*Technology Review*

# Continuous Transdermal Alcohol Monitoring

By Mark H. Wojcik*

## Background

The purpose of this article is to provide an up-to-date overview of "continuous alcohol monitoring," with a focus on the SCRAM Continuous Alcohol Monitoring® (SCRAM CAM®) bracelet and technology, including the science, research, and testing. Since its introduction in 2003, the SCRAM CAM bracelet has become one of the mostly widely used tools for alcohol monitoring in corrections. It is currently used in seven countries, all fifty US states, and over 4,800 US courts and agencies. As of this writing SCRAM CAM has been used to monitor over 790,000 unique individuals for a total of over 84,000,000 monitored days, and is being used to monitor over 23,000 unique individuals per day.

## Transdermal Alcohol Science[1]

The discovery that measurable amounts of ingested alcohol are excreted through human skin was first published in 1936, when Nyman and Palmlov estimated that 1% of ingested alcohol is ultimately excreted through the skin. The first product utilizing transdermal alcohol testing was an alcohol "sweat-patch" applied to the user's skin for a period of several days, where it absorbed liquid sweat excreted through the skin. The patch was removed and analyzed using separate equipment in order to determine the amount of ethanol[2] that the sweat-patch absorbed. Those results were then tied to the consumption of alcoholic beverages. A significant amount of research was performed with the sweat-patch between 1980 and 1984, and that research concluded there was a statistically significant linear relationship between the concentration of ethanol in sweat and the average blood alcohol concentration (BAC). One of the technical difficulties of the sweat-patch was that it was susceptible to diffusion of ethanol from the patch back across the skin.

While sweat-patch research focused on ethanol concentrations in liquid sweat, other research was conducted in the late 1980s that measured the ethanol concentration in vapors formed above the skin. Consumed alcohol distributes throughout the body in relationship to each organ's water content. The skin is an organ that has water content, so it will absorb some of that distributed alcohol. "Insensible Perspiration" is the water vapor that escapes through the skin throughout the day, and when the water in the skin also contains alcohol, the insensible perspiration above the skin also contains alcohol vapor. Research at the Indiana University School of Medicine measured this alcohol vapor by placing plastic bags around the hands of people who consumed alcohol, measuring the amount of ethanol in the insensible perspiration that accumulated in the bag, and comparing those measurements to known ethanol standards. Researchers concluded that, "Ethanol gas is readily excreted in insensible perspiration in sufficient quantities to allow reliable estimation of BAC." This study was also the first published research to note that ethanol concentrations above the skin had clear absorption and elimination phases that corresponded to BAC, and that there was a distinct, measurable lag between peak BAC and peak alcohol concentration above the skin. A follow up study by the same

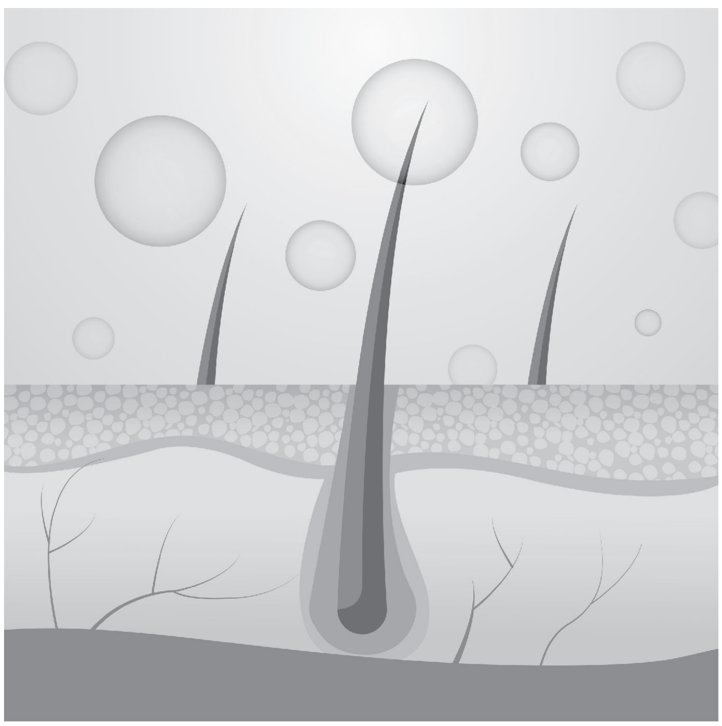

**Figure 1. The presence of alcohol can be detected in perspiration vapor above the skin.**

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researchers later concluded that the pharmacokinetic parameters for ethanol concentrations above the skin were different from those of BAC and Breath Alcohol Concentration (BrAC), so BAC could not be accurately estimated from transdermal alcohol concentration (TAC) in the same manner as from BrAC. Similar research was performed at the University of Toronto during the late 1980s; however, this research dispensed with the polyethylene bags and complex laboratory equipment and used a portable ethanol sensor placed directly above the skin to measure ethanol vapors excreted by both rats and humans. Like prior studies, the researchers concluded there was a very high correlation between ethanol concentration above the skin to both BAC and to BrAC. In addition, the study recorded distinct absorption, peak, and elimination phases in controlled dosage experiments. Finally, the researchers suggested that electrical signals triggered by high skin vapor ethanol concentrations could be used to activate a warning device for problem drinkers or law enforcement, and in fact, their crude device was probably the closest precursor to today's SCRAM CAM bracelet.

The late 1990s and early 2000s ushered in new devices for transdermal alcohol measurement, including the Wrist Transdermal Alcohol Sensor (WrisTAS) by Giner, Inc., the Secure Continuous Remote Alcohol Monitor (SCRAM; now called SCRAM CAM) by Alcohol Monitoring Systems, Inc. (AMS), and the Transdermal Alcohol Detector (TAD) by BI, Inc. Of these, SCRAM CAM has the most usage in the corrections marketplace.

*A note on terminology*: Prior to the introduction of SCRAM CAM a variety of terms and units were used to refer to the concentration of alcohol in both liquid sweat and insensible perspiration. SCRAM CAM used the term Transdermal Alcohol Concentration, or TAC, which has become the de facto standard unit. TAC is analogous to BrAC in that the actual measured transdermal alcohol concentration is transformed by parameters that equate it to BAC, on average. However, as stated previously, pharmacokinetic parameters for TAC are different from those of BAC and BrAC, so TAC cannot be used to accurately estimate BAC the way BrAC can. Although TAC is an accurate, quantitative measure of the alcohol concentration in the vapor above the skin, it is considered a semi-quantitative or qualitative measure of BAC or BrAC and should simply be used to determine whether a person consumed alcohol or not.

## The SCRAM CAM Bracelet

The SCRAM CAM bracelet functions like an alcohol breath testing device, except it is worn on the ankle and tests automatically. A faceplate rests against the monitored individual's skin. This faceplate has holes that lead to a collection chamber, which is simply a volume of space that collects the insensible perspiration coming from the monitored individual's skin.

Every thirty minutes the bracelet performs a measurement (often called a "TAC reading") by running a pump that pulls the contents from the collection chamber across an alcohol sensor. The alcohol sensor is an electrochemical fuel cell like those used in evidential and preliminary alcohol breath testing devices. Alcohol molecules chemically react with a substance on the electrochemical fuel cell, and this chemical reaction produces an electrical signal. Molecules other than alcohol do not react with the substance on the electrochemical fuel cell. If alcohol is present in the volume of insensible perspiration, then the electrochemical fuel cell's electrical signal output will increase in proportion to the amount of alcohol. If no alcohol is present, there will be no measurable increase in the electrical signal.

There are numerous engineering techniques for measuring electrical outputs of sensors, including alcohol sensors. Description of these techniques is beyond the scope of this article, but it's worth pointing out that SCRAM CAM uses a method referred to as the Coulometric Method or Area-Under-Curve Method. This method was first patented by Alcotek, Inc. in 1988 and is considered superior for alcohol testing applications because it measures nearly all the alcohol that passes over the sensor, ensures the electrical signal drops very rapidly when alcohol is no longer present, and minimizes temperature dependency of the measurement.

If a non-porous object were placed between the SCRAM CAM bracelet and the leg of the monitored individual, it

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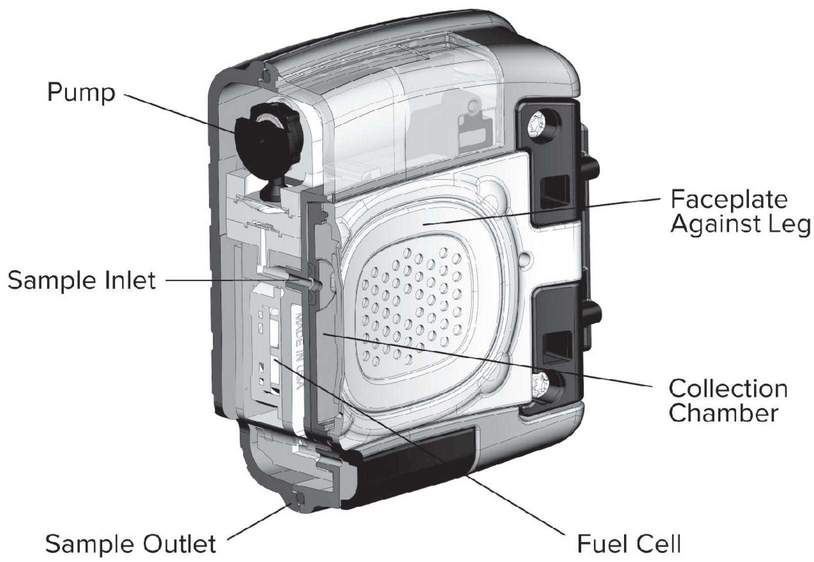


**Figure 2. The Secure Continuous Remote Alcohol Monitor.**

would prevent the flow of insensible perspiration through the faceplate into the collection chamber. Therefore, the SCRAM CAM bracelet also contains an infrared (IR) sensor, which can detect if an object is inserted between the bracelet and leg of the monitored individual or if the bracelet has been removed. IR sensors are common, commercially available sensors used for decades in numerous applications such as automatic faucets, photocopy machines, and industrial safety systems to detect if a human body part or other object is present. Infrared light (which is not visible to humans) is transmitted from the bracelet and reflected off the monitored individual's skin. If the amount of infrared light reflected back falls outside of certain parameters, it is indicative of an object inserted between the bracelet and leg or of the bracelet being removed.

Finally, the SCRAM CAM bracelet is affixed to the monitored individual using a strap containing an electrically conductive element. An electrical signal across the conductive element is monitored, and if the strap is cut the system is notified.

It should be noted that there have been two versions of the SCRAM CAM bracelet. The first version was large and wrapped around both sides of the monitored individual's ankle. That version (referred to simply as SCRAM) is now obsolete and has not been in use for years. The second version (referred to by various names including SCRAM, SCRAMx, and SCRAM CAM) appeared in approximately 2008 and is the version in use today. This version takes advantage of newer technology, is one-sided, and significantly smaller and lighter than the original SCRAM bracelet.

## The TAC Curve

Individual "TAC readings" from the monitored individual are charted over time to produce "TAC curves." A typical TAC curve for a drinking episode is shown in Figure 3. A TAC curve has many similarities to BAC or BrAC curves, but there are important differences because the pharmacokinetic parameters for TAC are different from those of BAC and BrAC. Particularly, the skin is the last place in a body that consumed alcohol reaches, so peak TAC lags behind peak BAC (see Figure 4). Also, it can take a long time for alcohol to completely diffuse through the skin and out of the body, so TAC will remain elevated after BAC or BrAC have returned to zero. The diffusion process is complex and can vary significantly from person to person, and even day to day, which means that similar drinking patterns can produce a wide range of TAC curves. The peak lag can range from 30 minutes to as much as several hours. In extreme cases of very large alcohol consumption events, TAC can remain elevated for as long as 24 to 48 hours after BAC has returned to zero.

Because of these differences, TAC curves cannot be used to determine what the monitored individual's BAC was at any given point in time. But TAC curves have the major benefit of providing a record of a person's alcohol consumption, 24 hours per day, 7 days per week, which is something that's not practical with blood or breath testing. In the simplest case, when a person consumes alcohol within a brief window of time then stops, the TAC curve will rise to a peak, and then fall back to zero. But real-word alcohol

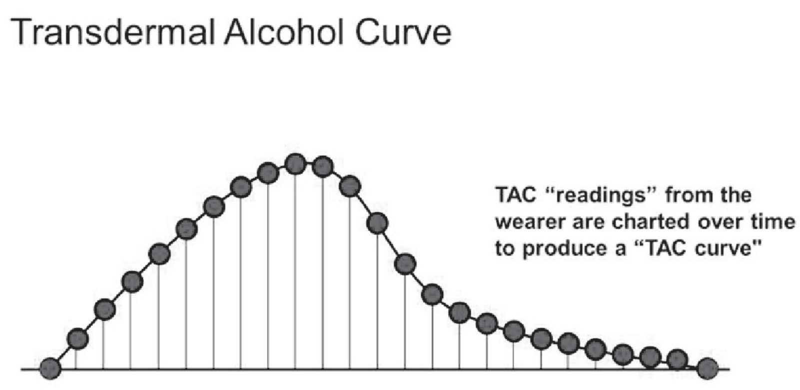


**Figure 3.**

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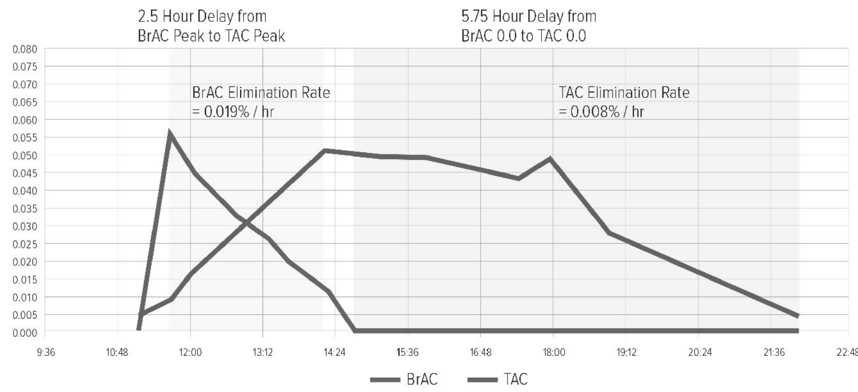


**Figure 4. TAC and BrAC Curves Measure Different Parameters**

consumption patterns rarely match this simplest case. People will drink at different times throughout the day and at different rates, which may cause the TAC curve to go up, down, flatten out, or many variants of these. In cases in which the monitored individual drinks daily, the TAC curve from the prior day may not reach zero before the current day's drinking starts, and these curves will string together as a single, large "multi-day" TAC curve. When viewing these more complicated TAC curves, it is important to understand they are not a real time reflection of BAC but are the result of TAC having different pharmacokinetic parameters than BAC. Alcohol may stay in the skin much longer than it is in the blood.

## Data Interpretation

It is not practical for the SCRAM CAM bracelet to form a perfect, air-tight seal against the monitored individual's skin, and this can cause two situations that must be addressed through data interpretation of the TAC curves. These are 1) the ability for environmental alcohol to be detected by the bracelet, and 2) variation in point-to-point TAC readings.

Alcohol from the outside environment can sometimes make its way into the bracelet's collection chamber and be detected by the alcohol sensor during a TAC reading. These detections are usually caused by incidental exposure to toiletry, beauty, and cleaning products that contain alcohol (cologne, perfume, hand sanitizer, etc.) and referred to as "environmental alcohol contaminants." There are safeguards in place to minimize the chance that these detections are interpreted as consumed alcohol. First, it is recommended that people wearing the bracelet avoid any contact with alcohol-containing products and never use anything except soap and water on their skin in the area around the bracelet. The bracelet will never record a positive TAC reading if there is no alcohol present, so avoiding such products altogether is a pragmatic first step.

Next, the TAC curves are analyzed, and data is interpreted according to a set of rules that have proven to be effective at minimizing false positives. These rules are referred to as the "confirmation criteria," and TAC curves must meet all criteria to be considered "passing" and therefore confirmed as consumed alcohol. The rules are: 1) the absorption rate of the TAC curve must be less than 0.100 TAC per hour; 2) the elimination rate of the TAC curve must be less than 0.035 TAC per hour; and 3) the event must pass an environmental contaminant test. These rules are explained in more detail below.

1. <u>The absorption rate of the TAC curve must be less than 0.100 TAC per hour</u>. As explained previously, TAC curves will rise and achieve their peak no faster than, and typically slower than, BAC curves. However, there is no established medical or scientific limit for how fast BAC curves can rise, so in theory there is no actual limit as to how fast TAC curves can rise. In practice, however, based on thousands of man days of testing, TAC curves from consumed alcohol generally do not rise faster than 0.100 TAC per hour. Conversely, curves produced by environmental alcohol contaminants typically achieve their peak values very quickly, in one to two readings, so rise at a rate faster than 0.100 TAC per hour; and often much faster. This is because the bracelet will quickly register that alcohol level as soon somebody steps into that environment or uses the alcohol-containing product. There is no slow build-up of alcohol in the skin over time like that associated with consuming alcohol.
2. <u>The elimination rate of the TAC curve must be less than 0.035 TAC per hour</u>. Previously it was stated that TAC curves will fall or decay from their peak no faster than, and typically slower than, BAC curves. Although the average BAC elimination rate for the human population is generally accepted as 0.015 BAC per hour, the typical elimination rate in a heavy drinking population is closer to 0.025 BAC per hour, and there are examples in the scientific literature of elimination rates as fast as 0.035 BAC per hour. Since SCRAM is primarily used on a heavy drinking population, 0.035 TAC per hour is therefore the established upper limit for TAC curve elimination rate. Curves produced by many environmental alcohol contaminants drop very quickly once the person leaves that environment, much faster than 0.035 per hour, because there is no slow decay of alcohol from the skin over time like that associated with consumed alcohol. In some cases in which an alcohol-containing product was applied to the skin or put on the bracelet itself, the curve may decay slower as the alcohol evaporates, but such cases would typically not pass at least one of the other confirmation criteria.
3. <u>The event must pass the environmental contaminant test</u>. To facilitate this test, the alcohol sensor in the

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> bracelet is exposed to the outside environment via a small opening in the bracelet that is away from the monitored individual's skin. Prior to every thirty-minute TAC reading, an additional alcohol sensor measurement is taken to determine if any alcohol from the environment is present at this opening. Just as with a TAC reading, alcohol present at this opening will cause the fuel cell's electrical signal output to increase in proportion to the amount of alcohol. If no alcohol is present, there will be no measurable increase in the electrical signal. The presence of virtually any alcohol at the opening to the outside environment will cause an elevated electrical signal on the alcohol sensor and is indicative of the presence of an environmental alcohol contaminant. Repeated detections of environmental alcohol contaminants across the duration of a TAC curve results in that TAC curve not being confirmed as consumed alcohol.

The second situation that results from the bracelet not forming an airtight seal against the monitored individual's skin is that TAC readings may vary from point-to-point and not form a perfectly smooth TAC curve that one might expect from alcohol making its way out of the body. As monitored individuals go about their daily routine, move around, cross their legs, etc. the faceplate may move slightly away from the skin then back into contact arbitrarily causing fresh air to be pulled and diluting the insensible perspiration. This can result in a zig-zagging type of sub-pattern in TAC curve as it rises and falls. For this reason, when calculating TAC curve absorption and elimination rates, you must look at the overall trend of the curve from the low point to the high point and not from individual reading to individual reading.

In practice, the data interpretation described above is conservative and much more prone to generate false negatives (i.e. actual drinking events that are not confirmed as consumption) than false positives. TAC curve absorption rates sometimes are faster than 0.100 TAC per hour during binge drinking. TAC curve elimination rates can be faster than 0.035 per hour if the bracelet faceplate moves away from the monitored individual's skin at just the right time. And the contaminant test is highly sensitive and sometimes causes actual drinking events not to be confirmed because a small amount of environmental alcohol was present in the air where the monitored individual was drinking.

## Calibration

Because there are slight variances among electrochemical fuel cells and pumps, each SCRAM CAM bracelet is calibrated before it is put into use to ensure it measures the correct TAC value, within an acceptable tolerance range, for a given amount of transdermal alcohol. The calibration process duplicates the way law enforcement and evidential breath testing devices are calibrated. The first step of this process is to place a water-alcohol liquid mixture of precise concentration (referred to as an alcohol standard, or simulator solution) into a device called a wet bath simulator, which is essentially a glass jar that heats the solution and maintains its temperature at 34°C. A water-alcohol vapor mixture of precise concentration then forms in the jar in the air above the liquid alcohol standard. This alcohol standard is procured from an independent laboratory. Next, the bracelet performs a TAC reading using this water-alcohol vapor mixture. A calibration factor is then calculated to make the measured TAC value match the known alcohol standard. This calibration factor will then be applied to every TAC reading while the bracelet is in use. The next step is to perform a "verify" step (sometimes referred to as cal check). This consists of performing another TAC reading as described above, and verifying that the TAC result, using the previously calculated calibration factor, is within the acceptable tolerance range of the known alcohol standard. The final step of the calibration process is to perform an "air-blank" step. This consists of performing another TAC reading using a controlled volume of clean air, containing no alcohol. This TAC reading must read 0.000.

If any of these process steps fail, then the calibration fails. Only bracelets that pass all steps are shipped for field use. This process is completely automated and performed using a machine that interacts with the bracelet via software. The calibration factor and other results are automatically written to a database upon completion, and there is no way to manually override any of the results. The database records are kept in perpetuity, and a calibration certificate can be provided for any bracelet upon request.

## Sources of Error and Safeguards

No technology is 100% perfect, and potential sources of error that can affect SCRAM results are tampering, mechanical errors, human errors, and environmental alcohol contaminants. Tampering with the bracelet by inserting an object between the bracelet and skin, or by removing the bracelet, can alter or mask TAC readings and alcohol consumption. As safeguards, the bracelet uses several different tamper detection technologies described previously. Certain conditions will generate various alerts, which are reviewed and confirmed as tampers if they meet pre-defined criteria. Supervising authorities should then follow up with the monitored individual after being notified of these confirmed tamper alerts. Mechanical errors include pump degradation and alcohol sensor degradation caused by submersion in water and usage over time. As a safeguard, and because a certain amount of degradation is normal and expected, the TAC measurement process is designed in a fail-safe manner—that is, a degraded pump or alcohol sensor will always cause the TAC reading to be lower than it should be, which benefits the monitored individual. As a further safeguard, the bracelet routinely performs self-diagnostic tests on itself and sends these results to the monitoring network. If diagnostic tests meet certain conditions, then the bracelet will be removed from use and

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replaced. Finally, every bracelet is returned to the factory for reconditioning and recalibration after 365 days of use, even if the self-diagnostic tests indicate the bracelet is functioning properly. Human errors are possible because the data interpretation process is not completely automated by software, and humans can make mistakes in doing the calculations and interpreting the data. As safeguards, confirmed alerts are reviewed and checked by more senior employees, and any alert can be reviewed again upon request of the supervising authority. Environmental alcohol contaminants are the final potential source of error, and this topic has already been discussed previously in the Data Interpretation section.

## Peer Review, Scientific Acceptance, Product Testing, and Error Rates

The SCRAM CAM bracelet has been the subject of or used in twenty-seven independent, peer-reviewed studies from 2003 – 2017. Those studies encompassed 472 unique participants across 15,410 monitored days on the bracelet. It continues to be used in an ongoing stream of research, and SCRAM is generally accepted by the scientific community to be a reliable method of determining if a person consumed alcohol. Key findings from these studies are described below.

Eight of the twenty-seven studies statistically classified SCRAM CAM results in a way that they can be placed in an error matrix, allowing calculation of various values of interest such as true positives, false negatives, false positives, and positive predictive value. These eight studies encompass 214 unique participants across 2,785 monitored days on the bracelet. Over these 2,785 monitored days there were 1,308 known, self-reported drinking days and 1,477 self-reported, non-drinking days. Key results are:

- 948 of the 1,308 known drinking days produced TAC curves that passed SCRAM data interpretation rules and were confirmed as alcohol consumption, while 360 were not confirmed. This results in a true positive rate of 72% and a false negative rate of 28%.
- There were no TAC curves confirmed as alcohol consumption in 1,473 of the 1,477 non-drinking days. On four of the non-drinking days there were TAC curves that were confirmed as alcohol consumption. However, the author noted that the four false positives were likely due to self-reporting errors. Even if one assumes the worst case scenario that there were no reporting errors on these four days, then the true negative rate is 99.7% and the false positive rate is 0.3%. The remaining peer reviewed literature shows no evidence of any false positives in field and laboratory settings.

SCRAM Systems regularly conducts blind product testing using paid test participants for the purposes of understanding product accuracy and making product improvements. Results from product testing consistently align with those in the peer reviewed literature.

A common discussion point in much of this research is that SCRAM confirmation criteria are conservative and much more likely to result in false negatives than false positives. In fact, some researchers have recommended that SCRAM CAM confirmation criteria be more aggressive for purposes of clinical intervention, but they agree that this may not be appropriate in a criminal justice setting where the consequences are high.

## Conclusion

The SCRAM CAM is an ankle-worn bracelet that automatically measures and reports on the presence of transdermal alcohol concentration (TAC) to detect the ingestion of alcohol by individuals sanctioned under court order. Over years of development, testing, and iterative improvement, the SCRAM system has achieved a level of accuracy and reliability that have made it the most widely used technology of its kind by the courts and corrections. In this article, I have outlined the basic science underlying TAC monitoring, described the ways in which the equipment is designed, built, and calibrated for field use, and analyzed how the data generated by SCRAM is interpreted and applied.

## *Endnotes*

[1]This section is excerpted and paraphrased from Hawthorne, JS and Wojcik MH: *Transdermal Alcohol Testing: A Review of the Literature*. Can. Soc. Forensic Sci. J. Vol. 39. No 2 (2006) pp. 65–71

[2]There are several types of alcohol, and ethanol is the type of alcohol that people drink. For this article the words ethanol and alcohol are used interchangeably. ■