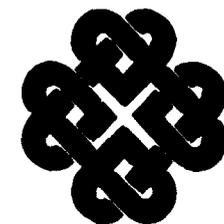


Evaluation of Transdermal Alcohol Devices

NHTSA Task Order
DTNH22-02-D-95121

Paul Marques
Scott McKnight

Pacific Institute for Research and
Evaluation (PIRE)
Calverton, MD



Note regarding presentation

- Anything other than slides labeled “Company Data” are ALL preliminary findings – examples, not conclusions.
- There will be no written publication of these results until NHTSA has a chance to review.
- Evaluation contract will now extend to Nov 30, 2005.
- Nothing reported here today should be regarded as reflecting US DOT NHTSA viewpoint.
- PIRE is a 501C3 non-profit research company that does research and program development in areas of public health and safety, especially as related to drugs and alcohol.

Contact Info: marques@pire.org



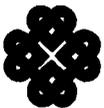
3 ways to control DUI offender

- Prevent driving
 - Jail
 - House arrest
 - Impoundment
- Prevent drinking-driving
 - Successful treatment
 - Ignition interlock
- Prevent drinking
 - Jail
 - Periodic alcohol monitoring (BAC or biomarkers)
 - Continuous alcohol monitoring (transdermal)



Ethanol in the Body

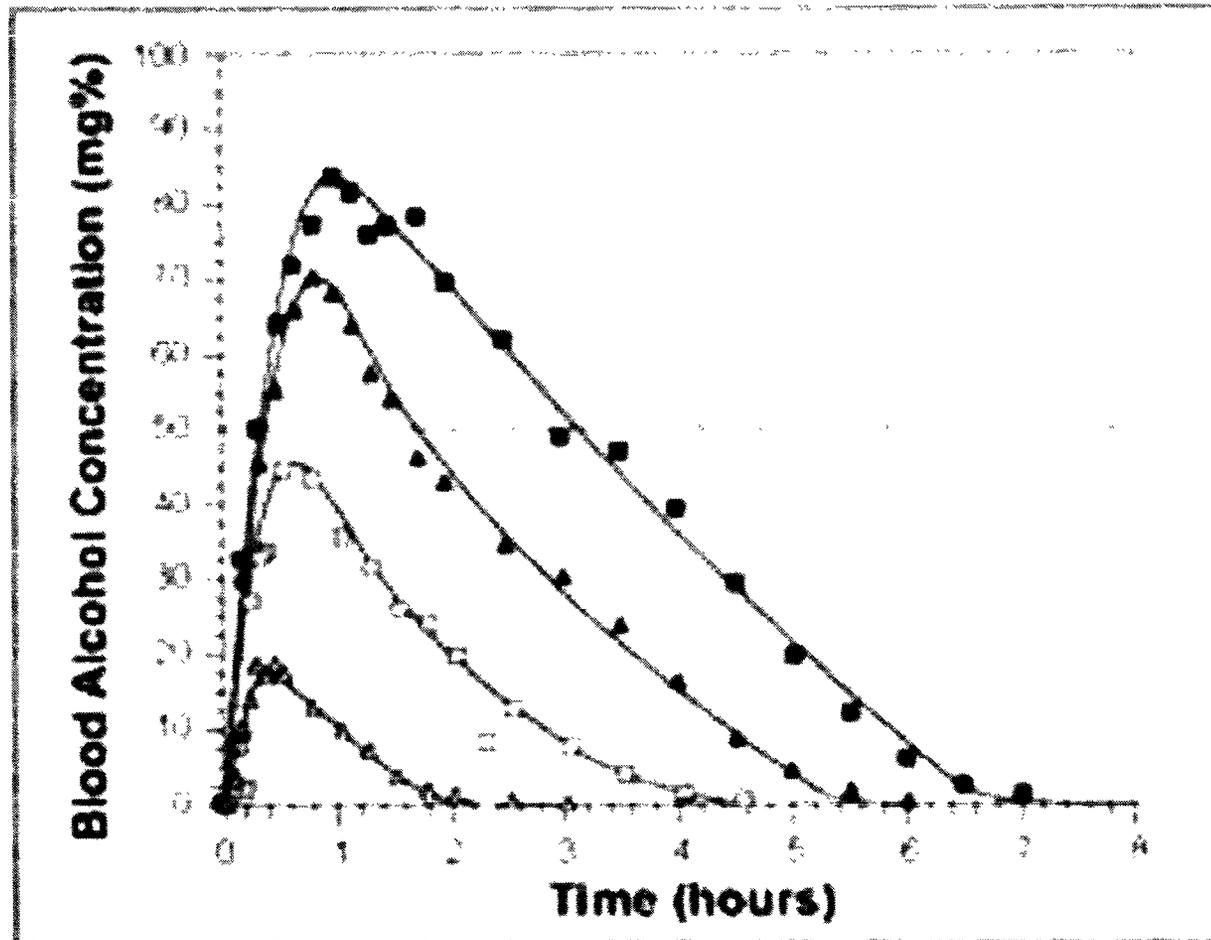
- Ethanol distributes freely in all body water
- The majority of ethanol is transformed in liver to acetic acid and water via dehydrogenase enzymes
- About 5% is lost unchanged through breath, sweat, urine – a higher percent if levels of consumption are very high.
- The amount lost through sweat is in the range of 1% or less.
- Note sweat: sensible and insensible (vapor)



Breath alcohol concentration (BAC)

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1-4 drinks rapid consumption



Biochemical alcohol markers

Other trace indicators of ethanol presence can be used to estimate past exposure from serum, red cells, urine, hair, saliva

- Indirect markers
 - ALT, AST, GGT, MCV, CDT
 - Time course: days, weeks
- Direct markers (including BAC)
 - FAEE, EtG, PEth, WBAA, 5HTOL, GTOL etc.
 - Time course (hours, days, weeks, months)



Detection windows of some ethanol biomarkers

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Some Alcohol Markers	Indirect or Direct		Breath	Serum/ Plasma	Whole Blood	Urine	Hair
Alanine Aminotransferase (ALT)	Indirect			weeks			
Aspartate Aminotransferase (AST)	Indirect			weeks			
Gamma Glutamyltransferase (GGT)	Indirect			days			
Mean Red Cell Volume (MCV)	Indirect				weeks		
Carbohydrate Deficient Transferrin (CDT)	Indirect*			week			
Apolipoprotein J (Apo J)	Indirect*			week			
Ethanol (ETOH)	Direct	hours		hours	hours	hours	
Phosphatidyl Ethanol (PEth)	Direct				week		
Ethyl Glucuronide (EtG)	Direct			hours		days	months
5-Hydroxytryptophol (HTOL/HIAA) ratio	Direct					days	
Glucuronide conjugate of HTOL (GTOL/HIAA) ratio	Direct					days	
Whole Blood Acetaldehyde (WBAA)	Direct				week		
Fatty Acid Ethyl Esters (FAEE)	Direct			hours/day			months

slide 7



Research Objective

“The objective of this (NHTSA) study is to obtain laboratory data on the precision and accuracy of ... available transdermal alcohol-detecting and alcohol-monitoring devices under a variety of controlled physiological and environmental conditions.”



Transdermal alcohol concentration (TAC)

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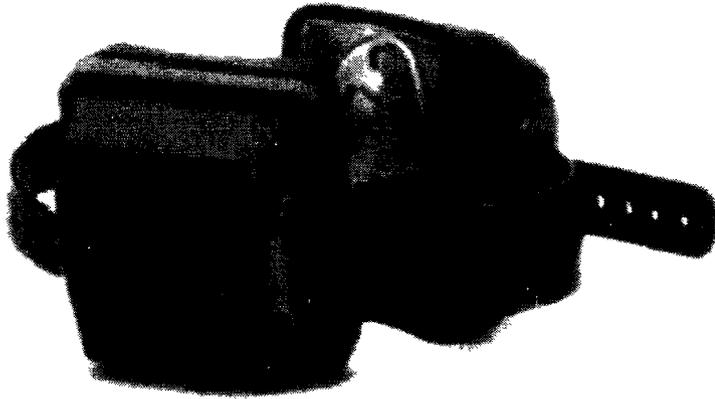
- Delayed response relative to BAC ~ 1-2 hrs later on the absorption (rise), more delay on burnoff (decline)
- Some individual differences in response
 - Differences in sweating rate
 - Differences in skin thickness and permeability
 - Skin properties can change when hydrated
- Environmental factors
 - Cold Skin (slows vapor loss)
 - Sweat (liquid sweat containing alcohol could be over or under detected depending on device)



Alcohol Monitoring Systems

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SCRAM



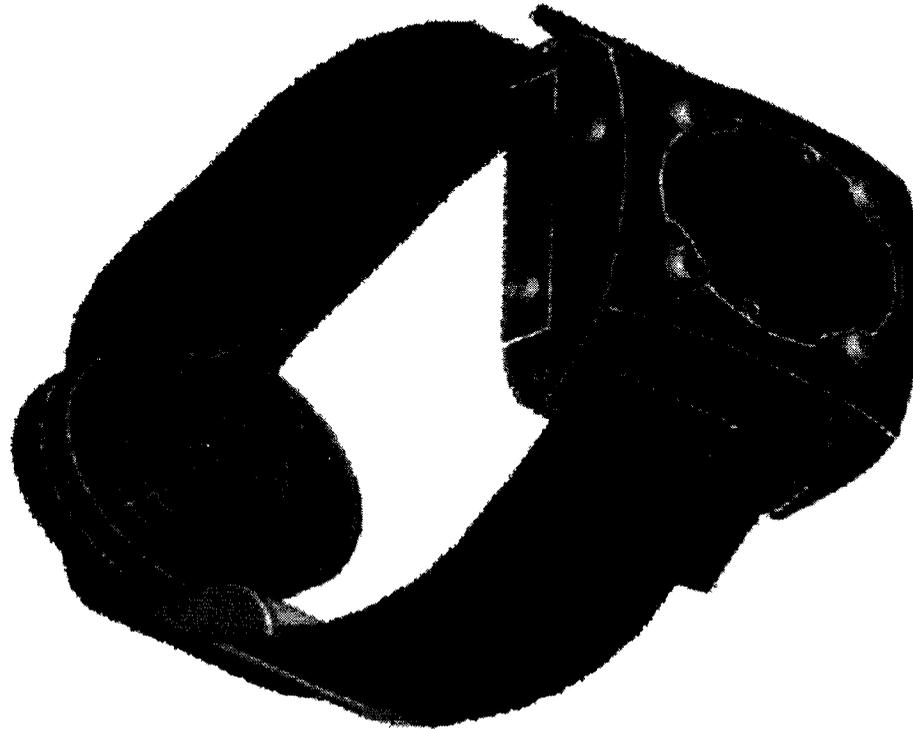
SCRAM features

- Two sides of device
 - Fuel-cell alcohol sensor (analog side)
 - Circumvention detection and uplink features (digital side)
- Samples water and alcohol vapor at 30-60 min
- Temperature and proximity (IR) sensors aid in circumvention detection
- Unit has calibration matched modem
- Unit locks on for weeks, months
- Modem does daily remote uplink to SCRAMNET (internet accessible by court monitor)
- Data storage for several days in device (before overwriting old data) if daily uplink delayed
- 7800 clients, 550,000 monitored mandates completed



Giner Inc. WrisTAS

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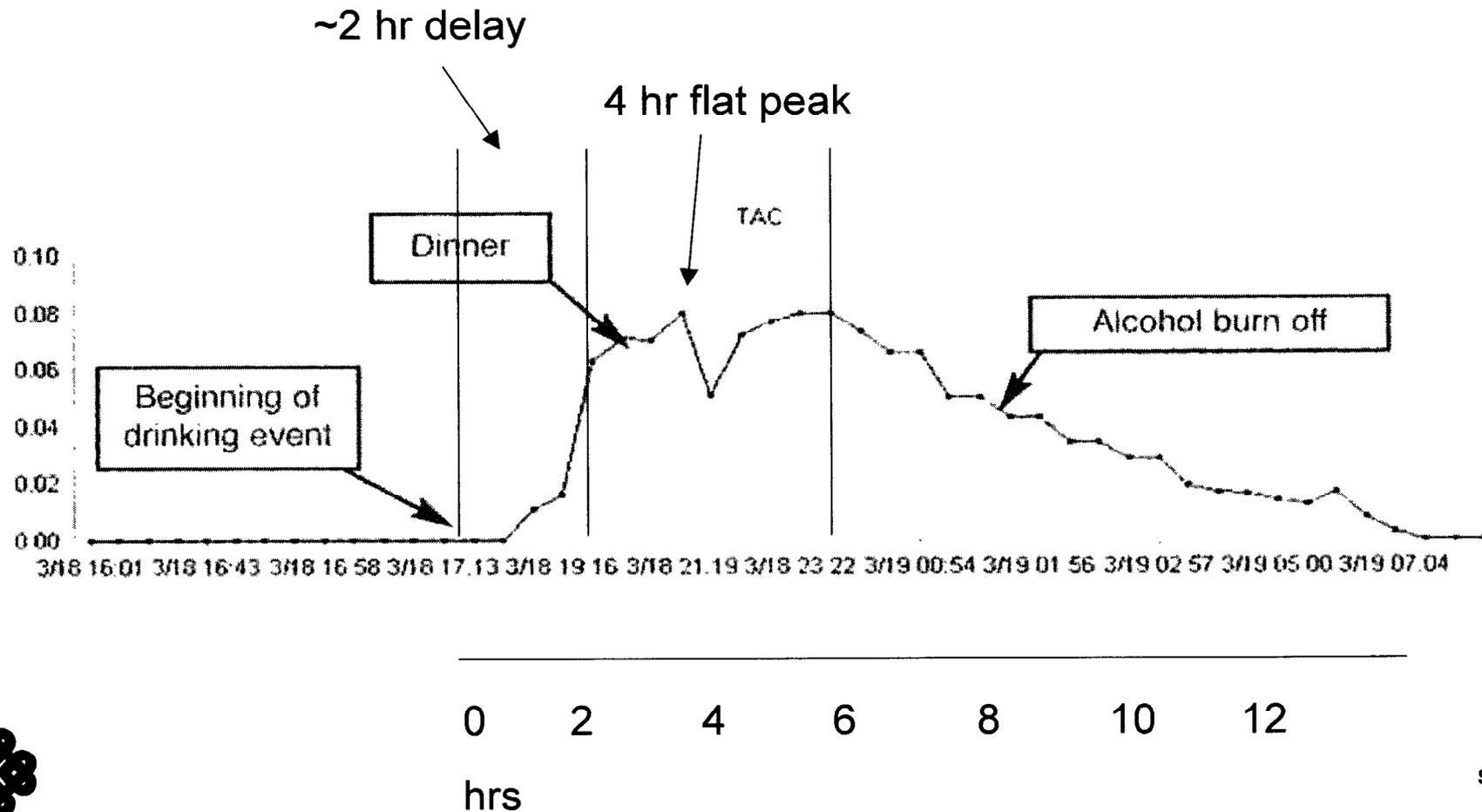


WrisTAS features

- WrisTAS is research prototype not commercial product.
- Accordingly the shell is not hardened to withstand abuse or water submersion – must remove for showering.
- Platinum electrode oxidizes alcohol – device measures the oxidation current passively and continuously.
- Chip averages the readings over x minutes (usually 5 min).
- Developed by Giner (a sensor company) with development support from NIH - NIAAA.
- Data retrieval is via cable link to computer port.
- Data storage ~ 17 days before download and service



Company Data: AMS SCRAM - one subject one device with dinner (slows)

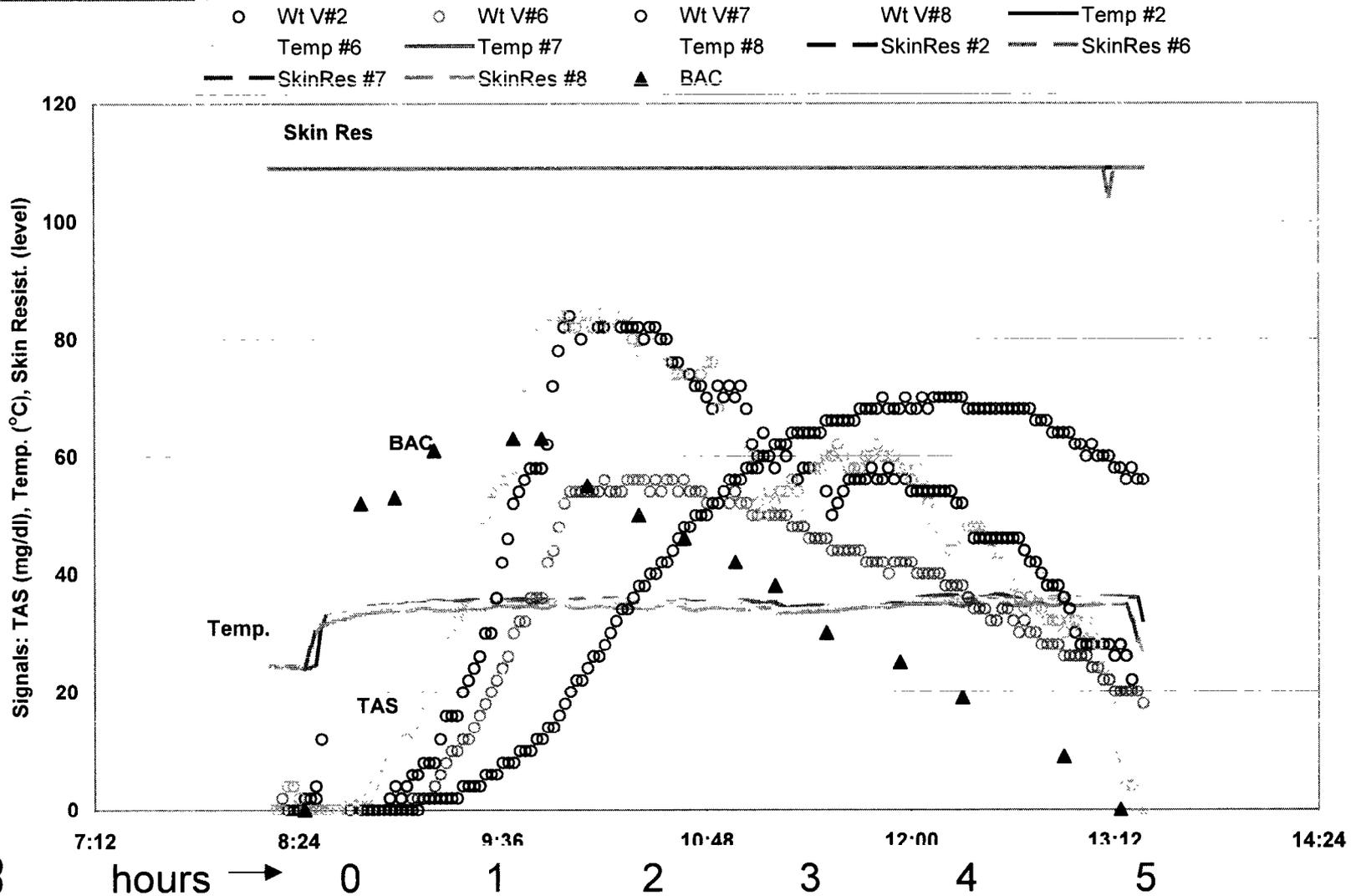


Company Data: Giner WristAS

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1 subject, 4 devices

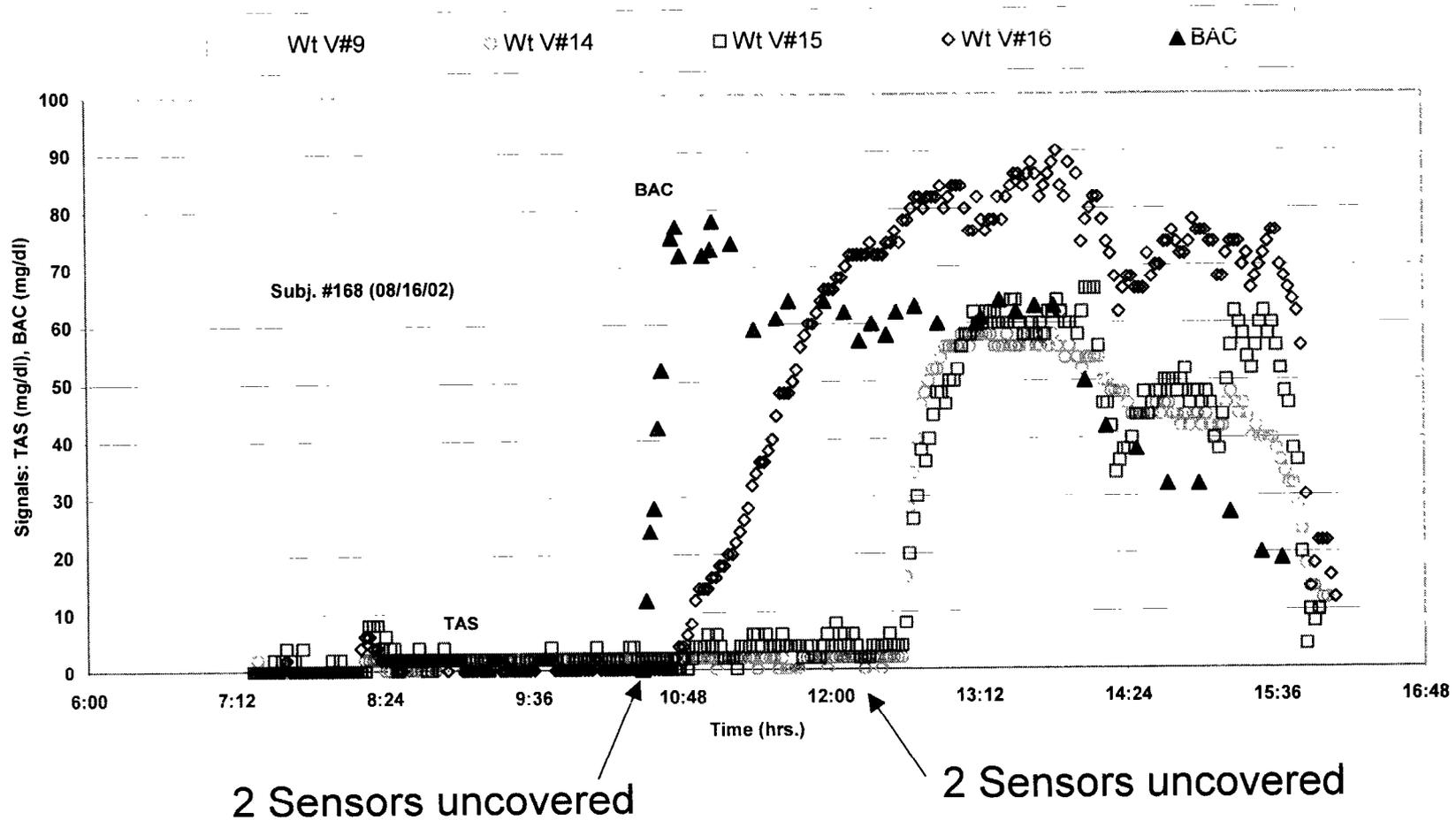
Calcs, #2, WristAS V #2, #6, #7, and #8 (8/16/02)



Univ Indiana - IV alcohol clamp study

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1 subject 4 devices



Evaluation Elements NHTSA study

1. Normal wear with self-paced drinking subjects fill in drink logs and self-measure with PBT (fuel cell breath tester) hourly while drinking
2. Laboratory dosed drinking to ~.08% with regular PBT/BAC measurement
3. Detection in cold
4. Detection with exercise induced sweating
5. Circumvention detection



PIRE - NHTSA protocol

- PIRE IRB review and approve
- Recruitment
 - Interview ~40 people to get 18: payment \$25 orientation
- Screening
 - Exclusion (pregnancy, drug use, alcohol dependence, health issues/diabetes etc., under age 21, over age 35)
 - Inclusion (binge/heavy drinker, both sexes, willing to stay the course, alcohol abuse and dependence assessments to exclude excess)
 - Incentive for 28 days wear incl. 2 dosing studies - \$800 for completion (4 x \$100/wk +\$400 bonus)



28 Day Wear - Acceptability Findings

- No important problems for research subjects
- Minor problems included:
 - SCRAM: some bouncing on ankle while exercising
 - SCRAM: minor delays at airport security (5-7 min)
 - SCRAM: minor bruising two female subjects
 - WrisTAS: raising rash on skin surface
 - WrisTAS: pads get stinky after a week
 - WrisTAS: must remove for showering
- Subjects routinely reported that testing and logging BAC results with the PBTs was much bigger nuisance than wearing the devices

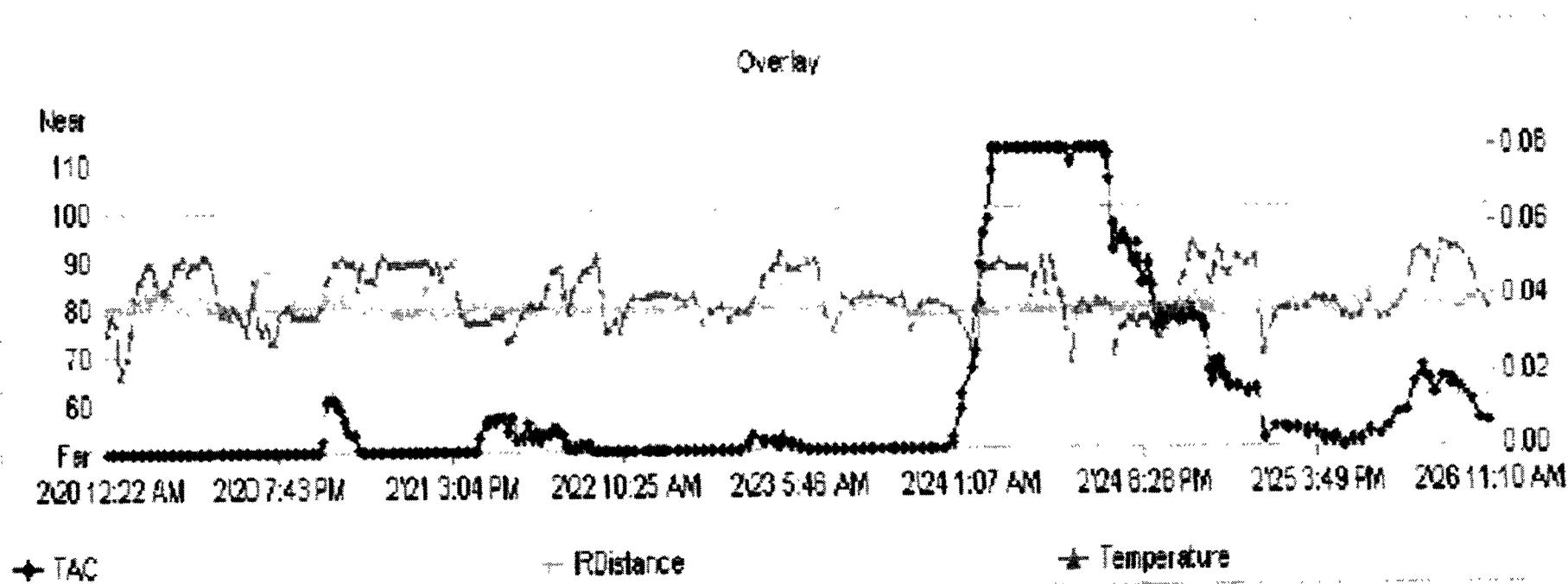


One week SCRAM.

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Normal Wear, Self-Paced Drinking

Software clamps SCRAM at .08%



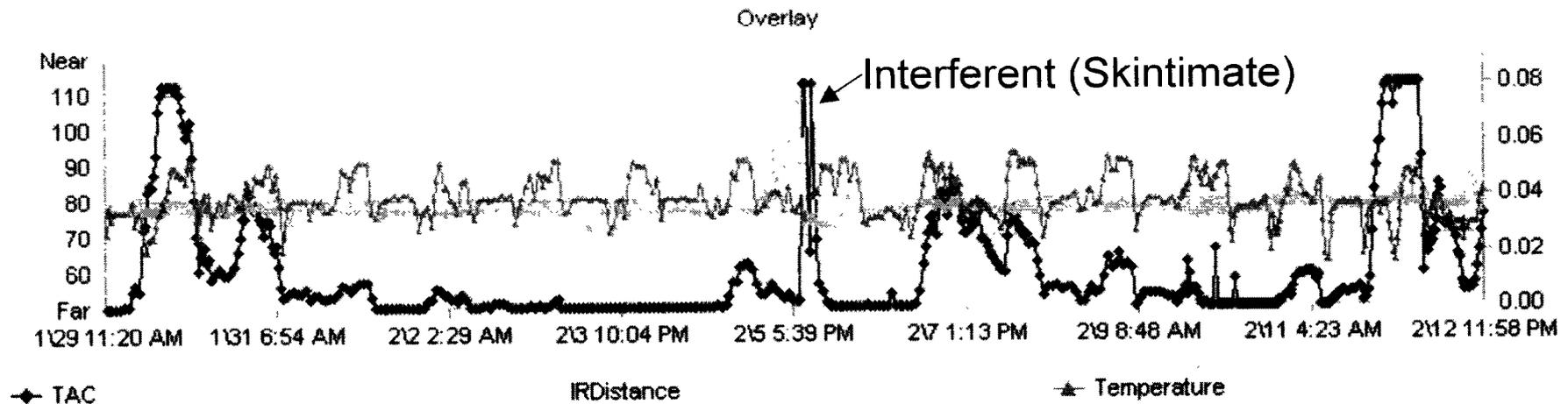
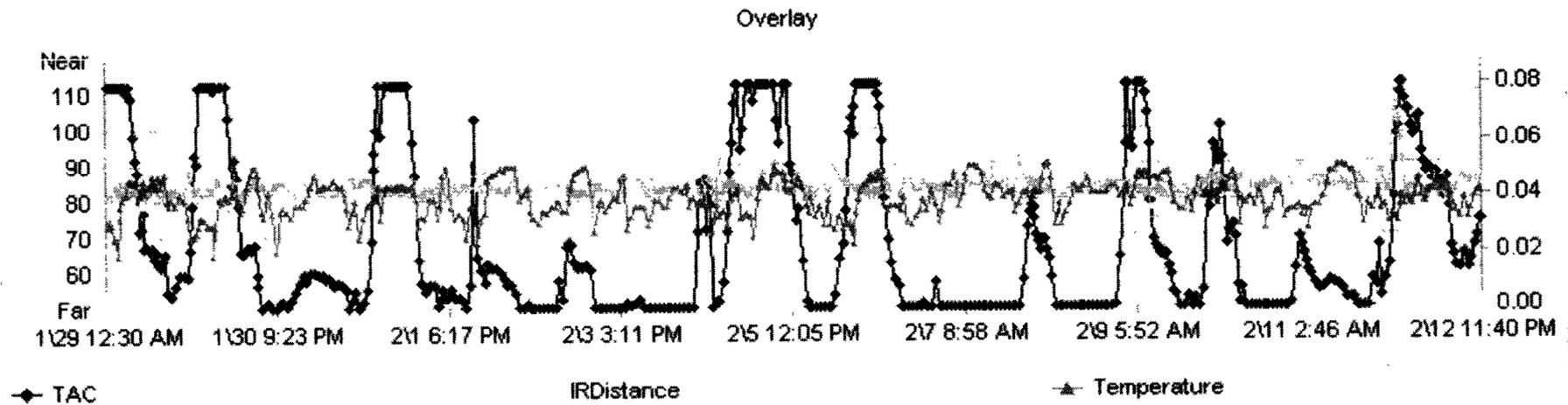
Transdermal alcohol, skin temperature and infrared (distance) all on one chart



2 weeks SCRAM data 2 subjects

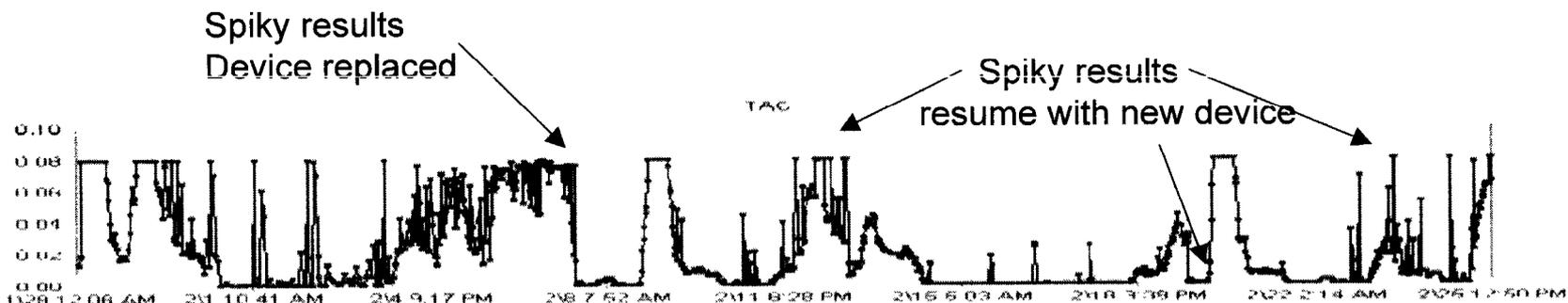
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male top, female bottom

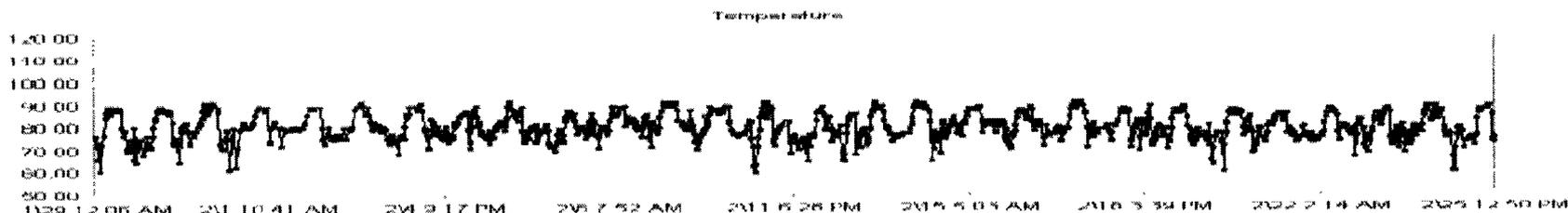


One month SCRAM: One subject before a design change

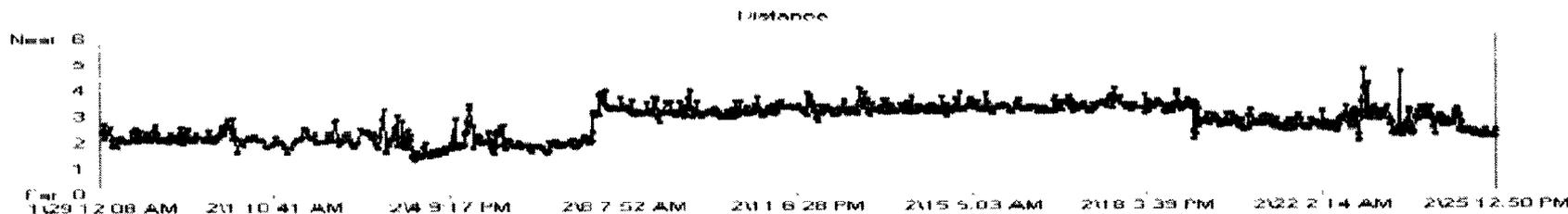
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Temperature Graph



Distance Graph



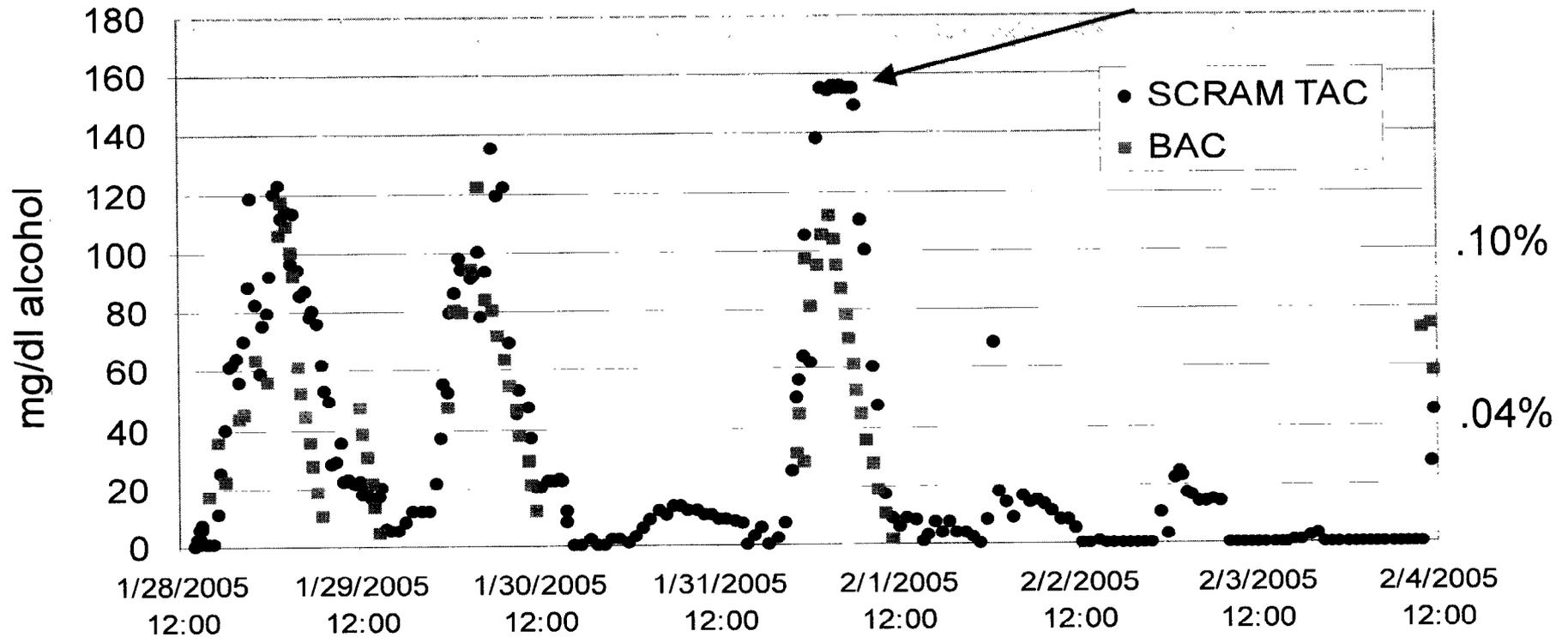
Same subject same dates with SCRAM

Normal Wear Self-dose Drinking

ERIGHT
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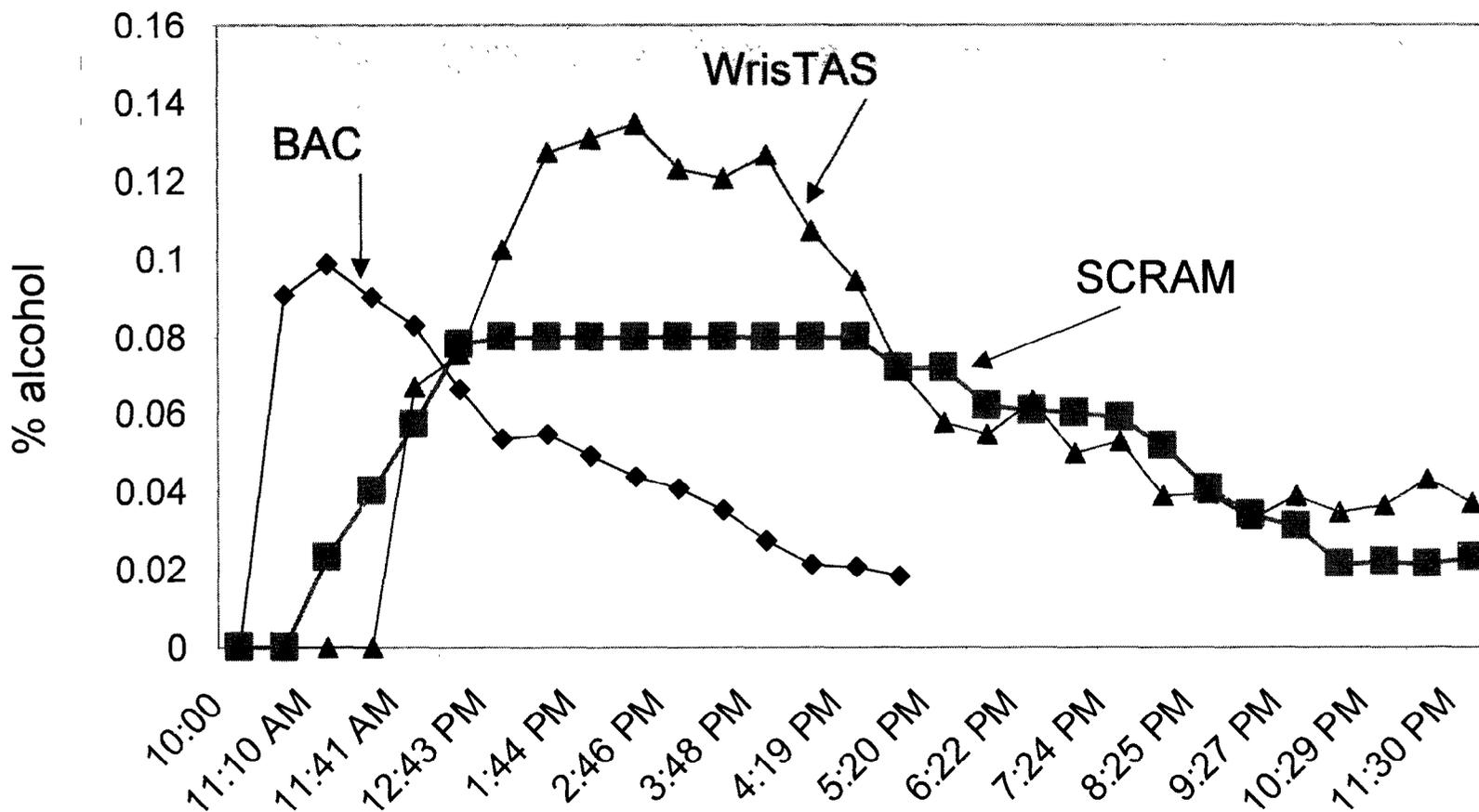
ZL SCRAM

Note: should be 80 not 160



Subject dosing study RR31

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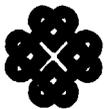
Some SCRAM-related issues

- Data may get spiky at times – probably water accumulating in the sensor – accuracy suffers
- If water is present, sensor may lose ability to detect ethanol or have delayed sensitivity – with a recent design change this may now be better
- Paced drinking with food may not trigger an “alert”
- Detection algorithm is good not perfect – it can misclassify rapid rise in BAC as an external interferent – their algorithm tries to protect against false positives
- Modem communications usually work well, but they do not work with mobile phones – this will be problem if no landline available to offender.
- A few landlines had trouble dialing out.



Some WrisTAS related issues

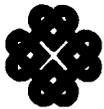
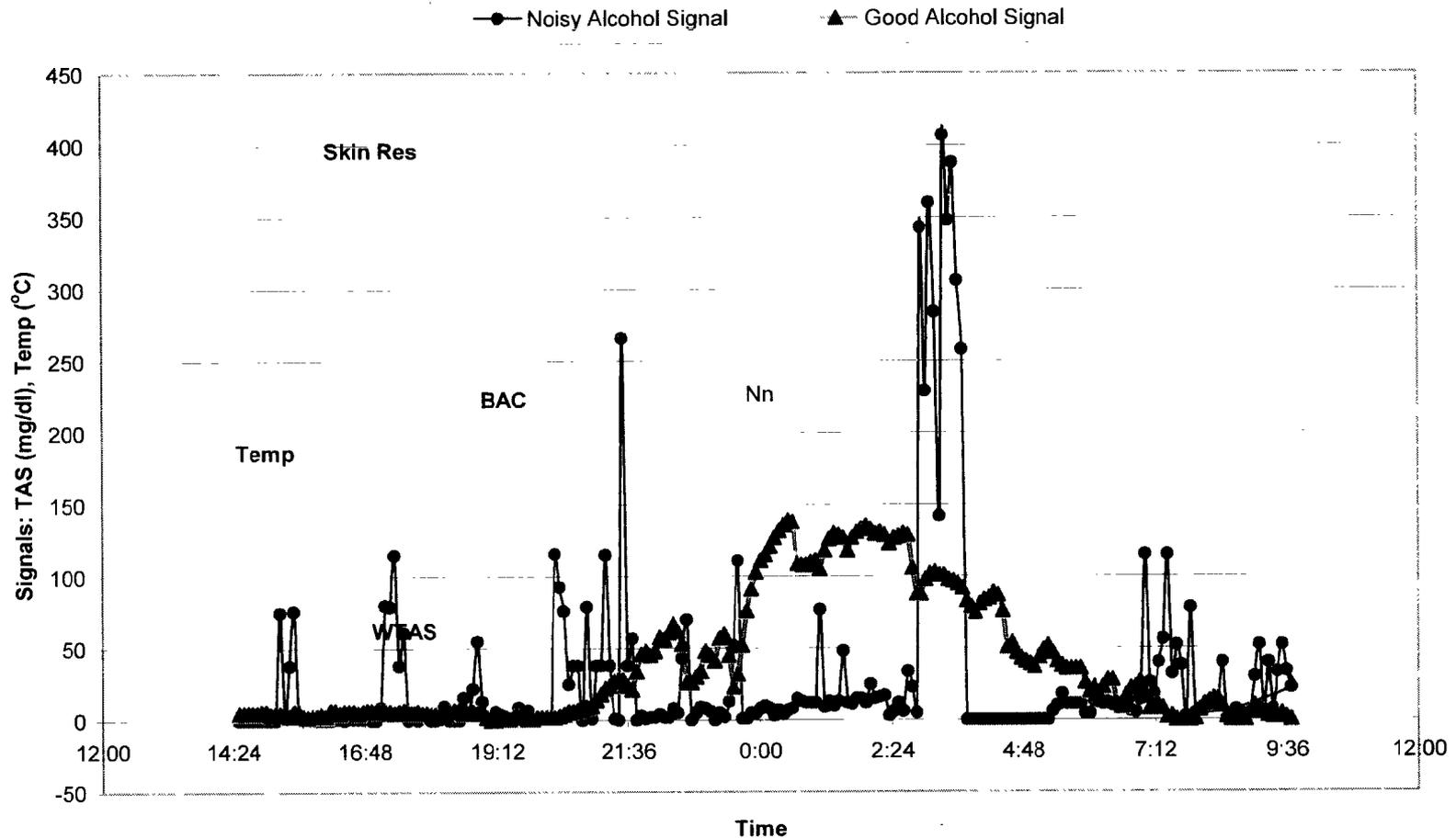
- Data download method, water resistance and strap attachment are not yet suited for corrections population. This is still a research prototype.
- Some devices lose baseline stability (fluctuating voltage) and at times it may become difficult to determine zero BAC point
- Storage and retrieval of info may lead device to lose BAC data and/or date info. The control and storage electronics are not yet perfected in this version
- Sensor is very innovative and seems to work well
- Occasionally get extremely high readings (e.g., .6%)
- Contact pad sweats out after some time and can get displaced potentially blocking sensor



One person Two wrists One good, one bad WrisTAS

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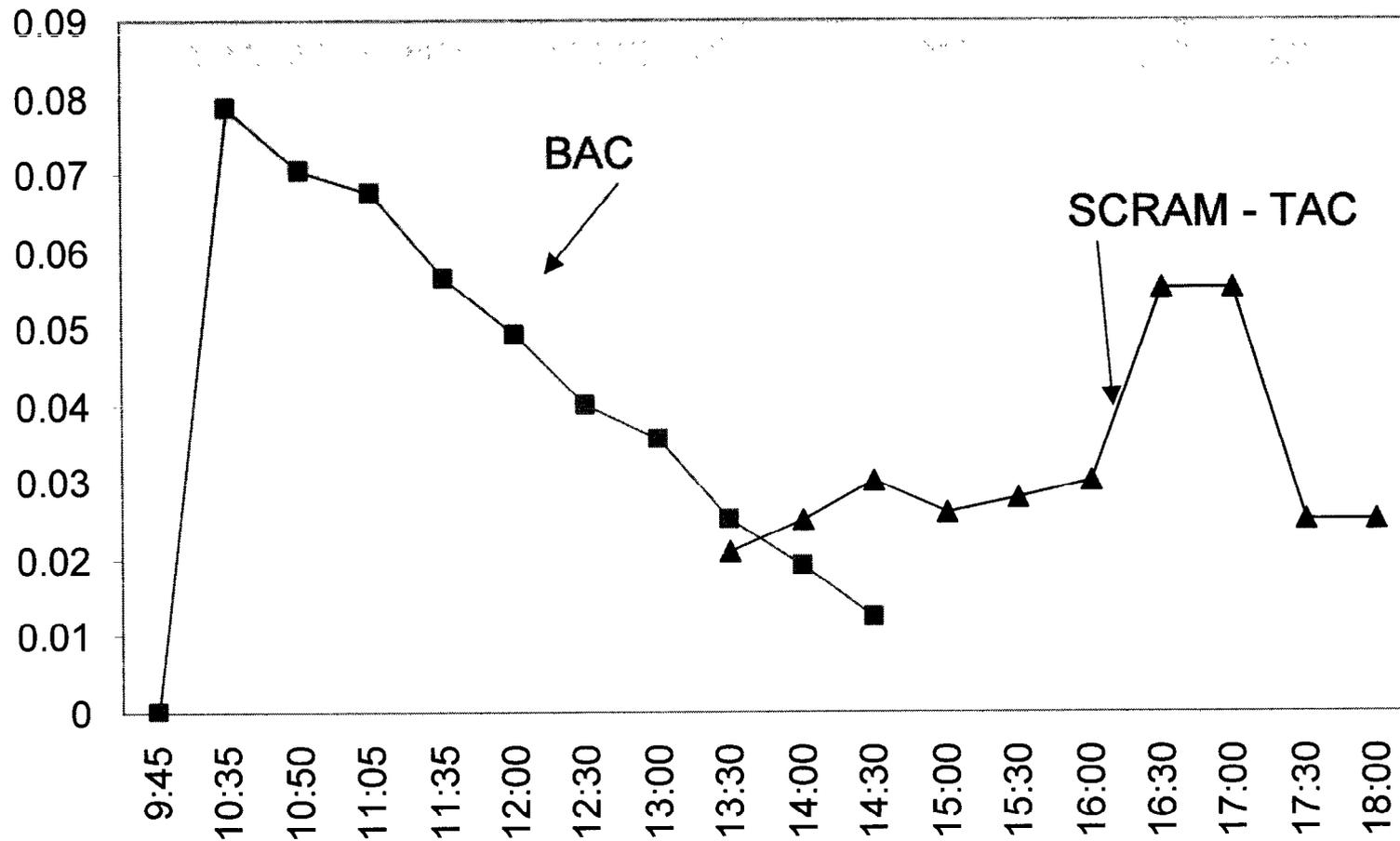
Two Concurrent WrisTAS Signals for the Same Subject



Example of SCRAM delayed response

ZT47

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Cold and Sweat

- We will be evaluating this during the summer in more detail.
- We have used a cold source to lower skin temp by about 8-10°C in 30 min.
- We have used a 30 min. treadmill uphill brisk walk to induce significant sweating with increase in skin T to near core T.
- Preliminary data show sweat or cold will alter the detectable response.



Circumvention

- Will study this summer
- Will study ideas from prior SCRAM offenders
- Will study our own hunches
- What is the value of this information?
- Distinguish importance of theoretical ability to circumvent vs practical ability
- Suggestions to test?

