“SCRAM” or the Secure Continuous Remote Alcohol Monitor

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Section 3

Defending the Alleged SCRAM Violation

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Introduction

The SCRAM (Secure Continuous Remote Alcohol Monitor) device is made by AMS (Alcohol Monitoring Systems), a corporation located in Highlands Ranch, Colorado. AMS began development of SCRAM in 1991, and since, have spent more than $14 million in development of the device. SCRAM was first introduced in 2003, and as of this writing, it is used in 44 states.

A detailed explanation of the science behind SCRAM is beyond the scope of this presentation, but the basic science is explained elsewhere in these materials. The primary focus of this presentation is to explore the various defenses -- and there are many -- that may be raised in a typical SCRAM violation.

While worn on the ankle, the SCRAM monitors three things: (i) the TAC (Transdermal Alcohol Content); (ii) the wearer's temperature; and (iii) the IR signal, which is basically the means by which the device monitors the distance of the device from the wearer's skin.

To best understand how to defend a SCRAM case, it is essential to first understand exactly how to establish a violation. Graphically, the "violation-confirmation" process is as follows:

Violation/Confirmation Process:

1. Positive findings are reported to AMS.
2. Data is analyzed by AMS as follows:

    a. If the answer to all of the following is "YES" then drinking is suspected:

    - Did TAC level begin at 0.00?
    - Was the absorption rate less than .05% p/h?
    - Was a peak value established?
    - Was the burn rate <.15% p/h?
    - Is an obstruction suspected?

3. If drinking is suspected, then there is a meeting at AMS to confirm the violation.
4. If drinking is confirmed, a report is written.
5. The suspect is then confronted for their explanation.
6. A violation report is sent to the court.
7. A hearing is held.

Possible Defenses at the SCRAM hearing

1. **Sweat/Blood Partition Ration** – Like breath testing, SCRAM testing is an indirect testing method. However, SCRAM testing is considerably less direct than breath testing because the results obtained are twice removed from blood. With SCRAM testing, the alcohol in the sweat itself is not directly measured. Instead, the SCRAM device captures the gas just above the skin and, using a fuel cell, tests this gas for the presence and amount of alcohol. A largely unknown formula is then used by AMS to convert this gas-ethanol measurement into a blood-ethanol measurement. However, because it is indirect, just like with breath testing, there are a variety of factors that can impact the amount of alcohol present in the sweat, but also, and perhaps more importantly, the amount of alcohol in the gas above the skin.

There has been a lot of research performed and written on the breath/blood partition ratio. By comparison, relatively little research has been done to establish the partition ratios involved with SCRAM testing. Consequently, there isn't an agreement in the relevant scientific community (whatever that is for SCRAM) that a particular partition ratio applies for a given percentage of the human population. As it appears, considerable research is needed before SCRAM testing reaches the level of forensic reliability possessed even by breath test results. See the attached literature survey and supplemental materials for a further explanation of this concept as it applies to both breath and sweat testing.

2. **Non-Specificity for Ethanol –** The SCRAM device uses a fuel cell to measure the amount of alcohol present in the gas above the skin. The trouble here, of course, is that fuel cells are not specific for beverage alcohol. There is also a question that ought to be raised relative to the maintenance and calibration of these devices. "Fuel cells change in sensitivity as they age, which may require more frequent recalibration than some other types of detectors, depending on how the signal is analyzed. Fuel cells are relatively specific for ethyl alcohol. Fuel cells can potentially respond to other alcohols such as methyl-, isopropyl-, and n-propyl alcohol and to acetaldehyde. All of these compounds appear endogenously in insignificant breath concentrations and are far more intoxicating than ethyl alcohol when ingested." Garriott, *Medical Legal Aspects of Alcohol*, 4th Ed. (Lawyers & Judges Publishing Company).

3. ***Daubert*** - **Skin Variability and General Unreliability** – A related question arises based on the fact that the thickness and location of skin can impact the manner, speed and concentration of the alcohol that actually passes out of the body through the skin. This is one reason that the results of sweat testing should only be used qualitatively, and should not be used as a quantitative measure. Because these factors have not yet been subjected to an appropriate level of scientific scrutiny, one may argue that SCRAM

doesn't satisfy *Daubert*. (*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)). In *Daubert*, the Supreme Court held that federal trial judges are the "gatekeepers" of scientific evidence. Under the *Daubert* standard trial judges must evaluate proffered scientific evidence to determine whether it is both "relevant" and "reliable," a two-pronged test of admissibility. Relative to the alleged SCRAM violation, the questions are: Does SCRAM have a known or potential error rate? Is it subject to "empirical testing," or in other words, is SCRAM falsifiable, refutable, and testable? Is it subject to false positives? Is SCRAM generally accepted by a relevant scientific community? Has SCRAM been subjected to peer review and publication?

4. ***Crawford* – Decision Made in Secret** – While *Daubert* essentially raises the question of reliability, *Crawford* raises the constitutional issue of confrontation. As can be seen from the above explanation of the verification process, once the data appears to support a possible "drinking event", it is sent to AMS in Colorado, where a panel reviews the data to determine if the "drinking event" conclusion can be confirmed. If this "secret panel" determines that the data does support the conclusion, then a report is generated. This is the final report that would be used by the state in a court violation proceeding, though the person who would testify at this hearing would not have any personal knowledge of the "meeting" that took place and could only reiterate the conclusions drawn. By way of analogy, this would be akin to a grand jury deciding the reliability of the scientific evidence presented at trial, and the conclusions to be drawn from this evidence. Their "verdict," i.e., that drinking occurred, is then sent to the judge on a "verdict form" (AMS report) that contains their conclusions and the reasons for their conclusions. The specific criteria used to make the drinking or no-drinking determination (the "jury instructions") are only partially known to the court and/or the parties. Further, there is no record -- meaning no transcript -- that can be reviewed at the hearing to evaluate the conclusion that a drinking event has occurred.

As a result, the advocacy that takes place on a SCRAM violation is really more like an appellate argument than an adversarial hearing, where the judge is making a determination relative to the jury's determination without the benefit of an actual written record. This of course is completely contrary to the case of *Crawford vs. Washington*, 541 U.S. 36 (2004). As should be well-known, *Crawford* overruled nearly a quarter-century of precedent, and re-invigorated the constitutional right of confrontation, creating a *per se* bar to out-of-court statements that are "testimonial" in nature when the defendant has no opportunity to cross-examine. The majority opinion, written by Justice Scalia, traced the origins of the Sixth Amendment's Confrontation Clause and concluded that the Constitution's Framers sought to avoid a civil law practice in which judicial officers conducted examinations outside of court and then introduced those statements at trial. The Framers included the Confrontation Clause to ensure that criminal defendants would face their accusers. Nevertheless, this is exactly what happens in a SCRAM case where an examination takes place outside the courtroom and the state seeks to admit only the conclusions drawn from such out-of-court examinations.

5. **Due Process/Delay** – This topic is covered in detail in the attached article *Justice Delayed is Justice Denied: Due Process Violations in SCRAM Cases*, DWI Journal: Law & Science, Vol. 21, No. 4 (April 2006).

6. **Lack of Discovery/Source Code** – It is often difficult to obtain sufficient information to evaluate the state's claim that a SCRAM violation has occurred. Depending on your jurisdiction, it may be necessary to file a motion and obtain a discovery order before sufficient discovery will be released. Attached below is a sample discovery letter that may be modified and used to begin the discovery process.

Defending Drinking Drivers

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Chapter 2

Chemical Evidence

§223.2 The Fixed Partition Ratio

The so-called fixed partition ratio is 2100:1. What this means is that at an average temperature of exhaled air (34°C), 2100 milliliters of alveolar air should contain the same quantity of alcohol as 1 Millimeter of pulmonary arterial blood. See Greenberg, "Physiological Factors Affecting Breath Samples," 5 *Journal of Forensic Sciences* 411 (1960). The 2100:1 partition ratio has been sanctioned by the National Traffic Highway Safety Administration and its Ad Hoc Committee on Blood/ Alcohol Ratio. As Mason and Dubowski state, this sanctioning was done "essentially by fiat." See Mason and Dubowski, "Alcohol, Traffic and Chemical Testing in the United States: A Resume and Some Remaining Problems," 20 *Clinical Chemistry* 126 (1974). There is still scientific debate on the validity of the 2100:1 ratio. See Alobaidi *et al*., "Significance of Variations in Blood/Breath Partition Coefficient of Alcohol," 2 *British Medical Journal* 147 (1976); Dubowski and O'Neill, "The Blood/Breath Ratio of Ethanol," 25 *Clinical Chemistry* 1144 (1979).

§223.3 Problems With the Fixed Partition Ratio

There are several problems which easily demonstrate that the 2100:1 constant is not applicable to all cases. First, the constant assumes that all breath leaves the mouth at 34°C. That may be an average figure, but many persons have a figure higher or lower than average. Moreover, the same person within one day can have a varying temperature. Police departments currently do not take a subject's temperature before running the breath test. See Mason and Dubowski, "Breath Alcohol Analysis: Uses, Methods and Some Forensic Problems-Review and Opinion," 21 *Journal of Forensic Science* 9 (1976).

Another problem with the constant has to do with the subject's hematocrit. Only if a subject has an average hematocrit of 47% will the constant be accurate. As stated previously, Henry's Law pertains to an alcohol-water solution and is applicable to the same. Blood, however, is a mixture of particular materials. It is made up of red blood cells, white blood cells, and platelets which are suspended in water. Therefore, a quantity of alcohol in the blood results in different concentrations of alcohol in the water of the blood if the mixture contains different amounts of particulates. The breath analyzer converts alcohol concentration into blood alcohol concentration on the assumption of a constant hematocrit of 47%. The subject's true hematocrit cannot be determined without a blood sample. The range of normal hematocrit is from 37% to 52%. That range applies to 95% of the health population. Five percent of healthy drivers are still beyond those limits. Moreover, subjects who are deemed to be unhealthy for one reason or another may be beyond those limits. See Mason and Dubowksi, "Breath Alcohol Analysis: Uses, Methods and Some Forensic Problems—Review and Opinion," 21 *Journal of Forensic Science* 9 (1976).

Another problem with the constant is the scientific literature which suggests ratios ranging from 1117:1 to 7289:1. See Dubowski and O'Neill, "The Blood/Breath Ratio of Ethanol," 25 *Clinical Chemistry* 1144 (1979); Harger *et al.*, "The Partition Ratio of Alcohol Between Air and Water, Urine and Blood; Estimation and Identification of Alcohol in These Liquids from Analysis of Air Equilibrated with Them," 183 *Journal of Biological Chemistry* 197 (1950); Jones, "Variability of the Blood/Breath Ratio in Vivo," 39 *Journal of Alcoholic Studies* 1931 (1978). Another study suggests that the mean ratio is 2280:1 for the healthy male population with normal body temperatures. This study implies that the ratio is different for the healthy female population, for those with an abnormal body temperature, or for those who may be unhealthy in some other respect. See Dubowski and O'Neill, "The Blood/Breath Ratio of Ethanol," 25 *Clinical Chemistry* 1144 (1979).

Despite the considerable authority to the contrary, all modern breath analyzers assume the validity of the 2100:1 ratio. Thus, the breath result is multiplied by 2100 to determine the presumed blood alcohol concentration.

Dr. Roy U. Schenk has concluded that various organic solvents can have an effect on the bloodbreath partition ratio. See Schenk, "The Effect of Organic Solvents on Evidential Breath Testers," 1 *DWI Journal: Law & Science* 4 at 58 (September/October 1986). In three separate tests involving one or two people exposed to high levels of organic solvents and one person not exposed, the exposed people had higher percent BAC's as measured by a Breathalyzer than the calculated maximum percent BAC, while the unexposed control people had percent BAC's lower than the calculated maximum. Maximum percent BAC was calculated on the basis of alcohol distribution in 68% of

body weight for males and 55% of body weight for females. *See* Widmark, *Principles and Applications of Medicolegal Alcohol Determination* at 107 (1932). An alcohol metabolism rate of 0.018% alcohol per hour was used. *See* Fisher, et al., *Alcohol in the Impaired Driver* at 22 (National Safety Council 1976).

The breath of the exposed people were tested on the Breathalyzer using standard methodology both prior to and following exposure to any solvents. Blood alcohol curves were then determined by measuring the percent BAC several times over a two-hour period following consumption of a measured amount of alcohol. Based upon the results of these studies, Dr. Schenk concluded that it "would appear to be that organic solvents lower the distribution ratio of alcohol between blood and breath (i.e., the blood/breath ratio) ... If further studies confirm that solvents do indeed affect the blood/breath ratio, much of the variability reported in the literature can be explained, particularly for the ratios less than 2100:1. Furthermore, the effect can occur whether the solvent itself reacted chemically in the Breathalyzer test solution. Consequently, the effect will cause errors in any breath alcohol testing device."

Although Dr. Schenk tested for various solvents, his test results led him to the following conclusion:

> Furthermore, if solvents affect the blood/breath ratio, it is likely that other substances do also. For example, acetone readings, which can be induced through diabetes, fasting or consumption of isopropyl alcohol, can be expected to affect the ratio, particularly in the high concentrations that are sometimes attained ... On the basis of these results, it also seems reasonable to question whether variations in blood sugar, triglycerides and other blood constituents may also affect the blood/breath ratio.

Other scientists have also questioned the fixed partition ratio. See Hlastala, "The Impact of Lung Physiology on Breath Alcohol Testing," 1 *DWI Journal: Law & Science* 5 at 31-48 (November/ December 1986). While Dr. Hlastala recognizes that almost all evidential breath testers assume a partition ratio of 2100:1, regardless of the amount of care given to the operation and accuracy of the machine, "all studies show that errors persist."

Dr. Hlastala lists several possible causes of error including intentional and unintentional variations of breathing techniques. That is, "a subject can change (by a large amount) the breath alcohol concentration and, hence, the estimated BAC. The differences are caused by heating and cooling of the breath and interaction of the alcohol with the surface of the airways. This dynamic interaction causes changes in alcohol concentration during exhalation which results in a large potential error. The magnitude of the error is dependent on the physiology of the individual and is unrelated to specific instrument problems."

Dr. Hlastala also concludes that while "most of the reasons for such errors are just being recognized ... the breath testing instrument manufacturers have not yet incorporated corrections into their procedures. *Because of this law enforcement agencies are unable to make the appropriate corrections to provide accurate blood alcohol measurements*. *Id*. at 33 (emphasis added).

Domenick LaBianca has also noted that current breath testing machines ignore important variables including blood to breath alcohol conversion ratios, effects of temperature variations on breathalcohol analysis and the fact that breath analyzers do not

collect large volumes of alveolar air for analysis, but rather analyze very small volume of breath then multiply the result by an appropriate factor to produce a final reading. LaBianca, "The Myth of Breath Test Accuracy: What the Studies Have Really Shown," 5 *DWI Journal: Law & Science* 11 (November 1990); see also LaBianca, "The Chemical Basis of the Breathalyzer: A Critical Analysis," 67 *J. Chem. Educ*. 259-261 (1990).

§260 SCRAM—ALCOHOL MONITORING ANKLE BRACELETS

The SCRAM (Secure Continuous Remote Alcohol Monitor) ankle bracelet measures the amount of alcohol in a person's body "transdermally," meaning that it tests the amount of alcohol in the perspiration after it passes unmetabolized through the skin. The idea of using perspiration for measuring bodily alcohol content goes back to the 1930s, and several studies during the last three decades have shown that there is a fairly good correlation between perspiration alcohol and blood alcohol. See Davidson, et al., "Behavior Effects and Pharmacokinetics of Low-Dose Intravenous Alcohol in Humans," 21 *Alcoholism: Clinical and Experimental Research* 7, at 1294 (Oct. 1997).

The SCRAM device is manufactured by Alcohol Monitoring Systems (AMS) based in Highlands Ranch, Colorado, and is currently used in 32 states. It is small enough to be worn continuously underneath clothing, and this smaller format allows the perspired alcohol to be discretely measured. The device produces qualitative measurements and can remain in use for large periods of time. In the context of drunk driving, these features make the device much more useful than the comparatively low-tech SWEAT Patch (see §741.1).

The SCRAM bracelet is most often used by courts to monitor an offender's use of alcohol when such use is prohibited as a bond condition or a condition of probation. In many instances a confirmation of a drinking episode via the SCRAM bracelet will form the sole basis for a court's determination that the offender has in fact consumed alcohol.

§261 THEORY AND OPERATION

Due to ethanol's affinity for water, it is rapidly distributed throughout the body by process of diffusion. Equilibrium occurs when all the fluids of the body will contain ethanol in close proportion to their water content. It can be assumed that there will be a relatively constant ratio between blood alcohol and perspiration alcohol so that despite relatively large concentration differences, the amount of alcohol excreted in the perspiration will parallel that in the blood over the entire excretion phase (rising and falling). This assumption underlies the use of perspiration to predict blood alcohol content. See Brown, "The Pharmacokinetics of Alcohol Excretion in Human Perspiration," 7 *Methods and Findings Experimental Clinical Pharmacology* 10, at 539 (Oct. 1985).

However, transdermal monitoring for alcohol presents a variety of challenges, particularly as it pertains to obtaining reliable quantitative measurements. For example, unlike breath, blood and urine, the manner in which alcohol passes through the skin (pharmacokinetics) is not well understood. This lack of understanding is partly caused by the comparatively larger number of variables that are involved in this passage. These variables include the subject's blood alcohol level and body temperature, the rate of diffusion through the skin, the skin type and location, the thickness of the stratum corneum (the major barrier to water), the amount being perspired, and the cutaneous

(inside the skin) blood flow. *See* Swift, "Transdermal Alcohol Measurement for Estimation of Blood Alcohol Concentration," 24 *Alcoholism: Clinical and Experimental Research* 4, at 422 (April 2000).

These variables and the lack of understanding make the quantitative measurement of alcohol passing through the skin impossible. Consequently, blood alcohol content cannot be accurately estimated from perspired alcohol content the same way that it is estimated from measuring breath and to a lesser extent, urine. The SCRAM bracelet, therefore, can only be properly regarded as a screening tool to help establish continued abstinence. This position is well established in the scientific literature, and is accepted by AMS. *See* Brown, *supra*, at 539.

Nevertheless, while placed on the subject's ankle, the device monitors the subject's perspiration by taking quantitative measurements every hour. If alcohol is detected, the quantitative measurements are taken twice per hour. The obtained quantitative measurements are then converted from a perspiration alcohol level to a blood alcohol level. For this purpose, AMS uses the acronym "TAC", meaning "transdermal" alcohol content. These TAC readings are communicated via a home-placed modem to a remote computer that is managed and hosted by AMS. The system uses a web-based application called "SCRAMnet." AMS employees monitor and interpret the transferred data to determine if a drinking episode can be confirmed. These TAC readings are transferred between the bracelet and the modem via a 900 MHz radio signal.

The monitoring agency also tracks the wearer's body temperature, as well as the distance of the device from the wearer's skin. These variables are independently plotted onto a three-color graph. AMS provides this graph to the monitoring agency to substantiate their claim that a drinking event has been verified. AMS claims that the graph for a drinking episode can easily be distinguished from a graph that is the product of an interfering (non-ethanol) substance because TAC readings from a verified drinking episode are expected to gradually rise and fall off, while readings from an interfering substance are expected to rapidly peak then fall. Thus, it is assumed that a drinking episode will follow the typical absorption, distribution and elimination curve, while an interfering substance will not. If the wearer attempts to block the device from taking readings, the graph will include a flat-line that reflects the insertion of a blocking substance between the device and wearer's skin. If this were to occur, the temperature readings would also be affected, and would also be reflected in the graph.

§262 THE POSSIBILITY OF FALSE POSITIVES

It has been AMS's position that the SCRAM bracelet has never produced a false positive. This position was at least partially confirmed by a laboratory study funded by AMS. The research for this study was done through the University of Colorado, and involved both a laboratory group and a community group. The laboratory group included 24 individuals who were given known doses of alcohol. During testing, these individuals were apparently kept in the laboratory. For this group, the authors unequivocally stated that there were no transdermally-produced false positives. A second community group, which included 20 individuals, self-reported alcohol use, and were otherwise allowed to go about their daily activities. With this community group, there was less agreement between breath and transdermal readings, including instances where the transdermal readings and self-reported alcohol consumption did not match. However, upon a close reading, it appears that the authors were not willing to state unequivocally that there were

no false positives for the community group, although the study does indicate that there were no false negatives. See Sakai, "Validity of Transdermal Alcohol Monitoring: Fixed and Self-Regulated Dosing," 30 *Alcoholism; Clinical and Experimental Research* 1, at 26-33 (2006).

Perhaps the most significant potential limitation to the SCRAM technology is that the device uses a fuel cell to measure the TAC (see §225), and fuel cells are known to be non-specific for beverage alcohol. For example, fuel cells can potentially respond to other alcohols that may be present in a person's body, such as methyl-, isopropyl- and n-propyl alcohol. Fuel cells can also respond to acetaldehyde. *See* Garriott, Medical-Legal Aspects of Alcohol, at 197 (4th ed. 2003). This problem with non-specificity is particularly important with the SCRAM device because the measurements are taken above the skin, and this might allow environmental factors to be inadvertently measured by the device. Thus, it is at least theoretically possible for both endogenous as well as exogenous alcohol to produce false TAC readings.

§263 DUE PROCESS ISSUES WITH SCRAM

Once a drinking episode has been confirmed by AMS, these findings are reported back to the local state agency, which is usually closely associated with the court where the offender's case is pending. The court will then notify the offender. The type and time of notice may depend on the status of the case when the violation occurs. For example, if the offender is on bond, he or she may face a bond revocation hearing. Alternatively, if the allegation of alcohol use occurs post-conviction, the offender may face a show cause hearing that could result in a revocation of probation. The result of an adverse finding for either violation may be lengthy incarceration. Where such violations are alleged, counsel should consider evaluating whether or not there has been a failure to provide the defendant with timely notice or perhaps a denial of the meaningful opportunity to be heard. Both are legitimate concerns because the "confirmation" process itself is not immediate. In practice, the total delay between drinking and notice of confirmation to the offender might be as much as several weeks.

Because of this delay, the ability to collect a potentially exculpatory independent breath or blood test at or near the time of the alleged drinking has long since passed. Thus, the offender will find him or herself in the unenviable position of having to prove a negative, that is, that they were not drinking, and they will have to do so without any ability to collect convincing evidence to support their denial.

A review of the applicable case law suggests that while this specific issue relative to the SCRAM bracelet has not been addressed at either the state or federal level, federal courts have resolved the more general right to obtain exculpatory evidence in favor of the accused. *See Brady v. Maryland*, 373 U.S. 83; 83 S.Ct. 1194; 10 L. Ed. 215 (1963).

§264 DEFENDING THE ALLEGED SCRAM VIOLATION

Defending an allegation of alcohol use requires counsel to first obtain the graphs from the monitoring agency. The graphs will contain three curves, one each for the infrared signal (used to monitor distance from the skin), the subject's temperature and the alleged TAC. These graphs should be accompanied by a linear numeric read-out of each individual TAC reading. Counsel must scrutinize these graphs to determine if in fact the "numbers" appear to reflect a typical blood alcohol curve, and whether or not any blocking episode coincides with the drinking. With respect to an analysis of the blocking

aspect, bear in mind the delay associated with the TAC relative to the BAC. While it may appear at first that the blocking coincides with the drinking, upon closer inspection a different picture may emerge. This is because the infrared signal is in "real time," while the TAC may actually be attenuated by as much as 120 minutes or more. See Swift, et al., "Studies on a Wearable, Electronic, Transdermal Alcohol Sensor," 16 *Alcoholism: Clinical and Experimental Research* 4, at 721 (Aug. 1992).

Counsel should also obtain a detailed medical history, as well as detailed narrative of what the defendant was doing before, during, and after the alleged drinking episode. It should be determined whether or not the offender has any medical conditions or has experienced a chemical or radio frequency exposure that could cause a false positive. A viable defense might emerge if there is a correlation between such exposure and the alleged drinking.

If there appears to be legitimate support for your client's contention that he or she was not drinking, counsel should request an evidentiary hearing based on FRE 702 and 703, and also pursuant to the *Daubert* and *Kumho Tire* cases, assuming the applicable rules for show cause or evidentiary hearings in your state allow. A due process claim should also be evaluated based on the inherent inability of your client to obtain a potentially exculpatory independent test.

TRANSDERMAL ALCOHOL MEASUREMENT A LITERATURE SURVEY

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1. ***Studies on a Wearable, Electronic, Transdermal Alcohol Sensor,*** **Robert M. Swift, Christopher S. Martin, Larry Swette, Anthony LaConti, and Nancy Kackley in *Alcoholism: Clinical and Experimental Research*, Vol. 16, No. 4, pp. 721- 725 (1992).**

This article reports the results of the testing of an admittedly "novel" transdermal alcohol sensor (TAS) developed by "Giner, Inc." While the description of the device appears very similar to the SCRAM device, it is not identical. The conclusion of the research was that the TAS results closely follow the BAC curve, although with delay.

For this study the TAS devices were calibrated in the laboratory based on the "projected" transdermal response with various concentrations of ethanol in water. The results obtained were compared with breath alcohol readings from an Intoximeter 3000. The devices were worn on different locations, but primarily the forearm. The curves obtained from the TAS were highly correlated with the BrAC curves, but lagged behind the BrAC by about 120 minutes. In this study there were no false positives for any subjects. (Why should there be, the subjects were dosed with alcohol in a laboratory setting).

Importantly, the author states in this article that:

> "At this time, the absolute values for BAC can be approximated, but not directly derived, from the transdermal ethanol signal. It should be noted that the TAS signal measures ethanol flux rather than concentration. This flux is related to concentration but is also affected by sensor geometry, type, and thickness of diffusion-lining membrane, rates of excretion and/or diffusion through the skin and upon evaporation. Since the TAS totally consumes ethanol during the analysis, ethanol vapor at the electrode is not in equilibrium with vapor at the skin surface. A Breathalyzer sampling breath alcohol vapor, similarly requires calibration according to the blood/breath partition ration."

2. **Editorial: *Transdermal Measurement of Alcohol Consumption,* Robert M. Swift in *Addiction*, Vol. 88, pp. 1037-1039 (1993).**

Dr. Swift indicates that multiple studies, using three different methods demonstrate that transdermal ethanol concentration generally follows the time course and amplitude of the blood alcohol concentration. However, he tempers this conclusion by acknowledging

that the pharmacokinetics of transdermal ethanol in humans is not well understood. He explains the complications involved in estimating ethanol concentrations.

One such complication simply involves individual differences in input and output rates (of ethanol through the skin), as well as the fact that skin permeability varies from area to area, with head and palm skin showing the highest concentrations and the skin of the extremities showing the lowest. Also, that removing the upper layers of the skin with tape increased ethanol permeability, and that exercise also increased ethanol concentration for skin areas with limited ethanol diffusibility. From these facts Swift concludes that the different ethanol permeability may require different calibration for different skin areas. Physical and cosmetic considerations are important as well. He concludes by indicating (in 1993) that additional research is being conducted to better elucidate the clinical pharmacology of transcutaneous ethanol and its relation to BAC, and to test reliability, specificity and acceptance of the transdermal methodology in different individuals over a range of research and clinical applications.

3. ***Behavior Effects and Pharmacokinetics of Low-Dose Intravenous Alcohol in Humans,*** **David Davidson, Paul Camara, and Robert Swift in *Alcoholism: Clinical and Experimental Research*, Vol. 21, No. 7, pp. 1294-1299 (1997).**

This interesting study involved data obtained from 7 females and 5 males, and compared the results obtained from a transdermal alcohol sensor with those obtained from both breath and blood. The study suggests a good correlation of the TAS with the other testing methods, but there were differences, and these differences (between TAS breath and blood values) are attributed to "differences in alcohol equilibration throughout body water compartments."

Another source of variation was introduced because of irregularity of data points on some of the concentration versus time curves produced from the TAS. This made it more difficult to compare accurately values with breath and blood estimates obtained at the same time point. This noise may have occurred from poor skin contact with the sensor during the experiment.

4. ***Transdermal Alcohol Measurement for Estimation of Blood Alcohol Concentration,*** **Robert Swift in *Alcoholism: Clinical and Experimental Research*, Vol. 24, No. 4, pp. 422-423(2000).**

Although published in 2000, Dr. Swift refers to the Transdermal Alcohol Sensor as a "novel" method for estimating blood alcohol concentration, but at the same time acknowledges that the idea of using perspiration to measure BAC goes back to the 1930s.

This article indicates that the pharmacokinetics of Transdermal alcohol is complex and depends on a number of factors. The measured transdermal alcohol signal is determined by the blood alcohol level, the rate of diffusion through the skin, the skin type and location, the thickness of the stratum corneum that is the major barrier to water, the amount of eccrine sweating, and possibly the cutaneous blood flow.

The alcohol in insensible perspiration is attenuated with respect to blood alcohol; the amount of attenuation depends on the location of the skin where it is measured. For example, when measured at the surface of the forearm, the attenuation factor is approximately 3.5:1 with respect to blood. When measured on the forehead, the attenuation factor is approximately 2:1.
The complexity of the transdermal alcohol derives from the fact that one is sampling a pharmacokinetic compartment that is related to blood, but is not the same as blood. The controversies about sampling one pharmacokinetic compartment, such as breath alcohol, and comparing it with another pharmacokinetic compartment, such as blood, have been discussed. When sampling across compartments, there is variability because the different compartments have different kinetic input and output constants for alcohol and the concentrations of alcohol in the different compartments will differ over time.

Our experiments suggested that the transdermal alcohol signal has two components. One component is the alcohol in insensible perspiration that diffuses through the skin. This component seems to be attenuated with respect to the BAC. The other component is the alcohol in eccrine sweat. The alcohol content of eccrine sweat is not attenuated with respect to BAC. Sweat is an ultra filtrate of plasma, and therefore yields a higher transdermal alcohol value than does diffusion.

For the future, we plan to perform more experiments that measure transdermal alcohol under more natural drinking conditions. We also plan to try to make the TAS smaller to make the device more comfortable and less obtrusive.

5. ***Ethanol Vapor above Skin: Determination by a Gas Sensor Instrument and Relationship with Plasma Concentration*, H.G. Giles, S. Meggiorini, G.E. Renaud, Alcoholism, Clinical and Experimental Research, Vol. 11, No. 3, pp 249-253 (1987).**

This study also found good correlation between the rate of decline of ethanol of skin vapor concentrations and plasma concentrations. However, very interestingly, the report found:

> It is clear that in experiments where skin vapor ethanol is measured, effort should be made to exclude extraneous ethanol. Such ethanol can come from a variety of ethanol containing toilet products used by many persons. To investigate the nature of this effect, 0.1 ml of pure ethanol was applied directly to the palm of one male and one female subject. Skin vapor measurements were taken on the same palm. [The results of this topical administration of ethanol are shown in fig. 4.] Since ethanol is volatile at skin temperature, one might have expected evaporation to be complete within a few minutes but the results show that ethanol remains in the skin vapor for a far longer time. The apparent anomaly may be explained by postulating that while the great majority of the ethanol is lost to the atmosphere, a sufficient amount is absorbed into, and later evaporates

from, the site to give a signal for an extended period on a sensitive instrument. This effect is somewhat similar to that encountered with the Breathalyzer when it is used soon after the consumption of an alcoholic beverage. In the latter situation, small quantities of the beverage remaining in the mouth result in a distortion of the measurement.

6. ***Sweat Ethanol Concentrations are Highly Correlated with Co-Existing Blood Values in Humans,*** **M.J. Buono, Experimental Physiology, Vol 84, pp 401-404 (1999).**

The results of this study also suggest that blood ethanol can rapidly equilibrate with sweat.

(Discussing prior research) "Knowing the dead space of the cylinder and making an estimate of the evaporation partition coefficient between sweat and air, they hypothesized the "real" concentration of ethanol in sweat should be about 15% more than whole blood. Their theoretical estimate, made over 60 years ago, is consistent with current results which show that, on volume, sweat ethanol concentration is approximately 19% more than whole blood".

7. ***A Method for Determining the Excretion of Volatile Substances Through Skin,*** **D.J. Brown, Methods and Findings Experimental Clinical Pharmacology, Vol 7(5), pp 269-274 (1985).**

This study did not involve a measurement of ethanol concentration, but instead was a measure of the air above the subject's hand that was placed into a plastic bag.

According to Henry's Law, if the temperature and pressure of the system remain relatively constant these vapors (ETOH) will be in equilibrium with the fluids of the skin at 37 deg. Celsius if given sufficient time to equilibrate, which is usually just a matter of a few minutes (14).

It would appear from this preliminary study that volatile substances are excreted through the skin in sufficient quantities to allow reliable estimation of blood concentration provided that equilibrium has been achieved. The data indicates that Henry's Law applies to insensible perspiration in the same manner that it applies to breath, suggesting that a fixed concentration ratio is established between the blood and the gasses excreted from the skin.

One possibility (to explain why the study showed higher ETOH readings from the perspiration concentration than corresponding BAC readings) was that the water bound in the stratum corneum of the skin may retain alcohol for a longer period of time than other body fluids. Therefore, for an accurate estimation of blood from perspiration, a conversion factor may be required to account for a difference in elimination rate.

8. ***The Pharmacokinetics of Alcohol Excretion in Human Perspiration*****, D.J. Brown, Methods and Findings Experimental Clinical Pharmacology, Vol 7(10), pp 539-544 (1985).**

It has long been established that alcohol is rapidly and freely distributed in the total body water by the process of diffusion. Moreover, it has been shown that fluids of the body will contain ETOH in proportion to their water content after equilibrium has been established. Harger and others have determined that the relationship between BrAC and BAC is a constant ratio such that one volume of blood contains approximately the same amount of ETOH as 2100 volumes of alveolar air in normal healthy humans. This means that, in spite of a rather large concentration difference, alcohol excreted in the breath parallels that of the blood over the entire excretion phase (rising and falling). This is the underlying principle for using breath to predict BAC, and a similar process would be expected for perspiration.

Therefore, in a situation analogous to the BrAC in the lungs, if liquid perspiration is given adequate time to equilibrate with the air above the skin, in a closed, constant temperature system, it should provide an accurate estimate of the capillary blood ETOH concentration even though the perspiration may be in very small quantities.

Harger used capillary blood (finger tip) to determine BAC and found that, especially during the absorption phase, capillary blood provided a better estimate of arterial ETOH concentration than cubital vein blood. Furthermore, it is well known that ETOH has a rapid pharmacological action of cutaneous vasodilatation that can result in a flushed appearance to the face and sweat production. This demonstrates that distribution of ETOH to the skin is very rapid, with a concentration that is essentially the same BrAC, and leads to the conclusion that, following excretion, the perspiration is no longer in equilibrium with the capillary blood.

In summary the conclusions that can be drawn from this study are as follows:

(a) The pharmacokinetic parameters for perspiration alcohol content are essentially different from those of BrAC and by association, those of BAC.

(b) BAC cannot be accurately estimated from perspired alcohol content in the same manner as from BrAC. Therefore, detection of ETOH consumption using a sweat collection system should be regarded only as a screening method to establish continued abstinence.

c) The mechanism(s) that result in the differences observed between perspired alcohol content and BAC remain to be explained but may involve loading and unloading of bound water in the stratum corneum or a counter-current exchange between arterial and venous blood.

9. ***Sweat-Patch Test for Alcohol Consumption: Rapid Assay with an Electrochemical Detector,*** **M. Philips, Alcoholism, Clinical and Experimental Research Vol. 6, No. 4, pp 532-534 (1982).**

This paper essentially describes a new method of analysis of a sweat patch that does not require the patch to be sent to an outside lab. This makes the method far more suitable to the clinical setting where it is important to know the patient's true drinking patterns. The method essentially involved using an Alco-Sensor III to measure the air in a sealed container into which the sweat patch was placed then allowed to equilibrate with the air within. At least three standard ethanol solutions (including a zero) were run simultaneously so that the sweat patch ethanol concentration could be determined from this "standard" curve.

The slope of the curve here was very sensitive to even minor changes in temperature, but repetition at different temperatures produced no change in linearity.

The conclusion by the authors is that "this method of measuring ethanol in the sweat-collecting patch appears to be rapid, simple and robust; it may be readily applied in a clinical outpatient setting to assist in the diagnosis and treatment of alcohol abuse.

10. ***Sweat-Patch Testing Detects Inaccurate Self-Reports of Alcohol Consumption,*** **M. Phillips, Alcoholism, Clinical and Experimental Research Vol. 8, No. 1, pp 532-534 (1984).**

The object of this study was to measure how accurately drinkers report their consumption of alcohol, and involved 22 volunteers. Duplicate sweat patches were affixed on either the ankle or shoulder. They were removed, then assayed using an Alco-Sensor III to measure the air in a sealed container into which the sweat patch was placed then allowed to equilibrate with the air within.

This article indicates that more than half (59.1%) of the self-reported alcohol consumption reports fell outside the category of "accurate" reporters, a surprisingly high percentage. This article also indicates that the sweat-patch is susceptible to a potential source of error, from back-diffusion of ethanol form collecting pad across the skin. The article concludes by indicating that the quantitative estimation of ethanol consumption by the sweat-patch test "has not been unequivocally demonstrated" outside the hospital environment. However, the article indicates that greater certainty can be asserted relative to distinguishing drinkers from non-drinkers. This is because the sweat-patch has been shown to be 100% specific and sensitive in distinguishing drinkers from non-drinkers.

The article does include the following proviso: "it is necessary to urge caution against generalizing from these results to the population at large, first because of the small size of the sample, and second because members of this group had selected themselves by volunteering for the study and returning for follow-up."

11. ***A Sweat-Patch Test for Alcohol Consumption: Evaluation in Continuous and Episodic Drinkers,*** **M. Philips, M. H. McAloon, Alcoholism: Clinical and Experimental Research, Vol. 4, No. 4, pp 391-395 (1980).**

In this interesting study the sweat-patch was evaluated over 8 days with 8 drinkers. The experiment was designed to simulate real-world patterns of continuous and episodic drinking. The test was evaluated for its sensitivity, specificity and ability to respond to variations in dosage. Blood was also collected from the subjects to compare with the sweat-patch data. The results of the test allowed the authors to conclude that the sweat-patch was 100% sensitive and specific. The sweat-patch was able to clearly distinguish between drinkers and non-drinkers. The authors do not assume however, that the results are applicable outside the laboratory setting.

The authors conclude by indicating that they plan a larger study, and wonder whether or not their study has applicability outside the laboratory. They indicate:

> We conclude that under the circumstances of a controlled drinking experiment, the sweat-patch test provided an objective index of alcohol drinking behavior. We suggest that this test has potential applications in clinical practice and research, but that further studies are needed to determine its acceptability to patients, its resistance to tampering, and its effect on drinking behavior.

12. ***New Instrument Using Gas Sensors for the Quantitative Analysis of Ethanol in Biolgical Liquids,*** **H.G. Giles, G.E. Renaud, S. Meggiorini, Y. Israel, Alcoholism, Clinical and Experimental Research, Vol. 10., No. 5, pp 521-525.**

The sample size for this study was 53. Here a gas sensor was built into an instrument to measure ethanol in biological liquids by determining head space ethanol concentrations without chromatography. In preliminary it was observed that the sensor had a high sensitivity to gaseous ethanol. The sensor also had a high sensitivity to gases such as propane, butane, and carbon monoxide and I was, therefore relatively non-specific. However, the authors indicate that in clinically relevant conditions, the only gas likely to be present in significant quantities in biological fluids after ethanol consumption was ethanol itself.

Interference tests were done on plasma samples to which methanol, isopropyl alcohol, toluene, acetone or acetaldehyde had been added. The authors indicate that:

> Specificity for ethanol in this method is achieved because ethanol is present in biological liquids at concentrations that are far greater than most endogenous compounds and because ethanol is volatile. While this may be sufficient for the great majority of applications, there are some clinical situations where this level of specificity is unsuitable. Five other volatile compounds were tested for interference. Predictably, methanol and

> isopropyl alcohol do interfere at concentrations that have been associated with clinical toxicity and were therefore investigated the possibility of distinguishing ethanol from these other alcohols.

The Authors indicate that “our method compares well with other methods for ethanol analysis”, but also indicates “the best way to analyze ethanol in biological liquids is by using a gas chromatography equipped with an automated head space sampler and an electronic data system. Further, that calibration at the beginning of an analytical run is still necessary, and that the effects of temperature of the sample and reference vials is marked and this should be taken into consideration for reliable quantization. In locations where the temperature changes rapidly, more frequent calibration would be necessary.

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CONTENTS

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Justice Delayed is Justice Denied: *Due Process Violations in SCRAM Cases*

Patrick T. Barone, J.D., Michael P. Hlastala, Ph.D.

Over the last twenty years societal and political pressures have turned the cause of eliminating drunk driving into the Nation's new prohibition. During this time the courts have struggled with ways to reliably monitor a drunken driving offender's pre-conviction and post-conviction use of alcohol. For this purpose, the courts are now employing a newer product known by the trade-name "SCRAM", an acronym meaning "secure continuous remote alcohol monitor".

The SCRAM device, manufactured by AMS, is a bracelet worn on the offender's ankle. AMS claims that it monitors the use of alcohol as it migrates through the offender's skin. The scientific underpinnings of SCRAM are discussed in more detail below.

While in place the bracelet takes alcohol readings once per hour. If alcohol is detected, the readings are taken twice per hour. The readings are then reported via a modem and the internet to a remote server located outside AMS' home office. The information is then plotted into a graph, which is reviewed by AMS to determine if a possible drinking episode can be "confirmed".

Before an event is confirmed as a consumption event, the manufacturer will submit any positive test results for alcohol to an internal review process. AMS contends that they impose strict, well-defined, and very conservative guidelines for this confirmation process. In addition, for any event to be a "confirmed event", it has to hold up to review by an internal, highly trained committee, and all parties must concur before the event is confirmed. One may conjecture that this arduous confirmation process is necessary in part because of distortions in the typical alcohol metabolism curve. These distortions complicate the interpretation of TAC (transdermal alco-

hol content) curves. This problem is discussed in more detail below.

Once a drinking episode is confirmed the manufacturer will report this confirmation back to the local monitoring agency, which is usually the court where the offender's case is pending. The court will then employ its own follow-up procedures that depend on the status of the case. If the offender is on bond, he or she may face a bond revocation hearing, while if the allegation of alcohol use occurs post-conviction, the offender may be facing a possible show cause hearing that could result in a revocation of probation.

Upon an adverse finding in court for either violation there is always the persistent and very real possibility that significant punitive sanctions will be imposed by the court. Depending on the circumstances, these sanctions might include a potentially lengthy incarceration. Consequently, in these instances certain due process protections ought to apply to the offender, including the essential due process rights of timely notice and the opportunity to be heard. However, in practice, these rights are difficult to protect because the "confirmation" process is not immediate, and then even after the drinking episode is ostensibly "confirmed" by AMS there is an additional delay, which is often as much as several weeks, between the time of the suspected drinking episode and the time the offender is notified of this allegation.

Due to these delays, the ability to collect a potentially exculpatory independent breath or blood test has long since passed by the time the offender receives notice of the allegation. Thus, the offender will find him or herself in the unenviable position of having to prove a negative, that is, that he or she was not drinking, and must do so without any ability to produce convincing evidence to support the denial.

Any attempt to prove the negative will be further frustrated by the lack of information available to the defense relative to the inner workings of the device. This lack of information is based in part on the proprietary nature of the device that understandably, the manufacturer wishes to keep confidential. These two factors, however, coalesce to create significant Constitutional problems for the accused. To fully comprehend these problems it is important for practitioners to first have a comprehensive understanding of what is known about the science that underlies the SCRAM bracelet.

The Science of Transdermal Alcohol Monitoring

The SCRAM device works by measuring the gas alcohol concentration over the skin. Alcohol is delivered to the skin via blood flow. Alcohol then diffuses through the perfused tissue layer, the epidermis and the *stratum corneum* and then into the gas above the skin[1]. The *stratum corneum* is made up of densely packed cells and represents the major barrier to alcohol diffusion. Thus the diffusion process is a "diffusion-limited" (depends on the resistance to diffusion) system which varies considerably depending on the physiological (or pathological) properties of the skin.

In addition to passive diffusion, detectable perspiration contributes a conductive component to the process. In the case of perspiration, alcohol dissolved in sweat contained in the sweat glands is carried to the surface by the convective liquid movement to the surface. Under normal circumstances, perspiration represents only a small component of the transdermal skin flux. However, under conditions of exercise (increase in body heat) or hyperthermia, the increase in sweat production to help in body cooling will enhance the rate of transdermal alcohol exchange.

The diffusive alcohol exchange occurs due to a net movement from a region with high concentration to a region with a lower concentration. When the blood alcohol concentration (BAC) is higher than that at the surface of the skin, there is a net alcohol flux from the blood to the gas above the skin. During the alcohol absorption phase, when the BAC is increasing, alcohol diffuses from the blood toward the skin surface.

During the elimination (burn-off) phase, the opposite occurs as alcohol diffuses from the gas above the skin toward the blood. Because the exchange is diffusion-limited in both directions, the shape of the transdermal alcohol concentration (TAC as denoted by AMS) curve is distorted relative to the shape of the BAC curve. The TAC curve is generally flatter (decreased peak height) and the rates of increase and decrease of TAC are reduced relative to the same values for the BAC curve (Anderson & Hlastala). This curve distortion complicates the interpretation of TAC curves.

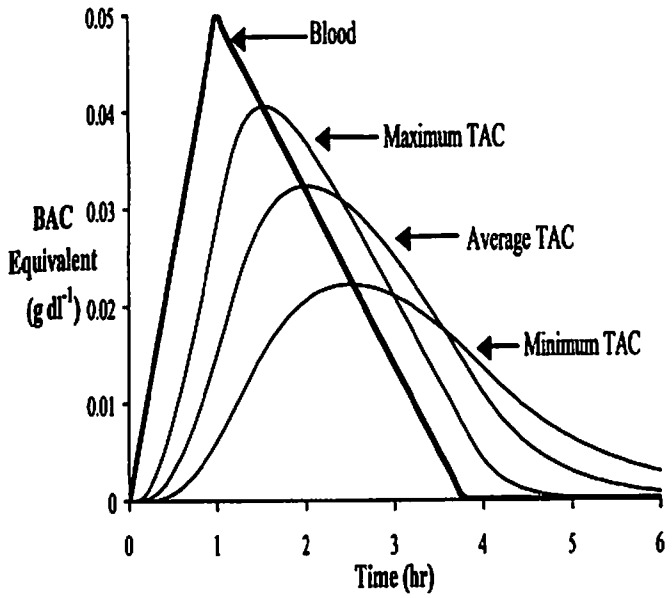

Figure 1 illustrates the distortion of the TAC curve relative to a hypothetical BAC curve given the inter-individual variation in skin diffusion properties.

Generally, the process of authenticating an alleged drinking episode requires two important assumptions. First, that the height of the TAC curve is directly related to the BAC curve and is determined by adjusting with a fixed correction factor. The practice of converting TAC curve by a constant multiplier assumes that the shape of the TAC curve is identical in form to the BAC curve. This assumption is flawed because the shapes are quite different (as shown in Figure 1). If the subject has an average TAC curve, then correction by a constant factor would be appropriate. However, if the subject has a near maximum TAC curve, then the peak BAC would be overestimated using an average correction factor. Similarly, if the subject has a near minimum TAC curve, then the peak BAC would be underestimated using the average correction factor.

Second, that the rate of TAC decline is decline is equal (or at least similar) to the rate of BAC decline (burn-off rate). Under normal circumstances neither of these assumptions can be true due to the variations in skin diffusion properties among the normal population, thus leading to false positives (apparent readings of supradermal gas alcohol concentration above 0.02 gm/dl when the BAC is actually lower than 0.02 gm/dl). The impact of errors in these assumptions have not yet been adequately evaluated. Because of the normal physiological variation in skin diffusion properties, the SCRAM device can yield either false positives or false negatives.

The method used by AMS to determine whether an alleged drinking event is a "Confirmed Drinking Event" is subjective at best. A data string showing the alleged event is reviewed by employees of AMS. The criteria used for determining whether the data truly indicates a drinking event is unclear and not specifically defined. This determination ostensibly relates to the examination of the TAC rate of decline with the assumption that this rate directly correlates with the BAC burn-off rate. However, the ability to make this determination depends critically on the assumption that diffusion properties of the specific subject's ankle skin are the same as an average ankle.

If AMS were to develop a set of specific criteria for judging an alleged drinking event, it would make the determination "objective" rather than "subjective," legitimizing the interpretation and minimizing the possibility of false-positive determinations of drinking events. Such an approach would also speed up notification to the subject when a positive drinking event is identified so that he or she can obtain exculpatory data.

Another concern relates to the resolution of determination of the "burn-off" rate of the TAC curve. The data points are obtained every 30 minutes (rather than continuously). In the presence of measurement or random noise, it becomes difficult to accurately measure the rate of decline of the TAC curve. A systematic analysis of the effects of measurement noise (error) has not yet been published.

How the Typical SCRAM Case Causes Science and Law to Collide

Aside from the apparent reliability problems discussed above, the very processes involved in the monitoring and confirmation of a drinking episode by the manufacturer requires a significant delay between the "confirmation" of a drinking episode and the actual notification of this "confirmation" to the offender. This systematic problem with SCRAM is exacerbated by the physiological delay in the expression of the alcohol through the skin. Scientific literature has shown

that this delay might be as much as 120 minutes[2], while the manufacturer claims that this delay might be as much as 180 minutes[3].

A third source of delay may be termed "judicial" delay, which is the delay that occurs between the notification of a Confirmed Event by the manufacturer and the subsequent notice to the offender by the monitoring agency. These delays create an almost certain violation of the offender's constitutional rights because they effectively preclude the offender from any opportunity to seek and obtain potentially exculpatory evidence in the form of an independent test. Independent testing is particularly crucial where, as here, recent scientific research suggests that the data and processes used to "confirm" drinking are respectively both unreliable and subjective[4].

A review of the applicable case law suggests that while this specific issue has not been addressed at the Federal level, Federal courts have resolved the more general right to obtain exculpatory evidence in favor of the accused[5]. On the other hand, the right to independent testing, or at least to be protected from active interference with this right, is protected by many state courts. For example, in Michigan, once a drunk driving accused has submitted to the chemical test of the police officer's choosing, he or she has the right to collect an independent test. If this right is interfered with it may result in a dismissal of the drunken driving case[6]. Many other state appellate courts have rendered analogous rulings[7].

Under federal law, the United States Supreme Court and the Circuit Courts have provided ample and consistent legal authority for the proposition that an accused is entitled to obtain exculpatory evidence[8]. This right has been explained as follows: "[d]efendants have a due process right to obtain evidence in the possession of the prosecutor if it is favorable to the accused and material to guilt or punishment[9]."

Additionally, the Sixth Circuit Court of Appeals similarly stated that, pursuant to *Brady*, a prosecutor is required to turn over evidence that is "favorable to the accused and 'material' to guilt or innocence." Plus, when evidence is not turned over, it results in a Constitutional violation[10]. Along this line, the United States Supreme Court has held that suppression by the prosecution of evidence favorable to an accused upon request violates due process where the evidence is material either to guilt or to punishment[11].

In the context of transdermal blood alcohol monitoring, the wearer of a SCRAM bracelet should be entitled to obtain an independent breath test or blood test, or both, if AMS indicates that an alcohol incident has occurred. For this type of protection to be meaningful, the SCRAM bracelet must have an audible alert signal that advises the wearer that a claimed "violation" has been detected. Then, an immediate blood draw could either refute the monitoring device's accuracy or quantify (through GC-MS analysis) what chemical has led to the alert being recorded.

The reason for this is, of course, that the wearer of the SCRAM bracelet would otherwise be subjected *exclusively* to AMS's alcohol analysis, which, as stated, is currently based on undisclosed *proprietary* evaluation methods, as well as technology that is inherently inferior to breath testing or a blood alcohol screen. Previous scientific research has shown that unlike traditional forms of breath and blood testing, SCRAM readings are not intended as an accurate or reliable quantitative measurement[12].

Nevertheless, judges and related court personnel may argue that there is no due process right to obtain exculpatory evidence relative to SCRAM bracelet situations because the case law that addresses exculpatory evidence pertains to the adjudication of guilt or innocence, as to a charged offense, whereas, typically, an individual who is required to wear a SCRAM bracelet has already been convicted of an alcohol-related crime, or he or she is simply being monitored for alcohol consumption while awaiting trial or disposition. However, an argument of this nature would actually be at odds with *Brady* and its progeny because often the penalty for consuming alcohol while in a home-monitoring program—where members of AMS would be the sole determiner of whether an alcohol event actually occurred—is incarceration. Therefore, regardless of how judges and court personnel may wish to characterize the matter, the fact remains that an individual may lose his or her liberty based on AMS's determination—unless the collection of independent evidence is permitted in order to potentially exculpate the accused.

Furthermore, whether existing evidence is suppressed, relative to the discussion in *Agurs*, or whether the accused is prohibited from going out

and obtaining exculpatory evidence, the result is the same – namely, an individual may end up incarcerated for allegedly consuming alcohol while wearing a SCRAM bracelet, when in fact there may have been no alcohol consumption whatsoever.

Consequently, if courts are going to employ the apparently inferior science of transdermal blood alcohol monitoring in connection with pre-conviction and post-conviction procedures, then those procedures must be safeguarded with more reliable technology in order to avoid the specter of an innocent person losing his or her liberty based only on a dubious and non-disclosed analysis from AMS. Indeed, the *Agurs* decision by the United States Supreme Court substantiates this conclusion. While addressing the issue of competing evidence, relative to exonerating an accused, the Court stated the following: "If, for example, one of only two eyewitnesses to a crime had told the prosecutor that the defendant was definitely not its perpetrator and if this statement was not disclosed to the defense, no court would hesitate to reverse a conviction resting on the testimony of the other eyewitness[13]."

The same is true with a statement from AMS that an individual has consumed alcohol—a court should not hesitate to permit the accused an opportunity to obtain exculpatory evidence, in the form of a more reliable breath test or blood test, in order to prevent an innocent person from being wrongfully incarcerated or subjected to other unwarranted penalties. Thus, if anything, the SCRAM bracelet should be used as merely a preliminary screening device—so long as the wearer is notified of AMS's determination that an alcohol incident has allegedly occurred, within sufficient time for exculpatory evidence to be obtained.

Presently, however, AMS's current technology and reporting protocol does not permit timely notification. Accordingly, the use of SCRAM technology, in its current form, is likely to violate an innocent user's due process rights. As a result, it appears that SCRAM bracelets should not be used for any purpose resulting in any form of penalty until appropriate notification procedures can be implemented. At best, a "positive" SCRAM reading should be merely a "presumptive" violation, and be required to be "confirmed" by an immediate forensic test.

Possible Solutions to SCRAM's Due Process Problems

In states where SCRAM is being utilized, courts often recommend it as an alternative to incarceration. Consequently, the SCRAM bracelet is often viewed by defense counsel as a pragmatic way to keep his or her client out of jail. While problems with the underlying science are discussed above, and there are many, it can nevertheless be said that the SCRAM bracelet probably works reasonably well at detecting an actual drinking event most of the time.

Thus, because of the possible benefits to the client it may not be necessary to advocate against the use of the SCRAM bracelet altogether. However, it is abundantly clear that the device should never be used for evidentiary purposes to "prove" the use of alcohol. Instead, the device should only be used to require that the wearer appear within a prescribed time for a more accurate alcohol test which would preferably be a blood test. Such a change would relegate the SCRAM bracelet to the position it ought to occupy, that of a simple screening test, or in other words, to the position of the roadside preliminary breath test. This conclusion is further compelling because the technology for both devices is identical, i.e., both use fuel cells to detect the presence of alcohol. They are both "presumptive" testing methods, not "confirmatory".

Provided the manufacturer can change their procedures and technology so that an offender can assuredly obtain "real time" notification of the alleged "confirmed" alcohol event, the wearer will be reasonably well protected by the ability to obtain an independent test. However, without such immediate notice there is no way to adequately protect the wearer's Constitutional rights. With such notice and audible alert capabilities, the SCRAM bracelet can becoming a powerful tool in the court's quest to monitor probationers on house arrest and effectively stop the offender's use of alcohol.

1. Joseph C. Anderson and Michael P. Hlastala. *The kinetics of transdermal alcohol exchange*, J Appl Physiol 100: 649-655, 2006.

2. Robert M. Swift, Christopher S. Martin, Larry Swette, Anthony LaConti & Nancy

Kackley, *Studies on a Wearable, Electronic, Transdermal Alcohol Sensor*, 17 Alcoholism: Clinical and Experimental Research 4 at 721- 725 (1992).

3. Testimony of Jeffery Hawthorn as provided in Evidentiary Hearing at 86, *People vs. Glaza*, Oakland County Dist. Ct., (Dec. 15, 2004) (04-003877).

4. Anderson and Hlastala, *supra*.

5. The linchpin of this proposition is the case *Brady v. Maryland*, 373 U.S. 83; 83 S.Ct. 1194; 10 L. Ed. 215 (1963).

6. *See.*, e.g., *People v Underwood*, 153 Mich App 598; 396 N.W.2d 443 (1986), (*Accord, People v. Anstey,* No. 255416, 2005 WL 292237 (Mich.App. Feb. 8, 2005)).

7. *See Commonwealth v. O'Brien,* 434 Mass. 615, 750 N.E.2d 1000 (2001). (No requirement exists that the police assist a defendant charged with driving while intoxicated (DWI) in obtaining an independent medical examination, but they may not *prevent or hinder* the defendant's reasonable and timely attempt to obtain such an examination, and *State v. Minkoff*, 308 Mont. 248, 42 P.3d 223 (2002) (Upholding a similar rule of "non-impedance" of a person's independent test rights. *See also State v. Dull,* 176 Ga. App. 152, 335 S.E.2d 605 (1985). (Holding that a failure to inform defendant of right to additional, independent chemical test, not failure to obtain and show waiver affirmatively, rendered results of chemical test administered at arresting officer's request inadmissible).

8. *See Brady v. Maryland.*

9. *People v. Stanaway*, 446 Mich 643, 666; 521 N.W.2d 557, 569 (1994).

10. *United States v. Frost*, 125 F. 3d. 346, 382 (6th Cir. 1997).

11. *See United States v. Agurs*, 427 U.S. 97; 96 S.Ct. 2392, 2398 n.10; 49 L.Ed.2d 342 (1976).

12. Daniel J. Brown, 7 (10) *The Pharmacokinetics of Alcohol Excretion in Human Perspiration*, 7 Methods and Findings Experimental Clinical Pharmacology 539 (1985).

13. *United States v. Agurs* at 2402, n.21.

Patrick T. Barone's firm is headquartered in Birmingham, Michigan. In March of 2006, Mr. Barone was selected by John Tarantino to assume authorship of "*Defending Drinking Drivers*" (James Publishing) a well-known and highly respected multi-volume national legal treatise on DUI-DWI Law and Practice. He also holds Sustaining Member status in The National College for DUI Defense. His law firm covers all of Michigan and represents only those accused of crimes involving impaired driving as a result of allegedly ingesting too much alcohol or drugs. He can be contacted at baronedefensefirm@sbcglobal.net

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Identification Of Transdermal Ethyl Alcohol

Michael P. Hlastala, Ph.D. and Patrick T. Barone, J.D.

The Secure Continuous Remote Alcohol Monitor (SCRAM) is a device used by courts throughout the United States to monitor a subject's abstinence from alcohol consumption over long periods of time. The device is worn over the ankle just above the skin, and the presence of alcohol is determined indirectly by examining the diffusion of alcohol through the skin.

Typically, the device is worn pre-conviction as a condition of bond, or post-conviction as a condition of probation. During this time, if the monitoring agency "confirms" that a subject has engaged in a drinking event then the consequences can be significant, even possibly including incarceration.

The use of SCRAM has increased since its introduction in 2002[1] and is now used in some fashion in at least 44 states. But just as its use has increased, so have the claims of false positive results. Therefore, when evaluating a client's contention that he or she is being falsely accused, it is important to have an understanding of the scientific, technical and legal developments of SCRAM. A review of prior work leading to the development of SCRAM has been presented by Hawthorne and Wojcik[2], and experimental data have been published by Sakai et al[3]. and Swift[4].

It is also important to have an understanding of the methods used by the device to identify alcohol as it passes from the subject's blood through the skin. This requires some knowledge of the physics and physiology that are involved.

Blood-Skin Gas Exchange

SCRAM utilizes fuel cell technology to measure the amount of ethyl alcohol above the surface of the skin.

Ethyl alcohol diffuses from the blood through the skin to the surface of the skin where it is measured.

The exchange process between blood and skin is a combination of diffusion (passive movement from a region of higher concentration to a region of lower concentration) and convection (liquid flow from the sweat glands carrying alcohol from the subcutaneous regions to the surface of the skin). A schematic of the skin is shown in Figure 1. Blood flow through blood vessels delivers alcohol to the skin. The alcohol can then diffuse through the upper part of the dermis and through the epidermis to the surface of the skin. Sweat glands, as shown in Figure 1, help cool the body by secreting liquid to the surface. The sweat then evaporates, cooling the skin. The sweat accumulates alcohol near the bottom of the dermis in the sweat gland and delivers it to the surface with the sweat.

It is interesting to note that the amount of sweat, and, therefore to some extent, the amount of alcohol being moved through the skin, does not remain static. For example, under conditions of exercise or heat, sweat contributes more alcohol to the surface of the skin to assist with the body's cooling mechanisms. That said, the delivery of alcohol to the surface depends on the blood alcohol concentration (BAC), blood flow to the skin, activity level and body temperature.

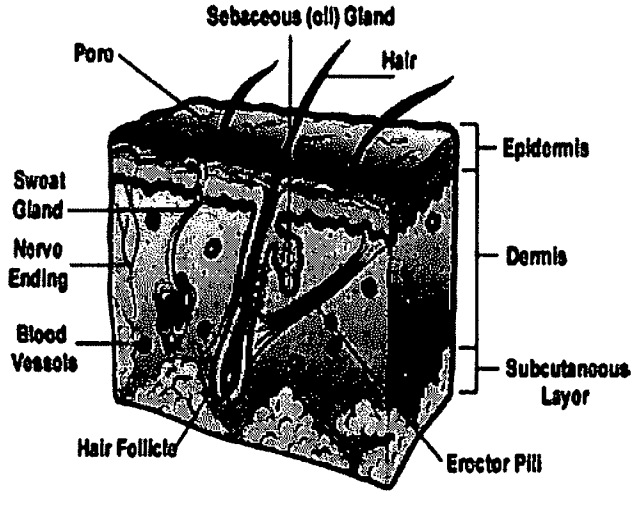

Figure 1. Artist's drawing of the human skin.

Blood Alcohol Dynamics and Metabolism

Consumed ethyl alcohol passes into the stomach where only a small fraction (~15%) is absorbed through the walls of the stomach and into the blood contained in the blood vessels surrounding the stomach. The stomach contents (containing alcohol) then passes into the small intestine (duodenum), which is richly vascularized and absorbs the remaining alcohol. The blood stream distributes alcohol throughout the body and delivers alcohol primarily to the watery tissues of the body (brain, muscle, etc.). The blood circulation also takes alcohol to the liver where it is broken-down (metabolized) and eliminated from the body.

The elimination of ethyl alcohol occurs primarily through the metabolism of it in the liver. Additional trace elimination occurs through the breath, urine, feces, as well as diffusion through the skin (the principle used by SCRAM). The rate of elimination (used interchangeably with burn-off) of BAC occurs at a rate that varies between 0.006 gm/dl/hr and 0.029 gm/dl/hr for 95% of the normal human population. The average elimination rate for males and females is 0.017 and 0.020 gm/dl/hr, respectively[1,2].

The rate and magnitude of TAC elimination is, however, less clear, though it can certainly be said that TAC decreases because the BAC is decreasing. If BAC is greater than the skin alcohol concentration, alcohol diffuses through the skin to the surface of the skin. When the BAC is lower than the skin alcohol concentration, alcohol diffuses from the skin back to the blood. This is a dynamic situation and is influenced by the BAC, properties of the local skin, and the change in BAC with time. There is no equilibrium between BAC and TAC[3]. Consequently, although blood alcohol concentration can be expressed in terms of "gm/dl" or "gm/100ml", supradermal alcohol concentration is expressed as "%".

It is difficult to describe the units of the readout of SCRAM. AMS, which manufactures SCRAM, chooses to assign an average "partition ratio" to the blood/skin of about 1500. Essentially, AMS assumes that the blood/skin partition ratio is 1500 and the blood/breath partition

ratio is 2100, and the TAC scale is adjusted by the ratio of these two. These assumptions require that the TAC scale be adjusted by a ratio of 2100/1500, which equals 1.4. It does appear, however, that like the breath/blood partition ratio, the "blood/skin" varies among different individuals due to a difference in skin diffusion characteristics. In fact, it would be expected to vary even more widely than breath/blood partition ratio because the amount of variation in skin diffusion characteristics is subject to far more variables among the human population than those involved with breath and blood. Therefore, the TAC scale is "rough" at best, rendering the calculation of elimination rates quite inaccurate.

Additionally, the blood alcohol dynamics cause this ratio to change dramatically as the BAC changes. AMS has chosen to use the unit "%". After correction of the TAC to an equivalent BAC (0.020 gm/dl BAC is assumed to be equal to a 0.020 % TAC for an average person). It should be noted that an adjusted TAC will never occur concomitant with the comparative BAC due to the time dependence of the diffusion process. According to AMS, this delay in peak absorption between TAC and BAC may be as much as 180 minutes.

The primary mechanism for the exchange of alcohol through skin in a non-exercising subject is passive diffusion. The alcohol molecules move from a region of high concentration to a region of low concentration. This exchange process has been evaluated in a study by Anderson and Hlastala[5]. The dynamics of skin exchange is illustrated in Figure 2. The straight solid thick lines show an idealized blood alcohol profile with an absorption time of 1 hour and a burn-off rate of 0.018 gm/dl/hr (the peak BAC of 0.050 gm/dl is eliminated at a rate of 0.018 gm/dl). The peak BAC of 0.050 mg/dl is eliminated after about 2.78 hours from peak to zero BAC. The curves labeled "Gas" are TAC (transdermal alcohol concentration) for a variety of subjects with varying skin properties over the range of known measurements in human subjects.

It should be noted that each gas curve is distorted relative to the blood curve because the peak of the TAC curve is reduced in magnitude and delayed relative to the BAC curve. The distortion results from the time that is required for diffusion through the skin. The other point to take from these curves is that the TAC burn-off is linear (a straight line) due to the metabolic characteristics of ethyl alcohol. The slope (change in TAC per unit change in time) varies depending on the characteristics of the skin, but in no case is the TAC elimination greater than the BAC elimination.

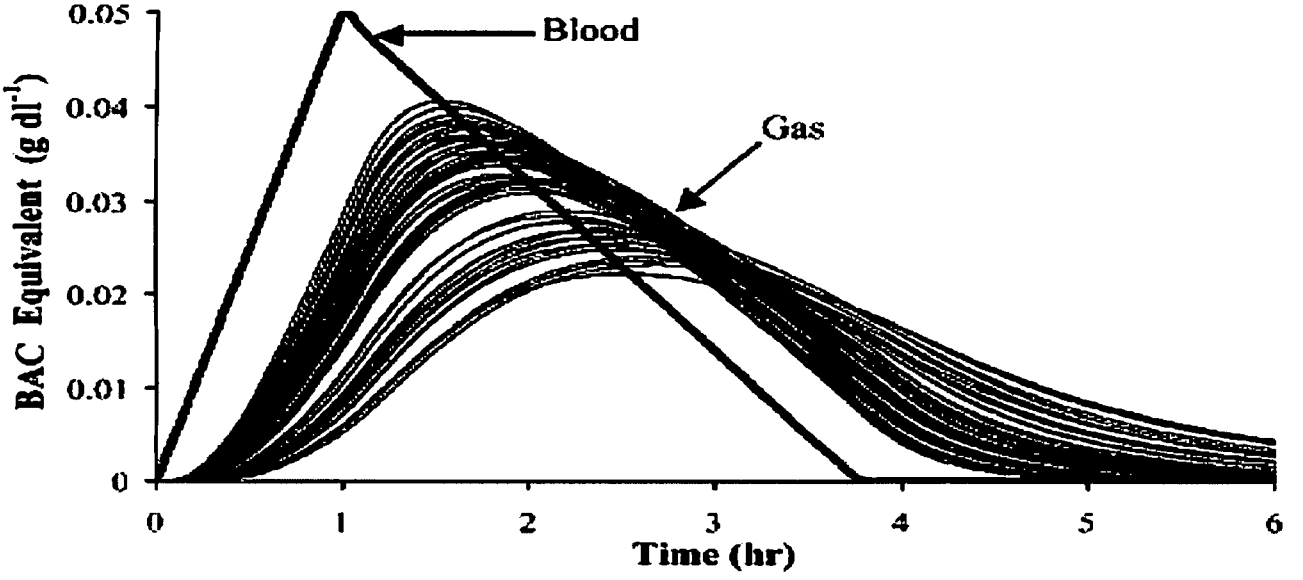

Figure 2. Variation in TAC (Gas) among individuals with differing skin characteristics each having the same BAC profile. From JAP 100: 649-655, 2006, reproduced with permission from the American Physiological Society."

Fuel Cells

The measurement of a subject's TAC by SCRAM is made with a fuel cell, and the numbers produced by these measurements are then used to plot the TAC curve. As a result, it may be said that a TAC curve is only as viable as the fuel cell used to produce it.

Fuel cells are electrochemical energy conversion devices. They produce electricity from external supplies of fuel and oxidant, which react in the presence of an electrolyte. SCRAM fuel cells sample at 60-minute intervals. If a TAC of greater than 0.020 % is seen, SCRAM will sample every 30 minutes. Fuel cells are not specific for ethyl alcohol. They react with any chemical that has a hydroxyl group (-OH), and will therefore react to chemicals other than beverage or ethyl alcohol. Potential contaminating (causing false positives) products include methyl alcohol[6,7] (methanol), n-propanol (propyl alcohol),[8] isopropyl alcohol[9,10,11,12,13] (2-propanol), n-butanol,[14] 2-butoxyethanol[15,16,17](ethylene glycol monobutyl ether), antifreeze (ethylene glycol and propylene glycol) and glycol ether (1-methoxy-2-propanol) [18,19]. All of these chemicals have at least one hydroxyl group and will react with a fuel cell. These contaminants get into the body when an individual is exposed to the product.

One possible reason for a false positive or an incorrectly "confirmed" drinking event is that contaminants can diffuse into the blood through the skin or be absorbed through the lungs due to the inhalation of vapors. Once in the body and the blood stream, the contaminant "behaves" much like beverage alcohol, in that it will diffuse through the skin and come into contact with the SCRAM fuel cell and potentially cause a false positive alcohol reading.

This potential problem is exacerbated by the method used for identification of ethyl alcohol -- it is indirect and based on the elimination rate for ethyl alcohol. The metabolism of ethyl alcohol in the liver is a linear (straight line) process (zero order kinetics) in which the alcohol elimination rate is independent of concentration except at very low concentrations. The alcohol elimination is linear (zero order) and contaminants are exponential (first order). The other contaminating products are eliminated in an exponential manner (first order kinetics) in which the rate of elimination depends on the concentration of the contaminant in the body. In order to identify an apparent drinking event as ethyl alcohol, the elimination must be linear and the elimination rate must be less than 0.025 %hr.

Another potential problem relates to the fact that SCRAM is passive, meaning the wearer is not independently observed or monitored in any way. This is an important fact because although fuel cells are sometimes used for evidentiary breath tests, their limitations are well known. Because of these limitations certain safeguards -- intended to increase the qualitative as well as the quantitative reliability of a positive test -- must always be followed. At a minimum, these safeguards include a 15-20 minute observation/deprivation period and duplicate testing. However, neither of these safeguards is practical for SCRAM, and neither is employed by AMS or any monitoring agency[20]. This fact alone should cast doubt on the reliability of any positive test.

Other Reasons Contaminants are Sometimes Misread as Alcohol

In addition to the "quantitative" identification of alcohol by the fuel cell, SCRAM must also qualitatively determine that it is metabolized alcohol that is being read and reported. To accomplish this task, AMS also uses the absorption rate as the major criterion for identifying and distinguishing ethyl alcohol from any potentially metabolized or environmentally occurring contaminant. According to AMS, the absorption time of ethyl alcohol must be less than 0.50 %hr. However, all contaminating products that are introduced to SCRAM through the skin have similar absorption times due to the diffusion limitation of the dermis. Only contaminants applied on the surface of SCRAM will have absorption times greater than 0.500 %/hr and are susceptible to being identified as contaminants. Thus, the absorption rate does not help to eliminate contaminating products that are absorbed through the skin or lungs into the blood.

The typical patterns of actual drinking events have been determined by AMS in con-

trolled studies as shown in Figure 3. The drinking events conform to the absorption criterion defined by AMS (absorption rate less than 0.5 0 %hr and the elimination less than 0.025 %hr). Notice that the decline of alcohol with time is a relatively linear process.

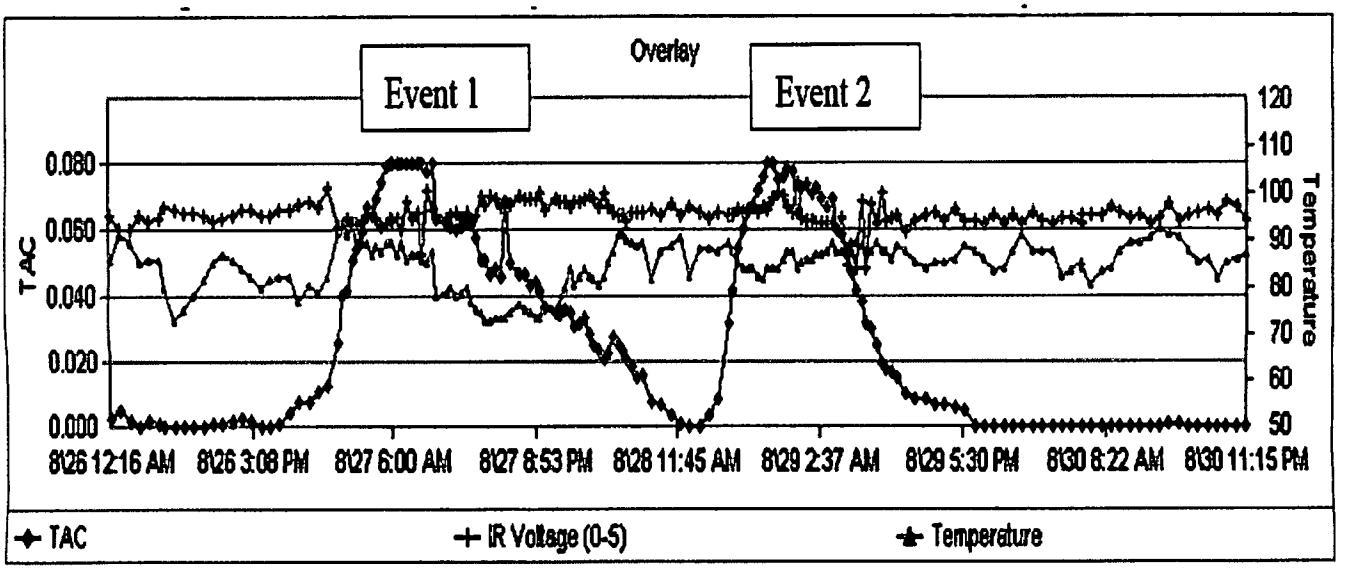

Figure 3. Sample SCRAM curves from an ethyl alcohol drinking subject.

It is also worth noticing the spike (abrupt increase) of approximately 0.020 %hr around *8:00 pm on 8/27.* The occurrence of the spike leads to concern regarding intermittent spikes in SCRAM, sometimes making it difficult to determine the elimination rate. It may be that the electronics are not stable, particularly after prolonged use. It is interesting that the elimination rate for event 2 is greater than that in event 1 in the same individual.

AMS has established a procedure for calculating the elimination rate. They determine the slope of a straight line originating at the peak of the curve and ending when the curve reaches zero. While this method is quite easy to perform, it does not adequately characterize the shape of the curve (linear vs. exponential). This is a particularly important issue in order to accurately determine if the curve is caused by ethyl alcohol. As described above, the elimination of alcohol is a zero-order (linear) process, whereas the elimination rate for all other contaminating gases is an exponential process (elimination rate depends on concentration). As concentration decreases, the elimination rate also decreases. This is why the estimate of the elimination rate of TAC is critical to determining if the curve is caused by ethyl alcohol. Unfortunately, the method used by AMS cannot separate contaminants from ethyl alcohol. Many SCRAM data charts are assumed to be alcohol when they are not.

Sample Cases

To fully understand these concepts, it is helpful to review some sample graphs. Figure 4 is an example of an alleged drinking event. It is important to recognize that the accuracy of fuel cell technology is poor at apparent BAC levels of 0.020 % and below. The alleged drinking event at 4 a.m. on 7/11/07 has two readings that are barely above 0.020 %. In this case, the burn-off calculated from the decreasing points after the alleged event is not sufficiently accurate to quantify burn-off because they are in the inaccurate zone (0.000 % to 0.020 %). The drinking event at 4 a.m. cannot be accurately determined.

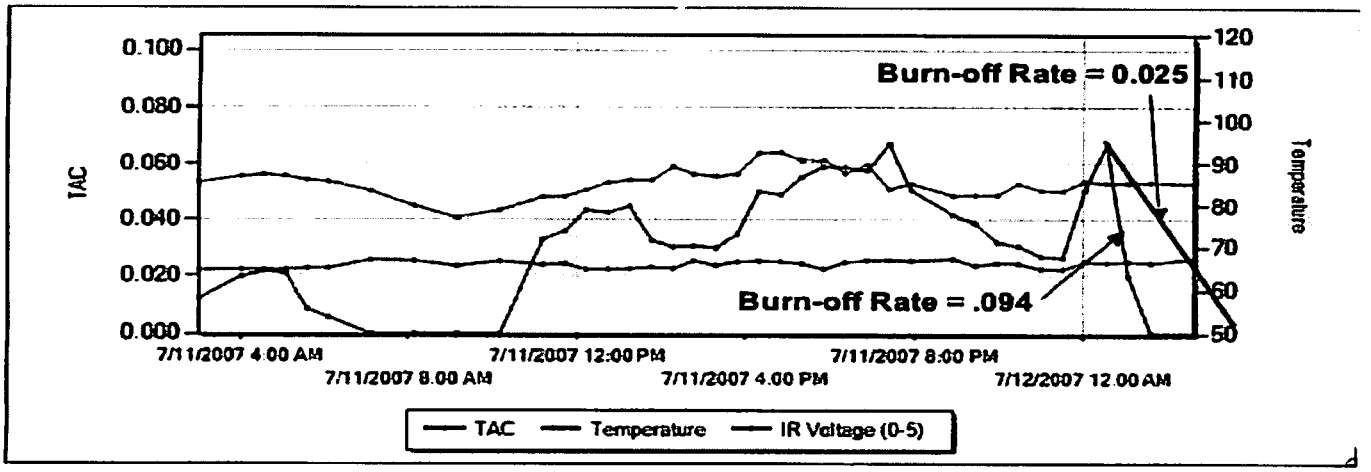

Figure 4. Sample SCRAM curve from a subject.

The second alleged drinking event shown in Figure 4 begins at approximately 10 a.m. on 7/11/07. The TAC rises to a maximum of 0.043 % at about 1 p.m. on 7/12/07. The TAC then decreases to approximately 0.030 % and then rapidly rises to a peak of about 0.060 % at about 7:30 a.m. on 7/11/07. The curve decreases at a rate of about 0.009 %/hr until 11 a.m. on 7/12/07. At this time, the TAC rises rapidly to 0.067 % at 12:30 a.m. and drops to 0.020 after 30 minutes. The elimination rate for the TAC is 0.094 %/hr, much greater than the maximum elimination rate of 0.025 %/hr (shown by the thick black line). Therefore, this alleged drinking event is inconsistent with ethyl alcohol and must be due to a contaminant.

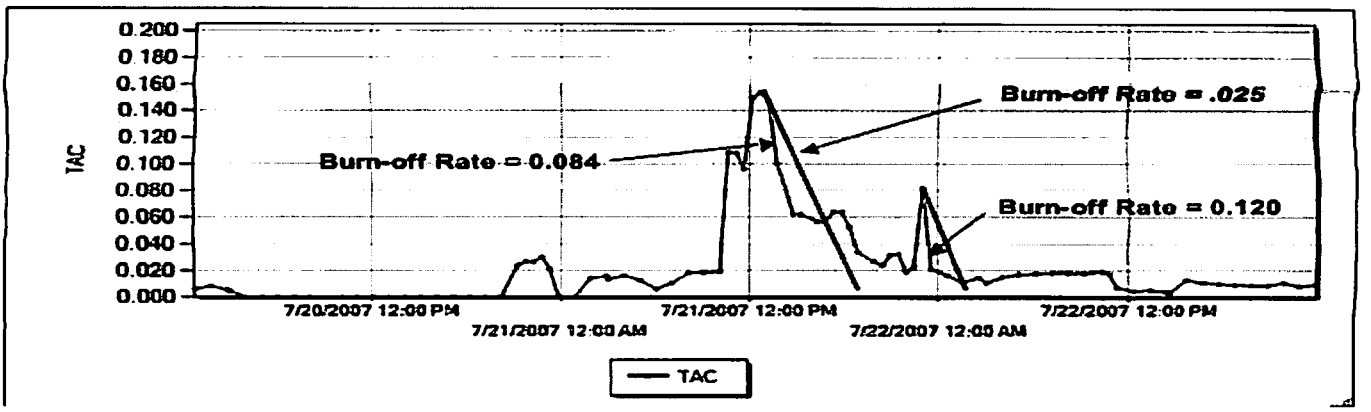

Figure 5. Sample SCRAM data with an alleged drinking event.

Figure 5 shows an example of SCRAM data in an individual who wrapped a SCRAM device with a large plastic bag and then sat in a hot tub. Under these circumstances, the SCRAM was exposed to water due to leakage of the plastic bag as well as increased pressure due to immersion in about three feet of water. The elevation of the TAC in this case may have been due to the water leakage or the increased pressure, or both. Two peaks in TAC are shown at approximately midnight on 7/21/07 and at 11:00 a.m. on 7/22/07. The decrease after the first peak shows an elimination rate of 0.084 %/hr. The TAC profile after the second peak shows an elimination rate of 0.120 %/hr (almost five times the maximum human ethanol elimination rate). Thus, the TAC profile is not consistent with ethyl alcohol due to the high elimination rates.

Figure 6 shows an example of a SCRAM unit exposed to water by an individual who showered daily. Water leakage resulted in sharp peaks with an abrupt rise in apparent TAC followed by a rapid return to zero. The peaks shown in this figure are quite varied in magnitude. Figure 6 illustrates a major weakness of SCRAM, namely sensitivity to the presence of small amounts of water.

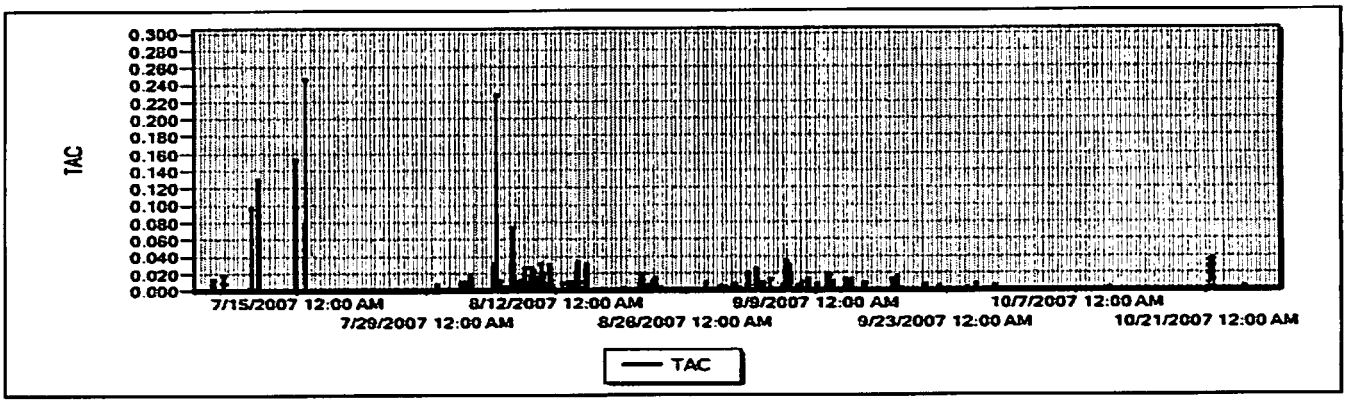

Figure 6. Sample SCRAM data after exposure to water caused by daily showering.

The Discovery Packet and The Defense of the SCRAM Case

SCRAM tracks three separate parameters: the "TAC"; the temperature; and the distance or IR voltage. The latter two factors are used to help determine if any tampering has occurred, and it will often be the case that alleged tampering and alleged drinking occur together. Separate graphs can be produced for each of the three parameters, and a composite graph can also be produced. This composite (Figure 7) has all three factors on the same graph. In most instances, only the composite graph is provided to the defense, and often this will be in the form of a faxed copy. One problem with a composite graph is that it requires color, because each factor is denoted on the graph by a different color. Consequently, black-and-white graphs are very difficult, if not impossible, to appropriately assess.

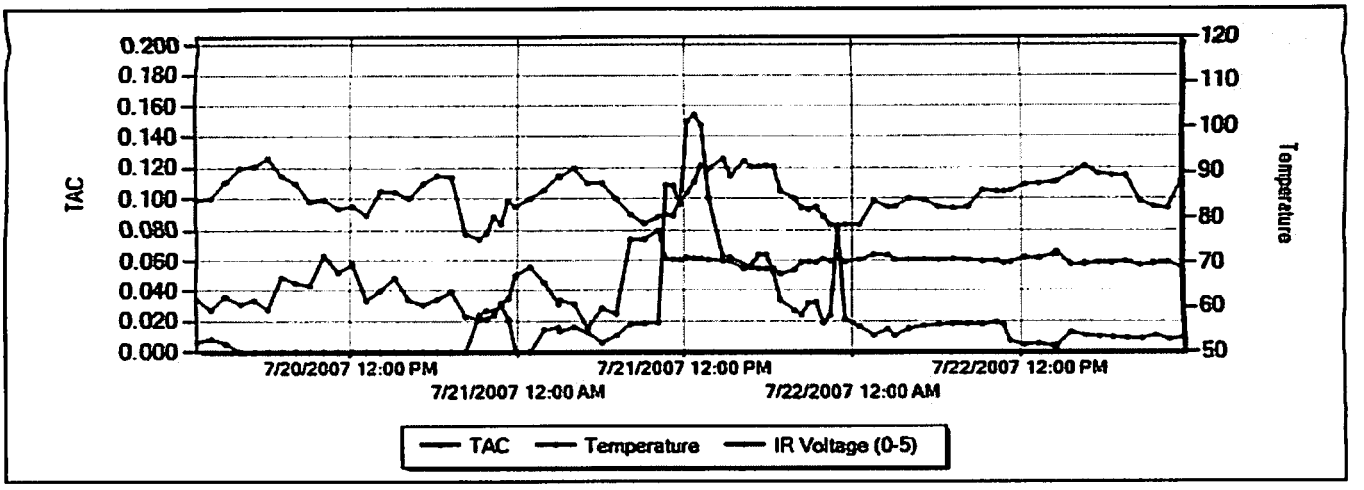

Figure 7. Composite graph with TAC, Temperature and IR Voltage associated with the subject shown

Along with these four types of graphs, also available is a summary of the hourly readings for each factor, and these should also be obtained and reviewed. These hourly (or half-hour) readings are essentially the numbers that are used to plot the graphs themselves. It would also be very helpful to obtain a copy of the written protocol used by AMS to distinguish between a "possible" violation and a "confirmed" violation.

Once these graphs are reviewed, be mindful of the fact that there are no clear methods for identifying ethyl alcohol profiles. In fact, AMS takes some liberty with the identification of ethyl alcohol. Fluctuations in the data are often ignored and an average curve is drawn through the fluctuations to cause the appearance of an ethyl alcohol curve. AMS defines the elimination by drawing a straight line between the peak of the TAC curve to a point where the TAC reaches zero. Using this method converts an ex-

ponential elimination rate to a linear elimination rate. So it is important to carefully examine the data to eliminate the possibility that an alleged drinking event is no more than a contaminant to which the subject was exposed.

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