Australian Government
Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network
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AN INITIATIVE OF THE NATIONAL, STATE AND TERRITORY GOVERNMENTS OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

EasyOne™ spirometer for the diagnosis and management of chronic respiratory disease and asthma

May 2007

AHTA
Adelaide Health Technology Assessment

[add ISSN]
[add Publications Approval Number]

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The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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PRIORITISING SUMMARY

REGISTER ID: **000302**

NAME OF TECHNOLOGY: **EASYONE™ SPIROMETER**

PURPOSE AND TARGET GROUP: **FOR THE DIAGNOSIS AND MANAGEMENT OF CHRONIC RESPIRATORY DISEASE AND ASTHMA**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☒	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	81644
☐	No		
☐	Not applicable		

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia		✓	
New Zealand		✓	
Multi-centre – South America	✓		
United States	✓		

IMPACT SUMMARY:

The EasyOne™ spirometer is manufactured by ndd Medizintechnik (Switzerland) and distributed in Australia by Niche Medical. The EasyOne™ spirometer is designed for the diagnosis and management of chronic respiratory disease and asthma. The EasyOne™ is registered on the TGA and received approval from the FDA in 2000.

BACKGROUND

Undiagnosed airway obstruction is common in the general population. In the adult population not diagnosed with asthma, the main cause (90%) of airflow limitation is chronic obstructive pulmonary disease (COPD) due to cigarette smoking. COPD may also be caused by airborne irritants such as coal dust, air pollution from burning wood, asbestos or solvents (Enright & Kaminsky 2003). The main symptoms of COPD include

dyspnea (shortness of breath) which may be accompanied by wheezing, persistent cough with sputum and chronic bronchitis. A rare complication may be the partial or complete collapse of the lung, usually due to an obstruction of a bronchus (Wikipedia 2007). COPD is a progressive condition if left untreated or exposure to the causative agent is not halted, however COPD is preventable and treatable but not fully reversible (GOLD executive committee 2006).

The gold standard for the detection of airflow limitation and the diagnosis of COPD in its preclinical stage is spirometry. Spirometry is a non-invasive test which measures the volume of exhaled air, after a maximal inhalation, during a specified period of time (Enright & Kaminsky 2003). The results of a spirometry test are expressed as the FEV_1/FVC ratio, where FEV_1 is the forced expiratory volume in one second and FVC is the forced vital capacity, or the total amount of air forcibly exhaled after full inspiration. The severity of COPD is classified according to the following ratios:

Stage I (mild):	$FEV_1/FVC < 0.70$, $FEV_1 \geq 80\%$ predicted[1];
Stage II (moderate):	$FEV_1/FVC < 0.70$, $50\% \leq FEV_1 < 80\%$ predicted;
Stage III (severe):	$FEV_1/FVC < 0.70$, $30\% \leq FEV_1 < 50\%$ predicted; and
Stage IV (very severe)	$FEV_1/FVC < 0.70$, $FEV_1 < 30\%$ predicted or $FEV_1 < 50\%$ predicted plus chronic respiratory failure (GOLD executive committee 2006).

Spirometry may be conducted by general practitioners in their practices using hand held spirometers. Recent updated international guidelines have recommended that the accuracy of diagnostic spirometers be checked (ie calibrated) at least once daily using a syringes with a volume of at least 3 litres. A recent survey found that although 64 per cent of general practices in Australia owned a spirometer, only 22 per cent of these practices use a calibration syringe to calibrate the spirometer and that only 1.5 per cent actually perform this task daily. Failure to calibrate may produce spurious results (Walters et al 2006).

Figure 1 The EasyOne™
(printed with permission Niche Medical)

The EasyOne™ is a handheld spirometer which utilises an ultrasonic sensor to measure airflow (Figure 1). The EasyOne™ has no moving parts, therefore its accuracy is not dependent on mechanical function and it does not require calibration. In addition, the EasyOne™ is not dependent on the measurement of variables such as pressure or displacement volume (Niche Medical 2003; Walters et al 2006).

[1] Predicted values are based on values from normal population and are calculated using the patient's height, weight and gender

Disposable spirettes (mouthpiece) with a bacterial shield are fitted for each new patient. Transducers are fitted on both sides of the spirette cavity which receive sound in alternating directions (Figure 2). When gas flow (breath sample) is present in the tube, a pulse that is travelling with the flow (downstream) (Figure 2b) reaches the opposite transducer faster than the pulse that is travelling against the flow (upstream), which is slower and takes a longer time to reach the opposite transducer (Figure 2c). The transit time of the sound pulses are measured and the gas flow through the spirette is calculated from these times. The EasyOne™ can be used as a stand alone device which is capable of storing up to 700 patient results, or the results may be uploaded via a USB port for data storage (Niche Medical 2003).

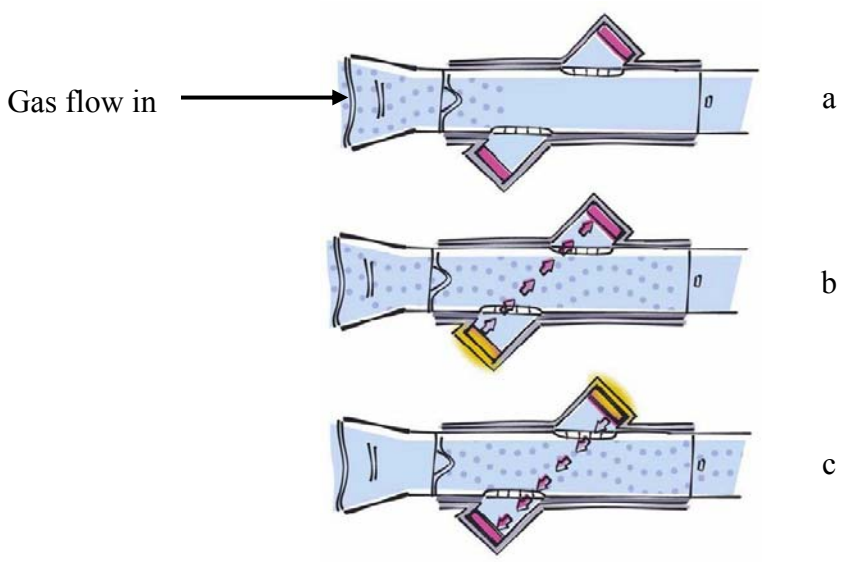

Figure 2 Gas flow into the EasyOne™ (Niche Medical 2003)

CLINICAL NEED AND BURDEN OF DISEASE

Chronic respiratory diseases are a major health problem in Australia, in 2001 it was estimated 5.8 million Australians suffered at least one long-term respiratory condition. The two major manifestations of chronic respiratory disease are asthma and COPD.

COPD is a group of long-term lung diseases, the major forms of which are emphysema and chronic bronchitis, characterized by progressive shortness of breath associated with abnormal inflammation of the lungs. The major cause of COPD is smoking; other causes are exposure to environmental hazards and genetic predisposition. In Australia COPD is a major cause of mortality and morbidity, being the underlying cause of death in 5,378 deaths in 2003 and resulting in more than 53,000 hospital separations averaging 7.5 days per separation (AIHW 2005b). Although the prevalence of COPD is difficult to determine, in 2001 it was estimated that 3.5 percent of Australians suffered from emphysema or bronchitis, although this is likely to be an underestimate as, generally, only

advanced COPD is diagnosed. Females are affected slightly more than males and increasing age is also a risk factor for diagnosis of COPD.

Asthma is a chronic disease characterised by inflammation of the airways, resulting in constriction of the airways leading to chest tightness, wheezing and shortness of breath. It is believed this cascade of events is the result of exposure to specific triggers, such as allergens, exertion, stress etc. Since the mid 1990s the prevalence of asthma in Australia may have plateaued, despite this, Australia's rate remains one of the highest levels in the world at 10-12% in children and 14-16% in adults (AIHW 2005a). In 2002-03 asthma was the principal diagnosis in 37,230 hospital separations averaging 2.5 days per separation (AIHW 2005b). Asthma was the underlying cause of death in 314 (1.6 per 100,000 population, 95% CI [1.4, 1.8]) and an associated cause of death in 934 cases in 2003 (AIHW 2005a).

Together, asthma and COPD are estimated to cost the Australian health care system over one billion dollars a year (AIHW 2005b).

DIFFUSION

The EasyOne™ is in limited use in several hospitals and clinics in Australia and New Zealand. Applications of the EasyOne™ spirometer in Australia now include: COPD, asthma and epidemiological research, use in emergency departments, respiratory wards, respiratory investigation units, COPD outreach programmes, respiratory outpatient clinics, cystic fibrosis clinics, occupational health clinics, community health centres and general practice.

COMPARATORS

Spirometers other than the EasyOne™ may be used to diagnose COPD, however these require daily calibration. Other methods for measuring airflow limitation include a simple forced expiratory time using a stethoscope and timing the expiration. If the forced expiratory time exceeds six seconds it is likely that the patient has airflow limitation, however this method results in a high misclassification rate. Peak expiratory flow (PEF) is low in patients with airflow limitation. Clinical practice guidelines recommend PEF to be used to *manage* but not to *diagnose* asthma. PEF is insensitive to airflow limitation, and intra-subject and inter-subject variability is approximately twice that of FEV. Airway obstruction increases airway resistance, which can be measured using plethysmography, a more expensive technique than spirometry and may also give variable results (Enright & Kaminsky 2003).

EFFECTIVENESS AND SAFETY ISSUES

Walters et al (2006) examined the reproducibility and accuracy of results obtained with six EasyOne™ spirometers used in general practice for between 15.1 and 26.6 weeks (mean time 23.9 weeks) (level IV diagnostic evidence). Calibration checks were carried out on the spirometers with a 3-litre calibration syringe with a certified accuracy of ± 0.5

per cent. A total of 1,041 patients were tested using the six spirometers and 75 paired syringes calibrations were performed using both a single dedicated calibration spirette and new spirette randomly chosen. All calibrations met the accuracy criteria for both expiration and inspiration checks (Table 1), however, the mean volumes for both expiration and inspiration were significantly higher ($p<0.001$) when using a random spirette when compared to the dedicated spirette. The authors conclude that this study supports the manufacturers claim that the EasyOne™ does not require calibration (Walters et al 2006).

Table 1 Results of paired calibration checks with dedicated and random spirettes

Dedicated spirette		Random spirette	
Volume deviation from 3-L		Volume deviation from 3-L	
Absolute (mean ± SD)	% (mean ± SD)	Absolute (mean ± SD)	% (mean ± SD)
Expiration	Expiration	Expiration	Expiration
0.011 ± 0.033	0.373 ± 1.11	0.046 ± 0.034	1.523 ± 1.125
Inspiration	Inspiration	Inspiration	Inspiration
-0.036 ± 0.03	-1.209 ± 0.992	0.003 ± 0.039	0.09 ± 1.303

SD = standard deviation

A similar study conducted in five Latin American cities collected calibration data from 70 EasyOne™ spirometers used for a population based survey of COPD (level IV diagnostic evidence). This study reported that 97 per cent of the calibration volumes were within ± 64ml (2.1%) of the 3-litre calibration signal, and that 98% were within ± 50 ml (1.7%) (Perez-Padilla et al 2006).

A study by Liistro et al (2006) compared the ease of use and accuracy of 10 spirometers, including the EasyOne™, which could be routinely used in general practice. These spirometers were compared to standard diagnostic spirometers the Vmax 20C, a flow sensing spirometer, and the Morgan TLC, a volume sensing device (level III-2 diagnostic evidence). Devices were calibrated daily with a 3-litre syringe. All testing was repeated in three laboratories following the same protocol. Pulmonary function tests (PFTs) were performed in healthy non-smoking subjects and COPD patients, with each performing five successive forced expirations, resulting in a within subject standard deviation (Sw). The larger the Sw, the lower the precision of the spirometer. A total of 399 different subjects were studies in the three centres (Liistro et al 2006).

The 95% limits of precision (1.96 x Sw) for forced vital capacity (FVC) in healthy subjects for the EasyOne™ was >200ml at 0.25, but was 0.19 for the forced expiratory volume (FEV), compared to the standard spirometer Sw values of 0.15 and 0.14 respectively. Only two other spirometers had a FVC Sw value higher than that reported for the EasyOne™ (0.34 and 0.43), with the remaining seven spirometers reporting a mean of 0.17 ± 0.016. One spirometer reported a FEV Sw value of 0.29 (limits of precision >200ml) with the remaining nine spirometers (including the EasyOne™) reporting a mean of 0.15 ± 0.03. The EasyOne™ did not return a significant bias from

zero (when compared to standard spirometers) for FVC (0.07 95%CI [0.00, 0.15], limits of agreement[2] -0.43 to 0.57, r= -0.15), or FEV_1/FVC (1.8 95%CI [0.6, 3.0], limits of agreement -6.4 to 10.0, r= -0.26). The EasyOne™ did present with a significant bias ($p<0.01$) for FEV_1, however this remained in the acceptable limit of ≤ 100ml. Note: only one other device presented a significant bias for FVC, four devices for FEV_1 and two devices for FEV_1/FVC. In conclusion, the repeatability of FVC and FEV_1/FVC measurements was good for the EasyOne™, was poorer for FEV_1 measurements but the level of agreement between the EasyOne™ and standard devices was good. The EasyOne™ was found not to be as precise measuring FVC but precision was good measuring FEV_1, when compared to standard spirometers (Liistro et al 2006).

A study by Schoh et al (2002) conducted at a health fair in a community hospital over two days, compared the spirometry results obtained with the EasyOne™ to a standard spirometer, the Vmax. A minimum of three tests were conducted with both the EasyOne™and the Vmax devices. A total of 394 subjects were tested over the two days with the EasyOne™ and although confirmatory testing with the Vmax was offered to all participants, only those with an airflow limitation tended to take up this option. As a result, only 115 participants had a spirometry assessment with both the EasyOne™ and the Vmax. Correlations between the EasyOne™ and the Vmax were good for FEV_1 (r=0.93), and for FEV_6[3] (r= 0.96) and FEV_1/ FEV_6 (r= 0.72) (*p*= 0.001 for all comparisons). The 95% limits of agreement were -0.18 to 0.69 for FEV_1, -0.24 to 0.81 for FEV_6, and -0.12 to 0.13 for FEV_1/FEV_6. The EasyOne™ device was found to slightly underestimate the results of the Vmax which the authors felt was a result of a learning curve effect as the spirometry technicians were well versed in the use of the standard Vmax device (level III-2 diagnostic evidence) (Schoh et al 2002).

COST IMPACT

The EasyOne™ spirometer costs approximately $3,000 (Walters et al 2006).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

CONCLUSION:

Based on the available evidence it appears that the EasyOne™ is a reliable device which is easy to use in a general practitioner setting. Readings from the EasyOne™ correlate well with readings from standard spirometers and the EasyOne™ device has the added

[2] 95% limits of agreement = mean difference between the two spirometers ± 1.96 standard deviations
[3] FEV_6 = forced expiratory volume in the first 6 seconds

advantage of not requiring calibration on a daily basis. The EasyOne™ is portable and may be used in the field, clinic or hospital ward.

HealthPACT action:

The EasyOne™ appears to be an effective tool for the diagnosis of chronic respiratory disease in the general practitioner setting. Although HealthPACT has recommended that further assessment of this technology is no longer warranted, information contained within this summary should be disseminated to inform the clinical community.

Sources of Further Information:

AIHW (2005a). *Asthma in Australia 2005. AIHW Asthma Series 2,* Australian Institute of Health and Welfare, http://www.aihw.gov.au/publications/acm/aia05/aia05.pdf.

AIHW (2005b). *Chronic respiratory diseases in Australia: their prevalence, consequences and prevention.,* Australian Institute of Health and Welfare, http://www.aihw.gov.au/publications/phe/crdapcp/crdapcp.pdf.

Enright, P. L. & Kaminsky, D. A. (2003). 'Strategies for screening for chronic obstructive pulmonary disease', *Respir Care,* 48 (12), 1194-1201; discussion 1201-1193

GOLD executive committee (2006). *Global initiative for chronic obstructive lung disease (GOLD)*, Portland, Oregon,

Liistro, G., Vanwelde, C. et al (2006). 'Technical and functional assessment of 10 office spirometers: A multicenter comparative study', *Chest,* 130 (3), 657-665

Niche Medical (2003). *EasyOne Spirometer* [Internet]. Niche Medical. Available from: http://www.nichemedical.com.au/web/frames/nddTECH_frame.html [Accessed 4th April 2007].

Perez-Padilla, R., Vazquez-Garcia, J. C. et al (2006). 'The long-term stability of portable spirometers used in a multinational study of the prevalence of chronic obstructive pulmonary disease', *Respir Care,* 51 (10), 1167-1171

Schoh, R. J., Fero, L. J. et al (2002). 'Performance of a new screening spirometer at a community health fair', *Respir Care,* 47 (10), 1150-1157

Walters, J. A., Wood-Baker, R. et al (2006). 'Stability of the EasyOne ultrasonic spirometer for use in general practice', *Respirology,* 11 (3), 306-310

Wikipedia (2007). *COPD* [Internet]. Wikipedia. Available from: http://en.wikipedia.org/wiki/COPD [Accessed 5th April 2007].

List of Studies included

Total number of studies	
Level IV diagnostic evidence	2
Level III-2 diagnostic evidence	2

Search Criteria to be used:

Pulmonary Disease, Chronic Obstructive
Spirometry
Bronchospirometry
Forced Expiratory Volume
Respiratory Function Tests
Asthma
Respiratory Tract Diseases