

Evaluation of a Non-Invasive Respiratory Volume Monitor Without Patient-Specific Calibration

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Introduction: Continuous monitoring of respiratory status is important for identifying potentially life-threatening respiratory compromise, performing clinically appropriate interventions, and monitoring patient recovery. Recently, a non-invasively Respiratory Volume Monitor (RVM, ExSpiron, Respiratory Motion) was developed and has been shown to have better than 10% accuracy for minute ventilation (MV), tidal volume (TV), and respiratory (RR) in both non-intubated and intubated patients.[1,2] The current RVM requires a patient-specific, single-point calibration with a spirometer in order to make quantitative measurements of MV and TV. To facilitate broader use of the technology and eliminate error introduced by variability in the use of the spirometer itself, the RVM has been updated to make quantitative measurements of MV and TV without the need for a patient-specific calibration. Here, we evaluated the accuracy of the RVM without patient-specific calibration compared to three different FDA-cleared in healthy volunteers.

Methods: Twenty subjects from a broad ambulatory population completed the study (11 males, BMI=26.8 kg/m² (18.7-41.8), 49.2 yrs (22-80)). MV, TV, and RR were simultaneously recorded by the RVM without patient-specific calibration and an FDA-cleared device. On Day 1, each subject completed 3, 10 min trials with different devices: Pneumotachometer (Heated FVL, Morgan Scientific), Wright Respirometer (Mark 14, nSpire Health, Inc.), and RVM with patient-specific calibration (ExSpiron, Respiratory Motion). After the completion of the breathing trials, subjects kept the RVM electrode pads on and the same 3 breathing trials were repeated 24 hours later (Day 2). Relative errors between RVM without patient-specific calibration and predicate device measurements of MV, TV, and RR were calculated over 30s segments and bias, precision, and accuracy were calculated using Bland-Altman analyses. Paired-difference equivalence tests were performed with equivalence margins of 10% relative error. As a secondary test of the agreement between devices, we performed repeated measures single-factor ANOVAs with the differences between MV, TV, and RR measurements as the response variable. The null hypotheses were that the differences between the measurements were not different than zero.

Results: Combined across Day 1 and Day 2, the RVM's mean measurement biases for MV and TV were within 2.2% compared to all three predicate devices and within 0.2% for RR (Table 1).

The mean measurement accuracies were better than 11.6% for MV and TV compared to the predicate devices and better than 4.1% for RR. The equivalence tests rejected the null hypotheses that the RVM and predicate devices have different means values of MV, TV, and RR and therefore conclude the measurements are equivalent within $\pm 10\%$. Repeated measures ANOVAs revealed no significant effect of factor "Day" on MV, TV, and RR measurement errors ($p > 0.14$).

Conclusion: We showed the RVM without patient-specific calibration provides substantially equivalent accuracy compared to three FDA-cleared devices in human subject testing.

References: [1] Voscopoulos, C et al. *Anesth Analg* 117:91-100, 2013; [2] Voscopoulos, C et al. *J Clin Monit Comput* 29:223-39, 2015

Table 1. Mean Bias, Precision, and Accuracy of RVM without patient-specific calibration compared to three FDA-cleared devices.

Predicate Device:	Pneumotachometer			Wright Spirometer			RVM with Patient-Specific Calibration		
	MV	TV	RR	MV	TV	RR	MV	TV	RR
Bias, mean, %	2.2	2.2	0.0	-1.8	-1.5	-0.2	2.2	2.2	0.0
Precision, mean, %	7.2	7.3	4.0	8.4	8.4	1.7	7.0	6.9	0.1
Accuracy, mean, %	11.0	11.2	4.1	11.6	11.5	1.7	11.5	11.4	0.1