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EnPRO 351-Business Plan

Alcometre-Advancing Technologies, Saving Lives

"Don't drink and drive. Use Alcometre to save lives."

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1.0 Executive Summary

Drunk driving causes 14,000 fatalities a year in the United States. Over 160 million people in the United States consume alcohol. The U.S. spends nearly $9 billion per year on costs related to drunk driving. (NHTSA, 2007) All of this could be prevented if there was a foolproof way to prevent intoxicated individuals from driving.

Currently, only convicted DUI offenders with a court mandate must have a system in their vehicles to prevent impaired driving. The most commonly used device is a breathalyzer that is integrated into the ignition of a car preventing the car from starting if the driver has alcohol content over a preset limit. These devices are called blood alcohol ignition interlock devices (BAIIDs).

Although breathalyzers are the most commonly used BAIID systems, they have many shortcomings. Breathalyzers are large and cumbersome and very noticeable in someone's vehicle. Therefore, they have a social stigma attached to them. Breathalyzers have no way of identifying if the person submitting the breath sample is the person driving, they can take up to several minutes to get a positive reading, and they are sensitive to many external factors such as if an individual uses mouthwash. Some people have difficulties with breathalyzers because they do not have a lung capacity to submit a breath sample. The fuel cells in a breathalyzer also deteriorate over time which requires frequent calibration to keep the device accurate.

Alcometre is a new type of BAIID. It provides a non-invasive way to measure a person's blood alcohol concentration (BAC) by using low level light waves. The sensor is small and requires only a person's finger to measure the alcohol level. When a finger is place into the device, the low light emitter and receiver combined with the biometrics scanner, measures the amount of light passing through the blood to determine the BAC and also identifies the individual trying to start the vehicle.

The technology Alcometre provides is not only more convenient than a breathalyzer; the light technology is quicker, more accurate and requires less calibration.

2.0 Introduction

Accidents involving drunk drivers cause nearly 14,000 fatalities a year in the United States. Over 160 million people in the United States consume alcohol at any given time. Drunk driving causes an estimated loss of $9 billion per year in the United States. (NHTSA, 2007)

Imagine you have been out drinking with friends. After a long night, you decide to try to drive yourself home. When you try to start your car, it will not start—you realize you installed an Alcometre device and must scan your finger for your blood alcohol concentration (BAC) to be measured and the biometric ensures that it is the intended driver operating the vehicle. After scanning your finger, Alcometre registers that you have a BAC over 0.08 and prevents you from starting your car and thus nipping the problem in the bud immediately.

This is where Alcometre saves the day…preventing drinking and driving.

2.1 Vision

Alcometre's vision is a world in which drunk driving does not exist. Alcometre also envisions itself being one of the leaders to provide the technology to make this happen.

2.2 Product Overview

The main objective for this IPRO is to research and design a simple and accurate noninvasive blood alcohol ignition interlock device (BAIID). The intended application is to prevent drunk driving. We decided to integrate infrared (IR) technology and biometrics to detect blood alcohol concentrations, as well as, identify the operator of the vehicle. The device will either prevent or allow an individual to start the car based on who they are, and whether or not they have consumed a quantity of alcohol that may endanger them or others operating the vehicle. The BAIID device has to be small enough to fit into a regular passenger car, yet be efficient enough to determine the amount of alcohol in the blood quickly and accurately. During this semester we have tried to develop a crude prototype that will serve as our proof of principle. We have come up with many directions in which we could take our product such as having a standalone unit or an in vehicle control center that will be capable of calling a cab for the person if they are intoxicated. The device will also act as an anti-theft device that will prevent people who are not supposed to be driving the vehicle from do operating it. We would like to save lives with this product and hopefully we can reduce some of the 14,000 fatalities per year caused by drunk driving. We feel confident that it is possible to do that with a noninvasive device we have designed, researched and developed.

2.3 Product Prototypes

Alcometre has created a conceptual prototype to display the circuit and technology in the device. Currently, the prototype consists of a switch to emulate the blood alcohol scanner and a key to represent the ignition interlock capabilities of the device. If the switch is “on” (representing a scan with a BAC above 0.08) when the key is turned, the red light is turned on. If the switch is in the “off” position (representing a scan with a 0.00 BAC), the key turns on the green light, indicating the driver can start the car. (Picture can be seen below)

3.0 External analysis

3.1 Industry Overview

Alcometre will be operating within the impaired driving prevention industry. Currently, the government regulates the court-ordered BAIID users (the mandatory market) for this industry. Public and private companies and individuals (the voluntary market) such as zero-tolerance parents, public transportation, car rental companies, etc. have underserved areas.

3.1.1 Industry Analysis

<u>Barriers to entry</u>

Overall, the barriers of entry for Alcometre are relatively significant. The industry is growing very fast and competitors keep developing new products. The cost of entering the market is also a barrier. Detailed barriers can be divided in the following categories:

Patent position: Currently, there a few patents that are inhibiting the development of our product. (see Appendix 8.1) Alcometre must differentiate its technology enough to not infringe upon any patent rights, or license patent rights from its competitors.

Advertising: the firm is new and cannot afford to spend much on advertising. However, for a product like Alcometre, it is important to let people understand the product, especially for the voluntary section of the target market. The expense of advertisement would be a concern.

Cost advantage: Alcometre could be expensive to make. As a starting business like ours, the upfront investment would be big, so the cost of production is a concern.
Intellectual property and government regulation: Alcometre has to deal with lots of different parties. The intellectual property of the technology is a barrier as well as the government's potential influence.

Research and development: this is a fast developing area so we need to keep the firm innovative. This means that there has to be people doing research constantly to improve the product.

<u>Threats of substitutes</u>

The threat of substitutes for Alcometre is always high since there are so many competitors. We have to recognize that there are firms that have superior funding and technologies thinking about going into this industry. Once the prototype is developed, Alcometre should get a patent immediately to limit the competition.

3.1.2 Competitors in the Industry

Alcometre has one direct competitor in the industry. That company is:

- TruTouch Technologies, Inc.

There is also an indirect competitor in the industry. That company is:

- Alcohol Countermeasure Systems Corporation

TruTouch Technologies, Inc. is an Albuquerque, New Mexico based company, which develops and manufactures non-invasive alcohol testing systems. TruTouch focuses on their innovative new way to measure alcohol in the blood that helps save money by reducing setup costs and helps save lives by being more accurate than conventional blood measuring systems. Their innovative new way to measure blood alcohol content is similar to our infrared technology design idea.

TruTouch has a number of competitive advantages in this industry. First, TruTouch has established themselves with construction sites and large factories and has been operating for almost ten years. TruTouch also has an innovative and well-established product and design. TruTouch has also been the breakthrough technology into other markets, which Alcometre would like to operate.

Given these competitive advantages, TruTouch can be seen as an extreme threat. However, its product line proves that a market exists and has the potential to be capitalized upon. Alcometre has to find a way to serve the neglected markets.

Alcohol Countermeasure Systems Corp. (ACS), is a Toronto, Canada headquartered company, which develops and produces breath alcohol measuring devices. ACS has been operating since 1975 and originally targeted the law enforcement market. ACS most recently had collaborated with Volvo to integrate its breath alcohol-measuring device into Volvo vehicles.

Alcohol Countermeasure Systems Corp. is an indirect competitor to Alcometre because ACS focuses on the breath measuring systems. Alcometre is pursuing light technology and ACS's competitive advantage is that they have managed to collaborate with a major vehicle manufacturer and implement their technology into the vehicle. If ACS successfully implements their blood alcohol measuring and interlock system into the Volvo vehicles, a pathway to that market could open up for future capitalization with other car manufacturers.

3.2 Target Market

Alcometre targets parents with children under 21years of age. We believe that there is sufficient need and reason for parents to monitor the use of vehicles by their children. Here are a few sobering facts.

- Motor vehicle crashes remain the number one cause of death among youths, ages 15-20.
- Twenty-eight percent (28%) of 15- to 20-year-old drivers who were killed in motor vehicle crashes in 2005 had been drinking.
- 28.5% of high school students nationwide had ridden one or more times in a car or other vehicle driven by someone who had been drinking alcohol. (2005)
- In 2005, about 10.8 million persons ages 12-20 (28.2% of this age group reported drinking alcohol in the past month. Nearly 7.2 million (18.8%) were binge drinkers, and 2.3 million (6%) were heavy drinkers.
- Three of out every four students (75%) have consumed alcohol (more than a few sips) by the end of high school.

Drivers 21 years of age or older:

- For the past 6 years, more than 17,000 people have been killed annually in alcohol-related traffic crashes. In addition, approximately 300,000 people are injured annually in alcohol-related crashes. (2003)
- Of the 42,815 traffic related fatalities that occurred in 2002, an estimated 17,419 (41%) were alcohol related.
- Drivers convicted of DWI have an average blood alcohol concentration of .16 to .18 at the time of arrest.

(U.S. Census, 2000)

One article reports that researchers were surprised to discover that the majority of people support devices, like the Alcometre, that will stop drunken driving accidents. A new survey by the Insurance Institute for Highway Safety found that people liked the idea of using technology that would prevent drunk drivers from starting their vehicles. The survey polled 1,004 individuals and found that about 2 of 3 respondents favored alcohol detection devices. In fact, nearly 40 percent said they would want one of these devices in their vehicles. To date, approximately 180,000 interlocks are being used nationwide. The article also reported that, "There are a lot of hurdles that will need to be overcome for these alcohol detection devices. The device will need to be suitable for all drivers and will need to require little maintenance." (NHTSA, 2007) The Alcometre address these issues by being a fast, non-invasive, maintenance free device.

3.3 Primary Research

3.3.1 Existing Technology

The current devices that are in the market today use one of four types of technology.

- The breathalyzer analyzes a sample of the users' breath by its chemical reaction to a mixture of sulfuric acid, potassium dichromate, silver nitrate and water. A meter then measures the chemical reaction and determines the BAC.
- The alcosensor utilizes full cell technology. It has two platinum electrodes with an acid-electrolyte material between them. When the users breath sample crosses the electrode the resistance changes and that change is measured and processed to determine the BAC of the user.
- The intoxilyzer also measures the users' breath sample but, the difference is that it measures the absorption of IR light in the sample to determine the blood alcohol concentration.

Those three devices are used in automotive applications.

- The fourth type of device also uses IR light to determine BAC. However, analyzing the IR light absorption through the skin, into the blood stream and out, can indicate the measurement.

TruTouch Guardian is currently on the market and is manufactured by a company in New Mexico, TruTouch. That product sold and intended to be used to check the sobriety in a workplace environment. The mere existence of the TruTouch product has been encouraging to us. We know that the technology to analyze BAC in a way that is noninvasive, quick and accurate leads us to believe that we are capable of applying that technology to our product.

4.0 Internal Analysis

4.1 Core Team (Backgrounds and Capabilities)

Alcometre is comprised of 11 members, each with their unique talents and backgrounds.

Kunle Apampa is a Chemical Engineering major who created the Alcometre idea.

Renee Arrowood is a Human Resources management and finance major.

Olaoluwa Adeola is a Mechanical and Aerospace Engineering major.

Eduardo Morales is a Business major with experience in marketing.

Pawel Tyrala is an Electrical engineering major.

Jason Entler is an Engineering Management major with experience in both business and engineering.

Jeremy Geelen is an Electrical engineering major.

Khairul Abdullah is an Electrical engineering major.

Johnathan Eckhardt is a Business major.

Kyu Sung Hwang is an Electrical engineering major.

Xingshuo Liu is a Business major focusing on Finance.

4.2 Team Role Requirements

Alcometre will need to fill the following roles for success:

- Management and Business Development
- Sales and Marketing
  - End-User
  - Political Activist Supporters
    - MADD
  - Automobile Manufacturers
  - Insurance Companies
- Product Development
  - Sensor Development
  - Network Administration and Maintenance
- Legal
- Human resources

4.3 S.W.O.T. Analysis

Strengths	Weaknesses
Fingerprinting is not being implemented nor are there any identification interlock systems.	Mandatory Customers can have only limited use.
No calibration needed.	The device is not transferable.
Alcometre is non-invasive and less conspicuous than breathalyzers.	Car Companies may decrease the need for aftermarket product.
Market for BAIID devices is steady due to DUI mandates.	Big Five R&D involved with BAIID systems as option on cars
Groups such as MADD and RID are likely to support this type of technology.	Resistance to Use- If not mandatory, people, may be against use, especially, if in workers union.
The Alcometre technology (fingerprint and light) can be developed into different products to fit the market.	Function ability depends on the car's conditions.

Opportunities	Threats
U.S. government does not have a systematic law system for drunk driving, making Alcometre necessary for the public.	Patents on infrared design technology that we plan to use.
The technology is out there, but Alcometre could stand out as being more accurate and faster. The barriers to entry for the industry is low, however, innovation is needed.	Government regulated and controlled mandatory market, partially tapped voluntary market.
Alcometre can extend to be the device that not only detects alcohol level.	Societal stigmas attached to impairment devices in vehicles.
The liability of DUIs would be significant for companies	Voluntary market may be less inclined to spend money on something not required in this economy.
	(Legal) Potential liabilities if device malfunctions and a driver who is impaired operates a vehicle and injures someone else.

Table 1 - S.W.O.T. Analysis

4.4 Critical Success Factors

Technology Development: With limited knowledge of blood chemistry, infrared technology and how to measure blood alcohol content with light technology; our technology development is our main critical success factor. We need to partner with the Biomedical Engineering department on campus to learn more about the technology and determine if our current project path is viable.

Prototype Development: With existing patents and technology in our competitive market, developing a prototype design with our current project path is our one of our more critical success factors. We need to pursue technology paths that will allow us to measure a person's blood alcohol concentration accurately but without infringing on patents.

Financing: Financing will be a hurdle considering our competition has been able to secure heavy financing to research this field of technology and develop a niche in the marketplace. We need to experiment with different prototype designs and determine the best way to integrate this technology into a vehicle which will be costly.

5.0 Business planning and objectives

5.1 Organization Structure

Alcometre will be organized as a C Class Corporation in the State of Illinois. Upon establishment, founder's shares will be split among the founding team members. This type of organization structure will help establish credibility and also ease the process of external investment.

5.2 Product Positioning

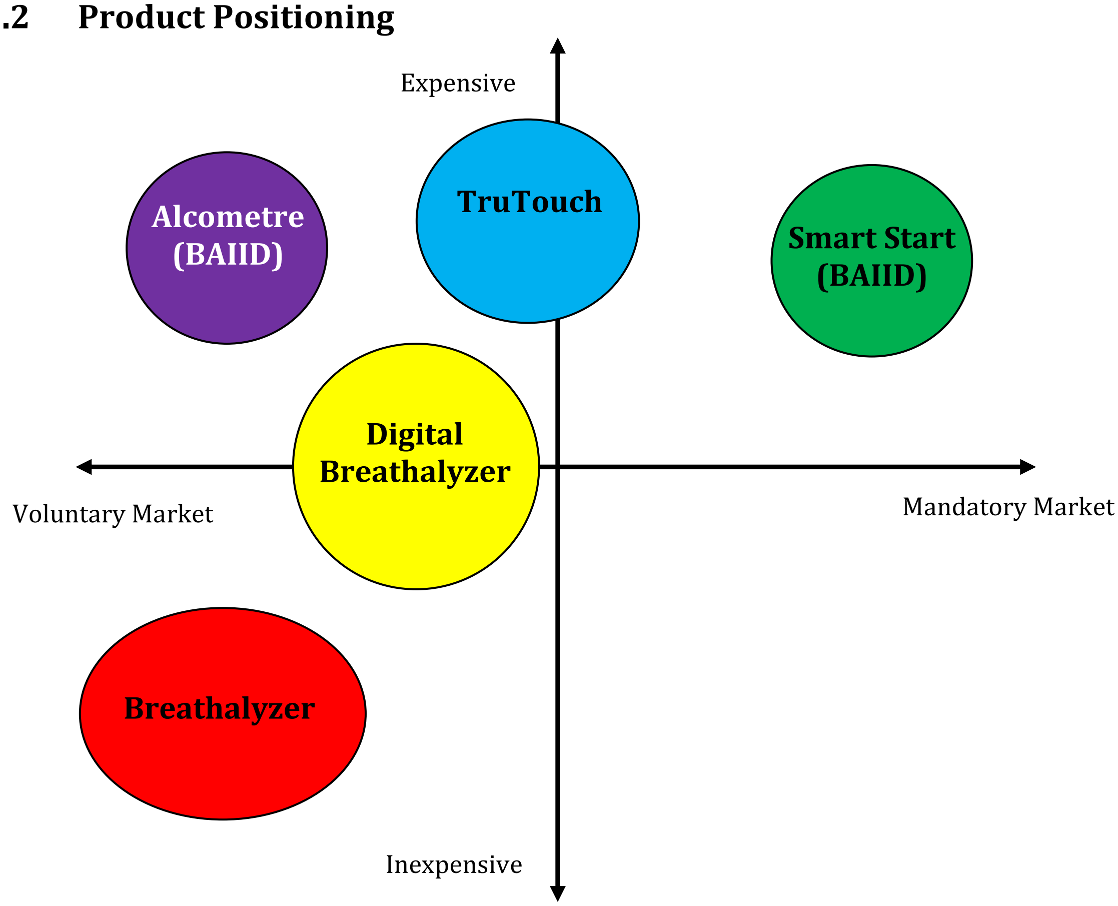

Figure 1 - Product Positioning

Alcohol measuring systems and blood alcohol ignition interlock devices (BAIIDs) make up the mandatory and voluntary market segments of our industry. The mandatory market segment is government-controlled and therefore not a very easy segment to enter. Our main competitor is TruTouch which offers similar technology; however, we are implementing ours into BAIIDs which grants us a whole new area of the voluntary market to enter.

5.3 Business Model

Alcometre will contain three different components and offer a service as well. The product will include a measuring device which the teenager or young adult uses to test for BAC, a car receiver, which receives messages from the computer system to allow the car to start, and another receiver that parents have so that they can get information for the computer system. The service would include a computer system that takes the BAC measurements received by the measuring device, acts similar to an On-Star based service. It can tell the location of the car, the person who tested what their BAC was, and then ask the parent if they allow the car to start or not. For further information consult the diagram below.

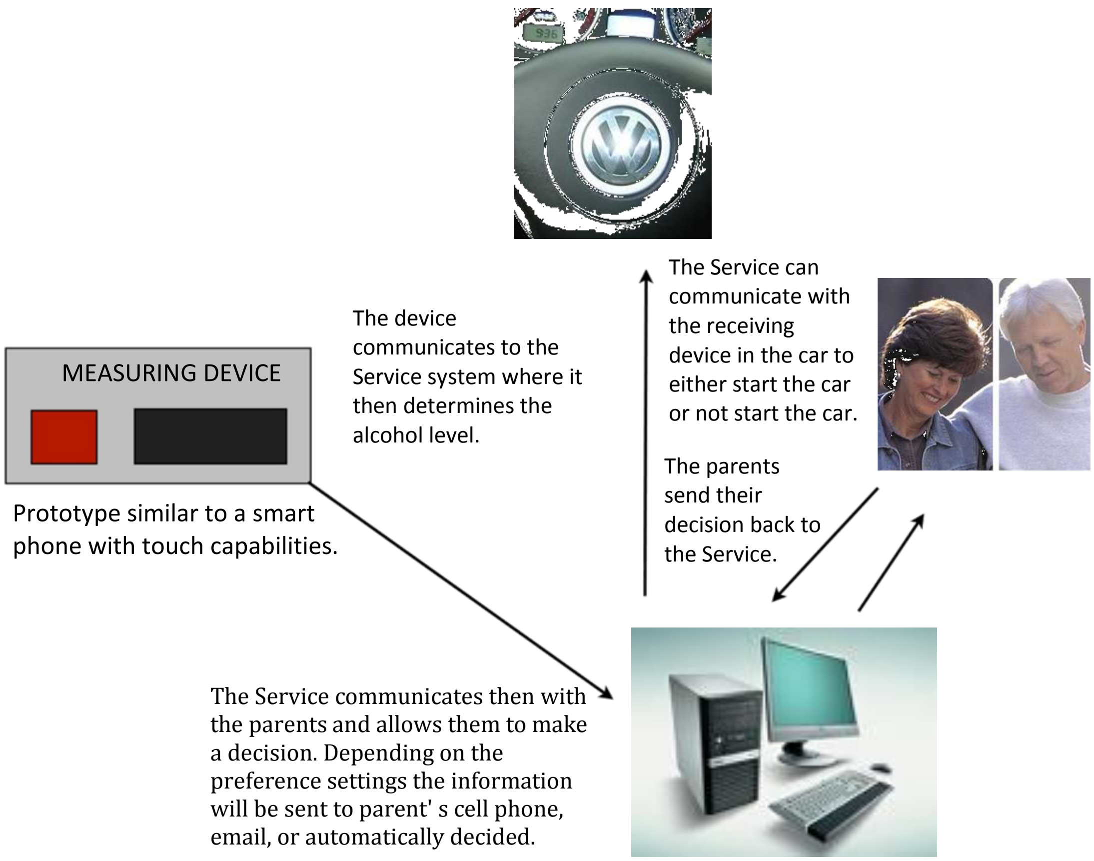

Figure 2 - Business Model

We are targeting a price point of $300 dollars for the device and the service. Unfortunately, that price may be a little unrealistic. Devices with similar complexity typically retail for between $300-$400 dollars. In order for the device and service to operate as we intend it to, there would need to be a transponder installed in the vehicle. A rough estimate for the price of the transponder is approximately $125 dollars. We asked some automotive technicians what the price would be to install such a device and we received figures in the $100-$200 dollar range. There would also be a monthly service fee associated with the service that could range from $30-$50 dollars. When all of the supporting fees for the devices, installation and services are totaled the product could require an initial investment of approximately $700 dollars with a residual responsibility of approximately $30-$50 dollars a month. The service will cost a yearly fee, and there will be two types of packages customers can order. A basic package that just sends the information, and a premium package that offers more information, such as the location of the messaging device, or a history of tests.

Alcometre will mostly likely be sold on the Internet as a Business-to-Business product. Alcometre has a potential to be sold in auto repair stores, or at local mechanics, as an aftermarket type device, such as a stereo system. Auto shops would be able to buy the devices offline and then sells them to consumers in the stores. Since professional installation would be required, Alcometre would be sold in auto stores, and repair shops, so that we could preserve good relations with B-2-B customers. Most auto repairs shops don't like customers bringing in outside equipment to install on cars for the main fact that one, they might have deals or sponsorships with certain brands, and two they don't want to be liable for any problems with that equipment. So Alcometre will be sold in auto shops and auto repair shops for parents who want to install this for the safety of their children.

5.4 Financial Analysis

Alcometre is a first semester EnPRO and was focused more on proving a market exists this semester for our idea. We also focused more time on researching the patents that are major roadblocks for this project and therefore do not have financial information available at this time.

6.0 Conclusion

Alcometre is a new type of BAIID. It provides a non-invasive way to measure a person's blood alcohol concentration (BAC) by using low level light waves. The sensor is small and requires only a person's finger to measure the alcohol level. When a finger is place into the device, the low light emitter and receiver combined with the biometrics scanner, measures the amount of light passing through the blood to determine the BAC and also identifies the individual trying to start the vehicle.

The technology Alcometre provides is not only more convenient than a breathalyzer; the light technology is quicker, more accurate and requires less calibration.

Unfortunately, we were unable to produce a working prototype this semester that can detect BAC. However, the intoxilyzer and the TruTouch Guardian are proof enough that it is possible to detect BAC using light. We also discovered several patents that also refer to using IR and low levels of light to measure BAC.

We were able to build a simulation automotive ignition switch that is ready to accept the working sensing technology. The circuitry associated with the successfully building of the sensing technology went beyond the current knowledge base of the students in this EnPRO. It would invaluable to have a technical liaison who has experience with electronics and/or IR spectrography.

The prototype for the Alcometre uses the concepts of infrared and near infrared spectroscopy in order to read oxygen saturation in the blood. The intended function of the prototype is to use spectroscopy in order to read the blood alcohol content of the user. The current prototype is a demonstration of how the technology will work. The difference between detecting oxygen and detecting alcohol is a shift in the electromagnetic spectrum. Minor adjustment to the oxygen sensing device can be made to correctly detect specific components in the blood that would give us an accurate BAC reading.

The recommend course of action for Alcometre is to continue the development of the prototype and enhance the appearance and technological capabilities of it. The team also needs to engage the market more and develop the business model farther and look into expanding our focus into other underserved markets (public transportation, car rental companies, car manufacturers, and private companies with corporate cars)

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8.0 Appendix

8.1 Patent Analysis

Vehicle Ignition Interlock Systems: A Crowded Field

The booming market for alcohol detection and vehicle ignition interlock systems has spawned a large number of patents. It will be it difficult for EnRPO 351 to create a non-infringing invention in this increasingly crowded field. The innovation in this field is reflected by the patents on file at the United State Trademark and Patent Office. In order to create a novel, non-infringing product, EnPRO 351 will have to specialize its device for use in a niche market that has not been disclosed or contemplated by an existing patent. This report will focus on the patents for three different devices that are similar to the original device proposed by EnPRO 351, followed by a discussion of what EnRPO 351 can do to distinguish its device from these patents.

Patent 7,616,123: "Apparatus and method for noninvasively monitoring for the presence of alcohol or substances of abuse in controlled environments"

This patent was filed in 2006 and granted in 2009 and is now assigned to TruTouch Technologies, Inc., a company in Albuquerque, New Mexico. The protectable term of this patent ends in 2026. In this patent, the primary inventor Trent Ridder discloses an invention that determines a spectroscopic signal from the response of a user's tissue to incident electromagnetic radiation. Ridder also claims a system using one or more of: "near infrared absorption spectroscopy, near infrared emission spectroscopy, infrared absorption spectroscopy, infrared emission spectroscopy, Raman spectroscopy, visible absorption spectroscopy, or fluorescence spectroscopy." Additionally, Ridder does not limit his application to vehicles. Instead, he claims an apparatus for "initiating an action responsive to an individual entering or leaving a controlled environment." This is a very broad claim that includes applications within alcohol treatment facilities, hospitals, prisons, aircraft, courts and factories. Ridder also uses multivariate analysis, using a "neural network, K-nearest neighbors, discriminant analysis, classification analysis, and principal components analysis, partial least squares regression, classical least squares regression, logistic regression, nonlinear regression, or a combination thereof." Due to Ridder's focus on expansive, generalized claims, the breadth of this patent is enormous. An image from Ridder's patent showing his method of using various angles for better light collection is displayed below as Fig. 1. Furthermore, the actual product being marketed by TruTouch Technologies, Inc. can be found at http://trutouchtechnologies.com. TruTouch has one primary product called the TruTouch Guardian. TruTouch advertises the Guardian as being capable of creating its own biometric profiles and printing and communicating its results. EnPRO 351 should keep this in mind as they explore novel ways of building and using its alcohol detection device.

Figure 1

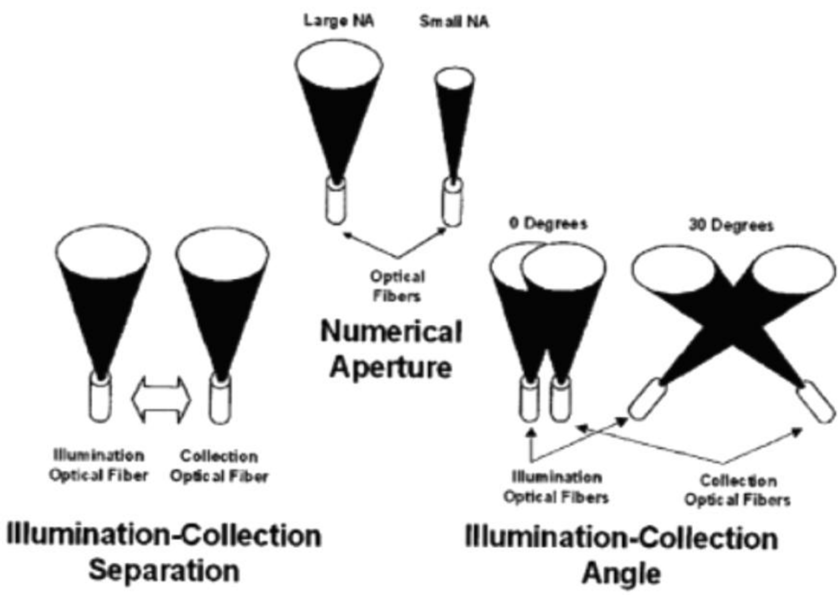
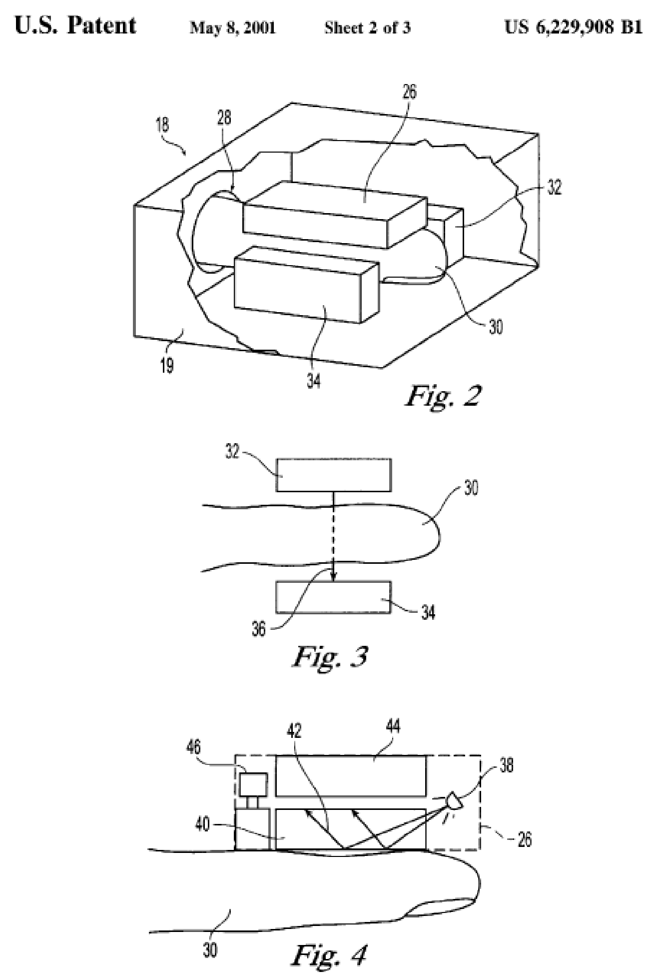


Fig. 13

Patent 6,229,908: "Driver Alcohol Ignition Interlock"

This patent was filed in 1997 and granted in 2001 to two inventors from Virginia. The protectable term of this patent ends in 2017. In this patent, the inventors Edmonds and Hopta disclose an ignition interlock incorporating a spectroscopic alcohol measurement of the finger (or a "bodypart") and a method for generating a fingerprint image. The spectroscopic measurement of the bloodstream is conducted by passing a light through a finger into a sensor on the opposite side. In this patent, the fingerprint image is taken with an automated system and is distinct from the spectroscopic measurement, increasing the potential for user-circumvention. A representative image taken from this patent is attached to this report as Fig. 2.

Figure 2



Patent 5,743,349: "Non-Invasive Optical Blood Alcohol Concentration Reader and Vehicle Ignition Interlock System and Method"

This patent was filed in 1996 and granted in 1998 to an inventor from Arizona named Steven Steinberg. Although Steinberg's patent term would have lasted until 2016, this patent has since been abandoned (according to Trent Ridder, inventor of patent 7.616,123). At any rate, Steinberg discloses a vehicle ignition interlock that uses a spectroscopic means for noninvasively measuring blood alcohol concentration. This patent does not disclose any method of identifying the tested individual. Steinberg also discloses using electromagnetic radiation in the 250 to 3000 nm wavelength range by introducing radiation to a finger and measuring the light exiting on the opposite side of the finger. A representative diagram from the patent is displayed below as Fig. 3.

Figure 3

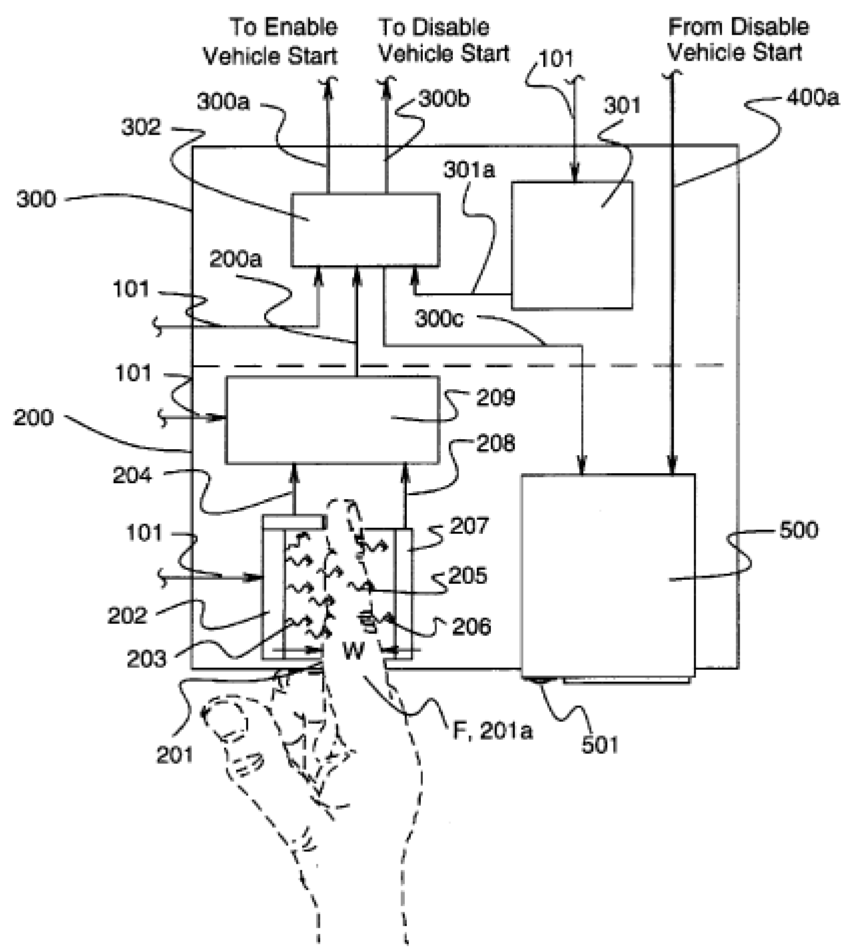


Fig. 2

Patentability – Legal Discussion

In order for EnPRO 351 to distinguish its device from the patents that were just described, it must improve upon them. This can be accomplished by focusing on the specialization and refinement of its original idea.

In patent law, an invention is patentable if it is new, useful and non-obvious. In order for a patent to be "new" or "novel," it must not be anticipated by a prior patent. A device is anticipated when each and every feature of the device is expressly or inherently disclosed by a *single* existing patent or other prior art reference. EnPRO 351 may actually have a good chance at proving that its existing idea is not anticipated by any prior patents or any other published materials. It can accomplish this with even the smallest differences, such as the sensor placement or wavelength preferences. Furthermore, an existing patent can only anticipate if it enables a person of ordinary skill in the art to build the claimed invention. If EnPRO 351 truly believes that an existing patent is impossible to make, it may argue that said patent cannot anticipate its own device.

The test for determining whether a device is "useful" is very easy to meet and requires only specific and substantial utility. These requirements will be surely be met by any type of alcohol-detection device purposed for legal or industrial use.

EnPRO 351's final hurdle is non-obviousness. This is where the current device will run into the most trouble. A device will be considered obvious when a person of ordinary skill in the art does not find an "inventive step." In practice, examiners at the patent office will combine the ideas from multiple patents in order to determine whether something is non-obvious. Looking at the patents described above, there is a blood alcohol detector, a finger-print detector, and many different methods and functions for determining blood alcohol concentration. Patent 7,616,123, owned by TruTouch Technologies, Inc. will be the primary problem for EnPRO 351 because it discloses so many different embodiments and uses for its device. Any examiner would find that EnPRO 351's current device is obvious in light of this patent alone. In order for EnPRO 351 to jump this final hurdle, it must come up with a specialized design that has not been contemplated by the existing patents.

Possible examples of novel and non-obvious innovations may include:

(1) Using the unit in hospitals and integrating it with a series of other, commonly performed tests. The unit may have specialized connections or may perform more than one test at a time.
(2) Integrating the device with factory machinery (forklifts, industrial saw, etc.) in such a way that a supervisor may be alerted, or that a substitute worker will be called to the station. The device may be specially made to withstand harsh, industrial conditions or to be installed and maintained on moving vehicles.
(3) Creating a combination alcohol/drug detection unit for use in public schools. Students on sports teams or extracurricular activities may have to pass tests the

night before major events. The unit may record the results and send them to the proper coaching authority.

(4) For people who want to monitor their own health, create a device that records data over long periods of time (months, years) and gives recommendations for healthier living. This data may even be monitored by health insurance companies so that individuals may retain cheaper coverage for maintaining good, healthy behavior. (Admittedly, this idea raises some privacy concerns).

Conclusions

If EnPRO 351 is able to come up with a specialized use that requires a custom design that has not been disclosed or contemplated by the prior patents, it may have a chance at creating a successful, non-infringing product. Although TruTouch Technologies, Inc. has already built, tested, and released a patented product, the Guardian is bulky and heavy, making it inefficient for use in automobiles. If EnPRO 351 still plans to enter the automobile-interlock market, it should focus on a design that is smaller, lighter, and more adaptable to a vehicle's interior design. Note that EnPRO 351 may only gain protection for the part of its final design that is novel and non-obvious. EnPRO 351 may also gain an edge over the competition through the personalized service it plans to offer its target markets of parents and private business. Unfortunately, providing better service will not eliminate the legal patent problems being faced by EnPRO 351. If the final design incorporates any of the elements described in the existing patents, those elements must be licensed from the proper assignees.

8.2 Prototype Research

Analysis and Findings

The Alcometre is a non-invasive device that is used for measuring the alcohol concentration in the blood. The principle operator for detecting BAC with the Alcometre is by measuring the absorption of red and infrared light that passes through a user's finger by utilizing infrared light and photo sensors. The first step to building a device that will detect BAC using IR is to understand how the device works. Since we where treading in unchartered territories we found it necessary to reverse engineer a pulse oximeter. A pulse oximeter is used in the medical industry to detect oxygen concentrations in the blood. We focused our efforts in understanding the operation of oximetery so that we could affectively apply that knowledge to developing a device tuned towards our application.

Spectrophotometers

Spectrophotometery is the basis for all Oximeters. The atoms of all molecules vibrate in specific patterns for each unique substance. As light passes through a substance, the frequencies of light similar to the vibration frequencies of the substance, are absorbed. A spectrophotometer measures the intensity of light transmitted through a particular substance at particular wavelengths. The fraction of light absorbed at a specific wavelength is determined by the absorptive, or extinction coefficient, of the substance. The extinction coefficient of a substance can be graphed at various wavelengths as a spectrum. This spectrum is unique for every substance.

The second major component is a photo detector. A photo detector is a device that converts light intensity into an electric current. A given intensity of light transmitted through a substance produces an electric current proportional to the intensity. By measuring the intensity of incident light on a substance (IO) and measuring the intensity of light transmitted through the substance (I), the transmittance (T) of the substance can be calculated:

$$T = \frac{I}{I_0}.$$

Because each molecule absorbs an equal portion of light, the absorbance of light through a substance is linearly related to the concentration of substance present. From the measured transmittance (T), the absorbance (A) can be calculated from

$$\boldsymbol{A} = \boldsymbol{2} - \log (\%T)$$

Beer's law can now be used to find the amount of substance in a solution. Beer's law can be stated as $A = \varepsilon(\lambda)\ c\ d$

Where $\boldsymbol{\varepsilon}$ (A) is the extinction coefficient of the substance at a given wavelength (A) of light, d is the length of the light path, and *c* is the concentration of the substance. For all substances, the linear relationship between absorbance and concentration only holds up to a certain concentration. Below this limit we can determine a calibration constant. The calibration constant can then be used as a standard to determine the unknown concentration of a substance with the same extinction coefficient as the standard.

For a solution with two unknown compounds, the absorbencies at two wavelengths can be used to calculate the concentrations of both compounds. At the isosbestic point, where the two extinction coefficients are equal, Beer's Law for the two samples can be written as

$$d = \frac{A_{\text{ec}}}{[c_1 + c_2]\varepsilon(\lambda_{\text{ec}})}$$

Where A is the absorbance at the isosbestic point and E (ε) is the extinction coefficient of the two substances at the isosbestic point. At the second wavelength Beer's Law gives

$$A0 = d[cl\, \varepsilon\, l(\lambda O) + C2\, \varepsilon\, 2(\lambda O)I$$

Where A0 is the absorbance and $\varepsilon\, 1(\lambda 0)$ and $\varepsilon\, 2(\lambda 0)$ are the extinction coefficients for the two compounds at the second wavelength.

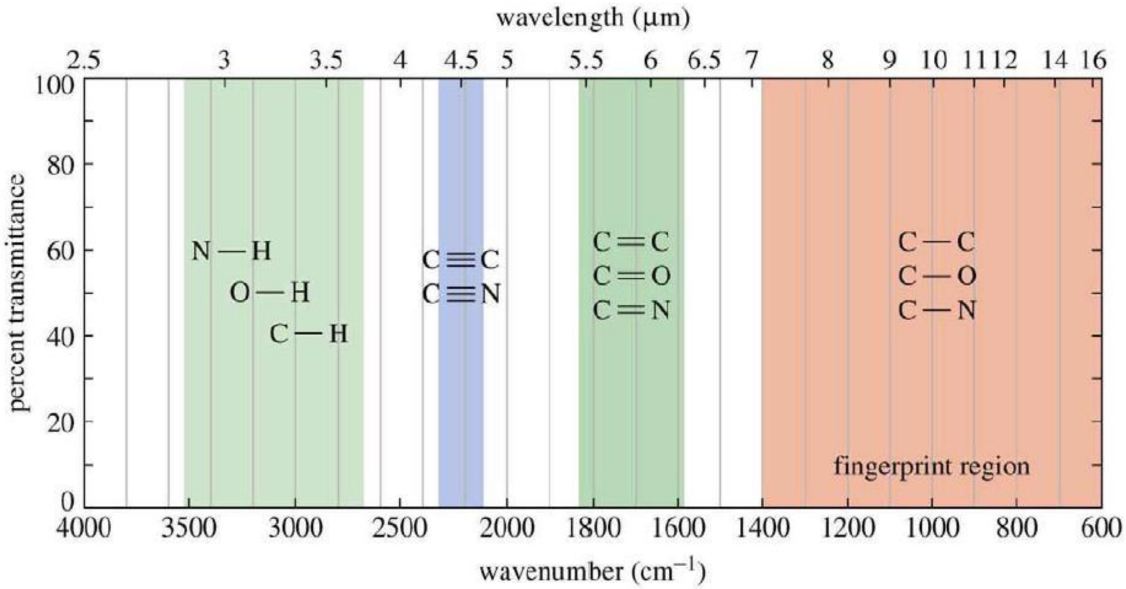
Pulse Oximeters

The idea of exploiting the pulsate nature of arterial blood using oximetery first belonged to Takuo Aoyagi while working in Japan for Nihon Kohden Corporation (Severinghaus 1987). Nihon Kohden's device used analog circuitry, had bulky fiber optic cables, and still had some of the instability problems of the Hewlett-Packard device. Other companies such as Minolta came up with similar products with similar problems (Santamaria and Williams 1994).

An anesthesiologist named William New saw the pulse oximeter marketed by Minolta and saw how to improve it. New, also an electrical engineer, teamed with Jack Lloyd to found Nellcor, Inc. Nellcor produced a microprocessor-based pulse oximeter, the N100, which was smaller, less expensive, needed no user calibration, and was accurate enough for clinical use. Nellcor is still the market leader in pulse oximetry (Santamaria and Williams, 1994). About the same time, Ohmeda came up with a similar device, the Biox 11**,** which had similar success (Wukitsch *et a1* 1988). Today, pulse oximeters exist in every intensive care unit, surgical suite, and in many emergency rooms in the United States (Santamaria and Williams 1994)

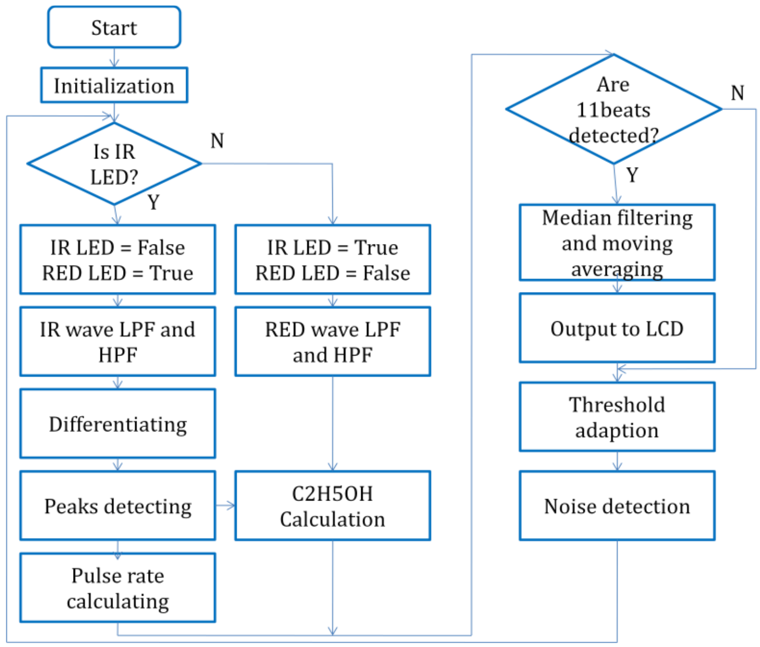
LEDs

One of the large improvements of the pulse oximeter over earlier products is the use of light emitting diodes(LEDs) as the light source. The LEDs can transmit large intensities of light proportional to the amount of drive current. The LEDs are capable of operating within the wavelength range of 600nm-4000nm. The figure below displays the region that is optimal for detecting a substance in the fingertip.



(Figure 1)

The LED control block is depicted below in Figure 2. It displays the controls of the LEDs. The amount of drive current and the timing of the LEDs are critical. The timing of the pulsations and the photodiode cannot distinguish between different wavelengths of light. The pulse oximeter relies on the microprocessor system to synchronize the pulsations of the LEDs with the samples taken by the ADC so that the absorbance's detected by the photodiode can be attributed to the correct LED.



(Figure 2)

Photodiode

The photodetector is a silicon photodiode that produces current linearly proportional to the intensity of light striking it. Advances in silicon technology have allowed the photodiode to be small enough to fit in small, finger tip probes. These advances have helped make the pulse oximeter much more accurate and convenient than earlier devices. Early oximeter devices needed frequent calibration because the photoelectric devices used as sensors were often inconsistent (Miller 1966).
A photodiode cannot distinguish between red and infrared light, but to accommodate this, the microprocessor system alternately turns each LED on and off. The pulse oximeter repeatedly samples the photodiode output while the red LED is on, while the infrared LED is on, and while both are off. By sampling with both LEDs off, the pulse oximeter is able to subtract any ambient light that may be present (Pologe 1987).

Conclusions and Recommendations

The research that was conducted by others has shown that BAC can be dectected using IR. Unfortunately, we were unable to produce a working device that can detect BAC. The Intoxilyzer and the TruTouch Guardian is proof enough that it is possible to detect BAC using light. We also discovered several patents that are written in such a way that is almost describes our product perfectly.

The Alcometre is an incredibly complex product that can have a variety of applications. Originally, we intended to integrate biometrics into the Alcometre so it would add another layer of safety and precaution. As the semester progressed it became painfully clear the size and scope of this project went beyond what we were capable of completing in one semester.

We were able to build a simulation automotive ignition switch that is ready to accept the working sensing technology. The circuitry associated with the successfully building of the sensing technology went beyond the current knowledge base of the students in this IPRO. It would invaluable to have a technical liaison who has experience with electronics and/or IR spectrography.

The prototype for the Alcometre uses the concepts of infrared and near infrared spectroscopy in order to read oxygen saturation in the blood. The intended function of the prototype is to use spectroscopy in order to read the blood alcohol content of the user. The current prototype is a demonstration of how the technology will work. The difference between detecting oxygen and detecting alcohol is a shift in the electromagnetic spectrum. Minor adjustment to the oxygen sensing device can be made to correctly detect specific components in the blood that would give us an accurate BAC reading.

The prototype itself is a complete proof of concept. The idea to use light in order to measure the amount of alcohol in the blood is entirely understandable given that it can be used to detect another substance such as oxygen.

The recommend course of action for the prototype is to continue to develop and enhance the appearance and technological capabilities of it. The first step is to include the ability to read blood alcohol concentrations, rather than oxygen saturation in the blood. Once this is accomplished, enhancements on efficiency followed by functionality and finally appearance must be made.