

Four-Year Calibration Stability of the EasyOne Portable Spirometer

Gwen S Skloot MD, Nicole T Edwards MSc, and Paul L Enright MD

BACKGROUND: Clinical practice guidelines recommend daily spirometer calibration checks and weekly linearity checks. The long-term stability of the volume and flow accuracy of a specific model of spirometer should be carefully characterized before modification of the frequency of calibration checks is considered for that model of spirometer. **METHODS:** The EasyOne ultrasonic flow-sensing spirometer was chosen for use by the clinical centers at the 2002 inception of the World Trade Center Worker and Volunteer Medical Screening Program. The screening program quality-control procedure required that the expiratory and inspiratory volume accuracy of each spirometer be checked every day of testing, and the flow accuracy (linearity) checked every week. The calibration check results were transferred to a central database for summary. **RESULTS:** Over 5,000 calibration-check results (4,109 single-speed and 1,189 three-speed) were accumulated from a total of 34 spirometers during the period February 2003 through March 2007. The mean single-speed calibration errors (and 5th–95th percentiles) were -2 mL (-80 to 70 mL) for exhalation and -10 mL (-80 to 60 mL) for inhalation. 98% of the exhalation and 97% of the inhalation calibration checks were accurate within 3.0%. There was no evidence of significant non-linearity according to the results of the 3-speed calibration checks (mean errors of -3 , -5 , and -6 mL at each speed). **CONCLUSIONS:** The EasyOne retained inhalation and exhalation volume accuracy of better than 3% for at least 4 years. Routine multiple-speed volume calibration checks may not be necessary with the EasyOne. The acceptability and repeatability of patient efforts should be the primary focus of quality-assurance programs with spirometers that have been demonstrated to remain accurate for long periods. *Key words:* spirometry; quality control; calibration; accuracy; reliability. [Respir Care 2010;55(7):873–877. © 2010 Daedalus Enterprises]

Introduction

Since 1995 the American Thoracic Society (ATS) spirometry standards have recommended daily spirometer cal-

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ibration checks with a 3.00-L calibration syringe, to ensure better than 3% volume accuracy.¹ The standards were most recently updated in 2005, when a recommendation for weekly linearity checks (by emptying the calibration syringe at 3 different speeds) was added.² However, the clinical value of daily calibration checks has not been established.³ The National Lung Health Education Program recommended that alternatives to 3-L calibration syringe accuracy checks be developed and validated.⁴

In practice, the manufacturers and distributors of many spirometers designed for the primary care setting advertise that their spirometers remain accurate over prolonged periods, so calibration is not necessary. Three groups of investigators have reported the stability of office spirometers, using daily single-speed calibration checks.⁵⁻⁷ However, the longest period reported was 6 months, which is much less than the usual life of a spirometer. In addition, weekly three-speed linearity checks were not done in those studies, and the accuracy of inspiratory volumes was not reported.

As part of the quality-assurance program for the World Trade Center Worker and Volunteer Medical Screening Program, it was required that the spirometers' volume accuracy be checked every day and the linearity checked every week.⁸ The results of the calibration checks during the first 4 years enabled characterization of the long-term stability of the accuracy of the EasyOne spirometer (EasyOne 2001 diagnostic, firmware version 02.09.00.00, ndd Medical Technologies, Zurich, Switzerland).

Methods

This study was done at the World Trade Center Medical Monitoring Program at Mt Sinai Medical Center, New York, New York. The program and the participants' baseline spirometry results have previously been described.⁹ In summary, 6 medical institutions in the greater New York City area performed baseline examinations, with a data coordinating center located at Mt Sinai Medical Center. The majority of the spirometry tests were done at the Mt Sinai clinical center. Responders from the Fire Department of New York were enrolled in a separate but similar program, and their methods and baseline results have been reported separately.¹⁰

The screening program purchased new spirometers for each spirometry site. The EasyOne spirometer was chosen considering the goals that it: retain accuracy for a prolonged period; minimize the risk of cross-contamination when performing both the expiratory and inspiratory forced vital capacity (FVC) maneuvers; provide automated quality checks and messages; and store the results in an easily accessible database. Technologists were guided by the screening program's manual of procedures, which followed the ATS guidelines¹ and specified that the inspiratory and expiratory volume accuracy of each spirometer be verified every day it was used. A 3.00-L calibration syringe (Hans Rudolph, Kansas City, Missouri) connected to a grey adapter (Spirette model 2030-1, ndd Medical Technologies, Zurich, Switzerland) was used at each clinical site. The adapter was designed to minimize ultrasonic reflections from the calibration syringe. The same "dedicated" Spirette was used for calibration checks at each site. To minimize temperature differences, the technologists were asked to store the calibration syringes near the spirometers.

We did not send Levey-Jennings trend graphs of calibration check results to the technologists during the study, as did Perez-Padilla and co-workers.⁷ We did not perform routine biological control checks. We did not return the calibration syringes periodically to the manufacturer for checks of the volume delivered by each syringe. None of the calibration syringes was reported by the technologists to have been broken, for example, by an accident such as falling from a table to the floor, nor were any returned to

the manufacturer or distributor, but the grey Spirette adapters were replaced with an improved model during the first few months of the study.

Technologists were instructed to check the spirometer volume accuracy daily, and the linearity weekly. The linearity check involved emptying the syringe into the spirometer at 3 different speeds; when such a "Multi-Flow Cal Check" was selected, the EasyOne software (firmware) required the calibration syringe to be emptied at a speed within an acceptable period (goals of 1 s, 3 s, and 6 s). No attempt was made to vary the syringe filling speed (inspiratory flow). Recalibration (adjustment of the calibration coefficients) of the EasyOne spirometer is not possible by users, so the technologists almost always repeated the calibration checks until the check was successful. The EasyOne stores only the final calibration check in a given session. The technician is prompted to retry after a failed calibration check; hence, the majority of the saved calibration checks are the successful ones. Thus, our analysis was limited to the range of calibration results for successful calibration checks.

Statistical Analyses

Since both forced expiratory and forced inspiratory spirometry (producing flow-volume loops) were performed by each participant, the results of both expiratory and inspiratory volume checks and expiratory linearity checks were summarized. When there was more than one calibration check session saved for an EasyOne unit on a single date, only the results from the last calibration check session were included in the summary; the number of volume checks on a given date ranged from 1–22 (although more than 2 checks in one day were rarely done), whereas the number of linearity checks on a given day ranged from 1 to 6. Descriptive statistics of the results of volume and linearity calibration checks were calculated with statistics software (SAS version 9.1, SAS Institute, Cary, North Carolina).

Results

Over 5,000 calibration check results (4,109 single-speed and 1,189 three-speed) were accumulated from the 34 spirometers used during the period February 2003 through March 2007, during which more than 10,000 participants were tested at the 6 sites.⁹ Usage data for each spirometer is summarized in Table 1. During the study, 2 of the 34 spirometers were returned to the manufacturer due to repeated failure to meet the calibration check accuracy goals.

Daily Calibration Checks

The mean volume error was only -2 mL (5th and 95th percentiles -80 mL and $+70$ mL) (Table 2). 98.1% of the

FOUR-YEAR CALIBRATION STABILITY OF THE EASYONE PORTABLE SPIROMETER

Table 1. Number of Calibration Checks of the 34 Spirometers Used in the Program, July 2002 through March 2007

Serial Number	Months*	1-Speed Calibration Check	3-Speed Calibration Check
40169	5	95	25
40338	11	12	3
40345	15	39	14
43238	4	29	10
43355	10	85	58
44055	11	84	17
44754	6	63	29
44769	40	76	68
45256	9	99	18
45258	8	129	52
45259	5	86	44
45412	13	56	24
45413	48	202	125
45414	5	94	16
45437	6	51	13
45472	7	72	11
45644	7	66	31
45648	47	84	33
46389	30	262	37
46691	1	1	0
46793	48	157	98
46829	31	344	89
47026	6	88	6
47099	2	30	4
47106	47	603	160
47269	1	17	2
48254	2	40	4
48303	39	385	61
49362	30	97	56
49374	1	9	3
50831	24	213	16
56738	11	79	50
57229	8	124	8
58845	5	39	4

* Months between first and last calibration check. Each clinic kept more than one spirometer "on the shelf" to cover days with a large number of spirometries (and technologists), so the number of months listed above is larger than the number of months that the spirometer was actually used to test patients (see Figure 1 for an example).

exhalation and 97.3% of the inhalation calibration checks were accurate within 3.0%. Actual results are shown in Figure 1 for the spirometer with the most calibration checks.

Weekly Linearity Checks

The results of these checks are summarized in Table 3. The goals for syringe-emptying time were 1, 3, and 6 seconds. The percentage of checks with results within 3.0% were 97.6%, 98.6%, and 97.6%, respectively. Early in the study, many of our technologists, who had never performed

Table 2. Daily Single-Speed Calibration Checks of Expiratory and Inspiratory Flow of the 34 spirometers*

	Flow (L/s)	Volume Error (mL)	% Error
Exhalation flow check (mean)	4.39	-2	-0.05
5th and 95th percentiles†	1.01, 7.95	-80, +70	-2.50, +2.46
Inhalation flow check (mean)	4.97	-10	-0.46
5th and 95th percentiles	1.87, 7.98	-80, +60	-2.69, +2.17

* $n = 4,109$. The maximum acceptable volume error was 90 mL (3% of 3,000 mL).

† The 5th and 95th percentiles are an index of the distribution of the results.

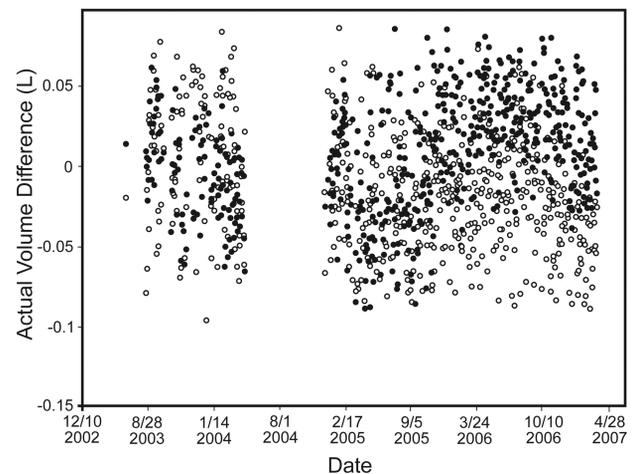


Fig. 1. Single-speed calibration check results from the EasyOne spirometer with the largest number of calibration checks ($n = 603$, serial number 47106). The actual volume differences in liters (measured minus 3.00 L) include expiratory volume errors (black diamonds) and inspiratory volume errors (white diamonds). This spirometer was not used for testing patients during the gap in measurements.

spirometer linearity checks before this project began, found it difficult to satisfy the syringe-emptying-time goals with only a few attempts. However, conversations with an nnd Medical Technologies customer service representative, as well as experience, soon allowed them to do the 3-speed calibration checks without multiple attempts.

Discussion

Our results expand on those of Walters et al⁶ and Pérez-Padilla et al,⁷ who reported the accuracy of EasyOne spirometers from single-speed calibration checks over less than 6 months of use at multiple sites. Although the ATS guidelines allow errors of up to 3.5% when checking the accuracy of spirometers (including a 0.5% error for the calibration syringe), we report a very low rate of errors on saved calibration-check results above a more conservative threshold of 3.0% (90 mL).

Table 3. Weekly 3-Speed Linearity Checks for Expiratory Flow From the 34 Spirometers*

	Flow (L/s)	Volume Error (mL)	% Error
1 s (mean)	3.07	-6	-0.21
5th and 95th percentiles†	2.60, 3.64	-70, +60	-2.48, +2.04
3 s (mean)	1.03	-5	-0.15
5th and 95th percentiles	0.87, 1.22	-80, +80	-2.60, +2.60
6 s (mean)	0.53	-3	-0.10
5th and 95th percentiles	0.45, 0.61	-80, +80	-2.69, +2.73

* $n = 1189$. The target syringe-emptying times for the 3.00-L syringe were 1, 3, and 6 s, per the American Thoracic Society recommendations.

† The 5th and 95th percentiles are an index of the distribution of the results.

We found that weekly 3-speed linearity checks were not necessary to verify the inspiratory or expiratory volume accuracy of this EasyOne model. When emptying the calibration syringe in about 1 second, as recommended by the ATS standards, the highest flow generated is less than 4 L/s (see Table 3), so the accuracy of the spirometer for measuring peak flows above 4 L/s is not verified. This confirms and expands previously published results showing good linearity with variable peak expiratory flow from daily single calibration checks as a surrogate for weekly 3-speed linearity checks.⁷

Since the World Trade Center Worker and Volunteer Medical Screening Program was designed to measure baseline spirometry and subtle spirometry changes over several years in this cohort of workers,¹¹ verification of spirometer accuracy over several years was very important. Many previous epidemiologic studies of longitudinal spirometry have selected a volume spirometer,^{12,13} while other studies used complete pulmonary-function-testing systems with permanent flow sensors, designed for hospital laboratories.¹⁴ We chose an ultrasonic flow-sensing spirometer, which minimizes the risk of cross-contamination because it uses disposable flow sensors, and is much smaller and easier to maintain. The EasyOne was also chosen for use by the Burden of Obstructive Lung Disease (BOLD) group and the Latin American COPD Prevalence Study (PLATINO).^{7,15} The accuracy of this EasyOne model had been verified with a waveform generator,¹ but such one-time bench-testing does not ensure long-term spirometer accuracy in field conditions.

Despite our finding of excellent long-term volume accuracy with this EasyOne model, and despite the claims of various salespeople, when the results will be compared for detecting changes from one visit to another, we recommend (per ATS guidelines) that, regardless of which spirometer model is used, its accuracy is verified every day it is used.

Limitations

By rotating calibration syringes, Linn and co-workers found that apparent errors in volume calibration were more likely due to the calibration syringe than to the dry-rolling seal spirometers used in their study.¹³ A portion of the errors in our study is also due to the calibration syringes, but since the same calibration syringe was always used to check a given spirometer, we cannot determine the proportion of the error due to the calibration syringe.

When a calibration check failed to fall within acceptable accuracy, the spirometer prompted the technologist to repeat the check. If they did so, the results from the first calibration check were not stored in the database. While this reduced the rate of errors that were apparently due to faulty technique in emptying the syringe, the reported rate of calibration-check failure was thereby reduced, and we have no record of how many times this occurred. Our experience, and that of others (even when using other spirometer models), is that initial "failure" to verify instrument accuracy is almost always due to human error, such as failure to completely fill or empty the calibration syringe, a leak in the connection between the syringe and spirometer, or a difference in the temperature between the syringe and the spirometer. The technologist usually fixes these mistakes before trying the calibration check again.

Spirometers may pass daily volume calibration checks but still suffer from unacceptable variability when testing healthy control subjects.^{6,14} Many factors probably contribute to FEV₁ and FVC measurement errors and variability when humans are tested with flow-sensing spirometers. These factors include body-temperature-and-pressure-saturated (BTPS) corrections, inter-batch differences in mouthpiece internal diameter, alterations in the laminar flow profile at the flow sensor due to biting down on the mouthpiece, and motion of the hand-held sensor assembly.

Errors due to the application of BTPS correction factors are not detected by syringe calibration checks, since both the syringe and the spirometer are at ambient temperature. However, since exhaled flow is measured within 5 cm of the mouth with the EasyOne spirometer, variable cooling of exhaled air is not a major factor, and the BTPS correction is constant, as determined by empirical testing by the manufacturer. We did not measure the ambient temperature nor the temperature of the calibration syringes, so we do not know how these differences contributed to volume errors.

A recent study suggested that the precision of FVC results from the EasyOne spirometer (when 9 experienced technologists blew into it 5 times) was not as good as laboratory systems (standard deviations of 250 mL vs 150 mL).¹⁶ We speculate that that difference could be due to biting down on the plastic mouthpiece, which causes

turbulent flow inside the spirometer where flow is measured. Until a study of this hypothesis is published or stiffer mouthpieces are developed, consider instructing patients to avoid biting down on the mouthpiece during the FVC maneuver. Several factors have been identified that may cause falsely high results from flow-sensing spirometers, even when accuracy has been verified with a 3.0-L syringe.¹⁷

It is necessary to measure the ambient temperature and use it for BTPS corrections when measuring forced inspiratory flow and then converting that measurement to inspiratory FVC. We did not study the accuracy of this conversion.

Conclusions

In the World Trade Center Worker and Volunteer Medical Screening Program, the EasyOne retained inspiratory and expiratory volume accuracy of better than 3% for at least 4 years. The acceptability and repeatability of patient efforts should be the primary focus of spirometry quality-assurance programs.¹⁸ For spirometer models that have been proven to remain stable for long periods, daily calibration checks are less important than vigorous coaching of patients or study participants for maximal breathing efforts.

DEDICATION

We dedicate this paper to the memory of Hank Glindmeyer PhD, a pioneer in the promotion of good-quality spirometry.

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