Secure Continuous Remote Alcohol Monitor: SCRAM
SCRAM

- The purpose of the device is to assess and/or monitor the wearers’ alcohol use
- The device measures Transdermal Alcohol Concentration (TAC)
- The device is a semi-quantitative tool for determining Blood Alcohol Concentration (BAC)
  - Test results can enable a technician to accurately and reliably determine whether a person consumed a small, moderate or large amount of alcohol
  - The results cannot permit anyone to determine simultaneous BAC
transdermal alcohol

• People eliminate a small amount of waste products transdermally (through the skin) as perspiration
  – Sensible perspiration: sweat in the liquid phase
  – Insensible perspiration: sweat in the vapor phase (constantly present and unnoticeable)
• Approximately 1% of consumed alcohol is eliminated this way
How SCRAM Works

• The SCRAM anklet utilizes the same fuel cell technology as some evidential breath testing instruments and most preliminary breath testers
  – Draeger manufactures the fuel cell and uses the device in its Alcosensors
  – Over 50,000 Alcosensors are used worldwide across five continents
The fuel cell is set to measure the ethanol content of vapors to within 10% during calibration.
How SCRAM Works

- Sample Inlet
- Pump
- Fuel Cell
- Collection Chamber
- Faceplate Against Leg
- Infrared Sensor
- Sample Outlet
TAC and BAC

- TAC and BAC are related
- TAC absorption and elimination curves are similar, but not identical, to corresponding BAC curves
- TAC curves are delayed because it takes time for the body to metabolize enough alcohol to begin excreting it through the skin
  - Simultaneous TAC and BAC readings will almost never match
  - TAC peaks typically are lower than BAC peaks
  - A person’s TAC will be elevated for a time after BAC drops to zero
TAC and BAC: Absorption and Elimination Curves

2.5 Hour Delay from BrAC Peak to TAC Peak
BrAC Elimination Rate = 0.019% / hr

5.75 Hour Delay from BrAC 0.0 to TAC 0.0
TAC Elimination Rate = 0.008% / hr
Example of variations in the Stratum Corneum and how it affects TAC curves

Sensitivity

• SCRAM does not “flag” an event until three consecutive readings exceed 0.02%
  – The average person will not reach a 0.02% TAC unless the person has more than one drink in his or her system
  – This gives the wearer the benefit of the doubt
SCRAM Alcohol Measurement

- Real-World, Social Drinking
- 60+ drinking events on a variety of male subjects, 180 pound average
- Drinks consumed are self-reported
- Type of drink varies
- Existence of food in stomach and amount of food varies
- Duration of drinking varies from 30 minutes to all-day; 2 hour average

- Bracelets set to 60 minute reading intervals
- Any event whose peak TAC is less than 0.02 is not flagged by definition
Confirmation Process Tampers & Consumption

Service Provider ➔ AMS

AMS technician analyzes data

Does event meet AMS criteria?

No ➔ Interferant

If YES ➔ Committee peer reviews decision

Is the data conclusive?

No ➔ If YES

AMS Criteria for a Tamper

Tamper over:
1) 8 hours with the IR voltage deviation equal to or greater than (+)12% of the baseline voltage, and no TAC level.
2) 3 hours with the IR voltage deviation equal to or greater than (+)12% of the baseline voltage, and a TAC level present during the same time span.

AMS Criteria for Consumption

1) Was zero established?
2) Was absorption rate less than 0.05% P/H?
3) Was a peak established?
4) Was zero re-established?
5) Was elimination rate less than 0.025% P/H (peak < 0.15%) or less than 0.035% P/H (peak >0.15%)?
6) The total elimination time must fit within that produced by an elimination rate from .003% to .025% (peak<0.15%) or 0.035% (peak>0.15%)
7) Does it pass the contaminate test?
Reporting Process

Service Provider

Submit Violation Report to Authority

Client is questioned

Does client have an excuse?

If YES

Provide all relevant Material to AMS

Reviewed by AMS. Is there reason to believe potentially environmental?

If YES

Develop test plan and test environment

Does testing indicate environment could produce a detection?

If YES

Rescind confirmation and notify authority

Environmental Claims will be evaluated
1) Work environment and schedule required entry into SCRAMNet.
2) Many environments already evaluated

Violation Stands

NO

NO

NO
Compliant Subject
Non-Compliant Subject

Subject consumed: 5 Screwdrivers

Absorption Rate = 0.031% per hour

Elimination Rate = 0.010% per hour
Compliant IR Distance Readings

95% of all IR readings should remain within the range identified by the red lines.
Multiple IR Obstructions

- Wet Paper Towel
- Tan Sock
- Aluminum Foil

Graph showing temperature changes over time with specific dates and times.
• SCRAM flags potential drinking events
  – It regularly records alcohol levels at pre-determined intervals
• A trained and experienced technician interprets the reported results to confirm potential drinking events
• The process is designed to eliminate false confirmations
AMS Internal Study Results

- Total Events = 3228
- A “true negative” is assumed to be any 12 hour period where there was NO drinking and where a drinking event was NOT confirmed.

<table>
<thead>
<tr>
<th>SCRAM System Result</th>
<th>Actual Event</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>True Positive 406</td>
<td>False Positive 2</td>
</tr>
<tr>
<td>Negative</td>
<td>False Negative 108</td>
<td>True Negative 2712</td>
<td></td>
</tr>
</tbody>
</table>

“False Positive” Error Rate = 0.074% *
False Negative Error Rate = 21%

*Commercially Available Drug Kits have a False Positive Rate of 5.0%
Potential Sources of Error

- Tampering
- Interferants
- Mechanical errors
- Human error
Tampering

- SCRAM is designed to be tamper resistant.
- It features a:
  - Tamper strap and securing clip
  - Temperature sensor
  - Infrared sensor to detect obstructions
- The device flags potential tampers
- Technicians confirm tampers
  - They give every reasonable benefit of the doubt to the wearer
  - If they are not sure, they will ask the service provider to interview the wearer and inspect the device
Obstruction Confirmation Criteria

Tamper over:
- 8 hours with the IR voltage deviation equal to or greater than (+)12% of the baseline voltage, and no TAC level.
- 3 hours with the IR voltage deviation equal to or greater than (+)12% of the baseline voltage, and a TAC level present during the same time span.

• Tamper Under:
- 8 hours with the IR deviation equal to or less than (-)17% of the baseline voltage, and no TAC level.
- 3 hours with the IR voltage deviation equal to or less than (-)17% of the baseline voltage, and a TAC level present during the same time span.
Interferants

- Interferants are contaminants that may cause an elevated alcohol concentration reading
- AMS provides users with a list of interferants to avoid
  - Users sign agreements promising to avoid these interferants
- Detecting interferants is relatively easy for trained technicians
  - Consumed alcohol and interferants produce distinctly different alcohol curves
  - Technicians can distinguish consumed alcohol from interferants by examining absorption and elimination rates
Detecting Interferants: Using the Absorption Curve

- Interferants typically produce “absorption” curves between 0.096% and 0.573% per hour
- People usually absorb alcohol more slowly
- AMS will not confirm events where the absorption rate is greater than 0.05% per hour
  - This gives the defendant the benefit of the doubt
Interferant: Un-leaded Gasoline Spilled Indoors

Un-leaded Gasoline Spilled Indoors results:
Peak value: 0.437%
Absorption Rate: 0.514% Per Hour
Elimination Rate: 0.041% Per Hour
Absorption Rate > 0.150% per hour
Alcohol interferant referenced in “Ethanol vapor above skin: determined by a gas sensor instrument and relationship with plasma concentration”

Detecting Interferants: Using the Elimination Curve

- Alcohol is eliminated in a fairly linear and predictably slow fashion
  - The average person eliminates between 0.015% to 0.020% per hour
  - An alcoholic can eliminate a bit faster, some as high as 0.035% per hour
- AMS will not confirm events where the elimination rate is greater than 0.025% per hour if the peak TAC is less than 0.15% or 0.035% per hour if the peak TAC is greater than 0.15%.
- Interferants are “eliminated” much more rapidly or much more slowly and produce distinctly different curves
Interferant: “Awesome Cleaner”

Absorption Rate = 0.191% per hour  
Absorption Rate = 0.022% per hour
Interferant: “Awesome Cleaner”

Elimination Rate = 0.030% per hour

Elimination Rate = 0.014% per hour
Mechanical Error

- Mechanical errors may include:
  - Pump errors caused by submersion in water and corrosion to the pump case
  - Strap errors caused by wearers forcing the strap to stretch and breaking the flex circuit inside

- AMS ensures that mechanical errors do not cause false confirmations by:
  - Testing all devices before distributing them
  - Calibrating each device before placing it “on line”
  - Continually running remote diagnostics checks
  - AMS fixes or replaces devices that appear to function incorrectly in the laboratory or in the field
Human Error

• Human errors include misinterpreting results and failing to identify alternate causes of elevated readings
• AMS trains all of its technicians and utilizes a peer review process to minimize human error
  – All positive events are peer reviewed by the AMS Director of Technical Services or Chief Technological Officer
• AMS periodically evaluates its technicians to eliminate mistakes
Safeguards and Assurances

- Mistakes can be readily identified
  - The wearer’s TAC is regularly recorded, which allows for pattern analysis and recognition
  - AMS uploads all SCRAM readings
  - The results are charted and available
  - The wearer, his or her attorney or expert, and the court can review the data
- AMS has tested multiple interferants
- AMS strives to give every reasonable benefit of the doubt to the wearers
  - AMS will test any alleged contaminants or faulty devices upon request
History of Transdermal Transport and TAC Testing

1936-1980
- Initial studies on transdermal transport

1980-1984
- Research on sensible perspiration and sweat patches

1985-2000
- Studies on insensible perspiration and fuel cell devices

Conclusions:
- Ethanol excreted in sufficient quantities; reliable estimation of BAC
- Transdermal peak values delay behind breath peak values by 30-180 minutes
- No false positives occurred in sober test subjects during daily activity, sleep, or vigorous exercise
Transdermal Transport is Widely Recognized

- Nicotine patches
- Birth control patches
- Scopolamine patches (for seasickness)
- Nitroglycerine for chest pain
- Blood pressure drugs
- Narcotic pain medicines
- Vick’s Vapor Rub
- Muscle relaxants
Transdermal alcohol testing is a generally accepted method to measure alcohol use.
Studies Conducted with SCRAM Bracelet

- National Law Enforcement and Corrections Technology Center (NLECTC)- NW in Alaska
- Acadiana Criminalistics Laboratory, LA
- Michigan Department of Corrections (MDOC)
- University of Colorado Health Sciences ("Validity of Transdermal Alcohol Monitoring: Fixed and Self-Regulated Dosing" (Sakai JT (2006) Alcohol Clin. Exp. Res. 30:1, 26-33))
- Sam Houston State University ("Quantitative Determination of Caffeine and Alcohol in Energy Drinks and the Potential to Produce Positive Transdermal Alcohol Concentrations in Human Subjects" (Kerrigan, Sarah (2009) Journal of Analytical Toxicology, Vol. 33, 27-33)
University of Colorado Health Sciences Study

- A peer-reviewed study funded by NIDA, NIMH, NIH & AMS
- 44 Subjects, 20 in lab; 24 in real-life settings for 8 days
- Laboratory Study:
  - No False-Positives in the no-dose group
  - No False-Negatives in the dosing group.
- Study corroborated validity of transdermal testing
- TAC peak lagged behind BrAC peak by 2-3 hours, TAC peak was lower had additional delay in returning to zero
- TACs and BACs not equivalent due to delay

The NHTSA Study

• The study was completed in early 2006
• Two drinking protocols
  – Laboratory Dosing
    • Target BAC = 0.08% g/dL after 30 minutes
  – Self Dosing
    • Mean BAC 0.077% g/dL
    • Log all food & Alcohol
    • Breath test after drinking
• Subject pool: 22 total subjects (mean age 26.7):
  – 15 Males (5 repeated for phase 2)
  – 7 Females (3 repeated for phase 2)
• 96 weeks of wear among 22 subjects
“There is no doubt that the transdermal concept is valid as long as expectations of quantitative parity with BAC are moderated.” (p. 3)
Sensitivity

• SCRAM’s overall true positive rate was 57%
  – SCRAM’s true positive rate was 88% when BAC was 0.08% or greater.

• SCRAM missed a significant number of drinking events (false negatives), especially at lower BACs
  – We expected to miss the low level drinking events since we designed our criteria to give every reasonable benefit of the doubt to the wearer
  – However, the researchers found that SCRAM’s ability to read alcohol declined after a couple of weeks due to moisture accumulation
The Results Led to Major Improvements

• Since the NHTSA study began, AMS has made three significant design changes to SCRAM that resolved the performance issues encountered in the first-generation product studied by NHTSA
  – AMS removed the check valve in the SCRAM I system to allow more moisture to exit the device. NHTSA utilized this version during the later stages of the study
  – Our engineers then delivered a comprehensive upgrade in 2006 (Patent Application #11/454,491)
  – Since then, we've further redesigned the bracelet and rolled out SCRAM II (January 2008) (Patent Application #12/013,931)
False Positives are Not an Issue

- SCRAM will measure alcohol from external sources. However ............
- “We can say with some confidence that there are few or no events that the devices created that look like drinking but were really not drinking.” (p. 20)
- SCRAM has no problems with false positives
  - No potential drinking events were confirmed when true BAC was < 0.02% g/dL
  - Technicians were able to distinguish drinking events from environmental contaminants by reviewing the data and the curves they generated
  - Participants kept logs of their activities
• It “seems unlikely that circumvention by obstruction can constitute a real threat to the integrity of this system while drinking.” (p. 3)
  – Circumvention is not a “serious problem” for SCRAM (p. 48)
Data Collection and Reporting are Exceptional

• The communication of the SCRAM bracelet with its remote server, along with data retrieval and reporting technology, is exceptionally innovative.” (p. 50)
  – SCRAMNET is “fairly seamless in the way it communicates and uplinks data from the ankle bracelet.” (p. 46)
TAC and BrAC

- TAC peak was lower than BrAC peak, as expected
  - TAC peak lagged behind BrAC peak by up to 4.5 hours
• Purpose:
  • The purpose of the study was to determine whether the consumption of energy drinks could produce TAC measurements that were suggestive of an actual drinking episode.

• Results:
  • Even after consuming as many as eight energy drinks, to the extent that most subjects experienced some sort of unpleasant effect, TAC readings were not elevated (< 0.02%) and no “alcohol alerts” were generated for any of the subjects. Based on these results, it seems unlikely that non-alcoholic beverage consumption alone is a viable defense for elevated TAC.
Results of Sam Houston State University Study

- **Energy drink selection**
  - Of the 11 energy drinks tested, 180 Red Energy had the highest ethanol concentration, estimated to be 0.230% (w/v).
  - One would have to consume more than 30 8-oz servings of the energy drink (180 Energy Red) to achieve the equivalent of a standard 12-oz serving of beer containing 5% alcohol (w/v).
SCRAM Usage

- Alcohol Test Performed: 839,719,758
- Unique Clients Monitored: 220,535
- Monitored Days: 20,448,379
- Highest Daily Number of Monitored Clients: 14,677
- States with Scram Programs: 49 (Not in Hawaii)
- Jurisdictions with SCRAM Programs: 2,000+

*As of the end of March, 2012*
<table>
<thead>
<tr>
<th>Product</th>
<th>Contains Yeast</th>
<th>Ethanol Concentration (g/100g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Downey’s Original Jim Beam Kentucky Bourbon Cake</td>
<td>Y</td>
<td>1.662</td>
</tr>
<tr>
<td>Rosemary Onion Bread</td>
<td>Y</td>
<td>0.980</td>
</tr>
<tr>
<td>Home Pride Wheat Bread</td>
<td>Y</td>
<td>0.470</td>
</tr>
<tr>
<td>Thomas’ Sourdough English Muffin</td>
<td>Y</td>
<td>0.445</td>
</tr>
<tr>
<td>Great Harvest Apple Walnut Roll</td>
<td>Y</td>
<td>0.956</td>
</tr>
<tr>
<td>Sun Maid Raisin Bread</td>
<td>Y</td>
<td>0.276</td>
</tr>
<tr>
<td>QFC Chocolate Donut</td>
<td>Y</td>
<td>0.289</td>
</tr>
</tbody>
</table>

How much Rosemary Onion Bread would have to be ingested to equal 1-12oz beer (4% alcohol by weight)?

Calculate the Ethanol Dosage by weight:

\[
1 \text{ beer} \times 12 \text{ oz} \times 29.6 \text{ ml} \times \frac{4 \text{ ml}}{100 \text{ ml}} \times \frac{0.789 \text{ g}}{\text{ml}} = 11.21 \text{ g}
\]

Calculate the amount of Rosemary Onion Bread in Pounds:

\[
11.21 \text{g} \times \frac{100 \text{ g}}{0.980 \text{ g}} \times \frac{0.789 \text{ g}}{29.6 \text{ ml}} \times \frac{16 \text{ oz}}{1 \text{ lbs}} = 3 \text{ lbs}
\]
# Baked Goods and BAC

<table>
<thead>
<tr>
<th>Type of Food</th>
<th>Jim Beam Kentucky Bourbon Cake</th>
<th>Rosemary Onion Bread</th>
<th>Home Pride Wheat Bread</th>
<th>Thomas’ Sourdough English Muffin</th>
<th>Great Harvest Apple Walnut Roll</th>
<th>Sun Maid Raisin Bread</th>
<th>QFC Chocolate Donut</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theoretical BAC Produced</strong></td>
<td><strong>Theoretical BAC</strong></td>
<td><strong>0.002%</strong></td>
<td>1.81</td>
<td>3</td>
<td>6.38</td>
<td>6.74</td>
<td>3.14</td>
</tr>
<tr>
<td></td>
<td>10.023%</td>
<td>3.62</td>
<td>6</td>
<td>12.76</td>
<td>13.48</td>
<td>6.28</td>
<td>21.74</td>
</tr>
<tr>
<td></td>
<td>0.044%</td>
<td>5.43</td>
<td>9</td>
<td>19.14</td>
<td>20.22</td>
<td>9.42</td>
<td>35.61</td>
</tr>
<tr>
<td></td>
<td>0.065%</td>
<td>7.24</td>
<td>12</td>
<td>25.52</td>
<td>26.96</td>
<td>12.56</td>
<td>43.48</td>
</tr>
<tr>
<td></td>
<td>0.086%</td>
<td>9.05</td>
<td>15</td>
<td>31.9</td>
<td>33.7</td>
<td>15.7</td>
<td>54.35</td>
</tr>
<tr>
<td></td>
<td>0.107%</td>
<td>10.86</td>
<td>18</td>
<td>38.28</td>
<td>40.44</td>
<td>18.84</td>
<td>65.22</td>
</tr>
</tbody>
</table>

Matrix was calculated assuming: 180 Lb. Male. Rosemary Onion Bread (.98% g/100g. 3Lbs is equivalent to 1 4.0% 12oz beer)
Baked Goods and BAC: Donuts

- Given that a raised Chocolate Donut weighs 3.2 ounces per donut and a Cake Chocolate Donut weighs 2.4 ounces per donut a person would have to consume:

- Breads and juices cannot be consumed in large enough quantities to produce a positive TAC.

<table>
<thead>
<tr>
<th>Theoretical BAC Produced</th>
<th>Number of Donuts That must be Consumed in 1 Hour to Reach the Theoretical BAC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Raised Donuts</td>
</tr>
<tr>
<td>0.002%</td>
<td>51.4</td>
</tr>
<tr>
<td>0.023%</td>
<td>103.8</td>
</tr>
<tr>
<td>0.044%</td>
<td>155.7</td>
</tr>
<tr>
<td>0.065%</td>
<td>207.6</td>
</tr>
<tr>
<td>0.086%</td>
<td>259.5</td>
</tr>
<tr>
<td>0.107%</td>
<td>311.4</td>
</tr>
</tbody>
</table>
**TAC and BAC: Absorption Rates**

Breath absorption rates vs TAC absorption rates for controlled single dose testing

<table>
<thead>
<tr>
<th></th>
<th>Absorption Rate per Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Breath</td>
<td>0.071%</td>
</tr>
<tr>
<td>Median TAC</td>
<td>0.021%</td>
</tr>
<tr>
<td>Minimum Breath</td>
<td>0.043%</td>
</tr>
<tr>
<td>Maximum Breath</td>
<td>0.125%</td>
</tr>
<tr>
<td>Minimum TAC</td>
<td>0.007%</td>
</tr>
<tr>
<td>Maximum TAC</td>
<td>0.059%</td>
</tr>
</tbody>
</table>

N = 50
Alcohol Absorption Rates in a Social Drinking Environment

Absorption Rates in a Social Drinking Environment

<table>
<thead>
<tr>
<th></th>
<th>Absorption Rate per Hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median TAC</td>
<td>0.017%</td>
</tr>
<tr>
<td>Minimum TAC</td>
<td>0.002%</td>
</tr>
<tr>
<td>Maximum TAC</td>
<td>0.044%</td>
</tr>
</tbody>
</table>

N = 50

Number of Tests

Social Drinking Absorption

Median TAC Absorption
Absorption Rates For Topical Interferants

TAC Absorption rates for Interferant substances applied to the SCRAM Bracelet

N=50

<table>
<thead>
<tr>
<th>Absorption Rate per Hour</th>
<th>Median TAC</th>
<th>Minimum TAC</th>
<th>Maximum TAC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.201% / hr</td>
<td>0.068% / hr</td>
<td>0.93% / hr</td>
</tr>
</tbody>
</table>

Sample Number

TAC Absorption Rate / hour vs. Median TAC Absorption