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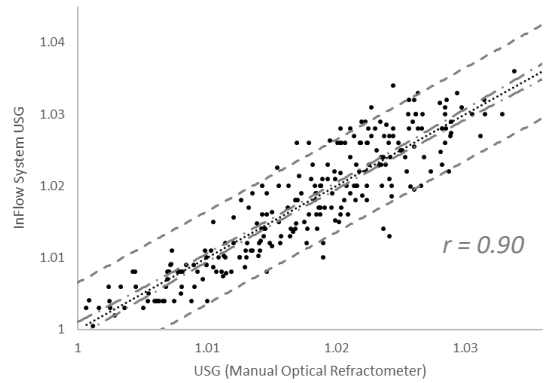
Test Development, Characterization, and Performance

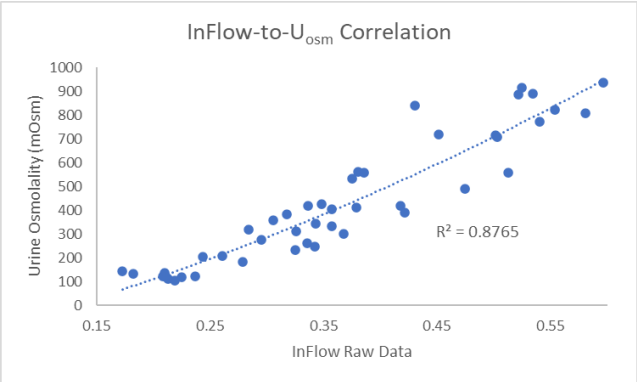
InFlow as a hydration marker (USG)

Athlete field testing (n=247) comparing InFlow measurements of urine specific gravity (USG), a well-used marker of hydration status, against an optical refractometer. Mean absolute error is 0.0029 ± 0.0021 (151 users). Dotted line (···) is linear regression (r=0.90). Dot-dash line (-·-) is 95% confidence interval. Dashed line (- -) is 95% prediction interval.



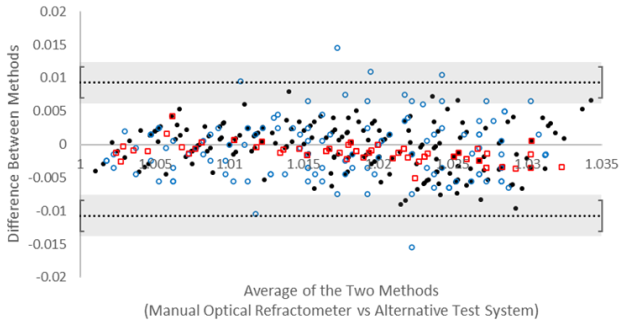
InFlow as a hydration marker (Osmolality)

Additional internal testing (n=45) also demonstrated a positive, significant correlation (R^2=0.88) between InFlow measurements and urine osmolality, a well-used marker of hydration status and often used as a gold-standard for urine hydration assessment.



Interchangeable with Digital Refractometer

A Bland-Altman Plot of Agreement shows the InFlow system (●), the MISCO digital optical refractometer (○), and the Atago 3741 digital optical refractometer (□) fall within the limits of agreement based on inter- and intraindividual biological variation of USG, demonstrating InFlow and these methods are interchangeable for hydration monitoring.



InFlow is Superior Over Dipsticks

Field test data shows InFlow is nearly twice as accurate as dipsticks (n=119; p<0.001; α=0.05).

	Mean Absolute Error	SD of Error
Dipstick	0.0051	0.0047
InFlow	**0.0029**	**0.0021**

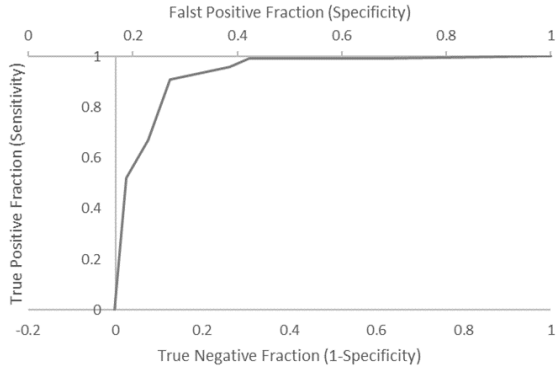
Test Performance at U_{SG}=1.020 Threshold

True condition is represented by dehydration (U_{sg} (Optical Refractometer) ≥ 1.020) and a negative condition is represented by hydration (U_{sg} (Optical Refractometer) < 1.020). A negative test is represented by U_{sg} (InFlow) < 1.020 and a positive test represented by U_{sg} (InFlow) ≥ 1.020. Field testing (n=247) correctly classified by the test are represented by TP and TN cells.

		U_{sg} (Optical Refractometer)		
		≥ 1.020	< 1.020	Total
U_{sg} (InFlow)	≥ 1.020	TP 38.9% (n=96)	FP 6.8% (n=17)	113
	< 1.020	FN 5.7% (n=14)	TN 48.6% (n=120)	134
Total		110	137	247
		Sensitivity 87%	Specificity 88%	Accuracy 87%

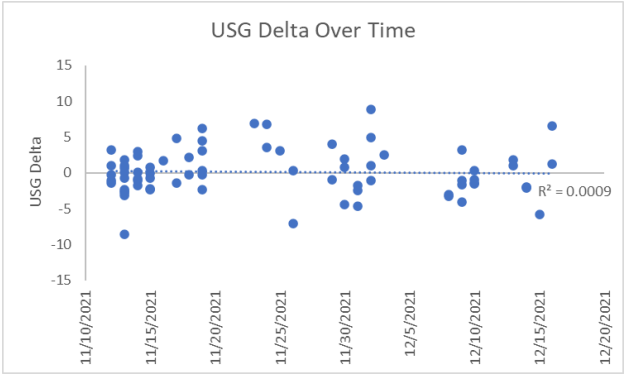
Receiver Operating Curve (ROC)

The test quality was assessed at varying thresholds to examine the relationship between sensitivity and specificity when delineating hydrated versus dehydrated. An AUC of 0.94 exceeds the generally acceptable threshold for a good quality test.



Back-to-Back Testing Over Time

Testing for device drift over time was assessed via repeat testing (n=74) for 35 days with a single device without rinsing. The device showed no discernable change to accuracy, no increase in imprecision, and no introduction of systematic bias.



Interpretations & Conclusions

InFlow has demonstrated appropriate accuracy, sensitivity, and specificity for use in the quantification of urine specific gravity for the purposes of assessing hydration status. Given the combination of bias (systematic error), random error (test precision), and biological variability (inter- and intra-individual U_{SG} variability), the results demonstrate the test is fit for purpose with accuracy similar to digital refractometers and exceeding that of urine dipsticks tests.

Limitations & Future Development

Current testing is limited by a small amount of field trial data (n=247; 3 institutions). Increasing the number of test subjects, test samples, and diversity of subject demographics and physiological states will lead to an improvement in the reliability of the test statistics. Repeat testing data is also limited by a lack of field trial data at lengths of time spanning several months.