

TECHNICAL REPORT

Stability of the EasyOne ultrasonic spirometer for use in general practice

JULIA A.E. WALTERS, RICHARD WOOD-BAKER, JUSTIN WALLS AND DAVID P. JOHNS

Cardio-Respiratory Research Group, School of Medicine, University of Tasmania, Hobart, Tasmania, Australia

Stability of the easyone ultrasonic spirometer for use in general practice

WALTERS JAE, WOOD-BAKER R, WALLS J, JOHNS DP. *Respirology* 2006; 11: 306–310

Objective and background: Spirometry is recommended for the diagnosis and management of chronic respiratory diseases in the community. Spirometer accuracy is critical, but few general practitioners meet the American Thoracic Society and European Respiratory Society (ATS/ERS) recommendation for daily calibration. The aim of this study was to assess the accuracy and stability of a portable ultrasonic spirometer (EasyOne) that the manufacturer claims does not require regular calibration.

Methods: Six EasyOne spirometers were used in a practice-based spirometry study. Inspiratory and expiratory accuracy was checked periodically using a certified 3-L syringe. Paired calibration checks were performed using a dedicated mouthpiece assembly (spirette) and randomly selected spirettes.

Results: The six spirometers were used for up to 26 weeks (mean 23.9 weeks) and a total of 1041 spirometry tests and 75 syringe calibrations were performed. All inspiratory and expiratory calibration checks using a dedicated or randomly selected spirette met the ATS/ERS accuracy criterion (3.00 ± 0.105 L). The mean (range) expiratory volume deviation from target volume (3.00 L) was 0.011 L (–0.06–0.09 L) using a dedicated spirette and 0.046 L (–0.09–0.10 L) using randomly selected spirettes. The deviation from target was not affected by the mean flow generated during the calibration procedure. There was no change in calibration during the study.

Conclusions: This study supports the manufacturer's claim that the EasyOne spirometer maintains its calibration during routine clinical use in general practice and does not require daily calibration as specified in international spirometry guidelines.

Key words: accuracy, primary care, spirometry.

INTRODUCTION

Spirometry is the gold standard for the detection and quantification of airflow limitation and is recommended in practice guidelines for the diagnosis and management of COPD and asthma.^{1–4} However, the

value of spirometry depends on the quality of the measurement, which in turn is determined by the accuracy of the spirometer and the performance of correct breathing manoeuvres. Without quality measurements, comparison with reference values is meaningless and no confidence can be placed in the interpretation of a serial result.

The EasyOne (ndd Medizintechnik, Zurich, Switzerland) is a handheld spirometer that uses an ultrasonic sensor to measure air flow. The manufacturer claims that, except in the case of structural damage, the spirometer will maintain its accuracy throughout its operational life and, therefore, does not require regular calibration. It measures respired gas velocity from the transit-time of bidirectional ultrasonic pulses directed diagonally across the gas stream. Flow is computed from the measured gas velocity and known cross-sectional area of the gas stream, and volume is obtained by integration. Unlike many other

Correspondence: David P. Johns, School of Medicine, University of Tasmania Clinical School, 43 Collins Street, Hobart, Tasmania 7000, Australia.
Email: david.johns@utas.edu.au

Funding for the purchase of the EasyOne spirometers and consumables was obtained from the Royal Hobart Hospital Respiratory Research Fund.

Received 21 November 2005; invited to revise 12 December 2005; revised 15 December 2005; accepted 16 December 2005 (Associate Editor: YC Gary Lee).

types of spirometer, the EasyOne has no moving parts, therefore accuracy is not dependent on mechanical function, nor is it dependent on the measurement of variables such as pressure or displacement volume. Providing the cross-sectional area of the gas stream is fixed, the only variable requiring accurate measurement is the transit-time of the ultrasonic pulses between the two transmitters to receivers. The potential stability of the calibration was one reason why this spirometer was selected for use in an international multicentre study (the burden of obstructive lung disease initiative (BOLD)) to determine the prevalence and economic burden of COPD.⁵

Recently updated international guidelines have confirmed the view that the accuracy of diagnostic spirometers must be checked at least daily⁶ using a syringe with a volume of at least 3 L. During a recently conducted survey the authors of the present study found that although 64% of general practices in Australia owned a spirometer, only 22% of these use a calibration syringe to check the accuracy of their spirometer, and only 1.5% actually perform this on a daily basis.⁷ This has the potential to reduce the clinical value of spirometry measurements unless spirometers used in general practice are known to maintain their accuracy. Although the manufacturer claims that the EasyOne maintains its calibration, there is no published data to support this in a clinical setting.

The aim of this study was to assess the accuracy and stability of the EasyOne spirometer using a certified 3-L syringe in a general practice setting.

METHODS

Six EasyOne spirometers were used in a study comparing models of spirometry provision in primary care. Four spirometers were assigned to a specific general practice and two were used by trained nurses at regular spirometry sessions at four other practices in Southern Tasmania. The trained nurses carried out calibration checks periodically according to clinical usage.

Calibration checks were carried out using a calibration syringe (Hans Rudolph, Kansas, MI, USA) with a certified accuracy of $\pm 0.5\%$ to deliver 3 L of room air through the spirometer (expiratory calibration check) then withdrawn back into the syringe (inspiratory calibration check). Operators were instructed to empty, then fill the syringe within 6 s. The volumes measured by the spirometer and mean flow during the calibrations were recorded. To meet the accuracy requirements the volume recorded by the spirometer using a 3-L syringe should be within the range 2.895–3.105 L.⁶

The spirometer uses a disposable mouthpiece assembly (spirette) consisting of a biodegradable polyethylene tube inserted into the device and through which the subject performs the spirometry test and the operator performs the calibration check. For each spirometer, paired syringe calibrations were performed using a single dedicated spirette reserved for calibration and a new spirette randomly selected on each occasion.

STATISTICS

For each device the mean and SD of expiratory and inspiratory volumes (L) and flows (L/s) were calculated for both the dedicated and random spirettes. Differences between measured and 3.00 L target volume were plotted against time of spirometer use and flow. Paired calibrations with dedicated and new spirettes were compared using the method of Bland and Altman.⁸

RESULTS

The six EasyOne spirometers were used in clinical practice for between 15.1 and 26.6 weeks (mean 23.9 weeks). Throughout the study each spirometer functioned reliably with no obvious hardware or software problems. As detailed in Table 1, the six spirometers were used to perform a total of 1041 spirometry tests and 75 paired syringe calibration checks.

All expiratory and inspiratory calibration checks performed on each of the six spirometers using either the dedicated or a random spirette met international accuracy criteria⁶ of 3.00 ± 0.105 L (Table 2). Throughout the study period the volume accuracy across all spirometers using dedicated and random spirettes remained stable, with no evidence of deterioration over time (Fig. 1). There was no association between the deviation from target volume and the mean flow generated during the calibration procedure (Fig. 2).

Although all calibrations met the accuracy criteria, the mean volume recorded by the spirometers for both the expiratory and inspiratory checks was significantly ($P < 0.001$) higher when using random compared with a dedicated spirette (Table 2). Similarly, there was a significant difference ($P < 0.001$) between inspiratory and expiratory calibration test volumes, with expiratory volumes higher than inspiratory volumes.

DISCUSSION

The international standard for a calibration test of a spirometer, using a 3-L syringe with a certified accuracy $\pm 0.5\%$, requires that the volume recorded should be within the range 2.895–3.105 L at a range of flows between 0.5 and 12 L/s.⁶ This study provides strong

Table 1 Usage data for each spirometer

Spirometer serial no.	Days in clinical use	Patients tested (total = 1041)	No. calibration checks (total = 75)
47996	175	38	7
50758	175	3	8
50759	106	53	4
50763	179	337	23
50764	181	60	5
50946	186	550	28

Table 2 Results of paired calibration checks (dedicated and random spirettes) of six EasyOne spirometers using a syringe to deliver 3.00 L during the expiratory and inspiratory calibration

	Dedicated spirette (<i>n</i> = 75)			Random spirette (<i>n</i> = 75)		
	Flow [†] (L/s)	Measured volume [‡] (L)	Volume deviation from 3 L Absolute (L)	Flow [†] (L/s)	Measured volume [‡] (L)	Volume deviation from 3 L Absolute (L)
Expiration						
Mean	5.768	3.011	0.011	6.117	3.044	0.046
Range	2.30–8.32	2.94–3.09	-0.06–0.09	2.87–8.51	2.91–3.10	-0.09–0.10
SD	1.175	0.033	0.033	1.235	0.036	0.034
			0.373			1.523
			-2.00–3.00			-3.00–3.33
			1.111			1.125
Inspiration						
Mean	5.411	2.964	-0.036	5.513	3.003	0.003
Range	1.08–9.28	2.91–3.05	-0.09–0.05	2.22–8.32	2.92–3.07	-0.08–0.07
SD	1.575	0.030	0.030	1.323	0.039	0.039
			-1.209			0.090
			-3.00–1.67			-2.67–2.95
			0.992			1.303

[†]Mean flow generated during calibration.

[‡]Volume recorded by spirometer during procedure.

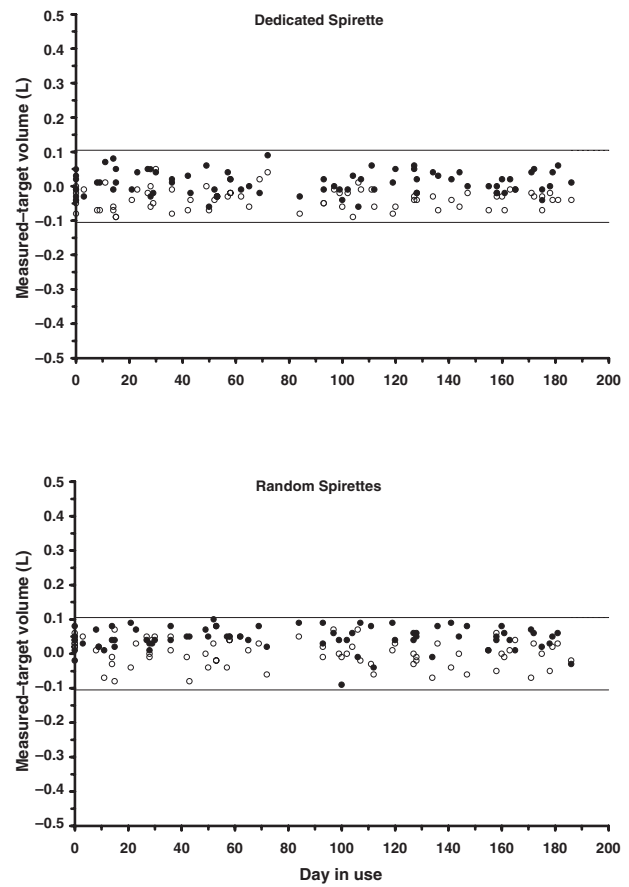


Figure 1 Accuracy of the expiratory (solid circles) and inspiratory (open circles) calibration checks for all six spirometers using a 3-L syringe. Shown is the difference between the measured and target volume (3.00 L) for all six spirometers using dedicated and random spirettes as a function of time (*n* = 75). The lines show the upper and lower American Thoracic Society and European Respirioly Society accuracy limits (2.895 and 3.105 L) when delivering 3.00 L.⁶

evidence to support the claim made by the manufacturer that the EasyOne spirometer is accurate and maintains its accuracy during clinical use for at least 26 weeks. This has practical implications in general practice, as it implies that this spirometer does not require daily calibration as recommended in the latest guidelines⁶ and supports the statement in the BOLD study protocol⁵ that the spirometer does not need regular calibration. Although the EasyOne spirometer maintains its accuracy for at least 6 months, this does not negate the need to regularly check overall performance using a biological control.

The EasyOne spirometer is accurate compared with standard office-based spirometers. In one study on children with asthma comparing the EasyOne and a dry rolling seal spirometer simultaneously, the reproducibility across devices was 97% for FEV₁ and 75% for FVC.⁹ An 'in-field' study in a community fair found good agreement between the EasyOne and a laboratory spirometer for FEV₁ and FEV₆.¹⁰ The EasyOne spirometer costs about AU\$3000, provides feedback

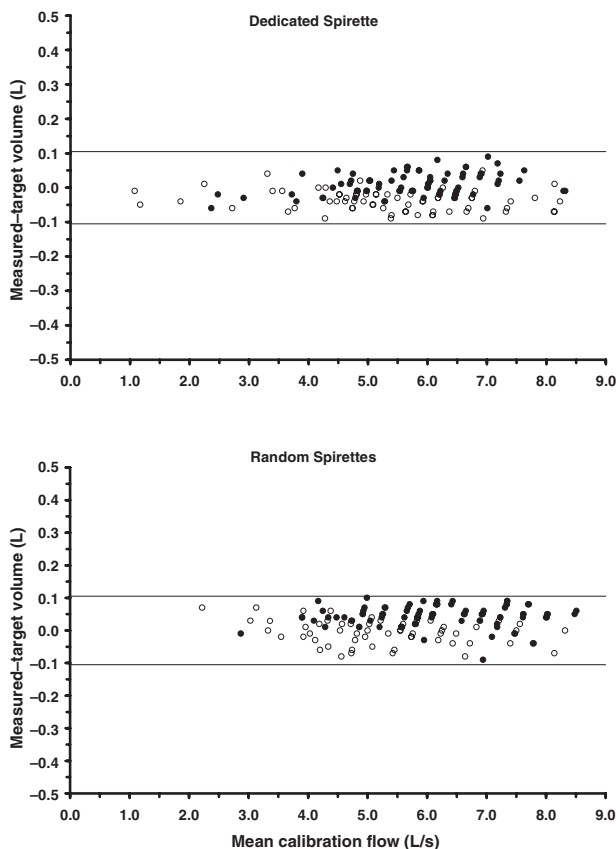


Figure 2 Accuracy of the expiratory (solid circles) and inspiratory (open circles) calibrations checks using a 3-L syringe for all six spirometers as a function of the mean flow generated during the calibration ($n = 75$). Shown is the difference between the measured and target volume (3.00 L) using dedicated and random spirettes. The lines show the upper and lower American Thoracic Society and European Respiriography Society accuracy limits (2.895 and 3.105 L) when delivering 3.00 L.⁶

to the operator on the quality of each test, the unit itself can store up to 700 patient results, and the risk of cross-infection is minimized by using disposable spirettes. These features, together with the stability of the calibration, should help improve the quality of spirometry in primary care.

Although this study has confirmed the stability of the volume accuracy of the EasyOne spirometer, the authors found small differences between syringe calibrations using dedicated and random spirettes. These differences are probably related to minor variations in cross-sectional area, as the spirometer obtains volume by integrating the flow signal with respect to time, and flow is derived by dividing the measured gas velocity by the internal cross-sectional area of the spirette. However, as variability between calibrations was similar for the one dedicated and the random spirettes, this indicates that the manufacturing tolerances (i.e. with respect to variations in internal cross-sectional area) were very small. The authors' observation that the volume recorded during the expiratory calibration was about 0.04 L higher than

during the inspiratory calibration (Table 2) is probably due to a combination of: (i) the different flow geometries upstream and downstream of the spirettes and (ii) minor differences in temperature between the syringe and inspired gas. The latter can be caused by frequent handling of the syringe during the calibration procedure.

General practitioners are at the forefront of health-care delivery and, therefore, uniquely positioned to monitor the respiratory health of the community. In order to facilitate the increasing use of spirometry in primary care the Global Initiative for Chronic Obstructive Lung Disease called for the development of simple and accurate spirometers.³ The National Lung Health Education Program suggested that alternative solutions were needed to the daily use of 3-L calibration syringes to check the accuracy of spirometers intended for use in primary care.² The need for this is highlighted by surveys confirming that daily calibration of spirometers does not occur in primary care. As it is likely that the use of spirometry in primary care will increase as the recommendations of clinical guidelines in COPD and asthma are adopted, accurate and easy-to-use spirometers are essential. Information on comparative features of spirometers is being made available to practices (Spirometer Buyers guide¹¹), and an important criterion when selecting a spirometer is the stability of the calibration and how frequently this needs to be checked. There will be advantages for practices in being able to rely on the spirometer maintaining its accuracy over time and continued use. Current guidelines stating the need for daily calibration may need to be revised in the light of these findings.

This study has demonstrated that the claim of stability made for the EasyOne spirometer on theoretical grounds is substantiated in primary care and, therefore, spirometer guidelines may need to be reviewed to reflect this.

ACKNOWLEDGEMENTS

The authors wish to thank Sue Davoren and Elizabeth Hammer for their assistance in carrying out the calibrations. J.W. is the recipient of a GSK Postgraduate Supporting Grant.

REFERENCES

- 1 Petty TL, Weinmann GG. Building a national strategy for the prevention and management of and research in chronic obstructive pulmonary disease. National Heart, Lung and Blood Institute Workshop Summary. Bethesda. *JAMA* 1995; **277**: 246–53.
- 2 Ferguson GT, Enright PL, Buist S, Higgins MW. Office spirometry for lung health assessment in adults: a consensus statement from the National Lung Health Education Program. *Chest* 2000; **117**: 1146–61.
- 3 Pauwels RA, Buist AS, Calverley PM, Jenkins CR, Hurd SS. GOLD Scientific Committee. Global strategy for the diagnosis, management, and prevention of chronic

- obstructive pulmonary disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. *Am. J. Respir. Crit. Care Med.* 2001; **163**: 1256–76.
- 4 McKenzie DK, Frith PA, Burdon JG, Town GI, Australian Lung Foundation, Thoracic Society of Australia and New Zealand. The COPDX Plan: Australian and New Zealand guidelines for the management of chronic obstructive pulmonary disease. *Med. J. Aust.* 2003; **178**: S7–39.
 - 5 Buist AS, Vollmer WM, Sullivan F *et al.* The burden of obstructive lung disease initiative (BOLD): rationale and design. *COPD: J. Chron. Obstruct. Pulm. Dis.* 2005; **2**: 277–83.
 - 6 Miller MR, Hankinson J, Brusasco F *et al.* ATS/ERS Task Force. Standardisation of spirometry. *Eur. Respir. J.* 2005; **26**: 319–38.
 - 7 Johns DP, Burton D, Walters JAE, Wood-Baker R. National survey of spirometer ownership and usage in general practice in Australia. *Respirology* 2006; **3**: 292–298.
 - 8 Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; **1**: 307–10.
 - 9 Mortimer KM, Fallot A, Balmes JR, Tager IB. Evaluating the use of a portable spirometer in a study of pediatric asthma. *Chest* 2003; **123**: 1899–907.
 - 10 Schoh RJ, Fero LJ, Shapiro H *et al.* Performance of a new screening spirometer at a community health fair. *Respir. Care* 2002; **47**: 1150–7.
 - 11 Burton D, Johns DP, Swanney M. *Spirometer Buyers' Guide*. 2005. ISBN 0642827850. [Cited 3 October 2006.] Available from URL: <http://www.nationalasthma.org.au/>