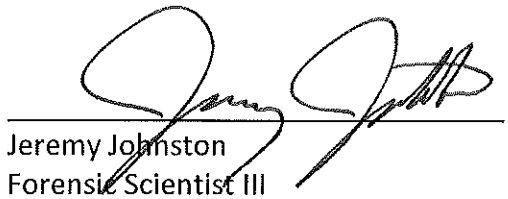
Idaho State Police Forensics – Breath Alcohol Testing Program

Supplemental Validation of the Lifeloc FC20 Evidentiary Breath Testing Instrument

Software versions 8.7.21 (rev 7) and 6.49 (rev 4.5) units

This executive summary report is by:



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Introduction:

The intent of this validation study was to determine the Lifeloc FC20BT instruments' performance when utilizing both wet bath and dry gas standards for performance verifications and laboratory calibrations. Dry gas standards are more consistent than wet bath simulators for the calibration of portable breath testing instruments. Dry gas standards contain a known concentration of ethanol suspended in pressurized nitrogen gas. Because the ethanol is suspended in the gas, the mixture is homogenous. Furthermore, as long as sufficient pressure exists within the gas tank, and environmental conditions such as barometric pressure and altitude remain constant, dry gas standards deliver consistent ethanol concentrations for multiple samples. Dry gas ethanol reference material produced by ISO 17025 laboratories will not require secondary confirmation of the target values or further certification beyond the calibration certificate for the cylinder standards. Wet bath simulators, by comparison, are designed to heat an aqueous solution of known ethanol concentration to the temperature of expired human breath. The simulators require an air pump or expired air from an operator to deliver a sample. The passage of external air through the simulator decreases the ethanol concentration of the solution. After 20 to 25 samples, the values from a wet bath simulator repeatedly decrease in ethanol concentration, potentially resulting in samples outside of a prescribed tolerance. Portable fuel cell instruments (the Lifeloc FC20) and a dry gas delivery system (EasyCal) are being used for the measurement purposes for an assessment of the software in the FC20 (rev 4.5 and rev 7) as well as the EasyCal dry gas delivery unit. The ethanol contained in the dry gas cylinders is identical to the ethanol contained within the wet bath simulator solutions. Dry gas standards are more convenient, accurate, and consistent over the lifetime of the standard when compared to wet bath simulators. This is the summary of the data obtained when validating the rev 7 and the updated rev 4.5 versions of the Lifeloc FC20

With the new Bluetooth functionality on the FC20BT versions, the testing was performed in the presence of Bluetooth frequencies being used. There were no interferences observed or aberrations in the data being collected due to the presence of Bluetooth frequencies being used.

Results and Discussion:

The acceptance criteria target for the validation of the new FC20 version was set so that they shall be within the acceptable acceptance criteria for laboratory calibrations. The dry gas performance verification checks and the wet bath solution checks shall all be within 5% or 0.004 (whichever is greater) of the target value of the standard in use. The FC20 units (Rev 4.5 and Rev 7 versions) shall be considered to be validated upon meeting this criterion.

In the evaluation process, multiple units were tested multiple times at different levels. They were evaluated using a dry gas calibration. The units were first calibrated using a dry gas standard of 0.160. The units were then evaluated using the standardized field performance verification procedure at the levels of 0.080 and 0.200 (both utilizing dry gas standards). Upon completion of this process, the units were evaluated utilizing wet bath standards with target values of 0.040, 0.080 and 0.200.

During the validation process it was discovered that the cal station acceptance criteria was set too narrow (+/-5% exclusive) and it needed to be changed to +/- 10% inclusive. This accounts for the UM for the instrument, the standards utilized, the barometric pressure sensors and the dry gas correction factors parameters. It was also discovered that in the factory updates for the units, the dry gas correction factor (DGCF) was not being set due to the fact that dry gas hadn't previously been used. This will necessitate a change in the update/calibration protocol to include a check and potential adjustment of the dry gas correction factor. Lifeloc will also provide a script program for assessing the fuel cell performance to help circumvent any unnecessary checks/adjustments to a fuel cell that is beyond its lifecycle.

Once the instruments were updated and their DGCF were set properly for use of both wet and dry standards, the instruments were tested.

Rev 4.5 data:

Dry gas: 0.080

ave	0.0797
std dev	0.000864
2 std dev	0.001727
	2.16%

0.200

ave	0.1961
std dev	0.001935
2 std dev	0.00387
	1.94%

Wet Bath: 0.040

ave	0.0392
std dev	0.001539
2 std dev	0.003077

0.080

ave	0.0786
std dev	0.001631
2 std dev	0.003262
	4.08%

0.200

ave	0.1949
std dev	0.00252
2 std dev	0.00504
	2.52%

Rev 7 data:

Dry gas: 0.080

ave	0.0805
std dev	0.001107
2 std dev	0.002215
	2.77%

0.200

ave	0.1996
std dev	0.002676
2 std dev	0.005351
	2.68%

Wet Bath: 0.040

ave	0.0404
std dev	0.000774
2 std dev	0.001548

0.080

ave	0.0802
std dev	0.001533
2 std dev	0.003066
	3.83%

0.200

ave	0.2034
std dev	0.002389
2 std dev	0.004779
	2.39%

The rev 4.5 and rev 7 instruments were then tested at altitude by taking a sampling (5) of the previously tested instruments and transporting them to a higher elevation. This was done to assess if there was a barometric pressure factor in the instruments performance. Both the rev 7 instruments and the rev 4.5 showed no effects when being assessed at different elevations and barometric pressures. All the instruments samples showed comparable results at high and low elevations.

All of the data is being centrally stored and is viewable upon appointment in any one of the ISPFS forensic laboratories.

Conclusions:

The instruments performed within the prescribed parameters and meet the acceptance criteria for use in evidential field testing. Both units respond accordingly with either wet bath solutions or dry gas standards and may be used interchangeably in the field performance verification procedures once the EasyCal station has been validated for use.