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1.0 Purpose and Scope

1.1. The purpose of this manual is to describe the process used by Vermont Forensic Laboratory (VFL) staff for the verification, adjustment, calibration, and maintenance of the Intox DMT infrared breath alcohol analysis instruments designated for use as evidentiary breath testing devices. This procedure follows the guidance set forth in the Vermont Department of Public Safety Breath and Blood Alcohol Analysis Rule.

1.2. The goal of the DMT Manual is to set forth specific analytical methods and procedures that are currently used with the DMT evidentiary breath alcohol testing instruments by Toxicology Section staff. This manual does not cover all troubleshooting and error conditions that may be encountered in the maintenance of the DMT units, but it does set guidelines and standards that are applicable to the majority of circumstances that may arise.

2.0 Responsibility

2.1. It is the responsibility of staff performing these tasks to follow the procedure as written and to note any omissions, errors, or unclear instructions in the procedure and bring them to the attention of the Toxicology Section Supervisor.

2.2. This manual will be reviewed periodically by Toxicology Section staff. Revisions of the manual will be made when a need is identified.

2.3. All analysts performing these procedures for the purpose of reporting analytical results for forensic purposes must be fully trained and demonstrate initial competency in the use of these procedures in accordance with the Toxicology Training Manuals.

2.4. Analysts will ensure that an adequate amount of solutions, supplies, and spare parts are available at all times. Orders should be placed, or solutions requested, when supplies are low to ensure that new stock arrives before supplies are completely empty.

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 the testing of an instrument must be retained, including those displaying error messages or failures. All records will be saved in each instrument's physical and/or electronic folders.

3.3. Handling of Instruments

3.3.1. Care should be taken when transporting instruments, especially through precipitation. Simulator solution should be protected from freezing during cold weather.

3.3.2. Simulators shall be stored and transported 'dry' – i.e. simulator solution should be removed.

3.3.3. Upon arrival, inspect the instrument to ensure no damage occurred during transport. Document any damage or problems observed.

3.3.4. Instruments that are not for evidential use shall be labeled as such.

3.3.5. Any instrument unable to be repaired or successfully recalibrated shall be returned to the vendor for repair or replacement.

4.0 Quality Assurance

4.1. It is expected that the analyst will report any unacceptable or anomalous behavior of any analytical system immediately to the Toxicology Section Supervisor. It is further expected that appropriate actions will follow as soon as possible and be properly documented**.**

4.2. All instruments requiring calibration shall be inspected prior to adjustment. No instrument shall be calibrated for evidential use that does not conform to specifications set forth in this manual.

4.3. Periodic software updates may be necessary to keep up with changing needs in the user interface. Prior to being deployed in the field, new software will be tested and verified following the DMT Software BETA Testing Guide. It is the responsibility of the Toxicology Section Supervisor to determine the extent of testing needed based on the changes made to the software.

4.4. Equipment

4.4.1. Thermometers

4.4.1.1. Measurements made using the Toxicology Section thermometers are critical.

4.4.1.2. Thermometers used by the Toxicology Section will be maintained in accordance with QA_P100_6.4_Equipment QC.

4.5. Instrumentation

4.5.1. DMT Instruments

4.5.1.1. Refer to the Intox DMT Training Binder for information regarding repair and maintenance of DMT Instruments.

4.5.2. Guth 12V500 Wet Bath Simulators

4.5.2.1. Refer to the Guth 12V500 Operator's Manual for information regarding repair and maintenance of simulators.

4.5.2.2. The temperature of each simulator must be checked using a NIST traceable thermometer before being placed into service and at least annually. See Section 5 for the annual simulator check instructions.

4.6. Simulator Solution Reference Materials

4.6.1. Manufacturer Control Solution (MCS)

4.6.1.1. A NIST traceable ~0.10 g/210 L aqueous ethanol simulator solution is used as an alternate source QC check subsequent to the calibration of a DMT. The solution is purchased from an ISO 17034 accredited supplier. The certificates of analysis will be maintained.

4.6.1.2. Prior to using a new lot of MCS, the lot should be run on the GC as a sample (in duplicate) to verify the lot falls within ± 5% of the manufacturer's certified concentration. A new shipment of the same lot does not require verification. See the TOX_P500_Certified Reference Material Manual and TOX_P100_Alcohol Analysis Manual for analysis instructions.

4.6.1.3. If the GC result is not within range, the solution may be reanalyzed or rejected.

4.6.1.4. The chromatograms from the analysis will be reviewed and documentation of passing QC recorded in the Reagent Preparation Log. Analytical results will be maintained.

4.6.2. Blank diH_2O Solution

4.6.2.1. Deionized water will be used as a blank to perform an adjustment on a DMT.

4.6.2.2. Document the preparation in the Reagent Preparation Log.

4.6.2.2.1. The preparation date is the date the deionized water is added to the simulator.

4.6.2.2.2. The lot number is BL-DMTMMDDYYYY, where MMDDYYYY is the date of preparation.

4.6.2.3. After deionized water is added to a simulator, a 750 µl aliquot is analyzed via GC *without* the addition of internal standard solution to verify that it is free of analytes of interest and other interfering compounds.

4.6.2.4. The chromatograms from the analysis will be reviewed and documentation of passing QC recorded in the Reagent Preparation Log. Analytical results will be maintained.

4.6.2.5. The prepared water blank is approved for use until consumed or contamination is suspected.

4.6.3. Mouth Alcohol Test Solution

4.6.3.1. A dilute ethanol solution is prepared for use as a mouth alcohol test solution. This solution is neither qualitative nor quantitative in purpose and does not require a lot number or performance check. It is approved for use until consumed or depleted.

4.6.4. In-House Prepared Reference Solutions (See the TOX_P500_Certified Reference Material Manual for Certified Reference Material preparation and certification.)

4.6.4.1. The following table lists some of the commonly prepared concentrations and their intended use. Additional concentrations may be prepared according to the procedures in the TOX_P500_Certified Reference Material Manual.

Concentration	Intended Use
0.10 g/210 L	Adjustment solution Quality control solution
0.02 g/210 L	Calibration solution
0.08 g/210 L	Calibration solution
0.16 g/210 L	Calibration solution
0.36 g/210 L	Calibration solution
0.01 g/210 L acetone in 0.08 g/210 L ethanol	Interference solution for calibration and verification
0.025 g/210 L	Verification solution
0.20 g/210 L	Verification solution
0.34 g/210 L	Verification solution
0.02 g/210 L methanol in diH2O	Interference solution for verification
0.01 g/210 L isopropanol in diH2O	Interference solution for verification

5.0 DMT Maintenance Procedures

5.1. Materials and supplies

5.1.1. DMT instrument with keyboard.

5.1.2. DMT compatible printer with USB cable.

5.1.3. UPS or line conditioners.

5.1.4. Torx T10 security screws.

5.1.5. Tethered stylus.

5.1.6. Adhesive-backed Velcro®.

5.1.7. NIST traceable thermometer.

5.1.8. Mouthpieces.

5.1.9. Mouth alcohol test solution.

5.1.10. Radio frequency transmitter.

5.1.11. Extra-large syringe.

5.1.12. Assorted tools, wrenches, screwdrivers, O-rings, cable-ties, etc.

5.1.13. Wet bath simulators and simulator solutions.

5.2. Preparing a simulator for use

5.2.1. Inspect the simulator components, rubber gasket, and jar for apparent damage and perform any required maintenance.

5.2.2. Ensure the simulator temperature check is not due and complete if required.

5.2.3. Verify the simulator solution to be used has not passed its expiration date. The expiration of the solution refers to the date in which the solution expires in the bottle.

5.2.4. Carefully pour the simulator solution into the simulator, avoiding excessive splashing or glugging.

5.2.5. Affix one simulator solution label to the simulator and note the date opened and your initials. Affix the other simulator solution label to the appropriate log (sim solution use log, maintenance log, etc.) and note the date opened and your initials.

5.2.6. Once the simulator comes to temperature, simulator solutions must equilibrate for at least 15 minutes before use. For some maintenance protocols, a 15-minute equilibration timer may be built in.

5.3. Performing an annual simulator temperature check

5.3.1. Unscrew the temperature testing port and insert the thermometer into the simulator solution. Allow thermometer to equilibrate.

5.3.2. Ensure the simulator temperature displays 34ºC ± 0.05 and that reported temperature matches the NIST traceable thermometer within ± 0.1ºC. Adjust if necessary.

5.3.3. Document the temperature check of the simulator using the TOX_F200_5_Simulator Temperature Check Worksheet.

5.3.4. Affix a label to the simulator with your initials, the date checked, and the due date of the next temperature check.

5.3.5. Remove the simulator head from the jar. Inspect the simulator jar for cracks and chips. Replace the jar as necessary.

5.3.6. Replace the gasket in the simulator head and any other o-rings that need replacement.

5.3.7. Thread the simulator head onto the simulator jar. Using the pressure gauge, check the simulator for leaks. If the simulator leaks, repair or replace as necessary.

5.3.8. The results of the temperature check will be reviewed by the Toxicology Section Supervisor or their designee.

5.4. New Instrument Set-up and Verification Testing

5.4.1. Inspect the instrument upon receipt to ensure there is no visible damage from shipping. Document any damage or problems observed and contact the vendor, if necessary.

5.4.2. Plug the power cord into an outlet and the back of the instrument.

5.4.3. Insert the breath tube and its power plug into their corresponding ports.

5.4.4. Affix a Vermont serial number sticker and a DPS property tag to the DMT.

5.4.5. Attach a tethered stylus to the DMT using the center right screw-hole nearest the simulator ports. Wrap a small piece of adhesive-backed Velcro® around the top of the stylus and affix the other side to the face of the DMT.

5.4.6. Attach the keyboard to the top of the DMT using adhesive-backed Velcro® and plug the cord into the USB port.

5.4.7. Turn on the DMT and allow it to come to temperature and stabilize. See the Intox DMT Training Binder for technical specifications and detector optimization methods.

5.4.8. Adjust and calibrate the instrument.

5.4.9. Prior to beginning testing and after analyzing a solution, purge the simulator ports without a simulator attached until the detector voltage stabilizes.

5.4.10. Linearity Tests:

5.4.10.1. Three concentrations of EtOH solution will be used: 0.025, 0.20, and 0.34 g/210 L.

5.4.10.1.1. The acceptance criteria for the linearity solutions are ± 5% rounded to three decimal places or ± 0.004 g/210 L from the certified value of the simulator solution, whichever is greater.

5.4.10.2. Each solution will be run using the Accuracy and Precision test set at n = 10.

5.4.10.3. All three concentrations will be run consecutively and will count as one linearity test.

5.4.10.4. Three linearity tests will be run on the instrument. Once a linearity test is begun, it must be completed (all 3 solutions analyzed) on the same day.

5.4.10.5. No more than one linearity test may be performed per day.

5.4.11. Interference Tests:

5.4.11.1. The following concentrations will be tested using the Accuracy and Precision test. The instrument should report “Interference” or a numerical result which falls within the

accuracy requirement of the solution (indicating the interfering compound did not impact the accurate determination of the ethanol concentration).

5.4.11.1.1. 0.01 g/210 L acetone in 0.08 g/210 L ethanol.

5.4.11.1.2. 0.02 g/210 L methanol in diH_2O.

5.4.11.1.3. 0.01 g/210 L isopropanol in diH_2O.

5.4.11.2. If interference is detected at least 80% of the time, but less than 100% of the time, and any numerical results are less than the target concentration of the interferent, additional testing may be performed to demonstrate that the DMT is capable of detecting interference at the target concentrations; i.e. 0.01 g/210 L for acetone and isopropanol and 0.02 g/210 L for methanol.

5.4.12. Record Keeping

5.4.12.1. Make entries in the Simulator Solution Use Log and DMT Electronic Control Chart. All results must be documented, including analytical results that do not meet the acceptance criteria.

5.4.12.2. All testing information will be entered into TOX_F200_1_ DMT Verification Summary.

5.4.12.3. The completed package includes:

5.4.12.3.1. TOX_F200_1_ DMT Verification Summary.

5.4.12.3.2. All reports generated during the verification process.

5.4.12.4. Upon successful completion of analysis, the analyst must perform a primary data review of the package prior to submitting the complete package for technical review.

5.4.12.5. An administrative and director review will be completed subsequent to the technical review.

5.5. Adjustment

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

5.5.2. Perform “As found” calibration, if necessary.

5.5.3. Activate Technician Mode using the appropriate password.

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

5.5.5. The detector voltage should be ± 0.100 V of zero. If voltages are optimized, the DMT should be allowed to stabilize for at least one hour.

5.5.6. Prepare a simulator containing adjustment solution and connect it to the DMT.

5.5.6.1. A previously used adjustment solution may be used under the following conditions:

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

5.5.6.1.2. If the solution has been used no more than twenty (20) times.

5.5.7. Prepare a simulator containing blank diH_2O solution, if necessary.

5.5.8. On the DMT touch screen, press the DMT logo to open the drop-down menu. Select: Protocols → Adjustment. Enter the name of the individual performing the adjustment and the solution concentration and lot number in the required fields.

5.5.9. Follow the instructions prompted by the DMT.

5.5.9.1. When prompted, connect the diH_2O simulator to the breath tube and CAL port on the DMT. Press "OK" when ready.

5.5.9.2. When prompted, disconnect the diH_2O simulator from the breath tube and the CAL port. Press "OK" when complete.

5.5.9.3. After ethanol analysis, the instrument will ask for a signature. Sign on the line provided and press "finished" when complete. The calibration report will be generated.

5.5.10. Record Keeping

5.5.10.1. Make an entry in the Simulator Solution Use Log. All results must be documented, including analytical results that do not meet the acceptance criteria.

5.5.10.2. An adjustment is typically performed in conjunction with other maintenance or repair protocols, therefore completed packages may vary. A calibration must be performed subsequent to any adjustment protocols before deployment in the field. Adjustment reports will be included with the calibration package.

5.6. Calibration

5.6.1. All instruments shall be calibrated:

5.6.1.1. Annually.

5.6.1.2. Prior to and subsequent to:

5.6.1.2.1. A change to the computer system that could impact analytical results.

5.6.1.2.2. The replacement or repair of a DMT component that could impact analytical results.

5.6.1.2.3. An adjustment.

5.6.2. Instances where a calibration cannot be performed prior to service shall be documented and justified.

5.6.3. Any instrument failing its calibration shall be adjusted or repaired as necessary and a successful calibration shall subsequently be performed.

5.6.4. Ensure simulators are prepared containing the appropriate EtOH calibration solutions (~0.02, 0.08, 0.16, 0.36 g/210 L) and acetone interference solution (0.01 g/210 L acetone in 0.08 g/210 L ethanol).

5.6.4.1. The acceptance criteria for the calibration solutions are ± 5% rounded to three decimal places or ± 0.004 g/210 L from the certified value of the simulator solution, whichever is greater.

5.6.4.2. Quantitative calibration solutions are replaced on a quarterly basis, when the solution falls out of acceptable range, or when the solution has been used more than twenty (20) times. Interference solutions are replaced as needed.

5.6.5. From the technician screen, introduce fresh air through the system by purging the simulator ports without a simulator attached until the detector voltage stabilizes.

5.6.6. For as found calibrations, the detector voltage should be ± 0.300 V of zero. If an adjustment is performed, the detector voltage should be ± 0.100 V of zero.

5.6.7. On the touch screen, press the DMT logo to open the drop-down menu. Select: Protocols → Calibration. Enter the appropriate password. Enter the name of the individual performing the calibration.

5.6.8. Follow the instructions as prompted by the DMT.

5.6.8.1. The calibration process works like a checklist. To begin each step in the calibration process, press the button for that step.

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

5.6.8.3. The first step in the calibration process is a diagnostic test.

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

5.6.8.4.1. Solutions not meeting the acceptance criteria may be re-run. A fresh bottle of solution may also be opened and analyzed if the previous solution was not freshly opened.

5.6.8.5. Once all four linearity solutions have passed, press the button labeled "R2" to perform a linear regression analysis and generate an R^2 coefficient of determination value.

5.6.8.6. The next step is the Acetone Interference Test. Enter the lot number of the interference solution then press the "Acetone" button. The interference solution is blown through the simulator into the breath tube when prompted "Please Blow".

5.6.8.6.1. The acceptance criterion for the Acetone Interference Test is "Interference Detected".

5.6.8.7. The next step is the invalid sample detection test, also known as the Mouth Alcohol Test. To complete the Mouth Alcohol Test, a mouthpiece is loaded with ethanol by sucking air into the mouthpiece from the bottle of mouth alcohol test solution.

5.6.8.8. Press the "Mouth Alc" button to begin the test. When prompted "Please Blow", slowly blow out through the ethanol-laden mouthpiece into the breath tube.

5.6.8.8.1. The acceptance criterion for the Mouth Alcohol Test is "Mouth Alcohol Detected".

5.6.8.9. To complete the Radio Frequency (RF) Detection Test, press the "RF" button. When the detector voltage box pops up, key a radio frequency transmitter near the breath tube. The instrument should beep, indicating that a radio frequency is detected.

5.6.8.9.1. The acceptance criterion for the RF Detection Test is "Passed".

5.6.8.9.2. It is normal for the detector voltage to fluctuate a small amount; however, the detector voltage should not change by more than 0.003V.

5.6.8.9.3. If the detector voltage changes by more than 0.003V and radio frequencies (RF) are not detected, press "Fail" to stop the test. Adjust the RF sensitivity in Technician Mode before repeating the calibration attempt.

5.6.8.10. To begin the Sample Acceptance Test press the "Sample Acc" button. Open a new mouthpiece and press "OK" when you are ready to start the test.

5.6.8.10.1. The DMT will run through a series of quality control checks.

5.6.8.10.2. When prompted “Please Blow” and an intermittent tone is heard, insert the mouthpiece into the breath tube.

5.6.8.10.3. A proper Sample Acceptance Test consists of 3 types of samples: a shallow breath, intermittent breath, and a valid, ~1.5 L alcohol-free sample. During the testing sequence, the bottom left corner of the screen will display each instruction for fifteen (15) seconds for each type of breath. It may not be necessary to use the entire fifteen seconds per sample type.

5.6.8.10.3.1. **Shallow Breath**: Using a mouthpiece, blow a low force breath through the breath tube. The air flow should be gentle, but strong enough to register on the screen. Blow for a few seconds then stop. The air flow line (blue) should “ride” the minimum flow rate line (green) for at least 2-3 seconds.

5.6.8.10.3.2. **Intermittent Breath**: Blow 3-4 short, somewhat forceful breaths into the mouthpiece for 1-2 seconds each. Be careful not to suck back on the mouthpiece between puffs of air.

5.6.8.10.3.3. **1.5 L Alcohol Free Sample:** While watching the total volume box in the bottom right corner of the screen, take a deep breath and exhale into the instrument with a steady breath flow rate and provide a sample equal to or slightly larger than 1.5 L of air. The instrument should accept a sample that is at least 1.5 L of air.

5.6.8.10.4. Once the last sample has been provided to the instrument, it will end the testing sequence.

5.6.8.10.5. A box will pop up asking “Did Instrument Pass All Sample Acceptance Checks? Yes/No”

5.6.8.10.5.1. If the sample acceptance passes, select “Yes” and move on to the next step.

5.6.8.10.5.2. If the sample acceptance test fails, select “No”. The instrument will then prompt the operator to enter a reason for the failure. Enter the reason for the failure.

5.6.8.10.5.3. If the shallow or intermittent breath test was accepted by the instrument as a valid breath (meaning it ended the testing sequence) the test is considered failing.

5.6.8.10.5.4. If the alcohol line (black) is elevated by equal to or greater than half of the calibration method’s LLOQ at any point during the sample acceptance test, the test is considered failing.

5.6.8.11. The calibration date is the date the calibration was started, which defines the calibration interval in the software. Calibrations may be completed the following day provided it is completed within 1 calendar day of starting and a notation is made documenting what work was done when.

5.6.8.12. Once all tests have been successfully completed, the instrument will ask for a signature. Sign on the line provided and press “finished” when complete. The calibration report will now be generated.

5.6.9. Perform an alternate source QC check by analyzing the manufacturer control solution.

5.6.9.1. Prepare simulator containing MCS, if necessary.

5.6.9.2. From the technician screen, introduce fresh air through the system by purging the simulator ports without a simulator attached until the detector voltage stabilizes.

5.6.9.3. Attach a simulator containing the MCS to the DMT.

5.6.9.4. On the touch screen, press the DMT logo to open the drop-down menu. Select: Accuracy & Precision.

5.6.9.5. In the first name field, enter the initials of the individual performing the test. In the last name field, enter "MCS". Enter the solution concentration and lot number in the required fields. Review the data entered for accuracy, then press "OK".

5.6.9.6. The instrument will analyze the solution ten times and calculate the average and standard deviation. The average result must be within ± 5% of the certified concentration of the solution with a standard deviation ≤ 0.002. The MCS may be re-run if it fails to meet the acceptance criteria on the first attempt. A fresh bottle of MCS may also be opened and analyzed if the previous solution was not freshly opened. The instrument shall be readjusted if the results do not meet these criteria.

5.6.10. Record Keeping

5.6.10.1. Make entries in the Simulator Solution Use Log, DMT Electronic Log, and DMT Electronic Control Chart. All results must be documented, including analytical results that do not meet the acceptance criteria.

5.6.10.2. The DMT serial number, date of adjustment, date of calibration, and the analytical results from the calibration procedures with their associated measurement uncertainty will be entered into TOX_F200_2_DMT Certificate of Calibration. The analytical results from the calibration procedure will include any 'as found' and 'as left' results as applicable. The date of calibration is the date the 'as left' calibration was started.

5.6.10.3. The DMT Certificate of Calibration will be signed by the certifying analyst.

5.6.10.4. A calibration is performed prior to and subsequent to all adjustments. It may also be performed in conjunction with other maintenance or repair protocols. At a minimum, the DMT Certificate of Calibration, the calibration report(s), the MCS report, and any additional reports generated during testing, including those with failing results, will be included in the package. A Technical Support Inquiry (TOX_F200_3) is included with any maintenance/repairs performed on a DMT.

5.6.10.5. Upon successful completion of analysis, the analyst must perform a primary data review of the package prior to submitting the complete package for technical review.

5.6.10.6. An administrative and director review will be completed subsequent to the technical review.

5.7. Installation

5.7.1. Contact the agency representative at the site of the pending installation to schedule a date and time for the instrument installation.

5.7.2. Site Inspection and DMT Placement for New Sites

5.7.2.1. The area of instrument placement must meet the specifications outlined on the TOX_F200_4_ DMT Site Evaluation Checklist. This checklist must be completed with an agency representative prior to an instrument being installed at an agency.

5.7.2.2. A site evaluation is not required when reinstalling an instrument at an agency subsequent to an instrument repair or annual calibration.

5.7.3. Setting up the DMT

5.7.3.1. Plug the UPS or line conditioner into an electrical outlet. Plug the DMT, simulator power cord, and printer into the UPS or line conditioner.

5.7.3.2. If the agency has networking capabilities, plug an Ethernet cable into the DMT and the wall port.

5.7.3.3. Prepare a simulator containing a quality control solution. It is permissible to use a simulator with a temperature check due, as this may be completed during installation.

5.7.3.4. Once the solution has come to temperature, perform an annual simulator check, if required.

5.7.3.5. Plug in the head of the simulator and ensure it is powered on and the paddle is rotating.

5.7.3.6. Attach the RS232 cable from the simulator to the DMT. Ensure the DMT registers a temperature for the simulator. Plug the simulator into the DMT using the quick-connect ports, allow the simulator to come to temperature, and ensure the simulator temperature reaches 34ºC ± 0.05.

5.7.3.7. Plug in the printer, turn it on and connect it to the DMT using a USB cable. Fill the printer with ink and paper (as necessary).

5.7.3.8. Connect the keyboard to a USB slot in the back of the DMT.

5.7.3.9. Turn the DMT on. When the instrument reaches temperature it will display “Ready, Push Run”.

5.7.3.10. On the “Ready, Push Run” screen, press the DMT logo to open the drop-down menu. Select “Technician Mode”. Enter password.

5.7.3.11. On the Technician screen, press the “Set RF” button to set the Radio Frequency sensitivity. The instrument will adjust the RF sensitivity to the ambient level. Press “Save” to save the RF setting.

5.7.3.12. Exit when complete.

5.7.4. Installation Software Protocol

5.7.4.1. Open the drop-down menu. Select: Protocols → Installation. Fill in all fields on the data entry screen as required and review before continuing.

5.7.4.2. The instrument will now perform a mandatory 15-minute wait period which gives the simulator solution time to equilibrate.

5.7.4.3. Once the wait period is complete, the instrument will automatically begin the installation protocol. Follow all instructions on the screen. The instrument will only continue on to the next step once each check passes.

5.7.4.4. The first step is a Diagnostic Check which also resets the subject testing options to default. The instrument will run a self-check of software, hardware, optics, and mechanical function to ensure all specifications are met.

5.7.4.5. The second step is an Accuracy and Precision Check. The instrument will run five replicates of the simulator solution and calculate an average and standard deviation. The

average must be within ± 5% of the certified simulator solution concentration and the standard deviation must be <0.0020.

5.7.4.6. The third step is the Radio Frequency Detection Test.

5.7.4.6.1. When prompted to perform the RF Detection Test, if the agency has a console radio located in their building, have dispatch key commonly used frequencies. The instrument should not react to dispatch frequencies. If a dispatch frequency causes an RF error, post a sign alerting operators to be aware of the potential RF detection warnings.

5.7.4.6.2. Key a handheld radio within two feet of the instrument. It should detect the RF. If the instrument does not report RF detected, reset the RF sensitivity and begin the test again.

5.7.4.6.2.1. It is normal for the detector voltage to fluctuate a small amount; however, the detector voltage should not change by more than 0.003V.

5.7.4.6.2.2. If the detector voltage changes by more than 0.003V and radio frequencies (RF) are not detected, press “Fail” to stop the test. Adjust the RF sensitivity in Technician Mode before repeating the calibration attempt.

5.7.4.7. The final step is a Sample Acceptance Check.

5.7.4.7.1. Press “OK” when you are ready to start the test. The DMT will run through a series of quality control checks.

5.7.4.7.2. When prompted “Please Blow” and an intermittent tone is heard, insert a new mouthpiece into the breath tube. Provide appropriate breath samples as described in the calibration protocol instructions. The bottom left corner of the screen will also display the type of breath to deliver.

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

5.7.4.8. Once the protocol is complete, the instrument will prompt for a signature. Sign in the box and press “finished”.

5.7.5. Record Keeping

5.7.5.1. In the DMT Maintenance Log, affix one copy of the simulator solution label, document your name, the date of installation, and any corrective actions that may have been performed.

5.7.5.2. When the installation report prints, file one copy with the onsite maintenance records.

5.7.5.3. The completed installation data package includes the installation report, TOX_F200_5_Simulator Temperature Check Worksheet (if applicable), TOX_F200_4_DMT Site Evaluation Checklist (if a new site), and any failing records generated during the installation process.

5.7.5.4. Upon successful completion of the installation, the person performing the installation must complete a primary data review of the package prior to technical and administrative review.

5.8. Routine Performance Check (RPC)

5.8.1. Each instrument shall have an RPC performed every February, June, and October by a trained DMT Supervisor or VFL staff. Any instrument unable to successfully complete their RPC shall be repaired or returned to VFL for service as necessary.

5.8.2. Prepare a simulator containing a quality control solution. Allow the solution to come to temperature before beginning the RPC protocol.

5.8.3. The RPC software protocol is nearly identical to the installation software protocol except that a console radio check is not required and the options do not reset. Additionally, when RPC is selected from the main menu, the minimum required level of password is Supervisor rather than Technician. See the installation software protocol for instructions.

5.8.4. Record Keeping

5.8.4.1. In the DMT Maintenance Log, affix one copy of the simulator solution label and document your name, the date of the RPC, and any corrective actions performed.

5.8.4.2. When the RPC report prints, file one copy with the onsite maintenance records. A copy of the report and any failing reports generated during the RPC process will be reviewed by VFL staff.

5.8.4.3. The completed RPC package includes the RPC report, any failed reports, and any communication with the agency regarding the RPC, if applicable.

5.8.5. A qualified individual from the VFL will perform a technical review of the RPC report(s).

5.8.5.1. Check the date of the RPC to ensure the correct time frame. RPCs may be completed as early as the 15th day of the previous month (Jan. 15, May 15, and Sept. 15).

5.8.5.2. The RPC must be submitted in color (electronic or paper).

5.8.5.3. If, after review, the VFL deems an RPC as unacceptable, the agency will be immediately notified and the instrument designated out of service until such time as a passing RPC can be completed. Communication with the agency to ensure appropriate actions and notifications are made will be documented.

5.8.6. Upon completion of the technical review, an administrative review will be completed.

5.9. Simulator Solution Change (SSC)

5.9.1. Prepare a simulator containing a quality control solution. Allow the solution to come to temperature before beginning the SSC protocol.

5.9.2. The instrument will now perform a mandatory 15-minute wait period which gives the simulator solution time to equilibrate.

5.9.3. Once the wait period is complete, the instrument will automatically begin the SSC protocol.

5.9.4. The only step is an Accuracy and Precision Check. The instrument will run five replicates of the simulator solution and calculate an average and standard deviation. The average must be within ± 5% of the certified simulator solution concentration and the standard deviation must be <0.0020.

5.9.5. Once the protocol is complete, the instrument will prompt for a signature. Sign in the box and press “accept”.

5.9.6. Record Keeping

5.9.6.1. In the DMT Maintenance Log, affix one copy of the simulator solution label, document your name, the date of SSC, and any corrective actions that may have been performed.

5.9.6.2. When the SSC report prints, file one copy with the onsite maintenance records.

5.9.6.3. The completed SSC package includes the SSC report, any failed reports, and any communication with the agency regarding the SSC, if applicable.

5.9.6.4. Upon successful completion of the SSC, the person performing the SSC must complete a primary data review of the package prior to technical review. An administrative and director review is not required.

6.0 Document Review

6.1. Technical Review

6.1.1. Different types of reports may include different information. Review all applicable information.

6.1.2. Temperatures.

6.1.2.1. Sample Chamber Temperature acceptable range: 44 - 52ºC.

6.1.2.2. Breath Tube Temperature acceptable range: 38 - 50˚C.

6.1.2.3. Digital Sim Temperature acceptable range: 12V500: 34ºC ± 0.05

6.1.2.3.1. Verify the 12V500 simulator has been temperature checked within the last calendar year.

6.1.3. Settings

6.1.3.1. The lamp voltage should be no higher than 2.55 V and the cooler voltage no higher than 2.52 V.

6.1.4. Pump Information

6.1.4.1. Flow rate should be between 3.5 L/min and 6.5 L/min.

6.1.5. Filter Information

6.1.5.1. All filters should report ZERO = TRUE.

6.1.6. Blank Test

6.1.6.1. Acceptable result: 0.000.

6.1.7. Accuracy and Precision Check

6.1.7.1. Concentration: Ensure the proper simulator solution concentration and acceptable range is entered.

6.1.7.2. Lot: Ensure the concentration matches the lot that was entered.

6.1.7.3. Verify that the simulator solution used was opened prior to its expiration date.

6.1.7.4. For adjustment and calibration solutions, verify they have not exceeded their in-simulator expiration requirements.

6.1.7.5. Verify that the average result is within the accuracy requirement for the relevant procedure.

6.1.7.6. Verify the standard deviation is ≤ 0.0020.

6.1.7.7. If an incorrect lot number or target concentration is entered on an RPC or Simulator Solution Change (SSC), the DMT Supervisor will be notified immediately. An SSC

protocol may be performed to assign the correct solution to the instrument. A physical change of the solution is not necessary. The SSC report will be sent to the VFL and attached to the original RPC/SSC report. This is deemed acceptable as long as the original average reported on the RPC/SSC is within ± 5% of the actual target value. If the DMT Supervisor cannot correct the lot number or target concentration immediately, the instrument will be designated out of service until the correction can be made.

6.1.8. Interference Test

6.1.8.1. Acceptable result: “Interference Detected” or “INTERFERENCE”.

6.1.9. Mouth Alcohol Test

6.1.9.1. Acceptable result: “Mouth Alcohol Detected” or “Invalid Sample”.

6.1.10. RF Detection Test

6.1.10.1. Acceptable result: “RF Detected” or “PASSED”.

6.1.11. Sample Acceptance Test

6.1.11.1. Acceptable result: “Passed”.

6.1.11.2. The graph should reflect a shallow, intermittent, and alcohol free breath sample.

6.1.11.3. A passing sample acceptance test should not show the presence of apparent ethanol at a result equal to or greater than half of the calibration method’s LLOQ. If the alcohol profile shows any ethanol reading at or above half of the LLOQ, the DMT Supervisor shall be contacted and requested to perform a new sample acceptance test on a check-in ticket. The check-in ticket will be sent to the VFL and attached to the RPC. If the second attempt at a sample acceptance test still displays apparent ethanol, further investigation by Toxicology Section staff is required.

6.1.12. Linearity Check Results

6.1.12.1. Acceptable result: $R^2 > 0.99$

6.1.13. The technical review will be documented by the reviewer.

6.2. Administrative Review

6.2.1. The completed record meets administrative expectations defined in the QA Manual.

6.2.2. Where applicable, the Simulator Solution Use Log, DMT Electronic Log, and DMT Electronic Control Chart must be filled out properly.

6.2.3. If applicable, the Simulator Temperature Check Worksheet (TOX_F200_5) must be filled out properly.

6.2.4. If applicable, the DMT Verification Summary (TOX_F200_1) must be filled out properly.

6.2.5. If applicable, the DMT Certificate of Calibration (TOX_F200_2) must be filled out properly.

6.2.6. Ensure any communication, failing reports, or other associated documentation are included in the package.

6.2.7. A technical review must be completed.

6.2.8. The administrative review will be documented by the reviewer.

6.3. Director Review

6.3.1. Confirm that the required reviews have been completed.

6.3.2. Verify the report and associated paperwork, including the certificate of calibration, meet administrative expectations. Document the review.

7.0 Estimation of Uncertainty of Measurement

7.1. The estimation of measurement uncertainty is performed using the GUM Approach as defined in the ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – Annex A.

7.1.1. Uncertainty is expressed as an expanded uncertainty at the 95.45% level of confidence and a coverage factor (k) of approximately 2, in accordance with ISO/IEC 17025 and ANAB Accreditation Requirements for Forensic Testing and Calibration.

7.1.2. The uncertainty estimate is evaluated using the data from the fleet of evidentiary DMT instruments used in the field. All instruments with a reported measurement uncertainty for their calibration are included in, or evaluated against, the current measurement uncertainty estimate. Instruments not used for evidentiary testing are not included in the uncertainty estimate.

7.1.3. The expanded uncertainty will be rounded up to two significant figures.

7.2. Calculate the interval for each calibration solution result by multiplying the measured result by the expanded uncertainty. This value will be reported along with the measured result at each concentration level of the instrument calibration and for the result of the MCS.

7.2.1. The reported estimated measurement uncertainty will be truncated to four decimal places, then rounded up to three decimal places. Reporting to three decimal places is in compliance with the Vermont Department of Public Safety Breath and Blood Alcohol Analysis Rule.

7.2.2. Calibration results are reported as X ± Y, where, at measured value X, measurement uncertainty equals Y.

7.2.3. To assist with the application of calibration results, the interval will be reported in the following format:

$$0.XXX \pm 0.YYY \text{ g/210 L}$$

7.3. The estimated uncertainty of measurement will be evaluated at least annually or if any significant change in the expanded uncertainty is detected.

7.4. The reported result and associated uncertainty applies only to the adjustment and calibration of the DMT instrument using aqueous ethanol simulator solutions of a known concentration.

8.0 HOST Use and Record Retention

8.1. Personal Identifying Information Security

8.1.1. DMT data is securely stored on a DPS server and can be accessed locally using DM Host. Personal identifying information retained as part of the record is confidential. Routine summary reports, or reports generated as part of a discovery request, are anonymized and contain no personal information.

8.2. HOST Checks

8.2.1. DM HOST will be checked regularly, typically daily, for new records. All new SSC or RPC records will be reviewed and filed electronically. Breath records will be reviewed for anomalies. Appropriate action will be taken to correct any errors identified on field instruments. Those

instruments with errors that cannot be immediately remedied will be designated out of service. If a DMT Supervisor or other person at an agency is unavailable to either designate a DMT out of service or mark it as unusable, an analyst may remove the instrument from service remotely. Communication with the agency to ensure appropriate actions have been completed and notifications are made will be documented.

8.3. Ethernet Connectivity Check

8.3.1. On the first and fifteenth of each month, each DMT will perform a diagnostic test. DM HOST will be checked to confirm that the report was transmitted. Any instruments found to have not transmitted a report will be followed up on to ensure continuous Ethernet connectivity throughout the fleet of evidentiary DMT instruments.

8.4. Monthly Update Reports

8.4.1. At the beginning of each month, summary reports will be created documenting the previous month's breath tests and error messages. These reports will be made available for discovery.

9.0 DMT Field Use

9.1. DMT operation by certified law enforcement personnel- refer to TOX_D200_2_DMT Operator Manual.

9.2. DMT maintenance and repairs by properly trained and authorized DMT Supervisors- refer to TOX_D200_1_DMT Supervisor Manual.

10.0 References

10.1. Intox DMT Training Binder
10.2. Guth 12V500 Operator's Manual
10.3. TOX_F200_1_DMT Verification Summary
10.4. TOX_F200_2_DMT Certificate of Calibration
10.5. TOX_F200_3_Technical Support Inquiry
10.6. TOX_F200_4_ DMT Site Evaluation Checklist
10.7. TOX_F200_5_Simulator Temperature Check Worksheet
10.8. TOX_D200_2_ DMT Operator Manual
10.9. TOX_D200_1_ DMT Supervisor Manual
10.10. DMT Maintenance Log
10.11. Reagent Preparation Log
10.12. Simulator Solution Use Log
10.13. DMT Electronic Log
10.14. DMT Electronic Control Chart
10.15. TOX_P100_Alcohol Analysis Manual
10.16. Toxicology Training Manuals
10.17. TOX_P500_Certified Reference Material Manual
10.18. QA_P100_6.4_ Equipment QC
10.19. DMT Software BETA Testing Guide
10.20. Vermont Department of Public Safety Breath and Blood Alcohol Analysis Rule
10.21. ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories
10.22. ANAB Accreditation Requirements for Forensic Testing and Calibration (2023)
10.23. ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – Annex A

DOCUMENT HISTORY			
DATE	**VERSION**	**APPROVED BY**	**ACTIVITY OR REVISION**
03/06/2017	1	Lab Director	ALC_P200 replaces P-ALC 201 (Power-Up), P-ALC 202 (Calibration), P-ALC 203 (Certification), P-ALC 204 (Installation), P-ALC 205 (APM) & P-ALC 206 (RPC); F-ALC 202 (TSI) becomes ALC_F200_3; F-ALC 203 becomes DMT Maintenance Log (uncontrolled); F-ALC 204 becomes DMT Operators' Log (uncontrolled); F-ALC 205 (Site Evaluation) becomes ALC_F200_4; ALC_F200_1 (DMT Verification Summary) & ALC_F200_5 (Sim Temp Check Worksheet) are created; F-ALC 201 (Calibration Logbook) is retired; F-ALC 206 (Simulator Solution Log) is retired; F-ALC 209 (Simulator Solution Use Log), F-ALC 210 (Supplies Request) & F-ALC 211 (Contact Information) become uncontrolled documents.
09/10/2018	2	Lab Director	TOX_P200 replaces ALC_P200 (DMT Manual); added measurement uncertainty section; removed Guth 34C simulators; changed cal check supplier and procedure; minor changes throughout; TOX_F200_1 replaces ALC_F200_1 (DMT Verification Summary); added TOX_F200_2_DMT Certificate of Calibration; TOX_F200_3 replaces ALC_F200_3 (Technical Support Inquiry); TOX_F200_4 replaces ALC_F200_4 (DMT Site Evaluation Checklist); TOX_F200_5 replaces ALC_F200_5 (Simulator Temperature Check Worksheet); • TOX_D200_2 refers to ALC_D200_2 (DataMaster DMT Operator Manual) • TOX_D200_1 refers to ALC_D200_1 (DMT Supervisor Manual) • TOX_P300 refers to ALC_P300 (Alcohol Training Manual) • TOX_P500 refers to ALC_P500 (Certified Reference Material Manual)
11/5/2018	3	Lab Director	Updated sections 4.7 (proficiency testing), 5.4.4.5 (linearity), and 7.2.1 (rounding language); minor formatting changes throughout; updated F200_2 DMT Certificate of Calibration (removed reference to balance; updated MU rounding); updated F200_3 Technical Support Inquiry (converted to an Excel file)
07/13/2020	4	Lab Director	Removed "suck back test" from sample acceptance tests throughout; minor changes throughout; TOX_P300 is currently ALC_P300 but will be changed in the next version; TOX_F200_5 updated to add agreement criteria.
09/23/2024	5	Lab Director	Updated calibration and adjustment language; removed APM references and merged with install; changed equilibration times; removed references to cal checks errors/Xq; changed interference testing values; nomenclature changes from external standard to quality control solution and "cal check" to manufacturer control solution and updated its verification acceptance criteria; removed sections regarding proficiency testing and abbreviations; updated TOX_F200_1, TOX_F200_2, TOX_F200_3, and TOX_F200_5.
02/11/2025	6	Lab Director	Addition of 5.4.11.2 to allow supplemental interference testing
11/24/2025	7	Lab Director	Updated calibration and adjustment language for as found calibrations; clarified shallow breath instructions; simplified reporting and reviewing language to allow for paperless record retention