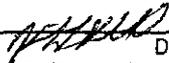


Title: Laboratory Certification of DataMaster DMT		Page 1 of 8
Doc. No. P-Alc-118 Revision No.1	Approved By:  Owner: Kirk Kimball, Organic Chemistry Program Chief	Date: 8/4/11 5-4-11 Date Effective: 8/4/11

1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the optical bench of the instrument will be certified after having first been powered up and calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Organic Chemistry Program Chief.
- 2.2. This procedure will be reviewed periodically by Organic Chemistry staff. Revisions of the procedure will be made when a need is identified.

3.0 Precautions

- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3. Instruments must have a power up procedure performed and be calibrated prior to certification. See power up procedure (P-Alc-116) and calibration procedure (P-Alc-117).
- 3.4. When connecting simulators during the linearity testing, if Guth 2100 simulators are being used, ensure that tubing connections are as short as possible. Direct connection simulators are preferred.

4.0 Procedure Steps

4.1. Materials and Supplies are all located in Room 124.

- 4.1.1. DataMaster DMT Instrument.
- 4.1.2. NIST traceable thermometer.
- 4.1.3. DataMaster Mouthpieces.
- 4.1.4. Mouth alcohol test solution.
- 4.1.5. A radio frequency transmitter.
- 4.1.6. Wet bath simulators.

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Doc. No. P-AIC-118 Revision No.1	Approved By: <i>KAC</i> Owner: Kirk Kimball, Organic Chemistry Program Chief	Date: 8/4/11 <i>8-4-11</i>	Date Effective: 8/4/11

Figure 1: Certification Solutions

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.02 EtOH	± 0.002 (10%)
Linearity 2	Ethanol	0.08 EtOH	± 0.004 (5%)
Linearity 3	Ethanol	0.16 EtOH	± 0.008 (5%)
Linearity 4	Ethanol	0.40 EtOH	± 0.020 (5%)
Interference	Acetone in Ethanol	0.01% Acetone (% by vol) in 0.080 EtOH	INTERFERENCE

4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a thermometer calibrated to NIST standards. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, solution lot number, target concentration, date opened, expiration date and simulator solution NIST (traceable thermometer) temperature of each concentration.

4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter your password. Enter the name of the technician performing the certification.
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
 - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
 - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
 - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
 - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

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- 4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R²" to perform an R² statistical analysis.
- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button. The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
- 4.3.2.7.1. To complete the mouth alcohol test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
- 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube.
- 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RF detection test press the "RF" button. When the detector voltage box pops up, key a handheld radio near the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
- 4.3.2.9.1. The DMT will run through a series of quality control checks.
- 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
- 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
- A) Shallow Breath:** Very lightly blow a small amount of air into the mouth piece, allowing some air to escape out the sides of your mouth. The air flow should be very slight, but strong enough to just register air flow (blue line) on the screen. Blow for a few seconds then stop. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- B) Intermittent Breath:** Strongly blow into the mouth piece for 1-2 seconds and stop a couple of times. Be careful not to suck back on the mouth piece between puffs of air. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- C) Suck Back Test: VERY GENTLY** suck back on the mouth piece just enough so you feel a one-way valve stop the air flow (less than one second of pressure). If you suck too hard, you may damage the one-way valve. Once you feel this one way valve hit, you are finished. **Do not continue to suck back on the breath tube. Once is enough.**

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Doc. No. P-Alc-118 Revision No. 1	Approved By: <i>AKR</i> ⁸⁻⁴⁻¹¹ Owner: Kirk Kimball, Organic Chemistry Program Chief	Date: 8/4/11	Date Effective: 8/4/11

The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.

D) 1.5L Alcohol Free Sample: While watching the total volume box in the bottom right corner of the screen, provide a sample of ~1.5L of air to the instrument. The instrument should accept a sample of 1.5L of air. The instrument should **not** report an alcohol response.

E) If any elevation of the alcohol line above 0 is visible, rerun the Sample Acceptance Test.

4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.

4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.

4.3.4. Inspect the certification report and ensure that all tests are acceptable. See Appendix A for an example of a passing Certification Report.

4.3.5. Assign a simulator to the DataMaster DMT Instrument, see Appendix B: How to Assign a Simulator to a DMT.

4.3.6. Once the simulator has been assigned to the DMT, perform a diagnostic check to demonstrate that the temperature of the simulator is being monitored and is within range.

4.3.7. Give all documents and the Certification Log book to another program staff member for review. All documents must be reviewed by three VDHL personnel, including the analyst.

4.3.8. Once the review is complete, the certification paperwork is filed as follows.

4.3.8.1. One copy is attached to the Technical Support Inquiry associated with the maintenance/repair.

4.3.8.2. One copy of the document is put in filing cabinet A in room 124, in the folder designated for the current month's completed work.

4.3.8.3. A third copy of the certification paperwork will be brought with the instrument during installation and will remain in the custody of the agency where the unit is installed.

4.3.8.4. An electronic copy of the certification (if available) will be placed in the instruments electronic folder on the VDH server

Y:\VDH\VDH All Share\Lab\Alcohol\Datamaster DMT electronic documents

Title: Laboratory Certification of DataMaster DMT		Page 5 of 8
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5.0 Emergency or High Priority Situations

- 5.1. The Laboratory Director or Organic Chemistry Program Chief may designate any DataMaster DMT certification to be a high priority and request certification is completed as soon as possible.

6.0 Quality Criteria and Corrective Action

- 6.1. For each step in the certification, a technician will attempt the test no more than three times. If the instrument fails to pass the step after three attempts, the certification will be deemed failing and further troubleshooting should be initiated.
- 6.2. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.3. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another organic chemistry staff member. Try to correct the problem and document the event.
- 6.4. All work performed must be documented on a Technical Support Inquiry (AIC 626). TSI's are filed in each instrument's file located in one of the two locked filing cabinets in Room 124.

7.0 Preventative Maintenance and Backup Procedures

- 7.1. If a problem is encountered that cannot be resolved by Organic Chemistry staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.
 - 7.1.1. Contact NPAS at 1-800-800-8143 or service@npas.com.
- 7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

8.0 References

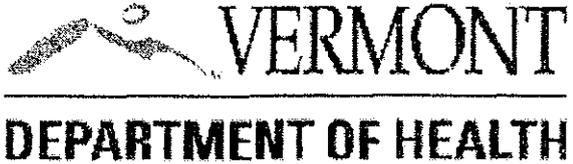
- 8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2. VDHL DataMaster DMT Technical Manual.
- 8.3. Technical Support Inquiry (AIC 626).
- 8.4. Logbook: DataMaster Certification Solution Information
- 8.5. Appendix A: Acceptable Certification Report.
- 8.6. Appendix B: How to Assign a Simulator

Appendix A
Acceptable Certification Report

Handwritten initials and date: 12/16/08

CERTIFICATION REPORT

DataMaster DMT: 101708
Calibration Date: 12/16/2008
Certification Date: 12/16/2008
Certified by: STEVEN E HARNOIS



Diagnostic Results

VERSIONS

DMT 1.00
PIC 2.05
Modem 1.04
Questions 1.00
Reports 1.00

TEMPERATURES

Sample Chamber = 48.80°C
Breath Tube = 46.63°C

SETTINGS

Lamp Voltage = 2.20 V
Cooler Voltage = 2.05 V
Bias Voltage = 120.1 V
Chopper Freq = 537.5 Hz

PUMP INFO

Flow Rate = 4.625 L/M

DETECTOR INFO

PUMP ON OFF
MAX(V) -0.0236 -0.0197
MIN(V) -0.0264 -0.0224

FILTER INFO

Filter 1 -0.023 Zero = true
Filter 2 0.420 Zero = true
Filter 3 0.648 Zero = true

CALIBRATION CHECK

Xq = 0.1275 0.14%

Options

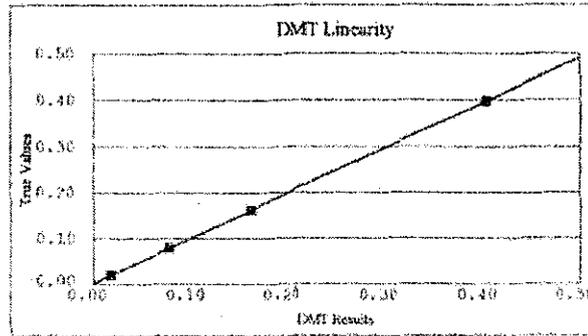
Printer: yes
Number of Copies: 3
Number of Supervisor Tests: 10
Tolerance Check: yes
Data Collection: yes
Units: g/210L
Simulator Check: yes
Uses Wet Bath Simulator: yes
Simulator Nominal: 0.101
Digital Simulator: none
Simulator Before: yes
Simulator Between: yes
Simulator After: no
Number of Subject Tests: 2
AskQuestions: yes
Query Refusal: yes
Alcohol Display: yes
Show Two Digits: no
Volume Display: yes
Number of Calibration Tests: 1
Calibrate with Wet Bath: yes
Calibration Nominal: 0.100

Roll 8-4-4

Linearity Check Results

True Value	Reported Average	Std Dev
0.020 g/210L	0.018 g/210L	0.001
Lot # 09-06-020		
0.080 g/210L	0.078 g/210L	0.001
Lot # 09-01-080		
0.162 g/210L	0.161 g/210L	0.000
Lot # 09-03-160		
0.397 g/210L	0.404 g/210L	0.001
Lot # 09-12-400		

R² = 0.9999



Acetone Interference Test

Lot # 09-01-08A

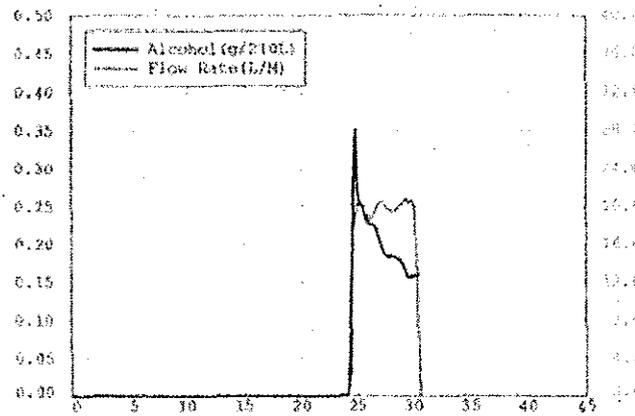
Interference Detected

Mouth Alcohol Test

Mouth Alcohol Detected

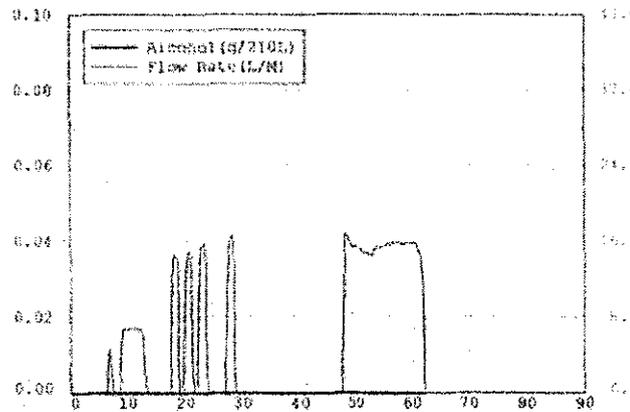
RF Interference Test

RFI detected



Sample Acceptance Test

Passed



CERTIFICATION PASSED

Performed by [Signature]

Date 12/16/2008

Reviewed by [Signature]

Date 12/16/08

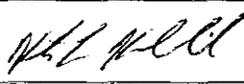
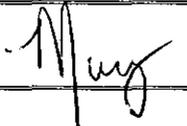
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8-4-11

Appendix B How to Assign a Simulator to a DataMaster DMT

1. Procure a simulator to be assigned to a DataMaster.
2. Check the 2-wire temperature board in the simulator head. Replace any Rev-A boards.
3. Preliminarily check the simulator to see if it will closely fit to the simulator tower of the DataMaster in question.
4. Adjust the quick-connect on the simulator head so that the button to release the lock is pointed up. Take care not to twist or kink the tubing during adjustment.
5. Adjust the distance between the quick-connects on the tower of the DataMaster so that when connected, the BNC cable will fit into it's designated opening.
 - a. The BNC cable should not touch the sides of the opening to prevent damage to the rubber coating on the BNC cable and grounding of the simulator temperature reporting system.
 - b. The two quick connect ports attaching the simulator to the tower of the DataMaster should easily align. The height of the jar may be a factor in this alignment and can be adjusted by using a different simulator jar.
 - c. If the simulator cannot be made to easily attach to the tower of the DataMaster, it may be necessary to try a new simulator.
6. Ensure that the release buttons to the quick connects on the DataMaster tower are pointed upwards to allow ease of use.
7. Tighten the quick connects on the simulator tower so that they do not move from the ideal location. Take care not to twist or kink the tubing during adjustment.
8. Check the jar for chips and/or cracks and replace as necessary.
9. Check the O-ring on the head of the simulator to ensure it is present, appropriately seated and free from damage. Replace as necessary.
10. Fill the simulator with 500mL of water or simulator solution.
11. Perform a pressure check on the simulator to ensure an adequate seal. Repair and/or replace as necessary.
12. Allow the simulator temperature to equilibrate (at least 30 minutes).
13. Insert a NIST traceable thermometer into the simulator via the temperature testing port.
14. Ensure that the simulator is maintaining the appropriate temperature ($34^{\circ}\text{C} \pm 0.2^{\circ}$).
 - a. Adjust the heater on the simulator as necessary.
 - b. If the heater is adjusted, allow 30 minutes for the temperature to re-equilibrate.
15. Attach the BNC cable from the DataMaster DMT to the simulator.
16. Allow the thermometer and DMT to equilibrate (approximately 2 minutes).
17. Ensure the DataMaster is registering the same temperature as reported by the NIST traceable thermometer.
 - a. Adjust the signal from the simulator to the DataMaster as necessary.
 - b. If the signal is adjusted, allow the signal to re-equilibrate and ensure correlation.
18. Once complete, close the temperature testing port by snugly threading the bolt into the opening.
19. Once all adjustments have been made, close the arms of the simulator tower around the simulator head and secure with a lock.

Vermont Department of Health Laboratory Procedure and Document Review Coversheet

Document Title: Lab Certification of DMT	
Document #: P-Alc-118	Revision #: 1
File Name:	
Author or Editor: Bolduc	Owner: Kimball
Start Date: 062011	Due Date: 06/27/11

Name and Title of Reviewers	Signature	Comments? Y/N *	Date of Signature	Control Copy #
Kirk Kimball		Y <input checked="" type="checkbox"/>	6-30-11	
Steve Merrill		Y <input checked="" type="checkbox"/>	06/21/11	
Steve Harnois		Y <input checked="" type="checkbox"/>	6/29/11	
Ed Luce				
Mary Celotti		Y <input checked="" type="checkbox"/>	7/15/11	
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* (Y) in checkbox indicates reviewer comments have been discussed and incorporated if applicable.

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Doc. No. P-Alc-118 Draft Revision No. 1 5/11	Approved By: Owner: Organic Chemistry Program Chief	Date: Date Effective:

1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the optical bench of the instrument will be certified after having first been powered up and calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Organic Chemistry Program Chief.
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- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3. Instruments must have a power up procedure preformed and be calibrated prior to certification. See power up procedure (P-Alc-116) and calibration procedure (P-Alc-117).
- 3.4. When connecting simulators during the linearity testing, if Guth 2100 simulators are being used, ensure that tubing connections are as short as possible. Direct connection simulators are preferred.

4.0 Procedure Steps

4.1. Materials and Supplies are all located in Room 124.

- 4.1.1. DataMaster DMT Instrument.
- 4.1.2. NIST traceable thermometer.
- 4.1.3. DataMaster Mouthpieces.
- 4.1.4. Mouth alcohol test solution.
- 4.1.5. A radio frequency transmitter.
- 4.1.6. Wet bath simulators.

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Figure 1: Certification Solutions

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.02 EtOH	± 0.002 (10%)
Linearity 2	Ethanol	0.08 EtOH	± 0.004 (5%)
Linearity 3	Ethanol	0.16 EtOH	± 0.008 (5%)
Linearity 4	Ethanol	0.40 EtOH	± 0.020 (5%)
Interference	Acetone in Ethanol	0.01% Acetone (% by vol) in 0.080 EtOH	INTERFERENCE

4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a thermometer calibrated to NIST standards. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, solution lot number, target concentration, date opened, expiration date and simulator solution NIST (traceable thermometer) temperature of each concentration.

4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter your password. Enter the name of the technician performing the certification.
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
 - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
 - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
 - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
 - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

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- 4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R²" to perform an R² statistical analysis.
- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button. The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
- 4.3.2.7.1. To complete the mouth alcohol test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
- 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube.
- 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RF detection test press the "RF" button. When the detector voltage box pops up, key a handheld radio near the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
- 4.3.2.9.1. The DMT will run through a series of quality control checks.
- 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
- 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
- A) Shallow Breath:** Very lightly blow a small amount of air into the mouth piece, allowing some air to escape out the sides of your mouth. The air flow should be very slight, but strong enough to just register air flow (blue line) on the screen. Blow for a few seconds then stop. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- B) Intermittent Breath:** Strongly blow into the mouth piece for 1-2 seconds and stop a couple of times. Be careful not to suck back on the mouth piece between puffs of air. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- C) Suck Back Test: VERY GENTLY** suck back on the mouth piece just enough so you feel a one-way valve stop the air flow (less than one second of pressure). If you suck too hard, you may damage the one-way valve. Once you feel this one way valve hit, you are finished. **Do not continue to suck back on the breath tube. Once is enough.**

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The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.

D) 1.5L Alcohol Free Sample: While watching the total volume box in the bottom right corner of the screen, provide a sample of ~1.5L of air to the instrument. The instrument should accept a sample of 1.5L of air. The instrument should **not** report an alcohol response.

E) If any elevation of the alcohol line above 0 is visible, rerun the Sample Acceptance Test.

- 4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.
- 4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.
- 4.3.4. Inspect the certification report and ensure that all tests are acceptable. See Appendix A for an example of a passing Certification Report.
- 4.3.5. Assign a simulator to the DataMaster DMT Instrument, see Appendix B: How to Assign a Simulator to a DMT.
- 4.3.6. Once the simulator has been assigned to the DMT, perform a diagnostic check to demonstrate that the temperature of the simulator is being monitored and is within range.
- 4.3.7. Give all documents and the Certification Log book to another program staff member for review. All documents must be reviewed by three VDHL personnel, including the analyst.
- 4.3.8. Once the review is complete, the certification paperwork is filed as follows.
- 4.3.8.1. One copy is attached to the Technical Support Inquiry associated with the maintenance/repair.
- 4.3.8.2. One copy of the document is put in filing cabinet A in room 124, in the folder designated for the current month's completed work.
- 4.3.8.3. A third copy of the certification paperwork will be brought with the instrument during installation and will remain in the custody of the agency where the unit is installed.
- 4.3.8.4. An electronic copy of the certification (if available) will be placed in the instruments electronic folder on the VDH server

Y:\VDH\VDH All Share\Lab\Alcohol\Datamaster DMT electronic documents

Title: Laboratory Certification of DataMaster DMT		Page 5 of 8
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5.0 Emergency or High Priority Situations

- 5.1. The Laboratory Director or Organic Chemistry Program Chief may designate any DataMaster DMT certification to be a high priority and request certification is completed as soon as possible.

6.0 Quality Criteria and Corrective Action

- 6.1. For each step in the certification, a technician will attempt the test no more than three times. If the instrument fails to pass the step after three attempts, the certification will be deemed failing and further troubleshooting should be initiated.
- 6.2. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.3. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another organic chemistry staff member. Try to correct the problem and document the event.
- 6.4. All work performed must be documented on a Technical Support Inquiry (AIc 626). TSI's are filed in each instrument's file located in one of the two locked filing cabinets in Room 124.

7.0 Preventative Maintenance and Backup Procedures

- 7.1. If a problem is encountered that cannot be resolved by Organic Chemistry staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.
 - 7.1.1. Contact NPAS at 1-800-800-8143 or service@npas.com.
- 7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

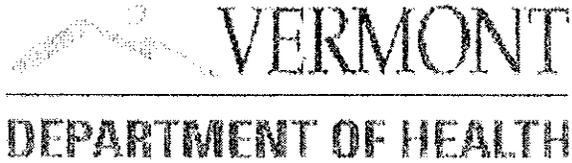
8.0 References

- 8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2. VDHL DataMaster DMT Technical Manual.
- 8.3. Technical Support Inquiry (AIc 626).
- 8.4. Logbook: DataMaster Certification Solution Information
- 8.5. Appendix A: Acceptable Certification Report.
- 8.6. Appendix B: How to Assign a Simulator

Appendix A
Acceptable Certification Report

CERTIFICATION REPORT

DataMaster DMF: 101708
Calibration Date: 12/16/2008
Certification Date: 12/16/2008
Certified by: STEVEN E HARNOIS



Diagnostic Results

VERSIONS

DMF 1.00
DC 2.05
Modem 1.04
Questions 1.00
Reports 1.00

TEMPERATURES

Sample Chamber = 48.80°C
Inlet Tube = 46.63°C

SETTINGS

Lamp Voltage = 2.70 V
Cuvette Voltage = 2.05 V
Bias Voltage = 1.00 V
Chopper Freq = 532.5 Hz

PUMP INFO

Flow Rate = 4.075 L/M

DETECTOR INFO

PUMP ON OFF
MAX(V) 4.0236 4.0197
MIN(V) 4.0264 4.0124

FILTER INFO

Filter 1 0.023 Zero = true
Filter 2 0.120 Zero = true
Filter 3 0.648 Zero = true

CALIBRATION CHECK

X₀ = 0.275 0.10%

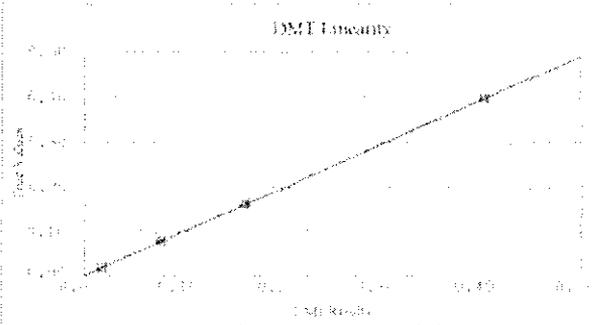
Options

Printer: yes
Number of Copies: 3
Number of Supervision Tests: 10
Tolerance Check: yes
Data Collection: yes
Units: g/210l
Simulator Check: yes
Uses Wet Bath Simulator: yes
Simulator Nominal: 0.100
Digital Simulator: none
Simulator Before: yes
Simulator Between: yes
Simulator After: no
Number of Subject Tests: 2
Ask Questions: yes
Query Refusal: yes
Alcohol Display: yes
Show Two Digits: no
Volume Display: yes
Number of Calibration Tests: 1
Calibrate with Wet Bath: yes
Calibration Nominal: 0.100

Linearity Check Results

True Value	Reported Average	Std Dev
0.020 µg/210L	0.018 µg/210L	0.001
0.040 µg/210L	0.038 µg/210L	0.001
0.080 µg/210L	0.078 µg/210L	0.001
0.160 µg/210L	0.155 µg/210L	0.001
0.320 µg/210L	0.305 µg/210L	0.001
0.640 µg/210L	0.605 µg/210L	0.001

R² = 0.9999



Acetone Interference Test

Lot # 09-01-085

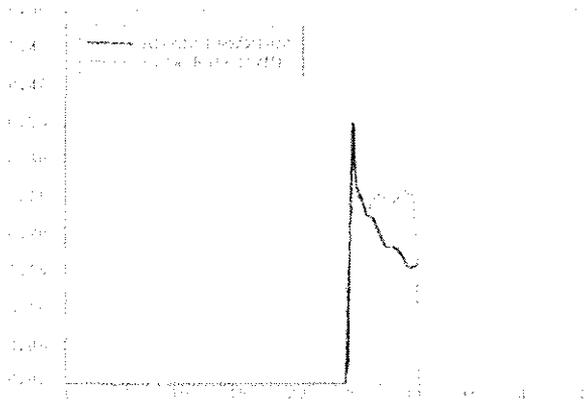
Interference Detected

Mouth Alcohol Test

Mouth Alcohol Detected

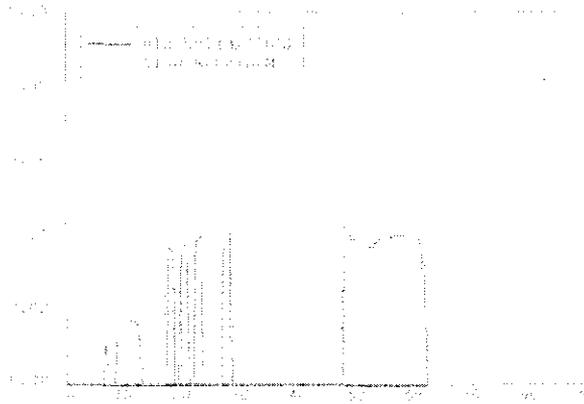
RF Interference Test

RF Detected



Sample Acceptance Test

Passed



CERTIFICATION PASSED

Performed by *[Signature]*

Date 12/16/2008

Reviewed by *[Signature]*

Date *[Signature]*

Appendix B

How to Assign a Simulator to a DataMaster DMT

1. Procure a simulator to be assigned to a DataMaster.
2. Check the 2-wire temperature board in the simulator head. Replace any Rev-A boards.
3. Preliminarily check the simulator to see if it will closely fit to the simulator tower of the DataMaster in question.
4. Adjust the quick-connect on the simulator head so that the button to release the lock is pointed up. Take care not to twist or kink the tubing during adjustment.
5. Adjust the distance between the quick-connects on the tower of the DataMaster so that when connected, the BNC cable will fit into it's designated opening.
 - a. The BNC cable should not touch the sides of the opening to prevent damage to the rubber coating on the BNC cable and grounding of the simulator temperature reporting system.
 - b. The two quick connect ports attaching the simulator to the tower of the DataMaster should easily align. The height of the jar may be a factor in this alignment and can be adjusted by using a different simulator jar.
 - c. If the simulator cannot be made to easily attach to the tower of the DataMaster, it may be necessary to try a new simulator.
6. Ensure that the release buttons to the quick connects on the DataMaster tower are pointed upwards to allow ease of use.
7. Tighten the quick connects on the simulator tower so that they do not move from the ideal location. Take care not to twist or kink the tubing during adjustment.
8. Check the jar for chips and/or cracks and replace as necessary.
9. Check the O-ring on the head of the simulator to ensure it is present, appropriately seated and free from damage. Replace as necessary.
10. Fill the simulator with 500mL of water or simulator solution.
11. Perform a pressure check on the simulator to ensure an adequate seal. Repair and/or replace as necessary.
12. Allow the simulator temperature to equilibrate (at least 30 minutes).
13. Insert a NIST traceable thermometer into the simulator via the temperature testing port.
14. Ensure that the simulator is maintaining the appropriate temperature ($34^{\circ}\text{C} \pm 0.2^{\circ}$).
 - a. Adjust the heater on the simulator as necessary.
 - b. If the heater is adjusted, allow 30 minutes for the temperature to re-equilibrate.
15. Attach the BNC cable from the DataMaster DMT to the simulator.
16. Allow the thermometer and DMT to equilibrate (approximately 2 minutes).
17. Ensure the DataMaster is registering the same temperature as reported by the NIST traceable thermometer.
 - a. Adjust the signal from the simulator to the DataMaster as necessary.
 - b. If the signal is adjusted, allow the signal to re-equilibrate and ensure correlation.
18. Once complete, close the temperature testing port by snugly threading the bolt into the opening.
19. Once all adjustments have been made, close the arms of the simulator tower around the simulator head and secure with a lock.

*Can, please
to*

Title: Laboratory Certification of DataMaster DMT		Page 1 of 8
Doc. No. P-Alc-118 Draft Revision No. 1 5/11	Approved By: Owner: Organic Chemistry Program Chief	Date: Date Effective:

1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the optical bench of the instrument will be certified after having first been powered up and calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Organic Chemistry Program Chief.
- 2.2. This procedure will be reviewed periodically by Organic Chemistry staff. Revisions of the procedure will be made when a need is identified.

3.0 Precautions

- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3. Instruments must have a power up procedure preformed and be calibrated prior to certification. See power up procedure (P-Alc-116) and calibration procedure (P-Alc-117).
- 3.4. When connecting simulators during the linearity testing, if Guth 2100 simulators are being used, ensure that tubing connections are as short as possible. Direct connection simulators are preferred.

4.0 Procedure Steps

4.1. Materials and Supplies are all located in Room 124.

- 4.1.1. DataMaster DMT Instrument.
- 4.1.2. NIST ^{traceable} ~~certified~~ thermometer.
- 4.1.3. DataMaster Mouthpieces.
- 4.1.4. Mouth alcohol test solution.
- 4.1.5. A radio frequency transmitter.
- 4.1.6. Wet bath simulators.

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Figure 1: Certification Solutions

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.02 EtOH	± 0.002 (10%)
Linearity 2	Ethanol	0.08 EtOH	± 0.004 (5%)
Linearity 3	Ethanol	0.16 EtOH	± 0.008 (5%)
Linearity 4	Ethanol	0.40 EtOH	± 0.020 (5%)
Interference	Acetone in Ethanol	0.01% Acetone (% by vol) in 0.080 EtOH	INTERFERENCE

4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a thermometer calibrated to NIST standards. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, solution lot number, target concentration, date opened, expiration date and simulator solution NIST temperature of each concentration.

4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter your password. Enter the name of the technician performing the certification.
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
 - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
 - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
 - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
 - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.
 - 4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R²" to perform an R² statistical analysis.

- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button. The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
- 4.3.2.7.1. To complete the mouth alcohol test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
- 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube. *is an intermittent tone heard*
- 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RF detection test press the "RF" button. When the detector voltage box pops up, key a handheld radio near the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
- 4.3.2.9.1. The DMT will run through a series of quality control checks.
- 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
- 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
- A) Shallow Breath:** Very lightly blow a small amount of air into the mouth piece, allowing some air to escape out the sides of your mouth. The air flow should be very slight, but strong enough to just register air flow (blue line) on the screen. Blow for a few seconds then stop. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- B) Intermittent Breath:** Strongly blow into the mouth piece for 1-2 seconds and stop a couple of times. Be careful not to suck back on the mouth piece between puffs of air. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- C) Suck Back Test: VERY GENTLY** suck back on the mouth piece just enough so you feel a one-way valve stop the air flow (less than one second of pressure). If you suck too hard, you may damage the one-way valve. Once you feel this one way valve hit, you are finished. **Do not continue to suck back on the breath tube. Once is enough.** The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.

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D) 1.5L Alcohol Free Sample: While watching the total volume box in the bottom right corner of the screen, provide a sample of ~1.5L of air to the instrument. The instrument should accept a sample of 1.5L of air. The instrument should **not** report an alcohol response.

E) If any elevation of the alcohol line above 0 is visible, rerun the Sample Acceptance Test.

- 4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.
- 4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.
- 4.3.4. Inspect the certification report and ensure that all tests are acceptable. See Appendix A for an example of a passing Certification Report.
- 4.3.5. Assign a simulator to the DataMaster DMT Instrument, see Appendix B: How to Assign a Simulator to a DMT.
- 4.3.6. Once the simulator has been assigned to the DMT, perform a diagnostic check to demonstrate that the temperature of the simulator is being monitored and is within range.
- 4.3.7. Give all documents and the Certification Log book to another program staff member for review. All documents must be reviewed by three trained personnel, including the analyst. *(needs rewording) (or by two additional trained personnel to equal a triple review?)*
- 4.3.8. Once the review is complete, the certification paperwork is filed as follows:
- 4.3.8.1. One copy is attached to the Technical Support Inquiry associated with the maintenance/repair.
 - 4.3.8.2. One copy of the documents is put in filing cabinet A in room 124, in the folder designated for the current month's completed work.
 - 4.3.8.3. A third copy of the certification paperwork will be brought with the instrument during installation and will remain in the custody of the agency where the unit is installed.
 - 4.3.8.4. An electronic copy of the certification (if available) will be placed in the instruments electronic folder on the VDH server

Y:\VDH\VDH All Share\Lab\Alcohol\Datamaster DMT electronic documents

Title: Laboratory Certification of DataMaster DMT		Page 5 of 8
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5.0 Emergency or High Priority Situations

- 5.1. The Laboratory Director or Organic Chemistry Program Chief may designate any DataMaster DMT certification to be a high priority and request certification is completed as soon as possible.

6.0 Quality Criteria and Corrective Action

- 6.1. For each step in the certification, a technician will attempt the test no more than three times. If the instrument fails to pass the step after three attempts, the certification will be deemed failing and further troubleshooting should be ~~begun~~ initiated.
- 6.2. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.3. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another organic chemistry staff member. Try to correct the problem and document the event.
- 6.4. All work performed must be documented on a Technical Support Inquiry (AIc 626). TSI's are filed in each instrument's file located in one of the two locked filing cabinets in Room 124.

7.0 Preventative Maintenance and Backup Procedures

- 7.1. If a problem is encountered that cannot be resolved by Organic Chemistry staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.
 - 7.1.1. Contact NPAS at 1-800-800-8143 or service@npas.com.
- 7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

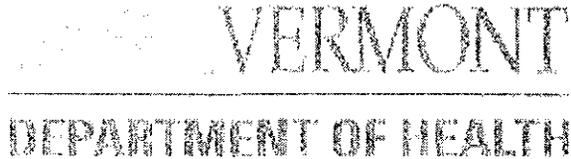
8.0 References

- 8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2. VDHL DataMaster DMT Technical Manual.
- 8.3. Technical Support Inquiry (AIc 626).
- 8.4. Logbook: DataMaster Certification Solution Information
- 8.5. Appendix A: Acceptable Certification Report.
- 8.6. Appendix B: How to Assign a Simulator

**Appendix A
Acceptable Certification Report**

CERTIFICATION REPORT

DataMaster DMT: 101708
Calibration Date: 12/16/2008
Certification Date: 12/16/2008
Certified by: STEVEN E HARNOIS



Diagnostic Results

VERSIONS

DMT 1.00
HCL 2.05
Modem 1.00
QUESTions.LIB
Reports 1.00

TEMPERATURES

Sample Chamber = 48.8°F
Breath Inlets = 46.6°C

SUPPLIES

Lamp Voltage = 7.30 V
Cooler Voltage = 2.05 V
Bias Voltage = 130.1 V
Chopper Freq = 537.5 Hz

PUMP PRESS

Flow Rate = 4.02 L/M

RESPIRATOR

PUMP ON = OFF
MAXVAL = 0.0136 - 0.0137
MINVAL = 0.0064 - 0.0224

ELUTRINED

Filter 1 = 073 Zero = true
Filter 2 = 070 Zero = true
Filter 3 = 068 Zero = true

CALIBRATION CHECK

N = 0.1775 - 0.1110

Options

Print: yes
Number of Copies: 3
Number of Supervisor Tests: 10
Idle-time Check: yes
Data Collection: yes
Units: g/210L
Simulator Check: yes
Use Wet Bath Simulator: yes
Simulator Nominal: 0.100
Digital Simulator: none
Simulator Before: yes
Simulator Between: yes
Simulator After: no
Number of Subject Tests: 2
Ask Questions: yes
Query Initial: yes
Alcohol Display: yes
Show Two Digits: no
Volume Display: yes
Number of Calibration Tests: 1
Calibrate with Wet Bath: yes
Calibration Nominal: 0.100

Linearity Check Results

True Value	Reported Average	Std Dev
0.000 (2.10)	0.000 (2.10)	0.000
0.000 (2.10)	0.000 (2.10)	0.000
0.000 (2.10)	0.000 (2.10)	0.000
0.000 (2.10)	0.000 (2.10)	0.000
0.000 (2.10)	0.000 (2.10)	0.000
0.000 (2.10)	0.000 (2.10)	0.000
0.000 (2.10)	0.000 (2.10)	0.000

Re: 12/16/08

Acetone Interference Test

For Acetone (2.10)
 0.000 (2.10)

Methyl Alcohol Test

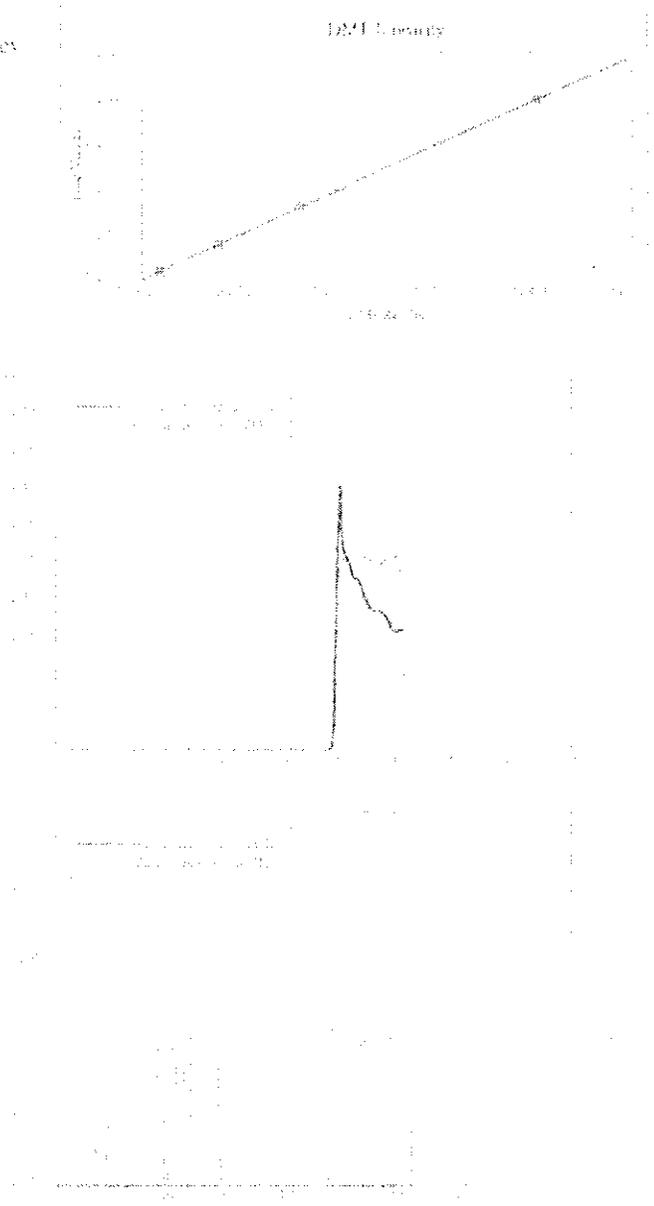
For Methyl Alcohol (2.10)

RF Interference Test

RF Interference

Sample Acceptance Test

Flow



CERTIFICATIONS PASSED

Performed by *[Signature]*

Date 12/16/2008

Reviewed by *[Signature]*

Date

Appendix B

How to Assign a Simulator to a DataMaster DMT

1. Procure a simulator to be assigned to a DataMaster.
2. Check the 2-wire temperature board in the simulator head. Replace any Rev-A boards.
3. Preliminarily check the simulator to see if it will closely fit to the simulator tower of the DataMaster in question.
4. Adjust the quick-connect on the simulator head so that the button to release the lock is pointed up. Take care not to twist or kink the tubing during adjustment.
5. Adjust the distance between the quick-connects on the tower of the DataMaster so that when connected, the BNC cable will fit into it's designated opening.
 - a. The BNC cable should not touch the sides of the opening to prevent damage to the rubber coating on the BNC cable and grounding of the simulator temperature reporting system.
 - b. The two quick connect ports attaching the simulator to the tower of the DataMaster should easily align. The height of the jar may be a factor in this alignment and can be adjusted by using a different simulator jar.
 - c. If the simulator cannot be made to easily attach to the tower of the DataMaster, it may be necessary to try a new simulator.
6. Ensure that the release buttons to the quick connects on the DataMaster tower are pointed upwards to allow ease of use.
7. Tighten the quick connects on the simulator tower so that they do not move from the ideal location. Take care not to twist or kink the tubing during adjustment.
8. Check the jar for chips and/or cracks and replace as necessary.
9. Check the O-ring on the head of the simulator to ensure it is present, appropriately seated and free from damage. Replace as necessary.
10. Fill the simulator with 500mL of water or simulator solution.
11. Perform a pressure check on the simulator to ensure an adequate seal. Repair and/or replace as necessary.
12. Allow the simulator temperature to equilibrate (at least 30 minutes).
13. Insert a NIST traceable thermometer into the simulator via the temperature testing port.
14. Ensure that the simulator is maintaining the appropriate temperature ($34^{\circ}\text{C} \pm 0.2^{\circ}$).
 - a. Adjust the heater on the simulator as necessary.
 - b. If the heater is adjusted, allow 30 minutes for the temperature to re-equilibrate.
15. Attach the BNC cable from the DataMaster DMT to the simulator.
16. Allow the thermometer and DMT to equilibrate (approximately 2 minutes).
17. Ensure the DataMaster is registering the same temperature as reported by the NIST thermometer.
 - a. Adjust the signal from the simulator to the DataMaster as necessary.
 - b. If the signal is adjusted, allow the signal to re-equilibrate and ensure correlation.
18. Once complete, close the temperature testing port by snugly threading the bolt into the opening.
19. Once all adjustments have been made, close the arms of the simulator tower around the simulator head and secure with a lock.

Title: Laboratory Certification of DataMaster DMT		Page 1 of 8
Doc. No. P-Alc-118 Draft Revision No. 1 5/11	Approved By: Owner: Organic Chemistry Program Chief	Date: Date Effective:

1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the optical bench of the instrument will be certified after having first been powered up and calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Organic Chemistry Program Chief.
- 2.2. This procedure will be reviewed periodically by Organic Chemistry staff. Revisions of the procedure will be made when a need is identified.

3.0 Precautions

- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3. Instruments must have a power up procedure performed and be calibrated prior to certification. See power up procedure (P-Alc-116) and calibration procedure (P-Alc-117).
- 3.4. When connecting simulators during the linearity testing, if Guth 2100 simulators are being used, ensure that tubing connections are as short as possible. Direct connections ~~are preferred.~~ *simulators*

4.0 Procedure Steps

4.1. Materials and Supplies are all located in Room 124.

- 4.1.1. DataMaster DMT Instrument.
- 4.1.2. NIST certified thermometer.
- 4.1.3. DataMaster Mouthpieces.
- 4.1.4. Mouth alcohol test solution.
- 4.1.5. A radio frequency transmitter.
- 4.1.6. Wet bath simulators.

Figure 1: Certification Solutions

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.02 EtOH	± 10%
Linearity 2	Ethanol	0.08 EtOH	± 5%
Linearity 3	Ethanol	0.16 EtOH	± 5%
Linearity 4	Ethanol	0.40 EtOH	± 5%
Interference	Acetone in Ethanol	0.01% Acetone (% by vol) in 0.080 EtOH	INTERFERENCE

Define for software look

4.2. Preparation

4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.

4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a ~~NIST certified~~ thermometer. Each fresh solution requires a minimum 30 minute equilibration time.

4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include ~~the technician's name, date, DataMaster serial number, solution lot number, target concentration, date opened, expiration date and simulator solution NIST~~ temperature of each concentration.

Calibrated Tractable to NIST Standards

An Entry For Each Header

4.3. Protocol

4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter your password. Enter the name of the technician performing the certification.

4.3.2. Follow the instructions as prompted by the DataMaster DMT.

4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.

4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.

4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.

4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

2 level of NIST

4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R²" to perform an R² statistical analysis.

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- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button. The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
- 4.3.2.7.1. To complete the mouth alcohol test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
- 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube.
- 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RF detection test, press the "RF" button. When the detector voltage box pops up, key a handheld radio near the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
- 4.3.2.9.1. The DMT will run through a series of quality control checks.
- 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
- 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
- A) Shallow Breath:** Very lightly blow a small amount of air into the mouth piece, allowing some air to escape out the sides of your mouth. The air flow should be very slight, but strong enough to just register air flow (blue line) on the screen. Blow for a few seconds then stop. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- B) Intermittent Breath:** Strongly blow into the mouth piece for 1-2 seconds and stop a couple of times. Be careful not to suck back on the mouth piece between puffs of air. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- C) Suck Back Test:** **VERY GENTLY** suck back on the mouth piece just enough so you feel a one-way valve stop the air flow (less than one second of pressure). If you suck too hard, you may damage the one-way valve. Once you feel this one way valve hit, you are finished. **Do not continue to suck back on the breath tube. Once is enough.** The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.

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D) 1.5L Alcohol Free Sample: While watching the total volume box in the bottom right corner of the screen, provide a sample of ~1.5L of air to the instrument. The instrument should accept a sample of 1.5L of air. The instrument should **not** report an alcohol response.

E) If any elevation of the alcohol line above 0 is visible, rerun the Sample Acceptance Test.

4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.

4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.

4.3.4. Inspect the certification report and ensure that all tests are acceptable. See Appendix A for an example of a passing Certification Report.

4.3.5. Assign a simulator to the DataMaster DMT Instrument, see Appendix B: How to Assign a Simulator to a DMT.

4.3.6. Once the simulator has been assigned to the DMT, perform a diagnostic check to demonstrate that the temperature of the simulator is being monitored and is within range.

4.3.7. Give all documents and the Certification Log book to another ^{Program Staff member} technician for review. All documents must be reviewed by ~~two~~ ^{three} or more trained personnel.

4.3.8. Once the review is complete, one copy of the documents ^{are} put in the filing cabinet in room 124, filing cabinet A, in the folder designated for the current months completed work. The second copy of the certification paperwork will be brought with the instrument during installation and will remain in the custody of the agency where the unit is installed. ^{An electronic copy is placed in the} ~~pastime~~ ^{pastime} electronic folder on the VDH allshare/lab/mtb/ol

5.0 Emergency or High Priority Situations

5.1. The Laboratory Director or Organic Chemistry Program Chief may designate any DataMaster DMT certification to be a high priority and request certification is completed as soon as possible.

6.0 Quality Criteria and Corrective Action

6.1. For each step in the certification, a technician will attempt the test no more than three times. If the instrument fails to pass the step after three attempts, the certification will be deemed failing and further troubleshooting should be begun.

6.2. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.

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- 6.3. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another organic chemistry staff member. Try to correct the problem and document the event.
- 6.4. All work performed must be documented on a Technical Support Inquiry (AIC 626). TSI's are filed in each instrument's file located in one of the two locked filing cabinets in Room 124.

7.0 Preventative Maintenance and Backup Procedures

- 7.1. If a problem is encountered that cannot be resolved by Organic Chemistry staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.
 - 7.1.1. Contact NPAS at 1-800-800-8143 or service@npas.com.
- 7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

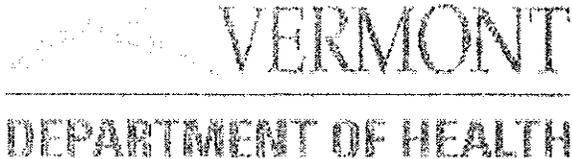
8.0 References

- 8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2. VDHL DataMaster DMT Technical Manual.
- 8.3. Technical Support Inquiry (AIC 626).
- 8.4. Logbook: DataMaster Certification Solution Information
- 8.5. Appendix A: Acceptable Certification Report.
- 8.6. Appendix B: How to Assign a Simulator

Appendix A
Acceptable Certification Report

CERTIFICATION REPORT

DataMaster DMT: 101708
Calibration Date: 12/16/2008
Certification Date: 12/16/2008
Certified by: STEVEN E HARNOIS



Diagnostic Results

VARIABLES

DMT 1.00
PIC 3.05
Meters 1.00
Questions 1.00
Reports 1.00

TEMPERATURES

Sample Chamber: -48.80°F
Bath Tube: -46.67°C

SUPPLIES

Lamp Voltage: 7.70 V
Circulator Voltage: 2.05 V
Bio. Voltage: 120.1 V
Circulator Freq: 537.5 Hz

FLOW RATES

Flow Rate: 0.675 L/M

DMT CHARACTERISTICS

PTIME ON: 0.0P
MAX(V): 0.0276 -0.0197
MIN(V): 0.0264 -0.0220

FILTER INFO

Filter 1: 0.023 Zero: true
Filter 2: 0.120 Zero: true
Filter 3: 0.648 Zero: true

CALIBRATION CHECK

X0: 0.1275 -0.19%

Options

Print: yes
Number of Copies: 3
Number of Supervisor Tests: 10
Telecoms Check: yes
Data Collection: yes
Units: g/100L
Simulator Check: yes
Uses Wet Bath Simulator: yes
Simulator Nominal: 0.100
Digital Simulator: none
Simulator Before: yes
Simulator Between: yes
Simulator After: no
Number of Subject Tests: 2
Ask Questions: yes
Query Refuse: yes
Alcohol Display: yes
Show Two Digits: no
Volume Display: yes
Number of Calibration Tests: 1
Calibrate with Wet Bulb: yes
Calibration Nominal: 0.100

Linearity Check Results

True Value	Reported Average	Std Dev
0.078 g/210l	0.078 g/210l	0.001
0.084 g/210l	0.084 g/210l	0.001
0.089 g/210l	0.078 g/210l	0.001
0.162 g/210l	0.161 g/210l	0.001
0.301 g/210l	0.301 g/210l	0.001
0.301 g/210l	0.301 g/210l	0.001

RF = 0.8838

Acetone Interference Test

0.078 g/210l (std)
 Interference Detected

Mouth Alcohol Test

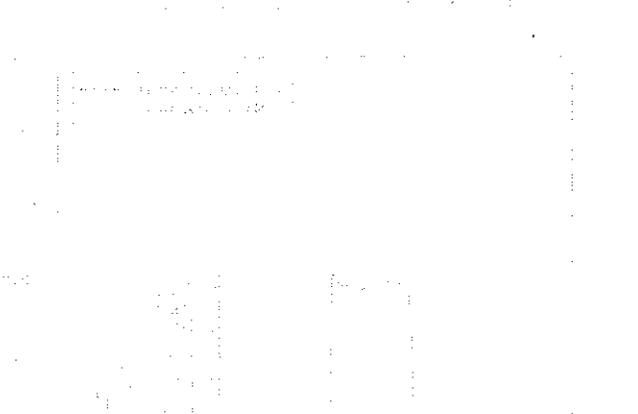
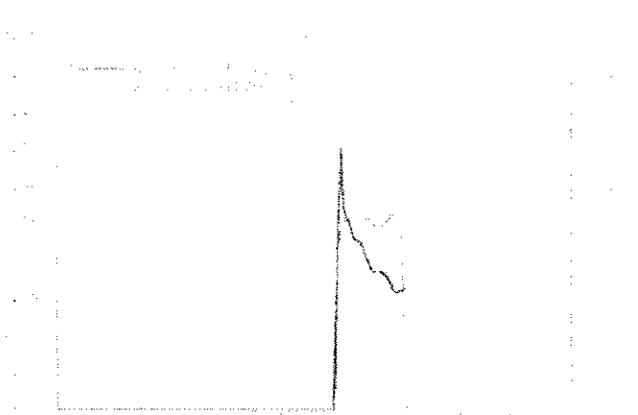
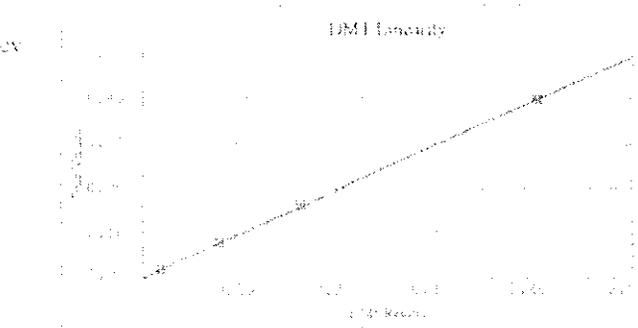
Mouth Alcohol Detected

RF Interference Test

RF's detected

Sample Acceptance Test

Passed



CERTIFICATION PASSED

Performed by *[Signature]*

Date 12/16/2008

Reviewed by *[Signature]*

Date 12/16/2008

DMF Control Number #100708

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12/16/2008 09:41

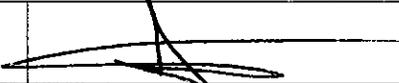
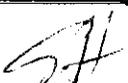
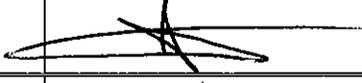
Change

Appendix B How to Assign a Simulator to a DataMaster DMT

1. Procure a simulator to be assigned to a DataMaster.
2. Check the 2-wire temperature board in the simulator head. Replace any Rev-A boards. *(with what board)*
3. Preliminarily check the simulator to see if it will closely fit to the simulator tower of the DataMaster in question.
4. Adjust the quick-connect on the simulator head so that the button to release the lock is pointed up. Take care not to twist or kink the tubing during adjustment.
5. Adjust the distance between the quick-connects on the tower of the DataMaster so that when connected, the BNC cable will fit into its designated opening.
 - a. The BNC cable should not touch the sides of the opening to prevent damage to the rubber coating on the BNC cable and grounding of the simulator temperature reporting system.
 - b. The two quick connect ports attaching the simulator to the tower of the DataMaster should easily align. The height of the jar may be a factor in this alignment and can be adjusted by using a different simulator jar.
 - c. If the simulator cannot be made to easily attach to the tower of the DataMaster, it may be necessary to try a new simulator.
6. Ensure that the release buttons to the quick connects on the DataMaster tower are pointed upwards to allow ease of use.
7. Tighten the quick connects on the simulator tower so that they do not move from the ideal location. Take care not to twist or kink the tubing during adjustment.
8. Check the jar for chips and/or cracks and replace as necessary.
9. Check the O-ring on the head of the simulator to ensure it is present, appropriately seated and free from damage. Replace as necessary.
10. Fill the simulator with 500mL of water or simulator solution.
11. Perform a pressure check on the simulator to ensure an adequate seal. Repair and/or replace as necessary.
12. Allow the simulator temperature to equilibrate (at least 30 minutes).
13. Insert a NIST traceable thermometer into the simulator via the temperature testing port. *certified*
14. Ensure that the simulator is maintaining the appropriate temperature ($34^{\circ}\text{C} \pm 0.2^{\circ}$).
 - a. Adjust the heater on the simulator as necessary.
 - b. If the heater is adjusted, allow 30 minutes for the temperature to re-equilibrate.
15. Attach the BNC cable from the DataMaster DMT to the simulator.
16. Allow the thermometer and DMT to equilibrate (approximately 2 minutes).
17. Ensure the DataMaster is registering the same temperature as reported by the NIST thermometer.
 - a. Adjust the signal from the simulator to the DataMaster as necessary.
 - b. If the signal is adjusted, allow the signal to re-equilibrate and ensure correlation.
18. Once complete, close the temperature testing port by snugly threading the bolt into the opening.
19. Once all adjustments have been made, close the arms of the simulator tower around the simulator head and secure with a lock.

**Vermont Department of Health Laboratory
Procedure and Document Review Coversheet**

Document Title: Laboratory Certification of DataMaster DMT	
Document #: P-Alc-118	Revision #: 1
File Name: Y:\VDH\VDH All Share\Lab\Document Control\Organic Chemistry\Alcohol docs\Alc. SOP DRAFTS	
Author or Editor: Bolduc	Owner: Org Chem Chief
Start Date: 5/6/11	Due Date: 6-20-11

Name and Title of Reviewers	Signature	Comments? Y/N *	Date of Signature	Control Copy #
A. Bolduc		Y <input type="checkbox"/>	5/6/11	
S. Merrill		Y <input type="checkbox"/>	05/06/11	
S. Harnois		Y <input type="checkbox"/>	5/6/11	
K. Kimball		Y <input type="checkbox"/>	5/12/11	
E. Luce		<input type="checkbox"/>		
M. Celotti		<input type="checkbox"/>		
New Review	5/13/11	<input type="checkbox"/>		
A. Bolduc		N <input type="checkbox"/>	5/13/11	
S. Merrill		Y <input checked="" type="checkbox"/>	05/13/11	
Steven Harnois		Y <input type="checkbox"/>	6/14/11	
Kirk Kimball Program Chief		Y <input type="checkbox"/>	6-15-11	
		<input type="checkbox"/>		
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* () in checkbox indicates reviewer comments have been discussed and incorporated if applicable.

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1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the optical bench of the instrument will be certified after having first been powered up and calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Organic Chemistry Program Chief.
- 2.2. This procedure will be reviewed periodically by Organic Chemistry staff. Revisions of the procedure will be made when a need is identified.

3.0 Precautions

- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3. Instrument must have a power up procedure performed and be calibrated prior to certification. See power up procedure (P-Alc-116) and calibration procedure (P-Alc-117).
- 3.4. DataMaster DMT simulator temperature monitoring must be turned off during certification. Access the set-up menu and select *none* under the *Digital Sim* options.
- 3.5. When connecting simulators during the linearity testing, if Guth 2100 simulators are being used, ensure that tubing connections are as short as possible. Direct connections using a Guth 34CNP simulator is preferred.

Remove
Access
Need to
be done
on
new
software.

4.0 Procedure Steps

4.1. Materials and Supplies are all located in Room 124.

- 4.1.1. DataMaster DMT Instrument.
- 4.1.2. NIST traceable thermometer.
- 4.1.3. DataMaster Mouthpieces.
- 4.1.4. Mouth alcohol test solution.
- 4.1.5. A radio-frequency transmitter.
- 4.1.6. Guth 34C and/or 2100 wet bath simulators.

2 Way Handheld Radio



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Figure 1: Certification Solutions

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.020 EtOH	± 10%
Linearity 2	Ethanol	0.080 EtOH	± 5%
Linearity 3	Ethanol	0.160 EtOH	± 5%
Linearity 4	Ethanol	0.400 EtOH	± 5%
Interference	Acetone in Ethanol	0.010 Acetone in 0.080 EtOH	INTERFERENCE

4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a NIST traceable thermometer. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, solution lot number, target concentration, date opened, expiration date and simulator temperature of each concentration.

4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the ~~technician level~~ password. Enter the name of the technician performing the certification. *Your*
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
 - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
 - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
 - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
 - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

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- 4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R²" to perform an R² statistical analysis.
- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button. The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
- 4.3.2.7.1. To complete the mouth alcohol test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
- 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube.
- 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RFI test press the "RFI" button. When the detector voltage box pops up, key a handheld radio within two feet of the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
- 4.3.2.9.1. The DMT will run through a series of quality control checks.
- 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
- 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
- A) Shallow Breath:** Very lightly blow a small amount of air into the mouth piece, allowing some air to escape out the sides of your mouth. The air flow should be very slight, but strong enough to just register air flow (blue line) on the screen. Blow for a few seconds then stop. The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.
- B) Intermittent Breath:** Strongly blow into the mouth piece for 1-2 seconds and stop a couple of times. Be careful not to suck back on the mouth piece between puffs of air. The instrument should not report an alcohol response (black line) and should not accept the sample.
- C) Suck Back Test: VERY GENTLY** suck back on the mouth piece just enough so you feel a one-way valve stop the air flow (less than one second of pressure). If you suck too hard, you may damage the one-way valve. Once you feel this one way valve hit, you are finished. **Do not continue to suck back on the breath tube. Once is enough.**

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The instrument should **not** report an alcohol response (black line) and should **not** accept the sample.

- D) **1.5L Alcohol Free Sample:** While watching the total volume box in the bottom right corner of the screen, provide a sample of ~1.5L of air to the instrument. The instrument should accept a sample of 1.5L of air. The instrument should **not** report an alcohol response.
- E) If any elevation of the alcohol line above 0 is visible, rerun the Sample Acceptance Test.

- 4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.
- 4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.
- 4.3.4. Inspect the certification report and ensure that all values are within acceptable ranges. See Appendix A for an example of a passing Certification Report.
- 4.3.5. On the touch screen, press the NPAS logo to open the drop down menu. Select: Functions → Reset Options. This will ensure all options are reset to default including turning the simulator temperature monitoring back on.
- 4.3.6. Assign a simulator to the DataMaster DMT Instrument, see Appendix B: How to Assign a Simulator to a DMT.
- 4.3.7. Once the simulator has been ~~calibrated~~ *assigned* to the DMT, perform a diagnostic check to demonstrate that the temperature of the simulator is being monitored and is within range.
- 4.3.8. Give all documents and the Certification Log book to another technician for review.
- 4.3.9. Once the review is complete, the documents are put in the filing cabinet in room 124, filing cabinet A, in the folder designated for the current months completed work.

5.0 Emergency or High Priority Situations

- 5.1. The Laboratory Director or Organic Chemistry Program Chief may designate any DataMaster DMT certification to be a high priority and request certification be completed as soon as possible.

6.0 Quality Criteria and Corrective Action

- 6.1. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.

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- 6.2. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another organic chemistry staff member. Try to correct the problem and document the event.
- 6.3. Each new instrument being tested will have its own testing and maintenance binder. This binder contains a notebook for documenting instrument performance issues and errors.
- 6.4. Once an instrument has completed its initial testing and is prepared for deployment, all performance issues and errors are documented on a Technical Support Inquiry (Alc 626). TSI's are filed in each instrument's file located in one of the two locked filing cabinets in Room 124.

7.0 Preventative Maintenance and Backup Procedures

7.1. If a problem is encountered that cannot be resolved by ^{Organic Chemistry} ~~Toxicology~~ staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.

7.1.1. Contact NPAS at 1-800-800-8143 or service@npas.com.

7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

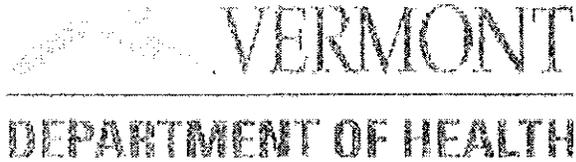
8.0 References

- 8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2. VDHL DataMaster DMT Technical Manual.
- 8.3. Technical Support Inquiry (Alc 626).
- 8.4. Logbook: DataMaster Certification Solution Information.
- 8.5. Appendix A: Acceptable Certification Report.
- 8.6. Appendix B: How to Assign a Simulator,

Appendix A
Acceptable Certification Report

CERTIFICATION REPORT

DataMaster DMT: 101708
Calibration Date: 12/16/2008
Certification Date: 12/16/2008
Certified by: STEVEN E HARNOIS



Diagnostic Results

VERSIONS
DMT 1.00
PIC 2.05
Modem 1.00
Questions 1.00
Reports 1.00

TEMPERATURES
Sample Chamber: -48.89°C
Bypass Tube: -46.63°C

SETTINGS
Lamp Voltage: 2.76 V
Cooler Voltage: 2.05 V
Bias Voltage: 120.1 V
Chopper Freq: 537.5 Hz

PUMP INFO
Flow Rate: 0.625 L/M

DETECTORS INFO
PUMP ON: OFF
MAX(V): 0.0236 -0.0197
MIN(V): 0.0264 -0.0224

FILTER INFO
Filter 1: 0.023 Zero: true
Filter 2: 0.420 Zero: true
Filter 3: 0.648 Zero: true

CALIBRATION CHECK
Xg: 0.1275 0.1402

Options

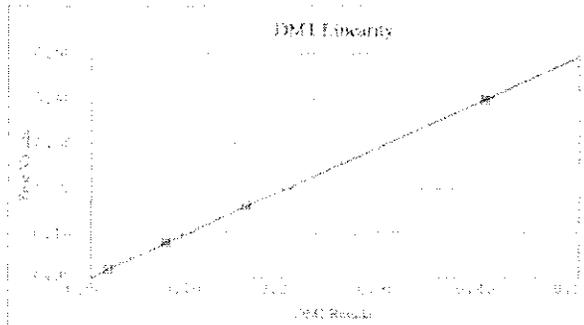
Printer: yes
Number of Copies: 3
Number of Supervisor Tests: 10
Tolerance Check: yes
Data Collection: yes
Units: g/210L
Simulator Check: yes
Uses Wet Bath Simulator: yes
Simulator Nominal: 0.101
Digital Simulator: none
Simulator Before: yes
Simulator Between: yes
Simulator After: no
Number of Subject Tests: 2
Ask Questions: yes
Query Refused: yes
Alcohol Display: yes
Slow Two Digits: no
Volume Display: yes
Number of Calibration Tests: 1
Calibrate with Wet Bath: yes
Calibration Nominal: 0.100

*Change to
Current
look*

Linearity Check Results

True Value	Reported Average	Std Dev
0.020 µg/210µl	0.018 µg/210µl	0.001
Lot # 09-65-02*		
0.060 µg/210µl	0.076 µg/210µl	0.001
Lot # 09-01-09*		
0.162 µg/210µl	0.161 µg/210µl	0.000
Lot # 09-03-17*		
0.332 µg/210µl	0.334 µg/210µl	0.001
Lot # 09-02-00*		

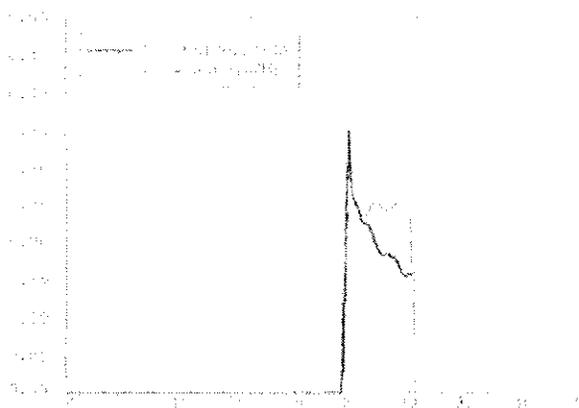
R² = 0.9999



Acetone Interference Test

Lot # 09-01-09*

Interference Detected



Mouth Alcohol Test

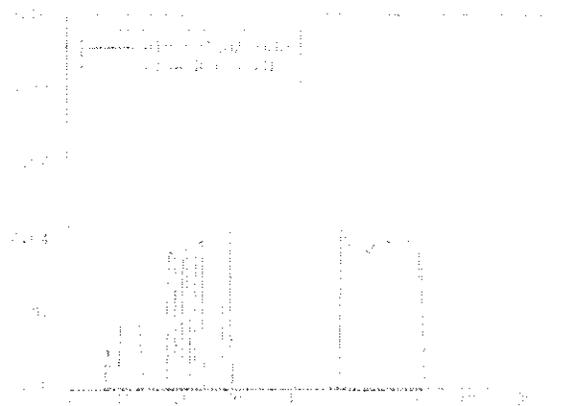
Mouth Alcohol Detected

RF Interference Test

RF Detected

Sample Acceptance Test

Passed



CERTIFICATION PASSED

Performed by *A. B. [Signature]*

Date 12/16/2008

Reviewed by *[Signature]*

Date *[Signature]*

DML Serial Number 10 / MX

Page 2 of 2

12/16/2008 09:34

*Change Scan
different
name*

*Change
to
current
date!*

Appendix B

How to Assign a Simulator to a DataMaster DMT

1. Procure a simulator to be assigned to a DataMaster.
2. Check the 2-wire temperature board in the simulator head. Replace any Rev-A boards.
3. Preliminarily check the simulator to see if it will closely fit to the simulator tower of the DataMaster in question.
4. Adjust the quick-connect on the simulator head so that the button to release the lock is pointed up. Take care not to twist or kink the tubing during adjustment.
5. Adjust the distance between the quick-connects on the tower of the DataMaster so that when connected, the BNC cable will fit into it's designated opening.
 - a. The BNC cable should not touch the sides of the opening to prevent damage to the rubber coating on the BNC cable and grounding of the simulator temperature reporting system.
 - b. The two quick connect ports attaching the simulator to the tower of the DataMaster should easily align. The height of the jar may be a factor in this alignment and can be adjusted by using a different simulator jar.
 - c. If the simulator cannot be made to easily attach to the tower of the DataMaster, it may be necessary to try a new simulator.
6. Ensure that the release buttons to the quick connects on the DataMaster tower are pointed upwards to allow ease of use.
7. Tighten the quick connects on the simulator tower so that they do not move from the ideal location. Take care not to twist or kink the tubing during adjustment
8. Check the jar for chips and/or cracks and replace as necessary.
9. Check the O-ring on the head of the simulator to ensure it is present, appropriately seated and free from damage. Replace as necessary.
10. Fill the simulator with 500mL of water or simulator solution.
11. Perform a pressure check on the simulator to ensure an adequate seal. Repair and/or replace as necessary.
12. Allow the simulator temperature to equilibrate (at least 30 minutes).
13. Insert a NIST traceable thermometer into the simulator via the temperature testing port.
14. Ensure that the simulator is maintaining the appropriate temperature ($34^{\circ}\text{C} \pm 0.2^{\circ}$).
 - a. Adjust the heater on the simulator as necessary.
 - b. If the heater is adjusted, allow 30 minutes for the temperature to re-equilibrate.
15. Attach the BNC cable from the DataMaster DMT to the simulator.
16. Allow the thermometer and DMT to equilibrate (~~approximately 2 minutes~~).
17. Ensure the DataMaster is registering the same temperature as reported by the NIST thermometer.
 - a. Adjust the signal from the simulator to the DataMaster as necessary.
 - b. If the signal is adjusted, allow the signal to re-equilibrate and ensure correlation.
18. Once complete, close the temperature testing port by snugly threading the bolt into the opening.
19. Once all adjustments have been made, close the arms of the simulator tower around the simulator head and secure with a lock.

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1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the analytical portion of the instrument will be certified after having first been powered up and calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief.
- 2.2. This procedure will be reviewed periodically by Toxicology staff. Revisions of the procedure will be made when a need is identified.

3.0 Precautions

- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3. Instrument must have a power up procedure preformed and be calibrated prior to certification. See power up procedure (P-Alc-116) and calibration procedure (P-Alc-117).
- 3.4. DataMaster DMT simulator temperature monitoring must be turned off during certification. Access the set-up menu and select *none* under the *Digital Sim* options.
- 3.5. When connecting simulators during the linearity testing, if Guth 2100 simulators are being used, ensure that tubing connections are as short as possible. Direct connections using a Guth 34CNP simulator is preferred.

4.0 Procedure Steps

4.1. Materials and Supplies are all located in Room 124.

- 4.1.1. DataMaster DMT Instrument.
- 4.1.2. NIST traceable thermometer.
- 4.1.3. DataMaster Mouthpieces.
- 4.1.4. Mouth alcohol test solution.
- 4.1.5. A radio frequency transmitter.

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4.1.6. Guth 34C and/or 2100 wet bath simulators.

Figure 1: Certification Solutions

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.020 EtOH	± 10%
Linearity 2	Ethanol	0.080 EtOH	± 5%
Linearity 3	Ethanol	0.160 EtOH	± 5%
Linearity 4	Ethanol	0.400 EtOH	± 5%
Interference	Acetone in Ethanol	0.010 Acetone in 0.080 EtOH	INTERFERENCE

4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a NIST traceable thermometer. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, *and* room temperature. Also, the solution lot number, concentration, date opened, expiration date and simulator temperature of each concentration.

4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the technician level password. Enter the name of the technician performing the certification.
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
 - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
 - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
 - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
 - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). *Seven* replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

- 4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R²" to perform an R² statistical analysis.
- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button. The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
- 4.3.2.7.1. To complete the mouth alcohol ^{Extraspell} test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
- 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube.
- 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RFI test press the "RFI" button. When the detector voltage box pops up, key a handheld radio within two feet of the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
- 4.3.2.9.1. The DMT will run through a series of quality control checks.
- 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
- 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.

- A) **Shallow Breath Test:** Blow lightly into the mouth piece so that flow is visible on the display, ~~but the tone remains intermittent.~~ The test is considered failed if the DMT accepts a shallow breath. *tone does not change*
- B) **Intermittent Breath Test:** Blow and stop repeatedly. The test is considered failed if the DMT accepts an intermittent breath.
- C) **Suck Back Test:** Inhale gently through the breath tube for two to three seconds. You should feel some slight resistance. The test is considered failed only if the DMT accepts a suck back breath as a valid sample or if while sucking back, alcohol is reported. **NOTE:** The DMT's breath tube is equipped with a one-way valve. If you suck back extremely hard or blow then suck rapidly, the one-way valve may be damaged requiring the replacement of the breath tube.
- D) **Alcohol Free Test:** Blow normally until at least 1.5L of air has been delivered. The test is considered failed if the result for alcohol was 0.002 g/210L or greater, or if the breath sample was not accepted and at least 1.7L of air has been delivered.

See - Pop - Acceptance Test - for more detailed explanation

→ Add to this procedure

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4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.

4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.

4.3.4. Inspect the certification report and ensure that all values are within acceptable ranges. See Appendix A for an example of a passing Certification Report.

4.3.5. On the touch screen, press the NPAS logo to open the drop down menu. Select: Functions → Reset Options. This will ensure all options are reset to default including turning the simulator temperature monitoring back on.

4.3.6. Assign a simulator to the DataMaster DMT Instrument, see ~~Appendix B~~ Appendix B → How to Assign a Simulator to a DMT.

4.3.7. Once the simulator has been calibrated to the DMT, perform a diagnostic check to demonstrate that the temperature of the simulator is being monitored and is within range.

4.3.8. Give all documents to a reviewer.

4.3.9. Once reviewed and accepted instr. is ready for ~~deployment~~ installation.

5.0 Emergency or High Priority Situations

5.1. The Laboratory Director or ~~Toxicology~~ ^{Chemistry} Program Chief may designate any DataMaster DMT certification to be a high priority and request certification be completed as soon as possible.

6.0 Quality Criteria and Corrective Action

6.1. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.

6.2. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event.

6.3. Each new instrument being tested will have its own testing and maintenance binder. This binder contains a notebook for documenting instrument performance issues and errors.

6.4. Once an instrument has completed its initial testing and is prepared for deployment, all performance issues and errors are documented on a Technical Service Inquiry (AIC 626). TSI's are filed in each instrument's file located in the locked filing cabinet in Room 124.

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7.0 Preventative Maintenance and Backup Procedures

7.1. If a problem is encountered that cannot be resolved by Toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.

7.1.1. Contact NPAS at 1-800-800-8143 or service@npas.com.

7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

8.0 References

8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).

8.2. DataMaster DMT Service Manual. >

8.3. Technical Support Inquiry (Alc 626).

8.4. Logbook: DataMaster Certification Solution Information.

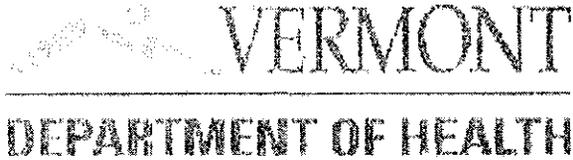
8.5. Appendix A: Acceptable Certification Report.

8.6. Appendix B: How to Assign a Simulator.

Appendix A
Acceptable Certification Report

CERTIFICATION REPORT

DataMaster DMT: 101708
Calibration Date: 12/16/2008
Certification Date: 12/16/2008
Certified by: STEVEN E HARNOS



Diagnostic Results

VERSIONS

DMT 1.00
PIC 2.05
Modem 1.04
Questions 1.00
Reports 1.00

TEMPERATURES

Sample Chamber = 38.80°C
Inhalb Tube = 46.63°C

SETTINGS

Lamp Voltage = 2.20 V
Cooler Voltage = 2.05 V
Bias Voltage = 130.1 V
Chopper Freq = 537.5 Hz

PUMP INFO

Flow Rate = 4.625 L/M

DETECTOR INFO

PUMP ON OFF
MAX(V) 0.0236 -0.0197
MIN(V) 0.0264 -0.0224

FILTER INFO

Filter 1 0.023 Zero = true
Filter 2 0.420 Zero = true
Filter 3 0.048 Zero = true

CALIBRATION CHECK

Xq = 0.1275 0.14%

Options

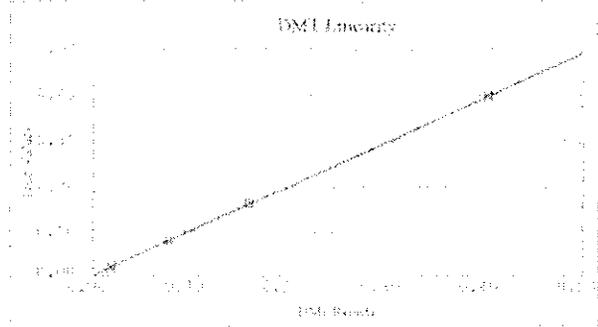
Printer: yes
Number of Copies: 3
Number of Supervisor Tests: 10
Tolerance Check: yes
Data Collection: yes
Units: g/210L
Simulator Check: yes
Uses Wet Bath Simulator: yes
Simulator Nominal: 0.100
Digital Simulator: none
Simulator Before: yes
Simulator Between: yes
Simulator After: no
Number of Subject Tests: 2
Ask Questions: yes
Query Refusal: yes
Alcohol Display: yes
Show Two Digits: no
Volume Display: yes
Number of Calibration Tests: 1
Calibrate with Wet Bath: yes
Calibration Nominal: 0.100

Replace with current Not Darcy

Linearity Check Results

True Value	Reported Average	Std Dev
0.000 (p210)	0.008 (p210)	0.001
Lot # 09-04-020		
1.080 (p210)	0.078 (p210)	0.001
Lot # 09-01-080		
4.160 (p210)	0.561 (p210)	0.040
Lot # 09-03-160		
8.360 (p210)	0.504 (p210)	0.001
Lot # 09-12-400		

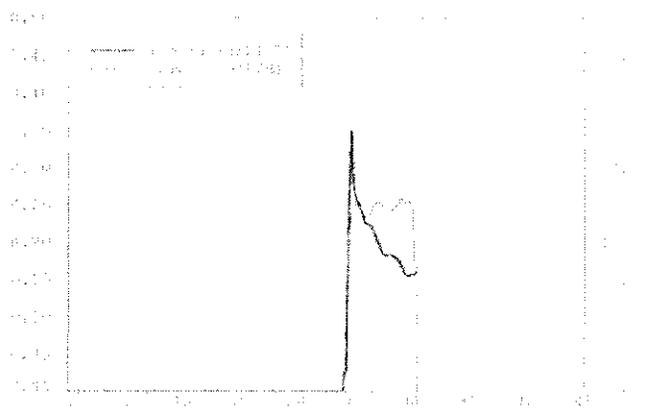
R² = 0.9999



Acetone Interference Test

Lot # 09-01-080A

Interference Detected



Mouth Alcohol Test

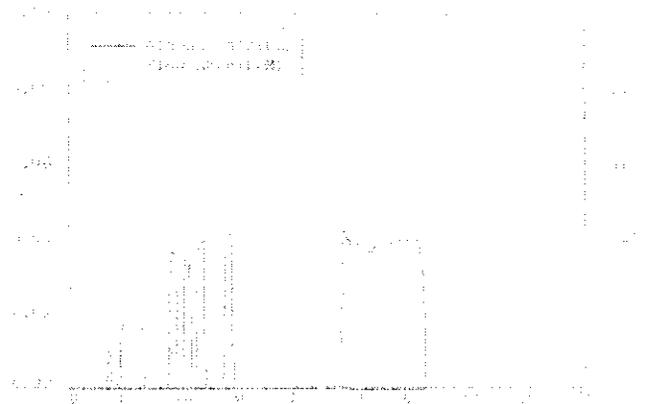
Mouth Alcohol Detected

RF Interference Test

RF detected

Sample Acceptance Test

Passed



CERTIFICATION PASSED

Performed by *[Signature]*

Date 12/16/2008

Reviewed by *[Signature]*

Date *[Signature]*

Appendix B How to Assign a Simulator to a DataMaster DMT

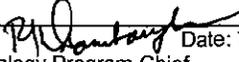
1. Procure a simulator to be assigned to a DataMaster. Preliminarily check the simulator to see if it will closely fit to the simulator tower of the DataMaster in question.
2. Check the jar for chips and/or cracks and replace as necessary.
3. Check the O-ring on the head of the simulator to ensure it is present, appropriately seated and free from damage. ~~Repair and/or~~ replace as necessary.
4. Check the 2-wire temperature board in the simulator head. Replace any Rev-A boards.
5. Fill the simulator with 500mL of water. *do we use H₂O or an EtOH/H₂O mixture?*
6. Perform a pressure check on the simulator to ensure an adequate seal. Repair and/or replace as necessary.
7. Allow the simulator temperature to equilibrate (*at least overnight*, approximately 30 minutes).
8. Insert a NIST traceable thermometer into the simulator via the temperature testing port.
9. Ensure that the simulator is maintaining the appropriate temperature ($34^{\circ}\text{C} \pm 0.2^{\circ}$).
 - a. Adjust the heater on the simulator as necessary.
 - b. If the heater is adjusted, allow 30 minutes for the temperature to re-equilibrate. *no spec*
10. Attach the BNC cable from the DataMaster DMT to the simulator.
11. Allow the thermometer and DMT to equilibrate (approximately 2 minutes).
12. Ensure the DataMaster is registering the same temperature as reported by the NIST thermometer.
 - a. Adjust the signal from the simulator to the DataMaster as necessary.
 - b. If the signal is adjusted, allow the signal to re-equilibrate and ensure correlation.
13. Once complete, close the temperature testing port by snugly threading the bolt into the opening.
14. Adjust the quick-connect on the simulator head so that the button to release the lock is pointed up. Take care not to twist or kink the tubing during adjustment.
15. Adjust the distance between the quick-connects on the tower of the DataMaster so that when connected, the BNC cable will fit into it's designated opening.
 - a. The BNC cable should not touch the sides of the opening to prevent damage to the rubber coating on the BNC cable and grounding of the simulator temperature reporting system.
 - b. The two quick connect ports attaching the simulator to the tower of the DataMaster should easily align. The height of the jar may be a factor in this alignment and can be adjusted by using a different simulator jar.
 - c. If the simulator cannot be made to easily attach to the tower of the DataMaster, it may be necessary to try a new simulator.
16. Ensure that the release buttons to the quick connects on the DataMaster tower are pointed upwards to allow ease of use.
17. Tighten the quick connects on the simulator tower so that they do not move from the ideal location. Take care not to twist or kink the tubing during adjustment.

Bryce-Parrott, Cara

From: Celotti, Stella
Sent: Thursday, August 04, 2011 12:37 PM
To: Kimball, Kirk
Cc: Bryce-Parrott, Cara
Subject: Procedure Approved

Hello, P-ALC-118, Rev 1, Lab Certification of the DMT and P-ALC-119, Rev 1, DataMaster DMT Installation Procedure, have been approved and can be moved to Document Control. Thanks, Stella.

Mary (Stella) Celotti
Laboratory Director
Vermont Department of Health Laboratory
195 Colchester Avenue
Burlington, Vermont 05401
802-863-7570
(Fax) 802-863-7632
Stella.Celotti@ahs.state.vt.us

Title: Laboratory Certification of DataMaster DMT		Page 1 of 7
Doc. No. P-Alc-118 Revision No.0	Approved By:  Date: 7/1/09 Owner: Toxicology Program Chief	Date Effective: 6/24/09

1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the analytical portion of the instrument will be certified after having first been powered up and calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief.
- 2.2. This procedure will be reviewed periodically by Toxicology staff. Revisions of the procedure will be made when a need is identified.

3.0 Precautions

- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3. Instrument must have a power up procedure preformed and be calibrated prior to certification. See power up procedure (P-Alc-116) and calibration procedure (P-Alc-117).
- 3.4. DataMaster DMT simulator temperature monitoring must be turned off during certification. Access the set-up menu and select *none* under the *Digital Sim* options.
- 3.5. When connecting simulators during the linearity testing, if Guth 2100 simulators are being used, ensure that tubing connections are as short as possible. Direct connections using a Guth 34CNP simulator is preferred.

4.0 Procedure Steps

4.1. Materials and Supplies are all located in Room 124.

- 4.1.1. DataMaster DMT Instrument.
- 4.1.2. NIST traceable thermometer.
- 4.1.3. DataMaster Mouthpieces.
- 4.1.4. Mouth alcohol test solution.
- 4.1.5. A radio frequency transmitter.

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4.1.6. Guth 34C and/or 2100 wet bath simulators.

Figure 1: Certification Solutions

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.020 EtOH	± 10%
Linearity 2	Ethanol	0.080 EtOH	± 5%
Linearity 3	Ethanol	0.160 EtOH	± 5%
Linearity 4	Ethanol	0.400 EtOH	± 5%
Interference	Acetone in Ethanol	0.010 Acetone in 0.080 EtOH	INTERFERENCE

4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a NIST traceable thermometer. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, room temperature. Also, the solution lot number, concentration, date opened, expiration date and simulator temperature of each concentration.

4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the technician level password. Enter the name of the technician performing the certification.
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
 - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
 - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
 - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
 - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

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- 4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R²" to perform an R² statistical analysis.
- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button . The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
- 4.3.2.7.1. To complete the mouth alcohol test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
- 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube.
- 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RFI test press the "RFI" button. When the detector voltage box pops up, key a handheld radio within two feet of the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
- 4.3.2.9.1. The DMT will run through a series of quality control checks.
- 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
- 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
- A) Shallow Breath Test:** Blow lightly into the mouth piece so that flow is visible on the display, but the tone remains intermittent. The test is considered failed if the DMT accepts a shallow breath.
- B) Intermittent Breath Test:** Blow and stop repeatedly. The test is considered failed if the DMT accepts an intermittent breath.
- C) Suck Back Test:** Inhale gently through the breath tube for two to three seconds. You should feel some slight resistance. The test is considered failed only if the DMT accepts a suck back breath as a valid sample or if while sucking back, alcohol is reported. **NOTE:** The DMT's breath tube is equipped with a one-way valve. If you suck back extremely hard or blow then suck rapidly, the one-way valve may be damaged requiring the replacement of the breath tube.
- D) Alcohol Free Test:** Blow normally until at least 1.5L of air has been delivered. The test is considered failed if the result for alcohol was 0.002 g/210L or greater, or if the breath sample was not accepted and at least 1.7L of air has been delivered.

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- 4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.
- 4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.
- 4.3.4. Inspect the certification report and ensure that all values are within acceptable ranges. See Appendix A for an example of a passing Certification Report.

5.0 Emergency or High Priority Situations

- 5.1. The Laboratory Director or Toxicology Program Chief may designate any DataMaster DMT certification to be a high priority and request certification be completed as soon as possible.

6.0 Quality Criteria and Corrective Action

- 6.1. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.2. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event.
- 6.3. Each new instrument being tested will have its own testing and maintenance binder. This binder contains a notebook for documenting instrument performance issues and errors.
- 6.4. Once an instrument has completed its initial testing and is prepared for deployment, all performance issues and errors are documented on a Technical Service Inquiry (Alc 626). TSI's are filed in each instrument's file located in the locked filing cabinet in Room 124.

7.0 Preventative Maintenance and Backup Procedures

- 7.1. If a problem is encountered that cannot be resolved by Toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.
- 7.1.1. Contact NPAS at 1-800-800-8143 or service@npas.com.
- 7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

8.0 References

- 8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2. DataMaster DMT Service Manual.
- 8.3. VDHL DataMaster DMT Power-Up Procedure (P-Alc-116).

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- 8.4. VDHL Laboratory Calibration of DataMaster DMT (P-Alc-117).
- 8.5. Technical Support Inquiry (Alc 626).
- 8.6. Logbook: DataMaster Certification Solution Information
- 8.7. Appendix A: Acceptable Certification Report.

Title: Laboratory Certification of DataMaster DMT		Page 6 of 7
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**Appendix A
Acceptable Certification Report**

CERTIFICATION REPORT

DataMaster DMT: 101708
 Calibration Date: 12/16/2008
 Certification Date: 12/16/2008
 Certified by: STEVEN E HARNOIS



Diagnostic Results

VERSIONS
 DMT 1.00
 PIC 2.05
 Modem 1.04
 Questions 1.00
 Reports 1.00

TEMPERATURES
 Sample Chamber = -48.80°C
 Breath Tube = -46.63°C

SETTINGS
 Lamp Voltage = 2.20 V
 Cooler Voltage = 2.05 V
 Bias Voltage = 120.1 V
 Chopper Freq = 537.5 Hz

PUMP INFO
 Flow Rate = 4.625 L/M

DETECTOR INFO
 PUMP ON OFF
 MAX(V) -0.0236 -0.0197
 MIN(V) -0.0264 -0.0224

FILTER INFO
 Filter 1 -0.023 Zero = true
 Filter 2 -0.420 Zero = true
 Filter 3 -0.648 Zero = true

CALIBRATION CHECK
 Xq = 0.1275 0.14%

Options

Printer yes
 Number of Copies: 3
 Number of Supervisor Tests: 10
 Tolerance Check: yes
 Data Collection: yes
 Units: g/210L
 Simulator Check: yes
 Uses Wet Bath Simulator: yes
 Simulator Nominal: 0.101
 Digital Simulator: none
 Simulator Before: yes
 Simulator Between: yes
 Simulator After: no
 Number of Subject Tests: 2
 AskQuestions: yes
 Query Refusal: yes
 Alcohol Display: yes
 Show Two Digits: no
 Volume Display: yes
 Number of Calibration Tests: 1
 Calibrate with Wet Bath: yes
 Calibration Nominal: 0.100

Doc. No. P-AIC-118 Revision No.0

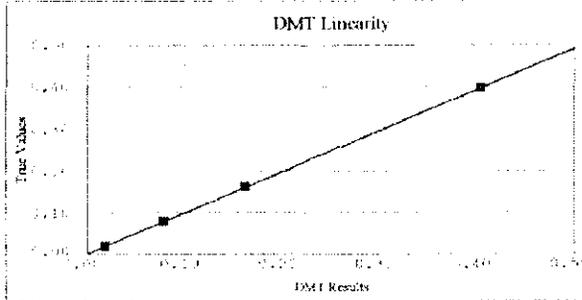
Approved By: *[Signature]* Date: 7/1/09
 Owner: Toxicology Program Chief

Date Effective: 6/24/09

Linearity Check Results

True Value	Reported Average	Std Dev
0.020 g/210L	0.018 g/210L	0.001
Lot # 09-06-020		
0.080 g/210L	0.078 g/210L	0.001
Lot # 09-01-080		
0.162 g/210L	0.161 g/210L	0.000
Lot # 09-03-160		
0.397 g/210L	0.404 g/210L	0.001
Lot # 09-12-400		

R² = 0.9999



Acetone Interference Test

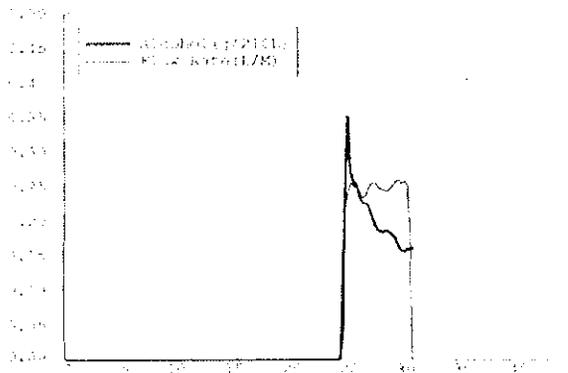
Lot # 09-01-08A
 Interference Detected

Mouth Alcohol Test

Mouth Alcohol Detected

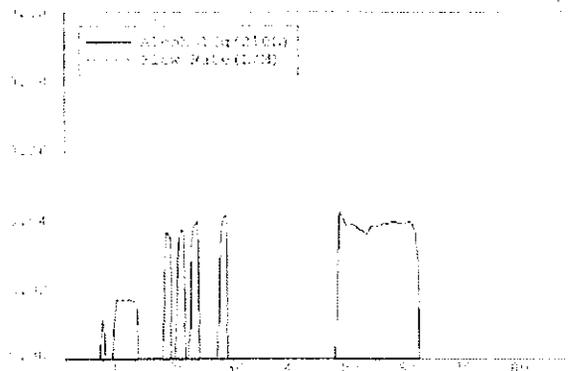
RF Interference Test

RFI detected



Sample Acceptance Test

Passed



CERTIFICATION PASSED

Performed by: *[Signature]*

Date 12/16/2008

Reviewed by: *[Signature]*

Date: *[Signature]*

Vermont Department of Health Laboratory
Procedure and Document Review Coversheet

Document Title: <i>Laborator Certification of DMT</i>	
Document #: <i>P-AIC-118</i>	Revision #: <i>0</i>
File Name:	
Author or Editor: <i>A. Boland</i>	Owner: <i>TOX</i>
Start Date: <i>1/5/09</i>	Due Date: <i>1/23/09</i>

Name and Title of Reviewers	Signature	Comments? Y/N *	Date of Signature	Control Copy #
<i>Darcy</i>	<i>Darcy [Signature]</i>	<i>N</i> <input type="checkbox"/>	<i>1/6/09</i>	
<i>Steve</i>	<i>Steven Harrois</i>	<i>Y</i> <input type="checkbox"/>	<i>1/8/09</i>	
<i>Bob</i>	<i>[Signature]</i>	<i>N</i> <input type="checkbox"/>	<i>1/8/09</i>	
<i>Ed</i>	<i>Edmund P. Luce</i>	<i>Approved</i> <input type="checkbox"/>	<i>6/12/09</i>	
<i>Stella</i>	<i>Mary [Signature]</i>	<i>N</i> <input type="checkbox"/>	<i>6/24/09</i>	
		<input type="checkbox"/>		
	<i>for final approval</i>	<input type="checkbox"/>		
		<input type="checkbox"/>		

* (√) in checkbox indicates reviewer comments have been discussed and incorporated if applicable.

Title: Laboratory Certification of DataMaster DMT		Page 1 of 7
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1.0 Purpose and Scope

- 1.1. The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2. The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the analytical portion of the instrument will be certified after having first been powered up and calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1. It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief.
- 2.2. This procedure will be reviewed periodically by Toxicology staff. Revisions of the procedure will be made when a need is identified.

3.0 Precautions

- 3.1. Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2. All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3. Instrument must have a power up procedure performed and be calibrated prior to certification. See power up procedure (P-Alc-116) and calibration procedure (P-Alc-117).
- 3.4. DataMaster DMT simulator temperature monitoring must be turned off during certification. Access the set-up menu and select *none* under the *Digital Sim* options.
- 3.5. When connecting simulators during the linearity testing, if Guth 2100 simulators are being used, ensure that tubing connections are as short as possible. Direct connections using a Guth 34CNP simulator is preferred.

4.0 Procedure Steps

4.1. Materials and Supplies are all located in Room 124.

- 4.1.1. DataMaster DMT Instrument.
- 4.1.2. NIST traceable thermometer.
- 4.1.3. DataMaster Mouthpieces.
- 4.1.4. Mouth alcohol test solution.
- 4.1.5. A radio frequency transmitter.

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4.1.6. Guth 34C and/or 2100 wet bath simulators.

Figure 1: Certification Solutions

Use	Component	Nominal Concentration	Acceptance Criteria
Linearity 1	Ethanol	0.020 EtOH	± 10%
Linearity 2	Ethanol	0.080 EtOH	± 5%
Linearity 3	Ethanol	0.160 EtOH	± 5%
Linearity 4	Ethanol	0.400 EtOH	± 5%
Interference	Acetone in Ethanol	0.010 Acetone in 0.080 EtOH	INTERFERENCE

4.2. Preparation

- 4.2.1. Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.2.2. Simulators must indicate solution temperature of 34°C +/- 0.2°C. Check the temperature of each solution using a NIST traceable thermometer. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.2.3. Make an entry in the Logbook: DataMaster Certification Solution Information. Each entry shall include the technician's name, date, DataMaster serial number, room temperature. Also, the solution lot number, concentration, date opened, expiration date and simulator temperature of each concentration.

4.3. Protocol

- 4.3.1. On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the technician level password. Enter the name of the technician performing the certification.
- 4.3.2. Follow the instructions as prompted by the DataMaster DMT.
 - 4.3.2.1. The certification process works like a check-list. To begin each step in the certification process, press the button for that step.
 - 4.3.2.2. When each step is successfully completed, the box to the left of the step will be checked. Each step must pass in order to go on to the next test.
 - 4.3.2.3. The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
 - 4.3.2.4. The next four steps are the linearity tests ("Linearity 1", "Linearity 2", etc). Seven replicates of each of the four concentrations of ethanol will be analyzed. Run the solutions from lowest to highest concentration to avoid carryover. Enter the solution lot number, concentration and acceptance range (see figure 1) before pressing the "Linearity #" button to begin each step.

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- 4.3.2.5. Once all four linearity solutions have passed, press the button labeled "R²" to perform an R² statistical analysis.
- 4.3.2.6. The next step is the acetone interference test. Enter the lot number of the solution then press the "Acetone" button . The interference solution is blown through the breath tube when prompted "Please Blow".
- 4.3.2.7. The next step is the invalid sample detection test, also known as the mouth alcohol test.
 - 4.3.2.7.1. To complete the mouth alcohol test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from the bottle of mouth alcohol test solution.
 - 4.3.2.7.2. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", the technician will then blow out through the ethanol-laden mouthpiece into the breath tube.
 - 4.3.2.7.3. An "Invalid Sample" error must be generated in order to pass the mouth alcohol test.
- 4.3.2.8. To complete the RFI test press the "RFI" button. When the detector voltage box pops up, key a handheld radio within two feet of the breath tube. The instrument should beep indicating that a radio frequency is detected.
- 4.3.2.9. To begin the sample acceptance test press the "Sample Acc" button. Open a new mouth piece and press "OK" when you are ready to start the test.
 - 4.3.2.9.1. The DMT will run through a series of quality control checks.
 - 4.3.2.9.2. When prompted "Please Blow" and an intermittent tone is heard, insert the mouthpiece into the breath tube.
 - 4.3.2.9.3. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
 - A) Shallow Breath Test:** Blow lightly into the mouth piece so that flow is visible on the display, but the tone remains intermittent. The test is considered failed if the DMT accepts a shallow breath.
 - B) Intermittent Breath Test:** Blow and stop repeatedly. The test is considered failed if the DMT accepts an intermittent breath.
 - C) Suck Back Test:** Inhale gently through the breath tube for two to three seconds. You should feel some slight resistance. The test is considered failed only if the DMT accepts a suck back breath as a valid sample or if while sucking back, alcohol is reported. **NOTE:** The DMT's breath tube is equipped with a one-way valve. If you suck back extremely hard or blow then suck rapidly, the one-way valve may be damaged requiring the replacement of the breath tube.
 - D) Alcohol Free Test:** Blow normally until at least 1.5L of air has been delivered. The test is considered failed if the result for alcohol was 0.002 g/210L or greater, or if the breath sample was not accepted and at least 1.7L of air has been delivered.

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4.3.2.10. Once the sample acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No". If all checks passed, select "Yes". If any of the checks failed, select "No". When prompted, type in which check failed and why.

4.3.3. Once all tests have been successfully completed, the instrument will ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.

4.3.4. Inspect the certification report and ensure that all values are within acceptable ranges. See Appendix A for an example of a passing Certification Report.

5.0 Emergency or High Priority Situations

5.1. The Laboratory Director or Toxicology Program Chief may designate any DataMaster DMT certification to be a high priority and request certification be completed as soon as possible.

6.0 Quality Criteria and Corrective Action

6.1. If any of the certification factors are outside the manufacture or VDHL recommended specifications, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.

6.2. The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event.

6.3. Each new instrument being tested will have its own testing and maintenance binder. This binder contains a notebook for documenting instrument performance issues and errors.

6.4. Once an instrument has completed its initial testing and is prepared for deployment, all performance issues and errors are documented on a Technical Service Inquiry (Alc 626). TSI's are filed in each instrument's file located in the locked filing cabinet in Room 124.

7.0 Preventative Maintenance and Backup Procedures

7.1. If a problem is encountered that cannot be resolved by Toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support. This may include return or replacement of the instrument for warranty service.

7.1.1. Contact NPAS at 1-800-800-8143 or service@npas.com.

7.2. If an agency's instrument cannot be made field ready within two weeks of receipt at VDHL, a replacement instrument may be installed at that site.

8.0 References

8.1. VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).

8.2. DataMaster DMT Service Manual.

8.3. VDHL DataMaster DMT Power-Up Procedure (P-Alc-116).

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- 8.4. VDHL Laboratory Calibration of DataMaster DMT (P-Alc-117).
- 8.5. Technical Support Inquiry (Alc 626).
- 8.6. Logbook: DataMaster Certification Solution Information
- 8.7. Appendix A: Acceptable Certification Report.

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**Appendix A
Acceptable Certification Report**

CERTIFICATION REPORT

DataMaster DMT: 101708
 Calibration Date: 12/16/2008
 Certification Date: 12/16/2008
 Certified by: STEVEN E HARNOIS



Diagnostic Results

VERSIONS
 DMT 1.00
 PIC 2.05
 Modem 1.04
 Questions 1.00
 Reports 1.00

TEMPERATURES
 Sample Chamber = 48.80°C
 Breath Tube = 46.63°C

SETTINGS
 Lamp Voltage = 2.20 V
 Cooler Voltage = 2.05 V
 Bias Voltage = 120.1 V
 Chopper Freq = 537.5 Hz

PUMP INFO
 Flow Rate = 4.625 L/M

DETECTOR INFO
 PUMP ON OFF
 MAX(V) -0.0236 -0.0197
 MIN(V) -0.0264 -0.0224

FILTER INFO
 Filter 1 -0.023 Zero = true
 Filter 2 0.420 Zero = true
 Filter 3 0.648 Zero = true

CALIBRATION CHECK
 Xq = 0.1275 0.14%

Options

Printer: yes
 Number of Copies: 3
 Number of Supervisor Tests: 10
 Tolerance Check: yes
 Data Collection: yes
 Units: g/210L
 Simulator Check: yes
 Uses Wet Bath Simulator: yes
 Simulator Nominal: 0.101
 Digital Simulator: none
 Simulator Before: yes
 Simulator Between: yes
 Simulator After: no
 Number of Subject Tests: 2
 AskQuestions: yes
 Query Refusal: yes
 Alcohol Display: yes
 Show Two Digits: no
 Volume Display: yes
 Number of Calibration Tests: 1
 Calibrate with Wet Bath: yes
 Calibration Nominal: 0.100

Doc. No. P-AIC-118 Draft Revision No.0

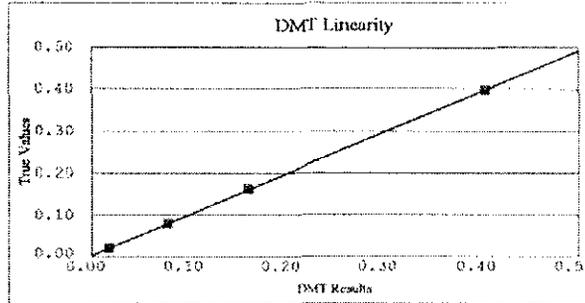
Approved By: _____ Date: _____
 Owner: Toxicology Program Chief

Date Effective: _____

Linearity Check Results

True Value	Reported Average	Std Dev
0.020 g/210L	0.018 g/210L	0.001
Lot # 09-06-020		
0.080 g/210L	0.078 g/210L	0.001
Lot # 09-01-080		
0.162 g/210L	0.161 g/210L	0.000
Lot # 09-03-160		
0.397 g/210L	0.404 g/210L	0.001
Lot # 09-12-400		

R² = 0.9999



Acetone Interference Test

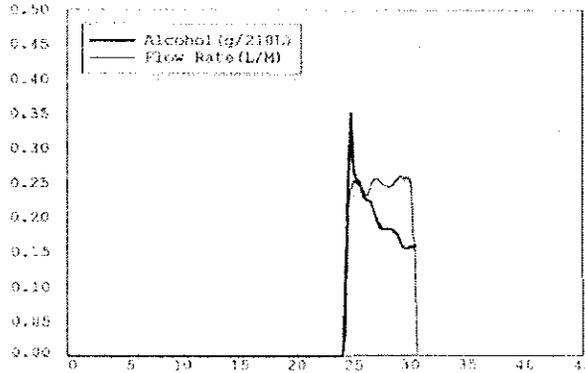
Lot # 09-01-08A
 Interference Detected

Mouth Alcohol Test

Mouth Alcohol Detected

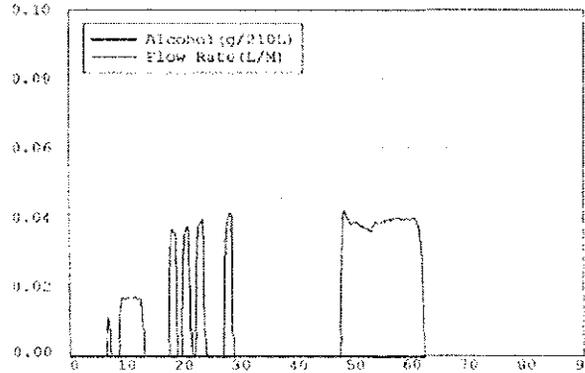
RF Interference Test

RFI detected



Sample Acceptance Test

Passed



CERTIFICATION PASSED

Performed by ASD

Date 12/16/2008

Reviewed by [Signature]

Date 12/16/08

P-ALC-118

spaces between paragraphs & indenting needed.

1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2 The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the analytical portion of the instrument will be certified after calibration by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1 It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed ^{annually} by Toxicology staff. Revisions of the procedure will be made when a need is expressed.

3.0 Precautions

- 3.1 Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2 All reports generated during this procedure must be retained; this includes those displaying error messages or failures.
- 3.3 *Ensure that tubing connecting simulators are not overly long.*

4.0 Procedure Steps

- 4.1 Materials and Supplies are all located in Room 124.
 - 4.1.1 DataMaster DMT Instrument.
 - 4.1.2 ^{34C} Guth 34C Wet Bath Simulators with acetone and ethanol solutions.
 - 4.1.3 ~~Field Service Tool Kit.~~
 - 4.1.4 NIST Traceable thermometer and ~~in-house calibrated thermometers.~~
 - 4.1.5 DataMaster Mouthpieces.
 - 4.1.6 ~~A bottle of an alcohol-containing beverage.~~ *Bottle of mouth Alc Test Soln*
 - 4.1.7 A radio frequency transmitter.

4.2 Preparation

- 4.2.1 Instrument must be calibrated prior to certification. See calibration procedure (P-Alc-xxx).
- 4.2.2 Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.3.3 Simulators must indicate solution temperature of 34°C +/- 0.5°C. Each fresh solution requires a minimum 30 minute equilibration time.
- 4.3.4 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the technician level password. Enter the name of the technician performing the certification.
- 4.3.5 Follow the instructions as prompted by the DataMaster DMT. The certification process works like a check-list. To begin each step in the certification process, press the button for that step. For tests that require a simulator solution enter the solution lot number, concentration and acceptance range as necessary before selecting the button to begin the process. Each step must pass in order to go on to the next test.

Turn off to monitor

list [x] of all solns

extrapolate solutions log books
DMT #
lot #
opened
exp.

NIST cal digi T°

When passed box is v-d

Title: DataMaster DMT Laboratory Certification		Page 2 of 5
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4.3.6 The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.

4.3.7 The next steps are the linearity tests. Seven replicates of each of the four concentrations of ethanol will be analyzed. The solution concentrations are nominally 0.020, 0.080, 0.160, and 0.400 g/210L ethanol. Run the solutions from lowest to highest concentration to avoid carryover. ~~Each simulator will be labeled with the solution's content, concentration, lot number, expiration date, and the date when the solution was put into the simulator.~~

Copybook

4.3.8 The acceptance values for the solutions is $\pm 5\%$ for each solution except the 0.02 solution. The acceptance value for the 0.02 solution is $\pm 10\%$.

display acceptance in a table?

4.3.9 The acetone test is a solution of ~~acetone~~ containing 0.01% acetone in 0.08% ethanol. This solution is ~~heated in a simulator to 34C~~ and is blown through the breath tube when prompted. *Inhalation detected*

4.3.10 To complete the "Mouth Alc" test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from ~~a bottle of an ethanol containing beverage (a Schnapps bottle)~~. When prompted "please blow", the technician will then blow out through the ethanol laden mouthpiece into the breath tube. An invalid sample must be generated in order to pass the mouth alcohol test.

Mouth alc test Saln

4.3.11 To complete the RFI test, key a handheld radio ~~in close proximity to~~ the breath tube. The instrument should beep when RFI is detected.

dim 2' of

4.3.12 To complete the sample acceptance test press "OK" when you are ready to start the test.

- a. The DMT will run through a series of quality control checks.
- b. When prompted "Please Blow" and an intermittent tone is heard, insert a new mouthpiece into the breath tube.
- c. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
 - i. **Shallow Breath Test:** Blow lightly into the mouth piece so that flow is visible on the display, but the tone remains intermittent. The test is considered failed if the DMT accepts a shallow breath.
 - ii. **Intermittent Breath Test:** Blow and stop repeatedly. The test is considered failed if the DMT accepts an intermittent breath.
 - iii. **Suck Back Test:** Inhale gently through the breath tube for two to three seconds. You should feel some slight resistance. The test is considered failed only if the DMT accepts a suck back breath as a valid sample or if while sucking back, alcohol is reported.

NOTE:

replace breath tube

- The DMT's breath tube is equipped with a one-way valve. If you suck back extremely hard or blow then suck rapidly, the instrument may display the error message "Suck Back Error". This is **NOT** a failing response.
- Press "OK" and redo the entire Sample Acceptance Test. If after two attempts the DMT is still displaying "Suck Back Error", perform a third Sample Acceptance Test. During the third attempt, do not perform a Suck Back Test.
- Note on the RPC Report that a "Suck Back Error" was generated and contact VDHL DataMaster Technical Services.

- iv. **Alcohol Free Test:** Blow normally until at least 1.5L of air has been delivered. The test is considered failed if the result for alcohol was 0.002 g/210L or greater, or if the breath sample was not accepted and at least 1.7L of air has been delivered.
- d. Once the Sample Acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No"
 - i. If all checks passed, select "Yes".
 - ii. If any of the checks failed, select "No". When prompted, type in which check failed and why.

4.3.13 The instrument will now ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.

4.3.14 Inspect the certification report and ensure that all values are within acceptable ranges. See Appendix A for an example of a certification report.

5.0 Emergency or High Priority Situations

5.1 The Laboratory Director or Toxicology Program Chief may designate any DataMaster DMT certification to be a high priority and request certification as soon as possible.

6.0 Quality Criteria and Corrective Action

6.1 If any of the certification factors are outside the ~~manufacturer~~ ^{man or VDAH} recommended specification, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.

6.2 The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the ~~in-house~~ ^{in-house} service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event. *where?*

6.3 ~~If the problem is not correctable without some repair or technical evaluation, a DataMaster Technical Support Inquiry worksheet (AIC 626) must be completed and placed in the instrument's file. This procedure may be begun again when the problem is resolved.~~

7.0 Preventative Maintenance and Backup Procedures

7.1 If a problem is encountered that cannot be resolved by Toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support.

7.2 If an agency's instrument cannot be certified in a timely manner, a replacement instrument ~~will be given to~~ ^{made field ready} that site. *win Zucks*

8.0 References

8.1 Chemical Hygiene Plan and Safety Manual (D-AD-003).

8.2 DataMaster DMT ~~Field~~ Service Manual.

8.3 Appendix A: Acceptable Certification Report.

8.4 ~~Appendix B: Technical Support Inquiry (AIC 626)~~ *OK*

8.5 Logbook: DataMaster Certification Solution

Appendix A
Acceptable Certification Report

Title: DataMaster DMT Laboratory Certification		Page 1 of 5	
Doc. No. P-Alc-XXX Draft	Revision No. 0	Approved By: Owner: Toxicology Program Chief	Date: Date Effective:

118

spaces between paragraphs
~~needed~~
indenting needed.

1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2 The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the analytical portion of the instrument will be certified after calibration by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1 It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief. *alternate point person for DMT's*
- 2.2 This procedure will be reviewed annually by Toxicology staff. Revisions of the procedure will be made when a need is expressed. *using this procedure*

3.0 Precautions

- 3.1 Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2 All reports generated during this procedure must be retained; this includes those displaying error messages or failures.

3.3 *Ensure that tubing connecting simulators are not overly long.*

4.0 Procedure Steps

- 4.1 Materials and Supplies are all located in Room 124.
 - 4.1.1 DataMaster DMT Instrument. *w/ breath tube?*
 - 4.1.2 Guth 34C Wet Bath Simulators with (acetone and ethanol solutions.)
 - 4.1.3 ~~Field Service Tool Kit.~~
 - 4.1.4 NIST Traceable thermometer and/or in-house calibrated thermometers.
 - 4.1.5 DataMaster Mouthpieces. *Cat # ; Supplier*
 - 4.1.6 A bottle of an alcohol containing beverage.
 - 4.1.7 A radio frequency transmitter. *- define current equipment*

define reagents

4.2 Preparation

- 4.2.1 Instrument must be calibrated prior to certification. See calibration procedure (P-Alc-xxx). *Review documentation (review sheet or checklist?)*
- 4.2.2 Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
- 4.3.3 Simulators must indicate solution temperature of 34°C +/- 0.5°C. Each fresh solution requires a minimum 30 minute equilibration time. *define*
- 4.3.4 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the technician level password. Enter the name of the technician performing the certification. *- screen shots*
- 4.3.5 Follow the instructions as prompted by the DataMaster DMT. The certification process works like a check-list. To begin each step in the certification process, press the button for that step. For tests that require a simulator solution enter the solution lot number, concentration and acceptance range as necessary before selecting the button to begin the process. Each step must pass in order to go on to the next test.

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- 4.3.6 The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test. - *How do you know it is done or okay?*
- 4.3.7 The next steps are the linearity tests. Seven replicates of each of the four concentrations of ethanol will be analyzed. The solution concentrations are nominally 0.020, 0.080, 0.160, and 0.400 g/210L ethanol. Run the solutions from lowest to highest concentration to avoid carryover. Each simulator will be labeled with the solution's content, concentration, lot number, expiration date, and the date when the solution was put into the simulator. *Recall/Enter info & IDs where?*
- 4.3.8 The acceptance values for the solutions is $\pm 5\%$ for each solution except the 0.02 solution. The acceptance value for the 0.02 solution is $\pm 10\%$. *display acceptance?*
- 4.3.9 The acetone test is a solution of acetone containing 0.01% acetone in 0.08% ethanol. This solution is heated in a simulator to 34°C and is blown through the breath tube when prompted. *acceptance/failure (+/- 5%)* *is a table? YES*
- 4.3.10 To complete the Mouth Alc test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from a bottle of an ethanol containing beverage (a Schnapps bottle). When prompted "please blow", the technician will then blow out through the ethanol laden mouthpiece into the breath tube. An invalid sample must be generated in order to pass the mouth alcohol test. *If valid...???*
- 4.3.11 To complete the RFI test, key a handheld radio in close proximity to the breath tube. The instrument should beep when RFI is detected. *if not detected then???*
- 4.3.12 To complete the sample acceptance test press "OK" when you are ready to start the test.

- ← a. The DMT will run through a series of quality control checks.
- b. When prompted "Please Blow" and an intermittent tone is heard, insert a new mouthpiece into the breath tube.
- c. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
- Shallow Breath Test:** Blow lightly into the mouth piece so that flow is visible on the display, but the tone remains intermittent. The test is considered failed if the DMT accepts a shallow breath.
 - Intermittent Breath Test:** Blow and stop repeatedly. The test is considered failed if the DMT accepts an intermittent breath.
 - Suck Back Test:** Inhale gently through the breath tube for two to three seconds. You should feel some slight resistance. The test is considered failed only if the DMT accepts a suck back breath as a valid sample or if while sucking back, alcohol is reported.

NOTE:

- The DMT's breath tube is equipped with a one-way valve. If you suck back extremely hard or blow then suck rapidly, the instrument may display the error message "Suck Back Error". This is **NOT** a failing response.
- Press "OK" and redo the entire Sample Acceptance Test. If after two attempts the DMT is still displaying "Suck Back Error", perform a third Sample Acceptance Test. During the third attempt, do not perform a Suck Back Test.
- replace breath tube* Note on the RPC Report that a "Suck Back Error" was generated and contact VDHL DataMaster Technical Services.

Title: DataMaster DMT Laboratory Certification		Page 3 of 5	
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- iv. **Alcohol Free Test:** Blow normally until at least 1.5L of air has been delivered. The test is considered failed if the result for alcohol was 0.002 g/210L or greater, or if the breath sample was not accepted and at least 1.7L of air has been delivered.
 - d. Once the Sample Acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No"
 - i. If all checks passed, select "Yes".
 - ii. If any of the checks failed, select "No". When prompted, type in which check failed and why.
 - 4.3.13 The instrument will now ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.
 - 4.3.14 Inspect the certification report and ensure that all values are within acceptable ranges. See Appendix A for an example of a certification report.
- 5.0 Emergency or High Priority Situations**
- 5.1 The Laboratory Director or Toxicology Program Chief may designate any DataMaster DMT certification to be a high priority and request certification as soon as possible.
- 6.0 Quality Criteria and Corrective Action**
- 6.1 If any of the certification factors are outside the manufacture recommended specification, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.
 - 6.2 The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the in-house service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event.
 - 6.3 If the problem is not correctable without some repair or technical evaluation, a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file. This procedure may be begun again when the problem is resolved.
- 7.0 Preventative Maintenance and Backup Procedures**
- 7.1 If a problem is encountered that cannot be resolved by Toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support.
 - 7.2 If an agencies instrument cannot be certified in a timely manner, a replacement instrument will be given to that site.
- 8.0 References**
- 8.1 Chemical Hygiene Plan and Safety Manual (D-AD-003).
 - 8.2 DataMaster DMT Field Service Manual.
 - 8.3 Appendix A: Acceptable Certification Report.
 - 8.4 Appendix B: Technical Support Inquiry (Alc 626).

Appendix A
Acceptable Certification Report

Title: DataMaster DMT Laboratory Certification		Page 1 of 5
Doc. No. P-Alc-XXX Draft Revision No.0	Approved By: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective:

1.0 Purpose and Scope

- 1.1 The purpose of this procedure is to describe the process used by Vermont Department of Health Laboratory staff for the certification of the DataMaster DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices.
- 1.2 The scope of this procedure includes new and repaired instruments. Any instrument which is new or has had repairs affecting the analytical portion of the instrument will be certified after calibration by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

- 2.1 It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed annually by Toxicology staff. Revisions of the procedure will be made when a need is expressed.

3.0 Precautions

- 3.1 Appropriate caution must be taken to avoid electrical shock when working with or using any electrically charged equipment.
- 3.2 All reports generated during this procedure must be retained; this includes those displaying error messages or failures.

4.0 Procedure Steps

- 4.1 Materials and Supplies are all located in Room 124.
 - 4.1.1 DataMaster DMT Instrument.
 - 4.1.2 Guth 34C Wet Bath Simulators with acetone and ethanol solutions.
 - 4.1.3 Field Service Tool Kit.
 - 4.1.4 NIST Traceable thermometer and/or in-house calibrated thermometers.
 - 4.1.5 DataMaster Mouthpieces.
 - 4.1.6 A bottle of an alcohol containing beverage.
 - 4.1.7 A radio frequency transmitter.
- 4.2 Preparation
 - 4.2.1 Instrument must be calibrated prior to certification. See calibration procedure (P-Alc-xxx).
 - 4.2.2 Ensure that the solutions needed for certification are current and warmed up. Solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not use solutions which have passed their expiration date.
 - 4.3.3 Simulators must indicate solution temperature of 34°C +/- 0.5°C. Each fresh solution requires a minimum 30 minute equilibration time.
 - 4.3.4 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Certification. Enter the technician level password. Enter the name of the technician performing the certification.
 - 4.3.5 Follow the instructions as prompted by the DataMaster DMT. The certification process works like a check-list. To begin each step in the certification process, press the button for that step. For tests that require a simulator solution enter the solution lot number, concentration and acceptance range as necessary before selecting the button to begin the process. Each step must pass in order to go on to the next test.

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- 4.3.6 The first step in the certification process is a diagnostic test. Press the button labeled "diagnostic" to begin the test.
- 4.3.7 The next steps are the linearity tests. Seven replicates of each of the four concentrations of ethanol will be analyzed. The solution concentrations are nominally 0.020, 0.080, 0.160, and 0.400 g/210L ethanol. Run the solutions from lowest to highest concentration to avoid carryover. Each simulator will be labeled with the solution's content, concentration, lot number, expiration date, and the date when the solution was put into the simulator.
- 4.3.8 The acceptance values for the solutions is $\pm 5\%$ for each solution except the 0.02 solution. The acceptance value for the 0.02 solution is $\pm 10\%$.
- 4.3.9 The acetone test is a solution of acetone containing 0.01% acetone in 0.08% ethanol. This solution is heated in a simulator to 34C and is blown through the breath tube when prompted.
- 4.3.10 To complete the Mouth Alc test, a mouthpiece is loaded with ethanol by sucking air into the mouth piece from a bottle of an ethanol containing beverage (a Schnapps bottle). When prompted "please blow", the technician will then blow out through the ethanol laden mouthpiece into the breath tube. An invalid sample must be generated in order to pass the mouth alcohol test.
- 4.3.11 To complete the RFI test, key a handheld radio in close proximity to the breath tube. The instrument should beep when RFI is detected.
- 4.3.12 To complete the sample acceptance test press "OK" when you are ready to start the test.
- a. The DMT will run through a series of quality control checks.
 - b. When prompted "Please Blow" and an intermittent tone is heard, insert a new mouthpiece into the breath tube.
 - c. Provide breath samples. The bottom left corner of the screen will display the type of breath to deliver.
 - i. **Shallow Breath Test:** Blow lightly into the mouth piece so that flow is visible on the display, but the tone remains intermittent. The test is considered failed if the DMT accepts a shallow breath.
 - ii. **Intermittent Breath Test:** Blow and stop repeatedly. The test is considered failed if the DMT accepts an intermittent breath.
 - iii. **Suck Back Test:** Inhale gently through the breath tube for two to three seconds. You should feel some slight resistance. The test is considered failed only if the DMT accepts a suck back breath as a valid sample or if while sucking back, alcohol is reported.

NOTE:

- The DMT's breath tube is equipped with a one-way valve. If you suck back extremely hard or blow then suck rapidly, the instrument may display the error message "Suck Back Error". This is **NOT** a failing response.
- Press "OK" and redo the entire Sample Acceptance Test. If after two attempts the DMT is still displaying "Suck Back Error", perform a third Sample Acceptance Test. During the third attempt, do not perform a Suck Back Test.
- Note on the RPC Report that a "Suck Back Error" was generated and contact VDHL DataMaster Technical Services.

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- iv. **Alcohol Free Test:** Blow normally until at least 1.5L of air has been delivered. The test is considered failed if the result for alcohol was 0.002 g/210L or greater, or if the breath sample was not accepted and at least 1.7L of air has been delivered.
 - d. Once the Sample Acceptance test is complete, the instrument will prompt "Did Instrument Pass All Sample Acceptance Checks? Yes/No"
 - i. If all checks passed, select "Yes".
 - ii. If any of the checks failed, select "No". When prompted, type in which check failed and why.
 - 4.3.13 The instrument will now ask for a technician signature. Sign on the line provided and press "finished" when complete. The certification report will now print in duplicate.
 - 4.3.14 Inspect the certification report and ensure that all values are within acceptable ranges. See Appendix A for an example of a certification report.
- 5.0 Emergency or High Priority Situations**
- 5.1 The Laboratory Director or Toxicology Program Chief may designate any DataMaster DMT certification to be a high priority and request certification as soon as possible.
- 6.0 Quality Criteria and Corrective Action**
- 6.1 If any of the certification factors are outside the manufacture recommended specification, the certification will be failed and corrective action must be taken. The action taken will vary depending on the specific problem.
 - 6.2 The standard approach to correct a problem would be to first repeat the test to confirm the problem. Consult the in-house service manual or ask for technical support from another toxicology staff member. Try to correct the problem and document the event.
 - 6.3 If the problem is not correctable without some repair or technical evaluation, a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file. This procedure may be begun again when the problem is resolved.
- 7.0 Preventative Maintenance and Backup Procedures**
- 7.1 If a problem is encountered that cannot be resolved by Toxicology staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support.
 - 7.2 If an agencies instrument cannot be certified in a timely manner, a replacement instrument will be given to that site.
- 8.0 References**
- 8.1 Chemical Hygiene Plan and Safety Manual (D-AD-003).
 - 8.2 DataMaster DMT Field Service Manual.
 - 8.3 Appendix A: Acceptable Certification Report.
 - 8.4 Appendix B: Technical Support Inquiry (Alc 626).

Appendix A
Acceptable Certification Report

Bryce-Parrott, Cara

From: Celotti, Stella
Sent: Wednesday, June 24, 2009 12:21 PM
To: Bolduc, Amanda; Drawbaugh, Bob
Cc: Bryce-Parrott, Cara
Subject: Procedures Approved

Hello, P-ALC-118, Rev 0, Lab Certification of the DMT and P-ALC-119, Rev 0, DataMaster DMT Installation have been approved and can be moved to Document Control. Thanks, Stella.

Mary Celotti
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Vermont Department of Health Laboratory
195 Colchester Avenue
Burlington, Vermont 05401
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