2. SOFTWARE/FIRMWARE VALIDATION and INITIAL INSTRUMENTATION TESTING

2.1. Initial Instructions

2.1.1. Initial instructions for Software/Firmware Testing

- This testing will be performed on a new firmware/software version using a training instrument.
- Upload new software/firmware version after ensuring that the instrument has been downloaded, if applicable.
- Print Software and Firmware Versions.
- Adjust the Instrument (Section: 3).
- Perform Instrument Calibration (Section: 4)

2.2. Instrument Testing

2.2.1. An evidential/subject test is a test that is used by certified operators to test motorists, pedestrians, or any other person under the influence of alcohol. Tests will be carried out to verify:

- Data entry
- Countdown timer
- Testing procedure
- Printout

2.2.2. A calibration test is a test used by the TBI Forensic Scientist to make an adjustment to the instrument's alcohol measuring device. Tests will be carried out to verify:

- Password protection
- Data entry
- Testing procedure

- Printout

2.2.3. An accuracy test is used by the TBI Forensic Scientist to test the instrument's accuracy and precision. Tests will be carried out to verify:
- Password protection
- Data entry
- Testing procedure
- Printout

2.2.4. A training test is a test used by the TBI Forensic Scientist that is identical to an evidential/subject test with the exception of a shorter observation countdown timer. Tests will be carried out to verify:
- Password protection
- Data entry
- Observation timer
- Testing procedure
- Printout

2.2.5. A quick test (when available) is a test used by TBI Forensic Scientists and Certified Operators to test someone's alcohol level for purposed other than evidence. Tests will be carried out to verify:
- Password protection
- Data entry
- Testing procedure
- Printout

2.3. Linearity

2.3.1. Run an accuracy check (3 samples) with a 0.020 dry gas standard.

2.3.2. Run an accuracy check (3 samples) with a 0.050 dry gas standard.

2.3.3. Run an accuracy check (3 samples) with a 0.080 dry gas standard.

2.3.4. Run an accuracy check (3 samples) with a 0.100 dry gas standard.

2.3.5. Run an accuracy check (3 samples) with a 0.200 dry gas standard.

2.3.6. Expected results for each of the above listed solutions:

- For accuracy, the samples must be within 5% or .005g/210L of the target, whichever is greater.
- For precision, the samples must be within 0.003g/210L of each other.

2.4. Record of Data

2.4.1. Retain all printouts from all tests performed.

2.5. Sample Reporting

2.5.1. Conduct an Evidential test and provide both breath samples with your own breath.

- Expected final result is 0.000 g/210L

2.5.2. Conduct an Evidential test.

- Sample 1- provide a successful sample of your own breath
- Sample 2- approximately 0.020 g/210L vapor equivalent or less
- Expected final result is 0.00 g/210L.

2.5.3. Conduct an Evidential test.

- Sample 1- approximately 0.020 g/210L vapor equivalent or less
- Sample 2- provide a successful sample of your own breath
- Expected final result 0.00 g/210L.

2.5.4. “Refusal” Tests. The “Refusal” message appears when the operator presses “R” on the keyboard to indicate that the subject

taking the test has refused to do so. The instrument will ask the operator to confirm the decision, then immediately abort the test.

- Conduct an Evidential Test. During the observation countdown timer is being displayed, press “R” and then confirm.
- Conduct an Evidential Test. When the instrument display reads “Please Blow”, press “R” and then confirm.

2.5.5. “No Sample Provided” Tests. The “No Sample Provided” message will be displayed when there is no sample given in the prescribed time limit in the Evidential or Training Test sequence.

2.5.5.1 Conduct a breath test.

- Sample 1- allow instrument to time out, do not provide a sample.
- “Retest Y/N” will be displayed, type “Y”

2.5.5.2 Conduct a breath test.

- Sample 1- provide a successful sample of your own breath
- Sample 2- allow instrument to time out, do not provide a sample.
- “Retest Y/N” will be displayed, type “Y”

2.5.5.3 Conduct a breath test.

- Sample 1- provide a successful sample of your own breath
- Sample 2 - > 0.030 g/210L vapor equivalent
- Sample 3- allow instrument to time out, do not provide a sample
- "Retest Y/N" will be displayed, type "N"

2.5.5.4 "Insufficient" Sample Tests. The "Insufficient" Sample message will be displayed when the breath sample fails to meet the prescribed limits for flow and/ or volume in the Evidential or Training test sequence.

2.5.5.4.1 Conduct a breath test.

- Sample 1- provide a sample that does not meet sample criteria;
- Repeat this process 2 more times;
- "Retest Y/N" will be displayed, type "Y", press enter.

2.5.5.4.2 Conduct a breath test.

- Sample 1- provide a successful sample of your own breath
- Sample 2- provide a sample that does not meet sample criteria

- Repeat this process 2 more times
- "Retest Y/N" will be displayed, type "Y", press enter.

2.5.5.4.3 Conduct a breath test.

- Sample 1- provide a successful sample of your own breath
- Sample 2- provide a sample that has a BAC over 0.020 g/210L
- Sample 3- provide a sample that does not meet sample criteria
- Repeat this process 2 more times
- "Retest Y/N" will be displayed, type "N", press enter.

2.5.5.5 "Mouth Alcohol" Test. This procedure will be carried out by rinsing the mouth with ethanol and immediately blowing into the instrument.

2.5.5.5.1 Conduct a breath test.

- Sample 1- Provide a sample of breath where the mouth has been rinsed with alcohol

- "Retest Y/N" will be displayed, type "Y", press enter.

2.5.5.5.2 Conduct a breath test.

- Sample 1- Provide a sample of your own breath
- Sample 2- Provide a sample of breath where the mouth has been rinsed with alcohol
- Sample 3- "Retest Y/N will be displayed, type "Y", press enter.

2.5.5.5.3 Conduct a breath test.

- Sample 1- Provide a sample of your own breath
- Sample 2- Provide a sample that has a BAC over 0.020 g/210L
- Sample 3- Provide a sample where the mouth has been rinsed with alcohol
- "Retest Y/N" will be displayed, type "N", press enter.

2.5.5.6 "High Blank" Test. During the evidential or training test sequence, the instrument must pass an ambient air check.

- Spray Lysol or another ethanol based spray.
- Conduct a breath test.

2.5.5.7 "Standard Out of Range" Test. During any Accuracy Test, if the instrument fails to meet the preset criteria, "standard out of range" will be displayed.

- Install a tank 0.200 g/210L and update tank lot number.
- Run an accuracy check. Target value should be 0.100 g/210L.

2.5.5.8 Three Sample Tests. Tests will be carried out to verify that the final result is the lowest of the three samples.

2.5.5.8.1 Conduct a breath test.

- Sample 1- Provide a sample of your own breath
- Sample 2- 0.080 g/210L vapor equivalent
- Sample 3- 0.020 g/210L vapor equivalent

2.5.5.8.2 Conduct a breath test.

- Sample 1- 0.080 g/210L vapor equivalent
- Sample 2- Provide a sample of your own breath
- Sample 3- 0.020 g/210L vapor equivalent

2.5.5.8.3 Conduct a breath test.

- Sample 1- 0.080 g/210L vapor equivalent
- Sample 2- 0.020 g/210L vapor equivalent
- Sample 3- Provide a sample of your own breath.

2.5.5.9 Sample Parameters Not Met. Tests will be carried out to verify that the 0.020 g/210L agreement between samples is functioning properly.

2.5.5.9.1 Conduct a breath test.

- Sample 1- Provide a sample of your own breath
- Sample 2- 0.080 g/210L vapor equivalent
- Sample 3- 0.200 g/210 vapor equivalent

2.5.5.9.2 Conduct a breath test.

- Sample 1- 0.080 g/210L vapor equivalent
- Sample 2- Provide a sample of your breath
- Sample 3- 0.160 g/210L vapor equivalent

2.5.5.9.3 Conduct a breath test.

- Sample 1- 0.080 g/210L vapor equivalent
- Sample 2- 0.160 g/210L vapor equivalent
- Sample 3- Provide a sample of your own breath

2.5.5.10 Timers

2.5.5.10.1 Observation Timer. The instrument shall display a countdown timer of 20 minutes during an Evidential Test and print the start time on the printout.

2.5.5.10.2 Conduct an Evidential Test.

- Sample 1- Provide a sample of your own breath.
- Sample 2- Provide a sample of your own breath.

2.5.5.10.3 Conduct an Evidential Test.

- During the 20 minute countdown, restart the timer. Press “T”.

- Sample 1- Provide a sample of your breath.
- Sample 2- Provide a sample of your breath.

2.6 Downloading Data

- Set up instrument by name in the software;
- Connect the instrument to your computer using a serial port cable;
- Download data of instrument onto the computer;
- View the report to verify that data was downloaded.

2.7 Use

2.7.1 Testing will be carried out to ensure the sampling system is measuring alcohol accurately and that the proper results are displayed when applicable;

2.7.2 For any portion of this procedure that does not fall within expected/ acceptable results or messages, due to undeterminable reasons, testing will be stopped. The Technical Leader will be consulted. Testing may be resumed at the direction of the Technical Leader. The Technical Leader will ensure that proper documentation will be generated and maintained;

2.7.3 No instrument shall be used as an evidential instrument prior to meeting all of the above listed criteria. If an instrument fails the testing criteria, it will be recalibrated and retested. If it fails again, it will be returned to the manufacturer. When the instrument comes back from the manufacturer, the instrument will be retested.

2.8 Initial instructions for Instrument Acceptance

2.8.1 This testing will be performed on every new instrument prior to evidential (field) use.

2.8.2 Upload the approved software/firmware version.

2.8.3 Record software and firmware versions on worksheet (see attachment)

2.8.4 Adjust the Instrument (Section: 3).

2.8.5 Perform Linearity Testing

2.8.6 Perform Evidential Blank Checks

2.8.7 Record all of these tests on the worksheet (see attachment)

2.8.8 Submit all test printouts from adjustment, linearity, blank check to Technical Leader who will certify the instrument for use.

2.8.9 Approved worksheet will be saved in the Breath Alcohol share drive in the folder specific to the instrument serial number.

2.8.10 Perform Instrument Calibration (Section: 4) prior to putting certified instruments into use.