

Title: Laboratory Calibration of DataMaster DMT		Page 1 of 9
Doc. No. P-Alc-117 Revision No.1	Approved By: <i>KJK</i> ⁸⁻⁴⁻¹¹ Owner: Kirk Kimball, Organic Chemistry Program Chief	Date: 8/3/11 Date Effective: 8/2/11

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 calibration 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 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 appropriate 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.

4.0 Procedure Steps

- 4.1 **Materials and Supplies are all located in Room 124.**
 - 4.1.1 DataMaster DMT Instrument.
 - 4.1.2 Thermometer, Calibrated traceable to NIST Standards.
 - 4.1.3 Four Wet Bath Simulators.
 - 4.1.4 Simulator containing volatile organic free, lab-pure water.

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- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Calibration Check Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.7 0.100 EtOH Secondary external source, certified standard, obtained from GUTH laboratories or another vendor.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for at least one hour.
- 4.2.2 Activate Technician Mode using your password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than +/- 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.
- 4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure it is within tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions.
- 4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution.
 - 4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.
 - 4.2.5.2 A previously used Calibration Solution may be used under the following conditions:
 - 4.2.5.2.1 If the solution has been open for no more than one calendar week.
 - 4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.
 - 4.2.5.3 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

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4.2.6 Prepare a simulator containing volatile organic free, lab-pure water.

4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7 Prepare a simulator containing ~0.10 EtOH Calibration Check Solution.

4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7.2 If a new bottle of Calibration Check Solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate.

4.2.8 Prepare a simulator containing a secondary source externally certified 0.100 EtOH solution.

4.2.8.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.8.2 If new bottle of a secondary source externally certified 0.100 EtOH solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate

4.3 Protocol Procedure

4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.2 Follow the instructions prompted by the DataMaster DMT.

4.3.2.1 Connect Simulator containing the Calibration Solution to the DataMaster DMT.

4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water." Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

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- 4.3.2.3 The instrument will now ask for a technician signature. Sign on the line provided and press "finished" when complete. The calibration report will print in duplicate.
- 4.3.3 Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report with acceptance ranges and Sections 6.1 and 6.2 for what to do if a value is not within range.
- 4.3.4 Perform a check of the calibration by analyzing a ~0.10 solution.
- 4.3.4.1 Attach a simulator containing ~0.10 Calibration Check Solution at 34°C +/- 0.2°C to the simulator tower.
- 4.3.4.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.4.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter "Cal Check". Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press "OK".
- 4.3.4.4 The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within ±3% of the certified value of the solution with a standard deviation ≤0.002. The instrument shall be recalibrated if the results do not meet these criteria.
- 4.3.4.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 Perform a check of the calibration by analyzing a second source externally certified 0.100 solution.
- 4.3.5.1 Attach a simulator containing the certified 0.100 Secondary Source Standard Solution at 34°C +/- 0.2°C to the simulator tower.
- 4.3.5.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.5.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter "2ND Source Cal Check". Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press "OK".

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- 4.3.5.4 The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within $\pm 3\%$ of the certified value of the solution with a standard deviation ≤ 0.002 . The instrument shall be recalibrated if the results do not meet these criteria.
- 4.3.5.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.6 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, for a triplicate review process.
- 4.3.6.1 After review, the reports are filed as follows:
- 4.3.6.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument's paper testing binder; discard the extra copies. Then place an electronic copy of all reports into the instrument electronic folder on the VDH allshare\lab\alcohol folder.
- 4.3.6.3 If the instrument is beyond preliminary testing, file one copy of the reports in the "Monthly Work Completed" file in the DataMaster records filing cabinet in the IR Lab (room 124). The second copies will be kept with the instrument until it is deployed, then they will be put with the instrument's on-site maintenance records. Then place an electronic copy of all reports into the instrument electronic folder on the VDHL server.
- 4.3.7 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the Technician's name and date, the DataMaster DMT serial number, calibration solution lot number, certified concentration, Second Source Lot number, and solution temperature. Also document the CAL factor, room temperature and whether or not a new bottle or a previously used solution was employed.

5.0 Emergency or High Priority Situations

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

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6.0 Quality Criteria and Corrective Action

- 6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.
- 6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 3\%$ of the certified value of the simulator solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.
- 6.4 If the average result from the Accuracy and Precision test used as a Second Source calibration check is not within $\pm 3\%$ of the certified value of the calibration solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.
- 6.5 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 program staff member. Correct the problem and document the event on a TSI (Alc. 626).
- 6.6 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented.
 - 6.6.1 If the instrument is still in the initial testing process, a TSI will be written and placed in the testing binder for that instrument. An electronic copy will also be filed in the instrument electronic folder.
 - 6.6.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.
 - 6.6.3 This procedure will be performed again when the problem is resolved.

7.0 Preventative Maintenance and Backup Procedures

- 7.1 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented on a TSI (Alc 626).

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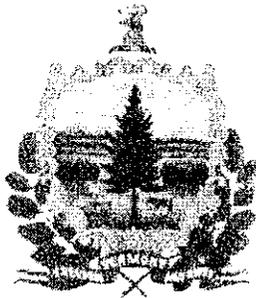
- 7.2 If a problem is encountered that cannot be resolved by organic chemistry staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support.
- 7.3 If an agency's instrument cannot be made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.
- 7.4 No back-up procedure available.

8.0 References

- 8.1 VDHL Safety Manual (D-AD-016).
- 8.2 DataMaster DMT In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Technical Support Inquiry (Alc 626).
- 8.8 Appendix A: Acceptable Calibration Report with ranges.
- 8.9 Appendix B: Acceptable Calibration Check Report.

Appendix B Acceptable Calibration Check Report

WPC
8-4-11



ACCURACY AND PRECISION TEST

STATE OF VERMONT

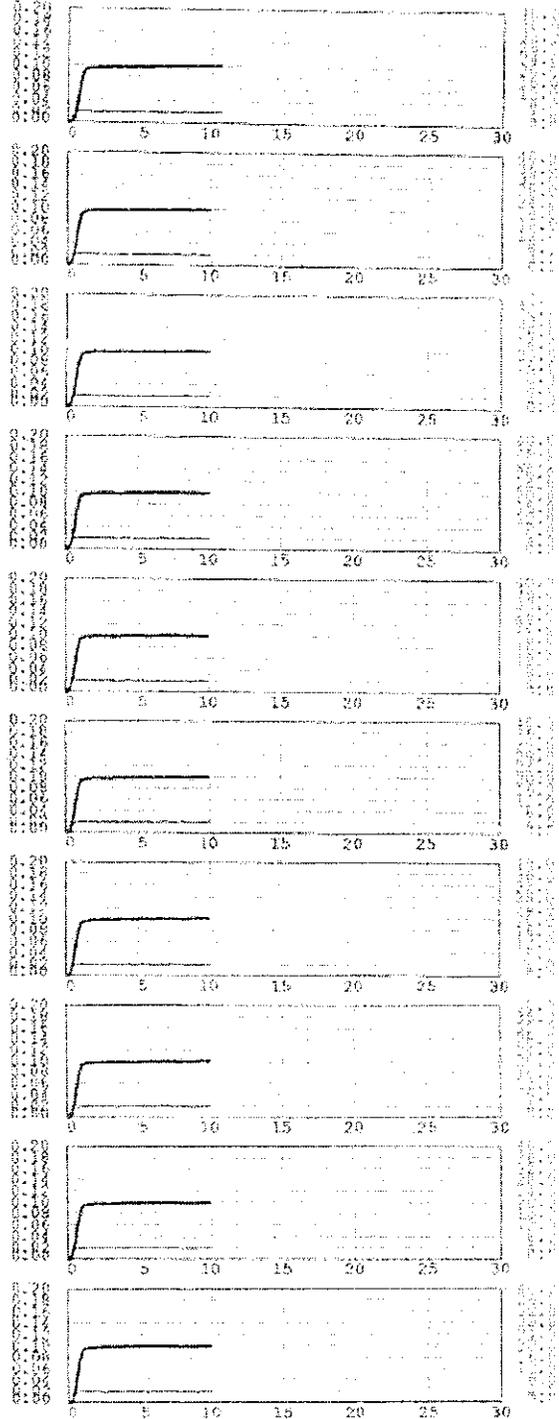
DATE: 03/16/2010
TIME: 07:08:56

SUPERVISOR NAME: ALE CAL CHECK

SOLUTION LOT #: 10-23-100
SOLUTION CONCENTRATION: 0.100

BLANK TEST	0.000	07:09
CALIBRATION CHECK	PASSED	07:09
SIMULATOR VAPOR (34.3°C)	0.099	07:10
SIMULATOR VAPOR (34.3°C)	0.100	07:11
SIMULATOR VAPOR (34.3°C)	0.099	07:12
SIMULATOR VAPOR (34.3°C)	0.100	07:13
SIMULATOR VAPOR (34.3°C)	0.099	07:14
SIMULATOR VAPOR (34.3°C)	0.100	07:15
SIMULATOR VAPOR (34.3°C)	0.101	07:16
SIMULATOR VAPOR (34.3°C)	0.100	07:17
SIMULATOR VAPOR (34.3°C)	0.100	07:18
SIMULATOR VAPOR (34.3°C)	0.100	07:19
BLANK TEST	0.000	07:20

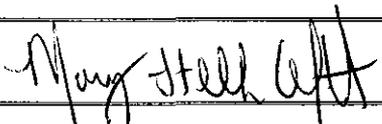
Average = 0.099
Std Dev = 0.0005



Procedures using this header are not valid unless accompanied by Approval History sheet showing current approvals (ADMIN 934).

Vermont Department of Health Laboratory Procedure and Document Review Coversheet

Document Title: Laboratory Calibration of DataMaster DMT	
Document #: P-ALC-117	Revision #: 1
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Name and Title of Reviewers	Signature	Comments? Y/N *	Date of Signature	Control Copy #
Amanda Bolduc PH III Chemist		Y <input checked="" type="checkbox"/>	6/22/11	
Steven Merrill PH II Chemist		N <input checked="" type="checkbox"/>	6/22/11	
Steven Harnois PH Electronics Technician		Y <input checked="" type="checkbox"/>	06/29/11	
Edward Luce QA/QC Officer	Unavailable - on leave 8/2/11 (E.L.)			
Mary-Stella Celotti Laboratory Director		Y <input checked="" type="checkbox"/>	7/1/11	
Kirk Kimball Organic Program Chief	NA author		8/2/11 Cik-M.C.	

* () 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 calibration 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 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 appropriate 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.

4.0 Procedure Steps

- 4.1 **Materials and Supplies are all located in Room 124.**
 - 4.1.1 DataMaster DMT Instrument.
 - 4.1.2 Thermometer, Calibrated traceable to NIST Standards.
 - 4.1.3 Four Wet Bath Simulators.
 - 4.1.4 Simulator containing volatile organic free, lab-pure water.

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- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Calibration Check Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.7 0.100 EtOH Secondary external source, certified standard, obtained from GUTH laboratories or another vendor.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for at least one hour.
- 4.2.2 Activate Technician Mode using your password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than +/- 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.
- 4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure it is within tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions.
- 4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution.
 - 4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.
 - 4.2.5.2 A previously used Calibration Solution may be used under the following conditions:
 - 4.2.5.2.1 If the solution has been open for no more than one calendar week.
 - 4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.
 - 4.2.5.3 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

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- 4.2.6 Prepare a simulator containing volatile organic free, lab-pure water.
- 4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary.
- 4.2.7 Prepare a simulator containing ~0.10 EtOH Calibration Check Solution.
- 4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.
- 4.2.7.2 If a new bottle of Calibration Check Solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate.
- 4.2.8 Prepare a simulator containing a secondary source externally certified 0.100 EtOH solution.
- 4.2.8.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.
- 4.2.8.2 If new bottle of a secondary source externally certified 0.100 EtOH solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate

4.3 Protocol Procedure

- 4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.
- 4.3.2 Follow the instructions prompted by the DataMaster DMT.
- 4.3.2.1 Connect Simulator containing the Calibration Solution to the DataMaster DMT.
- 4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to “Disconnect Water.” Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

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- 4.3.2.3 The instrument will now ask for a technician signature. Sign on the line provided and press “finished” when complete. The calibration report will print in duplicate.
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- 4.3.6.3 If the instrument is beyond preliminary testing, file one copy of the reports in the "Monthly Work Completed" file in the DataMaster records filing cabinet in the IR Lab (room 124). The second copies will be kept with the instrument until it is deployed, then they will be put with the instrument's on-site maintenance records. Then place an electronic copy of all reports into the instrument electronic folder on the VDHL server.
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6.0 Quality Criteria and Corrective Action

- 6.1** If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.2** The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.
- 6.3** If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 3\%$ of the certified value of the simulator solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.
- 6.4** If the average result from the Accuracy and Precision test used as a Second Source calibration check is not within $\pm 3\%$ of the certified value of the calibration solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.
- 6.5** 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 program staff member. Correct the problem and document the event on a TSI (Alc. 626).
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7.0 Preventative Maintenance and Backup Procedures

- 7.1** If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented on a TSI (Alc 626).

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- 7.2 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.
- 7.3 If an agency's instrument cannot be made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.
- 7.4 No back-up procedure available.

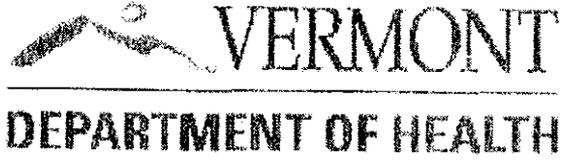
8.0 References

- 8.1 VDHL Safety Manual (D-AD-016).
- 8.2 DataMaster DMT In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Technical Support Inquiry (Alc 626).
- 8.8 Appendix A: Acceptable Calibration Report with ranges.
- 8.9 Appendix B: Acceptable Calibration Check Report.

Appendix A
Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 122306
Calibration Date: 08/21/2009
Calibrated by: STEVEN E HARNOIS
Lot: 10-02-100



Ca	0.101000		
FAI	1.002435	0.300 <= CAI < 1.200	
b1	0.000010	0.000 <= b1 < 0.008	
b2	0.004059	0.001 <= b2 < 0.012	
b3	0.000000	0.000 <= b3 < 0.004	
b4	0.000101	0.000 <= b4 < 0.200	
a01	1.159976	1.000 <= a01 < 1.300	
a02	0.459496	0.200 <= a02 < 0.600	

Acceptable range for b2 is
 $0.002 \leq b2 \leq 0.012$

Performed by *St. D.*

Date 08/21/2009

Title: Laboratory Calibration of DataMaster DMT		Page 1 of 9
Doc. No. P-Alc-117 Revision No. 1	Approved By: Owner: Kirk Kimball, Organic Chemistry Program Chief	Date: Date Effective: 12/21/10

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 calibration 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 calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

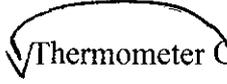
- 2.1 It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Organic Chemistry Program Chief.
- 2.2 This procedure will be reviewed periodically by appropriate 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.

4.0 Procedure Steps

4.1 Materials and Supplies are all located in Room 124.

- 4.1.1 DataMaster DMT Instrument.
- 4.1.2  Thermometer Calibrated, traceable to NIST Standards.
- 4.1.3 Four Wet Bath Simulators.
- 4.1.4 Simulator containing volatile organic free, lab-pure water.

- 4.1.5 0.10 EtOH DataMaster Calibration ^{Standard OIL} Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Calibration ~~Check~~ Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.7 0.100 EtOH Secondary external source, certified standard, ^{obtained} from GUTH laboratories or another vendor.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for at least one hour.
- 4.2.2 Activate Technician Mode using your password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than +/- 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.
- 4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure it is within tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions.
- 4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution. ^{Standard (Needs to be consistent with the M.C. Procedure) OIL}
- 4.2.5.1 Open a new bottle of Calibration ^{Standard OIL} Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.
- 4.2.5.2 A previously used Calibration ^{Standard OIL} Solution may be used under the following conditions:
- 4.2.5.2.1 If the solution has been open for no more than one calendar week.
- 4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.
- 4.2.5.3 Using a NIST ^{traceable} ~~certified~~ thermometer, check the temperature of the Calibration ^{Standard OIL} Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.6 Prepare a simulator containing volatile organic free, lab-pure water.

4.2.6.1 Using a NIST ^{traceable} ~~certified~~ thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7 Prepare a simulator containing ~0.10 EtOH Calibration Check Solution.

4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7.2 If ^a ~~new~~ bottle of external ~~standard~~ ^{calibration check solution} is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate. *(need to use consistent words)*

4.2.8 Prepare a simulator containing ^{a second source (del 4.3.5) M.C.} an externally certified 0.100 EtOH ^{4.3.5} Standard ~~containing a secondary external source~~

4.2.8.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary. *externally certified standard from solution 4.3.5*

4.2.8.2 If ^a ~~new~~ bottle of external ~~standard~~ ^{secondary external source certified std solution} is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate.

4.3 Protocol Procedure

4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.2 Follow the instructions prompted by the DataMaster DMT.

4.3.2.1 Connect Simulator containing the ^{Solution} Calibration Standard to the DataMaster DMT.

4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water." Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

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- 4.3.2.3 When instructed to “Connect Ethanol,” attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.
- 4.3.2.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to “Disconnect Ethanol.” Disconnect the simulator from the simulator tower. Press OK when ready.
- 4.3.2.5 The instrument will now ask for a technician signature. Sign on the line provided and press “finished” when complete. The calibration report will print in duplicate.
- 4.3.3 Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report with acceptance ranges and Sections 6.1 and 6.2 for what to do if a value is not within range.
- 4.3.4 Perform a check of the calibration by analyzing a ~0.10 solution.
- 4.3.4.1 Attach a simulator containing ~0.10 ^{Calibration Check} External Standard Solution at 34°C +/- 0.2°C to the simulator tower.
- 4.3.4.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.4.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter “Cal Check”. Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press “OK”.
- 4.3.4.4 The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within ±3% of the certified value of the solution with a standard deviation ≤0.002. The instrument shall be recalibrated if the results do not meet these criteria.
- 4.3.4.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 Perform a check of the calibration by analyzing a second source externally certified 0.100 solution.
- 4.3.5.1 Attach a simulator containing the certified 0.100 Secondary Source Standard Solution at 34°C +/- 0.2°C to the simulator tower.

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- 4.3.5.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.5.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter "2ND Source Cal Check". Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press "OK".
- 4.3.5.4 The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within $\pm 3\%$ of the certified value of the solution with a standard deviation ≤ 0.002 . The instrument shall be recalibrated if the results do not meet these criteria.
- 4.3.5.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.6 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, for a triplicate review process.
 - 4.3.6.1 After review, the reports are filed as follows:
 - 4.3.6.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument's paper testing binder; discard the extra copies. Then place an electronic copy of all reports into the instrument electronic folder on the VDH allshare\lab\alcohol folder.
 - 4.3.6.3 If the instrument is beyond preliminary testing, file one copy of the reports in the ~~Monthly Work Completed~~ file in the DataMaster records filing cabinet in the IR Lab (room 124). The second copies will be kept with the instrument until it is deployed, then they will be put with the instrument's on-site maintenance records. Then place an electronic copy of all reports into the instrument electronic folder on the VDHL server.
- 4.3.7 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the Technician's name and date, the DataMaster DMT serial number, calibration solution lot number, certified concentration, Second Source Lot number, and solution temperature. Also document the CAL factor, room temperature and whether or not a new bottle or a previously used solution was employed.

Title: Laboratory Calibration of DataMaster DMT		Page 6 of 9
Doc. No. P-AIC-117 Revision No. 1	Approved By: Owner: Kirk Kimball, Organic Chemistry Program Chief	Date: Date Effective: 12/21/10

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

- 6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.
- 6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 3\%$ of the certified value of the simulator solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.
- 6.4 If the average result from the Accuracy and Precision test used as a Second Source calibration check is not within $\pm 3\%$ of the certified value of the calibration solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.
- 6.5 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 program staff member. Correct the problem and document the event on a TSI (AIC. 626).
- 6.6 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented. *- confusing as related to 6.5, because you are starting a TSI*
- 6.6.1 If the instrument is still in the initial testing process, a TSI will be written in both instances. *what is the difference?*
and placed in the testing binder for that instrument. An electronic copy will also be filed in the instrument electronic folder.
- 6.6.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (AIC 626) must be completed and placed in the instrument's file. *Not confusing to those doing the TSI.*
- 6.6.3 This procedure will be performed again when the problem is resolved.

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7.0 Preventative Maintenance and Backup Procedures

- 7.1 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented on a TSI (Alc 626).
- 7.2 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.
- 7.3 If an agency's instrument cannot be made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.
- 7.4 No back-up procedure available.

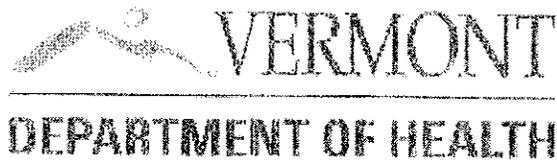
8.0 References

- 8.1 ~~VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003)~~⁰¹⁶.
- 8.2 DataMaster DMT In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Technical Support Inquiry (Alc 626).
- 8.8 Appendix A: Acceptable Calibration Report with ranges.
- 8.9 Appendix B: Acceptable Calibration Check Report.

Appendix A Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 122306
Calibration Date: 08/21/2009
Calibrated by: STEVEN E HARNOIS
Lot: 10-02-100



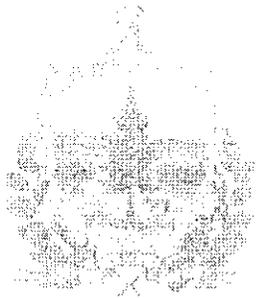
CA	=	0.181790		
CA3	=	7.7932435	0.800 <= CA3 < 1.200	
B1	=	0.000110	0.000 <= B1 < 0.004	
B2	=	0.004057	0.000 <= B2 < 0.012	
B3	=	0.000000	0.000 <= B3 < 0.004	
X2	=	0.108161	0.050 <= X2 < 0.200	
A2	=	1.193375	1.050 <= A2 < 1.300	
A3	=	0.419028	0.300 <= A3 < 0.500	

Acceptable range for b2 is
 $0.002 \leq b2 \leq 0.012$

Performed by *Steven E Harnois*

Date 08/21/2009

Appendix B Acceptable Calibration Check Report



ACCURACY AND PRECISION TEST

MILITARY APPROVAL

REPORT DATE: 04/11/08

REPORT NUMBER: 0101708

TEST CENTER:

APPROVED NAME: MR. DAN CHASE

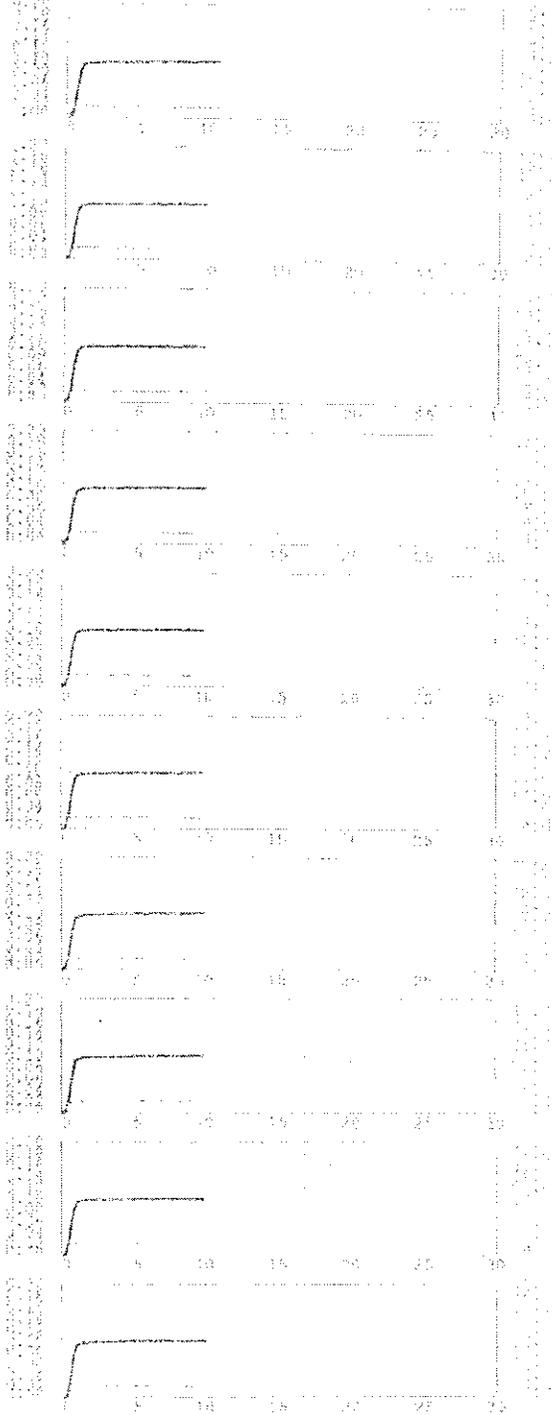
APPROVED BY: MR. DAN CHASE

DATE OF APPROVAL: 04/11/08

TEST ITEM	0.000	0.100
ACCELERATION	0.000	0.100
ACCELERATION (0.000)	0.000	0.100
ACCELERATION (0.100)	0.000	0.100
ACCELERATION (0.200)	0.000	0.100
ACCELERATION (0.300)	0.000	0.100
ACCELERATION (0.400)	0.000	0.100
ACCELERATION (0.500)	0.000	0.100
ACCELERATION (0.600)	0.000	0.100
ACCELERATION (0.700)	0.000	0.100
ACCELERATION (0.800)	0.000	0.100
ACCELERATION (0.900)	0.000	0.100
ACCELERATION (1.000)	0.000	0.100
ACCELERATION (1.100)	0.000	0.100
ACCELERATION (1.200)	0.000	0.100
ACCELERATION (1.300)	0.000	0.100
ACCELERATION (1.400)	0.000	0.100
ACCELERATION (1.500)	0.000	0.100
ACCELERATION (1.600)	0.000	0.100
ACCELERATION (1.700)	0.000	0.100
ACCELERATION (1.800)	0.000	0.100
ACCELERATION (1.900)	0.000	0.100
ACCELERATION (2.000)	0.000	0.100

APPROVED BY: MR. DAN CHASE

DATE OF APPROVAL: 04/11/08



Title: Laboratory Calibration of DataMaster DMT		Page 1 of 8
Doc. No. P-ALC-117 Revision No. 1	Approved By: _____ Owner: Kirk Kimball, Organic Program Chief	Date Effective: 12/21/10

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 calibration 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 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 Program Chief.
- 2.2 This procedure will be reviewed periodically by appropriate staff. Revisions of the procedure will be made when a need is identified. *chemistry*

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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.
- 3.4 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification. *Not necessary*

4.0 Procedure Steps

4.1 Materials and Supplies are all located in Room 124.

- 4.1.1 DataMaster DMT Instrument.
- 4.1.2 *Certified* NIST Traceable Thermometer.
- 4.1.3 *3 Wet bath* Guth 34C-NP Simulators.

Prober technology per CC.

Calibrated Traceable to NIST Standards

- 4.1.4 ~~Guth 2100 Simulator containing~~ volatile organic free, lab-pure water.
- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster ^{Cal Check} Simulator Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for ^{at least} one hour.
- 4.2.2 Activate Technician Mode using ^{your} ~~the technician level~~ password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than ~~0.003V~~ ^{+/- 0.100V} over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.

Check That The Detector Voltage is +/- 0.100

4.2.4 ~~The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions.~~

4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution.

4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.

4.2.5.2 A previously used Calibration Solution may be used under the following conditions:

4.2.5.2.1 If the solution has been open for no more than one week.

4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.

See 4.1.2

4.2.5.3 ^{certified} Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

Check Temp After Cal NOT Before

4.2.6 Prepare the ^a Calibration Simulator containing volatile organic free, lab-pure water.

4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary. *see 4.1.2*

4.2.7 Prepare a simulator containing ~0.10 EtOH External Standard Solution.

4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary. *see 4.1.2*

4.2.7.2 If new bottle of external standard solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate. *Cal Check see 4.1.2*

7 do we do this well

A prev. used Cal check may be used if...

4.3 Protocol Procedure

4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.2 Follow the instructions prompted by the DataMaster DMT.

4.3.2.1 When instructed to "Connect Water," attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using the small length of tygon tubing attached to the simulator. Press OK when ready. *4.3.2.05 Connect Calibration Simulator*

4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water." Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready. *Add Back in*

4.3.2.3 When instructed to "Connect Ethanol," attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

4.3.2.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol." Disconnect the simulator from the simulator tower. Press OK when ready.

Does not happen w/ new software

- 4.3.2.5 *If the Calibration passes,* The instrument will ~~now~~ ask for a technician signature. Sign ~~on the line provided and~~ press "finished" when complete. The calibration report will print in duplicate. *Make a 3rd copy*
- 4.3.3 *Output to USB?* Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report with acceptance ranges and Sections 6.1 and 6.2 for what to do if a value is not within range.
- 4.3.4 Perform a check of the calibration by analyzing a ~0.10 solution.
- 4.3.4.1 Attach a simulator containing ~0.10 ~~External Standard~~ *Cal Check* Solution at 34°C +/- 0.2°C to the simulator tower.
- 4.3.4.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.4.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter "Cal Check". Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press "OK".
- 4.3.4.4 The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within $\pm 1\%$ of the certified value of the solution with a standard deviation ≤ 0.002 . The instrument shall be recalibrated if the results do not meet these criteria. *or check Solution*
- 4.3.4.5 Print ³ ~~two~~ copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, for a triplicate review process.
- 4.3.5.1 After review, the reports are filed as follows:
- 4.3.5.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument's paper testing binder; discard the extra copy(s). Then place an electronic copy of all reports into the instrument electronic folder on the VDHL server.
- 4.3.5.3 If the instrument is beyond preliminary testing, file one copy of the reports in the monthly work completed file in the DataMaster records filing cabinet in the IR Lab (room 124).

3rd copy to go w/ TSI

The second copies will be kept with the instrument until it is deployed, then they will be put with the instrument's on-site maintenance records. Then place an electronic copy of all reports into the instrument electronic folder on the VDHL server.

3rd copy w/ TSI
Cal Subd
Check get logged somewhere?

does reviewer do this or tech?
Filling in a value for All Headers

4.3.6 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the Technician's name and date, the DataMaster DMT serial number, calibration solution lot-number, certified concentration, and solution temperature. Also document the CAL result, room temperature and whether or not a new bottle or a previously used solution was employed. *Used.*

~~Factor~~

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. ~~The action taken will vary depending on the specific problem.~~

6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.

Isn't this built into new software?

6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 3\%$ of the certified value of the simulator solution, or the standard deviation is >0.002 , the instrument ~~shall be recalibrated~~. *may require check solution first.*

6.4 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 program staff member. Correct the problem and document the event on a TSI. ~~not needed~~

6.5 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented. ~~not needed~~

6.5.1 If the instrument is still in the initial testing process, a TSI will be written and placed in the testing binder for that instrument. An electronic copy will also be filed in the instrument electronic folder.

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6.5.2 ~~If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook; then a~~
DataMaster Technical Support Inquiry worksheet (Alc 626) ~~must be~~ *must be*
completed and placed in the instrument's file. *Witt*

6.5.3 This procedure will be performed 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 organic chemistry staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support.

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

7.3 No back-up procedure available.

8.0 References

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

8.2 DataMaster DMT In-house Service Manual.

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

8.4 DataMaster DMT Certification Procedure (P-Alc-118).

8.5 Ethanol Simulator Solution Preparation (P-Alc-204).

8.6 DataMaster Calibration Logbook (Alc 668).

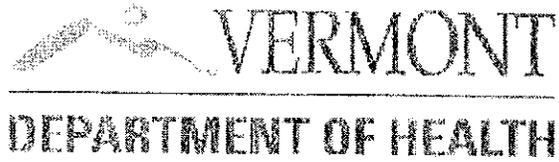
8.7 Appendix A: Acceptable Calibration Report with ranges.

8.8 Appendix B: Acceptable Calibration Check Report.

Appendix A
Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 122306
Calibration Date: 08/21/2009
Calibrated by: STEVEN E HARNOIS
Lot: 10-02-100



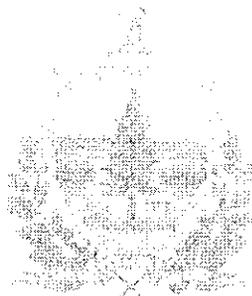
Ca	0.1191306	0.900	<=	0.00	<	1.200
Cr	7.1962435	0.900	<=	0.1	<	0.004
SI	0.000010	0.900	<=	0.2	<	0.005
SR	0.0000377	0.900	<=	0.1	<	0.004
BT	0.000000	0.900	<=	0.1	<	0.004
Zn	0.000101	0.900	<=	0.3	<	0.200
As	1.133370	1.000	<=	0.1	<	1.300
Se	0.459408	0.300	<=	0.5	<	0.900

Acceptable range for b2 is
 $0.002 \leq b2 \leq 0.012$

Performed by *Steve Harno*

Date 08/21/2009

Appendix B Acceptable Calibration Check Report



ACCURACY AND PRECISION TEST

FORM DOT 3100-1

DATE TEST RUN: 03/16/2010

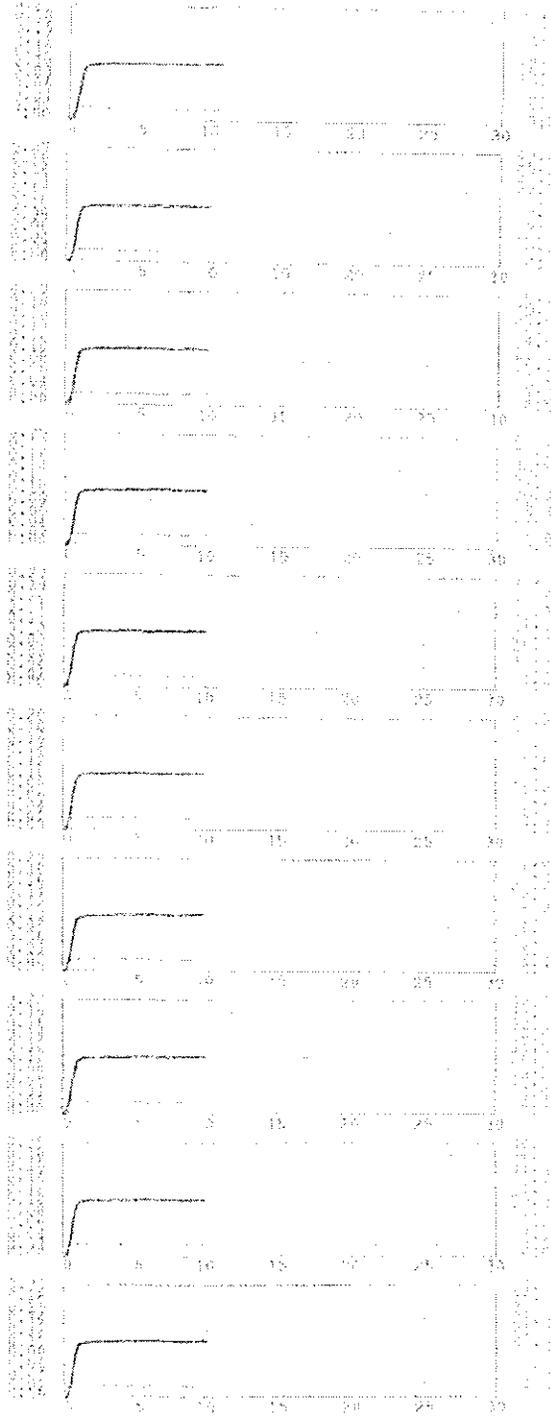
DATE RECEIVED:
TEST LOCATION:

DEPARTMENT NAME AND NO. STATE:

CALIBRATION BY: 10000-100
LABORATORY IDENTIFICATION NO. 0000

SLIP NO.	WEIGHT	TIME
00000	0.000	00:00
00001	0.000	00:00
00002	0.000	00:00
00003	0.000	00:00
00004	0.000	00:00
00005	0.000	00:00
00006	0.000	00:00
00007	0.000	00:00
00008	0.000	00:00
00009	0.000	00:00
00010	0.000	00:00
00011	0.000	00:00
00012	0.000	00:00
00013	0.000	00:00
00014	0.000	00:00
00015	0.000	00:00
00016	0.000	00:00
00017	0.000	00:00
00018	0.000	00:00
00019	0.000	00:00
00020	0.000	00:00

Average: 0.000
Std Dev: 0.000



Bryce-Parrott, Cara

From: Celotti, Stella
Sent: Tuesday, August 02, 2011 3:58 PM
To: Kimball, Kirk
Cc: Bryce-Parrott, Cara
Subject: Procedure and Form Approved

Kirk, P-ALC-117, Rev 1, Laboratory Calibration of the DataMaster DMT and Chem 642, Rev 2, Simulator Solution Preparation Log, 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 Calibration of DataMaster DMT		Page 1 of 8
Doc. No. P-Alc-117 Revision No.0	Approved By: <i>KAC</i> Owner: Kirk Kimball, Organic Program Chief	Date: 1/05/11 Date Effective: 12/21/10

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 calibration 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 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 Program Chief.
- 2.2 This procedure will be reviewed periodically by appropriate 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.
- 3.4 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification.

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 Two Guth 34C-NP Simulators.

- 4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.
- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Simulator Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for one hour.
- 4.2.2 Activate Technician Mode using the technician level password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.
- 4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions.
- 4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution.
 - 4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.
 - 4.2.5.2 A previously used Calibration Solution may be used under the following conditions:
 - 4.2.5.2.1 If the solution has been open for no more than one week.
 - 4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.
 - 4.2.5.3 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

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Doc. No. P-AIC-117 Revision No.0	Approved By: Owner: Kirk Kimball, Organic Program Chief <i>KJK</i>	Date: 1/05/11 Date Effective: 12/21/10

- 4.2.6 Prepare the Calibration Simulator containing volatile organic free, lab-pure water.
 - 4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary.
- 4.2.7 Prepare a simulator containing ~0.10 EtOH External Standard Solution.
 - 4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.
 - 4.2.7.2 If new bottle of external standard solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate.

4.3 Protocol Procedure

- 4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.
- 4.3.2 Follow the instructions prompted by the DataMaster DMT.
 - 4.3.2.1 When instructed to “Connect Water,” attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using the small length of tygon tubing attached to the simulator. Press OK when ready.
 - 4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to “Disconnect Water.” Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.
 - 4.3.2.3 When instructed to “Connect Ethanol,” attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.
 - 4.3.2.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to “Disconnect Ethanol.” Disconnect the simulator from the simulator tower. Press OK when ready.

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- 4.3.2.5 The instrument will now ask for a technician signature. Sign on the line provided and press “finished” when complete. The calibration report will print in duplicate.
- 4.3.3 Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report with acceptance ranges and Sections 6.1 and 6.2 for what to do if a value is not within range.
- 4.3.4 Perform a check of the calibration by analyzing a ~0.10 solution.
- 4.3.4.1 Attach a simulator containing ~0.10 External Standard Solution at 34°C +/- 0.2°C to the simulator tower.
- 4.3.4.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.4.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter “Cal Check”. Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press “OK”.
- 4.3.4.4 The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within $\pm 3\%$ of the certified value of the solution with a standard deviation ≤ 0.002 . The instrument shall be recalibrated if the results do not meet these criteria.
- 4.3.4.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, to a second technician for review.
- 4.3.5.1 After review, the reports are filed as follows:
- 4.3.5.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument’s testing binder; discard the extra copy.
- 4.3.5.3 If the instrument is beyond preliminary testing, file one copy of the reports in the monthly work completed file in the DataMaster records filing cabinet in the IR Lab (room 124). The second copies will be kept with the instrument until it is

Title: Laboratory Calibration of DataMaster DMT		Page 5 of 8
Doc. No. P-Alc-117 Revision No.0	Approved By: Owner: Kirk Kimball, Organic Program Chief <i>KJK</i>	Date: 1/05/11 Date Effective: 12/21/10

deployed, then they will be put with the instrument's on-site maintenance records.

- 4.3.6 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the Technician's name and date, the DataMaster serial number, calibration solution lot number, certified concentration, and solution temperature. Also document the CAL result, room temperature and whether or not a new bottle or a previously used solution was employed.

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

- 6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.
- 6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 3\%$ of the certified value of the simulator solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.
- 6.4 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 Blood Alcohol staff member. Try to correct the problem and document the event.
- 6.5 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented.
 - 6.5.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.
 - 6.5.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

Title: Laboratory Calibration of DataMaster DMT		Page 6 of 8
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6.5.3 This procedure will be performed 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 organic chemistry staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support.
- 7.2 If an agency's instrument cannot be made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.
- 7.3 No back-up procedure available.

8.0 References

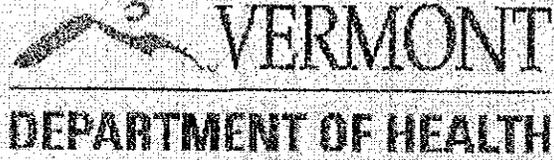
- 8.1 VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2 DataMaster DMT In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Appendix A: Acceptable Calibration Report with ranges.
- 8.8 Appendix B: Acceptable Calibration Check Report

REV
1-5-11

Appendix A Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 122306
Calibration Date: 08/21/2009
Calibrated by: STEVEN E HARNOIS
Lot: 10-02-100



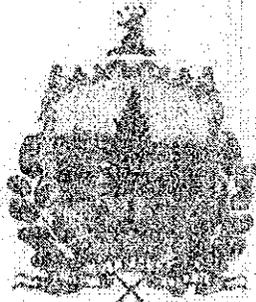
Ca =	0.101000		
CAL =	1.022435	0.800 <=	CAL < 1.200
b1 =	0.000010	0.000 <=	b1 < 0.004
b2 =	0.004077	0.001 <=	b2 < 0.012
b3 =	0.000000	0.000 <=	b3 < 0.004
Xq =	0.098161	0.050 <=	Xq < 0.200
a21 =	1.193076	1.050 <=	a21 < 1.300
a31 =	0.459486	0.300 <=	a31 < 0.800

Acceptable range for b2 is
 $0.002 \leq b2 \leq 0.012$

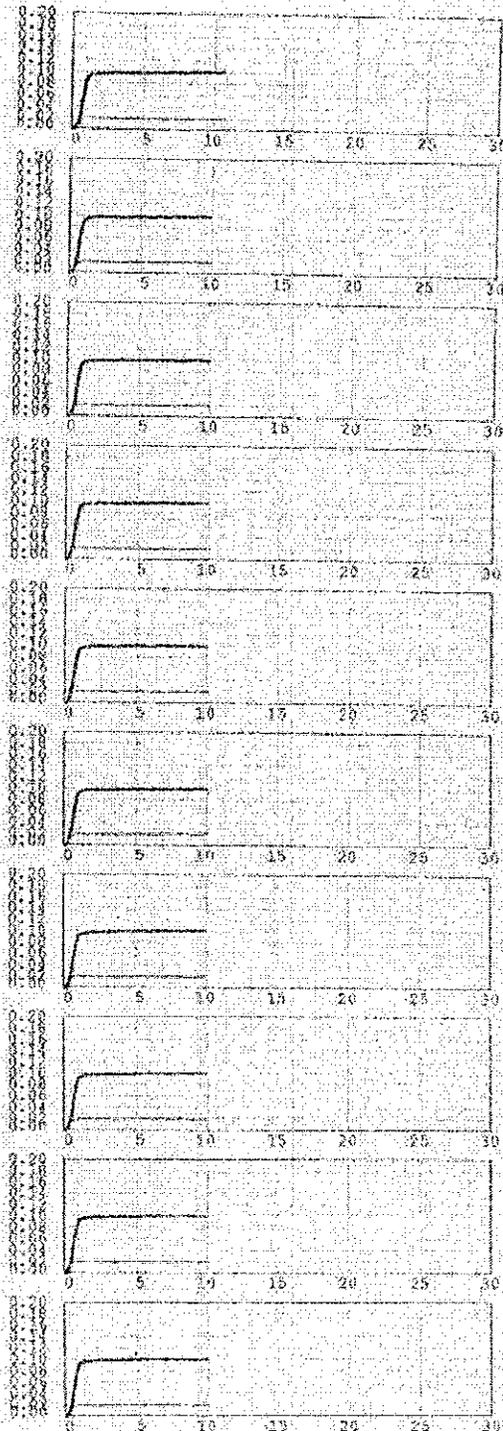
Performed by *St. H.*

Date 08/21/2009

Appendix B Acceptable Calibration Check Report



ACCURACY AND PRECISION TEST		
STATE OF VERMONT		
Reference IMI: 101708		
Date: 03/16/2010		
Time: 07:08:56		
SUPERVISOR NAME: ALE CRO CHECK		
SOLUTION LOT #: 10-23-100		
SOLUTION CONCENTRATION: 0.100		
BLANK TEST	0.000	07:09
CALIBRATION CHECK	PASSED	07:09
SIMULATOR VAPOR (34.3°C)	0.099	07:10
SIMULATOR VAPOR (34.3°C)	0.100	07:11
SIMULATOR VAPOR (34.3°C)	0.099	07:12
SIMULATOR VAPOR (34.3°C)	0.100	07:13
SIMULATOR VAPOR (34.3°C)	0.099	07:14
SIMULATOR VAPOR (34.3°C)	0.100	07:15
SIMULATOR VAPOR (34.2°C)	0.101	07:16
SIMULATOR VAPOR (34.3°C)	0.100	07:17
SIMULATOR VAPOR (34.3°C)	0.100	07:18
SIMULATOR VAPOR (34.3°C)	0.100	07:19
BLANK TEST	0.000	07:20
Average = 0.099		
Std Dev = 0.0006		



Vermont Department of Health Laboratory
Procedure and Document Review Coversheet

Document Title: Laboratory Calibration of DataMaster DMT Instruments	
Document #: P-Alc-117	Revision #: 0
File Name:	
Author or Editor: Amanda Bolduc	Owner
Start Date: 12/11/08 rewritten 12/31/09	Due D. 8/20/10

Name and Title of Reviewers	Signature
Darcy Richardson Chemist	<i>Darcy Richardson</i>
Steven Harnois Technician	<i>Steve Harnois</i>
Robert Drawbaugh Toxicology Program Chief	<i>Bob Drawbaugh</i>
Ed Luce QA Officer	<i>Edmond P. Luce</i>
Mary Celotti Lab Director	<i>Mary Celotti</i>
<i>Please re-review</i>	
Darcy	<i>Darcy Richardson</i>
Steve	<i>Steve Harnois</i>
Bob	<i>Bob Drawbaugh</i>
Ed	<i>Edmond P. Luce</i>
Mary	<i>Mary Celotti</i>
Kirk Kimball	<i>Kirk Kimball</i>

Ready for final review.

11/8/10
Kirk - once reviewed + if there are no changes - please return to me for close-out.
- thank u stella

11/19/10
Stella

Ready for final review.

CA

* (✓) in checkbox indicates reviewer comments have been

Title: Laboratory Calibration of DataMaster DMT		Page 1 of 8
Doc. No. P-Alc-117 Revision No.0	Approved By: _____ Owner: Kirk Kimball, Organic Program Chief	Date: 11/22/10 Date Effective: 11/22/10

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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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.
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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 Two Guth 34C-NP Simulators.

- 4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.
- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Simulator Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for one hour.
- 4.2.2 Activate Technician Mode using the technician level password.
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 - 4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.
 - 4.2.5.2 A previously used Calibration Solution may be used under the following conditions:
 - 4.2.5.2.1 If the solution has been open for no more than one week.
 - 4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.
 - 4.2.5.3 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

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Doc. No. P-AIC-117 Revision No.0	Approved By: Owner: Kirk Kimball, Organic Program Chief	Date: 11/22/10 Date Effective: 11/22/10

- 4.2.6 Prepare the Calibration Simulator containing volatile organic free, lab-pure water.
 - 4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary.
- 4.2.7 Prepare a simulator containing ~0.10 EtOH External Standard Solution.
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- 4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.
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 - 4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to “Disconnect Water.” Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.
 - 4.3.2.3 When instructed to “Connect Ethanol,” attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.
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Doc. No. P-AIC-117 Revision No.0	Approved By: _____ Owner: Kirk Kimball, Organic Program Chief	Date: 11/22/10 Date Effective: 11/22/10

- 4.3.2.5 The instrument will now ask for a technician signature. Sign on the line provided and press “finished” when complete. The calibration report will print in duplicate.
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Title: Laboratory Calibration of DataMaster DMT		Page 5 of 8
Doc. No. P-Alc-117 Revision No.0	Approved By: _____ Owner: Kirk Kimball, Organic Program Chief	Date: 11/22/10 Date Effective: 11/22/10

deployed, then they will be put with the instrument's on-site maintenance records.

- 4.3.6 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the Technician's name and date, the DataMaster serial number, calibration solution lot number, certified concentration, and solution temperature. Also document the CAL result, room temperature and whether or not a new bottle or a previously used solution was employed.

5.0 Emergency or High Priority Situations

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6.0 Quality Criteria and Corrective Action

- 6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.
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- 6.5.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.
- 6.5.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

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6.5.3 This procedure will be performed 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 organic chemistry staff, the instrument manufacturer, National Patent Analytical Systems, Inc. will be contacted for technical support.
- 7.2 If an agency's instrument cannot be made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.
- 7.3 No back-up procedure available.

8.0 References

- 8.1 VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2 DataMaster DMT In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Appendix A: Acceptable Calibration Report with ranges.
- 8.8 Appendix B: Acceptable Calibration Check Report

Appendix A
Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 122306
Calibration Date: 08/21/2009
Calibrated by: STEVEN E HARNOIS
Lot: 10-02-100



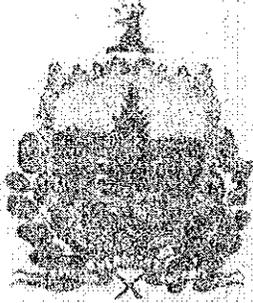
Ca	=	0.101000		
CAL	=	1.022435	0.800 <=	CAL < 1.200
b1	=	0.000010	0.000 <=	b1 < 0.004
b2	=	0.004077	0.001 <=	b2 < 0.012
b3	=	0.000000	0.000 <=	b3 < 0.004
Xq	=	0.088161	0.050 <=	Xq < 0.200
a21	=	1.193076	1.050 <=	a21 < 1.300
a31	=	0.459486	0.300 <=	a31 < 0.800

Acceptable range for b2 is
 $0.002 \leq b2 \leq 0.012$

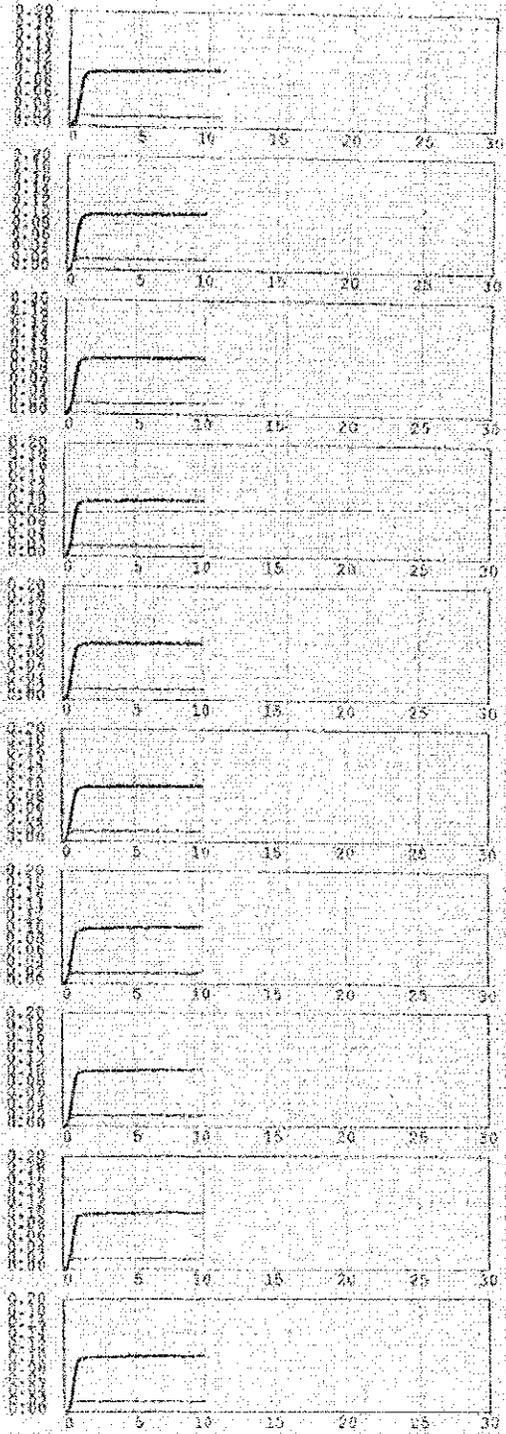
Performed by *St. P.*

Date 08/21/2009

Appendix B Acceptable Calibration Check Report



ACCURACY AND PRECISION TEST		
STATE OF VERMONT		
DEPARTMENT INT: 101708		
Date: 03/16/2010		
Time: 07:08:55		
SUPERVISOR NAME: ALB. CAL. CHECK		
SOLUTION LOT #: 10-25-105		
SOLUTION CONCENTRATION: 0.100		
BLANK TEST	0.000	07:09
CALIBRATION CHECK	PASSED	07:09
SIMULATOR VAPOR (34.5°C)	0.099	07:10
SIMULATOR VAPOR (34.3°C)	0.100	07:11
SIMULATOR VAPOR (34.3°C)	0.099	07:12
SIMULATOR VAPOR (34.3°C)	0.100	07:13
SIMULATOR VAPOR (34.3°C)	0.099	07:14
SIMULATOR VAPOR (34.3°C)	0.100	07:15
SIMULATOR VAPOR (34.3°C)	0.101	07:16
SIMULATOR VAPOR (34.3°C)	0.100	07:17
SIMULATOR VAPOR (34.3°C)	0.100	07:18
SIMULATOR VAPOR (34.3°C)	0.100	07:19
BLANK TEST	0.000	07:20
Average = 0.099		
Std Dev = 0.0005		



DMT Serial Number #101708

Page 1 of 1

03/16/2010 07:20

Title: Laboratory Calibration of DataMaster DMT		Page 1 of 8
Doc. No. P-Alc-117 Revision No.0	Approved By: _____ Owner: <u>Toxicology Program Chief</u>	Date Effective: _____

Organic Chemistry

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 calibration 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 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~~ ^{but ATC. appropriate} 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.
- 3.4 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification.

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 Two Guth 34C-NP Simulators.

Title: Laboratory Calibration of DataMaster DMT		Page 2 of 8
Doc. No. P-Alc-117 Revision No.0	Approved By: Owner: Technology Program Chief	Date: Date Effective:

- 4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.
- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Simulator Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for one hour.
- 4.2.2 Activate Technician Mode using the technician level password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.
- 4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions.
- 4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution.
 - 4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.
 - 4.2.5.2 A previously used Calibration Solution may be used under the following conditions:
 - 4.2.5.2.1 If the solution has been open for no more than one week.
 - 4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.
 - 4.2.5.3 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

Title: Laboratory Calibration of DataMaster DMT		Page 3 of 8
Doc. No. P-AIC-117 Revision No.0	Approved By: Owner: Toxicology Program Chief	Date: Date Effective:

4.2.6 Prepare the Calibration Simulator containing volatile organic free, lab-pure water.

4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7 Prepare a simulator containing ~0.10 EtOH External Standard Solution.

4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7.2 If new bottle of external standard solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate.

4.3 Protocol Procedure

4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.2 Follow the instructions prompted by the DataMaster DMT.

4.3.2.1 When instructed to "Connect Water," attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using the small length of tygon tubing attached to the simulator. Press OK when ready.

4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water." Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

4.3.2.3 When instructed to "Connect Ethanol," attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

4.3.2.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol." Disconnect the simulator from the simulator tower. Press OK when ready.

Title: Laboratory Calibration of DataMaster DMT		Page 4 of 8
Doc. No. P-AIC-117 Revision No.0	Approved By: Owner: Toxicology Program Chief	Date: Date Effective:

- 4.3.2.5 The instrument will now ask for a technician signature. Sign on the line provided and press “finished” when complete. The calibration report will print in duplicate.
- 4.3.3 Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report with acceptance ranges and Sections 6.1 and 6.2 for what to do if a value is not within range.
- 4.3.4 Perform a check of the calibration by analyzing a ~0.10 solution.
- 4.3.4.1 Attach a simulator containing ~0.10 External Standard Solution at 34°C +/- 0.2°C to the simulator tower.
- 4.3.4.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.4.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter “Cal Check”. Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press “OK”.
- 4.3.4.4 The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within $\pm 3\%$ of the certified value of the solution with a standard deviation ≤ 0.002 . The instrument shall be recalibrated if the results do not meet these criteria.
- 4.3.4.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, to a second technician for review.
- 4.3.5.1 After review, the reports are filed as follows:
- 4.3.5.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument’s testing binder; discard the extra copy.
- 4.3.5.3 If the instrument is beyond preliminary testing, file one copy of the reports in the monthly work completed file in the DataMaster records filing cabinet in the IR Lab (room 124). The second copies will be kept with the instrument until it is

Title: Laboratory Calibration of DataMaster DMT		Page 5 of 8
Doc. No. P-ALC-117 Revision No.0	Approved By: Owner: Toxicology Program Chief	Date: Date Effective:

deployed, then they will be put with the instrument's on-site maintenance records.

- 4.3.6 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the Technician's name and date, the DataMaster serial number, calibration solution lot number, certified concentration, and solution temperature. Also document the CAL result, room temperature and whether or not a new bottle or a previously used solution was employed.

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

- 6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.
- 6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.
- 6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 3\%$ of the certified value of the simulator solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.
- 6.4 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. *Big Alc*
- 6.5 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented.
- 6.5.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.
- 6.5.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

Title: Laboratory Calibration of DataMaster DMT		Page 6 of 8
Doc. No. P-Alc-117 Revision No.0	Approved By: Owner: Toxicology Program Chief	Date: Date Effective:

6.5.3 This procedure will be performed 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 made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.
- 7.3 No back-up procedure available.

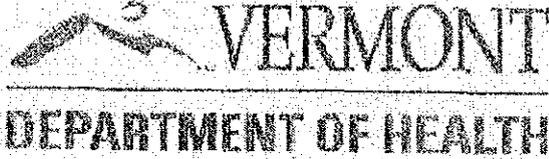
8.0 References

- 8.1 VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2 DataMaster DMT In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Appendix A: Acceptable Calibration Report with ranges.
- 8.8 Appendix B: Acceptable Calibration Check Report.

Appendix A
Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 122306
Calibration Date: 08/21/2009
Calibrated by: STEVEN E HARNOIS
Lot: 10-02-100



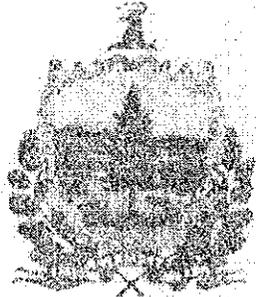
Ca	=	0.101000		
CAL	=	1.022435	0.800	<= CAL < 1.200
b1	=	0.000010	0.000	<= b1 < 0.004
b2	=	0.004077	0.001	<= b2 < 0.012
b3	=	0.000000	0.000	<= b3 < 0.004
Xq	=	0.009161	0.050	<= Xq < 0.200
a21	=	1.193075	1.050	<= a21 < 1.300
a31	=	0.459406	0.300	<= a31 < 0.800

Acceptable range for b2 is
 $0.002 \leq b2 \leq 0.012$

Performed by *St. H.*

Date 08/21/2009

Appendix B Acceptable Calibration Check Report



ACCURACY AND PRECISION TEST

STATE OF MARYLAND

Date/Tester: 03/16/2010

Time: 07:08:55

SUPERVISOR NAME: ALEX CHAU CHICK

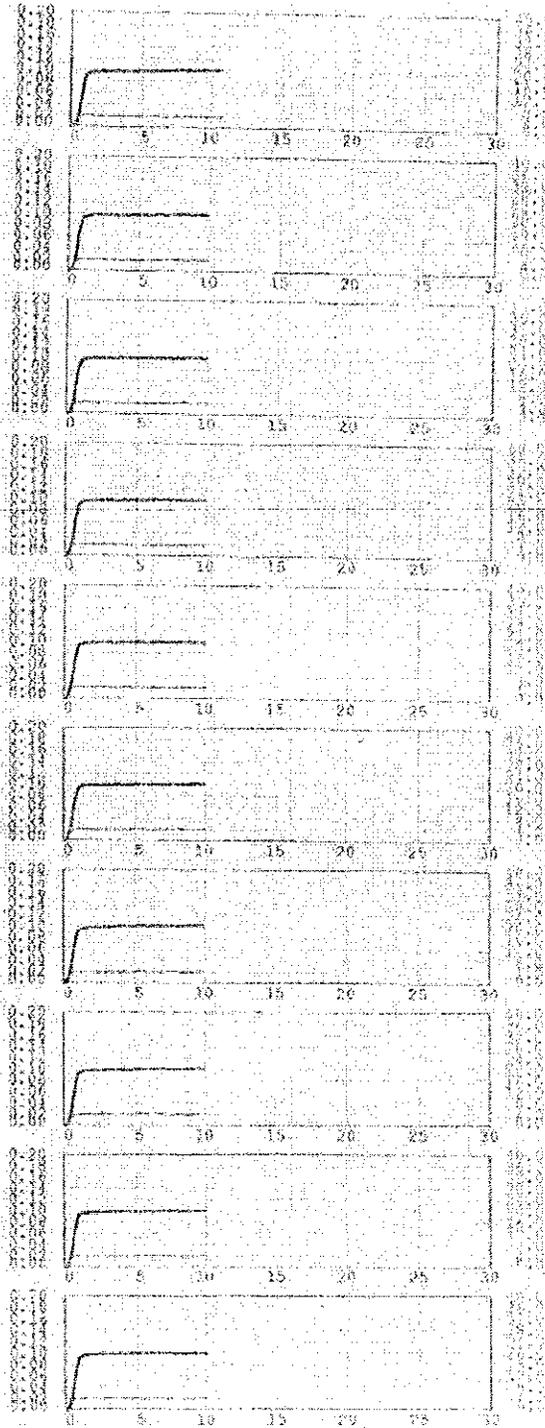
SOLUTION LOT #: 10-25-100

CONCENTRATION: 0.100

BLANK TEST	0.000	07:07
CALIBRATION CHECK	PASSED	07:09
SIMULATOR VAPOR (35.5°C)	0.099	07:10
SIMULATOR VAPOR (34.3°C)	0.100	07:11
SIMULATOR VAPOR (34.1°C)	0.099	07:12
SIMULATOR VAPOR (34.3°C)	0.100	07:13
SIMULATOR VAPOR (34.1°C)	0.099	07:14
SIMULATOR VAPOR (34.1°C)	0.100	07:15
SIMULATOR VAPOR (34.3°C)	0.100	07:17
SIMULATOR VAPOR (34.3°C)	0.100	07:18
SIMULATOR VAPOR (34.3°C)	0.100	07:19
BLANK TEST	0.000	07:20

Average = 0.099

Std Dev = 0.0006



DMT Serial Number 401708

Page 4 of 1

03/16/2010 07:20

Title: Laboratory Calibration of DataMaster DMT		Page 1 of 8
Doc. No. P-Alc-117 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 calibration 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 calibrated by trained laboratory staff before being installed in any location for evidentiary testing.

2.0 Responsibility

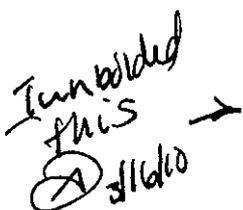
- 2.1 It is the responsibility of staff performing this task to follow the procedure as written, to note any omissions, errors or unclear instructions in the procedure and bring them to the attention of the Toxicology Program Chief.
- 2.2 This procedure will be reviewed periodically by toxicology staff. 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 **Any changes made to the bias, lamp or cooler voltages of an instrument necessitate a recalibration.**
- 3.4 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification.

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 Two Guth 34C-NP Simulators.

Embedded this


Title: Laboratory Calibration of DataMaster DMT		Page 2 of 8
Doc. No. P-Alc-117 Draft Revision No.0	Approved By: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective:

- 4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.
- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Simulator Solution prepared following the procedure noted in P-Alc-204; Ethanol Simulator Solution Preparation.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for one hour.
- 4.2.2 Activate Technician Mode using the technician level password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.
- 4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions.
- 4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution.
 - 4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature and equilibrate for at least 30 minutes.
 - 4.2.5.2 A previously used Calibration Solution may be used under the following conditions:
 - 4.2.5.2.1 If the solution has been open for no more than one week.
 - 4.2.5.2.2 If the solution has been analyzed no more than twenty (20) times.
 - 4.2.5.3 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C; adjust as necessary. *how?*

Title: Laboratory Calibration of DataMaster DMT		Page 3 of 8
Doc. No. P-AIC-117 Draft Revision No.0	Approved By: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective:

4.2.6 Prepare the Calibration Simulator containing volatile organic free, lab-pure water.

4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary. *how?*

4.2.7 Prepare a simulator containing ~0.10 EtOH External Standard Solution.

4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust *how?* as necessary.

4.2.7.2 If new bottle of external standard solution is opened, allow at least thirty minutes for the solution to come to temperature and equilibrate.

4.2.7.3 *Can a previously used solution allowed to be used?*

4.3 Protocol Procedure *like 4.2.5.2.*

4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.2 Follow the instructions prompted by the DataMaster DMT.

4.3.2.1 When instructed to “Connect Water,” attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using the small length of tygon tubing attached to the simulator. Press OK when ready.

4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to “Disconnect Water.” Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

4.3.2.3 When instructed to “Connect Ethanol,” attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

4.3.2.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to “Disconnect Ethanol.” Disconnect the simulator from the simulator tower. Press OK when ready.

- 4.3.2.5 The instrument will now ask for a technician signature. Sign on the line provided and press “finished” when complete. The calibration report will print in duplicate.
- 4.3.3 Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report with acceptance ranges.
- 4.3.4 Perform a check of the calibration by analyzing a ~0.10 solution.
 - 4.3.4.1 Attach a simulator containing ~0.10 External Standard Solution at 34°C +/- 0.2°C to the simulator tower.
 - 4.3.4.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
 - 4.3.4.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter “Cal Check”. Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press “OK”.
 - 4.3.4.4 The instrument will analyze the solution ten times and calculate ^{the} average and standard deviation. The average result must be within ±3% of the certified value of the solution with a standard deviation ≤0.002. The instrument shall be recalibrated if the results do not meet these criteria.
 - 4.3.4.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, to a second technician for review.

↓ What if they are not within range?
see section 6.1-6.2

will need to address review process w/ procedure or a checklist

- 4.3.5.1 After review, the reports are filed as follows:
- 4.3.5.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument’s testing binder; discard the extra copy.
- 4.3.5.3 If the instrument is beyond preliminary testing, file one copy of the reports in the monthly work completed file in the DataMaster records filing cabinet in the IR Lab (room 124). The second copies will be kept with the instrument until it is deployed, then they will be put with the instrument’s on-site maintenance records.

Title: Laboratory Calibration of DataMaster DMT		Page 5 of 8
Doc. No. P-Alc-117 Draft Revision No.0	Approved By: _____ Owner: Toxicology Program Chief	Date: _____ Date Effective:

4.3.6 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the Technician's name and date, the DataMaster serial number, calibration solution lot number, certified concentration, and solution temperature. Also, the CAL result, room temperature and whether or not a new bottle or a previously used solution was employed.

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.

6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.

6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 3\%$ of the certified value of the simulator solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.

6.4 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.

6.5 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented.

6.5.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.

6.5.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

6.5.3 This procedure will be performed again when the problem is resolved.

Title: Laboratory Calibration of DataMaster DMT		Page 6 of 8
Doc. No. P-Alc-117 Draft Revision No.0	Approved By: Owner: Toxicology Program Chief	Date: Date Effective:

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 made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.

7.3 *No back-up procedure available*

8.0 References

- 8.1 VDHL Chemical Hygiene Plan and Laboratory Safety Manual (D-AD-003).
- 8.2 DataMaster DMT In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Appendix A: Acceptable Calibration Report with ranges.
- 8.8 Appendix B: Acceptable Calibration Check Report

Appendix A
Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 122306
Calibration Date: 08/21/2009
Calibrated by: STEVEN E HARNOIS
Lot: 10-02-100



Ca	=	0.101000	
CAL	=	1.022435	0.800 <= CAL < 1.200
b1	=	0.000010	0.000 <= b1 < 0.004
b2	=	0.004077	0.001 <= b2 < 0.012
b3	=	0.000000	0.000 <= b3 < 0.004
Xg	=	0.088161	0.050 <= Xg < 0.200
a21	=	1.193076	1.050 <= a21 < 1.300
a31	=	0.459486	0.300 <= a31 < 0.800

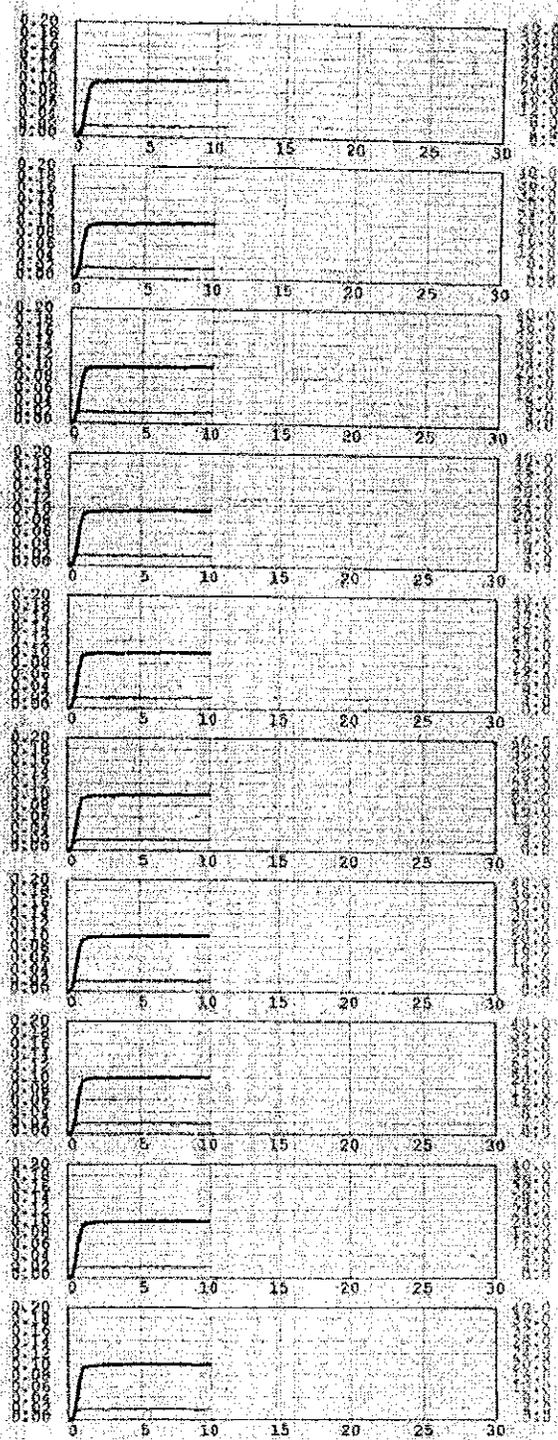
Acceptable range for b2 is
 $0.002 \leq b2 \leq 0.012$

Performed by *SE Harnois* Date 08/21/2009

Appendix B Acceptable Calibration Check Report



ACCURACY AND PRECISION TEST		
STATE OF VERMONT		
DataMaster ID#: 101708		
Date: 03/16/2010		
Time: 07:08:55		
SUPERVISOR NAME: ALB CAL CHECK		
SOLUTION LOT #: 10-23-190		
SOLUTION CONCENTRATION: 0.100		
BLANK TEST	0.000	07:09
CALIBRATION CHECK	PASSED	07:09
SIMULATOR VAPOR (34.3°C)	0.099	07:10
SIMULATOR VAPOR (34.3°C)	0.100	07:11
SIMULATOR VAPOR (34.3°C)	0.099	07:12
SIMULATOR VAPOR (34.3°C)	0.100	07:13
SIMULATOR VAPOR (34.3°C)	0.099	07:14
SIMULATOR VAPOR (34.3°C)	0.100	07:15
SIMULATOR VAPOR (34.2°C)	0.101	07:16
SIMULATOR VAPOR (34.3°C)	0.100	07:17
SIMULATOR VAPOR (34.3°C)	0.100	07:19
SIMULATOR VAPOR (34.3°C)	0.100	07:19
BLANK TEST	0.000	07:20
Average = 0.099		
Std Dev = 0.0006		



Procedures using this header are not valid unless accompanied by Approval History sheet showing current approvals (ADMIN 934).

Title: Laboratory Calibration of DataMaster DMT		Page 1 of 8
Doc. No. P-Alc-117 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 calibration 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 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification.

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 Two Guth 34(CNP) Simulators.
2100 2100
 - 4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.

- 4.1.5 0.10 EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.
- 4.1.6 0.10 EtOH DataMaster Simulator Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for one hour.
- 4.2.2 Activate Technician Mode using the technician level password.
- 4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.
- 4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions. **Any changes made to the bias, lamp or cooler voltages require a recalibration.** *]- move to sec. 3*

*Revised statement not needed since calibration has not been done yet
RWD
3/11/10*

- 4.2.5 Prepare the Calibration Simulator containing ~0.10 EtOH Calibration Solution.
 - 4.2.5.1 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature. *30 min equil.*
 - 4.2.5.2 A previously used Calibration Solution may be used under the following conditions:
 - 4.2.5.2.1 If the solution has been open for less than one week. *no more?*
 - 4.2.5.2.2 If the solution has been analyzed less than twenty (20) times.
 - 4.2.5.3 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

*Should mention minimum equilibration time before using. This could be a critical issue.
RWD
3/11/10*

- 4.2.6 Prepare the Calibration Simulator containing volatile organic free, lab-pure water.

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4.2.6.1 Using a NIST traceable thermometer, check the temperature of the water. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7 Prepare a simulator containing ~0.10 EtOH External Standard Solution.

4.2.7.1 Using a NIST traceable thermometer, check the temperature of the solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7.2 if open new bottle then equil.

4.3 Protocol Procedure

4.3.1 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.2 Follow the instructions prompted by the DataMaster DMT.

4.3.2.1 When instructed to "Connect Water," attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using the small length of tygon tubing attached to the simulator. Press OK when ready.

4.3.2.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water." Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

4.3.2.3 When instructed to "Connect Ethanol," attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

4.3.2.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol." Disconnect the simulator from the simulator tower. Press OK when ready.

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

*member use
at 5/20/10
KJ 5/21/10*

Where are "acceptable ranges" referenced? (4/3/10)

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

4.3.4 Perform a check of the calibration by analyzing a ~0.10 solution.

acceptable range

*reference need
 for sim. to have
 equilibrated RSD 3/11/10*

- 4.3.4.1 Attach a simulator containing ~0.10 External Standard Solution at 34°C +/- 0.2°C to the simulator tower.
- 4.3.4.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION.
- 4.3.4.3 In the first name field, enter the initials of the technician performing the test. In the last name field enter "Cal Check". Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press "OK".
- 4.3.4.4 The instrument will analyze the solution ten times and calculate and average and standard deviation. The average result must be within ±3% of the certified value of the solution with a standard deviation ≤0.002. The instrument shall be recalibrated if the results do not meet these criteria.
- 4.3.4.5 Print two copies of the Accuracy and Precision report to document the calibration check.
- 4.3.5 The calibration and calibration check reports are kept with the instrument until certification is complete. The reports are then submitted along with the certification report, to a second technician for review.
 - 4.3.5.1 After review the reports are filed as follows:
 - 4.3.5.2 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument's testing binder; discard the extra copy.
 - 4.3.5.3 If the instrument is beyond preliminary testing, file one copy of the reports in the monthly work completed file in the DataMaster records filing cabinet in the IR Lab (room 124).
 - ←→ The second copies will be put in the instrument's on-site maintenance records once the instrument is installed at an agency.
- 4.3.6 Make an entry in the DataMaster Calibration Logbook (AIC 668) which documents the DataMaster serial number, calibration solution lot number, calibration solution temperature, room temperature and humidity, analysts initials, and date.

*kept with instrument
 until installation? RSD
 3/11/10*

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

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

6.0 Quality Criteria and Corrective Action

- 6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.

- 6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.

6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 3\%$ of the certified value of the simulator solution, or the standard deviation is >0.002 , the instrument shall be recalibrated.

*There is no criterion for when S.D. is .002
RID 7/11/10*

- 6.4 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.

- 6.5 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented. ~~where~~ *2/21/10*

6.5.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.

6.5.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

6.5.3 This procedure will be performed 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.

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7.2 If an agency's instrument cannot be made field ready within two weeks of removal from the agency, 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 In-house Service Manual.

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

8.4 DataMaster DMT Certification Procedure (P-Alc-118).

8.5 Ethanol Simulator Solution Preparation (P-Alc-204).

8.6 DataMaster Calibration Logbook (Alc 668).

8.7 Appendix A: Acceptable Calibration Report.

8.8 Appendix B: 12/3/11

Appendix A
Acceptable Calibration Report

*include example
before final administrative
review. 3/10/10 R/D*

Appendix B Acceptable Calibration Check Report



ACCURACY AND PRECISION TEST

STATE OF VERMONT

DataMaster DMF: 121706

Date: 08/11/2008

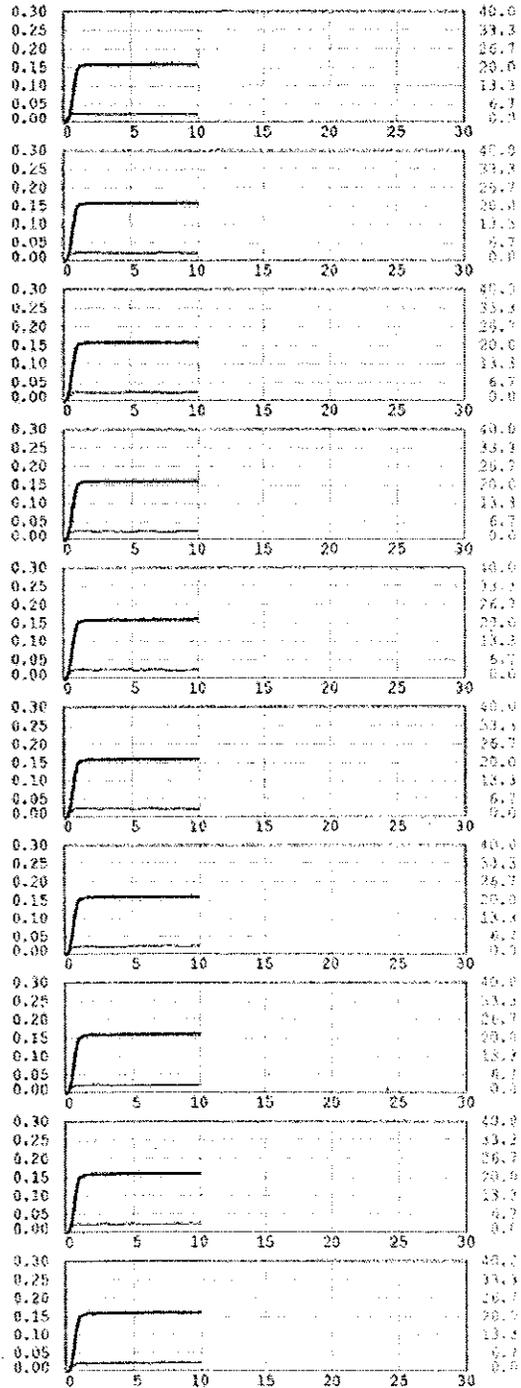
Time: 14:31:19

SUPERVISOR NAME: EARCY M RICHARDSON

SOLUTION LOT #: 08-22-160
SOLUTION CONCENTRATION: 0.159

BLANK TEST	0.000	14:32
INTERNAL STANDARD	PASSED	14:32
SIMULATOR VAPOR	0.158	14:32
SIMULATOR VAPOR	0.158	14:33
SIMULATOR VAPOR	0.157	14:34
SIMULATOR VAPOR	0.156	14:35
SIMULATOR VAPOR	0.159	14:36
SIMULATOR VAPOR	0.159	14:37
SIMULATOR VAPOR	0.158	14:38
SIMULATOR VAPOR	0.159	14:39
SIMULATOR VAPOR	0.159	14:40
SIMULATOR VAPOR	0.158	14:41
BLANK TEST	0.000	14:42

Average = 0.1583
Std Dev = 0.0007



DMF Serial Number #121706

Page 1 of 1

08/11/2008 14:42

Title: Laboratory Calibration of DataMaster DMT		Page 1 of 6
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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 calibration 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 calibrated by trained laboratory staff before being installed in any location for evidentiary testing. *and certified*

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 *When new* Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.3 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification.

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 Two Guth 34CNP Simulators.
- 4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.

4.1.5 0.10% EtOH DataMaster Calibration Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.

4.1.6 0.10% EtOH DataMaster Simulator Solution prepared following the procedure noted in P-Alc-204, Ethanol Simulator Solution Preparation.

Should this be g/100L? or perhaps just "0.10 EtOH"

4.2 Preparation

4.2.1 Allow the instrument to warm up for one hour.

4.2.2 Activate Technician Mode using the technician level password.

should we record this here?

4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.

Too much time should be ~ 15 sec

4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the Power-Up Procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions. **Any changes made to the bias or cooler voltages require a recalibration.**

Bias should not change unless detector is changed i.e. lamp or cooler

4.2.5 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into a calibration simulator and allow it to come to temperature.

This section is misleading @ the start we should determine the need to open a new bottle why one week

4.2.5.1 A previously used Calibration Solution may be used under the following conditions:

4.2.5.1.1 If the solution has been open for less than one week.

4.2.5.1.2 If the solution has been analyzed less than twenty (20) times.

This should be part of 4.2.5

4.2.6 Using a NIST traceable thermometer, check the temperature of the Calibration Solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the **required** fields.

Appropriate

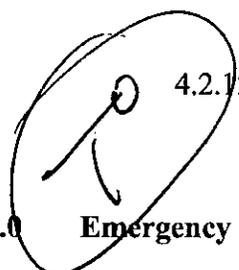
4.2.8 Follow the instructions prompted by the DataMaster DMT.

- 4.2.8.1 When instructed to "Connect Water," attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using a small length of tygon tubing. Press OK when ready. (2-3" max)
- 4.2.8.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water." Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready. This
Does NOT
Matter
1/2"
6" is
fine
- 4.2.8.3 When instructed to "Connect Ethanol," attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.
- 4.2.8.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol." Disconnect the simulator from the simulator tower. Press OK when ready.
- 4.2.8.5 The instrument will now ask for a technician signature. Sign on the line provided ^{with a stylus} and press "finished" when complete. The calibration report will print in duplicate.
- 4.2.9 Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report.
- 4.2.10 Perform a check of the calibration by analyzing a ~0.10 solution.
 - 4.2.10.1 Attach a simulator containing ~0.10 Simulator Solution at 34°C to the simulator tower. ↖ 1/2 0.2°C
 - 4.2.10.2 On the touch screen, press the NPAS logo to open the drop down menu. Select: ACCURACY AND PRECISION. Enter the name of the technician performing the test, the solution concentration and lot number in the required fields.
 - 4.2.10.3 The instrument will analyze the solution ten times and calculate and average and standard deviation. The average result must be within ±5% of the certified value of the solution with a standard deviation <0.002. The instrument shall be recalibrated if the results do not meet these criteria. do we want to tighten?
↑
 - 4.2.10.4 Print two copies of the Accuracy and Precision report to document the calibration check. 200
or
3%

Can we do
away with
0.08 ETOH or the
0.16 ETOH in the
Cert and Sub
in the 0.1 ETOH
Stock Solution

*We don't do this
We should present
the information for
Peer Review*

4.1.11 If the instrument is undergoing preliminary testing, file one copy of the calibration report and calibration check report in the instrument's testing binder; discard the extra copy. If the instrument is beyond preliminary testing, file one copy of the reports in the instrument's file in the filing cabinet in the IR Lab (room 124). The second copies will be put in the instrument's on-site maintenance records once the instrument is installed at an agency.



4.2.12 Make an entry in the DataMaster Calibration Logbook (Alc 668) which documents the DataMaster serial number, calibration solution lot number, room temperature and humidity, analysts initials, and date.

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

*This is a given
and does not need
to be here*

6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.



6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.

6.3 If the average result from the Accuracy and Precision test used as a calibration check is not within $\pm 5\%$ of the certified value of the simulator solution, or the standard deviation is > 0.002 , the instrument shall be recalibrated.

*This is a known
standard does
not need to be
in this doc*



6.4 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.

If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented.

6.5.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.

6.5.2 If the instrument has completed it's initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a

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DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

6.5.3 This procedure will be performed 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 made field ready within two weeks of removal from the agency, 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 In-house Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Ethanol Simulator Solution Preparation (P-Alc-204).
- 8.6 DataMaster Calibration Logbook (Alc 668).
- 8.7 Appendix A: Acceptable Calibration Report.

QA Audit Checklist for Procedure Final Approval

Procedure: Laboratory Calibration of DataMaster DMT
 Reviewed by: EL Date: 9/14/09
 P-AD-001 version in effect: _____

Accepted? Yes No see comments

Criteria for All Procedures	page <u>1</u> of <u>3</u>	Y	N	N/A
1. Section 1, Purpose and Scope				
1a. Purpose of procedure is clear.		✓		
1b. Scope includes extent of activity, range of operation. (Corresponds to flow chart) <u>N/A</u>		✓		
1c. Review schedule included.			<u>periodically</u>	
2. Section 2, Responsibilities				
2a. Procedure responsibilities identified by job title and clear. (Corresponds to flow chart) <u>N/A</u>		✓		
3. Section 3, Precautions and Safety Directives				
3a. Special considerations for use of procedure identified.		✓		
3b. Safety concerns identified.		✓		
4. Section 4, Procedure				
4a. Procedure steps in text match flow chart.				✓
4b. Lines of communication identified and clear (refer to flow chart) <u>N/A</u>		✓		
4c. Turn around times are stated.				✓
4d. Applicable standards, instrumentation, equipment manuals, reference data listed with their locations.		✓		
4e. All forms, worksheets used in procedure <u>referenced</u> and appended.		✓		
5. Section 5, Emergency or High Priority Situations				
5a. Emergency or high priority situations defined, procedures and communications clear.		✓		
6. Section 6, Quality Control and Corrective Action				
6a. Criteria for acceptable work are stated.		✓		
6b. Quality control materials and procedures defined.			<u>referenced</u>	
6c. Corrective action to be taken when quality measurements fail to meet the criteria of acceptability.		✓		

Additional Criteria for Analytical Procedures page <u>3</u> of <u>3</u>	Y	N	N/A
1. Requirements for sample/specimen collection and processing are referenced or appended.			✓
2. Criteria for sample/specimen storage and preservation are referenced or appended.			✓
2a. The testing schedule.			✓
2b. The longest sample holding time.			✓
3. Criteria for rejection of sample/specimen, and action to be taken when sample/specimen is rejected, are defined.			✓
4. The scientific principal of this analysis.			✓
4a. Reference methods that apply to this procedure.			✓
4b. State or federal regulations that apply to this procedure.			✓
5. Step-by-step performance of the procedure, including:			
5a. Instructions for the preparation of all materials used in the procedure, including slides, solutions, reagents, calibration standards, controls, stains, and other materials as needed.	<i>referenced</i>	1	
5b. Calibration and calibration verification procedures, and criteria for acceptable calibration.	✓		
5c. Calculations, as needed.			✓
5d. Instructions for the interpretation of results, as needed.			✓
5e. The system for reporting results, and for reporting panic values, including:			✓
1. the established reportable range for patient test results is included or referenced;			
2. the reference range or normal values;			
3. panic values			
4. if applicable, the exact wording for reports.			
5f. Limitations of the method, including interfering substances.			
5g. Criteria and instructions for the referral of specimens.			
6. The course of action to be taken if the test system becomes inoperative.	✓		

Comments: _____

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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 calibration 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 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116, DataMaster DMT Power-Up Procedure.
- 3.4 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification.

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 Guth 34CNP Calibration Simulator.

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4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.

Laboratory prepared Milli-Q water is used.

4.1.5 0.10% EtOH DataMaster Calibration Solution. *Prepared following reference procedure*

4.2 Preparation

4.2.1 Allow the instrument to warm up for one hour.

*P-Alc-204
EtOH Sim Soln
prep*

4.2.2 Activate Technician Mode using the technician level password.

4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than 0.003V over a one minute period. To do this, while in Technician Mode, activate the "Pump" and "Sim. Valve" options.

4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the power-up procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions. **Any changes made to the bias or cooler voltages require a recalibration.**

4.2.5 Open a new bottle of Calibration Solution (~0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into the calibration simulator and allow it to come to temperature.

4.2.6 Using a NIST traceable thermometer, check the temperature of the calibration solution. The temperature must read 34°C +/- 0.2°C, adjust as necessary.

4.2.7 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.2.8 Follow the instructions prompted by the DataMaster DMT.

4.2.8.1 When instructed to "Connect Water", attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using a small length of tygon tubing. Press OK when ready.

4.2.8.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water". Disconnect the

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simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

4.2.8.3 When instructed to "Connect Ethanol", attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

4.2.8.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol". Disconnect the simulator from the simulator tower. Press OK when ready.

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

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

4.2.10 If the instrument is undergoing preliminary testing, file one copy of the calibration report in the instrument's testing binder; discard the extra copy. If the instrument is beyond preliminary testing, file one copy of the calibration report in the instrument's file in the filing cabinet in the IR Lab (room 124). The second copy will be put in the instrument's on-site maintenance records once the instrument is installed at an agency.

4.2.11 Make an entry in the DataMaster Calibration Logbook ^(Alc 666) which documents the DataMaster serial number, calibration solution lot number, room temperature and humidity, analysts initials, date and time. *are we really recording the "time" (not noted in logbook)*

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.

6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.

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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 toxicology staff member. Try to correct the problem and document the event.

6.4 If the problem is not correctable without some repair or technical evaluation, the problem and resolution will be documented.

6.4.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.

6.4.2 If the instrument has completed it's initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

6.4.3 This procedure will be performed 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 made field ready within two weeks of removal from the agency, a replacement instrument may be installed at that site.

7.3 *need reference for where to find PM requirements*

8.0 References

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

8.2 DataMaster DMT In-house Service Manual.

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

8.4 DataMaster DMT Certification Procedure (P-Alc-118).

8.5 Preparation of DataMaster Simulator Solution for Calibration (P-Alc-210).

8.6 DataMaster Calibration Logbook. (Alc 626)

8.7 Appendix A: Acceptable Calibration Report.

Appendix A
Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 121506
Calibration Date: 06/20/2008
Calibrated by: A L B



Ca = 0.101000	
CAL = 1.022668	0.800 <= CAL < 1.200
b1 = 0.000000	0.000 <= b1 < 0.004
b2 = 0.003690	0.001 <= b2 < 0.012
b3 = 0.000000	0.000 <= b3 < 0.004
Xq = 0.146088	0.050 <= Xq < 0.200
a21 = 1.170804	1.050 <= a21 < 1.300
a31 = 0.484792	0.300 <= a31 < 0.600

Performed by ALB

Date 06/20/2008

Title: Laboratory Calibration of DataMaster DMT		Page 1 of 5
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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 calibration 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 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 Each instrument must complete a power-up prior to calibration. See P-Alc-116: DataMaster DMT Power-Up Procedure.
- 3.4 Ensure that the DataMaster DMT simulator temperature monitoring is turned off during calibration and certification.

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 Guth 34CNP Calibration Simulator. *w/ 10% EtOH*
- 4.1.4 Guth 2100 Simulator containing volatile organic free, lab-pure water.
- 4.1.5 0.10%EtOH DataMaster Calibration Solution.

4.2 Preparation

4.2.1 Allow the instrument to warm up for one hour. *at least*

4.2.2 Activate the ~~TECH~~ screen using the technician level password. *Technician mode*

4.2.3 Purge the simulator ports for approximately one minute or until the detector voltage has stabilized. The detector voltage must not drift by more than 0.003V over a one minute period. To do this, while in the ~~TECH~~ screen, activate the "Pump" and "Sim. Valve" options. *Technician mode*

4.2.4 The detector voltage should be +/-0.100V of zero. The voltage is set during the power-up procedure (P-Alc-116). It is prudent to double check the voltage prior to calibration to ensure tolerance. If the detector voltage is out of specification, refer to DataMaster DMT Power-Up Procedure (P-Alc-116) for instructions. *{ Any changes made to the bias or cooler voltages require a recalibration. } emphasize*

4.2.5 Open a new bottle of Calibration Solution (~0.100 EtOH). ~~Do not use solutions which have passed their expiration date.~~ Pour solution into the calibration simulator and allow it to come to temperature.

4.2.5.1 Using a NIST traceable thermometer, check the temperature of the calibration solution. The temperature must read 34°C +/- 0.2°C. *adjust if needed.*

4.2.6 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.2.7 Follow the instructions prompted by the DataMaster DMT.

4.2.7.1 When instructed to "Connect Water", attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using a small length of tygon tubing. Press OK when ready.

4.2.7.2 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water". Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

4.2.7.3 When instructed to "Connect Ethanol", attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

4.2.7.4 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol". Disconnect the simulator from the simulator tower. Press OK when ready.

CDR Use Calibration Sim that is lightly used

4.2.7.1-5 are the instructions

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4.2.7.5 The instrument will now ask for a technician signature. Sign on the line provided and press "finished" when complete. The calibration report will print in duplicate. — *what do do w/ reports?*

4.2.8 Inspect the calibration report and ensure that all values are within acceptable ranges. See Appendix A for an example of a calibration report. *where should they go?*

4.2.9 Make an entry in the DataMaster Calibration Logbook which documents the DataMaster serial number, calibration solution lot number, room temperature and humidity, analysts initials, date and time.

What is this Doc. #? SOP #?

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

6.1 If any of the calibration factors are outside the manufacturer's recommended specification, the calibration will be failed by the software. Corrective action must be taken. The action taken will vary depending on the specific problem.

6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. If b2 is not within specification, the analyst will report the calibration as failing and take corrective action.

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 toxicology staff member. Try to correct the problem and document the event.

6.4 If the problem is not correctable without ~~some~~ repair or technical evaluation, the problem will be documented *and resolution*

6.4.1 If the instrument is still in the initial testing process, a note will be written in the testing notebook for that instrument.

6.4.2 If the instrument has completed its initial testing and results are no longer being stored in the initial testing binder and testing notebook, then a DataMaster Technical Support Inquiry worksheet (Alc 626) must be completed and placed in the instrument's file.

6.4.3 This procedure will be performed 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.

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7.2 If an agency's instrument cannot be made field ready within two weeks of removal from the agency, 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 ^{in-house} Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-116).
- 8.4 DataMaster DMT Certification Procedure (P-Alc-118).
- 8.5 Preparation of DataMaster Simulator Solution for Calibration (P-Alc-210).
- 8.6 DataMaster Calibration Logbook.
- 8.4 Appendix A: Acceptable Calibration Report.

Appendix A
Acceptable Calibration Report

CALIBRATION REPORT

DataMaster DMT: 121506
Calibration Date: 06/20/2008
Calibrated by: A L B



Ce	=	0.101000		
CAL	=	1.022668	0.800 <=	CAL < 1.200
b1	=	0.000000	0.000 <=	b1 < 0.004
b2	=	0.003690	0.001 <=	b2 < 0.012
b3	=	0.000000	0.000 <=	b3 < 0.004
Xq	=	0.146000	0.050 <=	Xq < 0.200
a21	=	1.170804	1.050 <=	a21 < 1.300
a31	=	0.494792	0.300 <=	a31 < 0.600

Performed by 

Date 06/20/2008

Title: DataMaster DMT Laboratory Calibration		Page 1 of 6
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117
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 calibration 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 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. *Other point person for DMT's?*
- 2.2 This procedure will be reviewed ^{periodically} 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 ^{instrument?} 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.

- X 4.1.1 DataMaster DMT Instrument. *w/ breath tube*
- X 4.1.2 Guth 34CNP Calibration Simulator.
- X 4.1.3 Guth 2100 Simulator containing water.

Reagents
 LAB WATER
 Calibration Sol'n
Supplies
 tygon tubing (4.3.8)

4.2 Preparation *① Each instrument must have completed the "Power-Up procedure prior to calibration."*

- ② 4.2.1 Allow the instrument to warm up for one hour. *□ review & confirm documentation*

4.3.1.1 If this is the first time the instrument has been powered on by VDHL staff or if the instrument has received a new detector, a Power-Up procedure (P-Alc-XXX) must be completed prior to calibration.

→ 4.2.2 With instrument cover open, activate the TECH screen using the technician level password. Purge the simulator ports for approximately one

minute or until the detector voltage has stabilized. This is done to ensure no carry-over from any previous tests. To do this, while in the TECH screen, activate the "Pump" and "Sim. Valve" options.

4.2.3 The detector voltage should be within $\pm 0.100V$ of zero.

4.2.3.1 To set the detector voltage, first adjust the detector position to read the lowest detector voltage possible. Then adjust the cooler and bias voltages as necessary.

4.2.3.2 For Hamamatsu detectors, the cooler voltage should be $1.7V \pm 0.1V$. For Judson detectors, the cooler voltage should be set to the manufacturer recommended specification listed on a small tag connected to the detector wire. Adjust the bias voltage as necessary.

4.2.3.3 After adjusting voltage settings, allow instrument to stabilize for one hour before attempting calibration. Exit when complete.

4.3.4 Open a new bottle of Calibration Solution (~ 0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into the calibration simulator and allow it to come to temperature.

4.3.5 4.3.4.A Simulators must indicate solution temperature of $34^{\circ}C \pm 0.5^{\circ}C$. Each fresh solution requires a minimum 30 minute equilibration time.

4.3.6 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols \rightarrow Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.7 Follow the instructions prompted by the DataMaster DMT.

4.3.8 When instructed to "Connect Water", attach the breath tube on the instrument directly to the front port on the simulator containing lab water. Attach the other port on the simulator to the CAL port on the rear of the instrument using a small length of tygon tubing. Press OK when ready.

4.3.9 Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water". Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

4.3.10 When instructed to "Connect Ethanol", attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

4.3.11 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol". Disconnect the simulator from the simulator tower. Press OK when ready.

Chronological audit trail in each DMT?

IF OK?

IF NOT?

+CAL +/- 0.100V

the limits (acceptance limits)

initials, format, etc?

No cal port?

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

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

4.3.14 Write on each copy of the report the lot number, expiration date, and date opened of the calibration solution. Also note the room temperature and percent humidity at the time of calibration. Initial the notation.

date opened is assumed to be date of calibration report. Used repeatedly?

& acceptable ranges?

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

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

CAL OK CAL failed - corrective action - second report of - CAL OK?

6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. All other factors are listed on the Calibration report per manufacturer's recommendation.

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.

*1st repeat OK - report OK
Corrective action - second repeat OK - CAL OK?*

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.

will be repeated

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 calibrated in a timely manner, a replacement instrument will be given to that site.

*(define)
within - days.*

8.0 References

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

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- 8.2 DataMaster DMT Field Service Manual. *Copyright date / revision, etc.*
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-xxx)
- 8.4 Appendix A: Acceptable Calibration Report.
- 8.5 Appendix B: Technical Support Inquiry (Alc 626). *not required as appendix
- reference only is okay!*

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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 calibration 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 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} ~~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. ^{NIST etc}
- 4.1.2 Guth 34CNP Calibration Simulator. ^{organic-free}
- 4.1.3 Guth 2100 Simulator containing water. ^{lab-pure}
- 4.1.4 ^{.10 Calibration Solution}

4.2 Preparation

- 4.2.1 Allow the instrument to warm up for one hour.
- 4.2.1.1 If this is the first time the instrument has been powered on by VDHL staff or if the instrument has received a new detector, a Power-Up procedure (P-Alc-XXX) must be completed prior to calibration.
- 4.2.2 With instrument cover open, activate the TECH screen using the technician level password. Purge the simulator ports for approximately one

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minute or until the detector voltage has stabilized. *(draft not more than ±003)* ~~This is done to ensure no carry-over from any previous tests.~~ To do this, while in the TECH screen, activate the "Pump" and "Sim. Valve" options.

4.2.3 The detector voltage should be within $\pm 0.100V$ of zero.

is set during PURT. It is prudent to double check the voltage V to ensure tolerance.

4.2.3.1 To set the detector voltage, first adjust the detector position to read the lowest detector voltage possible. Then adjust the cooler and bias voltages as necessary.

4.2.3.2 For Hamamatsu detectors, the cooler voltage should be $1.7V \pm 0.1V$. For Judson detectors, the cooler voltage should be set to the manufacturer recommended specification listed on a small tag connected to the detector wire. Adjust the bias voltage as necessary.

4.2.3.3 After adjusting voltage *save setting.* settings, allow instrument to stabilize for one hour before attempting calibration. Exit when complete.

4.3.4 Open a new bottle of Calibration Solution (~ 0.100 EtOH). Do not use solutions which have passed their expiration date. Pour solution into the calibration simulator and allow it to come to temperature.

4.3.4
→ 4.3.5 Simulators must indicate solution temperature of $34^{\circ}C \pm 0.5^{\circ}C$. Each fresh solution requires a minimum 30 minute equilibration time. *Check Sim using MST*

4.3.6 On the touch screen, press the NPAS logo to open the drop down menu. Select: Protocols → Calibration. Enter the name of the technician performing the calibration, the solution concentration and lot number in the required fields.

4.3.7 Follow the instructions prompted by the DataMaster DMT.

~~4.3.8~~ When instructed to "Connect Water", attach the *breath tube* on the instrument directly to the front port on the simulator containing *water*. Attach the other port on the simulator to the CAL port on the rear of the instrument using a small length of tygon tubing. Press OK when ready.

~~4.3.9~~ Once the instrument has analyzed the water vapor, it will prompt the technician to "Disconnect Water". Disconnect the simulator from the breath tube and remove the tygon tubing from the CAL port. Press OK when ready.

→ 4.3.10 When instructed to "Connect Ethanol", attach the calibration simulator containing the calibration solution to the simulator tower on the instrument. Press OK when ready.

→ 4.3.11 Once the instrument has analyzed the ethanol vapor, it will prompt the technician to "Disconnect Ethanol". Disconnect the simulator from the simulator tower. Press OK when ready.

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

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

4.3.14 Write on each copy of the report the lot number, expiration date, and date opened of the calibration solution. Also note the room temperature and percent humidity at the time of calibration. Initial the notation.

make entry in

4314 - log book serial #, lot # on Cal Rpt. To, H%, date, init.

5.0 Emergency or High Priority Situations

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

6.0 Quality Criteria and Corrective Action

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

6.2 The calibration factor for b2 must be $0.002 \leq b2 \leq 0.012$. All other factors are listed on the Calibration report per manufacturer's recommendation.

6.3 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.

6.4 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~~ ^{performed} again when the problem is resolved.

note book or TB1

if not, analyst fails cal and corrective action taken

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 calibrated in a timely manner, a replacement instrument will be ~~given to~~ ^{made field ready} that site. ^{of} ~~may~~ ^{be} installed at ^{of} ~~removal~~ ^{of} ~~removal~~

8.0 References

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

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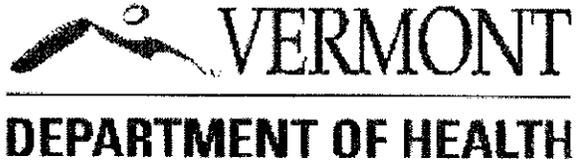
- 8.2 DataMaster DMT ~~Field~~ Service Manual.
- 8.3 DataMaster DMT Power-Up Procedure (P-Alc-xxx)
- 8.4 Appendix A: Acceptable Calibration Report.
- 8.5 ~~Appendix B: Technical Support Inquiry (Alc 626).~~

Solution Prep SOP
Logbook Cal

Appendix A

CALIBRATION REPORT

DataMaster DMT: 121506
Calibration Date: 06/20/2008
Calibrated by: A L B



Ca = 0.101000	
CAL = 1.022068	0.800 <= CAL < 1.200
b1 = 0.000000	0.000 <= b1 < 0.004
b2 = 0.003690	0.001 <= b2 < 0.012
b3 = 0.000000	0.000 <= b3 < 0.004
Xq = 0.146088	0.050 <= Xq < 0.200
a21 = 1.170804	1.050 <= a21 < 1.300
a31 = 0.484792	0.300 <= a31 < 0.800

Lot # xx-xx-100
Exp mm/dd/yyyy
Opened mm/dd/yyyy
Temp °F
Humidity #%
Initials

Performed by ALB

Date 06/20/2008

Acceptable Calibration Report

Bryce-Parrott, Cara

From: Celotti, Stella
Sent: Tuesday, December 21, 2010 2:58 PM
To: Bolduc, Amanda; Kimball, Kirk
Cc: Bryce-Parrott, Cara
Subject: Procedure Approved

Hello, P-ALC-117, Rev 0, Laboratory Calibration of DataMaster DMT, has 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