CHEST Online Supplement

Smartphone Biosensor With App Meets FDA/ISO Standards for Clinical Pulse Oximetry and Can Be Reliably Used by a Wide Range of Patients

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e-Table 1: Sensitivity analysis: Out-patient Study (n=250) - Comparison of bias (accuracy), standard deviation (precision), and root mean square deviation of the Test (Smartphone biosensor with APP) and Reference (Welch Allyn Spot Vital Signs) measurement systems, for heart rate and SpO_2. This sensitivity analysis excluded outlier measurements (observations ≥3 standard deviations in absolute value) as follows: HR: n=24 observations from 15 participants excluded, (Test n=18, Reference, n=6); SpO_2: n=18 observations from 18 participants excluded (Test n=14, Reference n=4). Bias and standard deviation correspond to β_2 and SD(ε_{ij}) in model equation (2). The bias comparison used the Wald test of mixed effects linear model. The standard deviation comparison used the likelihood ratio test of the mixed-effects linear model.

Outliers Removed	Bias (Accuracy) Test vs Reference System			Standard Deviation (Precision) Each System			Root Mean Square Deviation Each System	
Out-patient Study	Test	Reference	P-value	Test	Reference	P-value	Test	Reference
Heart Rate, bpm (95% CI)	0.18 (-0.10, 0.46)	0 (ref)	0.21	4.04 (3.78, 4.32)	3.32 (3.11, 3.55)	<0.001	4.04 (3.66, 4.43)	3.32 (3.11, 3.55)
SpO_2, % points (95% CI)	0.54 (0.45, 0.63)	0 (ref)	<0.001	0.94 (0.90, 0.99)	1.04 (0.99, 1.09)	0.058	1.08 (0.98, 1.18)	1.04 (0.99, 1.09)

Ref – reference; bpm – beat per minute; Test – Smartphone sensor with App; Reference – Welch Allyn Spot Vital Signs.

e-Table 2: Sensitivity analysis: Out-patient Study (n=250) - Comparison of bias (accuracy) and standard deviation (precision) for heart rate and SpO_2 *within* the Test (Smartphone sensor with App) and the Reference (Welch Allyn Spot Vital Signs) measurement systems. This sensitivity analysis excluded n=24 outliers for heart rate, and n=18 outliers for SpO_2. Between-units bias corresponds to β_3 (test units) and to β_4 (reference units), and standard deviations correspond SD(ε_{ij}) in model equation (2) (See Methods). The bias comparison used the Wald test of mixed effects linear model. The standard deviation comparison used the likelihood ratio test of the mixed-effects linear model.

Outliers Removed		Bias (Accuracy) Within System		Std. Deviation (Precision) Within System		
	Model	$Unit_1$-$Unit_2$	P-value	$Unit_1$	$Unit_2$	P-value
Heart Rate (bpm)	Test Units	0.10 (-0.32, 0.52)	0.63	4.16 (3.84, 4.49)	4.04 (3.74, 4.37)	0.53
	Reference Units	-0.43 (-0.71, -0.16)	0.002	3.16 (2.92, 3.41)	3.53 (3.27, 3.82)	0.009
SpO_2 (% points)	Test Units	-0.02 (-0.15, 0.11)	0.76	1.10 (1.05, 1.15)	0.99 (0.94, 1.04)	0.034
	Reference Units	0.52 (0.41, 0.63)	<0.001	1.00 (0.95, 1.05)	0.87 (0.83, 0.91)	0.005

Ref – reference; bpm – beat per minute; Test Units – In phone; Reference Units – Welch Allyn Spot Vital Signs.