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To cite this article: Brian Ring, Allison J. Burbank, Katherine Mills, Sally Ivins, James Dieffenderfer & Michelle L. Hernandez (2019): Validation of an app-based portable spirometer in adolescents with asthma, Journal of Asthma, DOI: [10.1080/02770903.2019.1702201](https://doi.org/10.1080/02770903.2019.1702201)

To link to this article: <https://doi.org/10.1080/02770903.2019.1702201>



Accepted author version posted online: 06 Dec 2019.  
Published online: 10 Dec 2019.



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## Validation of an app-based portable spirometer in adolescents with asthma

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### ABSTRACT

**Objectives:** Objective measurements of asthma impairment could aid teens in recognition of changes in asthma status over time. Ready access to a conventional spirometer is not realistic outside of the clinical setting. In this proof-of-concept study, we compared the performance of the VitalFlo mobile spirometer to the nSpire KoKo® sx1000 spirometer for accuracy in measuring Forced Expiratory Volume in one second (FEV<sub>1</sub>) and Forced Vital Capacity (FVC) in adolescents with asthma.

**Methods:** Two hundred forty pulmonary function measurements were collected from 48 adolescents with persistent asthma from the University of North Carolina's pediatric allergy and pulmonology subspecialty clinics. Participants performed spirometry with the nSpireKoKo® sx1000 spirometer and the VitalFlo spirometer during their clinic visits. 119 simulated FVC maneuvers were conducted on both devices to standardize measurements. Pearson correlations, Bland-Altman procedure, and two-sample comparison tests were performed to assess the relationship between the two spirometers.

**Results:** VitalFlo measurements were significantly highly correlated with nSpireKoKo® spirometer values for FEV<sub>1</sub> ( $r^2=0.721$ , [95% CI,  $0.749 \pm 0.120$ ],  $P < 0.001$ ) and moderately for FVC ( $r^2 = 0.617$ , [95% CI,  $0.640 \pm 0.130$ ],  $P < 0.001$ ) measurements. There were no statistically significant differences of the mean FEV<sub>1</sub> ( $M=0.00764$ ,  $SD = 0.364$ ,  $t(59)=0.16$ ,  $P=0.87$ ) and FVC measurements ( $M=0.00261$ ,  $SD = 0.565$ ,  $t(59)=0.036$ ,  $P=0.97$ ) between the VitalFlo and nSpireKoKo® systems. Both devices demonstrated significantly high correlation when comparing the automated FVC ( $r^2 = 0.997$ , [95% CI,  $1.00 \pm 0.00974$ ],  $P < 0.001$ ) measurements. Bland-Altman plots did not demonstrate significant bias between devices for both FEV<sub>1</sub> (0.00764 L) and FVC (0.00261 L) measurements.

**Conclusions:** Lung function measurements from the VitalFlo mobile spirometer were comparable to a commercially-available spirometer commonly used in clinical settings. This validated app-based spirometer for home use has the potential to improve asthma self-management.

**Abbreviations:** ATS: American Thoracic Society; ARRD: American Review of Respiratory Disease; BMI: Body Mass Index; EPR-3: Expert Panel Report 3; ERS: European Respiratory Society; FEV<sub>1</sub>: Forced expiratory volume in 1 second; FVC: Forced vital capacity; HIPAA: Health Care Information Portability and Accountability Act; NAEPP: National Asthma Education and Prevention Program; NHANES: National Health and Nutrition Examination Survey; NHLBI: National Heart, Lung and Blood Institute; PEF: Peak Expiratory Flow Rate

### ARTICLE HISTORY

Received 29 August 2019

Revised 13 November 2019

Accepted 4 December 2019

### KEYWORDS

Asthma; bronchial diseases; respiratory tract disease; obstructive lung diseases; respiratory hypersensitivity; immediate hypersensitivity; control; adolescent

### CLINICALTRIALS.GOV

NCT02671643;

NCT02662413

## Introduction

Asthma is a major public health issue and a significant cause of morbidity and mortality across the globe (1). Twenty-six million Americans are diagnosed with asthma with a prevalence of 8.3% in children (2). Despite improvement in various domains such as expanded pharmacological therapies and a general deeper understanding of the heterogeneity of the

disease process, poor asthma control remains a significant public health and economic problem (3). With direct and indirect costs related to asthma estimated to be over 80 billion dollars in the past decade, the effect of poor asthma control on both an economic and personal domain is far from trivial (4). Subjective perception of asthma control from both adolescents and caregivers is often poorly correlated with objective

measurements such as pulmonary function testing and frequency of asthma exacerbations requiring systemic corticosteroids (5). When combined with an adolescent's higher threshold for rescue treatment use, poor adherence to asthma controller medications, and the perceived normalcy of symptoms, adolescents are at higher risk for severe exacerbations, emergency department utilization, and overall morbidity (6,7).

Self-monitoring, or self-assessment, is a critical component of asthma management according to the National Heart, Lung, and Blood Institute (NHLBI) to reduce asthma-related complications and improve quality of life (8). Self-monitoring in the home environment has historically been conducted by means of symptom questionnaires and peak expiratory flow rate (PEFR) measurements. The burden of these activities lies in the manual tabulation of results as well as the lack of feedback and poor accuracy and reproducibility of measurements (9). With the increasing use of technology amongst young people, smartphone application (app) based programs could provide a convenient medium for asthma self-assessment in adolescents (10,11).

Use of home-based spirometry, in addition to the prescribed medication regimen for the treatment of persistent asthma, could prove feasible as part of a daily routine. Feedback systems with personal goal development and health tracking could empower the young asthmatic to retake control of their pulmonary disease process, improve adherence to medication, reduce asthma symptoms, and strengthen relationships between the patient and provider (12,13). Furthermore, measurements from accurate home-based spirometers, with associated mobile app, may facilitate the expansion of monitoring frontiers with regard to personal environmental risk factors specific to the asthmatic (14).

Providing a comprehensive, objective measure of asthma control has the potential to enable adolescents to have better control of their asthma and reduce the associated complications of uncontrolled asthma (15,16). An attractive, discrete, and interactive spirometer that could measure multiple pulmonary function values, store data, and act as an "asthma assistant" could help enhance the desired outcomes that are associated with proper self-monitoring. This proof-of-concept study was designed to test the ability of a novel, portable spirometer (the VitalFlo spirometer) to accurately measure forced expiratory volume in one second (FEV<sub>1</sub>) and forced vital capacity (FVC), using a commercially-available clinic-based spirometer as the gold standard.

## Materials and methods

### Study population

We recruited adolescents 12–18 years of age with a history of physician-diagnosed persistent asthma who were using a daily controller therapy. Adolescents who were unable to perform spirometry or who had health problems such as cystic fibrosis, immune deficiency, or vocal cord dysfunction were excluded from participation. Informed consent and/or assent were obtained from all participants (and parents if the participant was a minor child) prior to enrollment. This study was approved by the University of North Carolina's institutional review board (IRB 14–1532, IRB 15–1804) and is listed on Clinicaltrials.gov (NCT02671643, NCT02662413).

### Equipment

#### VitalFlo spirometry system

The VitalFlo spirometry system is an app-based iOS device that provides both instruction, incentive, and data recording/storage for each pulmonary function maneuver. The VitalFlo device is a pocket sized, turbine-based, pneumotachometer that translates fan speed into an electrical signal which is then stored in a microprocessor within the device. The exhaled air flow causes the turbine to rotate, generating a voltage analogous to the rate of air flow across the turbine. A proprietary simple linear regression model is used as the algorithm when translating the voltage measurements from the VitalFlo device to volume in liters. There is not a calibration process for the VitalFlo spirometers as the sensor technology is different from traditional flow sensors (an analog measurement of air velocity as opposed to a differential pressure measurement).

The spirometer has the capability to measure PEFR, FEV<sub>1</sub>, and FVC. These measurements are made simultaneously, much like other devices used for pulmonary function testing.

The device prompts the user to perform a minimum of three expiratory maneuvers and records the best of the three per American Thoracic Society and European Respiratory Society (ATS/ERS) standards, using NHANES III reference values. The measurements generated are collected on a microprocessor and then transmitted by a low power Bluetooth radio to the password-protected VitalFlo app on the user's smartphone. The user is alerted by the app if their expiratory effort is inadequate (e.g. early termination of exhalation <3 s) and is provided coaching for

proper technique by the app. Once collected, the data is then transmitted to a HIPAA-compliant cloud database. The microprocessor is also attached to an accelerometer to approximate the position of the device and its effects on spirometry measurements.

### **nSpire KoKo® sx1000 device information**

The nSpire KoKo® sx1000 spirometer is a PC-based system that allows for the measurement of multiple pulmonary function parameters. The pneumotachometer that is used in this system is a Brass Core Fleisch-type device that has a detectible flow range  $\pm 16$  L/sec, volume range of  $\pm 16$  L, and an accuracy of  $\pm 3\%$  or 0.150 L. Flow and volume measurements are developed via differential pressure gradients that are created from the flow that passes through a bundle of capillary tubes to create a laminar pattern of air movement. Difference in pressure, pre and post pressure transducer, is directly proportional to flow rate. The nSpire KoKo® sx1000 must be calibrated to barometric pressure, room temperature, relative humidity. In addition to the aforementioned parameters, the calibration process also involves the use of a known volume syringe of air (e.g. 3 L syringe) to be passed through the nSpire KoKo® sx1000 at variable flow rates to ensure accurate measurements prior to use.

The analysis of measurements is performed on a computer that can support a Windows 7 or higher operating system via McKay(ATS/ARRD 1991); ITS; Modified Ellis interpretation algorithm. The measurements that can be assessed during an expiratory maneuver with the nSpire KoKo® sx1000 are expansive, which is standard for clinic-based spirometry systems.

### **Procedure and acceptability criteria**

Participants performed spirometry with the nSpire KoKo® sx1000 spirometer and the VitalFlo mobile spirometer with a trained technician monitoring and evaluating procedure technique on two separate study visits that were approximately six to eight weeks apart. The technician demonstrated the proper technique to produce acceptable FEV<sub>1</sub> and FVC measurements and coached participants through each maneuver. Errors found in the participant's maneuvers were recognized and addressed through reinstruction.

Prior to data collection, the nSpire KoKo® sx1000 was calibrated per manufacturer's specifications. Pulmonary function measurements were collected once at the beginning of the participant's clinic visit with the nSpire KoKo® sx1000 spirometer and again at the end of the participant's visit with the VitalFlo

portable spirometer. Pulmonary function data were assessed per ATS/ERS pulmonary function standards for FEV<sub>1</sub> and FVC measurement. The greatest FEV<sub>1</sub> and FVC values of at least three maneuvers, but no more than eight, were accepted for analysis. NHANES III reference values were utilized for the assessment of pulmonary function relative to the participant's age, race/ethnicity, height, and sex.

### **Standardization of measurements**

In order to remove human variability, an automated breathing device using standard 3-liter calibration syringes were utilized to provide a standard dynamic airflow test. One hundred exhalations were simulated for lung volumes from 2 liters to 3.2 liters. These measurements were first performed on the nSpire KoKo® sx1000 spirometer and subsequently performed in the exact manner with the VitalFlo device. Both spirometers were calibrated per manufacturer's specifications prior to use to ensure accuracy of the measurements provided by each device.

### **Statistical analysis**

The participant FEV<sub>1</sub> and FVC values in liters from both the VitalFlo device and nSpire KoKo® measurements data were normally distributed using the D'Agostino-Pearson normalcy test for all data sets (GraphPad Prism, San Diego, CA). Pearson correlation analyses were computed to assess the relationship between measurements made by the two spirometers and reported as the coefficient of determination ( $r^2$ ) to represent the relative measure of fit for the data. Paired t-tests, assuming a significance of 5%, were used to compare both means for FVC and FEV<sub>1</sub> measurements between the devices. Confidence intervals (95%) were calculated with reference to the slope of the linear regression models for both FEV<sub>1</sub> and FVC measurements from the VitalFlo and nSpire KoKo® spirometry systems. The Bland-Altman analysis was utilized to assess the equivalency of measurement from *in vivo* measurements of FEV<sub>1</sub> and FVC between devices. Significance for all statistical endpoints were defined *a priori* by a  $p$  values  $< 0.05$ .

## **Results**

### **Participants**

Forty-eight adolescents with persistent asthma participated in the study, and 240 spirometry measurements were available for analysis. The median age of

**Table 1.** Subject demographics.

| Subject Demographics                          |                     | N = 48                                         |
|-----------------------------------------------|---------------------|------------------------------------------------|
| Age in years, median (max–min)                |                     | 13 (18–12)                                     |
| Sex–female, n(%)                              |                     | 22 (45)                                        |
| Race/Ethnicity                                |                     | 26 African-American<br>22 Non-African-American |
| BMI Percentile for age/sex, median (max–min)  |                     | 77 (99.7–0.1)                                  |
| % predicted FEV <sub>1</sub> , mean (max–min) |                     | 93 (138–54)                                    |
| % predicted FEV <sub>1</sub> , n (%)          |                     |                                                |
| <60%                                          |                     | 1 (2)                                          |
| 60–79%                                        |                     | 5 (10)                                         |
| 80–100%                                       |                     | 28 (58)                                        |
| >100%                                         |                     | 14 (29)                                        |
| NAEPP Treatment Step, n (%)                   | Step 2              | 6 (13)                                         |
|                                               | Step 3              | 15 (27)                                        |
|                                               | Step 4              | 8 (17)                                         |
|                                               | Step 5              | 13 (27)                                        |
|                                               | Step 6              | 1 (2)                                          |
|                                               | Unknown             | 3 (6)                                          |
| Asthma Control, n (%)                         | Well controlled     | 25 (52)                                        |
|                                               | Not well controlled | 23 (48)                                        |
| History of atopic disease, n (%)              |                     | 46 (96)                                        |

participants was 13 years (18–12 years of age), 45% female, and median BMI of 21 kg/m<sup>2</sup> (SD = 6.68). Nearly all participants had allergic asthma, and the majority of participants were receiving step 3 therapy or above, according to NAEPP criteria. The demographics of the study population are summarized in **Table 1**.

### Spirometry measurements

When comparing *in vivo* measurements provided by the nSpire KoKo® sx1000 PFT system to the VitalFlo spirometer, we found a high degree of agreement between the two devices for FEV<sub>1</sub> ( $r^2=0.721$ , [95% CI, 0.749 ± 0.120],  $P<0.001$ ) and a moderate degree of agreement for FVC ( $r^2=0.617$ , [95% CI, 0.640 ± 0.130],  $P<0.001$ ) (**Figure 1a, b**). Differences of the mean FEV<sub>1</sub> ( $M=0.00764$ , SD = 0.364,  $t(59) = 0.16$ ,  $P=0.87$ ) and FVC ( $M=0.00261$ , SD = 0.565,  $t(59) = 0.036$ ,  $P=0.97$ ) measurements from both devices did not demonstrate a statistically significant difference (**Figure 1c, d**). Bland-Altman plots did not demonstrate significant bias between devices for both *in vivo* FEV<sub>1</sub> (0.00764, SD = 0.364 L (95% limits of agreement = −0.706, 0.721 L) and FVC (0.00261, SD = 0.505 L (95% limits of agreement = −1.10, 1.10 L) measurements (**Figure 3a, b**).

### Machine-generated measurements

To measure the ability of the VitalFlo spirometer to accurately translate voltage measurements to flow measurements, and to account for variability in participant effort, an automated breath device was used

to generate 119 fixed volume mechanical efforts through both the VitalFlo spirometer and the nSpire KoKo® spirometry system. The machine-generated FVC measurements demonstrated a strong correlative relationship between the devices,  $r^2 = 0.997$ , [95% CI, 1.00 ± 0.00974],  $P<0.001$  (**Figure 2**).

### Discussion

The development of app-based, portable spirometry systems has created an opportunity to leverage on the popularity of smartphone devices amongst teenagers to improve self-management of asthma. The simplest comparison to the utility of portable spirometry for the adolescent with persistent asthma is the measurement of PEFR variability with a peak flow meter. With peak expiratory flow monitoring, patients are restricted to only one objective metric of lung function which is highly dependent on user effort and does not correlate well with other asthma control assessments (17). PEFR has shown poor concordance with actual signs and symptoms of asthma control when compared to FEV<sub>1</sub> measurements and degree of airway hyperresponsiveness (18). Furthermore, it is the burden of the participant to accurately record results, utilize recall for proper technique of the maneuver, and retain this tabulation for future clinic visits (9,18,19). EPR-3 guidelines suggest that PEFR alone is not sufficient to act as objective data measure for reporting variations in asthma control (8).

We have shown that VitalFlo spirometer measurements are tightly associated with measurements from a commercially-available spirometer commonly used in clinical practice and research settings. The VitalFlo device itself also demonstrated significant correlation to the nSpire KoKo® sx1000 spirometry system when human variability was taken out of the equation.

Developing portable technology that can be used to trend lung function, promote medication adherence, and connect to an electronic medical record (EMR) could prove beneficial for adolescents with asthma (20). In addition to providing various pertinent measurements, the use of portable, app-based spirometers could possibly be of service to underserved populations that lack the resources to seek timely and consistent preventive health care. The concentration of individuals without access to healthcare is more prevalent in underserved areas of the United States; these populations also have a higher incidence of persistent asthma as well as suffer from greater morbidity and mortality rates due to their asthma (21,22). With this in mind, the development of remote medical

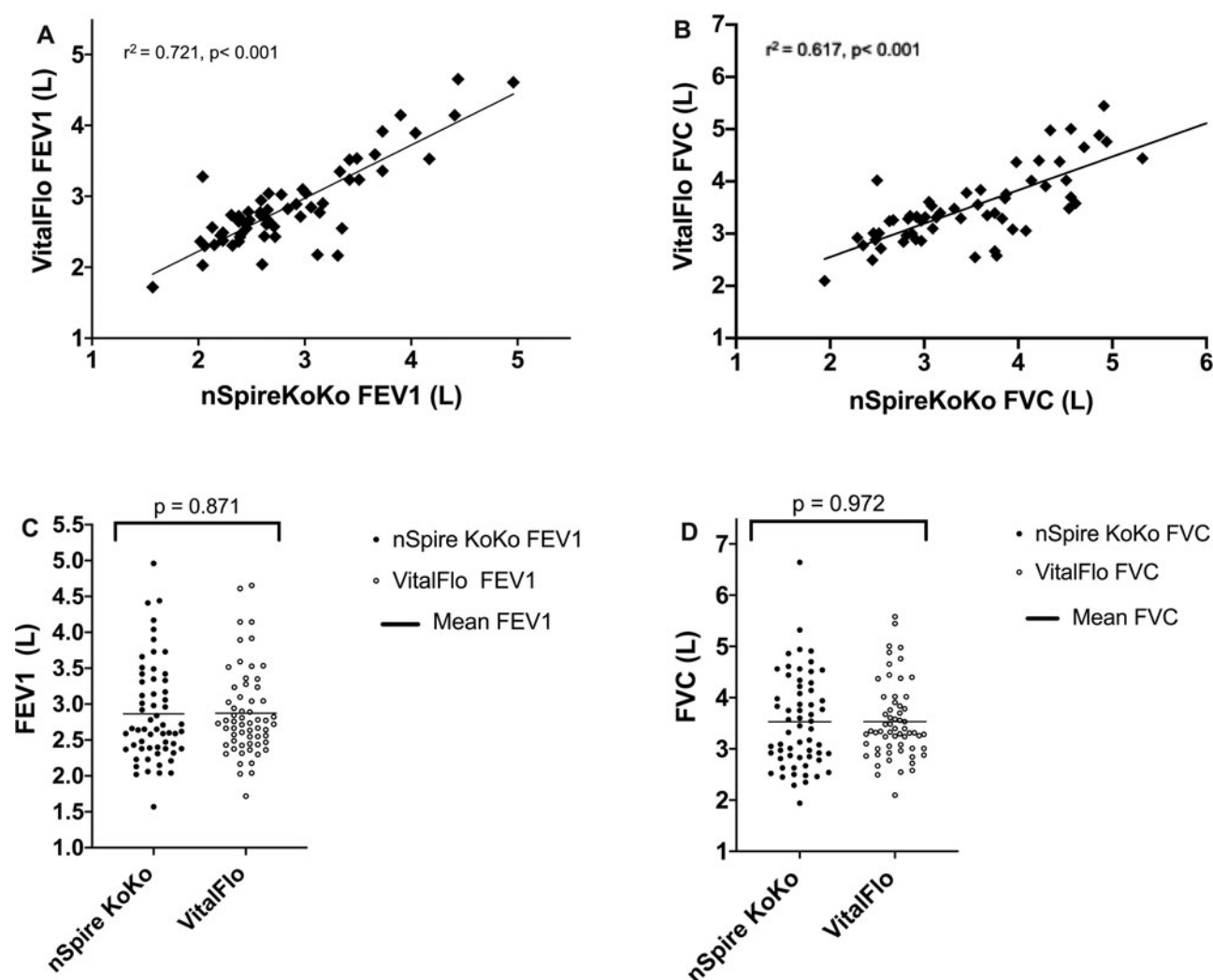


**Figure 1.** Comparison of FVC and FEV1 measurements from adolescents using the nSpire KoKo® spirometer and VitalFlo portable spirometer. Linear regression with Pearson correlation analysis of (A) FEV1 and (B) FVC measurements ( $N=60$ ); Paired analysis of (C) FEV1 and (D) FVC measurements for each subject on both devices ( $N=60$ ).

services, such as Telemedicine, could potentially offer portable, app-based spirometers as a surrogate for in-clinic measurements as demonstrated by the findings in this study; thus acting as a relief valve, so-to-speak, for providers and a medium for equitable access to asthma management resources for patients.

While the necessity of such advanced devices have not been fully realized, the use of interactive visual aids, personalized interactions with providers, and feedback mechanisms could prove appealing to young asthmatics (12,23,24). App-based spirometry units have the potential to fill the gaps that peak flow variability measurements lack. These app-based systems can provide expiratory maneuver analysis (e.g. flow-volume loops, predictive sets, etc.), HIPPA-compliant data storage and sharing, as well as the provision of detailed, objective pulmonary function data (e.g. FEV<sub>1</sub>, FVC, and FEV<sub>1</sub>/FVC). In addition to the feedback

mechanism for expiratory maneuvers, the VitalFlo provides environmental conditions, zones of asthma severity, flow-volume loops, and personal maintenance alerts. These functions are available to further assist patients with putting the big picture together for their asthma control. Finally, data is stored and managed via a Cloud based data management system. These data are accessible to the user and provider to paint a more accurate picture of the patient's asthma control and severity.

Our study has several limitations. Spirometry was performed under the supervision of study personnel and therefore may not reflect how the spirometer would perform in a home setting without coaching. Improper expiratory maneuvers are an issue with any sort of pulmonary functioning measurement done without the supervision of an experienced technician. While there is sufficient data to correlate the function

### Machine FVC

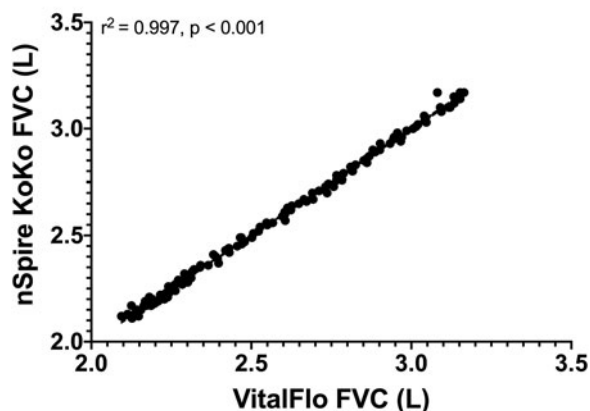


**Figure 2.** Linear regression with Pearson correlation analysis of FVC values generated by an automated breath device for the nSpireKoKo® and VitalFlo spirometers ( $N = 119$  values).

of this device in human subjects, there was not any available feedback on subject perception of the device or app-functions/utility; conclusions cannot be drawn about the usability of the VitalFlo/app interface for the adolescent persistent asthmatic based on this study. There is also limited evidence relating to the clinical impact of app-based, portable spirometers, so it is difficult to extrapolate clinical relevance of these devices (25). Finally, it has been found that spirometry measurements often demonstrate poor concordance with subjective symptoms associated with inadequately controlled asthma (26). What that in mind, pulmonary function measurements might not paint a vibrant picture regarding the degree of asthma control in this cohort.

From a practical standpoint, home-based spirometers are not currently covered by commercial

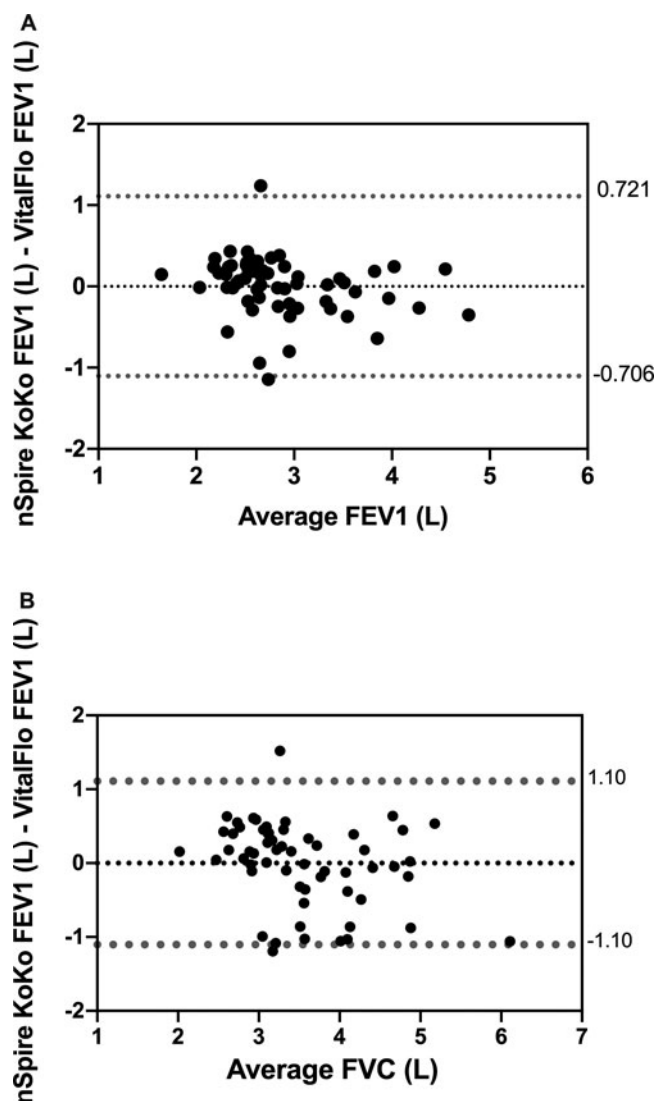


**Figure 3.** Bland-Altman plots with 95% Limits of Agreement (LoA) of (A) FEV1 and (B) FVC measurements from both the nSpire KoKo® spirometer and VitalFlo portable spirometer ( $N = 60$ ).

insurers for asthma, potentially impacting the generalizability of our findings.

## Conclusion

This proof-of-concept study was developed to compare the function of a portable app-based spirometry system to a clinic-based spirometry system to determine the feasibility of remote use. Our findings suggest that the VitalFlo portable spirometry system can accurately measure FEV1 and FVC compared to the gold standard KoKo spirometer in adolescents with asthma. Further study is needed to determine if use of a home-based spirometry system impacts asthma-related health outcomes such as emergency room utilization, hospitalization, or need for systemic corticosteroids.

## Disclosure statement

Dr. Dieffenderfer developed the VitalFlo spirometer. He is the Chief Technology officer for VitalFlo, Inc. Dr. Hernandez is an unpaid medical advisor for VitalFlo, Inc.

## Funding

This work was supported by a grant from the American Academy of Allergy, Asthma and Immunology Foundation, NHLBI 5 R01 HL135235 03, and NSF ASSIST Nanosystems Award Number EEC-1160483.

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