

# Clinical Evaluation of a Novel Interstitial Fluid Sensor System for Remote Continuous Alcohol Monitoring

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**Abstract**—This study describes the functioning of a novel sensor that measures the alcohol concentration in the interstitial fluid (ISF) of a human subject. ISF is extracted using vacuum pressure from micropores on the stratum corneum layer of the skin. The pores are created by focusing a near infrared laser on a layer of black die attached to the skin. This poration procedure is essentially painless. Clinical studies show that the sensor readings are correlated with alcohol levels in blood and collected using a breathalyzer. Alcohol could be detected in the subject's ISF within 15 min of the first oral intake of alcohol. Tests in a laboratory setup show that the sensor exhibits a linear response to alcohol concentrations in the range 0%–0.2%. The sensor is minimally invasive and alcohol monitoring using the sensor was shown to continue even when the subject is asleep. The sensor is viable for approximately three days after skin poration. The sensor is interfaced to a wireless health monitoring system that transfers sensor data over existing wide-area networks such as the Internet and a cellular phone network to enable real-time remote monitoring of subjects.

**Index Terms**—Alcohol monitoring, biological liquids, biomedical transducers, medical services, wireless LAN.

## I. INTRODUCTION

SAMPLING OF biochemical markers in the body plays an integral role in the diagnosis and management of several diseases. Measurement of metabolite concentrations in blood is the most common technique as it indicates the homeostatic level of the metabolite and the relative ease with which blood can be sampled in a clinical setting. However, due to its invasive nature, blood sampling is less suitable for use in nonclinical settings, especially when a continuous measurement is desirable. For instance, regular blood glucose monitoring is the primary means of ensuring glycemic control in diabetics [1]. However, diabetics often do not adequately monitor their blood glucose

as part of a self-care program [2], [3]. Therefore, there is significant value in developing less invasive means of metabolite sampling.

A less invasive and bloodless method for metabolite monitoring involves sampling interstitial fluid (ISF). ISF is an extracellular fluid that surrounds the cells in the human body. In composition, it is similar to blood plasma. Metabolites and proteins move into ISF as they move from capillaries to cells. Consequently, the metabolite concentration in ISF is correlated to their concentration in the capillaries. The difference in concentration is based in part on molecular weight [4], [5]. Clinical tests involving diabetic patients have shown that the correlation between ISF glucose concentration and blood glucose levels is as high as 0.90 in the 60–400 mg/dl glucose range [6]. In two separate studies using this methodology, Gebhart *et al.* reported correlations of 0.87 and 0.95 between blood and ISF glucose [6]. This technique has also been successfully used for continuous monitoring of glucose [7], [8]. In general, small to moderate sized molecules, including glucose and ethanol, are found in ISF in the same proportion as in blood. Thus, periodic calibration using blood sampling is not required to obtain the concentration of these metabolites from ISF. (Larger molecules such as certain lipids also are detectable in this body fluid, but at a reduced concentration relative to blood [9]–[11].) In this work, we demonstrate a new technique for ISF sampling for the purpose of continuous monitoring of alcohol concentration in the human body.

ISF is present just below the skin, but the low permeability of the epidermal keratinized layer (the stratum corneum) blocks the permeation of the fluid through the skin. In this paper, we describe a minimally invasive technique to access the ISF through the skin and measure metabolite concentrations in the collected fluid. The method applies a low-energy laser to create micropores in the stratum corneum, the uppermost layer of dead cells. The diameter of the micropores is approximately equal to that of a human hair (Fig. 1). The micropores only penetrate the stratum corneum and, hence, this procedure is essentially painless. ISF is drawn through these micropores continuously by application of a small amount of vacuum pressure. The ISF passes over an electrochemical system that is designed for sensing the desired metabolite concentration. We have developed a sensing system that can continuously measure ethanol. The sensor has a linear response between ethanol concentrations 0% and 0.2% with a resolution of 0.01%.

Our technique offers several advantages. The ISF extraction method enables an analysis of the complete ISF and not just

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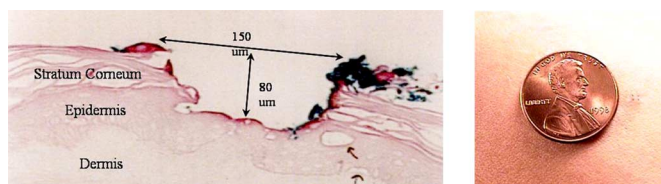


Fig. 1. Left: Cross section of a micropore. Note that the pore does not extend to the dermal layer. Right: Four pores relative to the size of a penny.

partial compositions. A relatively large amount of ISF is harvested (about  $10 \mu\text{l}$  per hour), so that the requirements for the sensor system are relatively liberal. Ethanol concentration can be directly measured by conventional assay techniques such as the alcohol oxidase method. The continuous monitoring system is usable for three days at a time, before the micropores become unusable due to healing. Moreover, the site of ISF extraction patch can be almost anywhere on the human body (arms, abdomen, legs) with no loss of accuracy. The application of vacuum pressure to extract ISF also significantly reduces the integration time required for accurately determining the metabolite concentration. Thus, it is possible to measure the time profile of the metabolite concentration. The lag between blood and ISF levels can contribute significantly to measurement error in continuous monitoring systems. Philip *et al.* show that mitigating this physiological lag is an important means for improving the accuracy, and hence the clinical utility, of continuous monitors [12]. They collected two ISF samples; one was collected using modulated pressure application (test ISF) and the second by using no perfusion elevation technique (control ISF). Average lag times (mean  $\pm$  SD values) between the two ISF samples and finger capillary blood glucose were determined to be  $38.3 \pm 11.5$  and  $2.5 \pm 6.6$  min, respectively, for the control and test ISF samples. Modulated pressure application mitigated the ISF physiological error by an average of 95% in this test. Data from our human subject trials show that the lag between our sensor readings and blood alcohol concentration is less than 12 min. This makes our system particularly suitable for real-time monitoring applications.

We have also developed a custom wireless data acquisition and transmission system that enables real-time monitoring of sensor data from a remote location. The ISF sensor is packaged with our custom miniature RF transceiver that is worn by the subject. The sensor readings are received by a portable base station (cell phone or PDA) that is either carried by the subject or placed within RF range. The base station in turn transmits data to a remotely located observer over a long-range network (Internet or cell phone network) for real-time monitoring and long-term storage. This system thus enables real-time, minimally invasive, monitoring of the subject's alcohol consumption over a large geographical area. Fig. 2 shows an overview of the different components of the system.

We expect several possible applications for a minimally invasive alcohol measurement device. For instance, real-time remote monitoring of a subject's ethanol concentration will enable new approaches in criminal justice applications (monitoring DWI/DUI offenders) and in the treatment of alcohol abuse and addiction. Long-term alcohol sensors will also be useful for monitoring operators performing critical tasks for

extended periods such as airline pilots, ship captains, and truck drivers.

## II. RELATED WORK

The relative ease with which metabolites are exchanged between plasma and ISF has led to research in transdermal glucose monitoring. However, the structure and physiology of the skin make transdermal fluid extraction difficult. Current techniques for transdermal fluid extraction employ different methods to compromise the barrier function of skin's outermost and least permeable layer, the stratum corneum. The GlucoWatch Biographer (Cygnus Inc., Redwood City, CA), measures glucose in ISF extracted through reverse iontophoresis, a process in which a weak electric current is employed to transport charged molecules through intact skin [13], [14]. Thus, the measurements are made without puncturing the skin. However, the slow transit time of the fluid through the skin produces a 20-min lag in the glucose reading as compared with blood glucose measurement. Moreover, this method requires periodic calibration with blood sampling (every day). The accuracy of the measurement is affected by the presence of sweat, and the low electric current passing through the skin may cause irritation [15], [16]. The MiniMed CGMS (MiniMed, Inc., Northridge, CA) consists of a sensor that is inserted just under the skin, usually at the abdomen. The sensor measures glucose concentration in ISF. While glucose concentration is measured at a high frequency, it has to be calibrated with blood glucose readings during the day. Thus, this device supplements invasive and noncontinuous blood glucose measurements [17]–[19].

Established alcohol measurement devices sample the breath, blood, or urine. Alcohol is metabolized relatively rapidly in the body and as these methods are not continuous, they are effective at detecting alcohol consumption only during a narrow window of time. In addition, blood sampling is invasive and breath sampling cannot be used for continuous monitoring. Recent research has led to the development of less invasive transdermal alcohol monitoring. The WrisTAS sensor (Giner, Inc., Newton, MA) continuously estimates ISF alcohol concentration by measuring vapor phase ethanol above the skin [20]–[22]. The ethanol vapors are oxidized and the resultant electrical current is calibrated to estimate blood alcohol concentration (BAC). The device shows a delayed response compared with true BAC (the peak readings are separated by approximately one hour [20]). This sensor can be worn for an extended period to track alcohol consumption over days or weeks. The Secure Continuous Remote Alcohol Monitor (SCRAM) bracelet (Alcohol Monitoring Systems, Denver, CO) measures alcohol concentration in the subject's sweat. The sensor readings are correlated to BAC but the peak sensor reading lags between 2 to 3 h compared with the peak BAC reading [23]. The large delay in response makes these sensors unsuitable for real-time monitoring. Ethanol concentration has been detected by using a low-power piezoresistive microcantilever [24]. Cantilever bending is proportional to the local ethanol concentration. This system has so far been tested on a phosphate-buffered saline solution (pH 7.4), a simulation of ISF.

Optical techniques to monitor metabolites are truly noninvasive. Dermal tissue is irradiated and the absorbed or scattered

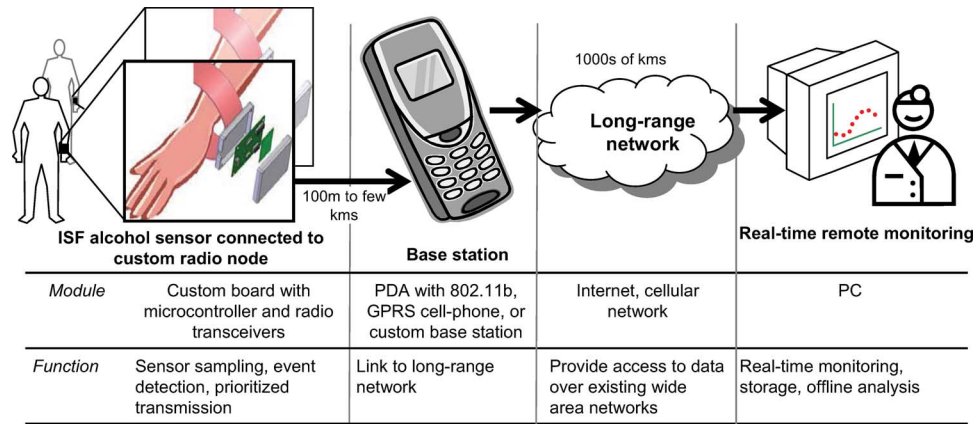


Fig. 2. Overview of the real-time monitoring system showing the sensor, short-range communication to the portable base station, and long-range data transmission to a remote location. The base station can either be dedicated to one subject or shared between multiple sensors.

radiation is analyzed to provide a measure proportional to the concentration of the desired metabolite in the tissue. Recently, TruTouch, Inc. (Albuquerque, NM), has developed a near infrared (NIR) spectroscopy-based technique to measure alcohol concentration *in vivo* [25], [26]. Issues that have to be addressed include characterizing the variation in optical properties of tissue within and among subjects. Experimental results indicate accuracy comparable to breathalyzer measurements. The physical size of the sensing apparatus makes this approach not applicable for continuous monitoring. Large-scale studies in support of these methodologies are as yet unavailable. Raman spectroscopy has also been demonstrated as a means of obtaining quantitative ethanol concentration in lipid tissue phantoms [27].

In our approach, the NIR laser is used only for creating the micropores on skin. The actual measurement of analyte (alcohol) “signature” (concentration) in ISF is performed with an electrochemical sensing system unlike the NIR technology, which uses infrared light to optically extract the analyte’s “signature” from ISF. Our electrochemical system is comparable to those systems currently being used successfully by diabetic individuals to monitor glucose levels either by fingerstick blood testing or ISF-based subcutaneous sensors [7], [8], [28], [29]. In contrast, NIR *in-vivo* optical technology has been proposed to monitor blood glucose level by passing infrared light in the 2–2.5  $\mu\text{m}$  wavelength range through a patient’s finger (or other body part) and sensing the amount of scattered light. This type of sensing system uses signal processing techniques to extract spectral data in the NIR scattered light. Complex digital filtering and multivariate statistical algorithms are used to extract the glucose “signature” from the complex mixture. For example, the concentration of blood glucose is determined using an artificial neural network [30], [31]. This method has been reported to have problems with signal-to-noise ratio. The main contributors of noise with NIR glucose sensing are the effect of skin optics, water absorption path length variations besides the environmental factors such as temperature and probe pressure. These problems do not affect the electrochemical sensor approach that has been adopted in our work.

Research is also being carried out to make blood sampling minimally invasive. Kumetrix, Inc. (Union City, CA), has de-

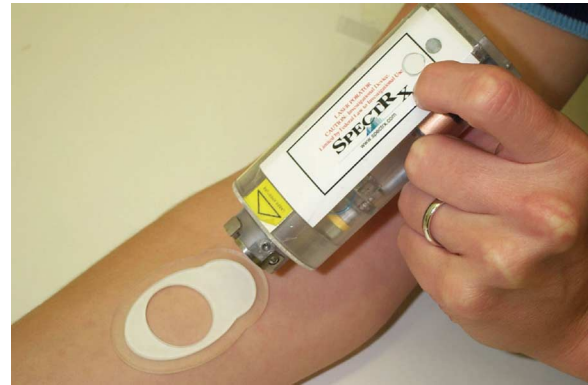


Fig. 3. Micropores are made using a handheld laser source focused on a layer of black dye attached to the skin. The concentrated energy then painlessly removes the upper level of dead skin cells (stratum corneum).

veloped a silicon microneedle that can sample the bloodstream painlessly [32]. The microneedle has the diameter of a human hair and can penetrate the skin painlessly. The main advantage of this technique is that metabolite concentrations in blood are often considered the “gold standard.” Assays have been developed for measuring glucose and lactate concentrations [32], [33].

### III. DESCRIPTION OF THE SENSOR SYSTEM

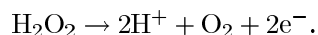
The first step in harvesting ISF is to porate the upper nonviable layer of the skin known as the stratum corneum (Fig. 3). A skin alignment ring is placed on the site (typically forearm or abdomen) and the distal end of the handheld laser porator is positioned inside the ring. The ring also ensures proper alignment of the fluid harvesting unit and the micropores. Ablation of the stratum corneum is performed by focusing a NIR laser on a layer of black dye material affixed to the skin by an adhesive. The interaction of the light at the dye layer causes a pyrotechnic event creating tiny pores (micropores) in the stratum corneum. The micropores are about the diameter of a human hair and remain viable for up to three or four days until healing occurs. The array of barely visible micropores ( $<100 \mu\text{m}$  in diameter) acts as a channel for ISF to be drawn into the fluid harvesting unit. Duration of the poration process is less than three seconds. Note

that by limiting the poration to only the outer layer of cells, the nerves and capillary bed, present in the layers 200 to 400  $\mu\text{m}$  below are not affected, allowing the process to proceed with minimal sensation and without blood loss.

Under vacuum pressure (6 to 9 inches of mercury) provided by an electromechanical pump, ISF is drawn continuously at a rate of about 10  $\mu\text{L}$  per hour into the harvesting unit which is affixed to the skin with medical adhesive. The harvesting unit contains the ethanol assay system. This is an electrochemical system that quantifies the  $\text{H}^+$  concentration in the collected ISF. Alcohol oxidase (AOX) is immobilized [34]–[36] on planar electrode surfaces. The immobilization method including additives and the sensor electrode design is proprietary (SpectRx, Inc., Norcross, GA). The amount of ethanol is estimated by measuring the formation of  $\text{H}_2\text{O}_2$ . AOX catalyzes the reaction



In the polarization voltage range from +0.6 to +0.7 V,  $\text{H}_2\text{O}_2$  is reduced at the anode



The electrochemical system quantifies the  $\text{H}^+$  concentration in the collected ISF. Thus, the oxidation current is a direct measure of local ethanol concentration. The sensor resides in a disposable collection device outside the body. This protects the sensor from effects such as platelet attachment that degrade sensor performance. The excess fluid exits the harvesting unit and is stored in a waste fluid depot until disposal. This fluid may also be used for external testing of alcohol using other commercially available alcohol measurement devices.

#### IV. SENSITIVITY TO ALCOHOL

##### A. Human Subject Trials

**Subjects:** Four subjects, aged between 21 and 30 years who had consumed four or more drinks in one setting previously were recruited for the study. The experimental protocol and devices were approved by the Office of the Institutional Review Board, Boston University Medical Center. Written informed consent was obtained from all the subjects.

**Protocol:** After arrival at the test center, the subjects ate a meal to ensure that they would not be dosed with alcohol on an empty stomach. Food consumption ended at 2 p.m. and participants did not eat until alcohol dosing was completed (8 p.m.). At approximately 4 p.m., the microporation process described earlier was performed on the forearm and the ISF ethanol sensor was attached at this time. ISF sensor readings (ISFAD) were sampled at 1 min intervals from this time. Baseline blood alcohol (BAC) and breath alcohol (BrAC) levels were taken at 30 min intervals from 4pm. Alcohol dosing using commercially available strong (7.2%) beer started at 6 p.m. The dose amount is determined based on the subject's sex and weight using data derived from previous studies. Each alcohol dose is expected to increase the BAC by 0.02%. Dosing is repeated at 25 min intervals four more times (when BAC is expected to reach approximately 0.10%). BAC and BrAC readings are taken 20 min after every dose and at 30 min intervals after the last dose until

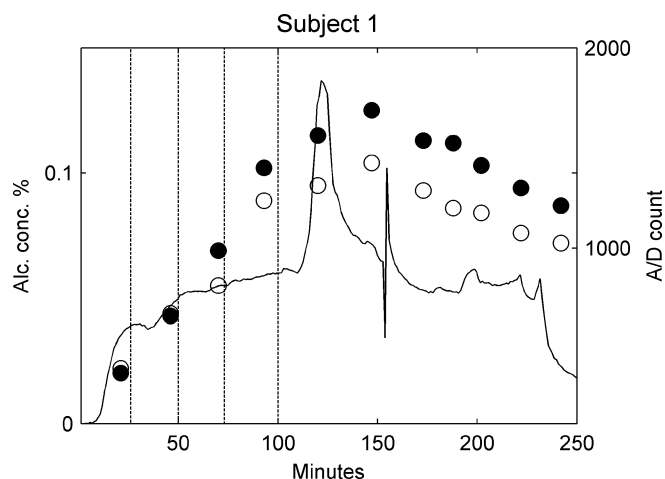


Fig. 4. ISFAD (solid line), BAC (filled circles), and BrAC (unfilled circles) readings from subject 1. The dashed lines indicate times of the alcohol doses.  $t = 0$  corresponds to first dose.

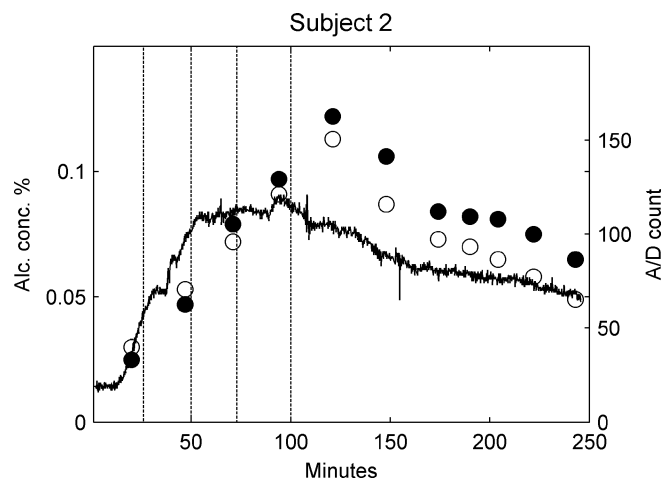


Fig. 5. ISFAD (solid line), BAC (filled circles), and BrAC (unfilled circles) readings from subject 2. The dashed lines indicate times of the alcohol doses.  $t = 0$  corresponds to first dose.

10 p.m. Subjects spent the night at the Center with the ISF sensor attached.

**Results:** One of the subjects was unable to complete the protocol satisfactorily, hence, only data from three subjects (female, weights 85.6, 68.5, and 72.2 kg) are shown. Figs. 4–6 show ISFAD and the BAC and BrAC measurements taken from the three subjects during the protocol. The numerical value of the ISF sensor is the output of an A/D converter and is proportional to the measured current. Two of the blood samples from the third subject were incorrectly recorded (Fig. 6). These samples are excluded from the data analysis. The Pearson's correlation coefficients between ISFAD and BAC of the three subjects are 0.866 ( $P < 0.01$ ), 0.788 ( $P < 0.01$ ), and 0.7203 ( $P < 0.02$ ), respectively. The correlation coefficients between ISFAD and BrAC are 0.894 ( $P < 10^{-3}$ ), 0.853 ( $P < 10^{-3}$ ), and 0.814 ( $P < 10^{-2}$ ), respectively. The correlation coefficients between BAC and BrAC (the two means of determining "ground truth") are 0.993 ( $P < 10^{-7}$ ), 0.975 ( $P < 10^{-7}$ ), and 0.981 ( $P < 10^{-6}$ ), respectively. There were periods when there was a large increase in ISF sensor readings (Subject 1: 120, 155 min). These were

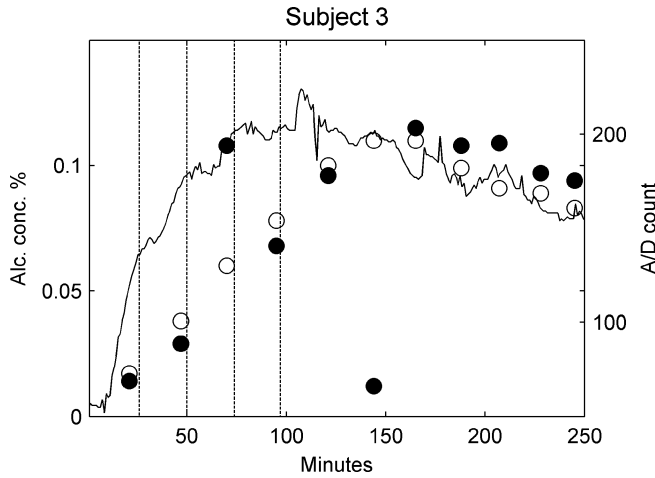


Fig. 6. ISFAD (solid line), BAC (filled circles), and BrAC (unfilled circles) readings from subject 3. The dashed lines indicate times of the alcohol doses.  $t = 0$  corresponds to first dose.

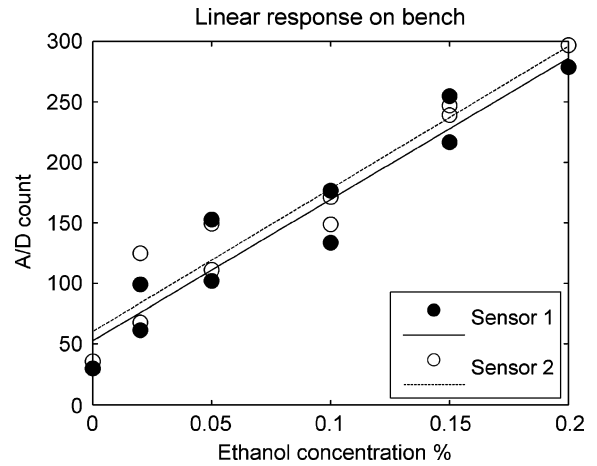


Fig. 8. Linear response of the ISF sensor to ethanol concentration.

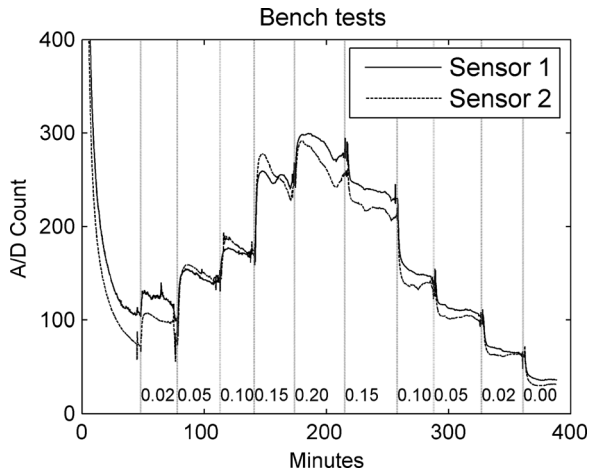


Fig. 7. Calibrating the response to ethanol of two sensors. Vertical lines indicate times when concentration of alcohol was changed.

the result of unexpected sensor disconnection from the measurement leads.

**B. Response to Ethanol in Laboratory Setting**

Two sensors were reversibility tested with the following ethanol concentration solutions: 0 (buffer), 0.01%, 0.02%, 0.05%, 0.10%, 0.15%, and 0.20%. Fig. 7 shows the response of the sensors to these alcohol concentrations. The meter readings of these sensors after settling at each of the different ethanol concentrations are shown in Fig. 8. The meter readings from both the sensors were positively correlated with ethanol concentrations ( $r = 0.9547, P < 0.0001; r = 0.9618, P < 0.0001$ ).

**C. Human Subject Trial With Multiple ISF Ethanol Sensors**

The two sensors that were characterized in the laboratory were subsequently used on a human subject. Written informed consent was obtained from the subject and Schulman Associates IRB (Cincinnati, OH), approved the protocol. The dosing protocol described earlier was followed with the exception that blood was not sampled. The two sensors were attached next to each other on the forearm. The readings recorded by the two sensors were scaled using the slope obtained from the best-fit

**Simultaneous measurements from two ISF sensors**

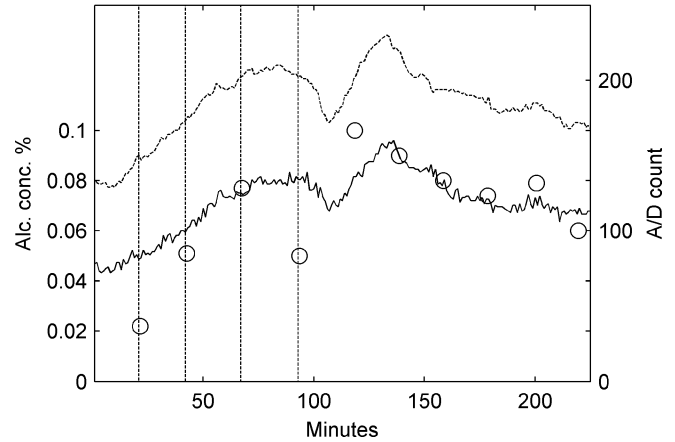


Fig. 9. ISF sensor readings (solid and dashed lines) from a human subject trial after calibration using laboratory test data (Fig. 7). BrAC is indicated by unfilled circles. The vertical dashed lines indicate times of the alcohol doses.  $t = 0$  corresponds to first dose.

linear response observed in the reversibility test of these sensors (Fig. 8). This converts the sensor readings into equivalent BrAC values. These are plotted with the corresponding breath alcohol measurements in Fig. 9. The subject consumed a smaller amount of alcohol compared with the other doses during the fourth dosing interval. Hence, there is a decrease in the alcohol concentration as measured by both the breathalyzer and the ISF sensor at the end of the fourth dose. The sensor readings are positively correlated with the breath alcohol measurements ( $r = 0.879, P < 10^{-4}; r = 0.878, P < 10^{-4}$ ).

**V. DISCUSSION**

The sensor readings in both laboratory settings and on human subjects after alcohol consumption are strongly correlated with corresponding blood/breath alcohol measurements. The sensor readings from two of the subjects in the first trial (Figs. 5 and 6) appear to lead the blood alcohol concentration in time. This apparent lead is an artifact of the scaling used in these plots as the sensor readings are not calibrated to show blood alcohol concentration. When the sensors were modified to exhibit a more linear response to ethanol concentrations most commonly found in the human body, the sensor readings follow the breath alcohol

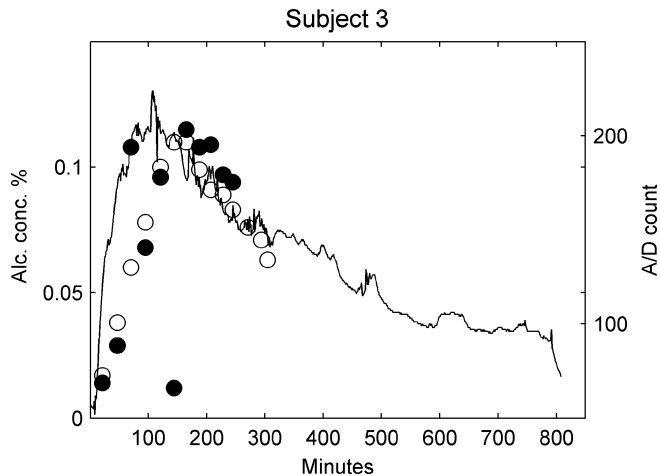


Fig. 10. ISF meter is able to continue recording measurements even when the subject is asleep (when breath and blood sampling is not possible). Filled and unfilled circles represent BAC and BrAC respectively.

measurements in time as expected (Fig. 9). Data from the laboratory experiments (Fig. 8) show that the linear response extends from 0% to 0.2% ethanol concentrations. The reversibility tests conducted on the ethanol sensors indicate that the sensor response to a particular ethanol concentration varies with time (Fig. 7). This sets the limit on the maximum resolution of the sensor. In a laboratory setting, this was found to be less than 0.01%.

Ethanol rapidly diffuses into all water compartments and the total body water (TBW) of the subject is the chief determinant of the measured ethanol concentration. Physiologically based models of ethanol distribution in the human body [37], [38] indicate that ethanol is mainly absorbed from the stomach and then is transported by blood into all extra cellular compartments. Thus, the concentration of ethanol in ISF is expected to be equal to that in plasma but is delayed in time. Breathalyzer measurements are not accurate for the first 15 min after alcohol consumption due to the presence of residual alcohol in the mouth (the breathalyzer utilizes only the expired air from the lungs). Hence, it is not possible to measure the time of first appearance of alcohol in blood after alcohol consumption using the breathalyzer. On the other hand, the ISF sensor measures ethanol concentration continuously at frequencies over one sample/min, and even during the time when alcohol is consumed. From the first measurement of the ISF sensor reading corresponding to nonzero ethanol concentration in the human subject trials, we estimate this lag to be between 8–12 min. This delay is due to physiological reasons (time for alcohol to empty from the stomach and diffuse into TBW [39]) and also due to any dead space volume of the ISF collection device. Continuous measurement of ethanol concentration in ISF is thus a reliable substitute for frequent blood sampling. This is of particular importance to applications such as monitoring of operators of critical equipment where it is important to quickly detect the consumption of alcohol.

In the human subject trials, we were able to record ISF ethanol concentrations even while the subjects were asleep after the dosing phase of the protocol (Fig. 10). The “ground

truth” measurements of blood and breath sampling were not possible during this time as these require active participation from the subject. The ISF alcohol sensor can thus be used to track the evolution of alcohol in the body at a much finer time resolution than is possible with traditional schemes such as breath sampling. This demonstrates the possibility of uninterrupted monitoring of alcohol consumption in a human subject over multiple days using the ISF sensor.

The sensor chemistry is designed to exhibit a linear response to ethanol concentrations between 0% and 0.20% with a resolution of 0.01% (Fig. 7). The chemistry may be modified to exhibit greater resolution at the expense of linear range. Thus, it is possible to design two sensors whose linear ranges together span the 0% to 0.20% range, but with resolution greater than that possible from a single sensor. These two sensors can be simultaneously attached to a subject as in the human subject trial described earlier.

The data from the calibration experiments when the sensor was exposed to known concentrations of ethanol (Fig. 7) indicate that the sensor readings sharply increase when there is a sudden change in concentration. The sensor readings then gradually return to stasis. This effect is also visible in the human subject trial when the sensor is first connected and also during unexpected disconnections (Fig. 4). A considerable warm-up or settling time is associated with the current alcohol sensor. Thus, the sensor has to be connected to the subject a 1–2 hours before the desired measurement period to enable the sensor to settle into its baseline readings. We are currently modifying the sensor construction to reduce the settling time. Unexpected disconnection of the sensor from the measurement leads caused large spikes in the readings during the human subject trial (Fig. 4). We are designing a more robust connector which will ensure that movement expected during use in the field will not cause sensor disconnection.

The correlation between BAC and BrAC was found to be high. Thus, noninvasive breath sampling is an acceptable substitute for invasive blood sampling in human subject trials. We have also measured the response of the sensor to ethanol in ISF when the subject has also ingested possible confounders such as acetaminophen [40], [41]. No significant change in sensor readings was seen in the presence of acetaminophen. Uric acid and ascorbic acid have been found to affect interstitial glucose measurement [42]. We tested if the presence of uric acid, ascorbic acid, or glucose altered the ethanol sensor in a laboratory setting. The measurement system was not affected by these three chemicals. Hence, we do not expect the presence of these chemicals in the human body to affect *in vivo* alcohol measurement.

## VI. WIRELESS REMOTE HEALTH MONITORING SYSTEM

Our wireless wearable health monitoring system is designed to accommodate a wide variety of medical sensors with digital and analog interfaces, including commercial ones such as pulse oximeters or mobile ECGs, and custom sensors such as the ISF alcohol sensor. The wireless wearable monitoring system is novel in three major aspects compared with other wireless health monitoring systems: 1) on-board intelligent processing and resource management capability that enables autonomous

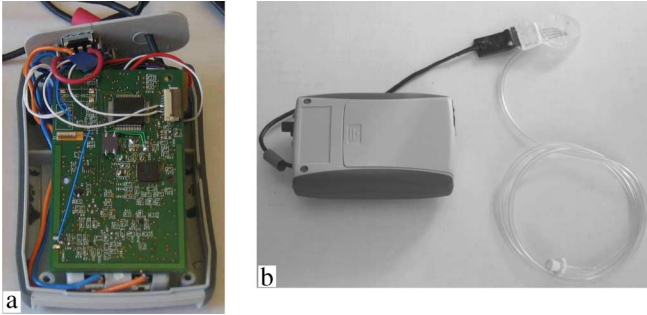


Fig. 11. (a) Prototype of the system containing the microcontroller and radio transceivers. (b) ISF alcohol sensor connected to Tier 1 hardware. (The tube to the vacuum pump is not connected.)

operation, dynamic adaptation of system bandwidth and communication resources in response to events, and *in-situ* event detection without compromising on power usage; 2) a new custom hardware board with frequency agile RF capability that enables robust communication over longer distances and in noisy environments; and 3) integrated cell phone capability in the system that allows remote monitoring across very long distances.

Our system is built as a three-tier system (Fig. 2), with the wireless wearable sensor at the first tier, a base station that acts as a relay point at the second tier, and a secure remote database at the third tier (see Fig. 2 for details of the functional architecture). The hierarchical layered architecture accommodates several individuals at Tier 1 to relay their medical data to a single Tier 2 base station; this facilitates use of this system in a hospital, old-age home, secured facility, or a mass emergency response scenario where several patients or individuals can share a single base station. The Tier 2 base station then relays data from the on-body ISF sensor(s) in real-time to a remote location over existing wide-area communication networks such as the Internet and the cellular phone network.

Our first version of the Tier 1 hardware [43], [44] involved the commercial Mica Mote (CrossBow Technologies, San Jose, CA) [45]. However, in order to achieve better flexibility in communication reliability and bandwidth, we have recently designed a custom Tier 1 wireless unit [Fig. 11(a)] that interfaces a low-power microcontroller (MSP430, Texas Instruments, Dallas, equipped with a CPU at 4–8 MHz) with a custom frequency agile and range agile radio circuit design capable of operating at the 900 MHz and 2.4 GHz radio frequency (RF) bands. The custom radio design allows RF data communication at distances ranging from a few meters to a few kilometers at varying bandwidth (1.2 to 412 Kb/s). The sensor, transceiver system, and interface boards are packaged into a unit that can be attached to the subject with minimal hindrance to daily activities. A photograph of the internal Tier 1 circuit is shown in Fig. 11(a) and a photograph of the unit interfaced to the ISF sensor is shown in Fig. 11(b). The Tier 2 base station is equipped with the same RF circuit and microcontroller as the Tier 1 board, and also has the additional capability to relay the information from the Tier 1 wearable sensor units to a remote database over a cell phone network (using the GSM standard), as shown in Fig. 2.

The entire system has been designed to conserve power in order to extend the useful lifetime of the system. The microcontroller and radio circuits are low-power devices that have been designed to operate at low current levels and can be put in a low-power consumption state when not being actively used. The current consumption when the radios are not transmitting is between 14–22 mA (depending on which transceiver is active) and between 20–130 mA during the periods of data transmission (depending on range and bandwidth). The current consumption in system standby mode is only 5  $\mu$ A.

Nevertheless, wireless communication is an energy intensive process and is often the limiting factor determining the lifetime of the system [46]. We have therefore developed embedded energy conservation algorithms that adapt the sampling and communication rates to the energy reserves of the system (*adaptive sensing*) [43], [44]. In addition, we have developed a wavelet-based lossy compression scheme that is used to reduce the amount of data transmitted during periods of low criticality. Algorithms have been developed to detect events or derive critical medical conditions from the measured signals. These algorithms are executed on the local microcontroller at each Tier 1 board. In this manner, our system is capable of intelligently trading off between the energy limits of the system and fast information throughput in real-time in response to medically critical events. At the receiving end, the data is displayed in close to real-time to the observer. In addition, this data is entered into a secure Internet-accessible database for offline analysis.

Similar systems have been developed to transmit medical sensor data over wireless links, but such systems have used off-the-shelf boards for short-range communication. For instance, the CodeBlue system [47] uses the commercial Mica and Telos platforms (CrossBow Technologies) as the basis for radio communication. The advantage of our custom design is that the frequency and range-agile radio are able to work more reliably in noisy environments and allow remote health monitoring at significantly greater ranges. Additionally, our embedded algorithms [43], [44], [48]–[50] explicitly adapt and regulate system resources to maximize the system lifetime; other available health monitoring systems [47], [51], [52] operate in a fixed-mode and typically do not adapt to changing situations.

## VII. FUTURE WORK

We are refining the parameters of the ISF harvesting process and assay technology so that the rate of ISF collection and the quantitative relationship between ISF and blood alcohol concentration meet the requirements for clinical accuracy.

We have obtained IRB approval to continue human subject trials. Future trials will involve additional subjects. The subjects will be between 21 and 65 years of age, in good health, do not have alcohol addiction tendencies, and nondiabetic. The total number of subjects for the entire protocol will not exceed 200. The purpose of future clinical trials is: 1) to evaluate developmental changes in the alcohol monitoring system and 2) to evaluate the effects of external factors acting either on the device or at the poration site. In these trials, the performance of

the sensor will be evaluated by comparing the alcohol concentrations obtained from our ISF sampling technique with conventional blood sampling.

### VIII. CONCLUSION

Measurement of alcohol concentration in human subjects by sampling ISF is a viable alternative to blood and breath sampling. The ethanol sensor described in this paper extracts ISF through micropores created on the skin using a relatively painless laser poration procedure. The sensor is minimally invasive, enables continuous monitoring of alcohol levels (even when the subject is asleep), and is useable for about three days before micropores heal. The sensor readings are correlated with alcohol levels in blood and alcohol could be detected in the subject's ISF within 15 min of the first oral intake of alcohol. A wireless health monitoring system that interfaces with the sensor uses existing wide-area networks such as the Internet and the cellular phone network to transmit data in real-time to a remote observer. Real-time remote monitoring of alcohol consumption using this sensor system will enable new approaches in criminal justice applications (monitoring DWI/DUI offenders), the treatment of alcohol abuse and addiction, and monitoring of operators performing critical tasks for extended periods.

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