TruTouch TECHNOLOGIES

THE FUTURE OF ALCOHOL MONITORING

TECHNOLOGY OVERVIEW

NO BODILY FLUIDS, NO DISPOSABLES, NO SUPERVISION

CONTENTS

SPECIAL POINTS OF INTEREST:

- Totally non-invasive: no blood, urine, saliva or breath involved
- Results in just one minute
- More accurate than urine tests; as accurate as the best breath devices
- An enrolled device that verifies testers' identity biometrically

NONINVASIVE TECHNOLOGY

TruTouch's technology combines the state-of-the-art in alcohol testing with an integral biometric identity verification capability. It is a 100% noninvasive, touch-based measurement that offers significant improvements in safety and ease-of-use relative to existing measurement approaches. The TruTouch measurement is performed by transmitting light into the skin via contact with an optical touch pad, and collecting a portion of the light reflected back by the skin. The collected light is analyzed to determine the tissue alcohol concentration and to verify the user's identity.

The light used in the TruTouch measurement is in the near-infrared (NIR) and is safe for human skin exposure. The light levels are less than the limits established by the FDA for non-ionizing radiation ("orders of magnitude less that that required to cause skin heating or damage such as sunburn.") It's similar to holding a low-powered flashlight against one's skin. It's safe for both short and long-term exposure.

TRUTOUCH SPECTROSCOPY

TruTouch devices measure the 4000-8000 cm^{-1} (1.25-2.5 mm) spectral region, which is of prime interest for making noninvasive alcohol measurements. It offers specificity for a number of analytes, including alcohol and other organic molecules present in tissue, while allowing optical pathlengths of several millimeters with acceptable absorbance characteristics. Figure 1 shows the NIR spectra (normalized to unit concentration) of alcohol and water acquired from the TruTouch device which demonstrates the effect of molecular structure on NIR absorption.

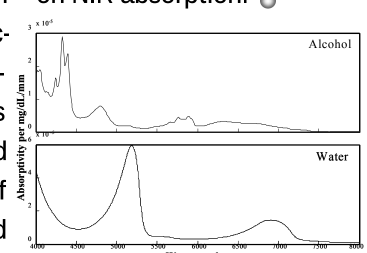


Figure 1 - NIR absorptivity of alcohol and water

ALCOHOL MEASUREMENT

An advantage of NIR spectroscopy is that the structure of a molecule dictates the specific manner in which it absorbs NIR light. Thus, the absorbance spectrum of each molecular species is unique, which allows the spectrum of alcohol to be discriminated from those of other molecules, such as water, that are commonly present in the body. In addition, Beer's Law states that the magnitude of the absorbance signal for a given substance (e.g. alcohol) is proportional to its concentration. Consequently, NIR spectroscopy provides noninvasive tissue measurements that are both sensitive and selective for alcohol.

The TruTouch noninvasive alcohol measurement technology has been tested in multiple clinical studies following IRB approved protocols. To date, over 325 subjects have participated in alcohol dosing studies that have spanned a wide range of demographics and environmental conditions. One of these studies is described in detail below.

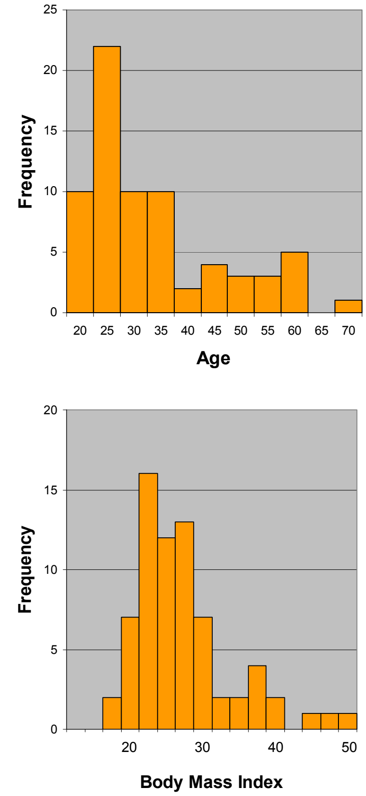
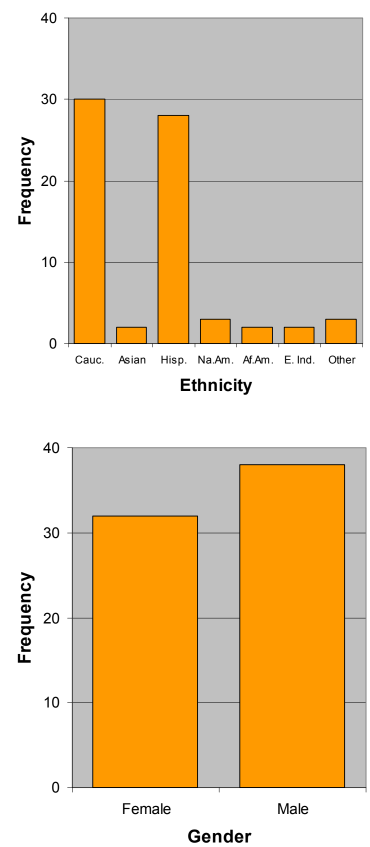
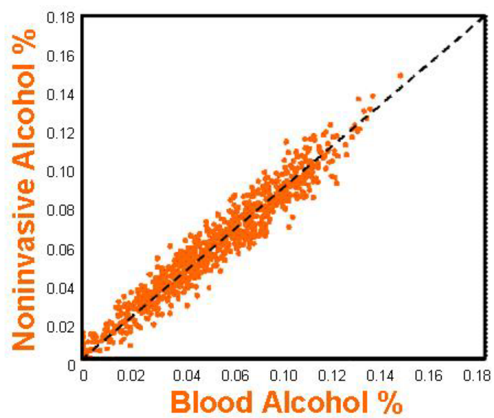


Figure 2
Demographics of the 70 Clinical Study Participants





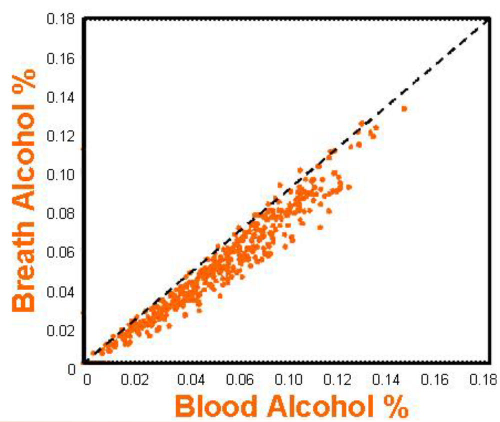


Figure 3a: Non-invasive alcohol concentration compared to contemporaneous blood alcohol concentration
Figure 3b: Breath alcohol concentration compared to contemporaneous blood alcohol concentration

SENSITIVITY AND SELECTIVITY

70 volunteer subjects (demographics in figure 2) were measured to assess the accuracy of TruTouch and breath alcohol relative to blood alcohol. Subjects were consented according to IRB-approved protocols (UNM-SOM Human Research Review Committee). Alcohol doses were administered to achieve peak blood alcohol (BAC) values of 120 mg/dL (0.12%). Blood alcohol measurements were acquired on approximately 15-minute intervals in order to monitor alcohol concentration. Once alcohol absorption was completed (15-40 minutes from ingestion, depending on the subject) and began to decline, repeated cycles of blood, breath and noninvasive alcohol measurements were acquired (~15 minutes per cycle) until the subject was below 20 mg/dL (0.02%). 1568 sets of noninvasive, blood and breath alcohol measurements were acquired from the 70 subjects. The results (Figure 3) show a strong TruTouch-blood correlation (r>0.95).

BIOMETRIC IDENTITY VERIFICATION

The skin is primarily comprised of the epidermis, dermis, and subcutaneous layers. Each layer has different characteristics that influence its relative contribution to the TruTouch spectroscopic measurement. For example, the subcutaneous layer is largely comprised of lipids (fats) while the dermal layer is composed primarily of water and collagen. The TruTouch measurement inherently contains contributions from each layer, which provides insight into both the chemical composition and structure of the tissue. Because all people have different tissue properties (dermal hydration, collagen density, and layer thicknesses), the TruTouch measurement captures these interpersonal differences and uses them as the basis for its unique biometric identity verification feature.

Figure 1 is a visual representation of the inter-subject resolving power of the TruTouch technology using 3 extracted properties. Each ellipsoid in Figure 1 encompasses 3 properties extracted from multiple TruTouch measurements (typically 10-15) obtained from a single subject (31 total). It is clear that with these properties, each subject resides in a different region of the 3-dimensional space. This example can be easily extended to include additional properties and thereby further improve the discriminatory power of the TruTouch identity verification technique.

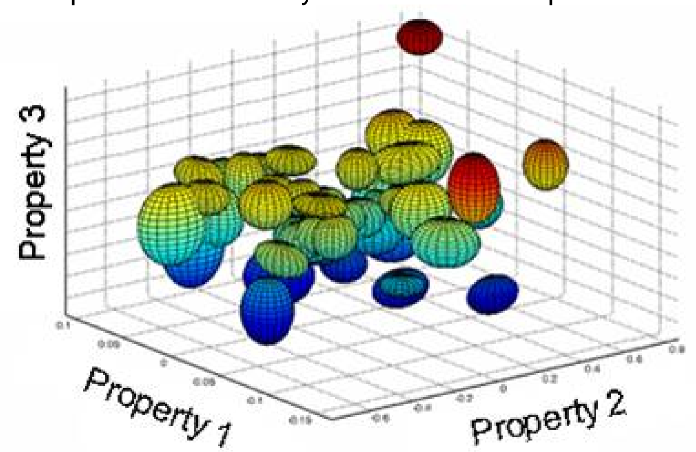
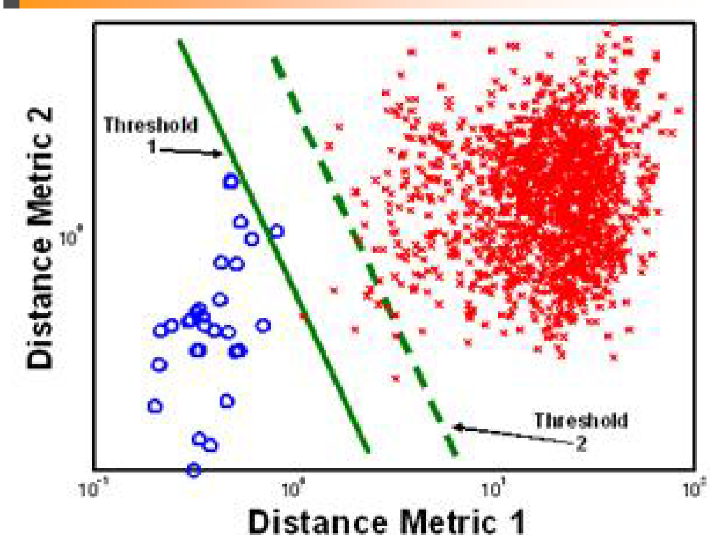


Figure 1
Visual representation of TruTouch biometric signal using 3 extracted properties

Figure 2
Graphical Representation of Distance Threshold



The properties obtained from each noninvasive measurement can be condensed into distances. In this framework, the distances of each measurement to a common origin become the differentiating property. Figure 2 is a graphical example that uses two distance metrics. The points denoted by O's represent the distances obtained from measurements of a single subject arbitrarily chosen from those in Figure 1 while the points denoted by X's represent the distances obtained from the other 30 subjects. It is clear that the distances form two distinct clusters in this two dimensional example. The green lines indicate potential thresholds between the two groups of points that correspond to different levels of stringency on the distance. Different lines are equally feasible, thus allowing the security level of the biometric to be tuned to the needs of the specific application under consideration.

SEAMLESS CONNECTIVITY

The TruTouch Guardian contains a powerful microprocessor which runs highly sophisticated logarithms to verify identity and alcohol level in just one minute. The Guardian is, in essence, a signal-generating, collecting, and processing computer. Because it derives its results from calculations rather than chemical reactions—such as urine on a test strip—the Guardian can seamlessly integrate its reporting system with yours. Do you want a full tabulated report generated and e-mailed to interested parties every Friday? We can make it happen. Want testing randomized so that only one in ten people get tested? One in one-hundred? No problem. Want the appropriate supervisor paged every time one of his/her employees gets a red light? Consider it done.

Our mission is preventing people under the influence of alcohol from doing harm, and we'll bend over backwards to help you make that happen. Welcome to a safer world.

PATENT ESTATE

TruTouch owns or has exclusive licenses to 39 Issued and 18 pending US Patents for the noninvasive measurement of alcohol that covers multiple aspects of the noninvasive measurement technology.

CLINICAL EVALUATIONS

TruTouch has conducted multiple clinical studies resulting in more than 10,000 measurements on 100's of participants during which controlled doses of alcohol were administered under medical supervision. All studies have been performed following a strict protocol approved by a hospital Institutional Review Board (IRB) to ensure the safety of the subjects and the safe use of the device.

The clinical studies have involved, and been funded by, several independent agencies including the National Institutes of Health, the University of New Mexico Clinical Trial Center, Department of Defense, Department of Justice, Bernalillo County (New Mexico) Sheriff's Department, and the US Army Medical Research Command.

PUBLISHED ARTICLES

Additional information regarding the TruTouch technology and its evaluation using clinical and laboratory studies can be found in the following peer reviewed journal articles.

T. Ridder, S. Hendee, C. Brown, "Noninvasive Alcohol Testing using Diffuse Reflectance Near-Infrared Spectroscopy", Applied Spectroscopy, 59(2), pp. 181-189, (2005).

C. Brown, T. Ridder, "A Framework for Multivariate Selectivity Analysis. Part 1: Theoretical and Practical Merits", Applied Spectroscopy, 59(6), pp. 787-803, (2005).

T. Ridder, C. Brown, B. Ver Steeg, "A Framework for Multivariate Selectivity Analysis. Part 2: Experimental Applications", Applied Spectroscopy, 59(6), pp. 804-815, (2005).

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