1. Introduction

The Draeger 9510 is the instrument used for breath alcohol analysis by all Connecticut state and local law enforcement. The Division of Scientific Services (DSS) has the responsibility to coordinate the maintenance and to verify working condition of the breath alcohol instruments prior to returning them to agencies for use in the field.

This procedure outlines the steps taken to evaluate Draeger 9510 instruments that have been returned to the laboratory from outside agencies or Draeger located in Texas.

2. Equipment/Materials/Reagents

2.1 Draeger 9510

2.2 Methanol (A454, Fisher Scientific or equivalent)

2.3 Certified Alcohol Reference Solution for Simulator (PM-0080-05, Guth Laboratories or equivalent)

2.4 Mouth Pieces (95-000250, Central Equipment or equivalent)

2.5 Simulator Apparatus (34C, Guth Laboratories or equivalent)

2.6 Draeger provided USB Data Drive

2.7 0.020 % Dry Gas (DG-U020-10, Calgaz or equivalent)

2.8 0.080 % Dry Gas (DG-U080-10, Calgaz or equivalent)

2.9 0.250 % Dry Gas (DG-U250-10, Calgaz or equivalent)

2.10 Thermal Printer Paper (4415520, Guth Laboratories or equivalent)

3. Preparation of Instrument Verification Solutions

3.1 Certified Alcohol Reference Solution for Simulator

3.1.1 The “Certified Alcohol Reference Solution for Simulator” is a purchased reagent containing an ethanol concentration of 0.08 g% when used with a simulator.

3.1.2 Certifcate of Analysis to be maintained within the BAU (i.e. electronically or hard copy)

3.1.3 The solution is placed into a simulator device and labeled with the following information:

1. Name
2. Expiration date
   - The expiration date is determined by the manufacturer.
3. Fill date
4. NFPA diamond and/or GHS pictogram

3.1.4 The solution is evaluated by performing the "Ethanol Detection" portion of a "Functionality Test". The solution is deemed acceptable for use if ethanol is detected by the instrument.

3.1.5 A solution sheet is updated accordingly in Excel and LIMS documenting the verification of this solution.

3.2 Methanol Solution for Simulator

3.2.1 The "Methanol Solution for Simulator" is prepared in-house by adding 2 mL of methanol to 498 mL of DI water.

3.2.2 The solution is placed into a simulator device and labeled with the following information:

1. Name
2. Expiration date
   - Stable at room temperature for 1 year
3. Fill date
4. NFPA diamond and/or GHS pictogram

3.2.3 The solution is evaluated by performing the "Methanol Interferent" portion of an "In-House Certification Test". The solution is deemed acceptable for use if "Interferent Detected" is the result on the instrument.

3.2.4 A solution sheet is updated accordingly in Excel and LIMS documenting the verification of this solution.

4. Procedure

Law enforcement agencies in Connecticut have Draeger instruments assigned to them. If issues arise these agencies contact the Breath Alcohol Unit (BAU) of the DSS to assist with either correcting the issue or having the device sent out for repairs to the manufacturer. Some items such as correcting date, time or IP address can be completed at the lab. For complex issues, the BAU coordinates the shipping of the instrument to the manufacturer. Additionally, the BAU assesses instruments prior to returning them for use in the field.

4.1 Updating Date, Time and Network Connectivity

There are four components that need to be regularly checked on the instrument; date, time, TraCS configuration and IP address. Agencies requiring corrections to these fields will be instructed to schedule an appointment to have this addressed at the lab.

4.1.1 Updating Date and Time

1. Plug a Draeger USB drive into the instrument to access the needed settings.
2. On the bottom left side of the touch screen select "**Menu**".
3. Open "**Settings**".

4. Double-click on "**Set date and time**".
5. Update the needed fields and click "**Save**" at the bottom of the screen.
6. When both the time and date are corrected click "**Save**" again.

4.1.2 Updating Network Connectivity

1. Plug a Draeger USB drive into the instrument to access the needed settings.
2. On the bottom left side of the touch screen select "**Menu**".
3. Open "**Settings**".
4. For the instrument to communicate correctly, information will need to be updated and verified in the "**TraCS Configuration**" and "**Network**" settings.
5. Double-click on "**TraCS Configuration**". Enter the following information:
   - Server IP/Hostname: 10.51.111.8
   - Automatic Transfer: 90 Sec.
   - Communication Port: 9513

   NOTE: The "TraCS Configuration" information remains the same for all instruments regardless of agency.
6. Click "**Save**". This may take a few minutes to save; once saved, close the window.
7. Double-click on "**Network**". The display on the right-hand side of the screen should have the IP option selected, not DHCP. Enter the specific agency IP information in the following format:
   - IP – Address: 123.456.789.123
   - Subnet – Mask: 255.255.255.000
   - Gateway: 123.456.789.001
   - DNS: remains blank (unless otherwise specified by the agency)

   NOTE: The "Network" information will not be the same for all instruments; it will be specific to the agency.
8. Click "**Save**". A message will be displayed asking that the instrument be restarted to save the changes. Click "**Okay**".

4.2 Loaner Instruments

Loaner instruments are issued when an agency's instrument requires calibration and/or repair. Once the agency's instrument has been calibrated and/or repaired by the manufacturer, the loaner is returned.

4.2.1 Issuing a Loaner Instrument

1. Loaners available to be assigned are scanned in LIMS to "Breath Analysis Section". A crystal report can be generated to see how many loaners are available.
2. In LIMS, go to "**Search**", then click "**Lab Case Number**". Uncheck "Use Case Mask" and enter the loaner instrument serial number (example: *DR-ARXX-XXXX*).
3. Go to the "**Request**" tab. For each loaner, there will be two requests available:
   - Loaner – Out in field
   - Loaner – Available for use
4. One request will be canceled (red) and the other will be active (blue). For loaner instruments that are scanned to the "Breath Analysis Section", the "Loaner-Available for use" should be active.
5. Right-click and cancel the "Loaner – Available for use" and then un-cancel the "Loaner – Out in field".
6. Transfer the loaner instrument to "Draeger Outgoing" or directly to the officer. "Draeger Outgoing" will be used if Evidence Receiving is assisting with a transfer to an agency.
   - From: Breath Analysis Section
   - To: Analyst making the transfer
   - Then to: Draeger – Outgoing **or** Agency + Officer
7. Under the "**Case Info**" tab, right-click and add an entry into "**Message and Synopsis**":
   - Date: Loaned to (Agency name). [initials]

4.2.2 Loaner Instruments Returned from an Agency

1. When a loaner instrument has been brought back to the lab, first, in LIMS, scan the instrument to "Breath Analysis Section".
   - From: Draeger Incoming **or** Agency + Officer
   - To: Analyst making the transfer
   - Then to: Breath Analysis Section
2. Go to the "**Request**" tab. For each loaner, there will be two requests available:

- Loaner – Out in field
- Loaner – Available for use

3. One request will be canceled (red) and the other will be active (blue). For loaner instruments that are being returned from an agency, the "Loaner – Out in field" should be active.
4. Right-click and cancel the "Loaner – Out in field" and then un-cancel the "Loaner – Available for use".
5. Under the "**Case Info**" tab, right-click and add an entry into "**Message and Synopsis**":
   - Date: Loaner returned from (Agency name), will check out. [initials]
6. Under the "**Request**" tab, a new request for the check out will be added.
   - Click the green "**Add**" button at the top left side of the screen.
   - Under "**Agency**" choose "Chemical Analysis Section – DSS lab (DESPP)".
   - Under "**Agency Rep**" choose the Toxicology Assistant Director or higher.
   - Click "**Select**" and a "**Select- Service**" window will open.
   - Under "**Lab**" select "DESPP – Division of Scientific Services".
   - Under "**Section**" select "Draeger".
   - Under "**Service**" select "Service: Instrument Evaluation – Lab Eval.".
   - Click "**Select**" and a "New Request" window will open.
   - Enter the analyst who will be assigned the check out into the "**Assigned Analyst**" box. Click "**Save**".
   - A "Related Entries for Request" window will open. Relate the evidence, individual and offense. Click "**Save**".
7. Once a request has been assigned, data on the instrument will need to be downloaded to the server.
   - Turn the instrument on and follow the instructions for "Updating Network Connectivity". Enter one of the lab-assigned IP addresses.
   - Allow time for the data to download; have the Lead Examiner or higher confirm all data has been transmitted to the server prior to disconnecting the ethernet cord.
8. The loaner instrument is now ready to undergo a functionality test prior to being approved for use.

4.3 **Performing a Functionality Test**

Functionality tests are performed on all Draeger instruments returned to the lab after being loaned out to an agency. A functionality test consists of running a blank test and an ethanol detection test. All test strips, including those that result in error message, shall be maintained.

1. Turn on and warm up the Ethanol Breath Simulator. This may take a few minutes. (After warm up is complete, allow to remain for a minimum of 5 minutes prior to starting testing)
2. Press the green button to warm up the instrument.
3. Attach a 0.08% dry gas tank to the instrument.
4. Press the green button again after the instrument has warmed up.
5. Run a blank test:
   - From the display pick "**Evidentiary Subject Test- Part Two Only**"
   - Fill out the following information hitting "**Next**" between each choice.

     Officer Agency Name: Other

     Officer Last Name: Operator's last name

     Officer First Name: Operator's first name

     Officer Badge/ID Number: Test

     Case Number: Test

     Subject Last Name: 0.000

     Subject First Name: Blank

     Subject Middle Name: (Leave blank)
6. Select "**Summary**" and then "**Save**".
7. Next the operator will be prompted to choose the test type:
   - Pick "**Breath**".
   - Then "**Summary**".
   - Then "**Save**".
8. The test will start:
   - The instrument will run through a series of internal and external tests and prompt the operator when to "blow" into the device.

- The instrument will provide a printout. The operator will save the slip from the test and initial the bottom of it.

9. Run an ethanol detection test:

   - Repeat Steps 1-4 from the blank test. Follow the same steps except update the fields below:

     Subject Last Name: Detection

     Subject First Name: Ethanol

10. The test will start:

    - The instrument will run through a series of internal and external tests and prompt the operator when to "blow". When the instrument prompts the operator to "blow" attach the Ethanol Breath Simulator before blowing. Promptly detach it when finished blowing.

NOTE: To avoid damage to the Draeger DO NOT attach a simulator before being prompted to "blow". Additionally the simulator must be removed immediately after the blowing step is completed. If the instrument goes to the purge step prior to the simulator being removed damage can occur.

- The instrument will provide a printout. The operator will save the slip from the test and initial the bottom of it.

11. Once all tests have been completed, fill out form BA 1.1 "Draeger 9510 Functionality Test Results".

12. Update the request in LIMS:

    - Open the case related to the instrument in LIMS.
    - Go to the "**Requests**" tab.
    - Right-click on the request you want to edit and choose "**Edit Findings**".
    - Highlight the Draeger, right click and "**Add Result**". In the top drop-down menu pick "**Results**" as the "**Result type**".
    - If the functionality test passed, type: "The breathalyzer instrument was evaluated within this laboratory and was verified as being acceptable for use."
    - If the functionality test failed, type: "The breathalyzer instrument was evaluated within this laboratory and was verified as not being acceptable for use. Will send for repair."
    - Click "**Save**".
    - Right-click on the request and select "**Draft Complete**".

13. Make a copy of all test strips; due to the degradation of the printed test strips, the copy will serve as the original at this step.
14. Scan the completed form BA 1.1 "Draeger 9510 Functionality Test Results" and both test strips. Save this file as: "*DSS Verify_(MM-DD-YY)_ARXX-XXXX*".
15. Upload the scanned document under the "**Attachments**" tab.
16. Once scanned, file the completed form BA 1.1 "Draeger 9510 Functionality Test Results" and the test strips in the instrument's respective file folder within the BAU.
17. Assign instrument for technical and administrative review.
18. After the technical and administrative reviews are complete, the final report is printed. The report is placed into an envelope that is labeled with "Loaner" and the serial number of the instrument. This envelope then gets attached to the instrument.

4.4 Sending an Instrument for Repair

The BAU facilitates the shipping of Draeger instruments to the manufacturer when they are in need of repair.

1. When an instrument that is in need of repair is brought in to the lab by an agency, the form BA 1.2 "Draeger 9510 Repair" should be started.

   NOTE: Older versions of this form, previously titled "Receipt/Return of the Draeger Alcotest 9510" may also be used.
2. In LIMS, scan the instrument to "Breath Analysis Section".
   - From: Draeger Incoming **or** Agency + Officer
   - To: Analyst making the transfer
   - Then to: Breath Analysis Section
3. Under the "**Case Info**" tab, right-click and add an entry into "**Message and Synopsis**" that explains why the instrument was brought in by the agency.
4. Under the "**Request**" tab, a new request for the check out will be added.
   - Click the green "**Add**" button at the top left side of the screen.
   - Under "**Agency**" choose the agency that the instrument belongs to.
   - Under "**Agency Rep**" choose the agency contact for the instrument.
   - Click "**Select**" and a "**Select- Service**" window will open.
   - Under "**Lab**" select "DESPP – Division of Scientific Services".
   - Under "**Section**" select "Draeger".

- Under "**Service**" select "Service: Instrument Evaluation – Lab Eval.".
- Click "**Select**" and a "New Request" window will open.
- Enter the analyst who will be assigned the check out into the "**Assigned Analyst**" box. Click "**Save**".
- A "Related Entries for Request" window will open. Relate the evidence, individual and offense. Click "**Save**".

5. Once a request has been assigned, data on the instrument will need to be downloaded to the server.
   - Turn the instrument on and document the current network information entered in the instrument. Verify this information is correct and the instrument has been communicating with the server while at the agency.
     - If the instrument is not communicating while at the agency, IT may need to be contacted. Consult the Lead Examiner or higher.
   - All data needs to be downloaded to the server prior to a repair. Follow the instructions for "Updating Network Connectivity". Enter one of the lab-assigned IP addresses.
   - Allow time for the data to download; have the Lead Examiner or higher confirm all data has been transmitted to the server prior to disconnecting the ethernet cord.
6. Update the request in LIMS:
   - Go to the "**Requests**" tab.
   - Right-click on the request you want to edit and choose "**Edit Findings**".
   - Highlight the Draeger, right click and "**Add Result**". In the top drop-down menu pick "**Results**" as the "**Result type**".
   - Enter a sentence describing the issue with the instrument.
     - Example 1: "Instrument received from department with error 124. Instrument will be sent for repair."
     - Example 2: Instrument received with external standard failure. Instrument will be sent for repair."
   - Click "**Save**".
   - Right-click on the request and select "**Draft Complete**".
7. Assign instrument for technical and administrative review.
8. After technical and administrative reviews are complete, send a service notification request to Draeger.

- In the top portion fill in the following information:
  - Date: date form is completed
  - Bill to Attn: Jessica Gleba
  - Bill to Company Name: DESPP – State of CT
  - Bill to Company Address: 278 Colony Street
  - City, State, Zip Code: Meriden, CT 06451
  - Phone: (203)-694-6504
  - Email: jessica.gleba@ct.gov
- In the top right portion fill in the following information:
  - Purchase Order Number: (leave blank)
  - Ship to Attn: Jessica Gleba
  - Ship to Company Name: DESPP – State of CT
  - Ship to Company Address: 278 Colony Street
  - City, State, Zip Code: Meriden, CT 06451
  - Phone: (203)-694-6504
  - Email: jessica.gleba@ct.gov

  NOTE: If an instrument was purchased by an agency and does not belong to the lab, the agency will be responsible for the bill and the "Bill to" and "Purchase Order Number" fields will need to be updated.
- In the middle portion, include a short description of the issue with the instrument as well as the model and serial numbers. Ensure the applicable "Calibration" and/or "Repair" checkboxes are also checked off.
  - If an instrument has not been calibrated within a year of sending out for repair, the instrument should also be calibrated.
  - Include "Calibration as per contract" within your short description.
- Email the completed service notification request to cs-idt@draeger.com.

9. Once Draeger has provided the acknowledgement via email, print a copy of the service notification request and acknowledgement.
10. Schedule the Fedex shipment pick-up online.
11. Scan the service notification request, acknowledgement and shipping label. Save as "*Service Request+Track_(MM-DD-YY)_ARXX-XXXX*".
12. Upload the scanned document under the "**Attachments**" tab in LIMS.
13. Include the copy of the service notification request and acknowledgement in the shipping box with the instrument. On the outside of the box, ensure the acknowledgement number of report is written and the shipping label is attached.
14. In LIMS, scan the instrument to "Mail Transport".
    - From: Breath Analysis Section

- To: Analyst making the transfer
- Then to: Mail Transport (indicate Federal Express using VIA)

15. Bring the instrument to the Federal Express pick-up location for the lab.

16. Place the form BA 1.2 "Draeger 9510 Repair" in the folder labeled "Draegers in TX". All outstanding repair forms should be kept in this folder to track how many instruments have been sent for repair and will be completed upon return to the lab.

4.5 **Receiving an Instrument after Repair**

Once an instrument has been repaired, the manufacturer will ship the instrument back to the lab. The BAU will evaluate the instrument prior to return to the agency.

1. When an instrument has been returned from repair, first, in LIMS, scan the instrument to "Breath Analysis Section".

   - From: Mail Transport (indicate Federal Express using VIA)
   - To: Analyst making the transfer
   - Then to: Breath Analysis Section

2. Under the "**Case Info**" tab, right-click and add an entry into "**Message and Synopsis**":

   - Date: Instrument returned from repair, will check out. [initials]

3. Under the "**Request**" tab, a new request for the check out will be added.

   - Click the green "**Add**" button at the top left side of the screen.
   - Under "**Agency**" choose the agency that the instrument belongs to.
   - Under "**Agency Rep**" choose the agency contact for the instrument.
   - Click "**Select**" and a "**Select- Service**" window will open.
   - Under "**Lab**" select "DESPP - Division of Scientific Services".
   - Under "**Section**" select "Draeger".
   - Under "**Service**" select "Service: Instrument Evaluation – Draeger Return".
   - Click "**Select**" and a "New Request" window will open.
   - Enter the analyst who will be assigned the check out into the "**Assigned Analyst**" box. Click "**Save**".
   - A "Related Entries for Request" window will open. Relate the evidence, individual and offense. Click "**Save**".

4. Retain all documents returned with the instrument from the manufacturer.

- These may include but are not limited to the delivery receipt, service note and/or certificate of accuracy.

5. The instrument is now ready to undergo an in-house certification test prior to being approved for use.

4.6 **Performing an In-House Certification Test**

In-house certifications are performed on all Draeger instruments returned to the lab after being sent out for repair to the manufacturer. An in-house certification consists of running three dry gas verifications, a blank test, an ethanol detection test and a methanol interferent test.

1. Turn on and warm up the Ethanol and Methanol Breath Simulators. This may take a few minutes. (After warm up is complete, allow to remain for a minimum of 5 minutes prior to starting testing)
2. Plug a Draeger USB drive into the instrument to access the needed settings.
3. Press the green button to warm up the instrument.
4. Calcheck Test for 0.02g%, 0.08g% and 0.25g% may be performed in any order.
5. Attach a 0.02g%, 0.08g% or 0.25g% dry gas tank to the instrument.
6. Run the dry gas verification tests:
   - From the display select "**Menu"**, then **"Maintenance"**.
   - Select **"Calcheck Test"**.
   - Enter the following information:

     Test-Gas: Dry

     Concen.: Applicable concentration (0.0200, 0.0800 or 0.2500)

     Units: g/210L

     Resolution: (remains blank)

     Test No.: 2

     Tol. abs. (+/-): 0.4000

     Tol. rel. (+/-): 5.0

     Sensor: EC+IR

     Gas-Input: Cal Gas Inlet 1
7. Click **"Run"**. The instrument will provide a printout. The operator will save the slip from the test and initial the bottom of it.

8. Repeat Steps 5 and 6 for the remaining two concentration dry gas tanks. The respective gas reference tank will be added for each test and the "Concen." field will need to be updated.
9. Once all dry gas verification tests have been run, re-attach the 0.08 g% dry gas tank and press the green button.
10. Run a blank test:
    - From the display pick "**Evidentiary Subject Test- Part Two Only**"
    - Fill out the following information hitting "**Next**" between each choice.

      Officer Agency Name: Other

      Officer Last Name: Operator's last name

      Officer First Name: Operator's first name

      Officer Badge/ID Number: Test

      Case Number: Test

      Subject Last Name: 0.000

      Subject First Name: Blank

      Subject Middle Name: (Leave blank)
11. Select "**Summary**" and then "**Save**".
12. Next the operator will be prompted to choose the test type:
    - Pick "**Breath**".
    - Then "**Summary**".
    - Then "**Save**".
13. The test will start:
    - The instrument will run through a series of internal and external tests and prompt the operator when to "blow" into the device.
    - The instrument will provide a printout. The operator will save the slip from the test and initial the bottom of it.
14. Run an ethanol detection test:
    - Repeat Steps 1-4 from the blank test. Follow the same steps except update the fields below:

      Subject Last Name: Detection

      Subject First Name: Ethanol

15. The test will start:

    - The instrument will run through a series of internal and external tests and prompt the operator when to "blow". When the instrument prompts the operator to "blow" attach the Ethanol Breath Simulator before blowing. Promptly detach it when finished blowing.

NOTE: To avoid damage to the Draeger DO NOT attach a simulator before being prompted to "blow". Additionally the simulator must be removed immediately after the blowing step is completed. If the instrument goes to the purge step prior to the simulator being removed damage can occur.

    - The instrument will provide a printout. The operator will save the slip from the test and initial the bottom of it.

16. Run a methanol interferent test:

    - Repeat Steps 1-4 from the blank test. Follow the same steps except update the fields below:

        Subject Last Name: Interferent

        Subject First Name: Methanol

17. The test will start:

    - The instrument will run through a series of internal and external tests and prompt the operator when to "blow". When the instrument prompts the operator to "blow" attach the Methanol Breath Simulator before blowing. Promptly detach it when finished blowing.

NOTE: To avoid damage to the Draeger DO NOT attach a simulator before being prompted to "blow". Additionally the simulator must be removed immediately after the blowing step is completed. If the instrument goes to the purge step prior to the simulator being removed damage can occur.

    - The instrument will provide a printout. The operator will save the slip from the test and initial the bottom of it.

18. Once all tests have been completed, fill out form BA 1.3 "Draeger 9510 In-House Certification Test Results".

19. Update the request in LIMS:

    - Open the case related to the instrument in LIMS.
    - Go to the "**Requests**" tab.
    - Right-click on the request you want to edit and choose "**Edit Findings**".

- Highlight the Draeger, right click and "**Add Result**". In the top drop-down menu pick "**Results**" as the "**Result type**".
- If the in-house certification test passed, type: "The breathalyzer instrument was evaluated by the manufacturer and maintenance was performed. The instrument was then further evaluated within this laboratory and was verified as being acceptable for use."
- If the in-house certification test failed, type: "The breathalyzer instrument was evaluated by the manufacturer and maintenance was performed. The instrument was then further evaluated within this laboratory and was verified as being not acceptable for use. Will send back for further repair."
- Click "**Save**".
- Right-click on the request and select "**Draft Complete**".

20. Make a copy of all test strips; due to the degradation of the printed test strips, the copy will serve as the original at this step.
21. Scan the documents returned by Draeger, the completed forms (BA 1.2 "Draeger 9510 Repair", BA 1.3 "Draeger 9510 In-House Certification Test Results") and all test strips. Save this file as: "*DSS Verify+Cert_(MM-DD-YY)_ARXX-XXXX*".
22. Upload the scanned document under the "**Attachments**" tab.
23. Once scanned, file the documents returned by Draeger, the completed forms (BA 1.2 "Draeger 9510 Repair", BA 1.3 "Draeger 9510 In-House Certification Test Results") and test strips in the instrument's respective file folder within the BAU.
24. Assign instrument for technical and administrative review.
25. After the technical and administrative reviews are complete, the final report is printed. The report is placed into an envelope that is labeled with the agency name and the serial number of the instrument. This envelope then gets attached to the instrument.
26. Reach out to the agency contact via email or phone to let them know their instrument has been returned from repair and is ready for pick-up. Schedule an appointment to pick-up the agency instrument and return the loaner instrument.
27. Transfer the instrument to "Draeger Outgoing" or directly to the officer. "Draeger Outgoing" will be used if Evidence Receiving is assisting with a transfer to an agency.
    - From: Breath Analysis Section
    - To: Analyst making the transfer
    - Then to: Draeger – Outgoing **or** Agency + Officer

5. Safety

This procedure is carried out in a laboratory environment and standard safety procedures appropriate for such an environment will be utilized, including gloves, safety glasses, and protective clothing (e.g., lab coat). Biological specimens will be handled using universal precautions and will be treated as biohazardous. Potentially contaminated items and surfaces will be cleaned prior to use.

6. References

State of Connecticut Draeger Alcotest 9510 Supervisor's Manual