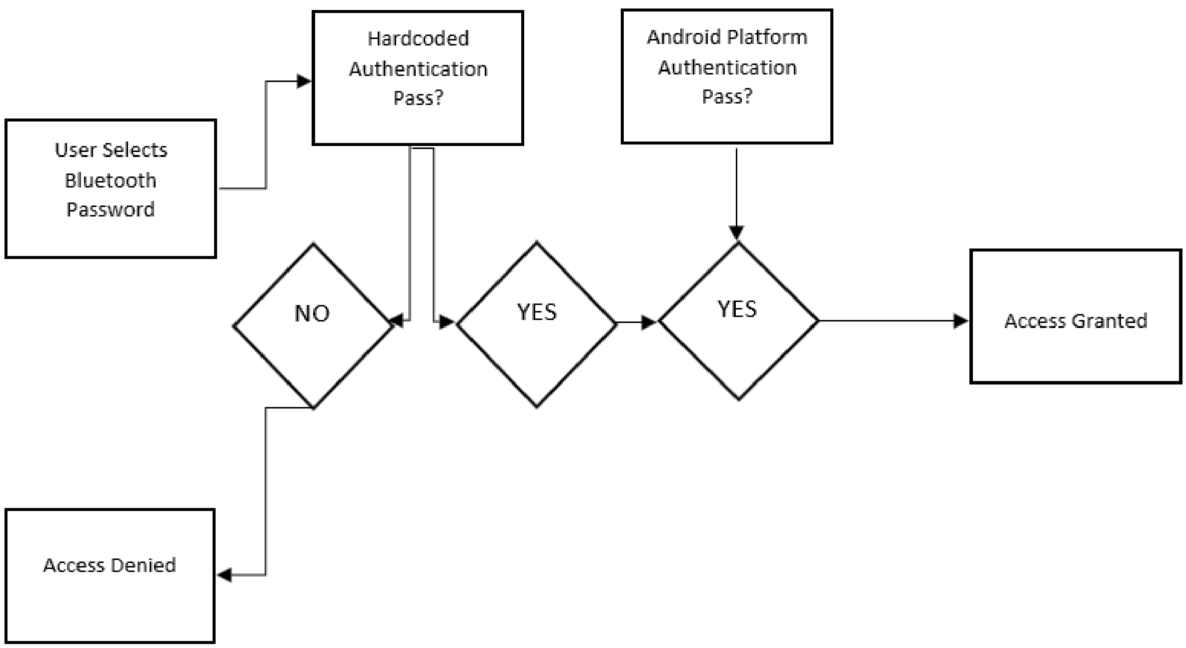
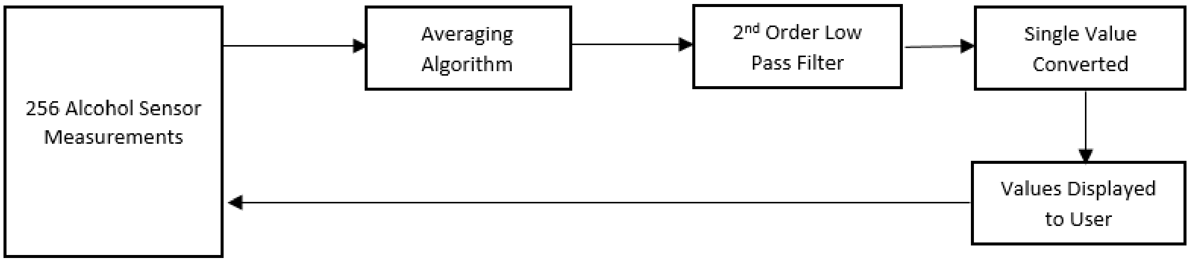


Figure 10. Overview of authentication protocol for the device.

4. Reliability and Frequency of Alcohol Measurements

The Transdermal Alcohol Monitoring system operates on a continuous basis and gathers multiple readings from the alcohol sensor before processing the gathered data and establishing a final decision. A minimum of 256 readings are taken in one second through an Analog-Digital Converter and processed, these readings are then averaged and processed through a 2^{nd} order low pass filter, the entire process takes less than one second as a result of robust processing capabilities. Listed below are a summarized series of steps for the frequency of alcohol measurement algorithm.

The averaging algorithm simply takes an average, as it is customary, of the large quantity of measurements delivered by the analog/digital converters. The second order low pass filter makes sure noise is removed



through software, preventing extraneous and incorrect measurements. When this process is done, a single value is converted into useful information, such as parts per million or BAC. The averaging algorithm and low pass filter ensure the measurements are reliable and there are no sudden spikes in any single reading which may distort overall system accuracy.

The reliability of the data has been determined using a commercially available potentiostat. Our miniaturized potentiostat results compare extremely favorability to the expensive commercial unit Figure 11 demonstrate the results from a commercially available potentiostat and the TAMS platform respectively.

The reliability of the measurements is compared to a commercially available potentiostat can be attributed to the filtering and averaging algorithms. We have seen the Transdermal Alcohol Monitoring system has the ability to compare to a commercial potentiostat, thereby guaranteeing accurate and reliable results on a continuous basis.

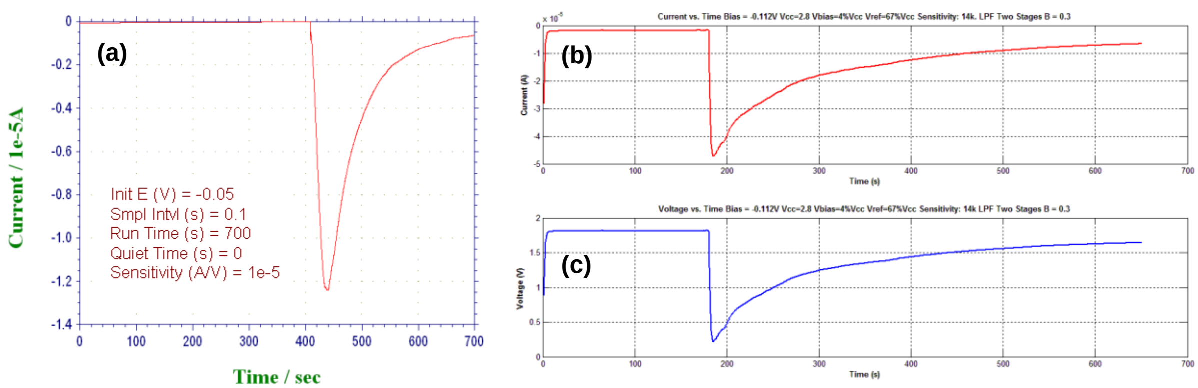


Figure 11. (a) Data from the commercially available potentiostat (CH instruments, Texas). (b) and (c) are the data from the developed Transdermal Alcohol Monitoring System.

5. Standardization of Manufacturing Process

The Transdermal Alcohol Monitoring System has been designed as a low cost and easy to manufacture device. All processes and procedures have been standardized as to enable fast and reliable reproduction of any TAMS platform. The entire production package for TAMS includes a complete set of instructions for manufacturing along with all essential files that include (a) Complete source code for a TAMS platform (b) Complete Printed Circuit Board (PCB) files with Gerbers files included for ease of PCB manufacturing, along with a thorough Bill of Materials (BOM) specifications (c) A mobile cellular phone android application with secure connection capabilities. Listed below is a preliminary bill of materials as required for the assembly of one entire Transdermal Alcohol System Unit. Please note that as of this submission, we have developed three fully working prototypes using the afore mentioned Printed Circuit Board files and C/C++ code.

The materials and components of in the TAMs can be separated in to two sections (i) fuel cell sensor and (ii) electronics components. The fuel cell sensor construction uses commercially available materials such as Nafion proton exchange membrane and metal porous sheets. The electronics components include commercially available green SMD LED, red SMD LED, 4.7uF capacitor, 10uF capacitor, 220uF capacitor, 100uF capacitor, 470uF capacitor, 330 Ohm resistors, 2k Ohm resistors, 100k Ohm resistors, 47k Ohm resistors, 4.7uH inductor, Bluetooth module RN-42 SMD, Lithium ion battery 400mAh, Liquid crystal display, MCP4725, Voltage Regulator (TPS61221), Voltage Regulator (LM4128), 1nF capacitor, MCP73831, Micro USB connector, LMP91000, Printed circuit board, and MSP430F5529.

6. Marketability Analysis

The market analysis for the alcohol sensor was held through the analysis of different market components. This analysis will determine if the product has an established market opportunity; if it can be sold for a profitable price and if it will be able to fulfil the client's needs and desires. This evaluating process will also include its impact in society, safety and performance. The ability of the product to be sold and the demand from users will determine the marketability and therefore the success of our design.

This product will be designed to have two different applications which are law-enforcement and commercial use. The market opportunity and clients of the device will differ between the two applications. With respect to the law-enforcement device, the market opportunity will be restricted to court use. It will be guarantee in individual cases with a condition of probation or parole. With respect to the commercial use of the device, the clients and market opportunity will be determining by the general public and it will not be restricted. Any person interested in measuring their blood alcohol concentration can be a customer. The use of similar law-enforcement products is in high demand; they are being used by court agencies in 46 States in the United States. The commercial use and demand of the product can be estimated using the survey provided for this project.

In reference to the commercial device; it will ensure not only the safety of the user but also the safety of nearby individuals. Any person using this device can control how much alcohol the person drinking and consequently avoid accidents or any alcohol related problems. In reference to law-enforcement, it will be used to ensure that offenders who have been order by court to remain sober and not drink alcohol. It will guarantee safety and have a positive impact in society by keeping offenders away from alcohol consumption.

Concerning the two applications, this device will be safe to wear. It will cause no harm to the person using it. TAMS will eventually be waterproof and overcome the challenges facing available products today. It will be resistant to humidity and will not function adversely in the presence of common chemicals resembling alcohol. The battery life and the sensor has been designed to last for a long period of time and be rechargeable, which would improve the performance of the device compared to the existing products. This improvement will postpone the need of maintenance and reduce the daily/monthly cost associated with it.

The User Survey, summarized was distributed to random general potential users. At the time of the survey a brief explanation of the project main idea was given to participants in order to have a uniform survey delivery. The questions present in the survey were intended to capture the acceptance our project will have as well as which direction to take in the design process to better suit the users' needs.

From the user survey a list of the user's need interpretation is shown below:

The User Needs Transdermal Alcohol Monitoring System (TAMS)

- The TAMS should be designed in the form of a wearable wristband.

<table>
<tr><th colspan="7">Survey Results.</th></tr>
<tr><th>Questions</th><th colspan="6">Answers</th></tr>
<tr><td>Number of people who took the survey?</td><td colspan="6">42</td></tr>
<tr><td rowspan="4">Gender and Age</td><td colspan="3">Male</td><td colspan="3">Female</td></tr>
<tr><td colspan="3">76.19%</td><td colspan="3">23.81%</td></tr>
<tr><td>21-25</td><td>26-35</td><td>>36</td><td>21-25</td><td>26-35</td><td>>36</td></tr>
<tr><td>65.63%</td><td>31.25%</td><td>3.13%</td><td>40.00%</td><td>20.00%</td><td>40.00%</td></tr>
<tr><td rowspan="2">Would you use a wearable device that can keep track of your Blood Alcohol Content?</td><td colspan="3">Yes</td><td colspan="3">No</td></tr>
<tr><td colspan="3">71.43%</td><td colspan="3">28.57%</td></tr>
<tr><td rowspan="2">How important is trend analysis of your alcohol content to you?</td><td colspan="3">I only want to monitor my current alcohol level.</td><td colspan="3">I want to keep records of my alcohol level over time to identify trends and manage drinking.</td></tr>
<tr><td colspan="3">56.10%</td><td colspan="3">43.90%</td></tr>
<tr><td rowspan="2">Will you be willing to wear the Alcohol Monitoring device in public?(Keep in mind that the device will have an appealing look)</td><td colspan="3">Yes</td><td colspan="3">No</td></tr>
<tr><td colspan="3">73.81%</td><td colspan="3">26.19%</td></tr>
<tr><td rowspan="2">Which of the following dimensions would you prefer?</td><td colspan="2">Covering an area of 1-2 inches and no more than 8 oz.</td><td colspan="2">Covering an area of 2-4 inches and no more than 8 oz.</td><td colspan="2">Dimensions and weight are not an issue to me.</td></tr>
<tr><td colspan="2">64.86%</td><td colspan="2">24.32%</td><td colspan="2">10.81%</td></tr>
<tr><td rowspan="2">If you were forced by law to wear an Alcohol Monitoring device, which of the following locations would you prefer?</td><td colspan="3">Wrist (Wrist Band)</td><td colspan="3">Ankle (Ankle Bracelet)</td></tr>
<tr><td colspan="3">62.16%</td><td colspan="3">37.84%</td></tr>
<tr><td rowspan="2">In terms of battery life, which of the following do you prefer?</td><td colspan="3">Non-rechargeable battery lasting 6 months. (Replacement Needed)</td><td colspan="3">Rechargeable battery lasting from 16-24 hours. (No Replacement Needed)</td></tr>
<tr><td colspan="3">47.37%</td><td colspan="3">52.63%</td></tr>
<tr><td rowspan="2">Within which of the following ranges would you like to be notified of your Blood Alcohol Concentration (BAC. % by vol)?</td><td colspan="2">0.020 - 0.079 (within legal limit)</td><td colspan="2">0.080 - 0.500 (above legal limit)</td><td colspan="2">0.001 - 0.500 (full range)</td></tr>
<tr><td colspan="2">54.05%</td><td colspan="2">27.03%</td><td colspan="2">18.92%</td></tr>
<tr><td rowspan="6">The base price of the Alcohol Monitoring device is $50, which of the additional peripherals would you pay extra for?</td><td colspan="2">$10.00 For additional memory storage capabilities.</td><td colspan="2">$29.99 For GPS tracking.</td><td colspan="2">$15.00 For extended battery life.</td></tr>
<tr><td colspan="2">22.22%</td><td colspan="2">25.00%</td><td colspan="2">47.22%</td></tr>
<tr><td colspan="2">None of the above.</td><td colspan="4">Other (please specify)</td></tr>
<tr><td colspan="2">0.00%</td><td colspan="4">5.56%</td></tr>
<tr><td colspan="2" rowspan="2"></td><td colspan="4">None</td></tr>
<tr><td colspan="4">I'd like for the device to be as small and inconspicuous as possible.</td></tr>
<tr><td rowspan="4">Are there any other suggestions you would like to make for this product?</td><td colspan="6">Add other features like a watch.</td></tr>
<tr><td colspan="6">Notify the user how many more drinks they can have before becoming illegal</td></tr>
<tr><td colspan="6">No</td></tr>
<tr><td colspan="6">Upgrade privacy policy in order to make us avoid drinking too much.
Never to increase problems with authority.</td></tr>
</table>

- The TAMS should display current alcohol levels only.
- The TAMS should be compact in size, lightweight and appealing.
- The TAMS should contain a rechargeable battery.
- The TAMS should have a variable alcohol notification window.
- The TAMS should have an extended battery life option.
- The TAMS should include the basic features of a wrist watch.
- The TAMS should notify the user before reaching illegal alcohol limits.

After analyzing the results from the survey and the market components; this analysis concluded that the project will be marketable. According to the survey this product will have a demand as a commercial device. Some users are willing to pay more for extra features increasing the marketability of the product. As a law-enforcement device it will have several advantages over the existing products. These advantages will increase the use of the device and therefore its market opportunity. Safety will be guaranteed for the users in any of its applications. The performance will exceed that of the existing products and the fewer maintenances will be performed. This market analysis provides a positive market opportunity for this device in both of its applications. We have addressed most of the user needs as seen in the survey, and continue to improve the features of TAMS and our first prototype.

7. Feasibility analysis

The Needs/Feasibility Analysis is designed to facilitate the engineering team in determining the specific needs of the client and all intended users through a sequence of stages followed during the initial project phase. It also provides the team with unambiguous insight into the problem statement and clearly defines goals. The client's needs were identified through a series of interviews and summarized in a final needs interview conducted with all parties involved, which included all of the clients and engineering team members. Identifying the needs of the intended users was accomplished through a survey that contained carefully constructed questions. The survey provided further insight into the needs of the intended user market which ultimately allowed our team to make unbiased decisions during the designer needs phase based on objective feedback from potential users.

The overall needs of the project were obtained through a combination of formal interviews, surveying potential users and brainstorming designer needs. All interviews and correspondence have been carefully documented as to not overlook any specific requested needs. As a result of the complex nature of the project and in order to conclusively determine our goals and challenges, we had the obligation of conducting preliminary research on the topic of wearable transdermal devices to fully familiarize ourselves with this newly emerging field of transcutaneous data analysis.

8. Intended users, uses and proposed design dimensions

8.1. Intended users and uses

This device is intended to have many users and two main applications. The intended users, intended uses and implicit uses of this product will be discussed in this section. The intended user will focus on the characteristics of the different users. Intended uses and implicit uses will focus on the predicted use of the device. Some characteristics of users and uses differ between the two applications while some others remain the same.

8.1.1. Intended users

This product is expected to be used within two different areas of interest; personal use and law-enforcement. This device could be used by any individual regardless of the age or gender. Its use will not be restricted. It can also be worn at any time and any place. The intended users are responsible people who will use the device as indicated. The users will follow the recommendations on how to use this product to avoid any false reading.

When using this device for personal uses, any individual that will like to evaluate and/or keep records of their BAC will be able to use it. The design of this product is going to be simple; in that way the user will easily learn how to use it. When using this device as a law-enforcement method a court will determine who the users are. This devise will send the results of the reading to a supervisor who will be monitoring the offender continuously. The user won't need to know how the device works because all the data will automatically be sent to the supervisor. These users will use the device for as long as it is ordered to them. The users will follow the recommendations on how to use the device. These recommendations will be provided by the supervisors.

8.1.2. Intended uses

This alcohol monitoring device will detect the presence of alcohol in the surface of the skin. It will measure the percent of alcohol present in the blood by calculating the voltage produced by the alcohol vapor near the transdermal device. In the case of personal use, the result from this measurement will be displayed to the user. In the case of law-enforcement, the results will be automatically sent to the agency responsible of supervising the offender. Places where the device will be used vary depending of the user. For personal use it is supposed to be used in a place where alcoholic beverages will be consumed or any daily activities. For law-enforcement the user is supposed to be wearing the device at all times. Any attempt to remove it will notify they supervisory agency. The implicit uses of this device will be providing safety to the users and the society. It will lower the risk of accidents caused by drunk drivers. It will also prevent alcohol related problems like aggressiveness and violent acts. When using it as a law-enforcement device, it will prevent offenders to drink while the court has order them to remain sober.

This product will be used as a personal device by average people regardless of gender. It will also be used as a law-enforcement device when an order from a court is present. Individuals will use this device as recommended and will not harm the device in any form. Regardless of the reason why this device is being used; users will support the safety of the society.

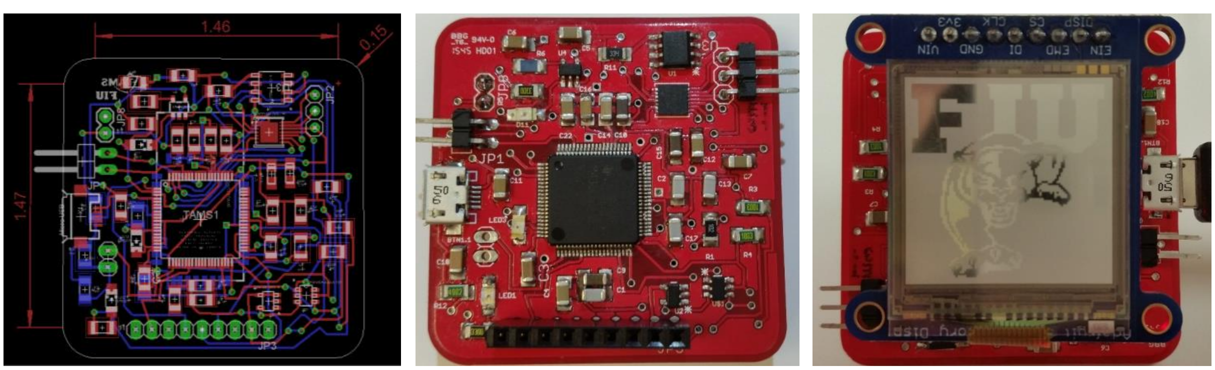


Figure 12. Left figure is the board file schematic for the TAMS, middle figure is top printed circuit board layer, and the right side figure is top printed circuit board layer with LCD display.

Figure 13. Left figure is a completely assembled TAMS as delivered, middle picture is a side view of the Transdermal Alcohol Monitoring System, Right picture is the Printed Circuit Board with components.

8.2. Dimensions of product design

TAMS will achieve the discreet and fashionable design that is expected of wearable designs. Our first prototype includes a PCB that is small in size, future plans include using components of smaller footprint to reduce size. Presented below are the dimensions of the PCB, which includes all the capabilities required to operate. The dimensions presented below represent the overall dimensions of the Printed Circuit Board and are in inches.

The Printed Circuit Board was manufactured and assembled using the custom made PCB shown above. All Gerber Board and Schematic files are fully available to ensure consistent manufacturing. The manufacturing vendor provided ten PCB boards for a low price, as of the day of this submission, six TAMS units have been fully assembled and tested. The PCB has been designed to house the LCD in order to continuously display information to user. Figure 12 and 13 shows a completely assembled top layer of a TAMS unit. The overall product dimensions are 45.72mm x 45.72 mm x 10mm.

9. Operating Environment and Considerations

This device is intended to be used in any open or closed area where the user is likely to consume alcohol. Some of the customers will use the device as a method of measurement and control of their BAC. Others will be force by law to use the device in order to supervise and monitor the offender’s BAC. The two applications presented with this project are different; however, they share the basic specifications needed in order for the device to work properly. Current alcohol detections devices rely on users to avoid any substances that may contain alcohol. Some of the most common substances are perfumes, colognes, lotions and hand sanitizer. Wherever the device is being used the spilling of any alcoholic beverage can occur over or near the device. Taking in consideration the existing products, these substances should not interfere with the reading and accuracy of TAMS and we will work to ensure interference with these substances do no cause undesired responses. The alcohol substances laying on the surface of the skin will cause the reading to go up much faster than when alcohol is consumed; it will also evaporate much faster than the body’s metabolize speed. Having in consideration these probabilities, the device should be able to distinguish when the alcohol is being consumed or placed in the skin. Some other substances often considered are cold medicines and mouthwash. These substances often leave residual alcohol in the mouth; therefore, they should not interfere with this product.

Users also need to take in consideration that although this device is waterproof it should not be submerged in water. This action, if it is maintained for a long period of time, could distort the accuracy of the reading. The law-enforcement application will have some extra considerations. These considerations are based on the existing products currently in use. The user will not be allowed to remove the device during the period of the sentence. Any attempt to obstruct the reading will notify to the authorities. The readings provided will be sent to the supervisors automatically and they will decide if an infraction of the verdict has occurred. When the user is wearing this device they need to avoid places with high levels of humidity. The presence of humidity may increase the conductivity of the transdermal membrane and lead to malfunction. Humidity, the amount of water vapor present in the air, is affected by wind and rainfall. Places near coastal regions and tropical forest have high levels of humidity.

Disturbance of the environment, mostly caused by human influences, needs to be taken in consideration when wearing the device since they could cause false readings. This device will be guaranteed to operate under these considerations. It should be able to distinguish whether it is a force situation or actual alcohol consumption and provide the proper reading to the user. Whether it is used for personal monitoring or law-enforcement; it is important that the user follows the considerations presented here. This will guarantee superior functioning of the device.

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