

DataMaster DMT Explanation of Status Codes and Their Limits

Based on Vermont Software as of 3/30/2009

“PUMP ERROR”

If at anytime during the purge cycle or the running of a wet bath external standard, the flow rate drops below approximately 3 liters per minute (derived from a flow voltage limit of 1.35 Vdc), the message “PUMP ERROR” will be generated.

This voltage and the corresponding flow rate of approximately 3 l/m is also used as the MINIMUM FLOW RATE required when determining subject sample acceptance.

“FILTER (1, 2 or 3) WON'T ZERO”

In the event the DMT's D to A converter is unable to adjust the output detector signal prior to an analysis at any of the three wavelengths (3.44 μ , 3.37 μ and 3.50 μ) to within 30 mV of 0.000 V, the message “FILTER (1, 2 or 3) WON'T ZERO” will be generated identifying which specific filter was unable to zero.

“AMBIENT FAIL”

During the initial purge cycle of a given test, the output signal of the detector is measured and quantified. The initial measurement is made 10 seconds after the pump comes on. A second measurement is made at the completion of the purge, 25 seconds from the start. When these 2 measurements are compared, if the difference is > .040 Vdc, the message “AMBIENT FAIL” will be generated.

“BLANK ERROR”

A Blank Test is performed subsequent to zeroing and prior to analysis when the primary, or 3.44 μ filter is in the optical path. If this measurement produces a measurement \geq 0.004 g/210 liters or equivalent, the message “BLANK ERROR” will be generated.

Additionally, if, after the allotted purge time after a sample has been delivered the displayed value \geq 0.008 g/210 liters or equivalent, the message “BLANK ERROR” will be generated.

“STANDARD OUT OF RANGE”

If the simulator tolerance check is enabled, the value of an external standard must be within \pm 0.005 g/210 liters, or equivalent, of the target ethanol concentration for values of 0.080 g/210 liters or equivalent and above. For target concentrations below 0.080 g/210

liters, the limit is ± 0.004 g/210 liters. If the result produce is outside the above allotted tolerances, the message "STANDARD OUT OF RANGE" is generated.

"SIMULATOR NOT TO TEMPERATURE"

When connected to a digital wet bath simulator, if the monitored temperature falls outside the limit of 33.5 to 34.5 degrees C inclusive when a test is conducted, the message "SIMULATOR NOT TO TEMPERATURE" will be generated.

"SIMULATOR TIMEOUT"

When running an external standard, if the sample acceptance parameters are not met within the allotted 30 second window, the message "SIMULATOR TIMEOUT" will be generated.

"INTERNAL STANDARD ERROR"

When performing a measurement of the internal quartz standard during the testing sequence, if the measured value equals or exceeds the Xq value stored in the calibration factors by $\pm 4\%$, the message "INTERNAL STANDARD ERROR" will be generated.

"INVALID SAMPLE"

Reference NPAS document DMT Invalid.doc dated 12/14/07 (attached).

"DETECTOR OVERFLOW"

When a voltage corresponding to the alcohol concentration (Detector Voltage) during any time the DMT is taking any type of measurement exceeds the limit of -2 Vdc to +2 Vdc, the message "DETECTOR OVERFLOW" will be generated. This voltage corresponds to an alcohol concentration outside the limits of detection of the DMT (approximately 0.83 (or -0.83 g/210 liters) as a reference).

SAMPLE CHAMBER TEMPERATURE CHECK

The temperature range for the sample chamber is 44 to 52 degrees C exclusive. The DMT will only allow a test to be conducted if the sample chamber temperature is above 44 and below 52 degrees C. If the temperature is outside this limit, a message stating so will be displayed when a test is attempted.

When the DMT is powered-up, the 20 minute wait period to the time that a test can be conducted is 20 minutes after the sample chamber temperature reaches 45 degrees C.

BREATH TUBE TEMPERATURE CHECK

The temperature range for the breath tube is 40 ± 10 degrees C inclusive. If the temperature is outside this limit, a message stating so will be displayed when a test is attempted.

“RFI DETECTED”

An antenna wire in the breath tube monitors the environment around the DMT for elevated levels of radio frequency interference. If the set threshold for detection is exceeded due to elevated levels of RFI the message “RFI DETECTED” will be generated.

“INCOMPLETE SAMPLE”

If the breath sample parameters are not met during the allotted 2 minute window for accepting a breath sample the message “INCOMPLETE SAMPLE” will be generated if it is determined that it is not a refusal.

“FILTER WHEEL ERROR”

2 optical sensors are used to validate proper positioning of the filters and quartz standard in the optical path. A stepper motor is used to move the filters and quartz standard into the proper position and a locking pin is actuated via a solenoid to secure in place. The software monitors the movement of these wheels and if there is misalignment during any of the movement sequences, the message “FILTER WHEEL ERROR” will be generated.

“SUCK BACK ERROR”

In addition to being able to determine the rate of airflow through the pathway, the mass airflow sensor can determine the direction of airflow. If the sensor detects airflow in the reverse direction during a breath test (sucking), the message “SUCK BACK ERROR” will be generated.

“INTERFERENCE DETECTED”

Each sample measured by the DMT is done so to determine the ethanol concentration. In addition, by measuring the sample at 3 wavelengths, we determine whether or not the sample is specific to ethanol. If a discrepancy is found compared to what is expected at the three separate filters, the sample is said to be non-specific to ethanol and the message “INTERFERENCE DETECTED” is generated. The limits for determining this are outlined in NPAS document DMT interference threshold.doc dated 1/18/2008 (attached).

Note: Status messages are in some instances software specific based upon customer requests. This list may not cover all scenarios and possible status messages. Additionally, allowable limits for certain checks may also differ among software / hardware configurations at the customers' request.

National Patent Analytical Systems, Inc.

Explanation of the INVALID SAMPLE message and the DataMaster DMT

12/14/07

Measurements of the alcohol concentration during breath sample delivery are taken every 250 milliseconds (4x per second).

A “positive slope” is defined as a comparison of a 2 consecutive point average to the previous where the trend is not in the negative direction. Both conditions of a positive change and no change are considered a positive slope.

The message “INVALID SAMPLE” will be produced while the instrument detects at least the minimum rate of airflow during sample delivery if:

There are three consecutive comparisons of two point averages where the trend is in the negative direction (values are decreasing) after seeing first a minimum of six positive comparisons of two point averages.

Or

Any final result ≥ 0.060 g/210 l is less than 95% of any previous high reading during that successfully delivered sample.

Or

Any final result ≥ 0.003 g/210 l but < 0.060 g/210 l is lower than any previous high reading during that successfully delivered sample by at least 0.003 g/210 l.

The “Filter Agreement” concept as it pertains to analytical principles incorporated in the DataMaster DMT breath test instruments. (Interference Detection)

Calibrating a DMT involves introducing known standards of water vapor and either wet or dry ethanol vapor. The purpose is twofold. First, the error in quantifying the ethanol, pre-calibration, as evidenced in the discrepancy between the known ethanol concentration (Ca) and that analyzed and displayed by the instrument upon introduction of that standard, is normalized to the known (Ca) by dividing the known value (Ca) into the reported (resulting in CAL). Second, by knowing that a true ethanol standard, free of any potential interfering substances, is introduced during the calibration procedure, the instrument determines the relative measurement of the ethanol sample when analyzing the vapor at each of the three narrow bandpass filter wavelengths (ref: a21, a31), thereby allowing subsequent analyses to be qualified as either containing or being free of interfering substance(s).

Water vapor is introduced so as to allow the amount evident at each of the filter wavelengths to be subtracted from all analyses thereafter. This water vapor concentration will be constant regardless of the ethanol concentration of the sample so a straight subtraction will suffice (ref: b1, b2, b3).

For discussion of the basic concept, we will show an example using 2 of the three filters (3.44 [filter 1] and 3.37 [filter 2] microns) and calibrating with water and ethanol. As stated above, water is introduced to determine the amount to be subtracted at 3.44 μ and 3.37 μ . These will not be the same value as water absorbs IR energy to a greater degree at 3.37 μ than at 3.44 μ . With the water content accounted for, the relative absorption by ethanol between 3.37 μ and 3.44 μ is determined. Since ethanol absorbs approximately 20% more IR energy at 3.37 μ than that at 3.44 μ , we would expect a21 to be in the neighborhood of 1.2 as a21 is defined as the value of ethanol measured at 3.37 μ with respect to that at 3.44 μ . As each IR filter has slightly different transmittance characteristics (center wavelength and half peak bandwidth), albeit within the published filter specifications, each instrument must be calibrated to determine the specific calibration factors for the use of those filters in a specific instrument. Those calibration factors are the characteristic values for that particular instrument. The a21 value is used on subsequent analyses to determine the presence (or absence) of an interfering substance.

This is done by first determining the concentration of the sample as analyzed at the 3.44 μ filter. The 3.37 μ filter is then inserted into the optical path and the sample is analyzed at that wavelength. The result analyzed at 3.44 μ is multiplied by a21. The result at 3.37 μ is subtracted from this product of the value at 3.44 μ x a21. If the difference is \leq the filter agreement threshold (default 0.005) then the sample is said to be free from an interfering substance. This is because the relative absorption seen between 3.37 μ and 3.44 μ for this sample is the same as that for the ethanol standard used to calibrate the instrument. When a substance other than ethanol, but still absorbing IR energy in the 3.4 μ region, is added to the sample, a disagreement becomes evident in the value at 3.37 μ with the result from

3.44 μ x a21. The greater the concentration of the interference, or the less like ethanol (a21), the greater the discrepancy becomes.

As some allowance for variation between the values (3.44 μ x a21 and 3.37 μ) is necessary due to expected variability in any measurement (± 0.002 for each measurement) the question arises as to at what level the discrepancy becomes significant and scientifically and legally of importance. The limit for the filter agreement threshold is 0.005. What this means is that once the discrepancy between the value at 3.37 μ and the value at 3.44 μ x a21 ≥ 0.005 , the sample is said to contain an interfering substance. This threshold can, however, be adjusted.

The following is an explanation of what might happen if the sample were to contain acetone in addition to ethanol. Lets assume the ethanol concentration of the sample as measured at 3.44 μ was 0.160. Knowing that ethanol absorbs approximately 20% more energy at 3.37 μ , we would anticipate the result at 3.37 μ to be $0.160 \times 1.2 = 0.192$. If acetone is also a component of the sample, it would be useful to know the characteristics of acetone at 3.44 μ and 3.37 μ . Test data has shown that acetone absorbs 2 to 3 times the amount of IR energy at 3.37 μ than it does at 3.44 μ (again, independent of the concentration). For this discussion we will use a 2:1 ratio. Assume a contribution of 0.010 at 3.44 μ . Since we expect in this example 2X that concentration at 3.37 μ , the value would be 0.020. If we add these concentrations of acetone to the ethanol portion we would see:

Reading at 3.44 μ = 0.160 (etoh) + 0.010 (ace) = 0.170 total concentration

Reading at 3.37 μ = 0.192 (etoh) + 0.020 (ace) = 0.212 total concentration

When multiplying the result at 3.44 μ by a21 we see:

$$0.170 \times 1.2 = 0.204$$

Comparing this to the result at 3.37 μ we see:

$$0.204 - 0.212 = -0.008$$

This exceeds the "filter agreement threshold", (preset at 0.005) by 0.03. This test would result in the message of "interference detected" if the software were designed to handle the discrepancy in this manner.

If the contribution by acetone were 0.005 at 3.44 μ in the above example, the amount at 3.37 μ would be expected to be 2X or 0.010. This, added to our base ethanol concentration would yield:

Reading at 3.44 = 0.160 (etoh) + 0.005 (ace) = 0.165 total concentration

Reading at 3.37 = 0.192 (etoh) + 0.010 (ace) = 0.202 total concentration

When multiplying the result at 3.44 μ by a21 we see:

$$0.165 \times 1.2 = 0.198$$

Comparing this to the result at 3.37 μ we see:

$$0.198 - 0.202 = -0.004$$

This would be below the set filter agreement threshold (0.005) and in this instance, the final result would be a reported ethanol concentration of 0.165.

The explanation above is repeated except filter 2 (3.37 μ) is replaced with filter 3 (3.50 μ) and a21 is replaced with a31.

This example is when acetone absorbs only 2x as much at 3.37 μ wrt 3.44 μ . As you approach a 3x relationship, the allowable contribution by acetone at 3.44 μ is reduced.

The filter agreement threshold will be adjustable. This settable level (2-10) implying, when referring to g/210L units of measurement, an adjustable threshold of between 0.002 g/210L and 0.010 g/210L will pertain to the difference in the calculated concentration at filter 1 (3.44 μ) and filter 2 (3.37 μ) or the difference in the calculated concentration at filter 1 and filter 3 (3.50 μ). The selected filter agreement threshold will be the absolute value for sample concentrations measured at filter 1 of up to 0.100 g/210L. For values at or greater than 0.100 g/210L the threshold will be a percentage of the analyzed concentration at 3.44 μ :

Filter Agreement if $3.44\mu \geq 0.100 \text{ g/210L} = (\text{Int} \times 0.001) \times (\text{value at filter 1} / 0.100)$
Where Int is the set filter agreement threshold value from 2 to 10

If the difference when comparing the results of 3.44 μ and 3.37 μ OR when comparing the results of 3.44 μ and 3.50 μ exceeds the threshold, a non-specific to ethanol sample is said to have occurred.

An additional filter agreement threshold calculation will also be employed where the threshold outlined above is not exceeded but the difference in the 2 calculated differences (filter 1-2 and filter 1-3) when combined reaches a level defined as:

For filter 1 measured concentrations of up to 0.100 g/210L interference detected will be the result if:

$$\text{Diff filter 1-2 plus Diff filter 1-3} \geq (\text{Int} \times 0.001) \times (7/5) = 0.007$$

For concentrations measured at filter 1 of 0.100 g/210L or greater interference detected will be the result if:

$$\text{Diff filter 1-2 plus Diff filter 1-3} \geq (\text{Int} \times 0.001) \times (\text{value at filter 1} / 0.100) \times (7/5)$$

See table below for example of thresholds with INT set to 5

Value @ Filt 1	Filter I1-2I Diff	Filter I1-3I Diff	Combined Diff I1-2I + I1-3I
0.025	0.0050	0.0050	0.0070
0.050	0.0050	0.0050	0.0070
0.075	0.0050	0.0050	0.0070
0.100	0.0050	0.0050	0.0070
0.150	0.0075	0.0075	0.0105
0.200	0.0100	0.0100	0.0140
0.250	0.0125	0.0125	0.0175
0.300	0.0150	0.0150	0.0210
0.350	0.0175	0.0175	0.0245
0.400	0.0200	0.0200	0.0280
0.450	0.0225	0.0225	0.0315
0.500	0.0250	0.0250	0.0350
0.550	0.0275	0.0275	0.0385
0.600	0.0300	0.0300	0.0420

Enter Int Thrshld
(2-10)
5

Separate worksheet allows changing Threshold setting to see limits.

104409 Middlesex VSP

Date	Time	Operator	Type of Test	Target	Lot #	Sim Result 1	Sim Temp 1	Sim Result 2	Sim Temp 2
12/18/2009	12:26:23	ALB	Install	0.098	10-15-100	avg = 0.097	34.1		
12/23/2009	23:10:09	Cop	DUI	0.098		0.096	33.9		
12/25/2009	1:29:30	Cop	DUI	0.098		0.096	34		
12/29/2009	8:35:09	Cop	DUI	0.098		0.095	34		
12/30/2009	14:16:41	SH	A&P Test	0.098	10-15-100	avg = .094	34.0 - 34.1		
12/30/2009	20:10:55	Cop	DUI	0.098		0.096	33.9		
12/30/2009	20:15:02	Cop	DUI	0.098		0.096	33.9		
1/1/2010	2:49:50	Cop	DUI	0.098		0.095	34		
1/7/2010	23:42:15	Cop	DUI	0.098		0.094	33.9	0.093	34
1/8/2010	21:04:17	Cop	DUI	0.098		0.094	34	0.095	34
1/11/2010	23:21:04	Cop	DUI	0.098		0.095	33.9	0.095	34
1/15/2010	0:02:05	Cop	DUI	0.098		0.094	33.9	0.093	33.9
1/16/2010	19:45:44	Cop	DUI	0.098		0.095	33.9	0.094	34
1/16/2010	21:14:28	Cop	DUI	0.098		0.094	34	0.094	34
1/25/2010	2:10:26	Cop	DUI	0.098		0.094	33.9	0.094	34
1/29/2010	1:05:45	Cop	DUI	0.098		0.093	33.9	0.093	34
2/1/2010	17:24:44	Cop	Sim Sol Ch	0.1	09-40-100	avg = .099	34		
2/2/2010	9:56:03	Cop	RPC	0.1	09-40-100	avg = .099	34		
2/2/2010	10:50:36	Cop	RPC	0.1	09-40-100	avg = .098	34		
2/2/2010	11:17:26	Cop	A&P Test	0.1	09-40-100	avg = .099	33.9 - 34.1		
2/20/2010	21:41:28	Cop	DUI	0.1		0.097	34	0.096	34
2/20/2010	22:07:36	Cop	DUI	0.1		0.096	33.9		
2/21/2010	9:08:11	Cop	DUI	0.1		0.097	33.9		

From: Richardson, Darcy
Sent: Monday, March 23, 2009 3:23 PM
To: Drawbaugh, Bob
Subject: Draeger Justification



Draeger 9510
Justification.doc...

*Darcy Richardson
Toxicology Program
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VERMONT DEPARTMENT OF HEALTH LABORATORY OFFICE
MEMORANDUM

TO: Alcohol Program Staff
FROM: Darcy Richardson
DATE: March 23rd, 2009
RE: Replacement of BAC DataMasters, Draeger model 9510

Currently we are tasked with replacing the remaining approximately 50 breath testing instruments in use through the state. Two models of instrument are currently available that would suit our needs, the DMT by NPAS and the 9510 by Draeger. In replacing the first 3 counties of Vermont we purchased the DataMaster DMT by NPAS. We own 20 instruments, 17 of which are field ready and are currently in use. Two of the remaining are in laboratory testing and the third is in the process of becoming ready for laboratory testing. At the time of purchase the 9510 was not available.

Since January 12th, 2009 we have had a 9510 unit in house for testing. Accuracy and Precision performance has been equivalent to the DMT. The instrument is user friendly and uses USB keyboards and printers (with the same Windows CE restrictions as the DMT). An additional feature is the virtual keyboard when a physical keyboard is not attached to the instrument. The Alcotest 9510 has connections for many types of equipment. This would allow us to easily add peripherals and would allow us to use projectors directly from the instrument which would greatly aid in training of officers.

Interference testing has shown that the instrument identifies interfering compounds well. Although further testing remains the interferant of concern, methanol, has been tested and is identified every time by the 9510 as an interferant. With the wavelength used for IR, acetone no longer acts as an interferant. The instrument has not accepted a test inappropriately through interference testing. The 9510, unlike the DMT, is radio frequency immune. This is a very valuable feature as we currently have agencies that are experiencing difficulty with multiple RFI interruptions. These interruptions take the instrument out of service and create arguments that we then must address in the court room.

The 9510 is well built with no moving parts. The detector and source line up simply by screwing them into the sample chamber allowing them to be lined up properly every time. Currently we physically manipulate every DMT that arrives in house to ensure that the detector is optimized and adjust voltage settings. We have replaced many filter wheels and chopper wheels in the DMTs we currently own and have often had to replace parts in the DMTs prior to the start of testing. The construction and engineering design of the 9510 would minimize the manipulation and maintenance we would have to perform on the instruments.

The 9510 uses both fuel cell and infrared energy in it's analysis of breath alcohol and appears on the Federal List of Conforming Products. Dual technology currently exists in 2 of the 4 main models of evidential breath alcohol testing equipment. We have recently been informed that NPAS will follow suit with the DMT. This will be a new venture for NPAS and will require a breaking in period. Draeger manufactures their own fuel cells

Breath Alcohol Test Instrumentation Purchase Specifications*

General Specifications:

Model provided must be approved by the USDOT National Highway Traffic Safety Administration for use as an evidential breath alcohol testing device

One year manufacturer's warranty for parts and labor

One year software support for change of security codes, test sequence, test record format and test data display and document printing format

Shipping and delivery costs included in quoted price

All units to be delivered within 120 days of purchase order

Manufacturer will provide a minimum of 2 days of on-site training for operation, maintenance and basic repair within 90 days of the first delivery of units

Physical Specifications:

Maximum footprint 24" x 24"

Maximum Unit weight: 25 lbs.

Operational with either AC or DC power

Power requirements: 115VAC \pm 5VAC / 60 Hz and 12 VDC

External printer capable; USB connection; HP-PCL capable

USB/PS2 keyboard

magnetic strip card reader capable

Liquid Crystal Display with ability to display: real time alcohol concentration during testing process; real time breath flow rate and volume; real time simulator temperature display; barometric pressure; detector voltage; instrument status checks, eg. heated zone temperatures , internal standard check result; data value vs time plot for all of the above

Heated breath and simulator vapor delivery tubes

Capability for both wet bath and dry gas calibration and test sequence calibration checks

1 RS-232 communications port

1 communications port for monitoring attached simulator temperature

1 USB port assigned for data transfer to external computer

2 unassigned USB ports for future additions

Breath Alcohol Test Instrumentation Purchase Specifications (continued)

1 high speed modem for data transfer via telephone lines

1 ethernet communications port

infrared-based analytical technology for both qualitative and quantitative determination of ethanol vapor; including at least 3 filters at appropriate wavelengths to identify potentially interfering substances

CPU operating at 128 MHz or faster

Operating software with complete documentation/ description of analytical algorithms available, with legal protections, for support of defense against legal challenges

Software capable of providing at least 4 levels of security defining access to various instrument functions

Capability for operating sequence, data collection, and diagnostic test software updates uploaded from remote source

Capability for transferring data to standard business software packages e.g. Microsoft Office or Corel Office

Performance Specifications:

In addition to meeting NHTSA performance criteria for evidential devices, the instrument must meet the following criteria:

Must require a minimum of 1.5 L of breath to be delivered in a single, steady exhalation for alcohol content to be reported

Breath volume for a successful test must be recorded and reported to +/- 0.1 L

Breath flow rate must be monitored and data available to print a graphic presentation of the breath flow profile

Must have a means of detecting mouth alcohol at a level of 0.02 g/210 L or greater or any other source of an apparent alcohol concentration spike occurring during the presentation of actual or simulated breath for analysis

Must report breath or simulated breath alcohol vapor concentration in g EtOH/210 L air

Must be capable of detecting and reporting the presence of potentially interfering volatile organic compounds at a level of 0.02 g/210 L, or greater, apparent alcohol concentration

Must be capable of determining the alcohol concentration of a vapor sample from a source with a known concentration to within $\pm 5\%$.

Must be capable of determining the concentration of replicate samples of alcohol vapor with a precision of no more than $\pm 5\%$ from the mean of the concentration and with a standard deviation of no greater than 2%

Must be capable of displaying alcohol concentrations in the range of 0.0 to 0.60 g/210L

Data Specifications

Instrument must be capable of collecting and storing calibration data and all monitored test data including the data from subject breath tests, supervisory/performance check tests, and diagnostic tests

System function errors or status checks which are out of control must be stored as retrievable data

System must be capable of storing test data for up to 500 tests and capable of transferring that data to an external computer through either Ethernet connection or via phone modem

Test record and report format to be determined at the time of purchase

* does not include custom software specifications for test sequence; test record data; etc. – tbd later
final purchase award will be based on manufacturer's ability to meet specifications provided

Physical Specs

- 24" x 24" footprint
- ≤ 25 lbs
- Card reader capable
- USB external printer
- USB/PS2 keyboard
- LCD display
 - Real time [alc]
 - Detector voltage
 - Flow rates & volume
 - Instrument checks
 - External Sim temp
 - Value vs. time plot for all of the above
- Heated breath and Sim hoses
- Wet bath Sim (dry gas capable)
- 120V AC / 60Hz / ~12V DC
- 2 extra USB ports for future expansion
- Infrared technology for alcohol identification and quantitation
- Software security
- Remote software updates
- > 128mHz processor
- Able to export data to standard business software

Performance Specs

- CPL
- 1.5L min volume required
- Report breath vol to ±0.1L
- Monitor flow rate
- Interference
 - RFI
 - Compounds
 - Mouth Alc
- Accuracy ±5% (0.02-0.4)
- Precision ±5%
- Std Dev <2%
- Display alcohol concentrations 0.0 - 0.6

Test Data / Report

- Breath test record
- Supervisor test record
- Calibration record
- Certification test record
- Error Messages
- Site Id, serial #, date, time (DST & leap year)

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One year software support for change of security codes, test sequence, test record format and test data display and document printing format

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Must report breath or simulated breath alcohol vapor concentration in g EtOH/210 L air

Must be capable of detecting and reporting the presence of potentially interfering volatile organic compounds at a level of 0.02 g/210 L, or greater, apparent alcohol concentration

Must be capable of determining the alcohol concentration of a vapor sample from a source with a known concentration to within $\pm 5\%$.

Must be capable of determining the concentration of replicate samples of alcohol vapor with a precision of no more than $\pm 5\%$ from the mean of the concentration and with a standard deviation of no greater than 2%

Must be capable of displaying alcohol concentrations in the range of 0.0 to 0.60 g/210L

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- Heated breath and Sim hoses
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- 120V AC / 60Hz / ~12V DC
- 2 extra USB ports for future expansion
- Infrared technology for alcohol identification and quantitation
- Software security
- Remote software updates
- > 128mHz processor
- Able to export data to standard business software

Performance Specs

- CPL
- 1.5L min volume required
- Report breath vol to ±0.1L
- Monitor flow rate
- Interference
 - RFI
 - Compounds
 - Mouth Alc
- Accuracy ±5% (0.02-0.4)
- Precision ±5%
- Std Dev <2%
- Display alcohol concentrations 0.0 - 0.6

Test Data / Report

- Breath test record
- Supervisor test record
- RPC Data
- Calibration record
- Certification test record
- Error Messages
- Site Id, serial #, date, time (DST & leap year)
- Sim Temp
- Sim [X]
- Breath Tube temp

Vermont Department of Health Laboratory
Toxicology Program
Memorandum

To: Mary Celotti, Laboratory Director
From: Robert Drawbaugh, Toxicology Program Chief
Date: April 14, 2011
Re : Breath Test Instrumentation

A purchase requisition and instrument specifications are provided with this memo. This purchase is not anticipated to encumber the full amount of funds available but we will also need to purchase printers and simulators with a security enclosure which will likely require a large portion of the remaining funds. Once the instrument purchase is decided and placed, we will also need to purchase maintenance and repair item, additional operating supplies, and training items. We should ask for a minimum bid turn-around time for these since all the vendors know that this is coming and we are pressed for time to encumber the money. Thanks for your help in moving this forward.

- Interference Detected
- Incomplete Sample
- Ambient Fail
- Printer Error
- System Error
 - Pump
 - Filter
 - Etc

CHIEFLETTER.txt

"letter_needed"	"ChiefID"	"Titles"	"FirstName"	"LastName"	
"LocationCode"	"Comments"				
57	"Constable"	"Thomas"	"Simpson"	"1404"	
58	"Sheriff"	"Amos"	"Colby" "0502"	"building"	
"X" 64	"Chief"	"Thomas"	"Hanley"	"0104"	
"X" 65	"Chief"	"Osburn"	"Glidden"	"0412"	
66	"Sheriff"	"RJ"	"Elrich"	"1107"	
67	"Sheriff"	"Gary"	"Forrest"	"0205"	
68	"Captain"	"Dean"	"George"	"1505"	"Troop Commander"
"X" 69	"Sheriff"	"Amos"	"Colby" "1501"	"mobile"	
70	"Ms."	"Jeanne"	"Johnson"	"1502"	"GHSP Coordinator"
sharp van/ not in use"	"Captain"	"Thomas"	"Fields"	"1503"	"Troop Commander"
"X" 72	"Captain"	"Jim"	"Dimmick"	"1504"	"Troop Commander"
"X" 73	"Captain"	"Kerry"	"Sleeper"	"1506"	"Troop Commander"
74	"Mr."	"Ronald"	"Morrell"	"1103"	"Executive Director"
75	"Mr."	"Robert"	"Drawbaugh"	"0404"	"Alcohol Program"
Chief"	"Chief"	"Ronald"	"Goff"	"0604"	
"X" 1	"Sheriff"	"John"	"Lawrence"	"0701"	
2	"Sheriff"	"Dennis"	"McClure"	"0902"	
"X" 3	"Sheriff"	"William"	"Graham"	"1305"	
4	"Sheriff"	"Gardner"	"Manosh"	"0801"	
5	"Sheriff"	"Donald"	"Edson"	"1206"	
6	"Chief"	"Joseph"	"Estey"	"1402"	
"X" 7	"Chief"	"Jeffrey"	"Billings"	"1403"	
8	"Chief"	"Manfred"	"Wessner"	"0203"	
"X" 9	"Chief"	"Brett"	"VanNoordt"	"0405"	
"X" 10	"Chief"	"Richard"	"Keith"	"0802"	
11	"Chief"	"Paul"	"Cucinelli"	"1205"	
12	"Chief"	"Eben"	"Merrill II"	"0301"	
13	"Chief"	"Douglas"	"Hoyt"	"1204"	
14	"Chief"	"J. Paul"	"Duquette"	"1002"	
15	"Chief"	"Philip"	"Mollitor"	"0903"	
"X" 16	"Chief"	"Anthony"	"Bossi"	"1104"	
17	"Chief"	"Leland"	"Graham"	"0408"	
18	"Chief"	"David"	"Demag"	"0601"	
19	"Chief"	"Kenneth"	"Kaplan"	"0803"	
"X" 20	"Chief"	"Joe"	"Anthony"	"0103"	"janthony@cji.net"
"X" 21	"Chief"	"William"	"Miller"	"0406"	
"X" 22	"Chief"	"James"	"Warden"	"0407"	
23	"Chief"	"Douglas"	"Johnston"	"1405"	
"X" 24	"Chief"	"W. Bruce"	"Pratt"	"0302"	
"X" 25	"Chief"	"Michael"	"McCarthy"	"0603"	
26	"Chief"	"Gary"	"Margolis"	"0409"	
27	"Chief"	"Trevor"	"Whipple"	"1201"	
28	"Chief"	"Frederick"	"Gardy"	"1301"	
29	"Chief"	"William"	"Jennings"	"1202"	
"X" 30	"Chief"	"Richard"	"Guthrie"	"1302"	
31	"Chief"	"Alana"	"Ennis"	"0401"	
32	"Chief"	"Robert"	"Edwards"	"1304"	
33	"Chief"	"Richard"	"Gauthier"	"0201"	
34	"Chief"	"Joseph"	"Arduca"	"1101"	
"X" 35	"Chief"	"Kevin"	"Gibbs"	"0101"	
"X" 36	"Chief"	"Charles"	"Kirker"	"0402"	
"X" 37	"Chief"	"Bob"	"Horton"	"0403"	
38	"Chief"	"Byron"	"DeMond"	"1406"	
39	"Chief"	"Stephen"	"McQueen"	"0411"	
40	"Lieutenant"	"Real"	"Robillard"	"1001"	
"X" 41	"Lieutenant"	"Robert"	"Casey"	"0102"	
42	"Lieutenant"	"William"	"O'Leary"	"1203"	
"X" 43	"Chief"	"Joseph"	"Szarejko"	"1307"	

CHIEFLETTER.txt

"X"	44	"Chief" "Jeffrey"	"Whitesell"	"0202"
"X"	45	"Chief" "Byron"	"Kelly" "1407"	
"X"	46	"Lieutenant"	"Dave" "Stanton"	"1105"
	47	"Lieutenant"	"James" "Baker" "0204"	
"X"	48	"Lieutenant"	"John" "Filipek"	"0602"
	49	"Lieutenant"	"George" "Hacking"	"0303"
"X"	50	"Lieutenant"	"Bruce" "Lang" "1401"	
	51	"Lieutenant"	"Michael" "Jennings"	"0901"
"X"	52	"Lieutenant"	"William" "Pettengill"	"1303"
		"wpetteng@dps.state.vt.us"		
	53	"Constable"	"Theodore" "Miller"	"0501"
	54	"Lieutenant"	"Dave" "Stanton" "1102"	
	55	"Lieutenant"	"Thomas" "L'esperance"	"1306"
		"tlespera@dps.state.vt.us"		
"X"	56	"Lieutenant"	"Chris" "Reinfurt"	"0410"

and have used dual technology in their previous model, the Alcotest 7110. Their experience in this area means that we will not be spending time helping the technology become perfected in a new model.

In March of 2009 I contacted Barbara O'Brien at the Office of Alcohol Testing in Massachusetts. Massachusetts has 475 Draeger 7110 units and is in the process of ordering the 9510 model. They have been extremely pleased with the service they have received from Draeger, indicating that they (Draeger) are "very responsive" and stand by their instrument. They do not currently have their 9510 models in house as they are still determining what their software will be, changing their regulations and writing new software protocols for their 7110 units. She indicated to me that they are the hold-up in receiving new instruments, not the manufacturer. Their experiences with the 7110s have shown them to be extremely low maintenance. Beyond replacing fuel cells in the instrument which is expected, they have had very few repairs on any of their units. She indicated the instruments are "never on the bench" and that the repairs they have had to do amount to new breath tubes which can be performed in the field.

Although testing of the 9510 continues, it is my opinion that the Alcotest 9510 should be purchased for the replacement of the remaining BAC DataMasters in Vermont. This opinion is based on my own testing of the 9510, the design of the instrument, the experience of Massachusetts with Draeger and the experiences of our program with the DMT. Although we expect the Alcotest 9510 to be priced higher than the DMT, I believe that this additional cost will quickly be recouped through the reduced man hours needed to get the instruments field ready and keep them operating. We have already had to repair DMTs in the field in the first months of deployment. We are also still waiting on the software that was requested several years ago. It is my opinion that ordering the Alcotest 9510 over the DataMaster DMT will ultimately result in a quicker deployment and cost saving measures over the upcoming years through reduced numbers of repairs and reduced man hours spent on getting and keeping the instruments field ready.

2008 Program Managers Meeting.txt

From: Neil Claasen [nclaasen@npas.com]

Sent: Thursday, January 10, 2008 3:42 PM

To: Beverly Adams; Annette Asamoto; Laura Bailey; Debbie Banks; Eldon Beachly; Jim Bleskacek; Jim Brady; Randy Brooks; Dewayne Carver; Perry Curtis; Drawbaugh, Bob; Shirley Ezelle; Rod Gullberg; Harnois, Steven; Jim Hawkins; Mike Hess; ajordan@sled.sc.gov; Ted Koperski; John Kucmanic; Lisa Lee; Corbett Lewis; Barry Logan; Brian Lutmer; Peter Method; Bob Monserrate; Todd Murray; Colleen O'Bryant; Randy Prokopanko; Becky Stinson; Jeanne Swartz; Mike Tate; Dean Ward; Bob Welsh; Fred Zwonechek; Richard Bosman; Alex Hemken; hank@psanatal.co.za; thorsten@psanatal.co.za; Jo McCreery; Gerard van Hoeven; Dale Visneskie; mcwassoc@aol.com; Laurie Wilson
Cc: Neha Chablani; Cliff Broeder; Danny Fusco; John Fusco; Scott Marhefka; Dave Radomski
Subject: 2008 Program Managers Meeting

Welcome to a new year to everyone! This means that our annual Program Managers Meeting is around the corner. This year it will take place in Phoenix, AZ. The meeting will be on Saturday, 17 May. The IACT convention starts on Sunday, 18 May.

While we normally try to hold the Program Managers Meeting in the same hotel as the IACT convention hotel that will not be the case this year. This year the meeting will take place at the Hampton Inn & Suites Phoenix/Tempe in the Arizona Hospitality Room. The hotel is a little more than 2 miles from the IACT conference hotel. We have also made arrangement for a room block at the Hampton and managed to get very reasonable rates for the duration of our stay in Phoenix. Room rates will be \$109.00 per night for a king room and \$139.00 for a suite (with kitchen). Clicking on the following link : Hampton Inn & Suites Phoenix/Tempe will take you directly to a page that will allow you to book your rooms and also has information on the meeting. For those that prefer to make your reservation by telephone, you can do so by dialing 480-675-9799. Be sure to ask for the NPAS rate. These rates are valid until April 24 or until the room block has sold out. The Hampton has an airport shuttle for those that would not be using rental cars. We will also be renting a minivan (or something similar) to help with transport to and from the IACT hotel.

This is also a call for presenters for the meeting. At this time, the format would be similar to previous years which means we need four presenters. If you are interested in presenting, please give me a call. Remember, this is your meeting and without your input it will not be the success it normally is.

Looking forward to seeing everyone in Phoenix!

syringe

1.6
1.56
1.58
1.5
1.59
1.43
1.61
1.62

ave. s.d. %c.v.
1.56 0.0649 4.2%

1.6

syringe

1.6
1.56
1.58
1.5
1.59
1.43
1.61
1.62
1.44
1.43
1.42

ave. s.d. %c.v.
1.53 0.0820 5.4%

1.5

tank air

1.66
1.85
1.71
1.75
1.78

ave. s.d. %c.v.
1.75 0.071764 4.1%

1.7

From: Caprice Fowler [CFowler@ascl-d-lab.org]

Sent: Monday, August 17, 2009 1:06 PM

To: undisclosed-recipients

Subject: ASCLD/LAB Assessor Training (Breath Alcohol Calibration) Offered - St. Louis, MO

ASCLD/LAB is pleased to announce an ASCLD/LAB-*International* Assessor Training Course (for Breath Alcohol Calibration) scheduled in St. Louis, MO, October 26-30, 2009. Please feel free to forward to other interested parties and organizations. I have attached the informational document and registration form for your convenience. All documents are also posted on our [website](#). Please take a moment to review the forms, as we hope they will answer most of your questions.

There is a \$475 fee for the assessor training. This registration fee includes a take home copy of ISO/IEC 17025. Upon serving as an assessor for an ASCLD/LAB-*International* assessment for the first time, the laboratory will be credited \$400 toward its next annual accreditation fee.

Anyone wishing to attend this class should complete the registration form and send it to me as soon as possible to reserve a seat. Once the registration form has been received, I will send you a confirmation email with the specific course location information. Please do not make travel arrangements until you have received confirmation of registration.

If you have any questions regarding our training program, please contact our Training Manager, Ms. Anja Einseln, at either anja@ascl-d-lab.org or telephone (571) 239-0363.

Thank you,

Caprice Fowler

Admin. Assistant, ASCLD/LAB
919-773-2600
919-773-2602 (fax)
www.ascl-d-lab.org

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_____ Information from ESET NOD32 Antivirus, version of
virus signature database 4343 (20090817) _____

The message was checked by ESET NOD32 Antivirus.

<http://www.eset.com>

Breath Alcohol Testing Instrument Performance Reviews

the task of reviewing the performance of four new and different breath alcohol testing instruments; the NPAS DataMaster DMT™, the CMI Intoxilyzer® 8000, the Drager Alcotest® 7110 MKIII-C and the Intoximeter EC/IR-II was undertaken in our laboratory. The instruments were analyzed for precision, accuracy, linearity, interference detection capabilities and mouth alcohol detection capabilities, ease of use, durability and overall performance.

The instruments were analyzed as provided by the manufacturer. No calibrations, certifications or other adjustments were made. The simulators used were Guth 2100 and Guth 34CNP.

Method:

- **Precision:**
 - Aqueous ethanol solutions of 0.08g/210L and 0.16g/210L were analyzed with n=10
 - The standard deviations were calculated
- **Accuracy**
 - Aqueous ethanol solutions with nominal concentrations of 0.02g/210L, 0.04g/210L, 0.08g/210L, 0.16g/210L and 0.40g/210L were analyzed as calibration checks.
 - All solutions were verified by Headspace gas chromatography with flame ionization detection. Actual concentrations are listed with results data.
- **Linearity**
 - The five aqueous ethanol solutions were prepared over a concentration range that will provide vapor concentrations from 0.02 through 0.40g/210L.
 - The ensuing results from the breath alcohol testing instruments were plotted against the known concentrations generated from the Headspace GC/FID.
 - The results formed a straight line with Correlation Coefficients (R^2 values) of at least 0.99.
- **Interference**
 - Compounds were prepared and tested in the instruments to evaluate the interference detection systems (N=5)
 - 0.02% Acetone in 0.08% EtOH
 - 0.05% Acetone in 0.08% EtOH
 - 0.10% Acetone in 0.08% EtOH
 - 0.04% Methanol
 - 0.04% Isopropanol
 - 0.04% Methanol in 0.08% EtOH
 - 0.04% Isopropanol in 0.08% EtOH
 - The mouth alcohol detection system was tested. Each test was taken at 3-5 minute intervals subsequent to the use of mouthwash until such time as no mouth alcohol was detectable.

Results:

• **Table 1: Standard Deviations (Precision)**

	DMT		INTox 8000		DRA-IR		INTOX EC/IR-II	
	N	Std Dev	N	Std Dev	N	Std Dev	N	Std Dev
0.02	10	0.0003	10	0.0007	10	0.0024	10	0.0003
0.04	10	0.0004	10	0.0005	10	0.001	10	0.0003
0.08	10	0.0004	10	0.0008	10	0.0013	10	0.0025
			10	0.0058	10	0.0043		
			10	0.0022	10	0.0005		
			10	0.0037	10	0.0045		
			10	0.0036	10	0.0026		
				0.0032		0.0026		
								Mean Std Dev
0.16	10	0.0008	10	0.0064	10	0.0017	10	0.0005
			10	0.0067	10	0.0011		
			10	0.0056	10	0.0229		
			10	0.0096	10	0.0011		
			10	0.0067	10	0.0051		
					10	0.004		
				0.007		0.006		
								Mean Std Dev
0.4	10	0.0008	10	0.0156	10	0.009	10	0.0023
				(.366-.317)				
		0.0005		0.0054		0.0042		0.0012
								Grand Mean Std Dev

• **Table 2: Accuracy for Intoxilyzer Instrument**

Date	Operator	Instrument	Sim Lot	Sim [X]	N=	Avg	Std Dev
12/15/2005	SH	INT	06-01-020	0.0203	10	0.0175	0.0007
12/16/2005	SH	INT	06-06-040	0.0376	10	0.031	0.0005
12/14/2005	SH	INT	06-05-080	0.0815	10	0.0728	0.0008
12/15/2005	SH	INT	06-05-080	0.0815	10	0.0841	0.0058
12/15/2005	ALB	INT	06-05-080	0.0815	10	0.0765	0.0022
12/16/2005	SH	INT	06-05-080	0.0815	10	0.0756	0.0037
12/19/2005	ALB	INT	06-05-080	0.0815	10	0.0777	0.0036
12/15/2005	SH	INT	06-07-160	0.1582	10	0.1523	0.0064
12/15/2005	ALB	INT	06-07-160	0.1582	10	0.1542	0.0067
12/19/2005	RD	INT	06-07-160	0.1582	10	0.1609	0.0056
12/20/2005	RD	INT	06-07-160	0.1582	10	0.1491	0.0096
12/21/2005	TM	INT	06-07-160	0.1582	10	0.1526	0.0067

• **Table 3: Accuracy for Drager Instrument**

Date	Operator	Instrument	Sim Lot	Sim [X]	N=	Avg	Std Dev
12/15/2005	SH	DRA-IR	06-01-020	0.0203	10	0.0207	0.0024
		DRA-EC				0.02	0
		IR & EC				0.0204	0.002
12/15/2005	ALB	DRA-IR	06-06-040	0.0376	10	0.0356	0.001
		DRA-EC				0.0364	0.0007
		IR&EC				0.036	0.0009
12/14/2005	SH	DRA-IR	06-05-080	0.0815	10	0.0784	0.0013
		DRA-EC				0.0787	0.0016
		IR&EC				0.0786	0.0014
12/16/2005	SH	DRA-IR	06-05-080	0.0815	10	0.0831	0.0043
		DRA-EC				0.0835	0.0041
		IR&EC				0.0833	0.0041
12/16/2005	ALB	DRA-IR	06-05-080	0.0815	10	0.0794	0.0005
		DRA-EC				0.0802	0.0006
		IR&EC				0.0798	0.0007
12/16/2005	RD	DRA-IR	06-05-080	0.0815	10	0.0822	0.0045
		DRA-EC				0.0829	0.0044
		IR&EC				0.0826	0.0043
12/20/2005	ALB	DRA-IR	06-05-080	0.0815	10	0.0825	0.0026
		DRA-EC				0.0827	0.0028
		IR & EC				0.0826	0.0026
12/16/2005	SH	DRA-IR	06-07-160	0.1582	10	0.1561	0.0017
		DRA-EC				0.1555	0.001
		IR&EC				0.1558	0.0014
12/19/2005	SH	DRA-IR	06-07-160	0.1582	10	0.1528	0.0011
		DRA-EC				0.1518	0.0012
		IR&EC				0.1523	0.0013
12/19/2005	ALB	DRA-IR	06-07-160	0.1582	10	0.1802*	0.0229
		DRA-EC				0.1831*	0.0238
		IR & EC				0.1817*	0.0228
12/19/2005	ALB	DRA-IR	06-07-160	0.1582	10	0.1584	0.0011
		DRA-EC				0.1611	0.0023
		IR & EC				0.1598	0.0022
12/20/2005	RD	DRA-IR	06-07-160	0.1582	10	0.1534	0.004
		DRA-EC				0.1527	0.003
		IR & EC				0.1531	0.0032
12/21/2005	TM	DRA-IR	06-07-160	0.1582	10	0.1491	0.0051
		DRA-EC				0.1483	0.0051
		IR & EC				0.1487	0.005
12/19/2005	ALB	DRA-IR	06-03-400	0.3807	10	0.3792	0.009
		DRA-EC				0.3831	0.0079
		IR & EC				0.3812	0.0085

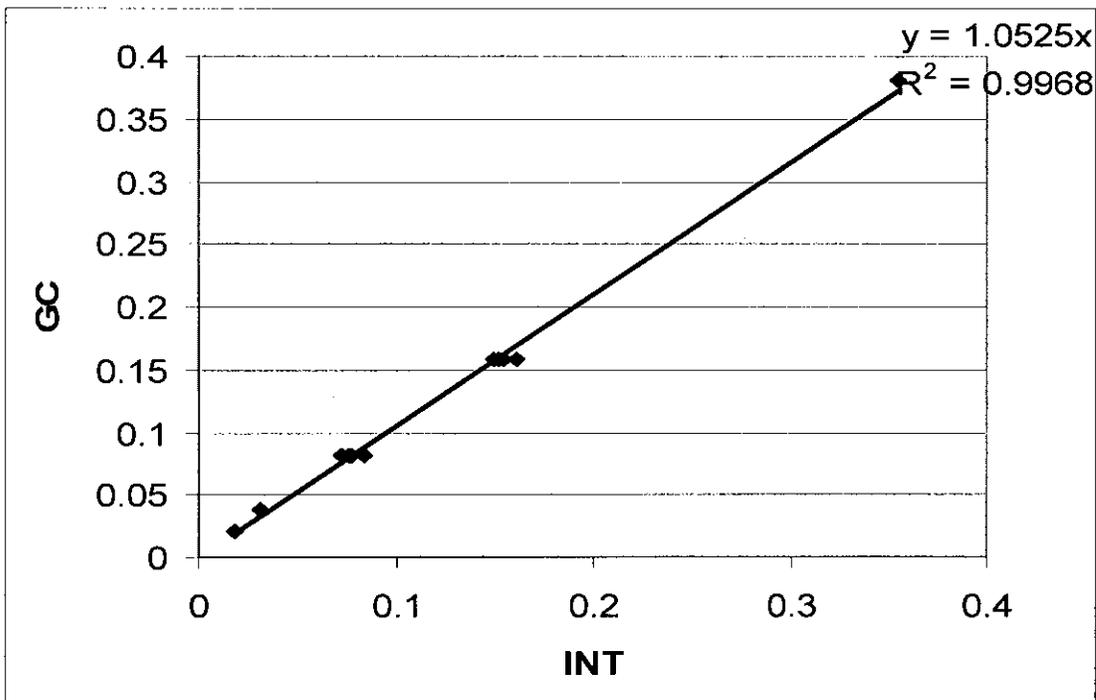
• **Table 4: Accuracy for DataMaster Instrument**

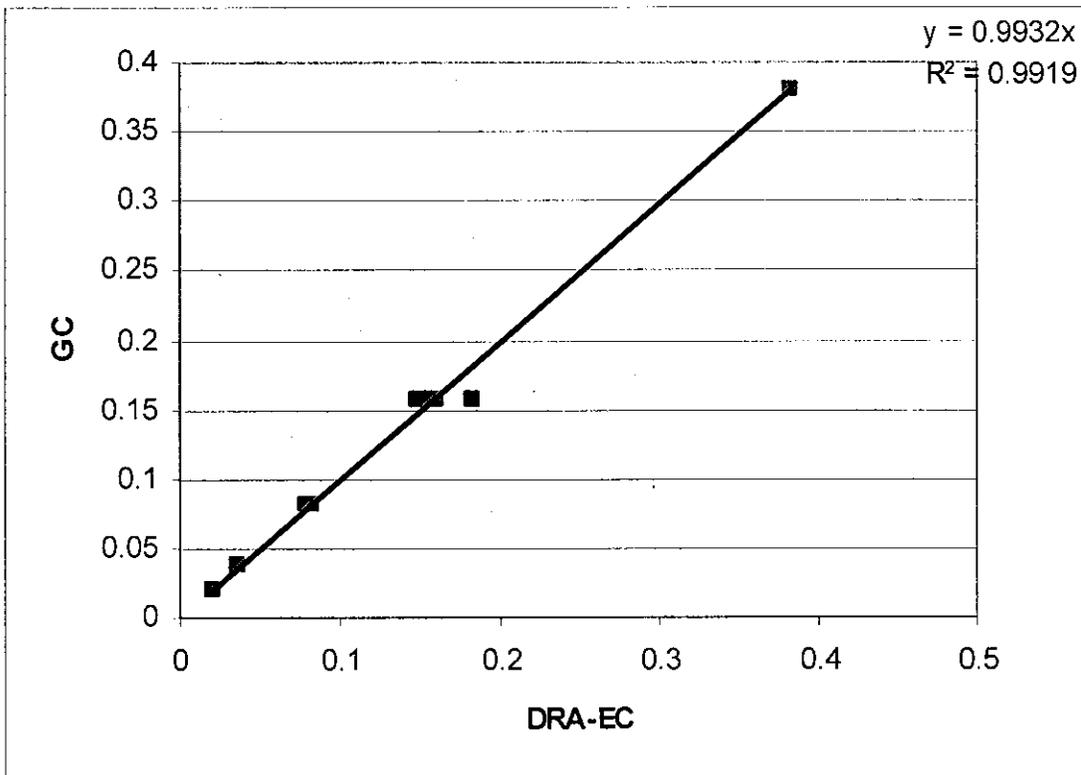
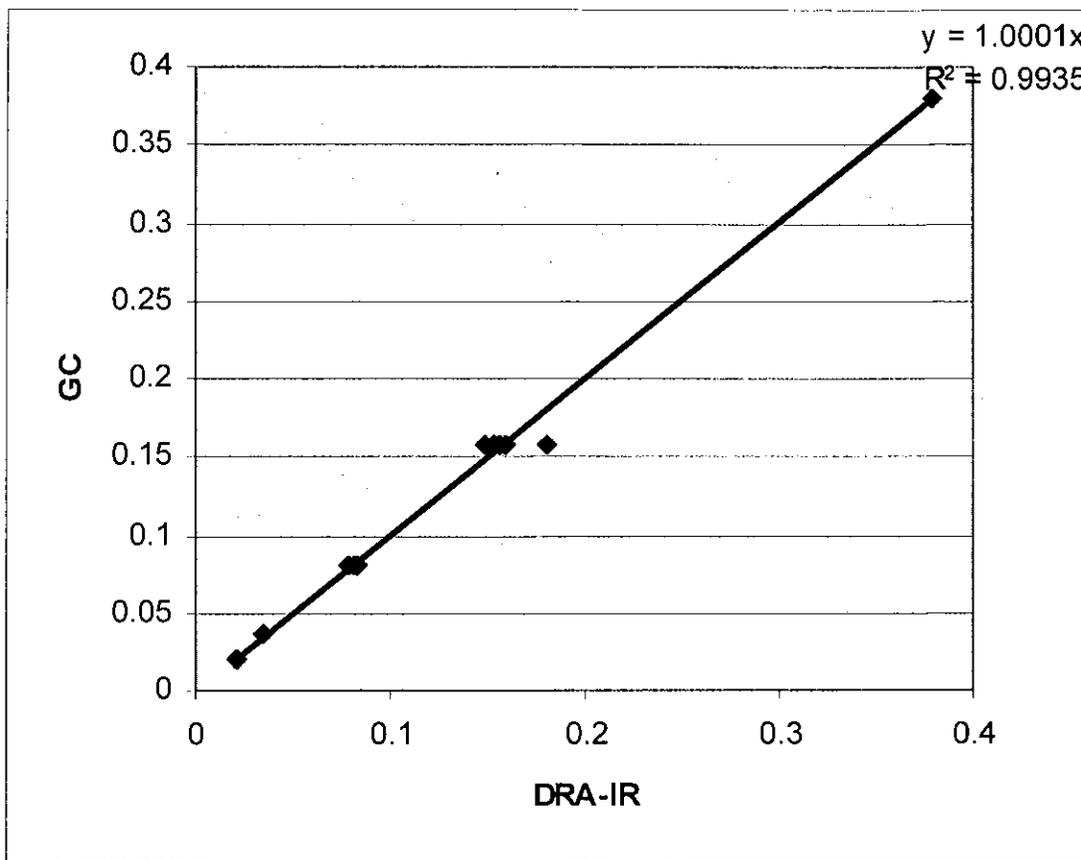
Date	Operator	Instrument	Sim Lot	Sim [X]	N=	Avg	Std Dev
3/8/2006	SH	DMT	06-01-020	0.0203	10	0.0214	0.0003
3/9/2006	ALB	DMT	06-06-040	0.0376	10	0.0375	0.0004
3/10/2006	DMR	DMT	06-05-080	0.0815	10	0.0791	0.0004
3/9/2006	DMR	DMT	06-07-160	0.1582	10	0.1602	0.0008
3/10/2006	DMR	DMT	06-03-400	0.3807	10	0.389	0.0008

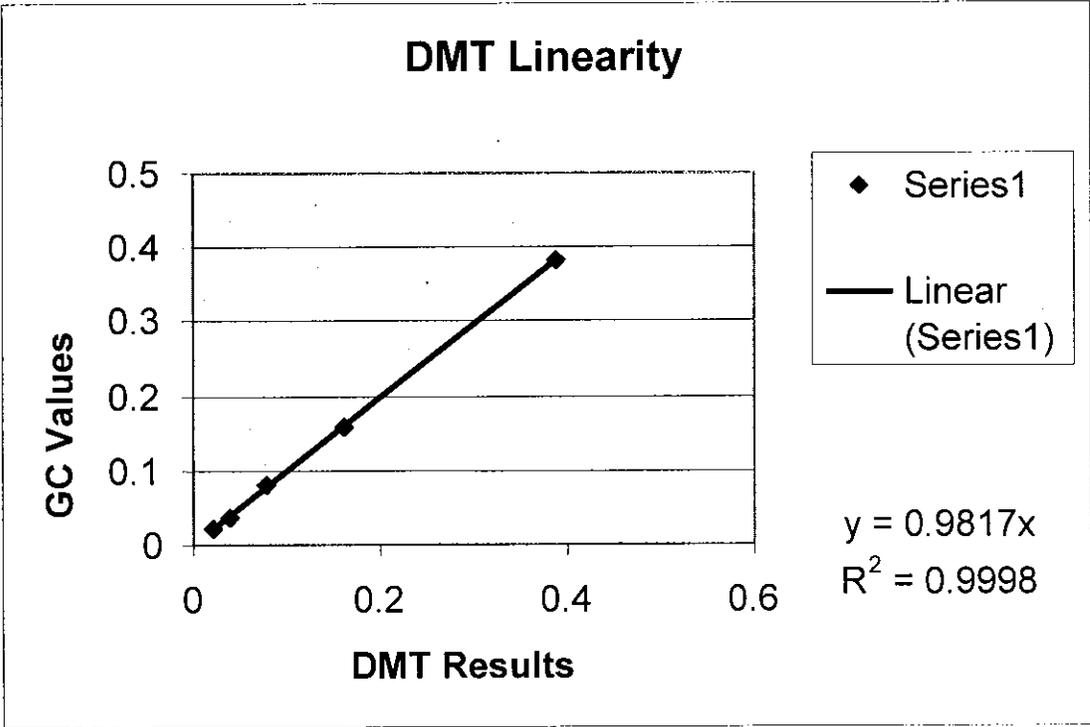
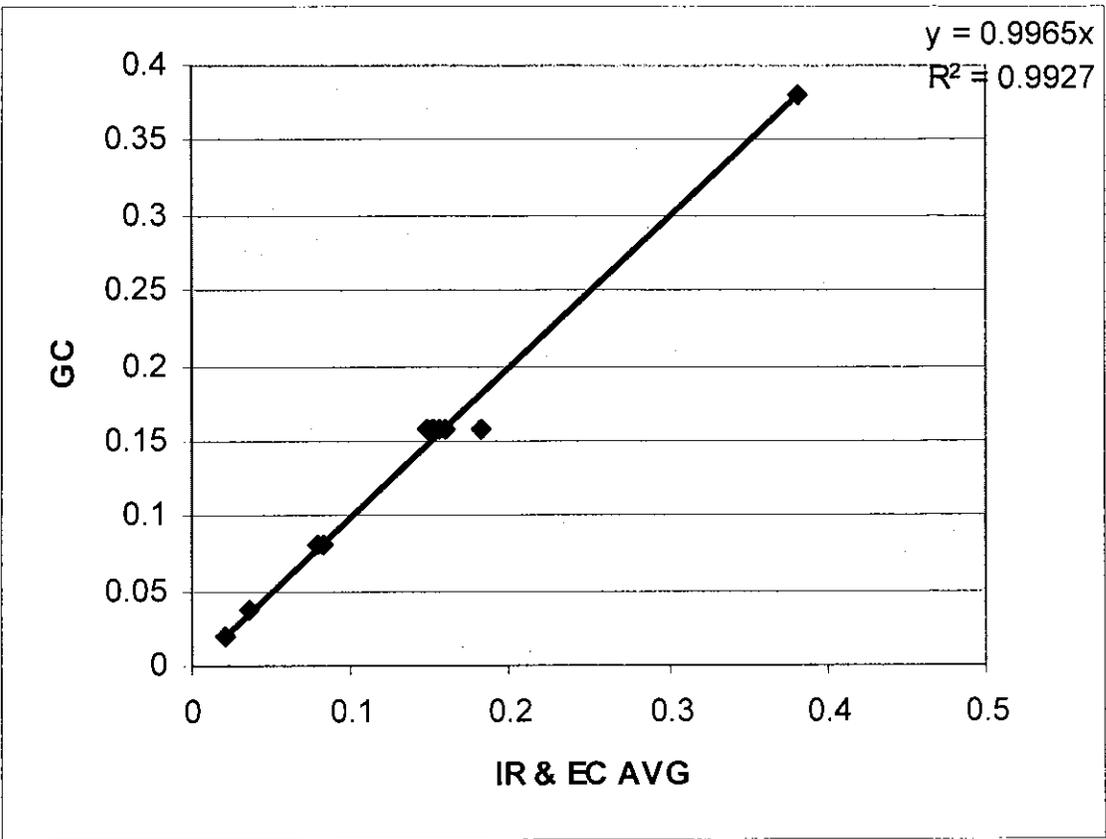
• **Table 5: Accuracy for Intoximeter Instrument**

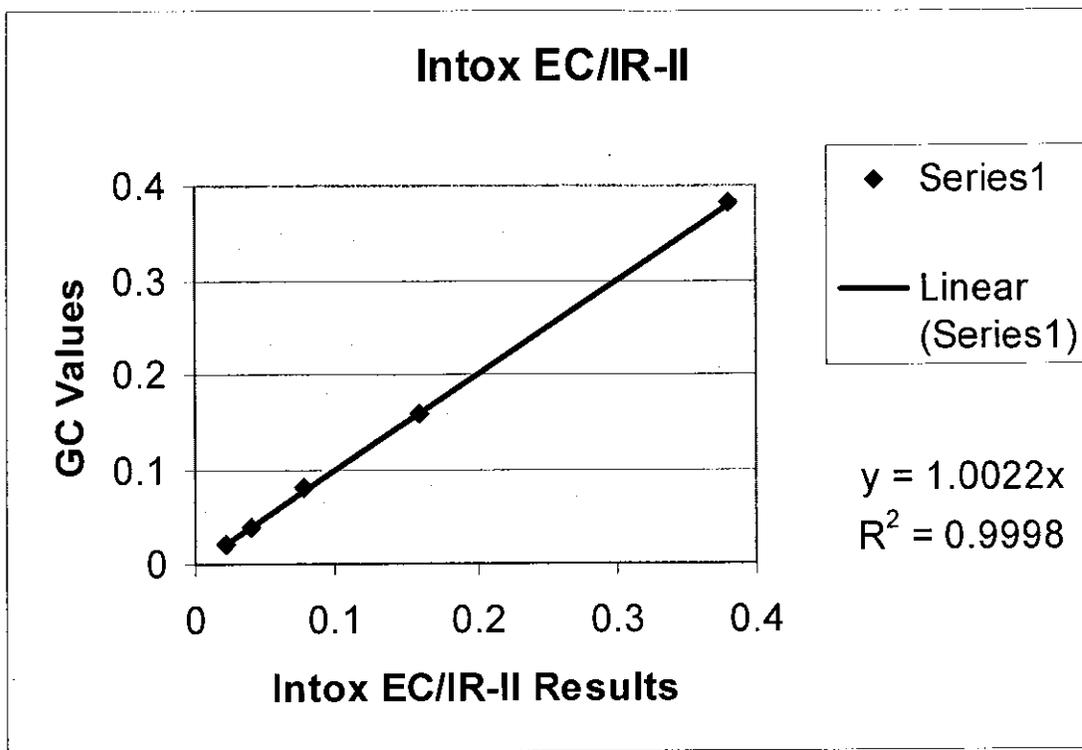
Date	Operator	Instrument	Sim Lot	Sim [X]	N=	Avg	Std Dev
3/8/2006	SH	INTox II	06-01-020	0.0203	10	0.0219	0.0003
3/9/2006	ALB	INTox II	06-06-040	0.0376	10	0.0389	0.0004
3/9/2006	DMR	INTox II	06-05-080	0.0815	10	0.078	0.0025
3/10/2006	DMR	INTox II	06-07-160	0.1582	10	0.16	0.0005
3/13/2006	ALB	INTox II	06-03-400	0.3807	10	0.379	0.0023

• **Linearity**









• **Table 5: Interference**

Positive Interference Message Given
X/N

N=5

Interferent	Date	DMT	Intox EC/IR	Date	INTOX 8000	DRA
.02% Acetone in 0.1% EtOH	2/28/06	6 for 6	0 for 5	12/21/05	1 for 5	0 for 5
Error Message reported		X.XXX	None (0.90- 0.97)		Invalid Sample	None (.071-.074)
.05% Acetone in 0.1% EtOH	3/1/06	6 for 6	0 for 5	12/22/05	5 for 5	0 for 5
Error Message reported		X.XXX	Mouth Alc, Sample over range, 0.95- 0.96		Invalid Spl(2); Interferent Detect(3)	None (.072-.077)
0.1% Acetone in 0.1% EtOH	3/1/06	6 for 6	0 fo 5	12/22/05	5 for 5	0 for 5
Error Message reported		X.XXX	EtOH Baseline err, Spl over rng, Mouth Alc, 0.98		Interferent Detect (4); Improper Spl (1)	None (.07-.079)
.04% Methanol	2/27/06	6 for 6	0 for 5	12/22/05	1 for 5	5 for 5
Error Message reported		X.XXX	None (0.36- 0.40)		Improper Spl (1); None(4) (.022g/210L)	Interference

.04% Isopropanol	3/3/06	6 for 6	0 for 5	12/23/05	5 for 5	5 for 5
Error Message reported		X.XXX	None (0.018- 0.020)		Interferent Detect	Interference
.04% MeOH in .08% EtOH	3/3/06	3 for 9	0 for 5	12/23/05	2 for 5	5 for 5
Error Message reported		X.XXX, None (0.096-0.097)	None (0.090-0.097)		Improper Spl (2), None (3) (.097-.099)	Interference
.04% Iso in .08% EtOH	3/8/06	6 for 6	0 for 5	12/23/05	5 for 5	5 for 5
Error Message reported		X.XXX	None (0.092 - 0.093)		Interferent Detect	Interference

• **Table 6: Mouth Alcohol Detection**

DMT

Elapsed Time (min)	Detected Y/N	BrAC
0:00	Mouthwash 1st used	
1:00	Y	INVALID
6:00	Y	INVALID
11:00	N	0.000

INTox 8000

Elapsed Time (min)	Detected Y/N	BrAC
0:00	Mouthwash 1st used	
5:00	Y	XXX*
9:00	Y	XXX*
12:00	Y	XXX*
16:00	N	0.000

*Invalid Sample

DRA

Elapsed Time (min)	Detected Y/N	BrAC
0:00	Mouthwash 1st used	
1:00	y	----
5:00	Y	----
10:00	N	0.057g/210L
		0.030
14:00	N	g/210L
16:00	N	0.000

INTOX EC/IR-II

Elapsed Time (min)	Detected Y/N	BrAC
0:00	Mouthwash 1st used	
5:00	N	0.029
9:00	N	0.008
15:00	N	0

Discussion:

- **NPAS DataMaster DMT™**

- **Features**

The DataMaster DMT™ uses the judicially accepted method of infrared spectroscopy to determine breath alcohol levels. The detector is a thermo-electrically-cooled PbSe detector regulated to operate at 0°C. Regulating the operating temperature of the detector allows for greater sensitivity while maintaining a stable detector output. This enhances the precision, repeatability and low-level performance of the DMT. A stepper motor precisely controls all the optical filters (including the quartz internal standard). The use of narrow bandpass (10 nanometer) optical filters at 3.44, 3.37 and 3.50 micron allows the passage of a limited frequency range of infrared energy. This makes the DMT highly specific to ethanol to the exclusion of other alcohols and interfering compounds. The long life gray body infrared source generated very little visible light. This maximizes power usage and reduces instrument temperatures giving the DMT a high level of stability.

A powerful 32 bit, 206 Mhz processor administers signal processing. This facilitates the use of a short sample path (57cm) and a small sample chamber volume (23cc). This allows for an accurate measurement of the deep lung sample across a wide range of blowing patterns and subject vital lung capacities. The processor permits the use of an advanced breath sampling system. This new system accurately measures the breath flow rate and volume, including negative flow rates, eliminating any questions about sample acceptance.

The DMT software is built on the Microsoft .NET framework. This platform provides for a familiar graphical user interface making the DMT operator friendly.

- **Precision**

The DMT had produced an average standard deviation of 0.0005 with a range of 0.0003-0.0008.

- **Accuracy**

The DataMaster performed to +/- 5% of the true value at each concentration with one exception. At 0.0203g/210L at N=10, the DMT had an average result of 0.0214g/210L and standard deviation of 0.0003. This gives a of 105.4% recovery.

- **Linearity**

The results were plotted against the GC value for each concentration and a line was generated. The formula for the line is $y=0.9817x$. $R^2=0.9998$.

- **Interference**

The DMT reports an error message of X.XXX instead of an ethanol concentration when an interfering agent is detected. At concentrations of .02%, .05% and 0.1% acetone in 0.10% ethanol, the DMT reported an interference message 100% of the time. At a concentration of 0.04% methanol in 0.08% ethanol, the DMT only reported an interference message 3 out of 9 tries. On 6 of 9 tries it reported the concentration at an average of 0.097g/210L EtOH.

Mouthwash was used by a subject who subsequently provided breath samples until such time as no mouth alcohol was detected. At an elapsed time since use of mouthwash of one minute, the DMT reported an invalid sample. Invalid was also reported at an elapsed time of six minutes. At an elapsed time of eleven minutes, no mouth alcohol was detected and the BrAC was reported at 0.000g/210L.

- **Ease of use, durability and overall performance**

The DMT is equipped with a full graphics touch screen which is extremely operator friendly. The windows-based operating system provides a very familiar platform for data entry. The processor permits the use of an advanced breath sampling system. The new system accurately measures the breath flow rate and volume, including negative flow rates, eliminating any questions about sample acceptance. The screen also displays a subject's breath flow curve in real time along with the alcohol absorption curve. This greatly enhances the operators ability to determine the subject's level of cooperation during a test. This information can also be part of the test ticket. The utilization of an external printer eliminates the need for special tickets.

The DataMaster Operation Guide is very clear, understandable and helpful. It had detailed instructions and explanations and photos to aid in instrument set up and software navigation. When

additional support was necessary, it was easy to contact National Patent's customer service department, who were knowledgeable and extremely helpful.

The DMT's overall performance would be classified "excellent".

- **CMI Intoxilyzer® 8000**

- **Features**

The Intoxilyzer is an infrared-based device designed for both mobile and stationary evidential breath alcohol testing. It utilizes an internal printer unit of either the impact or thermal type onto a paper roll. The Intoxilyzer has been designed in such a way that it will allow for prolonged use without the requirement for recalibration. The reason for this is there are no moving parts within the device. The infrared light is pulsed in order that the dual pyroelectric detectors may accurately quantify as well as qualify the alcohol concentration present within the analytical cell. The Intoxilyzer was also designed to operate using infrared light at two wavelengths, 3 and 9 microns. The absorption ratio that is generated when alcohol alone is supplied in the path of the infrared light creates what may be termed as a fingerprint and that allows the device to discriminate between those samples, which are contaminated by breath interferents, and those that are not.

- **Precision**

At a concentration of .08g/210L EtOH, the Intoxilyzer had a standard deviation range of 0.0008-0.0058 at N=10. At a concentration of 0.16g/210L EtOH, the Intoxilyzer had a standard deviation range of 0.0056-0.0096 at N=10.

- **Accuracy**

The Intoxilyzer did not perform to +/- 5% of the true value during almost every test. It has been approximately two years since the instrument was last calibrated. Although; the inter-day and intra-day results were also inconsistent.

- **Linearity**

The Intoxilyzer results were plotted against the GC value for each concentration and a line was generated. The formula for the line is $y=1.0525x$. $R^2=0.9968$.

- **Interference**

The Intoxilyzer gave three different error messages during the testing of interferents; "Invalid Sample", "Improper Sample" and "Interferent Detect". The operators manual did not define these error messages and calls to the CMT customer service center were not returned, therefore we cannot conclude if the error messages were due to interference or another problem. Assuming that "Invalid" and "Improper" samples were due to interference, the Intoxilyzer detected acetone 20% of the time at .02%, and 100% of the time at .05% and 0.1% concentrations. Methanol was detected 20% of the time at .04% MeOH in water and 40% of the time at .04% MeOH in .08% EtOH. Isopropanol was detected 100% of the time at both concentrations.

Mouthwash was used by a subject who subsequently provided breath samples until such time as no mouth alcohol was detected. Mouthwash was used at 15:08. Mouth alcohol was detected at 15:13, 15:17, and 15:20. No mouth alcohol was detected at 15:24 and the BrAC was 0.000.

- **Ease of use, durability and overall performance**

The CMI Intoxilyzer® 8000 is a compact unit which takes up far less workspace than other instruments. It is also designed for both mobile and stationary evidential breath alcohol testing. When the calibration of the device is verified during periodic checks, security tabs can be attached to the device in such a way that prevents any unauthorized opening of the casing. Provided they remain unbroken, the tabs confirm that the device has remained in a fully operational condition between the periodic verification checks. The Intoxilyzer has also been designed in such a way that it will allow for prolonged use without the requirement for recalibration. This is because there are no moving parts within the device.

The Intoxilyzer instrument provides quick calibrations and results. It has a fairly simple data input system when conducting a suspect test. The supervisor menu for maintenance, settings

adjustments and routine performance checks is cryptic at best. It is confusing to navigate and the manual provides little support or explanations. The customer service department was impossible to reach despite repeated attempts and messages.

The instrument does not utilize heated simulator solution hoses. Heated simulator hoses would prevent condensation which causes external calibration failures. The unit displayed frequent RAM failure messages causing the machine to become inoperable for periods of time. We were unable to diagnose, nor fix the RAM failure because the manual fails to address failure messages. We were also unable to determine the difference between sample failure messages "Invalid" and "Improper" for the same reason. We had hoped to contact customer support for assistance, but have so far been unable to reach anyone.

The Intoxilyzer's overall performance would be classified "unsatisfactory".

- **Draeger Alcotest® 7110 MKIII-C**

- **Features**

The Draeger utilizes two independent alcohol measuring technologies. The first is infrared which detects alcohol in the 9.5um region of the IR spectrum. It utilizes an absorption chamber (cuvette) with 70 mL chamber volume, gold-coated parabolic mirrors, an electronically modulated infrared transmitter, and a pyroinfrared detector with an integrated IR filter. The second method is an electrochemical sensor. This measures small samples from inside the cuvette. Once ethanol reaches the sensor, a chemical reaction is triggered. The resulting current is used to determine the amount of alcohol in the sample. By combining two distinct analytical systems to analyze a subject's breath, the DRA is able to provide two precise, accurate, and independent test results. The dual system also allows for a greater degree of sensitivity to any possible existence of interfering substances. Because the fuel cell is alcohol specific, and the IR sensor operates at 9.5um in the IR spectrum, the possibility of an interfering substance influencing a subject's ethanol reading is "virtually" impossible.

- **Precision**

At a concentration of 0.08g/210L EtOH, the DRA had a standard deviation range of 0.0005-0.0045 at N=10. At a concentration of 0.16g/210L EtOH, the DRA had a standard deviation range of 0.0011-0.0229 at N=10.

- **Accuracy**

The DRA performed to +/- 5% of the true value at each concentration with three exceptions. At concentration 0.0376g/210L the result was 0.0356g/210L with a standard deviation of 0.001 and a recovery of 94.7%. At concentration .1582g/210L one resulting average was .1802g/210L with a standard deviation of .0229 and a recovery of 113.9%. Also at this concentration there was an average of .1491g/210L with a standard deviation of .0051 and a recovery of 94.2%.

- **Linearity**

The DRA results were plotted against the GC value for each concentration and a line was generated. The formula for the line for the infrared (IR) result is $y=1.0001x$ $R^2=0.9935$. The formula for the line for the electrochemical (EC) result is $y=0.9932x$ $R^2=.09919$. The formula for the line for the average of both results is $y=0.9965x$ $R^2=0.9927$.

- **Interference**

The DRA's infrared sensor operates in the 9.5um range of the infrared spectrum. Because of this range, the DRA is free from the influence of acetone, toluene and acetaldehyde as they relate to a human submitting a breath sample. The DRA also employs an alcohol specific electrochemical (fuel cell) sensor which is not influenced by acetone, toluene or acetaldehyde. When tested for acetone in ethanol, the DRA reported only ethanol in the appropriate concentration which was neither influenced, nor interfered by the acetone. The DRA reported error messages for both the presence of methanol and isopropanol 100% of the time.

The DRA's mouth alcohol detection capabilities are not satisfactory. At one and five minutes after mouthwash use, the DRA detected mouth alcohol and reported an interference message. At ten minutes after mouthwash use, the DRA did not report mouth alcohol, but reported at BrAC of 0.057g/210L. At fifteen minutes after use it reported a BrAC of 0.030g/210L. At twenty minutes the BrAC was 0.000g/210L and no mouth alcohol was detected.

- **Ease of use, durability and overall performance**

The Drager Alcotest® 7110 MKIII-C is a dual detection, compact, portable breath alcohol analyzer capable of providing two precise, accurate, and independent test results. The DRA is powered by either AC or DC power which is convenient for portable use. The DRA is capable of using either an onboard or external printer. The onboard printer paper was difficult to replace. The externally generated evidence reports are neat and understandable. The onboard generated supervisor reports do not include averages or standard deviations. We were unable to find a way to include this in the generated report. Ticket reprint are possible only when the given test number is known. This may cause difficulties should tickets become lost.

The instrument employs a mandatory fifteen minute wait period after data is entered and before the breath is given. It is not possible to terminate the wait period once started. This means that should there be a need to restart the test period in the middle of the observation, it is not possible. We were also unable to override the wait period for testing purposes which was quite inconvenient. When problems such as this one arose, customer service at Drager was difficult to reach. We had to wait three business days for a response to our message.

The instruction manual is thorough, although difficult to understand. The layout of functions and explanation is confusing. The menu of options on the instrument is also difficult to navigate, and not intuitive. When attempting to use the manual to navigate the menu, it is difficult at best.

The overall performance of the instrument would be classified as "satisfactory".

- **Intoximeter EC/IR-II**

- **Features**

The Intoximeter EC/IR-II utilizes both an electrochemical sensor and an infrared detector. The infrared system is capable of simultaneously analyzing carbon dioxide concentrations and alcohol concentrations in the breath. This capability allows the instrument to determine a deep lung breath sample on both alcohol rich and alcohol free samples. It employs an easy to read 256 x 32 pixel graphic vacuum fluorescent display.

- **Precision**

The Intoximeter had an overall average standard deviation of 0.0012. At a concentration of 0.08g/210L EtOH, the Intoximeter had a standard deviation of 0.0025; n=10. At 0.4g/210L EtOH the standard deviation was 0.0023; n=10. All other concentrations had standard deviations < 0.0005.

- **Accuracy**

The Intoximeter performed to +/- 5% the true value with one exception. At 0.0203g/210L the Intoximeter reported the concentration as 0.0219g/210L with a standard deviation of 0.0003 and a 107.89% recovery.

- **Linearity**

The Intoximeter results were plotted against the GC value for each concentration and a line was generated. The formula for the line is $y=1.0022x$ $R^2=0.9998$.

- **Interference**

The Intoximeter failed to detect any of the introduced interferents. Customer support was contacted and the software was updated three times to correct the units ability to detect and report interfering compounds. The unit continued to fail to detect interferents.

- **Ease of use, durability and overall performance**

The Intoximeter EC/IR-II is a compact, easy to operate breath alcohol testing instrument. It utilizes dual technology, however only the electrochemical fuel cell is used to calculate the results of the suspect sample. The infrared result is used to rule out mouth alcohol and compound interference.

The instrument employs an onboard printer, however it is capable of printing to an external unit. The display was easy to read. For a basic test, the instrument was very straight forward and easy to use. To do more complicated or higher level functions on the instrument, the software was not intuitive and very difficult to navigate. The operators manual was minimally helpful. None of the reported error messages were explained in the operators manual.

The customer service at Intoximeter was sub-standard. Reported problems were not rectified. Additional equipment and support (including heated simulator hoses, and interferent detecting software) were promised by the company, however was never received.

The overall performance of the instrument would be classified "unsatisfactory".

State	Samples Required	Minutes Apart	Sample Agreement	Instrument(s) Used	Notes
Alabama	2	2	0.020	Draeger Alcotest 7110 MK III	
Alaska	1			DataMaster	
Arizona	2	5-10	0.020	Intoxilyzer 8000	
Arkansas	2	2	0.020	DataMaster & Intox EC/IR II	
California	2		0.02	Draeger Alcotest 7110 MK III-C; Intox PAS ASIV XL	Minutes apart varies by jurisdiction.
Colorado	2	2	0.020	Intoxilyzer 5000EN	Requires call check correlation. 2 callb checks during testing seq. Analysis must be within 10% and within 10% of target. Require two separate tests with a 30 minute wait between test cycles
Connecticut	1			Intoxilyzer 5000EN	
Delaware	1			Intoxilyzer 5000	
Florida	2	3	0.020	Intoxilyzer 8000	If agreement outside 0.020, require a third sample
Georgia	2	2	0.02	Intoxilyzer 5000	
Hawaii	1			Intoxilyzer 5000 & 8000	
Idaho	2	2	0.020	Intoxilyzer 5000	No specified separation time of sampling
Illinois	1			Intox EC/IR & EC/IR II & Intoxilyzer 8000	Moving to new instrumentation and two samples
Indiana	1			DataMaster	Moving to DataMaster DMT
Iowa	1			DataMaster cdm	
Kansas	1			Intoxilyzer 8000	
Kentucky	1			Intoxilyzer 5000	Trying to get new instrumentation approved
Louisiana	1			Intoxilyzer 5000	
Maine	2	2	0.020	Intoxilyzer 5000EN	
Maryland	2	2	0.020	Intox EC/IR	Require third test if outside agreement
Massachusetts	2	3-4	0.02	Draeger Alcotest 7110 MK III	Moving to Draeger Alcotest 9510
			.00-.14: .01 .15-.24: .02 .25-.34: .03 .35-above: .04		If outside set agreement, require a 3rd test. If 2 of 3 don't fall within set agreement, results are invalid, officer seeks warrant for blood sample. Moving to DataMaster DMT.
Michigan	2	2	0.02	DataMaster	
Minnesota	2	3	0.02	Intoxilyzer 5000EN	
Mississippi	2	2	0.02	Intoxilyzer 8000	
Missouri	1			DataMaster & Intoxilyzer 5000-66	
Montana	2	2	within 10% of mean	Intoxilyzer 8000	Require third test if outside agreement
Nebraska	1			Intoxilyzer 5000EN	
Nevada	2	2	0.02	Intoxilyzer 5000EN & 5000-66	Require third test if outside agreement
New Hampshire	2	2	0.020	Intoxilyzer 5000EN	Require third test if outside agreement
			Greater of: abs +/-0.005 of the mean of the 4 analyzes (2IR & 2FC) OR relative +/- 5% of the mean of all 4		
New Jersey	2	2	0.02	Draeger Alcotest 7110 MK III-C	
New Mexico	2	2	0.02	Intoxilyzer 8000	
				DataMaster & DMT; Draeger Alcotest 7110 & 9510; Intoxilyzer 5000	
New York	1			Intox EC/IR II	
North Carolina	2	2	0.02	Intoxilyzer 5000EN	Moving to Intoxilyzer 8000
North Dakota	2	5	0.020	Intoxilyzer 5000EN	Instruments approved prior to 1/09 require single test only- this includes everything but the Intoxilyzer 8000
				DataMaster & cdm; Intoxilyzer 5000- 66, -68, -68EN & 8000	Intoxilyzer 5000 is being phased out
Ohio	2	2	0.020	Intoxilyzer 5000 & 8000	
Oklahoma	2	2	0.03	Intoxilyzer 8000	
Oregon	2	2	within 10% of mean	DataMaster & Intoxilyzer 5000	Require third test if outside agreement
Pennsylvania	2	not specified	0.020	Intoxilyzer 5000	
Rhode Island	2	not specified	0.020	DataMaster DMT	
South Carolina	1			Intox EC/IR II	
South Dakota	1			DataMaster DMT	
Tennessee	1			Intox EC/IR II	
Texas	2	2	0.02	Intoxilyzer 5000EN & 5000-68	
Utah	1			Intoxilyzer 5000 & 8000	
Vermont	1			DataMaster & DMT	Second BT offered to subject- performed 3-7 minutes after first.
Virginia	2	2	0.02	Intox EC/IR II	Require third test if outside agreement
Washington	2	1-2	within 10% of mean	DataMaster & cdm	
West Virginia	1			Intox EC/IR II	
Wisconsin	2	3	0.02	Intox EC/IR II	
Wyoming	2	not specified	0.02	Intox EC/IR & EC/IR II	Require third test if outside agreement

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DRAFT # 3

Clean Version for Public Comment

2006
Supplemental requirements
for the accreditation of
breath alcohol calibration laboratories

Corresponds to ISO/IEC 17025:2005

Introduction

General requirements for the accreditation of calibration laboratories are found in ISO/IEC 17025: 2005, *General requirements for the competence of testing and calibration laboratories*. All applicable requirements in ISO/IEC 17025:2005 must be met for ASCLD/LAB-*International* accreditation. This document supplements ISO/IEC 17025 and contains supplemental accreditation requirements for breath alcohol calibration laboratories which also must be met for ASCLD/LAB-*International* accreditation.

The numbering scheme in this document follows that of ISO/IEC 17025:2005. Supplemental requirements for accreditation may be found in Sections 4 and 5 of this document. Within those sections, the phrase "*No Supplemental Requirement*" means that the American Society of Crime Laboratory Directors / Laboratory Accreditation Board – International (ASCLD/LAB-*International*) program of accreditation has no requirement for accreditation in addition to the requirements specified in ISO/IEC 17025. Within sections where supplemental requirements do exist, only appropriately numbered supplemental requirements appear in this document.

Throughout this document, "*Shall*" means that compliance with the supplemental requirement is mandatory to achieve accreditation. In some instances, a requirement may not apply to the work conducted in a laboratory. In such instances, the requirement will be regarded by ASCLD/LAB-*International* as "*not applicable*."

In this document, notes (appearing as "**NOTE**") are intended to provide clarification or examples and do not constitute an additional accreditation requirement.

1 Scope

The accreditation of breath alcohol calibration laboratories is intended to apply to any laboratory performing calibration activities on breath alcohol measuring instruments and/or certifying the content of reference materials to be used for calibration checks of breath test instruments by its external customers.

The calibration program must be an organizational unit of a crime laboratory or the calibration operation must fit within the definition of breath test calibration laboratory provided in Section 3 of this document. The calibration program's customers must be conducting breath alcohol testing for criminal justice purposes.

Note A calibration operation may also be performing calibrations for customers engaged in non-criminal justice testing; however, to fall within the scope of this program the operation must be doing some level of work for customer's engaged in testing for criminal justice purposes.

- 1.1** ASCLD/LAB-*International* offers calibration accreditation only in the area of breath alcohol measuring instruments and breath alcohol calibration reference materials.

The accreditation certificate issued by ASCLD/LAB-*International* will specify the Field of accreditation (Forensic Science Calibration). A corresponding scope of accreditation document will specify the discipline (Toxicology) and the Calibration Category (breath alcohol measuring instruments and/or breath alcohol calibration reference materials).

Field of Accreditation: Forensic Science Calibration

Discipline	Calibration Category
Toxicology	Breath alcohol measuring instruments
Toxicology	Breath alcohol calibration reference materials

- 1.2** This document applies to calibrations performed by methods that have been fully documented and validated. This may include regional, national and international standard methods as well as in-house methods. The validation of standard methods, however, should not be taken for granted and laboratories should satisfy themselves that the degree of validation of a particular method is adequate for its intended purpose. Similarly, laboratories should not feel constrained to use a standard method if an in-house method exists that has been adequately validated as defined in ISO/IEC17025 and in this document.

These accreditation requirements apply to calibration programs for breath alcohol measuring instruments and the certification of breath alcohol calibration reference materials.

2 **References**

American Society of Crime Laboratory Directors / Laboratory Accreditation Board (ASCLD/LAB), *Accreditation Manual*, 2005.

Dubowski, K.M., *Quality Assurance in Breath-Alcohol Analysis*, JAT, 1984, Vol. 18

U.S. National Safety Council (NSC), *Committee Handbook: Committee on Alcohol and Other Drugs*, National Safety Council, Itasca, IL., 1996

International Laboratory Accreditation Cooperation (ILAC), ILAC-P10:2002 – *ILAC Policy on Traceability of Measurement Results*, 2002.

International Organization of Standardization (ISO) / International Electrotechnical Commission (IEC), *ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories*, 2005.

ISO/IEC, *ISO/IEC 9000 - Quality management systems — Fundamentals and vocabulary*, 2000.

ISO/IEC, *Guide 30 – Terms and definitions used in conjunction with reference materials*, 1992.

VIM, International vocabulary of basic and general terms in metrology, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

3 Terms and definitions

In addition to the following terms and definitions, any relevant terms and definitions given in documents cited in Section 2 of this document apply.

Administrative documentation - Records such as conversations with customers or subcontractors, instrument receipts, service request documentation, correspondence received/sent, and other pertinent information except calibration documentation.

Administrative review - A procedure used to check calibration documentation, certificates, reports, and/or calibration labels for consistency with laboratory policy and for editorial correctness.

Analyst (however named) – One who, in addition to performing tests and calibrations, interprets data, reaches conclusions and authorizes the release of a calibration certificate, report or label.

Approved test provider - A proficiency test provider who has complied with the test manufacturing guidelines established by the ASCLD/LAB Proficiency Review Committees.

Breath alcohol instrument – An instrument that measures within known limits of uncertainty the concentration of alcohol in an exhaled sample of human breath.

Breath alcohol calibration reference material – A reference material with a certified concentration of ethanol designed for confirming the proper calibration of breath ethanol testing instruments.

Breath Test Calibration Laboratory – A laboratory (however named) with at least one analyst (however named) which calibrates breath alcohol measuring instruments or certifies alcohol reference standards for use by customers administering breath alcohol tests for criminal justice purposes.

Calibration certificate (calibration label) – A document declaring that the values indicated by a breath alcohol instrument or the values represented by a reference material are in acceptable agreement with the results from a traceable standard.

Calibration documentation (See also **Notes**) - Includes reference to procedures followed, test conducted, standards, reference materials and controls used, printouts, observations and results of calibrations.

Calibration record - Files containing administrative and calibration documentation generated or received by a laboratory pertaining to a particular instrument.

Calibration technician (however named) – One who performs tests and calibrations on breath alcohol instruments.

Certification – The act of issuing a calibration certificate or calibration label (however named).

Competency test - The evaluation of a person's ability to perform work in any functional area prior to the performance of independent casework.

Control (control sample) - A test performed in parallel with experimental samples and designed to demonstrate that a procedure worked correctly; a standard of comparison for verifying or checking the finding of an experiment.

Customer – For ASCLD/LAB-*International* accreditation purposes, the primary user of the calibrated breath alcohol instrument and/or calibration data. The laboratory may choose to expand this definition.

Direct Supervision – An individual clearly defined in the management structure as being immediately responsible for the work of the calibration technician. In this document, the term does not mean that the supervisor must personally observe work being performed.

Director - See Laboratory Director

External proficiency test - A test provided by a source external to the laboratory. In the case of a laboratory system, a test for each laboratory in the system shall be provided by a source external to the laboratory system.

Laboratory director (however named) - The highest ranking manager within an individual laboratory.

Management system - The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly.

Manager - A person with the responsibility for directing and controlling an organizational unit or program.

Measurand - Quantity measured.

NHTSA – United States National Highway Traffic Safety Administration.

Natural science - Chemistry, biology and physics.

Notes (*See also examination documentation*) - The documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, and other documents generated which are used to support the calibration.

NCS – United States National Safety Council.

Proficiency review committee (PRC) - A committee appointed by the Board of ASCLD/LAB, whose role is to evaluate the performance of accredited laboratories in proficiency tests.

Proficiency test - A test to evaluate the continuing capability of analysts and/or technicians and the performance of a laboratory; in open tests, the analysts and technicians are aware that they are being tested; in blind tests, they are not aware.

Secure area - A locked space (for example, cabinet, vault or room) with access restricted to personnel authorized by the laboratory director.

Supervisor - A person directly responsible for overseeing the work in an organizational unit.

Technical review - Review of notes, data and other supporting documents which form the basis for a scientific conclusion.

Toxicology (forensic science discipline) - Analysis of biological samples for the presence of drugs and other potentially toxic materials.

4 Management requirements

4.1 Organization

- 4.1.4.1 The laboratory shall have a laboratory director (however named), whose responsibilities and authorities shall be defined.

NOTE 1 The laboratory director should have a minimum of a baccalaureate degree in a natural science, toxicology, criminalistics or a closely related field and at least five years of forensic science experience performing casework or calibrations in one of the ASCLD/LAB-International accredited disciplines. If the director lacks a scientific education and forensic science experience, then there should be support within management by personnel with an appropriate scientific background. Additional education in management or business administration by college course work or short training courses (or both) is recommended and the laboratory director should have at least two years of experience in management.

NOTE 2 Breath alcohol calibration laboratory administrators should remain aware of education and training recommendations of the National Safety Council (NCS) and the International Association for Chemical Testing (IACT).

- 4.1.4.1.1 The laboratory director shall possess sufficient authority to make and enforce decisions.

- 4.1.5. g.1 Each subordinate shall be accountable to one and only one immediate supervisor per function.

- 4.1.7 The laboratory shall appoint a member of staff as Health and Safety Manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that a health and safety program is implemented and followed at all times.

4.2 Management system

With specific reference to ISO/IEC 17025 - 4.2.2:

NOTE 2 A written statement of objectives fulfills a need for direction through a careful analysis of what the director and the parent organization believe are the appropriate functions of the laboratory and the direction in which it should be moving. Objectives make a significant contribution to the management process and serve as a basis for a sound management philosophy.

NOTE 3 Objectives will vary from laboratory to laboratory depending on such things as the size, range of services provided, nature of the parent organization, whether the laboratory stands alone or is part of a system, the size of the population served, and the nature of the area served (e.g., dense urban, dispersed rural). Objectives should be clearly communicated to all employees.

4.3 Document control

No Supplemental Requirements

4.4 Review of requests, tenders and contracts

No Supplemental Requirements

With specific reference to ISO/IEC 17025 - 4.4.1

NOTE Calibration laboratories that perform calibrations or issue certificates pursuant to requirements outlined in statute or promulgated rule under authority of statute may not need to use a procedure wherein formal requests, tenders, or contracts are received. In such cases, the calibration laboratory should consider documentation of the relevant statutory authority and rules to be the contract for service.

4.5 Subcontracting of tests and calibrations

No Supplemental Requirements

4.6 Purchasing services and supplies

No Supplemental Requirements

4.7 Service to the customer

No Supplemental Requirements

4.8 Complaints

4.8.1 The laboratory policy and procedure for the resolution of complaints shall cover complaints concerning quality related aspects of the management system submitted by laboratory employees.

4.9 Control of nonconforming testing and/or calibration work

No Supplemental Requirements

4.10 Improvement

No Supplemental Requirements

4.11 Corrective Action

No Supplemental Requirements

4.12 Preventive action

No Supplemental Requirements

4.13 Control of records

4.13.2.2.1 Calibration documentation shall reflect the date(s) tests and/or calibration services are performed.

4.13.2.3.1 An addition made to calibration documentation shall be initialed and dated by the person making the addition.

NOTE In this context, "addition" means placing new information in the calibration documentation.

4.13.2.4 The laboratory procedure shall identify what documents will be maintained in calibration records.

NOTE 1 A laboratory calibration record consists of both testing and calibration documentation and administrative documentation which may be received or generated by the laboratory.

NOTE 2 The information maintained in a calibration record may include, but is not limited to, records of conversations, instrument receipts, records of observations and test/calibration results, reference to procedures used, and instrument print-outs.

4.13.2.5 Documentation to support calibrations shall be such that in the absence of the analyst or technician, another competent analyst, technician or supervisor could evaluate what was done and interpret the data.

NOTE Examples of ways to document the basis of conclusions derived from calibrations include, but are not limited to: worksheets which have photocopies attached or spaces or sections for the insertion of data or other observations made during various steps of the calibration procedure, or instrument printouts, or a combination of one or more of these approaches.

4.13.2.6 The laboratory's unique calibration record identifier and the analyst's handwritten initials (or secure electronic equivalent of initials or signature) shall be on each page of the calibration documentation in the record.

4.13.2.7 When calibration documentation is prepared by an individual(s) other than the analyst who interprets the results and prepares or authorizes the calibration certificate, the initials of that individual(s) shall be on the page(s) of calibration documentation representing his/her work.

NOTE 1 The electronic equivalent of handwritten initials or signature are acceptable when the laboratory can demonstrate that the electronic signature is secure and can only be applied by the individual whom the electronic initials or signature represent.

NOTE 2 It should be clear from the calibration record who has performed all stages of the calibration.

NOTE 3 Calibration documentation, such as instrumental data, which bears the appropriate identification (i.e. unique identifier(s) and initials) on an original document, may be copied for filing in multiple places without the necessity of placing original identifiers on each copy.

NOTE 4 It is recommended that when calibration documentation consists of multiple pages, a page numbering system be used.

- 4. 13.2.8** All administrative documentation, received or generated by the laboratory for a calibration record, shall be identified with the unique record identifier used by the laboratory.

NOTE The unique identifier may be hand written or machine generated. Multi-paged administrative documents which are bound together, in some manner, may be identified by a unique identifier on the front page of the document.

- 4. 13.2.9** The unique identifier of each record for which data was generated shall be appropriately recorded on the printout when data from multiple instruments is recorded on a single printout.

NOTE The printout may be kept in a single file and referenced in all files for which data was generated.

- 4. 13.2.10** When calibration documentation is recorded on both sides of a page, each side shall be treated (identified and initialed) as a separate page.

- 4. 13.2.11** Calibration documentation shall be of a permanent nature.

NOTE Written and printed examination documentation shall be reasonably indelible. Notations made with pencil are generally erasable, thus are unsuitable examination documentation. In this context, the term "permanent" has no application to record retention requirements.

- 4. 13.2.13** Where abbreviations or symbols specific to the laboratory are used in the calibration documentation, the meaning of the abbreviations or symbols shall be clearly documented by the laboratory.

4.14 Internal audits

- 4. 14.1.1** Internal audits shall be conducted at least annually.

- 4. 14.1.2** Internal audits shall be documented and the documentation retained for at least one ASCLD/LAB-*International* cycle of accreditation.

- 4. 14.5** The laboratory shall submit an Annual Accreditation Audit Report to ASCLD/LAB by the laboratory's accreditation anniversary date.

NOTE The ASCLD/LAB-*International* Annual Audit Report is used to verify that operations continue to comply with the requirements of the laboratory's management system and the standards under which ASCLD/LAB-*International* accreditation was granted. The report provides a foundation for surveillance visits.

4.15 Management reviews

- 4. 15.1.1** Management reviews shall be conducted at least annually.

- 4.15.1.2** Management reviews shall be documented and the documentation retained by the laboratory for at least one ASCLD/LAB-*International* cycle of accreditation.

5 Technical Requirements

5.1 General

- 5.1.3** The laboratory shall establish a documented procedure for routinely checking the reliability of its reagents.
- 5.1.3.1** Reagents prepared in the laboratory shall be labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Records shall be maintained identifying who made the reagent and that its reliability was tested and the reagent worked as expected.

5.2 Personnel

With specific reference to ISO/IEC 17025 - 5.2.1:

NOTE 3 Records should be sufficiently detailed to provide evidence that staff performing particular tasks have been properly trained and that their subsequent ability to perform these tests and calibrations has been formally assessed.

- 5.2.1.1** The laboratory shall have a documented training program that will be used to train personnel in the knowledge, skills, and abilities needed to perform the calibrations. The laboratory's management system shall also include procedures for retraining and maintenance of skills and expertise.

NOTE The training program should be sufficiently comprehensive to cover all aspects of the work performed by a laboratory.

- 5.2.1.2** Where applicable, training programs shall also include training in courtroom presentation.

With specific reference to ISO/IEC 17025 - 5.2.2:

NOTE 1 The laboratory's policy on employee development should address the various opportunities available to employees, such as:

- professional organizations and their meetings
- staff development seminars
- technical training courses
- in-house technical meetings, courses, and seminars
- laboratory sponsored seminars and conferences
- college level courses

NOTE 2 The development program should state how employees can participate in it and should identify the procedures to be followed when applying for such training. Any special laboratory criteria for selection of personnel should be stated. It is important that the program demonstrate planning for the development of individual employees, laboratory sections and the laboratory as a whole.

5.2.6 Technical personnel qualifications

5.2.6.1 Education

5.2.6.1.1 Analysts or calibration technicians (however named) working in the Toxicology sub-discipline of breath alcohol calibration who issue calibration certificates, reports or labels shall possess a baccalaureate or an advanced degree in a natural science, toxicology, criminalistics or a closely related field.

NOTE 1 Breath alcohol calibration laboratory administrators should remain aware of education and training recommendations of the National Safety Council (NSC) Committee on Alcohol and Other Drugs and the International Association for Chemical Testing (IACT) and consider those recommendations for analysts or calibration technicians when/if those recommendations exceed the requirements of 5.2.6.1.1.

NOTE 2 A qualified individual, whose degree is in a field other than a natural science, toxicology criminalistics or a closely related field, but who has taken extensive course work in biology and/or chemistry and has numerous years of experience may meet the educational requirements on a case by case basis as determined by ASCLD/LAB-*International*.

5.2.6.1.2 Calibration technicians (however named) performing duties under the direct supervision of a qualified laboratory employee shall meet the educational requirement(s) specified in the job description.

NOTE 1 A qualified employee is one who meets the education requirements specified in 5.2.6.1.1.

5.2.6.2 Competency testing

5.2.6.2.1 All analysts and calibration technicians, regardless of academic qualifications or past work experience, shall satisfactorily complete a competency test prior to assuming calibration responsibility in the laboratory.

NOTE 1 Satisfactorily completing a competency test means achieving the intended results. Failure to achieve the intended results would require review or retraining until testing results in achieving the intended results.

NOTE 2 Competency testing should include evaluation of knowledge of existing literature, written and/or oral examinations, examination and identification of known and unknown material, and moot court.

5.2.6.2.2 Any technical support personnel, regardless of academic qualifications or past work experience, shall satisfactorily complete a competency test prior to assuming independent responsibility for any task that could reasonably be expected to affect the outcome of any calibration reported by the laboratory.

- 5.2.7** The laboratory shall maintain or provide access to literature resources such as relevant books, journals and other literature dealing with breath alcohol calibration.

NOTE A forensic library may be located in multiple locations and electronic storage and/or access is permitted as one form of library materials as long as all employees have a reasonable means of access.

5.3 Accommodation and environmental conditions

- 5.3.4.1** The laboratory shall have written policies or procedures that address laboratory security to ensure that:

- a) Access to the operational area of the laboratory is controllable and limited. Visitors shall not have unrestricted access to the operational areas of the laboratory.
- b) Internal areas requiring limited/controlled access have a lock system.
- d) Accountability of all keys, magnetic cards, etc., is documented and their distribution limited to those individuals designated by the laboratory director to have access.
- e) Storage area(s) for instruments to be calibrated or awaiting return to the customer are secured to prevent theft or interference and there is limited, controlled access.

NOTE Laboratories should have a fire detection system.

- 5.3.6** The laboratory shall have and demonstrate use of a documented health and safety program.

NOTE Use of a documented health and safety program could be demonstrated by safety training records, safety inspections, and documentation of preventive action taken by the laboratory management, or action to address safety issues/concerns expressed by laboratory personnel.

5.4 Test and calibration methods and method validation

- 5.4.1.2** Appropriate controls, standards, and/or reference materials shall be specified in the calibration methods and their use documented in the calibration record.

5.4.2 Selection of methods

- 5.4.2.1** Prior to implementation of a validated method new to the laboratory, the reliability of the procedure shall be demonstrated in-house against any documented performance characteristics of that procedure. Records of performance verification shall be maintained for future reference.

5.4.3 Laboratory-developed methods

No Supplemental Requirements

5.4.4 Non-standard methods

No Supplemental Requirements

5.4.5 Validation of methods

With specific reference to ISO/IEC 17025 - 5.4.5.2:

NOTE 4 Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the laboratory itself (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

5.4.6 Estimation of uncertainty of measurement

No Supplemental Requirements

5.4.7 Control of data

No Supplemental Requirements

5.5 Equipment

No Supplemental Requirements

5.6 Measurement traceability

5.6.3 Reference standards and reference materials

- 5.6.3.2.2** Breath alcohol calibration reference materials, either obtained from an external source or manufactured by the laboratory, shall be labeled with, at a minimum, the identity of the reference material and the date of preparation or lot number. Records shall be maintained including applicable calibration certificates, the concentration of specified contents, the source or preparer of the material, and data arising from intermediate checks carried out to maintain confidence in the calibration status of the reference material.

- 5.6.3.2.3** Where applicable, reference materials shall be traceable to the appropriate national metrology institute or a program governed by the appropriate national metrology institute.

5.7 Sampling

No Supplemental Requirements

5.8 Handling of test and calibration items

No Supplemental Requirements

5.9 Assuring the quality of test and calibration results

- 5.9.3** The laboratory shall have a documented program of proficiency testing.

- 5.9.3.1** When participating in proficiency testing programs, the laboratory's own approved and documented procedures shall be used.

NOTE 1 The laboratory's overall performance in proficiency testing programs should be reviewed regularly and, where necessary, corrective action should be taken.

NOTE 2 Proficiency tests should not be subject to policies adopted by the laboratory for efficiency or expediency. All parts of a proficiency test provided by an approved test provider should be completed as thoroughly as the laboratory's capability allows.

- 5.9.3.2** The laboratory proficiency testing program shall comply with the *ASCLD/LAB Proficiency Review Program*.

NOTE The *ASCLD/LAB Proficiency Review Program* document is available at www.asclcd-lab.org.

- 5.9.3.3** Each employee shall successfully complete at least one internal or external proficiency test per calendar year.

NOTE 1 Successfully completing a proficiency test means either obtaining the correct response or completing corrective actions pursuant to laboratory policy and/or directives from an ASCLD/LAB Proficiency Review Committee (PRC).

- 5.9.3.4** The laboratory shall participate annually in at least one external proficiency test. An ASCLD/LAB approved test provider shall be used where available. Whenever there is not an ASCLD/LAB approved test provider available, the laboratory shall locate and use a source of an external test.

- 5.9.3.5** The laboratory shall maintain records of proficiency testing and the documentation of a laboratory's proficiency testing program shall include, at a minimum:

- The test set identifier
- How samples were obtained or created
- Identity of the person taking the test
- Date of completion
- Originals or copies of all data and notes supporting the conclusions
- The proficiency test results
- Any discrepancies noted
- An indication that performance has been reviewed and feedback provided to the analyst
- Details of the corrective actions taken (when necessary)

NOTE The laboratory should establish criteria for the evaluation of proficiency tests.

5.9.3.6 Proficiency testing records shall be retained not less than one full ASCLD/LAB-*International* accreditation cycle.

5.9.4 The laboratory shall establish a procedure for the technical review of the calibration documentation and calibration certificate or report. The procedure shall ensure that the calibration is supported by sufficient documentation. The procedure shall define the scope of the technical review, establish the parameters of the review process, specify how technical reviews are documented, and describe a course of action to be taken if a discrepancy is found.

NOTE Technical review may be carried out on a sample of completed calibrations (e.g., 25% or “X” number of cases, whichever is less, per examiner per month). The sampling rate may vary depending upon the situation, as defined by the laboratory's policy. For example, a new analyst may have 100% of calibrations reviewed while a very experienced analyst may have only a few reviewed each month.

5.9.4.1 Technical reviews shall be conducted by individuals having expertise gained through training and experience in the calibration of breath alcohol measuring instruments and/or breath alcohol calibration reference material.

NOTE 1 An individual conducting the technical review need not be an active analyst or currently being proficiency tested.

NOTE 2 Technical reviews, while important to the laboratory quality assurance program, should not shift the perceived responsibility for the calibration from the analyst to the reviewer.

5.9.5 The laboratory shall establish a procedure which requires administrative review of the calibration record and calibration certificate, report or label prior to the release of each certificate or report. Laboratory policy shall define the scope of the review, who may conduct administrative reviews, and how the administrative review is documented.

NOTE Administrative reviews, in whole or in part, may be independent of technical reviews or may be combined as one process.

5.10 Reporting the results

5.10.1.1 The laboratory shall meet the requirements of 5.10.2 and 5.10.4 by adopting one of the following means:

- The preparation and issuance of a calibration certificate or report which includes all of the information required by ISO/IEC 17025;
- The preparation and issuance of an attachment to the calibration certificate or report which includes any additional information required by ISO/IEC 17025;
- The preparation and issuance of a simplified calibration certificate, report or label referenced, by unique identifier, to a specific calibration record maintained at the issuing laboratory that contains all of the relevant information required by ISO/IEC 17025.

5.10.4.6 The laboratory shall have procedures for controlling the release of calibration information.

Note: Calibration reports need not be issued separately to each customer and each breath alcohol instrument providing that the calibration information needed by the various data users is available, for instance, in summary form filed at a central location.

5.10.4.7 The author(s) of a calibration certificate or report shall have conducted, participated in, observed, supervised, or technically reviewed the calibration process.

5.10.4.7.1 Laboratory personnel who issue calibration certificates, reports or labels based on calibration documentation generated by another person(s) shall complete and document the review of all relevant pages of documentation in the calibration record.

NOTE Documentation of the review may be accomplished in a number of ways, such as initialing each page of the documentation, the use of a review checklist, or specifying the pages of the records or dates of work that were reviewed and relied upon.

DataMaster Data Collection Plan - Short Term

Data will be downloaded from instruments in the field and data added to the DMHOST database as specific case-related requests are received. Downloading will be done via phone line where possible. Where there is no operating phone line connection a technician or program support chemist will travel to the site in question and use a configured laptop computer to connect directly to the instrument for data retrieval. A record of time and mileage will be kept for future billing information. Data will be downloaded and added to the database within 5 days of receipt of the request.

Sporadic requests for data from State's Attorneys that are intended for file updates will be responded to at our earliest convenience.

Instruments returned to the laboratory for service will be downloaded routinely before service is begun. Download will be accomplished through direct hook-up to the HOST computer. Incorporation of the data into the database will be completed within 2 days of the download.

Additional phone line hook-ups will be added to those instruments in frequent use and for which data requests are frequent as resources allow. A specific goal is set to facilitate this in all VSP field stations by the end of the summer.

DataMaster Data Distribution Plan – Short Term

Routine 'Discovery Reports' will be generated in response to specific case-related requests within 10 working days from when they are received. Reports will be generated by program support chemists; provided to clerical support persons in the Administrative and Customer Service Units along with any additional information required for full response to a discovery request.

Currently by the end of the first week of each month we are providing reports for data collected in the DataMasters the previous month and related documents created in the previous for five counties. Those counties represent those jurisdictions from which the greatest number of discovery requests originate. This practice will continue for the immediate future.

DataMaster Data Collection and Distribution Plan - Long Term

[The following options are offered for consideration of implementation based on the possibility that DataMaster individual data collection will be required on an on-going basis.]

I. Connect to all DataMasters

A. Actions Required – full connection for remote download

1. Connect all DataMaster instruments installed for evidential use by phone line.
2. automatically poll connected instruments on a regular basis, at least monthly, incorporating data into the DMHOST or equivalent database.
3. Generate serial number-specific reports on a monthly basis
4. distribute reports electronically to relevant States Attorney's offices for review by prosecution and defense attorneys.
5. provide summary data reports on a quarterly basis
6. provide 'raw' data files to research programs/ GHSP for evaluation.

B. Required Resources

1. dedicated computer with current version of DMHOST software
2. dedicated phone line in the laboratory for connecting to instruments
3. technician time to maintain connection capability in the instruments
4. agreement at law enforcement DataMaster sites to maintain phone connectivity
5. permanent part-time clerical position to maintain database and scanned DataMaster documents; create and distribute reports; and generate billing for reports provided

C. Implementation Time

1. identify technical connectivity needs; purchase and install switching equipment; arrange for site phone lines or to find other connectivity solutions - 8 months
2. create, recruit and hire for a clerical position to manage the data – 10 months
3. create protocols for data collection and reporting; train State's Attorneys' staff; create protocols for information archiving; etc. – 6 months

II. Individual Site Data Handling

A. Actions Required

1. purchase computer [where necessary] and/or printer for each site and set up for DM data collection use
2. acquire necessary software license agreements from NPAS to set up each site
3. establish protocols for data retrieval and reporting
4. train DataMaster supervisors in protocols
5. [OPTIONAL] periodically collect all data into a common database for statistical and demographic analysis

B. Resources Needed

1. funds for equipment purchase
2. funds for software license
3. staff time to develop data handling protocols
4. staff to develop and provide training to DM Supervisors
5. [OPTIONAL] staff to manage centralized database

C. Implementation Time

1. identify equipment needs and purchase – 6 months
2. establish data handling protocols -6 months
3. set up computers and train DM Supervisors – 10 months
4. [Optional] train staff to manage centralized database -2 months

II. New Breath Test Instrumentation

A. Actions Required

1. evaluate new breath test instrumentation types for compliance with requirements for application to state program
2. select best choice from equipment evaluated
3. determine adequate funding source
4. create purchase requisition that favors the instrument of choice
5. establish transition plan for certification and installation at evidential testing sites
6. create and implement a training program for operators and instrument supervisors
7. establish an information file that is designed to minimize legal challenge
8. train support staff in maintenance and repair of new instruments
9. set up parts and supplies inventories to support the equipment
10. establish and implement training for State's Attorney's staffs re: getting test results accepted by defense counsel and the judiciary
11. Install new instrumentation in field sites
- 12.

DataMaster Data Collection Plan - Short Term

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 - C. Implementation Time
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 2. create, recruit and hire for a clerical position to manage the data – 10 months
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8. train support staff in maintenance and repair of new instruments
9. set up parts and supplies inventories to support the equipment
10. establish and implement training for State's Attorney's staffs re: getting test results accepted by defense counsel and the judiciary
11. Install new instrumentation in field sites
- 12.

Evaluation of Breath Testing Instruments

This study will evaluate the performance of the NPAS DataMaster DMT®, the CMI Intoxilyzer® 8000, and the Drager Alcotest® 7110 MKIII-C instruments at various alcohol concentrations, with emphasis on 0.08g/210L and 0.16g/210L. In addition, the responses to mouth alcohol and potentially interfering compounds will be tested.

The Vermont Department of Health Laboratory of the Agency of Human Services oversees blood and breath alcohol testing activities in Vermont. Currently the National Patent Analytical Systems, Inc. BAC DataMaster® is the only breath alcohol analyzer approved by the VDHL.

Criteria that will be used in the evaluation of the instruments include accuracy, precision, linearity, response to mouth alcohol, and response to various potentially interfering agents. Emphasis will be placed on alcohol concentrations of 0.08g/210L and 0.16g/210L. Other issues that will be taken into consideration are ease of use, durability, and overall performance during experimental data collection .

Method:

- Precision:
 - Ethanol solutions of 0.08g/210L and 0.16g/210L will be analyzed (n=10), using the supervisor mode.
- Accuracy
 - Solutions at levels of 0.02, 0.04, 0.08, 0.16 and 0.40 g/210L will be analyzed (n=10) as calibration checks
 - All solutions will be verified by gas chromatography with flame ionization detection.
- Linearity
 - The five aqueous ethanol solutions are prepared over a concentration range that will provide vapor concentrations from 0.02 through 0.4g/210L. The ensuing results should form a straight line with all observed values within +/- 5% of the known value and with a Correlation Coefficient of at least 0.99
- Interference
 - The mouth alcohol detection system will be tested (n=10) Each test will be taken at 3-5min intervals until such time as no mouth alcohol is detected
 - 0.04% Methanol in water
 - 0.04% Isopropanol in water
 - 0.05% Acetone in water
 - 0.02% Acetone in 0.08% Ethanol
 - 0.05% Acetone in 0.08% Ethanol
 - 0.1% Acetone in 0.08% Ethanol
 - 0.04% Methanol in 0.08% Ethanol
 - 0.04% Isopropanol in 0.08% Ethanol

DataMaster Repair/ Service Schedule for:

UVM Instrumentation and Technical Services

April 14, 2011

881350	Simulator configuration and adjustment	
	Printer adjust, repair or replace	
950159	Correct no keyboard response; check/replace cable; check/replace key board	
921146	System won't zero; check/repair filter movement, alignment; check chamber debris, corrosion, replace as needed; check detector signal, voltage settings, replace as needed	
Sim G7683	Replace motor	
Sim G 4012	Upgrade configuration; adjust temp as needed	
Sim G 3866	Upgrade configuration; adjust temp as needed	

**Vermont Department of Health Laboratory
Toxicology Program**

Outside Contractor DataMaster Repair Plan

Example Specification of Work to be Performed

Attend operation, maintenance and repair training provided by instrument manufacturer.

Repair and service of BAC DataMaster infrared breath testing instruments [Manufacturer: National Patent Analytical Systems] to a level of operating performance adequate for certification for evidentiary use,

or,
clear identification that the unit can no longer be made serviceable for a cost less than one-half the current cost of a replacement unit.

Complete required repair and service documentation as needed.

Industry standard diagnostic procedures are required to determine the source of malfunction and to develop a repair strategy.

Repair and service extends to all internal and external electronic, electrical, mechanical and optical components of the instrument, including the external standard breath alcohol simulator.

Electronic component repairs are limited to circuit board replacement unless specifically designated as a discrete electronic component replacement by the manufacturer or the State.

Final dispensation on each repair must be determined within 1 month of the start of service except when instrument must be returned to the manufacturer for specialized repairs.

Determination of the need for repair and service will be determined by the State and Contractor will respond with initial diagnosis of the extent of service needed within one week of notification unless otherwise agreed to by the State.



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

Transportation
Systems Center

Kendall Square
Cambridge, Massachusetts 02142

August 25, 2004

National Patent Analytical Systems, Inc.
2090 Harrington Memorial Road
P.O. Box 1435
Mansfield, OH 44901

This is to confirm that the National Patent Analytical Systems, Inc. **DataMaster DMT** evidential breath tester that was submitted to this Center for evaluation has been found to meet all applicable requirements of the National Highway Traffic Safety Administration Model Specifications for screening units for breath alcohol testers, **FR 62 43416**.

The test report is enclosed. It is expected that the device will appear on the next update of the NHTSA Conforming Products List for screening devices.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ed Conde".

Edward Conde
Alcohol Countermeasures Support

C: James Frank/ NTS-31



U.S. Department
of Transportation

**Research and
Special Programs
Administration**

Transportation
Systems Center

Kendall Square
Cambridge, Massachusetts 02142

December 2, 2004

Mr. Cliff Broeder
National Patent Analytical Systems, Inc.
2090 Harrington Memorial Road
P.O. Box 1435
Mansfield, OH 44903

Dear Mr. Broeder:

This is to confirm that the National Patent Analytical Systems, Inc. Datamaster DMT evidential breath tester that was submitted to this Center for evaluation according to the National Highway Traffic Safety Administration Model Specifications for such devices, FR 58 48705, has been found to meet all applicable requirements.

It is expected that the device will appear on the next update of the NHTSA Conforming Products List for such devices.

This amends my letter dated August 25, 2004 which incorrectly stated that the Datmaster DMT had been found to meet all applicable requirements of the National Highway Traffic Safety Administration Model Specifications for screening units for breath alcohol testers, FR 62 43416.

Sincerely,

A handwritten signature in cursive script that reads "Edward Conde".

Edward Conde
Alcohol Countermeasures Support

C: James Frank/ NTS-31

Manufacturer: National Patent Analytical Systems, Inc. Datamaster DMT snDD000001

Test	1	2	3	4	5	6	7	8	9	10	Mean	SD	SE	Pass	
{target BAC indicated in brackets}															
1. Precision and Accuracy															
{0.020}	0.020	0.020	0.020	0.020	0.020	0.019	0.019	0.020	0.019	0.019	0.020	0.0005	0.000		
{0.040}	0.041	0.040	0.042	0.041	0.040	0.040	0.041	0.040	0.041	0.040	0.041	0.0007	0.001		
{0.080}	0.080	0.079	0.079	0.079	0.078	0.081	0.080	0.078	0.081	0.081	0.080	0.0012	0.000		
{0.160}	0.166	0.163	0.164	0.162	0.162	0.164	0.160	0.160	0.160	0.164	0.163	0.0021	0.002	YES	
{0.300}	0.312	0.309	0.307	0.308	0.306	0.308	0.305	0.304	0.303	0.302	0.306	0.0030	0.006	***	
2. Acetone Interference															
low acetone {0.020}	ID	ID	ID	ID											
high acetone {0.020}	ID	ID	ID	ID											
3. Blank Reading {0.000}	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	*YES
4. Breath Sampling {0.080}															
0.2 Liters/sec.	0.083	0.083	0.083	0.083	0.082	0.082	0.083	0.082	0.081	0.081	0.082	0.0008	0.002		
0.3 Liters/sec.	0.082	0.083	0.082	0.081	0.081	0.081	0.080	0.079	0.081	0.080	0.081	0.0012	0.001		
0.5 Liters/sec.	0.081	0.081	0.081	0.080	0.080	0.081	0.080	0.080	0.077	0.079	0.080	0.0012	0.000	YES	
5. Power {0.080}															
108 Volts, AC	0.080	0.079	0.080	0.078	0.078	0.080	0.078	0.078	0.079	0.078	0.079	0.0009	-0.001		
123 Volts, AC	0.083	0.082	0.081	0.081	0.081	0.081	0.081	0.081	0.080	0.079	0.081	0.0011	0.001	YES	
6. Temperature {0.080}															
20 deg. C	0.082	0.080	0.080	0.080	0.079	0.082	0.081	0.080	0.080	0.081	0.081	0.0010	0.000		
30 deg. C	0.082	0.080	0.080	0.080	0.080	0.081	0.080	0.079	0.079	0.079	0.080	0.0009	0.000	YES	
7. Post Vibration {0.080}	0.082	0.081	0.081	0.080	0.080	0.081	0.080	0.079	0.079	0.079	0.080	0.0010	0.000	YES	
8. Electrical Safety Insp.															
															YES

Units

BAC: 9m/210L Air
 SD: Standard Deviation
 SE: Syst. Error, Mean -target BAC
 ID: Interference detected
 Date: August, 2004

Acetone-in-air Concentration
 low: 0.3 mg/L
 high: 0.5 mg/L

Requirements
 SD: 0.0042 or less
 SE: plus or minus 0.005 BAC or 5 % whichever is greater
 *No single result greater than 0.005 BAC

***No requirement (information only)

Draeger Demo Unit Vermont Set-up
December 5, 2008

- Accuracy and Precision Test: Run a user-definable number of replicates [up to 10] of an external wetbath simulator and report each result and the average reported to three decimal places and the standard deviation.
- 2 test subject sample sequence with quality control checks prior to each sample and blank tests before and after all vapors (breath and simulator).
 - Blank
 - Internal Standard
 - External Standard
 - Blank
 - Subject Test
 - Blank
- Report volume of breath delivered.
- IR and EC results for each sample.
- Print reports to External printer; 8.5x11 paper

Any other standard protocol you include.

List of Evidential Breath Alcohol Test Instrument Vendors for possible bids

For Drager instruments:

Central Equipment Co.
116 Cottage Ave.
Millis, MA

OR

Drager Safety, Inc.
Breathalyzer Div.
185 Suttle St Suite 105
Durango, CO

For DataMaster instruments:

National Patent Analytical Systems, Inc.
Post Office Box 1435
Mansfield, OH 44901

National Patent Analytical Systems, Inc.
2090 Harrington Memorial Road
Mansfield, OH 44903

Phone:

(419) 526-6727
(800) 800-8143 toll free

Email/Fax:

salesteam@npas.com email
(419) 526-9446 fax

For Intoximeter instruments:

Intoximeters, Inc.

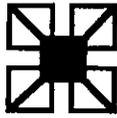
8110 Lackland Rd.
St. Louis, MO 63114
FAX: (314) 429-4170
Watts:(800) 451-8639
Local:(314) 429-4000

For Intoxylizer instruments:

CMI, Inc.

Representative:

Bill Collins
Toll Free Phone: 866-835-0690
Voice Mail: 270-685-6466
Cell Phone: 402-699-5087
Fax: 270-685-6678
E-mail: wfcollins@alcoholtest.com

 National Patent
Analytical Systems, Inc.

Mr. Robert Drawbaugh
Vermont Dept of Health
Box 70
Burlington, Vt. 05402-0700

March 15, 2010

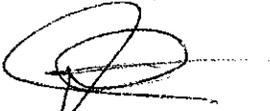
Dear Mr. Drawbaugh:

Regarding your request for clarification of our warranty policy: We do have a stated 2 year warranty on DataMaster Products, including the DMT. However, we have always considered the warranty to start upon actual deployment of the instruments to the field rather than the shipping date when multi instrument state orders are involved. Further, since the placement of the instruments is often staggered in time, we usually pick a mutually agreeable date that reflects, more or less, an average placement date. This is easier and more convenient for all concerned. This is not a policy that was ever reduced to written form and probably never will be but it certainly is helpful to our customers. The only caveat is that the warranty maintenance, repairs and recalibrations be done by a technician who has been certified by us as a maintenance technician.

Regarding the issue of your technician using parts from one of our demonstrator or loaner instruments to repair an instrument from your inventory. If it is helpful to your program we certainly support this remedy. We can send you a replacement part for the loaner instrument and your technician can install it.

Our records currently indicate that your employee Steve Harnois is certified by us to perform maintenance and recalibrations on the DataMasters and DMT instruments. Given his experience and level of expertise, it is my opinion that he should perform the maintenance on the new DMT instruments.

Sincerely,


John Fusco,
President

5. How is parts availability and quality? good
How is vendor service availability and quality? good
How is vendor technical support? Very good
6. Do you download information from field instruments? Not at this time
How is it done?
Percent of instruments from which you can download ~ 65 -70%
Is the software user-friendly? Not particularly
Does it provide built-in ability to perform statistical analysis on subgroups?
no
Does it allow you to perform any adjustments to the field instruments?
Examples: yes date/ time
7. When you chose the instrument, what were the deciding factors?

Knowing what you know now, would you choose differently? no
8. Are there any sources of frustration with the instrument or vendor? Not
for this model of instrumentation

Would you be willing to tell us what they are (if any)?

Questions for Breath Test Instrument users

Instrument: ___ DataMaster ___ DMT ___
Name ___ Bob Drawbaugh _____
Location ___ VT Dept. of Health Laboratory _____
Phone number ___ 802-863-7622 _____

1. Calibration value(s) used 0.10

 How often needed for a typical instrument? tbd

 Where is it done done? In alcohol program shop in lab

2. Day-to-day variability typically 0.5 to 1 % at ~ 0.10

 How is it measured? Multi-run test [supervisor test] run several times per week during initial check and setup period

3. Linearity: Range: 0.02 – 0.40

 Fit to line – how measured? Each conc. Run 7X ; r value determined for means

 Typical value(s) of fit results We require at leas 0.99nn and typically get 0.999n

4. Can instruments be repaired by you? Yes

 Number of instruments being used in the field None at this time ;
 estimated deployment Jan. 08

 Total No. of repairs per year: In field tbd
 (not per instrument)

 At your facilities tbd

 At vendor tbd

 Most frequent cause for repairs: tbd

5. How is parts availability and quality? Tbd

How is vendor service availability and quality? good

How is vendor technical support? good

6. Do you download information from field instruments? Not at this time

How is it done? Downloads will be done by site agency [PD, barracks, sheriff's dept.] data will be forwarded to us

Percent of instruments from which you can download 100%

Is the software user-friendly? tbd

Does it provide built-in ability to perform statistical analysis on subgroups?
Not anticipated that it will

Does it allow you to perform any adjustments to the field instruments?

Examples: yes , date/ time others to be determined

7. When you chose the instrument, what were the deciding factors? It represents the next generation of breath test design; many advantages having an on-board computer for processing tests and test data; graphic display ; breath volume measurement and report; size/weight; connectivity flexibility; analytical technology same as current instrument with refinements [easier to get through legal challenges

Knowing what you know now, would you choose differently? no

8. Are there any sources of frustration with the instrument or vendor?
Length of time required to standardize instrument design and components;
length of time for development of our operating software [we provided them with a rather complex set of protocol designs]

Would you be willing to tell us what they are (if any)?

DRAFT

Infrared Breath Test Equipment Replacement Plan

The State of Vermont has established that a person with a blood alcohol concentration (BAC) of .08 or higher shall not operate a motor vehicle. The application of this law requires Vermont to maintain the ability to reliably and accurately measure BAC. The method Vermont has decided to establish and maintain this capability is the Infrared (IR) breath testing technology.

Vermont has 77 units in a network of IR machines throughout the state. There are currently 63 active permanent testing sites in police agencies across Vermont. Additionally, there are four units in mobile breath alcohol testing vehicles (BATmobiles) and six machines at the police academy for training. There are also 2 units in the Department of Health lab for repairs (which, when repaired, will be used to replace units in the field requiring more work than can be accomplished on-site), and the remaining two are useful only to supply parts for repair of other units. Some repair parts are no longer available from the manufacturer, such as printers and simulators, which are frequent service calls.

DataMaster placement is based on geographic distribution and population coverage. When the plan was originally developed, every effort was made to ensure that police officers did not need to transport a test subject more than 45 minutes to a testing site. In order to qualify to host a DataMaster, a police agency needed to be accessible to all enforcement officers (not just their own agency's officers) 24 hours per day and 7 days per week, and provide a DataMaster Supervisor (a staff member trained to do routine maintenance). Since that time, several factors have evolved that have not been reflected in the DataMaster distribution plan.

1. Several police departments have been created that did not exist when DataMasters were originally placed (Montgomery, North Troy, Lyndonville, Bradford, Danville).
2. State Police barracks previously accessible 24/7 are now locked at 4:30 due to consolidated dispatching. Access by other departments to the DataMasters in non-PSAP locations varies around the state.
3. With the advent of State Act 117 DUI grants and OJJDP START funds, and the Administration's focus on impaired driving, more alcohol enforcement than ever is being conducted by all departments.

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4/14/11

DRAFT

4. Police agencies statewide are experiencing staffing shortages, and overtime grant funds often go unused because there are not enough officers to do the work. DUI enforcement is one of the more time-consuming tasks police officers execute, and reducing travel time and access issues improves effectiveness of limited police resources.

In 2000, a DUI Policing Summit was held, and one of the outcomes was documentation of equipment required by police agencies for effective DUI enforcement. A DataMaster purchase was one of the recommendations. This was further supported by the DUI Policing Task Force in 2004, when progress on fulfilling the equipment list was reviewed and updated.

There is no formal strategy or plan for regular replacement or enhancement of the DataMaster inventory. Purchase history has been based upon availability of “windfall” federal highway safety funds. (“Windfall” defined as funds not required for ongoing highway safety activities and eligible for this purpose.)

The BAC DataMaster breath testing instruments currently used for evidential testing are aging and replacing them with new units will address issues of increased out-of-service time and repair/maintenance costs, as well as reduce the maintenance load on the Department of Health technician responsible for maintaining the inventory in working order. Currently, the State has instruments from several manufacturing series in place, with the oldest dating back to 1988. As the instruments age, the frequency and extent of maintenance and repairs also increases.

Vermont Infrared Purchase History

40	between 1980 and 1993
30	in 1995-96
2	in 1997 for mobile units
4	in 2000 for Batmobiles

While the annual preventive maintenance program has been successful in reducing the number of service calls for maintenance and repair, the reasonable equipment lifetime is being pressed to the limit. Instruments are being removed from regular service at an increasing rate and will soon deplete our inventory of reliable replacements. It is reasonable to expect that any equipment that runs 24 hours per day for more than ten or fifteen years will eventually need to be replaced. The Department of Health reports that about twenty units are in need of replacement, then 6 to 10 per year to maintain turnover and cull out frequent services needs.

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In addition to maintaining existing equipment in order to minimize repair expense and down time, it may be advisable to add to the current inventory so that police agency personnel shortages do not impede DUI processing. In these times of police officer position vacancies statewide, it is not economically feasible to authorize off-duty police, or officers doing directed patrols, to come in off the road to let another officer in to use the DataMaster in a building without any officers on duty.

With no end in sight for police staffing shortages, it would be advantageous to maximize efficiency of the DUI process. The cost of a DataMaster is significantly less than the cost of adding police hours (*if* they were available) for DUI enforcement. By placing DataMasters in more locations, travel time will be reduced for suspected impaired operators, resulting in fewer police hours and more successful prosecution. Both the arresting officer's time will be reduced, and it will not be necessary to call in an off-duty or otherwise working officer just to make the DataMaster available. It also increases the likelihood of testing within a two-hour period of the stop, which simplifies prosecution issues.

Several options for implementing a DataMaster replacement program have been discussed. Department of Health, the Governor's Highway Safety Program, States Attorneys, Vermont Chiefs of Police, Sheriffs Association and Vermont State Police participated in the discussions as part of an informal infrared breath testing advisory committee. The options discussed include: phased purchase, mass purchase and perpetual replacement purchase programs.

1. Phased Purchase. To purchase 80 units to replace current models and add units in remote locations to cut police officer travel time, Vermont would purchase a set number of units for a set number of years. Twenty per year for four years would replace all of our aging units and provide equipment for new locations. The numbers and span of years would be determined by funding source and scheme.
2. Mass Purchase. Eighty units would be purchased on one order.
3. Perpetual replacement purchase. Vermont would commit to purchase 5 to 10 units per year. This would create an ever-rotating inventory of units without requiring a large, one-time layout of funds.

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The approach favored by many, but not all, discussion members is mass purchase of a large (i.e. 75-80) number of new DataMaster instruments at one time. Advantages in taking this approach are to assure consistency of equipment used for BAC testing (same design in one manufacturing series); simplify any training updates that may be needed when newer (different) models are installed, and reduce the cost per unit based on volume purchase (i.e. a savings up to \$35,000). It would take approximately a year for the manufacturer to deliver the total number of instruments and 18-24 months to for laboratory staff to certify and install them in the field. This schedule is expected to be compatible with current staffing resources. Those instruments placed into service between 1989 and 1995 would be the first to be replaced with a focus on those that have had a higher rate of need for service.

Cost per unit on current Vermont contract:

1-10 units	\$6,253.00
11-20 units	\$6,100.00
21 + units	\$5,998.00

It must be noted that if a graduated replacement plan is implemented, it will likely result in some differences among the instruments in use throughout the state. These differences will not affect the status of recognition by National Highway Traffic Safety Administration on their "Conforming Products" list nor change the way breath samples are analyzed. These differences will create the need for an increased parts inventory.

The group also discussed various funding options.

1. New state dollars – due to budget situation in Vermont, no new funds are anticipated to be available.
2. Current federal highway safety funds – the current and anticipated federal highway safety funds (~ \$720,000/year) for the foreseeable future are committed to on-going public education and law enforcement programs.
3. Penalty transfer funds – The current TEA 21 § 164 penalty provisions cause ~\$2,400,000 to be transferred to the highway safety program from the Vermont FHWA highway fund. The Vermont legislature utilizes a provision in TEA 21 to direct those funds to the Agency of Transportation for hazard elimination projects.

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The informal committee addressing this growing problem has no authority to designate a funding source for IR replacement. Our goal is to bring information to State managers so this looming problem can be addressed in a thoughtful, considered manner before it becomes a crisis.

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DRAFT BUDGET FOR IR REPLACEMENT:

80	DataMaster units @ \$6,000-7,000	\$480,000-\$560,000
80	External printers @\$100	\$8,000
20	Install phone lines for data download @ \$125	\$2,500
	Repair & replace DOH Lab shop repair equipment: \$4,000 Oscilloscope \$600 Multimeters \$400 Tools for field \$300 PDA \$25,000 Dedicated service vehicle \$3,000 Computerized set up for e m prompts	\$33,300
	3-year parts & supplies inventory for new DMs	\$30,000
8	Officer & DM supervisor regional training & updated materials Interactive computer based training and manual updates	\$12,000
	TOTAL	\$565,800 \$645,800

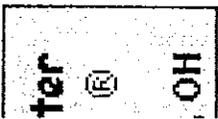
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4/14/11

**State of Vermont Health Department
Infrared Maintenance Shop**

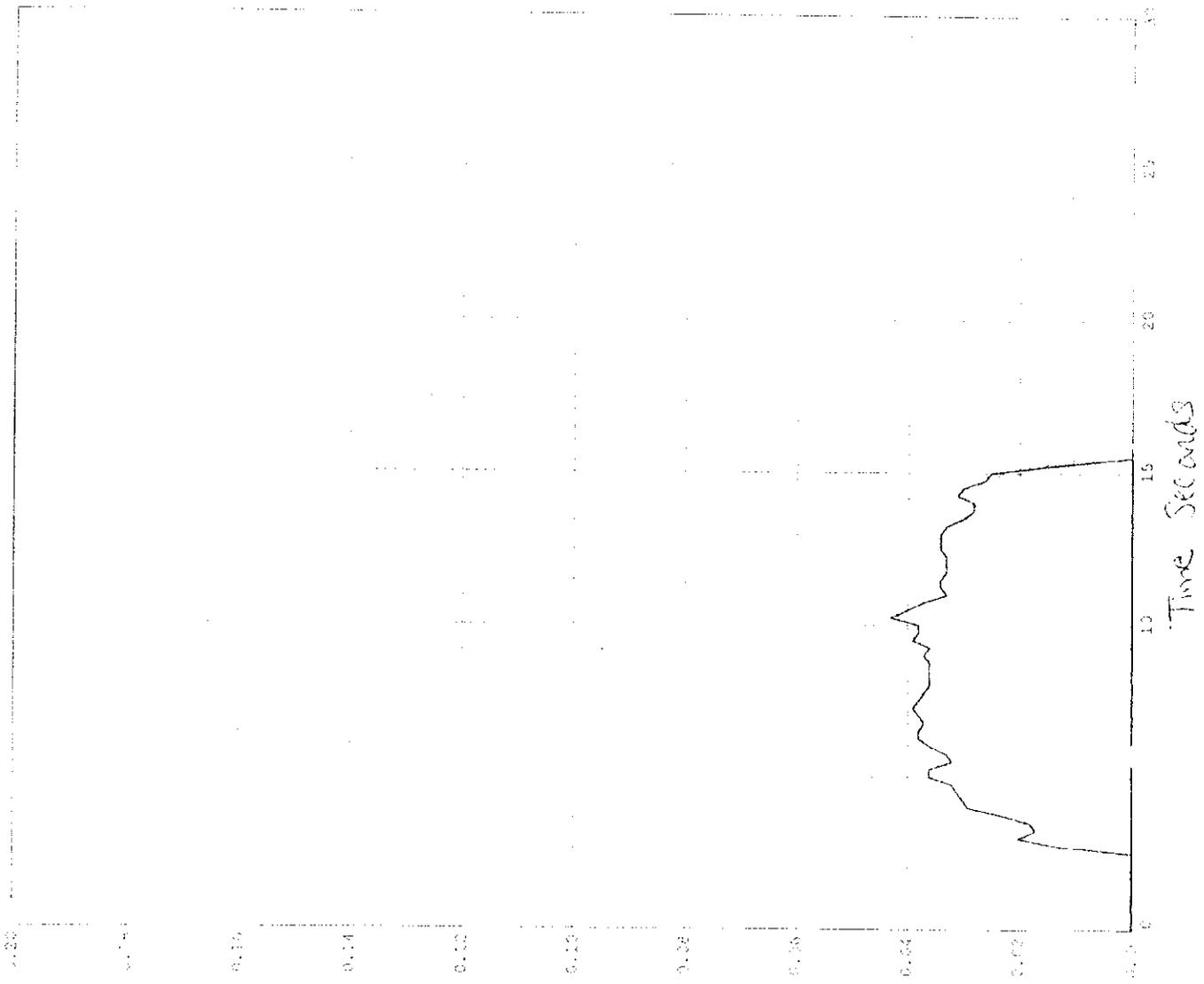
Cost of the Infrared Laboratory inventory of Spare Parts and Tools

BAC DataMaster inventoried spare parts	\$12,200
Guth Simulator Spare (s) and Parts (est.)	\$5,000
Miscellaneous Spares and supplies (est.)	\$2,000
Field Service tools (est.)	\$1000
Laboratory tools (est.)	\$2000
Laboratory Equipment (est.)	\$3500
Cost to set up new Infrared Maintenance shop (from Scratch) Tools and (small) Equipment	\$6000
Year to Year cost of Tools and Consumable Spare Equipment	\$1500



24122

- 17.115
- 17.128
- 17.130
- 17.138
- 17.141
- 17.151



VERMONT DEPARTMENT OF HEALTH LABORATORY OFFICE MEMORANDUM

TO: R. Drawbaugh, Program Chief

FROM: Darcy Richardson

DATE: November 30th, 2007

RE: The 0.020 level on Breath Testing Equipment

In testing the DMT breath alcohol testing device it has come to our attention that, like it's predecessor and other breath testing equipment, the DMT has difficulty providing results with a minimum accuracy of +/- 10% at the 0.020 BrAC level. The current rules state that all breath alcohol testing equipment used for evidentiary purposes in the state of Vermont must be capable of analyzing a sample of breath with an accuracy of +/-10%. This rule does not specify a concentration range in which the equipment must be capable of meeting this standard. It should also be noted that the Federal Rules for evidentiary breath testing equipment acknowledge this difficulty by expanding the minimum accuracy to 25% at the 0.020 level.

As all data that we are currently generating will be actively requested for discovery when the instruments are put into use in the field, we have three options in response to this performance.

- 1) Change nothing and acknowledge that the instrument fails outside the lower range at the 0.020 level but meets the minimum accuracy standard at all other levels. This will leave 0.080 as our lowest tested level meeting this performance criteria and may subject breath tests below this level to scrutiny in the courtroom.
- 2) Change our current Vermont Rules and Regulations to those of the federal rules and regulations which allow a wider range at the 0.020 level and would provide a more accurate depiction of the instrument's capability.
- 3) Leave the rules and regulations as they are and repeat the testing that has already been done with a standard at a 0.040 level. At this level the instrument will not have problems in meeting the minimum accuracy requirement and would also have the advantage of establishing the instrument's accuracy capability at another sanctioned level as 0.04 is the level for CDL drivers.

My recommendation is to change the rules and regulations to conform to those of the federal government. Failing this, I would recommend we repeat the previous testing with a 0.040 simulated breath alcohol concentration.

Department of Health Requisition

From: RJD Date: 4/5/06

Date: _____

Shipped To: 195 Colchester Avenue
Burlington VT 05401

Requisition # _____

Department ID #: _____

Program Code # _____

Date Required: 8/1/06

Fund Code # _____

Approved by Director _____

Item	Quantity	Unit	Description: Give complete description	Catalog #	Object Code	Total
	20	ea	Evidential Breath Alcohol test instruments meeting attached specifications Vendor bids must include description of specifications not met by the product being bid and, where appropriate, a description of how the required function is met by their design.			\$128,000.00
<p>Vendor Name list attached</p> <p>DEPT/PROGRAM CODES Administration 3420030810 39434 PERCENTAGE 100%</p> <p>DEPT/PROGRAM CODES Administration 3420030810 39434 PERCENTAGE 00%</p> <p>DEPT/PROGRAM CODES Administration 3420030810 39434 PERCENTAGE 0%</p> <p>DEPT/PROGRAM CODES Administration 3420030810 39434 PERCENTAGE 0%</p> <p>Approved by RJD Date: 4/5/06</p> <p>(If over \$1,000) Authorized by Laboratory Director</p> <p style="text-align: center;">Date: _____</p>						

Vermont Department of Health Laboratory
Toxicology Program
Memorandum

To: Mary Celotti, Laboratory Director
From: Robert Drawbaugh, Toxicology Program Chief
Date: April 14, 2011
Re: New Breath Testing Equipment

Attached is a brief review and recommendation for purchase of new breath testing equipment to be used for evidential dui testing in replacement of DataMaster instruments currently in inventory. Detailed specifications are nearly complete which should be used in the purchasing process. A sole vendor approach can be made based on our long-standing relationship with NPAS, the manufacturer of the DataMaster currently in use or, bids can be requested from all four manufacturers based on the specifications provided. If bids are requested, we must require statements from the bidders regarding which specifications they do not meet and a description of their equivalent technology or design.

Recommendations for Breath Testing Equipment Purchase

Based on completion of our evaluation of four different models of breath alcohol testing equipment, and incorporation of advice from Highway Safety, law enforcement and the State's Attorneys Assoc., our summary and recommendations regarding purchase of new instrumentation to replace some of the ageing DataMaster breath test units or those that need more frequent repairs is as follows.

Testing was performed over a span of 6 months with participation by five program staff including chemists, the electronics technician and a laboratory technician. The testing performed was designed to be an initial familiarization with the operation and basic performance characteristics of the equipment. Included in the considerations was the effectiveness of communication with the manufacturer regarding operation or setup of the instrument.

While all of the units tested perform the basic function of testing vapor or breath samples for presence of alcohol and reporting the alcohol concentration, there are various detection technologies and ways of using those technologies. It is our recommendation that new instrumentation to be purchased use only infrared technology for alcohol detection and quantitation. This criterion applies to two of the four tested models provided from different manufacturers. This is consistent with what has been in use in our program for more than 15 years and has been accepted as valid and reliable across the state for dui breath testing.

One infrared only model was provided by CMI, Inc. who has had a number of similar units in use nationally for a few years. The other infrared only model was provided by the manufacturer of the equipment currently in use but is significantly different in components and packaging. Both models use the same basic technology for alcohol identification and quantitation as that in current use. Data for these instruments from the testing performed show that they are both capable of performance requirements identified in the current breath testing rules as established by the Department of Health. During this testing the National Patent Analytical Systems, Inc. DMT model showed greater stability, as reflected in precision measurements, than the CMI, Inc. Intoxylizer 8000. There was also greater success in identifying potentially interfering substances in mixed vapor samples when tested with the NPAS DMT.

The manner in which breath test information is recorded and reported also differs in these two instruments. The real-time graphing of breath flow and report of breath volume as provided in the DMT could be advantageous to the operator by providing information about the quality of the breath sample being given by the test subject. There is also some favor expressed for the touch-screen interface incorporated into the DMT as it reduces the number of keystrokes needed for completing a processing.

Some concern has been expressed that the DMT is a new model and does not have a history of field use to rely upon for expectation of long-term performance and maintenance/repair needs. Additionally, the State's Attorney's Liaison noted that there would be little case law established for reference when prosecuting cases early in the transition. Since the DMT model is based on the same infrared technology now in use, we do not expect substantial legal challenges beyond what is currently experienced in routine dui legal proceedings.

At this time it would be our recommendation that purchase of new equipment for transition in the dui breath testing program be preferentially the NPAS DMT with the satisfaction of the following requirements: 1. the manufacturer can provide documentation of acceptance of the model by NHTSA for inclusion on its Conforming Products List; 2. price is not substantially greater than that of the CMI I-8000; 3. the required number of units meeting our operation and performance specifications can be delivered by no later than Oct. 31, 2006; 4. there are no substantive design changes to the instrument within the purchase and implementation time frame; 5. Instruments provided meet or exceed minimum product design, operation and performance specifications provided in an RFQ or Purchase Requisition.

January 15, 2010

Dear DataMaster Supervisor:

This kit contains ~~some of the~~ materials you will need to complete the year 2010 DataMaster Routine Performance Checks (RPC). These RPC's are recommended to demonstrate the performance reliability of the DataMaster in use at your site. The process and documentation are important for the effective prosecution of DUI offenders. RPC's are to be performed for the DataMaster instrument at your site during **February, June and October** of 2010.

We recommend using your DataMaster Supervisor Manual, during the performance of your RPC's. We have provided simulator solution for use in the RPC's or as needed to maintain the instrument between RPC's. Additional solution will be distributed in July. Please try to use the solution provided on a first in first out basis.

Please complete the Routine Performance Check and send us a copy of the data by the last day of the month due. You will receive reminders for each RPC cycle.

This kit is built specifically for your agency. There may not be ~~you may not have~~ mouth pieces or tickets supplied at this time based on frequency of use of type of instrument in your agency ~~usage~~. If you need additional supplies, you may request them by sending us a DataMaster Supplies Request Form [Alc 501]. Please recycle any unused old forms and remember all of our forms are available to instrument supervisors via e-mail attachment in Microsoft Word format.

If you have any questions about this process, instrument operation or service needs please call or E-Mail our program staff.

Thank you for your careful attention to this important process in assuring fair and accurate testing of DUI suspects.

Cordially Yours,

Steven Harnois
Public Health Electronics Technician
Sharnoi@vdh.state.vt.us
(802) 863 7641 or Toll Free (800) 660 9997 x 7641

January 13, 2010

To DataMaster DMT Agencies:

The Vermont Department of Health Laboratory Toxicology Program would like to thank you for your participation in the successful launch of the new DataMaster DMT evidential breath testing instrument in Washington and Windham counties.

The next step in the launch process is to train individuals to perform the duties of a DataMaster DMT Supervisor. Each agency is required to maintain at least one proficient DMT Supervisor. Supervisors will be trained to perform simple maintenance and repairs on the instrument. Anyone who was previously trained to be a BAC DataMaster Supervisor will need retraining in order to become a DMT Supervisor.

In addition, this DataMaster has many record keeping capabilities that the previous instrument did not. As such, this instrument will require people to be trained to perform the duties of a Record Administrator. A Record Administrator will be responsible for providing materials in response to discovery requests and/or providing monthly updates to the State's Attorney's Office if requested. A DataMaster DMT Supervisor may assume the duties of a Record Administrator if a second individual is not available.

The training requirements for a DataMaster DMT Supervisor is one, four (4) hour hands-on course. The Record Administrator training will be held simultaneously, however their portion of the course will only last approximately one hour at the beginning of the session.

Please contact Cindy Taylor-Patch at the Vermont Police Academy with the names of the people your department has assigned the duties of a DataMaster DMT Supervisor and Record Administrator. There are four training sessions available; Monday, February 1st from either 0800-1200 or 1230-1630 or Tuesday February 2nd from 0800-1200 or 1230-1630.

Thank you for your continued support and prompt response.

Sincerely,

Mary Celotti
Laboratory Director

January 13, 2010

To DataMaster DMT Agencies:

The Vermont Department of Health Laboratory Toxicology Program would like to thank you for your participation in the successful launch of the new DataMaster DMT evidential breath testing instrument in Washington and Windham counties.

The next step in the launch process is to train individuals to perform the duties of a DataMaster DMT Supervisor. Each agency is required to maintain at least one proficient DMT Supervisor. Supervisors will be trained to perform simple maintenance and repairs on the instrument. Anyone who was previously trained to be a BAC DataMaster Supervisor will need retraining in order to become a DMT Supervisor.

In addition, this DataMaster has many record keeping capabilities that the previous instrument did not. As such, this instrument will require people to be trained to perform the duties of a Record Administrator. A Record Administrator will be responsible for providing materials in response to discovery requests and/or providing monthly updates to the State's Attorney's Office if requested. A DataMaster DMT Supervisor may assume the duties of a Record Administrator if a second individual is not available.

The training requirements for a DataMaster DMT Supervisor is one, four (4) hour hands-on course. The Record Administrator training will be held simultaneously, however their portion of the course will only last approximately one hour at the beginning of the session.

Please contact Cindy Taylor-Patch at the Vermont Police Academy with the names of the people your department has assigned the duties of a DataMaster DMT Supervisor and Record Administrator. There are four training sessions available; Monday, February 1st from either 0800-1200 or 1230-1630 or Tuesday February 2nd from 0800-1200 or 1230-1630.

Thank you for your continued support and prompt response.

Sincerely,

Mary Celotti
Laboratory Director

January 13, 2010

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