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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, calibration, certification 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 in the maintenance of the DMT evidentiary breath alcohol testing instruments by Toxicology Section staff. This manual does not cover all troubleshooting and error conditions which may be encountered in the maintenance of the DMT units, but does set guidelines and standards which 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, 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 and technicians 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 Alcohol Training Manual (TOX_P300). Ongoing competency will be evaluated annually through the successful completion of either an internal or external proficiency test.

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 instruments physical and electronic folder.

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 or technician 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 employed 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 have their calibration evaluated and certified annually by an approved vendor. The resulting documentation will be maintained.

4.4.1.3. If a thermometer is sent out for service, an inspection of the package/thermometer will be performed to check for any shipping and handling concerns prior to being returned for use. The calibration certificate will be reviewed in accordance with QA_P100_6.4_Equipment QC.

4.4.1.4. If a question arises regarding the proper functioning of a thermometer, a performance check or calibration service by an approved vendor will be initiated.

4.4.1.4.1. The performance check will be performed at 34ºC and have a tolerance of ± 0.2ºC. See QA_P100_6.4_Equipment QC for procedure.

4.4.1.4.2. Performance checks will be reviewed by the Toxicology Section Supervisor, or their designee, and filed in the VFL Thermometers Equipment QA/QC Binder.

4.5. **Instrumentation**

4.5.1. DMT Instruments

4.5.1.1. Refer to 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. The temperature of the simulator must read 34ºC ± 0.2ºC and the simulator and NIST traceable thermometer must be within ± 0.1ºC of each other, adjust as necessary. This check will be documented using TOX_F200_5_Simulator Temperature Check Worksheet.

4.5.2.3. Each simulator will be labeled with the initials of who performed the check, the date checked, and the due date of the next temperature check.

4.5.2.4. The results of the temperature check will be reviewed by the Toxicology Section Supervisor or their designee. The resulting documentation will be maintained.

4.6. **Simulator Solution Reference Materials**

4.6.1. Calibration (Cal) Check Solution

4.6.1.1. A NIST traceable ~0.10 g/210 L aqueous ethanol simulator solution is used for a calibration check subsequent to the calibration adjustment of a DMT. The solution is purchased from an ISO 17034 or Guide 34 accredited supplier. The certificates of analysis will be maintained.

4.6.1.2. Prior to using a new lot of calibration check solution, the lot should be run on the GC as a sample (in duplicate) to verify the lot falls within ± 3% of the manufacturer's certified concentration. A new shipment of the same lot does not require verification. See 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 di$H_2O$ Solution

4.6.2.1. Deionized water will be used as a blank to perform a calibration 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, an aliquot is analyzed via GC and deemed acceptable for use when no peaks above threshold are observed when analyzed without the addition of internal standard solution.

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. 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 TOX_P500_Certified Reference Material Manual for Certified Reference Material preparation and certification)

| Concentration | Intended Use |
|---|---|
| 0.10 g/210 L | Calibration Solution<br>External Standard Solution |
| 0.02 g/210 L | Certification Solution |
| 0.08 g/210 L | Certification Solution |
| 0.16 g/210 L | Certification Solution |
| 0.36 g/210 L | Certification Solution |
| 0.02% vol/vol acetone in 0.08 g/210 L ethanol | Interference Solution<br>for Certification |
| 0.04% vol/vol methanol in diH2O | Interference Solution<br>for Verification |
| 0.04% vol/vol isopropanol in diH2O | Interference Solution<br>for Verification |

4.7. **Proficiency Testing**

4.7.1. The DMT Program must demonstrate ongoing proficiency by having one successfully completed proficiency test result forwarded to the accrediting body each year. The DMT Program uses inter- and intra-laboratory comparisons to satisfy the proficiency testing requirements.

4.7.2. Ongoing technician and analyst competency will be evaluated annually through the successful completion of either an interlaboratory or intralaboratory comparison.

4.7.2.1. The concentration of the comparison test solution will be unknown to the participant prior to testing. The participant must calibrate and certify the instrument before analyzing the comparison test solution.

4.7.2.2. Successful completion of an interlaboratory comparison requires the participant's mean result, when rounded to three decimal places, to be within 3SD of the consensus value of the solution.

4.7.2.3. Successful completion of an intralaboratory comparison requires the participant's mean result, when rounded to three decimal places, to be within 5% of the certified value of a VFL prepared simulator solution.

## 5.0 DMT Maintenance Procedures

5.1. Materials and supplies are located in Room 164

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. **New Instrument Set-up and Verification Testing**

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

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

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

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

5.2.5. Replace the four screws on the top of the DMT with 4 Torx T10 security screws.

5.2.6. Attach a tethered stylus to the DMT using a Torx T10 security screw in 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.

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

5.2.8. 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.

5.2.9. Calibrate and certify the unit following the procedures noted in sections 5.3 and 5.4, respectively.

5.2.10. Linearity Tests:

5.2.10.1. Four concentrations of EtOH solution will be used: 0.02, 0.08, 0.16, and 0.36 g/210 L.

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

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

5.2.10.3. All four concentrations will be run consecutively and will count as one linearity test.

5.2.10.4. Five linearity tests will be run on the instrument. Once a linearity test is begun, it must be completed (all 4 solutions analyzed) on the same day.

5.2.10.5. No more than two linearity tests may be performed per day. At least two qualified individuals must perform a portion of the testing.

5.2.11. Interference Tests:

5.2.11.1. 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).

5.2.11.1.1. 0.02% vol/vol acetone in 0.08 g/210 L ethanol.

5.2.11.1.2. 0.04% vol/vol methanol in di$H_2O$.

5.2.11.1.3. 0.04% vol/vol isopropanol in di$H_2O$.

5.2.12. Perform a final calibration check, see section 5.3.10.

5.2.13. Record Keeping

5.2.13.1. 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.

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

5.2.13.3. The completed package includes:

5.2.13.3.1. TOX_F200_1_ DMT Verification Summary.

5.2.13.3.2. All reports generated during the verification process.

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

5.2.13.5. The data must then undergo a technical review by a qualified analyst. See section 6.1 for review parameters.

5.2.13.6. Upon completion of the technical review, an administrative review will be completed by the Toxicology Section Supervisor or their designee, followed by a director review by the Lab Director or their designee. See sections 6.2 and 6.3 for review parameters.

5.3. **Calibration (Adjustment)**

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

5.3.2. Activate Technician Mode using appropriate password.

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

5.3.4. The detector voltage should be ± 0.100 V of zero.

5.3.5. Prepare the Calibration Simulator containing 0.10 g/210 L EtOH Calibration Solution.

5.3.5.1. If needed, open a new bottle of Calibration Solution (0.10 g/210 L 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.

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

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

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

5.3.6. Prepare a simulator containing blank di$H_2O$ solution (see section 4.6.2).

5.3.7. Prepare a simulator containing a Cal Check 0.100 g/210 L EtOH solution. If new solution is opened, allow at least 30 minutes for the solution to come to temperature and equilibrate.

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

5.3.9. Follow the instructions prompted by the DMT.

5.3.9.1. Connect the simulator containing the Calibration Solution to the DMT.

5.3.9.2. When prompted, connect the di$H_2O$ simulator to the breath tube and CAL port on the DMT.

5.3.9.3. When prompted, disconnect the di$H_2O$ simulator from the breath tube and the CAL port. Press "OK" when complete.

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

5.3.10. Perform a check of the calibration by analyzing the Cal Check 0.100 g/210 L EtOH solution.

5.3.10.1. Attach a simulator containing the Cal Check 0.100 g/210 L EtOH solution to the DMT.

5.3.10.2. On the touch screen, press the DMT logo to open the drop down menu. Select: ACCURACY AND PRECISION.

5.3.10.3. In the first name field, enter the initials of the qualified individual 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".

5.3.10.4. 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 concentration of the solution with a standard deviation ≤ 0.002. The Cal Check solution may be re-run if it fails to meet the acceptance criteria on the first attempt. A fresh bottle of Cal Check solution may also be opened and analyzed if the previous solution was not freshly opened. The instrument shall be recalibrated if the results do not meet these criteria.

5.3.11. Record Keeping

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

5.3.11.2. A calibration adjustment is typically performed in conjunction with other maintenance or repair protocols, therefore completed packages may vary. A Certification must be performed subsequent to any Calibration protocols before deployment in the field. Calibration reports will be included with the certification package as described in section 5.4.5.

5.4. **Certification**

5.4.1. Ensure simulators are prepared containing the four concentrations of EtOH certification solutions (0.02, 0.08, 0.16, and 0.36 g/210 L) and one interference solution (0.02% vol/vol acetone in 0.08 g/210 L ethanol).

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

5.4.1.2. Certification solutions are replaced on a quarterly basis or when the solution falls out of acceptable range. Do not open solutions which have passed their expiration date. Newly prepared solutions should be allowed to come to temperature and equilibrate for at least 30 minutes prior to testing.

5.4.2. The detector voltage should be ± 0.100 V of zero.

5.4.3. On the touch screen, press the DMT logo to open the drop down menu. Select: Protocols → Certification. Enter appropriate password. Enter the name of the qualified individual performing the certification.

5.4.4. Follow the instructions as prompted by the DMT.

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

5.4.4.2. 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.

5.4.4.3. The first step in the certification process is a diagnostic test.

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

5.4.4.4.1. 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.

5.4.4.5. 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.

5.4.4.6. 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”.

5.4.4.6.1. The acceptance criterion for the Acetone Interference Test is “Interference Detected”.

5.4.4.7. 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 mouth piece from the bottle of mouth alcohol test solution.

5.4.4.8. Press the “Mouth Alc” button to begin the test. When prompted “Please Blow”, the technician will then slowly blow out through the ethanol-laden mouthpiece into the breath tube.

5.4.4.8.1. The acceptance criterion for the Mouth Alcohol Test is “Mouth Alcohol Detected”.

5.4.4.9. 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.

5.4.4.9.1. The acceptance criterion for the RF Detection Test is “Passed”.

5.4.4.10. To begin the Sample Acceptance Test press the “Sample Acc” button. Open a new mouth piece and press “OK” when you are ready to start the test.

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

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

5.4.4.10.3. 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.

5.4.4.10.3.1. **Shallow Breath**: Place the mouthpiece between your teeth or lips, but keep the corners of your mouth open. Blow a small amount of air into the mouth piece, allowing the majority of air to escape out the sides of your mouth. 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 2-3 seconds.

5.4.4.10.3.2. **Intermittent Breath**: Blow 3-4 short, somewhat forceful breaths into the mouth piece for 1-2 seconds. This is similar to blowing up a balloon, but with quick breaths. Be careful not to suck back on the mouth piece between puffs of air.

5.4.4.10.3.3. **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.

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

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

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

5.4.4.10.5.2. 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.

5.4.4.10.5.3. 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.

5.4.4.10.5.4. If the alcohol line (black) is elevated at any point during the sample acceptance test, the test is considered failing.

5.4.4.11. 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 certification report will now print.

5.4.5. Record Keeping

5.4.5.1. 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.

5.4.5.2. Results will be entered into TOX_F200_2_DMT Certificate of Calibration. Each certificate of calibration will list the DMT serial number, date of calibration, date of certification, instrument location, and the analytical results from the calibration check and certification procedures with their associated measurement uncertainty. The DMT Certificate of

Calibration will be signed by the certifying analyst subsequent to technical review of the document. See section 7.0 for information regarding measurement uncertainty.

5.4.5.3. A Certification is performed subsequent to all Calibrations. It may also be performed in conjunction with other maintenance or repair protocols. At a minimum, the Calibration report, DMT Certificate of Calibration, the Certification report and any reports documenting a failure will be included in the package. A Technical Support Inquiry (TOX_F200_3) is included with any maintenance/repairs performed on a DMT.

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

5.4.5.5. The data must then undergo a technical review by a qualified analyst. See section 6.1 for review parameters.

5.4.5.6. Upon completion of the technical review, an administrative review will be completed by the Toxicology Section Supervisor or their designee, followed by a director review by the Lab Director or their designee. See sections 6.2 and 6.3 for review parameters.

5.5. **Installation**

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

5.5.2. Site Inspection and DMT Placement for New Sites

5.5.2.1. 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.

5.5.2.2. A site evaluation is not required when reinstalling an instrument at an agency subsequent to an instrument repair.

5.5.3. Setting up the DMT

5.5.3.1. Plug the UPS or line conditioner into an electrical outlet. Plug the DMT and printer into the UPS or line conditioner.

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

5.5.3.3. Verify that the simulator has been temperature checked within the last calendar year. For new simulators or simulators that need a temperature check performed, refer to section 5.6.2.2 of this manual for simulator temperature check requirements.

5.5.3.4. Add External Standard solution to the simulator. Replace the simulator head snugly. Affix one (1) simulator solution label to the top of the simulator head and note the date opened and your initials. Do not use solutions which have passed their expiration date.

5.5.3.5. Plug the simulator in to the UPS or line conditioner. Ensure the simulator is powered on correctly and the paddle is rotating.

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 34.0ºC ± 0.2.

5.5.3.6. 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).

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

5.5.3.8. Turn the DMT on. When the instrument reaches temperature it will display "Ready, Push Run".

5.5.3.9. On the "Ready, Push Run" screen, press the DMT logo to open the drop down menu. Select "Technician Mode". Enter password.

5.5.3.10. 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.

5.5.3.11. Exit when complete.

5.5.4. Installation Software Protocol

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

5.5.4.2. The instrument will now perform a mandatory 30 minute wait period which gives the simulator solution time to equilibrate.

5.5.4.3. 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.

5.5.4.4. 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.

5.5.4.5. 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.

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

5.5.4.6.1. When prompted to perform the RF Detection Test, if the agency has a console radio located in their building, have dispatch key all 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.

5.5.4.6.2. 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.

5.5.4.7. The final step is a sample acceptance check.

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

5.5.4.7.2. When prompted "Please Blow" and an intermittent tone is heard, insert a new mouthpiece into the breath tube. Provide breath samples as instructed in section

5.4.4.10.3. The bottom left corner of the screen will also display the type of breath to deliver.

5.5.4.7.3. 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.

5.5.4.8. Once the protocol is complete, the instrument will prompt for technician signature. Sign in the box and press "finished". Two copies of the report will now print.

5.5.5. Record Keeping

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

5.5.5.2. When the Installation report prints, file one copy with the onsite maintenance records.

5.5.5.3. 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.

5.5.5.4. Make entries in the DMT Electronic Log. All results must be recorded including analytical results that do not meet the acceptance criteria.

5.5.5.5. Upon successful completion of the installation, a qualified analyst must perform a primary data review of the package prior to submitting the complete package to the assigned reviewer for technical review.

5.5.5.6. The data must then undergo a technical review by a qualified analyst. See section 6.1 for review parameters.

5.5.5.7. Upon completion of the technical review, an administrative review will be completed by the Toxicology Section Supervisor or their designee. See section 6.2 for review parameters.

5.6. **Annual Preventative Maintenance (APM)**

5.6.1. All instruments shall be tested annually by trained laboratory staff. Any instrument failing their APM shall be repaired or returned to VFL for service as necessary.

5.6.2. Simulator inspection and temperature calibration check

5.6.2.1. Detach the simulator from the DMT.

5.6.2.2. Unscrew the temperature testing port and insert the thermometer into the simulator solution. Allow thermometer to equilibrate. Ensure simulator temperature is 34.0ºC ± 0.2 and the reported temperature matches the NIST traceable thermometer within ± 0.1ºC. Adjust if necessary. Document the temperature check of the simulator using TOX_F200_5_Simulator Temperature Check Worksheet. Label the simulator with the initials of who performed the check, the date checked, and due date of next temperature check.

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

5.6.2.4. Replace the gasket in the simulator head.

5.6.2.5. 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.

5.6.2.6. Reconnect the simulator to the DMT.

5.6.3. DMT inspection

5.6.3.1. Unscrew and open the top of the instrument. Inspect all tubing and wire connections. Ensure all are properly seated and free from kinks, cracks or other problems. Correct issues as necessary. Once complete, close the instrument.

5.6.4. Annual Preventative Maintenance Software Protocol

5.6.4.1. On the touch screen, press the DMT logo to open the drop down menu. Select: Protocols → Annual Preventative Maintenance. Enter password. Fill in all fields on the data entry screen as required. The instrument will now automatically complete the APM protocol. Follow all instructions on the screen. The instrument will only continue on to the next step once each check passes.

5.6.4.2. The first step is a Diagnostic Check. The instrument will run a self-check of software, hardware, optics, and mechanical function to ensure all specifications are met.

5.6.4.3. The second step is the Radio Frequency Detection Test. When prompted to perform the RF test, if the agency has a console radio located in their building, have dispatch key all commonly used frequencies. The instrument should not react to dispatch frequencies. Key a handheld radio within two feet of the instrument. RF should be detected and reported. If the instrument's radio frequency sensitivity is incorrect, reset the sensitivity and begin the test again.

5.6.4.4. The instrument will then analyze the simulator solution.

5.6.4.5. The final step is a Sample Acceptance Test. See section 5.4.4.10 for instructions.

5.6.5. Record Keeping

5.6.5.1. In the DMT Maintenance Log, document your name, date of APM performed and note any corrective actions that may have been performed.

5.6.5.2. Make an entry in the DMT Electronic Log.

5.6.5.3. The completed APM data package includes the APM report, the TOX_F200_5_Simulator Temperature Check Worksheet and any failing reports generated during the APM process.

5.6.5.4. Upon successful completion of the APM, a qualified analyst must perform a primary data review of the package prior to submitting the complete package to the assigned reviewer for technical review.

5.6.5.5. The data must then undergo a technical review by a qualified analyst. See section 6.1 for review parameters.

5.6.5.6. Upon completion of the technical review, an administrative review will be completed by the Toxicology Section Supervisor or their designee. See section 6.2 for review parameters.

5.7. **Routine Performance Check (RPC)**

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

5.7.2. The RPC software protocol is identical to the Installation software protocol except RPC is selected from the main menu and the minimum required level of password is Supervisor. See Installation software protocol (section 5.5.4) for instructions.

5.7.3. Record Keeping

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

5.7.3.2. 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.

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

5.7.4. A qualified individual from the VFL will perform a technical review of the RPC report(s). See section 6.1 for review parameters. The information in the RPC report will be logged in the DMT Electronic Log.

5.7.4.1. Check the date of the RPC to ensure the correct time frame. RPCs may be completed no more than 15 days prior to the RPC month. (1/17, 5/17 or 9/16).

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

5.7.4.3. 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. The Toxicology Section Supervisor should be informed to ensure appropriate actions and notifications are made.

5.7.5. Upon completion of the technical review, an administrative review will be completed by the Toxicology Section Supervisor or their designee. See section 6.2 for review parameters.

**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: 34.0ºC ± 0.2

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 2.6 V and the cooler voltage no higher than 2.2 V.

6.1.4. Pump Information

6.1.4.1. Flow rate should be between 3.0 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. Calibration Check

6.1.7.1. Xq acceptable range: ± 4%.

6.1.7.2. Acceptable result: “PASSED”.

6.1.8. Accuracy and Precision Check

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

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

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

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

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

6.1.8.6. Verify the standard deviation is ≤ 0.0020.

6.1.8.7. If an incorrect lot number or target concentration is entered on an RPC or Simulator Solution Change (SSC), the DMT Supervisor and Toxicology Section 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.

6.1.9. Interference Test

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

6.1.10. Mouth Alcohol Test

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

6.1.11. RF Detection Test;

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

6.1.12. Sample Acceptance Test;

6.1.12.1. Acceptable result: “Passed”.

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

6.1.12.3. A passing sample acceptance test should not show the presence of apparent ethanol. If the alcohol profile shows any ethanol reading above baseline, 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 qualified Toxicology Section staff is required.

6.1.13. Linearity Check Results

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

6.1.14. After technical review, the report will be dated and initialed by the reviewer.

6.2. **Administrative Review**

6.2.1. All pages must be numbered and initialed.

6.2.2. The instrument serial number must be on every page of the package.

6.2.3. The Simulator Solution Use Log, DMT Electronic Log and DMT Electronic Control Chart (where applicable) must be filled out properly.

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

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

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

6.2.7. A technical review must be completed.

6.2.8. After administrative review, the report will be dated and initialed 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 by dating and initialing the report.

## 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=2, in accordance with ISO/IEC 17025 and ANAB Forensic Science Testing and Calibration Laboratories Accreditation Requirements.

7.1.2. The uncertainty estimate is evaluated using the data from the fleet of evidentiary DMT instruments used in the field. 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 certification 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 certification and for the result of the calibration check.

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 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 ± 0.YYY 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 calibration and certification 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 printed, reviewed, scanned 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, the Toxicology Section Supervisor or their designee may remove the instrument from service remotely.

### 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 uploaded to the DMT Discovery website.

## 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 Abbreviations**

10.1. GC: Gas Chromatograph

10.2. TV: Target Value

10.3. TSI: Technical Support Inquiry

10.4. RF: Radio Frequency

10.5. UPS: Uninterruptable Power Supply

10.6. APM: Annual Preventative Maintenance

10.7. RPC: Routine Performance Check

10.8. SSC: Simulator Solution Change

10.9. Cert: Certification

10.10.Cal: Calibration

10.11.Sim: Simulator

10.12.A&P test: Accuracy and Precision Test

10.13.SD: Standard Deviation

**11.0 References**

11.1. Intox DMT Training Binder

11.2. Guth 12V500 Operator's Manual

11.3. TOX_F200_1_DMT Verification Summary

11.4. TOX_F200_2_DMT Certificate of Calibration

11.5. TOX_F200_3_Technical Support Inquiry

11.6. TOX_F200_4_ DMT Site Evaluation Checklist

11.7. TOX_F200_5_Simulator Temperature Check Worksheet

11.8. TOX_D200_2_ DMT Operator Manual

11.9. TOX_D200_1_ DMT Supervisor Manual

11.10.DMT Maintenance Log

11.11.Reagent Preparation Log

11.12.Simulator Solution Use Log

11.13.DMT Electronic Log

11.14.DMT Electronic Control Chart

11.15.TOX_P100_Alcohol Analysis Manual

11.16.TOX_P300_Alcohol Training Manual

11.17.TOX_P500 Certified Reference Material Manual

11.18.QA_P100_6.4_ Equipment QC

11.19. DMT Software BETA Testing Guide

11.20. VFL Thermometers Equipment QA/QC Binder

11.21. Vermont Department of Public Safety Breath and Blood Alcohol Analysis Rule

11.22. ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories

11.23. ANAB ISO/IEC 17025:2017- Forensic Science Testing and Calibration Laboratories Accreditation Requirements

11.24. 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);<br>• TOX_D200_2 refers to ALC_D200_2 (DataMaster DMT Operator Manual)<br>• TOX_D200_1 refers to ALC_D200_1 (DMT Supervisor Manual)<br>• TOX_P300 refers to ALC_P300 (Alcohol Training Manual)<br>• 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. |
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