

## **Introduction:**

The intent of this validation study was to determine the Lifeloc FC20 instrument **precision** (i.e. the reproducibility of the result). The instrumental **accuracy** was not tested as a part of this study. The instrumental accuracy varies depending upon the state of the calibration (or the state of the solution that was used to calibrate the instrument), and is evaluated in the field through calibration verifications (also called field performance verifications). Field performance verifications are the best indicator of the state of the instruments calibration and its accuracy. Field performance verification also provides an assessment of the trending of the instrument (i.e. it assesses if the instrument is consistently reading lower or higher than the target value). Trending gives an indication if the instrument is underreporting or over reporting the true alcohol content of the provided breath sample. Assessment of the trending of the instrument will vary from instrument to instrument depending upon many different factors. These factors include the temperature of the simulator, the length of the blow, the person doing the testing, and the overall condition of the fuel cell.

In order to provide the most accurate assessment of the Lifeloc FC20 instrument **precision**, as many contributing factors to error were eliminated and/or controlled. The first of which is the use of the wet bath simulators for the evaluation checks. The nature of a wet bath simulator dictates that each and every simulated breath sample passing through the solution will come to equilibrium, pick up some of the dissolved alcohol and carry it to the breath tube for sampling. This causes the target value to decrease slightly with every sampling event that takes place. In order to account for and control the “sliding” target value, the breath testing procedure was standardized with timed breath events. In order to determine the average loss per breath sample, a fresh solution was tested prior to any sampling and the same solution was tested again after 25 tests through the simulator.

## **Results and Discussion:**

The calculated loss per breath, on average, produced a result of -0.1524%. Using this result, each breath through the simulator should decrease the target value by 0.1524 percent. This percentage was used to produce a corrected value for the calculation of precision.

In the evaluation process, three solution values were used: 0.040, 0.083, and 0.206; the results of which are summarized in the following table. The five Lifeloc FC20 instruments used in the process were in varying stages of use within ISP. One FC20 was from the original lot that was used for the first validation plan, two were originally calibrated in October 2008, and two were calibrated in April of 2009.

Instrument	2 x Std Dev for 0.040	2 x Std Dev for 0.083	2 x Std Dev for 0.206
90201817	0.00111 or 2.95529%	0.00224 or 2.89069%	0.00853 or 4.51648%
90204874	0.00141 or 3.58937%	0.00172 or 2.1603%	0.00768 or 3.95121%
90204875	0.00145 or 3.71021%	0.00222 or 2.82827%	0.00909 or 4.72481%
90204483	0.00129 or 3.14877%	0.00237 or 2.82992%	0.00425 or 2.12921%
90204484	0.00122 or 2.97763%	0.00254 or 3.13763%	0.00808 or 4.14593%
Averages:	3.276%	2.769%	3.8935%

The above table represents the uncorrected two standard deviation averages for the instruments used in the evaluation. The following table represents the values for the results coupled with the correction for the “sliding” target value of the simulator solutions.

Instrument	2 x Std Dev for 0.040	2 x Std Dev for 0.083	2 x Std Dev for 0.206
90201817	0.00071 or 1.85%	0.00094 or 1.20%	0.00492 or 2.56%
90204874	0.00127 or 3.16%	0.00095 or 1.17%	0.00385 or 1.95%
90204875	0.00108 or 2.70%	0.00090 or 1.13%	0.00217 or 2.64%
90204483	0.00082 or 1.96%	0.00102 or 1.20%	0.00300 or 1.48%
90204484	0.00090 or 2.14%	0.00149 or 1.81%	0.00424 or 2.14%
Averages:	2.36%	1.30%	2.15%

Taking the worst performances from the corrected value table, the 95% confidence range is 0.03874-.04126 at the 0.040 level (+/- 3.16%); 0.0815-0.0845 at the 0.083 level (+/- 1.81%); and 0.20057-.21143 at the 0.206 level (+/- 2.64%). Using rounding rules to 3 digits (as the instrument would in a normal case), the ranges are 0.039-0.041, 0.082-0.085, and 0.201-0.211 respectively. Data (not shown) was also obtained over the complete acceptable operational temperature range of the instrument (between 10 and 37 degrees Celsius). The instrument performance is acceptable at all temperatures within the established ISPFs Analytical Method range. The results at each temperature support the results generated at room temperature.

### Conclusions:

We conclude that the readings obtained from the FC20 instrument are indeed more precise than the minimum criteria set by the USDOT (to be listed on their Conforming Products List). ISP Forensic Services Scientists will reference and use the ISP validation percentages listed below for FC20 related cases. All instruments tested in this validation performed at or better than the following percentages.

0.04g/210L	0.08g/210L	0.20g/210L
±3.16%	±1.81%	±2.64%