

Reproducibility and Validity of a Handheld Spirometer

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BACKGROUND: Handheld spirometers have several advantages over desktop spirometers, but worries persist regarding reproducibility and validity of data from handheld spirometers. We undertook an independent examination of the EasyOne handheld spirometer. **METHODS:** The laboratory testing included reproducibility and validity testing with a waveform generator. We used standard American Thoracic Society waveforms for in-line testing, calibration adaptor testing, and testing during compression of the mouthpiece. The clinical testing involved repeated tests with 24 spirometry-naïve volunteers and comparison to spirometry results from laboratory (volume-sensing dry rolling seal) spirometer. **RESULTS:** The EasyOne exceeded standard thresholds for acceptability with the American Thoracic Society waveforms. In-line testing yielded valid results from the EasyOne. Between the EasyOne and the reference spirometer readings the mean $\pm$ SD difference was 0.03 ± 0.23 L for forced vital capacity (FVC) and -0.06 ± 0.09 L for forced expiratory volume in the first second (FEV₁). The calibration adaptor showed no appreciable problems. Extreme compression of the mouthpiece reduced the measured values. In clinical testing the coefficients of variation and limits of agreement were, respectively, 3.3% and 0.24 L for FVC, 2.6% and 0.18 L for FEV₁, and 1.9% and 0.05 for the FEV₁/FVC ratio. The EasyOne readings were lower than those from the reference spirometer; the differences were: -0.12 L for FVC, -0.17 L for FEV₁, and -0.02 for FEV₁/FVC. The limits of agreement were within criteria for FVC but not for the FEV₁, possibly due to a training effect. **CONCLUSION:** The EasyOne spirometer yielded generally reproducible results that were generally valid, compared to the values from the laboratory spirometer. The use of the EasyOne in clinical, occupational, and research settings seems justified. *Key words:* spirometer, spirometry, forced vital capacity, FVC, forced expiratory volume, FEV₁. [Respir Care 2008;53(4):433–441. © 2008 Daedalus Enterprises]

Introduction

Potentially millions of Americans have symptomatic chronic obstructive pulmonary disease (COPD) but are

undiagnosed,¹ in part due to the lack of widespread acceptance of office spirometry by primary care providers.² One of the barriers to the use of office spirometers is a perception that they are inaccurate.³ Accuracy of portable spirometers is also important for screening and surveillance programs in occupational settings, epidemiological studies, and clinical trials.

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Handheld, flow-sensing spirometers have several advantages over traditional volume-sensing, desktop spirometers for clinical and epidemiological purposes, including portability, utility in the field or home setting, less risk of cross-contamination, battery power, and ease of cleaning.⁴ However, because early models of flow-sensing spirom-

eters were less accurate than volume-sensing spirometers, a perception persists that flow-sensing spirometers are less accurate, even with current fourth-generation models.⁵

The EasyOne handheld spirometer (ndd Medical Technologies, Chelmsford, Massachusetts) has been used for tens of thousands of spirometry tests in epidemiological surveys of COPD^{6,7} and for the detection of the respiratory effects of occupational exposures.⁸ Yet validation of this portable spirometer against an accepted standard, dry-rolling spirometer in adult subjects has been limited. One study reported suitability of the EasyOne for clinical use, but only 32% of the participants who underwent testing with the EasyOne had follow-up laboratory spirometry, and comparisons of the forced vital capacity (FVC) measurements were not reported.⁹ A prior report that evaluated 10 portable spirometers suggested that the EasyOne showed inadequate reproducibility for FVC and overestimated the forced expiratory volume in the first second (FEV₁), compared to a laboratory spirometer,¹⁰ but that report has not been confirmed.

Given the widespread use of the EasyOne spirometer in clinical and research settings, we undertook an independent examination of the reproducibility and validity of its measurements compared to a rolling-barrel spirometer. We conducted both laboratory diagnostics and clinical measurements.

Methods

Description of the Device

The EasyOne spirometer is a small handheld unit that consists of a flow sensor, electronics, a 14-button keypad, and a digital display that shows menus, subject data, waveforms, quality-control results, and spirometry results (Fig. 1). Instead of a conventional hose and mouthpiece, the EasyOne employs a disposable spirette that is a 13-cm pliable plastic tube that is inserted through the body of the spirometer. The spirette has an oval-shaped mouthpiece at one end, an opaque screen in the middle that allows transmission of ultrasound waves for velocity measurement, and is open on the non-mouthpiece end. The EasyOne

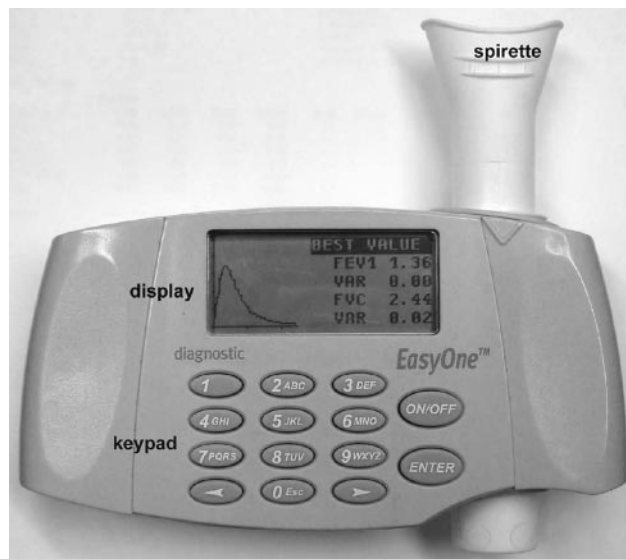


Fig. 1. The EasyOne Diagnostic spirometer and spirette.

can be used by itself or connected to a computer, upon which software can show flow-volume graphs and the results of quality checks in real time.¹¹ At present there are 2 EasyOne models: the Diagnostic model and the Frontline model. These appear identical and use the same spirette mouthpiece. We evaluated the Diagnostic model with firmware version 1.12, without connecting the spirometer to a computer.

The EasyOne spirometer uses an ultrasonic transit-time analysis to measure air flow.¹² Ultrasound transducers located diagonally on either side of the spirette cavity emit and receive sound in alternating directions. The gas flow through the disposable spirette slows the transmission of sound waves traveling against the gas flow and speeds up the transmission of sound waves traveling in the direction of the gas flow, so the flow rate can be calculated from the difference between the upstream and downstream transit times. This relationship is theoretically independent of gas composition, pressure, temperature, and humidity, and hence should eliminate errors due to those variables. The spirette has no sensor elements and therefore should not become inaccurate due to condensed moisture or exhaled phlegm (as do screen and capillary tube pneumotachometers).

The EasyOne spirometers and spirettes we used were purchased from the United States distributor at standard government and institutional prices.

Laboratory Testing

Standardized volume waveform testing was performed by an experienced technologist (KJS) at the National Institute for Occupational Safety and Health (NIOSH) laboratory, per the 1995 American Thoracic Society (ATS)

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The authors report no conflicts of interest related to the content of this paper.

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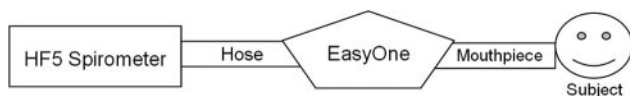


Fig. 2. In-line setup of the EasyOne spirometer and the laboratory reference spirometer (dry rolling seal HF5 spirometer).

guideline,¹³ which was current at the time the study was performed. The EasyOne was attached to a pulmonary waveform generator (Pulmonary Waveform Generator System, MH Custom Design, Midvale, Utah), which produced ambient temperature and humidity air (body-temperature-and-pressure-saturated [BTPS] standardized). The 24 volume ATS waveforms and the 26 ATS flow waveforms were tested 3 times each.

In-Line Testing

Tests were performed with the EasyOne set up in-line with the reference spirometer (a volume-sensing, dry rolling seal spirometer [Ohio 827, SensorMedics, Yorba Linda, California]), connected to a notebook computer. Custom software written by NIOSH staff provided automated calibration and operation, comparison of the subject's performance, and real-time display of flow-volume curves. This HF5 spirometry system is very similar to the HF4 spirometry system used in the National Health and Nutrition Examination Survey, from which we used the ATS-recommended spirometry reference equations.¹⁴

For the laboratory in-line testing we clamped the EasyOne in place and attached a hose from the non-mouthpiece end of the spirette to the HF5 spirometer (Fig. 2), and spirometry was performed by 12 volunteers, most of whom had extensive experience with spirometry testing.

Testing With the Calibration Adapter

A calibration adapter is required to connect the spirette to the round opening of a 3-L calibration syringe or waveform generator. The adapter is a gray plastic tube approximately 11 cm long, which has 2 screens within the body (newer EasyOne models now have a different calibration adapter that has no mesh screens). The screens help with noise-reduction issues (acoustics) that are relevant when using the calibration syringe or the waveform generator but not when testing human subjects. A selection of 5 flow waveforms were each run twice with the calibration adapter. The same flow waveforms were then also run (twice) by attaching the spirometer directly to the waveform generator. Then a selection of 5 volume waveforms were run twice, first with the calibration adapter, then with the spirometer directly connected to the waveform generator, and the latter process was also repeated as described above.

Testing the Effects of Mouthpiece Compression

The spirette mouthpiece was made of a white plastic that was somewhat pliable. When subjects were being tested, they sometimes bit down on and compressed the mouthpiece. We tested whether compressing the mouthpiece affected accuracy. The EasyOne and HF5 were attached to the waveform generator and a set of 2 flow waveforms were run 2 times each, with a clamp pinching the spirette mouthpiece to the following approximate openings: 1.3 cm, 1 cm, 0.6 cm, and 0.3 cm. The tests were done with the calibration adapter in-line. In further testing we had the subjects bite down on the mouthpiece during expiration. Since this testing the manufacturer has replaced that spirette design with a less pliable one.

Clinical Testing

With flyers we recruited 24 subjects who were not familiar with spirometry. People with poorly controlled lung disease were excluded. The volunteers received standardized instructions on the use of the EasyOne, according to ATS guidelines. These volunteers underwent 2 sets of expiratory measurements with the EasyOne Diagnostic spirometer, followed by a third (reference) set with a standard rolling-barrel spirometer system (2130 Computerized Spirometer, SensorMedics, Yorba Linda, California) in a university-based, certified pulmonary function laboratory, following the same protocol.

All spirometry measurements followed the 1995 ATS guidelines, which were current at the time the testing was performed.¹³ Participants were asked to perform 5–8 forced expiratory maneuvers, in an effort to meet the ATS acceptability and reproducibility goals. The highest values from the acceptable maneuvers were used in the analyses.

Ethics

Bench testing was originally performed for quality-control purposes only at NIOSH and did not meet the definition of research, as detailed in 45 Code of Federal Regulations 46.102(d), according to the human-subjects review board of NIOSH and the institutional review board of Columbia University. The protocol for clinical testing at Columbia University was approved by the institutional review board of Columbia University Medical Center, and informed consent was obtained for all participants.

Statistical Analysis

The descriptive statistics included mean and standard deviation and proportions. Comparisons were made with *t* tests or chi-square tests, as appropriate. All participants were retained in the analyses, regardless of spirometry

Table 1. In-Line Test Results: HF5 Laboratory Spirometer Versus EasyOne Handheld Spirometer

Sex	Asthma	FVC (L)				FEV ₁ (L)			
		Spirometer		Difference*		Spirometer		Difference*	
		HF5	EasyOne	Percent	Absolute	HF5	EasyOne	Percent	Absolute
F	Maybe	3.02	2.74	-9.3	-0.28	2.1	2.01	-4.3	-0.09
F	No	3.32	3.31	-0.3	-0.01	2.8	2.72	-2.9	-0.08
F	Yes	3.43	3.27	-4.7	-0.16	3.04	2.89	-4.9	-0.15
F	No	3.54	3.57	0.8	0.03	3.15	3.14	-0.3	-0.01
F	No	3.85	3.52	-8.6	-0.33	3.44	3.22	-6.4	-0.22
F	No	4.5	4.36	-3.1	-0.14	3.33	3.3	-0.9	-0.03
F	No	4.52	4.65	2.9	0.13	4.05	4.03	-0.5	-0.02
F	No	4.58	4.72	3.1	0.14	3.95	3.92	-0.8	-0.03
F	Yes	4.64	4.68	0.9	0.04	3.4	3.28	-3.5	-0.12
M	No	5.04	5.46	8.3	0.42	3.23	3.27	1.2	0.04
M	No	5.35	5.68	6.2	0.33	4.33	4.43	2.3	0.1
M	No	5.68	5.92	4.2	0.24	4.36	4.3	-1.4	-0.06
Mean $\pm$ SD		4.29 $\pm$ 0.85	4.32 $\pm$ 1.04	0.0 $\pm$ 5.5	0.03 $\pm$ 0.23	3.43 $\pm$ 0.66	3.38 $\pm$ 0.70	-1.9 $\pm$ 2.6	-0.06 $\pm$ 0.09

*EasyOne reading minus HF5 reading

FVC = forced vital capacity

FEV₁ = forced expiratory volume in the first second

PEF = peak expiratory flow

quality, to maximize generalizability. Reproducibility was assessed as coefficient of variation (coefficient of variation_i = SD_i/mean_i) and 95% limits of agreement ($1.96 \times \text{SD}_i$) between the 2 measurements made with the EasyOne. The validity was assessed with the absolute differences between the spirometers (eg, FVC value from the EasyOne minus the FVC value from the laboratory spirometer), and we adopted the convention that negative numbers indicated a lower value from the EasyOne than from the laboratory spirometer. Limits of agreement were calculated as mean difference $\pm 1.96 \times \text{SD}$, and plots were created following Bland-Altman methods and allowing for proportionality of error and mean values.¹⁵ This approach to the calculation of limits of agreement is conservative, should proportionality be present. We did not specify acceptable limits of agreement a priori, but followed the ATS reproducibility standard¹³ for FVC and FEV₁ (0.20 L), and, for comparative purposes, previously described 95% limits of agreement for validity of 0.50 L for FVC and 0.35 L for FEV₁.¹⁰ Statistical significance was defined as a two-tailed $p < 0.05$. All analyses were performed with statistics software (SAS 9.1, SAS Institute, Cary, North Carolina).

Results

Waveform Generator

The EasyOne spirometer passed the test in all categories, according to the ATS criteria.¹³

In-Line Testing

The mean values from the 2 spirometers were very similar (Table 1). The mean $\pm$ SD FVC values from the HF5 and EasyOne were 4.29 ± 0.85 and 4.32 ± 1.04 L, respectively (mean difference $0.0 \pm 5.5\%$). The mean $\pm$ SD FEV₁ values from the HF5 and EasyOne were 3.43 ± 0.66 and 3.38 ± 0.70 L, respectively (mean difference $-1.9 \pm 2.6\%$). The mean $\pm$ SD FEV₁/FVC values from the HF5 and EasyOne were 0.80 ± 0.08 and 0.79 ± 0.09 , respectively (mean difference $-1.8 \pm 3.4\%$). The mean difference for peak expiratory flow (PEF) was 3.7%.

Although the absolute mean differences between the spirometers were small for FVC and FEV₁ (see Table 1), the differences between the values from given individuals were larger. Nonetheless, the 95% limits of agreement for FVC were -0.42 L and 0.49 L, which were within the specified limits for validity. The 95% limits of agreement for FEV₁ were -0.23 L and 0.12 L, which were also within the specified limits for validity.

Figure 3 shows Bland-Altman plots of the differences between measurements from the 2 spirometers compared to the mean FVC and FEV₁ values from the 2 spirometers. The plot for FVC suggests that the difference between the measurements from the spirometers was proportional to mean FVC, and linear regression confirmed that the slope of the line on the Bland-Altman plot was statistically significantly different than the null ($\beta = 0.20$, $p = 0.001$). The plot for FEV₁ shows less proportionality, which was not statistically significant ($\beta = 0.05$, $p = 0.16$). Figure 3

Table 1. In-Line Test Results: HF5 Laboratory Spirometer Versus EasyOne Handheld Spirometer (Continued)

FEV ₁ /FVC				PEF (L/s)			
Spirometer		Difference*		Spirometer		Difference*	
HF5	EasyOne	Percent	Absolute	HF5	EasyOne	Percent	Absolute
0.69	0.73	5.2	0.04	6.32	7.37	16.6	1.05
0.84	0.82	-2.7	-0.02	9.50	9.40	-1.1	-0.10
0.89	0.88	-0.7	-0.01	7.05	6.97	-1.1	-0.08
0.89	0.88	-1.2	-0.01	7.88	8.57	8.8	0.69
0.89	0.91	1.8	0.02	8.71	8.19	-6.0	-0.52
0.74	0.76	-2.6	0.02	6.45	6.87	6.4	0.42
0.90	0.87	-3.0	-0.03	9.12	9.00	-1.4	-0.12
0.86	0.83	-3.6	-0.03	6.95	6.83	-1.8	-0.12
0.73	0.7	-4.5	-0.03	7.29	7.74	6.2	0.45
0.64	0.6	-6.4	-0.04	7.26	8.26	13.8	1.00
0.81	0.78	-3.7	-0.03	10.62	11.15	5.0	0.53
0.77	0.73	-4.8	-0.04	11.10	10.93	-1.5	-0.17
0.80 ± 0.08	0.79 ± 0.09	-1.8 ± 3.4	-0.01 ± 0.02	8.19 ± 1.60	8.44 ± 1.47	3.7 ± 6.95	0.25 ± 0.51

also shows 95% limits of agreement that allow for proportionality of mean differences versus mean values and that are considerably narrower than those listed in the preceding paragraph. The 95% limits of agreement that ignore proportionality are conservative (ie, wider), particularly for FVC.

Calibration Adapter Tests

The data collected with the calibration adapter were reproducible and within the targeted range. The data collected without the adapter had a much wider range, but was also acceptable.

Mouthpiece Compression

Compression of the spirette mouthpiece caused no appreciable change in FEV₁ or PEF with compression down to 0.6 cm, but there were large reductions in FEV₁ and PEF with compression down to 0.3 cm with both the EasyOne and the reference spirometer (Table 2). The readings from the 2 spirometers were similar except with the 0.3-cm opening, where the FEV₁ difference was -0.39 L with waveform 1, and the PEF differences were -1.40 L/s and 1.66 L/s on waveforms 1 and 19, respectively.

Similarly, biting down the spirette to an opening of 1.3 cm did not alter values appreciably. Further biting down to 0.3 cm did affect readings (data not shown) and caused air passing through the spirette and the EasyOne to sound obstructed.

Clinical Reproducibility

The characteristics of the 24 spirometry-naïve volunteers are shown in Table 3. The reproducibility of the

EasyOne spirometer varied by spirometry measure. The coefficients of variation were lowest for FEV₁/FVC, FEV₁, and forced expiratory volume in the first 6 seconds (FEV₆), and highest for the forced expiratory flow during the middle half of the forced vital capacity maneuver (FEF₂₅₋₇₅) and PEF (Table 4). The 95% limits of agreement for reproducibility were within the specified limits for the FEV₁ but not for the FVC.

Clinical Testing

There were modest mean absolute differences between the 2 spirometers. The EasyOne produced significantly lower values for all measurements except PEF (Table 5). The 95% limits of agreement were wider, particularly in the negative direction. The limits of agreement were within the specified boundaries for FVC and FEV₆, but not for FEV₁. Mean differences for FVC and FEV₁ were approximately proportional, such that the limits of agreement for FEV₁/FVC were considerably narrower than for either FEV₁ or FVC alone.

The FVC and FEV₁ slopes in the Bland-Altman plots from the clinical testing (Fig. 4) were slightly negative, in contrast to the results from the in-line testing. This proportionality of differences between measures to mean values was generally small and not statistically significant, with the exception of FEV₁, which was just significant (see Table 5).

Discussion

The results of independent laboratory and clinical testing of the EasyOne handheld spirometer are summarized here. Most of the laboratory testing yielded satisfactory

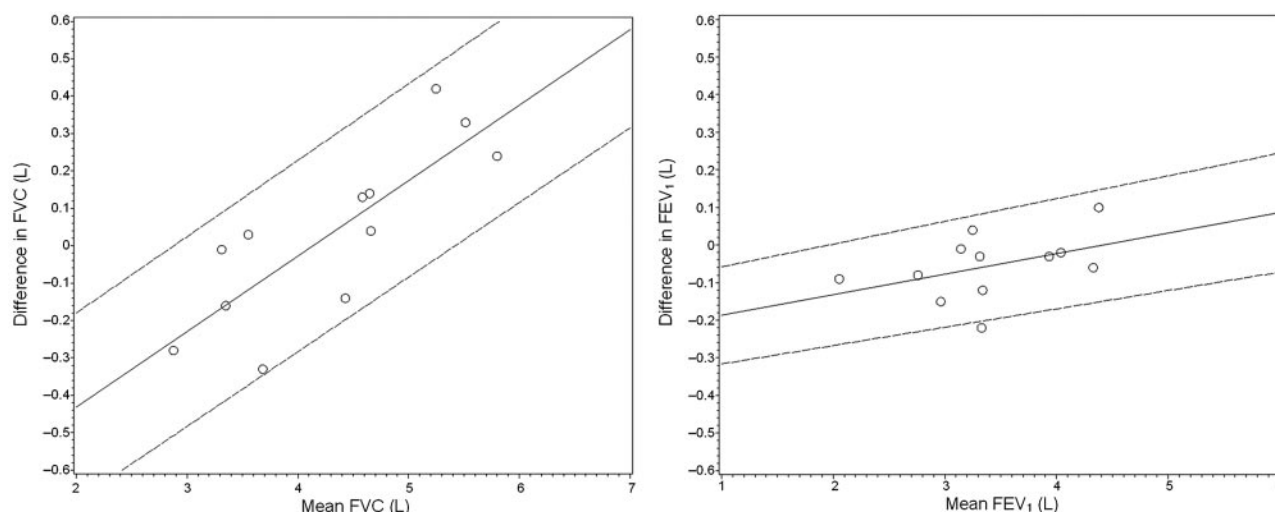


Fig. 3. Bland-Altman plots of the difference values versus mean values of forced vital capacity (FVC) (left) and forced expiratory volume in the first second (FEV_1) (right) from in-line testing of the EasyOne spirometer and the HF5 laboratory (reference) spirometer.

Table 2. Pinched Spirette Results: EasyOne Handheld Spirometer Versus HF5 Laboratory Spirometer

Approximate Diameter of Pinched Mouthpiece (cm)	ATS Wave Form Number	FEV_1 (L)			PEF (L/s)		
		HF5	EasyOne	Difference*	HF5	EasyOne	Difference*
1.3	1	3.52	3.53	0.01	7.87	7.87	0.00
1.3	19	3.19	3.17	-0.02	7.40	7.45	0.05
1	1	3.61	3.59	-0.02	8.13	8.00	-0.13
1	19	3.21	3.05	-0.16	7.43	7.02	-0.41
0.6	1	3.56	3.6	0.04	7.77	7.75	-0.02
0.6	19	3.24	3.25	0.01	7.47	7.50	0.03
0.3	1	2.56	2.17	-0.39	6.05	4.65	-1.40
0.3	19	2.6	2.58	-0.02	5.72	7.38	1.66

*EasyOne reading minus HF5 reading

ATS = American Thoracic Society

FEV_1 = forced expiratory volume in the first second

PEF = peak expiratory flow

results, although some deviations were noted and are discussed below. In clinical testing the EasyOne met the criteria for reproducibility for FEV_1 but not for FVC, and met the criteria for validity for FVC but not for FEV_1 .

The EasyOne performed well in standardized waveform testing. The in-line testing showed little bias. The mean FVC difference was close to zero, and the slightly negative FEV_1 result was probably attributable to a known error of 1–2% in the reference spirometer, because of its lack of real-time BTPS correction,¹⁶ rather than to error in the EasyOne. The limits of agreement for both the FVC and FEV_1 were within the specified criteria for validity. The in-line results were similar to those from a study of children with asthma (mean age 9 y) that compared the EasyOne in-line to a volume-sensing spirometer.¹⁷ That study found a similar lack of bias and similar limits of agree-

ment, although the percent error on a relative scale in that study was 2–3 times greater, given the smaller lung volumes of children.

The Bland-Altman plots from the in-line testing suggest that the FVC differences were proportional to mean FVC, such that larger differences were present at larger mean FVC values. Similar plots from the clinical testing, however, revealed no increase in differences in FVC proportional to mean FVC. The in-line setup may change the flow profile or increase downstream pressure in the EasyOne and thereby produce erroneous results (according to engineers at ndd Medical Technologies). We were not entirely able to rule out such error via additional testing. However, in-line testing in a much larger sample of children revealed no similar proportionality in the FVC,¹⁷ so the proportionality of FVC in

Table 3. Characteristics of Participants in Clinical Reproducibility and Validation Study ($n = 24$)

Male/female (n)	12/12
Age (mean $\pm$ SD y)	36.5 $\pm$ 13.1
Race/ethnicity (n and %)	
White	3 (13)
African American	6 (26)
Hispanic	9 (39)
Asian/other	6 (25)
Smoking status (n and %)	
Never	17 (71)
Former or current	7 (29)
Height (mean $\pm$ SD cm)	166.3 $\pm$ 9.5
Weight (mean $\pm$ SD kg)	72.3 $\pm$ 13.0
FVC (mean $\pm$ SD L)	3.90 $\pm$ 1.12
FEV ₁ (mean $\pm$ SD L)	3.11 $\pm$ 1.03
FEV ₁ /FVC (mean $\pm$ SD)	0.79 $\pm$ 0.07
FEV ₆ (mean $\pm$ SD L)	3.81 $\pm$ 1.13
FEF ₂₅₋₇₅ (mean $\pm$ SD L/s)	3.28 $\pm$ 1.45
PEF (mean $\pm$ SD L/s)	8.30 $\pm$ 2.55

FVC = forced vital capacity

FEV₁ = forced expiratory volume in the first secondFEV₆ = forced expiratory volume in the first 6 secondsFEF₂₅₋₇₅ = forced expiratory flow during the middle half of the forced vital capacity maneuver

PEF = peak expiratory flow

Table 4. Reproducibility of Readings From the EasyOne Spirometer in the Clinical Setting With Spirometry-Naïve Subjects

Spirometry Variable	Coefficient of Variation (%) and 95% Confidence Interval	95% Limits of Agreement (1.96 $\times$ SD _i)
FVC	3.3 (2.1–4.5)	0.24 L
FEV ₁	2.6 (1.8–3.3)	0.18 L
FEV ₁ /FVC	1.9 (0.9–3.0)	0.05
FEV ₆	2.8 (1.7–3.8)	0.23 L
FEF ₂₅₋₇₅	6.8 (3.1–10.4)	0.45 L/s
PEF	5.1 (3.1–7.1)	1.05 L/s

FVC = forced vital capacity

FEV₁ = forced expiratory volume in the first secondFEV₆ = forced expiratory volume in the first 6 secondsFEF₂₅₋₇₅ = forced expiratory flow during the middle half of the forced vital capacity maneuver

PEF = peak expiratory flow

the in-line testing in our study could be a false positive finding.

An additional potential source of error in the EasyOne system was the pliable mouthpiece of the spirette. Compressing or biting down on the spirette mouthpiece affected the measurements at the more severe degrees of constriction. Since this testing was performed, however, the manufacturer has re-engineered the spirette to make it less pliable.

We further assessed the reproducibility and validity of the EasyOne compared to a dry rolling seal spirometer in a clinical setting among healthy, spirometry-naïve volunteers. The reproducibility of FEV₁ was adequate, but the reproducibility of FVC exceeded standard criteria for reproducibility of 200 mL. Both of these findings are consistent with a prior report.¹⁰ Similar variability in the FVC was not evident in waveform or in-line testing (data not shown), and hence may be related to the clinical use of the EasyOne rather than intra-device measurement error. The EasyOne's liquid-crystal display shows a flow-volume loop but not a volume-time curve, and the unit relies on audible beeps to determine when plateau has been reached. The reproducibility of the FEV₁ may therefore be easier for the technician to establish than the reproducibility of the FVC. Connecting the EasyOne to a computer to display both the flow-volume loop and the volume-time curve at the time of testing might improve FVC reproducibility, but we did not test that strategy.

FVC values from the EasyOne were smaller than those from the laboratory spirometer, which was at variance with the in-line results. However, this decrement was in the range of short-term, intra-subject reproducibility of FEV₁ and FVC (about 5% coefficient of variation or 0.20 L), and thus of limited clinical importance. The EasyOne produced slightly lower FEV₁ values during both the in-line and clinical testing. The limits of agreement met previously published criteria¹⁰ for validity of FVC, but not of FEV₁.

These findings match and expand the results from a study of a convenience sample of people attending a community health fair. In that study, 32% of participants who underwent screening with the EasyOne returned for laboratory spirometry.⁹ Those results, although more variable than ours, also showed the mean FEV₁ and mean FEV₆ values from the EasyOne to be lower, by 0.25 L and 0.29 L respectively, than the laboratory-spirometer values. That difference was probably due to a training effect, because the participants performed spirometry first at the community health fair, with the EasyOne, then on a separate occasion with the laboratory spirometer. On the other hand, the recent study that compared 10 portable spirometers to laboratory testing, in a random fashion, among patients with and without COPD found the EasyOne to yield slightly higher FEV₁ and FVC values (by 0.08 L and 0.07 L, respectively) than the laboratory spirometer.¹⁰ A study from Australia also demonstrated the long-term reliability of EasyOne spirometers.¹⁸

Our laboratory and in-line testing was not subject to training effects, but our clinical testing may have been. We performed 2 separate tests on the EasyOne before performing the laboratory spirometry, and used the highest values from those tests, to minimize training effect; however, we did not randomize the order of testing.

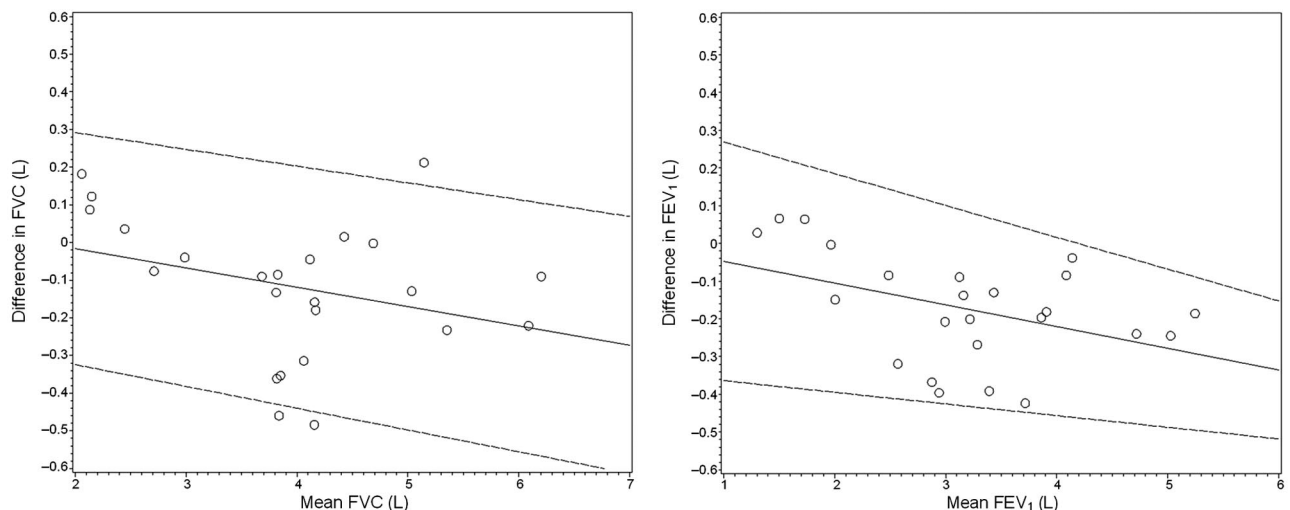
Table 5. Validity of Readings From the EasyOne Spirometer, Compared to Laboratory Spirometry, in the Clinical Setting, With Spirometry-Naïve Subjects

Spirometry Variable	Mean Difference and 95% Confidence Interval	95% Limits of Agreement	Slope of the Line in the Bland-Altman Plots of Absolute Difference Versus Mean Value	
			β	p
FVC (L)	-0.12 (-0.19 to -0.04)	-0.48 to 0.25	-0.05	0.14
FEV ₁ (L)	-0.17 (-0.23 to -0.11)	-0.45 to 0.11	-0.06	0.04
FEV ₁ /FVC	-0.02 (-0.03 to -0.01)	-0.05 to 0.02	0.06	0.26
FEV ₆ (L)	-0.14 (-0.21 to -0.07)	-0.48 to 0.19	-0.05	0.14
FEF ₂₅₋₇₅ (L/s)	-0.27 (-0.40 to -0.13)	-0.93 to 0.40	-0.04	0.37
PEF (L/s)	0.18 (-0.10 to 0.45)	-1.18 to 1.54	0.05	0.45

FVC = forced vital capacity

FEV₁ = forced expiratory volume in the first secondFEV₆ = forced expiratory volume in the first 6 secondsFEF₂₅₋₇₅ = forced expiratory flow during the middle half of the forced vital capacity maneuver

PEF = peak expiratory flow

Fig. 4. Bland-Altman plots of the difference values versus mean values of forced vital capacity (FVC) (left) and forced expiratory volume in the first second (FEV₁) (right) from clinical spirometry with 24 spirometry-naïve volunteers, with the EasyOne spirometer and the laboratory spirometer.

Some of the lower values obtained with the EasyOne therefore may have been due to training effect, which may have led to an overestimation of bias. Such a training effect may also have caused the limit of agreement for FEV₁ to not meet criteria for validity, because the width of the observed limits of agreement for FEV₁ (0.56 L) were well within the targeted width (0.70 L) but the downward bias from a training effect resulted in the lower threshold of validity criteria being crossed. We did not include patients with substantial obstructive airways disease in the current study and therefore cannot make firm generalizations to that population. Finally, the EasyOne's built-in software (firmware) has been updated several times since our evaluation was

completed, and those updates may influence the accuracy and reproducibility of currently available models.

Conclusions

The EasyOne yielded reproducible results for FEV₁ but not for FVC in clinical testing. The latter result may be due to operating characteristics of the unit and might be improved by connecting the EasyOne to a computer to allow simultaneous visualization of the flow-volume loop and the volume-time curve. Our in-line testing suggested a lack of bias, and valid results. Our clinical spirometry with naïve volunteers showed validity for FVC but not for FEV₁, which we believe was principally because of a training

effect. The use of the EasyOne in general clinical settings and for research and occupational purposes seems justified.

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