Testing Protocol

Initial Power-Up Testing
Linearity
Precision & Accuracy
Interference
Mouth Alcohol / Invalid
Breath Volume
Radio Frequency Interference
Monitor Temperature Zones
Calibration Stability
Filters
Practical Testing on live subjects at VCJTC
Performance
Test Record Retention
Time needed to deplete 0.10% simulator solution by 5%
Improper Breath Sample Acceptance
Power-Up Test
LOD/LOQ

- **Calibration**- Instruments calibrated using 0.10 Standard Solution according to the manufacturer's procedure.
- **Certification**- Instruments certified per VDHL standard procedure.
- **Linearity**- Four ethanol in water solutions are prepared over a concentration range that will provide vapor concentrations of the following amounts: 0.02, 0.08, 0.16, 0.40g/210L. These solutions are analyzed and the results will form a straight line with a correlation coefficient of at least 0.99.
- **Precision & Accuracy**- Known solutions providing vapor concentrations of 0.02, 0.08, 0.16, 0.40 g/210L are analyzed 10 times. All values are within ±0.002 of the average and mean result of the solution is within 10% of the GC certified value. Repeated 10 times varying operators, inter-day and intra-day and after days of non-use for a total of 100 tests at each concentration.
- **Interference**- Interfering compounds will be tested to ensure instruments are accurately reporting alcohol concentration from ethanol only.

  0.01% Acetone in 0.08% EtOH
  0.01% Acetone in 0.04% EtOH
  0.02% Acetone in 0.04% EtOH
  0.04% MeOH in Water
  0.04% MeOH in 0.08% EtOH
  0.04% Isopropanol in Water
  0.04% Isopropanol in 0.08% EtOH
  MTBE

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Toluene

- **Mouth Alcohol**- Mouth wash used prior to sample delivery. Breath tested at ~3 minute intervals until such time as no mouth alcohol is detected or 15 minutes, which ever comes last. Tested on drinking and non-drinking subjects.
  Mouth alcohol tested on drinking subjects using alcoholic beverages prior to sample delivery. Breath tested at ~3 minute intervals until such time as no mouth alcohol is detected.
  Drinking subjects to belch prior to sample delivery to demonstrate if stomach content of alcohol can be belched up causing mouth alcohol.
- **Breath Volume**- The accuracy and capacity (high and low) of the breath volume monitor will be tested using a syringe. 1.5L ± 0.2L.
- **Radio Frequency Interference**- Radio frequency sensitivity will be tested using a standard issue hand-held radio during subject test sequences.
- **Monitor Temperature Zones**- Temperature zones will be monitored throughout testing and results compared to the instrument's reported temperatures.
- **Calibration Stability**- The calibration factors will be periodically checked throughout testing to ensure stability. They will be printed at the beginning and completion of testing.
- **Filters**- On a diagnostic test, when subtracting the values for filters 2 and 3 from filter one, the values should be no more than ±5% from the mean. A diagnostic test will be run each time the instrument is run and the filter values will be recorded.
- **Practical Testing on live subjects at VCJTC-** See Other Protocol
- **Performance**- All reported errors or failures will be documented with proper follow-up based on the error reported.
- **Test Record Retention** Records will be downloaded at a predetermined time interval and
  - the download will be compared to the original to ensure accuracy.
- **Time needed to deplete 0.10% simulator solution by 5%-** A 0.10% simulator solution will be installed on each tested instrument. The instruments will be run repeatedly over many days until such time as the simulator solution has depleted by 5%, 8% and 10%.
- **Improper Breath Sample Acceptance**- Flow restriction used in lab setting. Live testing on drinking subjects not providing proper breath samples. The tester will attempt to provide an Invalid Sample not due to mouth alcohol.

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Power-Up Test Protocol

- The instruments will be thoroughly tested by the VDHL to ensure they function to the standards set forth in the instrument bid and purchase agreement. The initial software layout in the instruments is not the Vermont DataMaster DMT software protocol. The Vermont DataMaster DMT software will be downloaded and tested at a later date. The current software will be used to test the analytical functioning of the instrument, independent of the software. The first step in the testing protocol will be the initial power-up. The NPAS DataMaster DMT will be turned on and the basic functioning of the instrument will be examined. The menu options will be explored. We will examine the basic layout of the software to ensure we will be able to begin analytical testing of the instruments.
- Should the DataMaster DMT instrument software not function as required, NPAS will be contacted to re-download a functional software revision. Should the DataMaster DMT instrument analytically not pass these simple tests, the instrument will be returned to NPAS for repair and/or replacement. This will occur on the initial start-up of all instruments received by the VDHL from NPAS.
    - Initial tests to be performed:

1. Options Set-Up and Check
    a. We will ensure that the operating parameters are set up per VDHL normal operating specifications.
        i. Printer on
        ii. Supervisor test 10
        iii. Tolerance check
        iv. Data collection on
        v. Units g/210L
        vi. Simulator check
        vii. External Wet Bath Simulator
        viii. Simulator nominal at 0.1g/210L
        ix. Digital simulator : None
        x. Simulator before
        xi. Simulator between
        xii. Simulator after : No
        xiii. 2 subject test sequence
        xiv. Ask questions
        xv. Query refusal
        xvi. Alcohol display on
        xvii. Show 3 digits
        xviii. Volume display on
2. Print Calibration Factors
3. Diagnostic Check
    a. Parameters per VDHL specifications
        i. Temperatures
            1. Sample chamber 48º
            2. Breath tube 47º
            3. Simulator hose 45º
        ii. Voltages
            1. Lamp Voltage 2.5-3.5 V
            2. Cooler Voltage 2 V
            3. Bias Voltage 120 V
            4. Chopper Frequency 530-580 Hz

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iii. Pump Test
    1. Volume 0.6 - 0.8
    2. Flow Rate 3 – 5 L/M

iv. Detector Stability Test

Pump	On	Off
Max(V)	< 0.1	< 0.1
Min(V)	< 0.1	< 0.1

v. Filter Test
    1. Filter 1 Zero = true
    2. Filter 2 Zero = true
    3. Filter 3 Zero = true

vi. Internal standard
    1. Xq = < 3%

4. Accuracy and Precision Check
    a. Average within 5% of calculated solution value
    b. Std Dev <0.005
5. Sample Acceptance Check
    a. Instrument does not accept a shallow or intermittent or suck-back breath.
    b. Instrument accepts a valid, alcohol-free sample
6. Basic Subject Test
    a. Instrument accepts a valid, alcohol-free sample

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Accuracy, Precision and Linearity Testing:

- Four ethanol in water simulator solutions are prepared over a concentration range that will provide nominal vapor concentrations of the following amounts: 0.020, 0.080, 0.160 and 0.400g/210L.
- These solutions will be certified by Headspace GC-FID.
- 5 of the 20 DataMaster DMT instruments will be tested. The 5 tested instruments will be non-sequential in serial number and chosen for testing at random.
- Each DataMaster instrument will be tested over the four ethanol concentrations using an external simulator containing simulator solution.
- The DataMaster's Accuracy and Precision test sequence (n=10 for each solution) will be used.
- All four solutions will be run on the same day, in random order on a single instrument. More than one instrument may be tested at a time.
- More than one set of replicates of the 4 concentrations may be run on a single instrument in a single day, however, if one concentration is run, then all four concentrations must be run on the same day, by the same analyst.
- This will continue until 10 replicates of the four concentrations have been run by multiple analysts over inter- and intra- day analyses on all five testing instruments.
- The results will be statistically analyzed for accuracy, precision and linearity.
    - Accuracy: How close is the reported value to the known concentration?
    - Precision: How close are the 10 replicates to each other?
    - Linearity: Do the reported results form a straight line when plotted versus their known concentrations?
- All values are expected to be within 10% of the GC certified value (accuracy). All values are expected to be within ±0.002 of the mean (precision). The resulting linearity is expected to have a generated R^2 value of 1 ±0.010 (linearity).
- The acceptance range is based upon the bid requirements sent to the manufacturer, and current performance requirements for evidentiary breath testing equipment as stated in the Rules and Regulations 23 VSA Section 1203.
- Should the performance of the instruments not meet the acceptable criteria, the instruments will be returned to the manufacturer for repair or replacement.

Interference Testing:

- Solutions of interfering compounds will be put into external simulators.
- The DataMaster will run a standard breath test sequence testing the air/vapor from the external simulator.
- Air will be forced through the simulator into the breath sample tube.
- Interfering compounds should be detected. Should the instrument not detect interfering compounds, the instruments will be returned to the manufacturer for repair or replacement.

Mouth Alcohol:

- Non-drinking volunteer subjects to swish with mouth wash containing ~5% alcohol prior to sample delivery.
- Breath tested at ~3 minute intervals until such time as no mouth alcohol is detected or 15 minutes, which ever comes last.
- Drinking volunteer subjects to swish with alcoholic beverages prior to sample delivery.
- Breath tested at ~3 minute intervals until such time as no mouth alcohol is detected or 15 minutes, which ever comes last.
- Drinking subjects to belch prior to sample delivery to demonstrate if stomach content of alcohol can be belched up causing mouth alcohol

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Breath Volume:

- A syringe will be used to deliver a known quantity of air to the sample chamber via the subject test tube. Accuracy at 1.5L to ±0.2L. N=10 for each instrument.
- Should an instrument fail to accept a sample of greater than 1.5L or accept a sample that is less than 1.5L, the instrument will be returned to the manufacturer for repair or replacement.

Radio Frequency Interference:

- Radio frequency sensitivity will be set to just below maximum, when interference detection is no longer reported at ambient values.
- Radio will be keyed at different times during a subject test sequence.
- RFI detected should be reported each time the radio is keyed. Instrument should not report false changes in voltage detection because of RFI.

Temperature Zone Monitoring:

- Each time a set of tests is run by an analyst, the current temperature of the monitored zones based on the external monitors will be recorded. The DMT reported values will be ascertained by running a diagnostic check on the instrument.
- The zones to be monitored are:
    - Sample Chamber- Thermocouple wire and converter thermometer
    - Breath Tube- Thermocouple wire and converter thermometer
    - Simulator Hoses- Thermocouple wire and converter thermometer
    - Simulator Solution- Electronic thermometer

Calibration Stability:

- The Calibration factors will be printed at the beginning and end of testing.
- The Calibration factors will be printed at the beginning of each week during the instrument testing period.
- Calibration factors printed after simulated power failures using a variable transformer.
    - Total power failure
    - Brown-out
    - Power spike

Software Specifications:

- All aspects of the software will be tested to ensure compliance with the specifications listed in the Proposed DataMaster DMT Operating Protocol (D-Alc-008).
    - DMT Test sequence
        - DUI test
        - Check in test
    - Calibration Protocol
    - Certification Protocol
    - Installation Protocol
    - Annual Preventative Maintenance Protocol
    - Routine Performance Check Protocol
    - Simulator Solution Change Protocol
    - Diagnostic Test
    - Options Check
- All printouts, reports and tickets will be checked to ensure all necessary information is present.
- All menu options will be explored to ensure accuracy.

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- High and low levels of detection and quantification will be determined on a minimum of two instruments depending on results and repeatablity

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