

# Comparison of a New Desktop Spirometer (Diagnosa®) with a Laboratory Spirometer

D.M. Maree E.A. Videler M. Hallauer C.H. Pieper C.T. Bolliger

Lung Unit, Tygerberg Hospital, Department of Internal Medicine, University of Stellenbosch, Cape Town, South Africa

## Key Words

Flow-volume loop · Spirometry · Telemedicine

## Abstract

**Background:** The Diagnosa is a fully integrated system, able to determine spirometry, ECG, blood pressure and body composition. Real time data can be transferred via Internet to a remote receiving center. **Objectives:** The aim of this study was to perform biological testing of the spirometry component in subjects with normal and pathological pulmonary function. **Methods:** A group of 45 patients (mean age 43.3 years, 30 males) was tested on both the Diagnosa and the standard Jaeger Masterlab spirometer according to the guidelines of the American Thoracic Society. Three subgroups of 15 subjects each (normal spirometry, obstructive and restrictive airflow limitation) were selected. **Results:** All measurements performed with the Diagnosa (FVC, FIVC, FEV<sub>1</sub>, PEF, FEF<sub>25</sub>, FEF<sub>50</sub>, FEF<sub>75</sub>) correlated closely ( $r = 0.92–0.99$ ) with those performed with the Jaeger spirometer and showed good limits of agreement (the largest difference between the two devices being 0.2 liter for FEV<sub>1</sub>). Analysis of the 3 subgroups showed no difference for any parameters compared to the overall group. Electronic

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transfer of all data was successful. **Conclusions:** The Diagnosa spirometer is comparable to a standard laboratory spirometer and can be used reliably for telemedicine purposes.

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## Introduction

With the restraints of space in general practitioners' rooms and industrial health clinics, as well as in epidemiology study laboratories, it would be ideal to have some important measurement devices incorporated in one casing. This has been implemented by a new system (Diagnosa; Cyberscope, Cape Town, South Africa) which contains 4 modules for separate measurements of spirometry, electrocardiography, body composition and blood pressure (fig. 1). Its software allows for secure electronic transmission of recorded results, which is ideal for use in telemedicine [1–3]. Many new spirometers are currently being developed and marketed worldwide, and hospital-based pulmonary function laboratories are ideal for biological testing of these apparatuses as these laboratories routinely encounter various types of airflow limitations. The aim of this study was to compare the spirometry component of the Diagnosa to a standard laboratory spirometer (Masterlab 4.0; Jaeger AG, Würzburg, Germany) in a group of patients exhibiting the whole range of flow limitations.

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D.M. Maree  
A5 Laboratory, Department of Internal Medicine  
Tygerberg Hospital, Private Bag X  
Parow 7505 (South Africa)



**Fig. 1.** A patient is shown performing a flow-volume loop manoeuvre with the spirometer of the Diagnosa system.

## Materials and Methods

### Test Device

The spirometry component of the Diagnosa records the flow-volume loop test; the data are digitized by means of a 12-bit analogue-to-digital converter with a sampling speed of 200 Hz. The Diagnosa measures flow rates using an orifice plate pneumotachometer and the flow time curve is processed by a standard desktop computer. The following parameters are derived from the curve: forced inspiratory vital capacity (FIVC), FVC, FEV<sub>1</sub>, FEV<sub>1</sub>/FVC, peak expiratory flow rate (PEF), peak inspiratory flow rate (PIF) and the forced expiratory flows at 25, 50 and 75% of FVC (FEF<sub>25</sub>, FEF<sub>50</sub> and FEF<sub>75</sub>, respectively). FEV<sub>1</sub> is determined by back extrapolation as recommended by the American Thoracic Society (ATS) [5]. The results of the best curve, after all ATS criteria [5] are met, are displayed as an absolute value corrected for BTPS [4] and as a percentage of predicted normal. The program of Diagnosa requests a full calibration every day before any flow time curves can be measured. The testing procedure consists of maneuvers at different flow rates with a calibrated 3-liter calibration syringe.

The Diagnosa has an added feature of transmitting patient data via the Internet from the test site to the patient's general practitioner, treating physician or a respiratory consultant and confidentiality is maintained by removing the patient's identity.

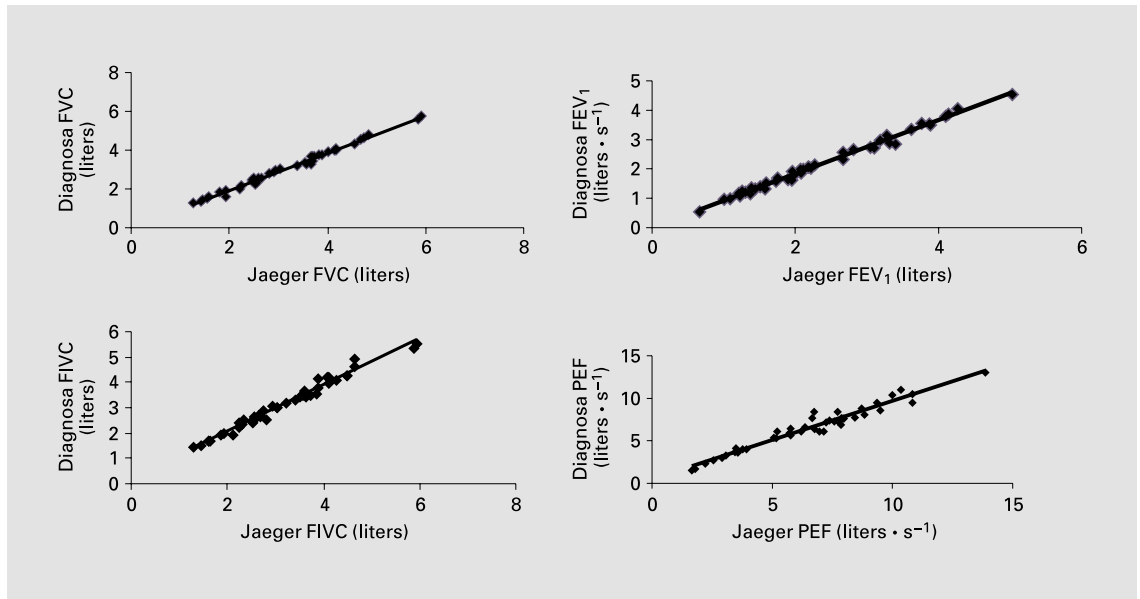
### Patients

Subjects eligible for this study were routine patients from the respiratory out-patient clinic of Tygerberg Hospital, where routine

pulmonary function testing is performed. The device was tested on 45 subjects. These subjects were subdivided into three groups of 15 subjects each (normal spirometry: mean age 35.1 years, range 19–61, 9 males; obstructive airflow limitation (stratified as follows: 9 with chronic obstructive airway disease and 6 with bronchial asthma): mean age 44.7 years, range 19–70, 11 males; restrictive airflow limitation: mean age 50.2 years, range 28–80, 10 males). Subjects were only drafted into the project if they had not previously had any flow-volume determination on any of the two test apparatuses, this eliminated any bias in favor of one of the apparatuses.

### Trial Design

The Diagnosa was compared to a worldwide commercially available standard spirometer, the Jaeger Masterlab 4.0. The Diagnosa used in this study was a standard model with all the extra attachments for the other components of the system. Respiratory technologists tested the subjects according to the guidelines of the ATS [5]. To achieve a balanced design, each subject performed 3 acceptable maneuvers alternatively on each device, making up a total of 6 maneuvers. Each subject randomly selected which spirometer he or she wanted to use first, thereby allowing the learning effect to be evenly distributed between both instruments. All tests had to be sent to the manufacturer via the Internet; the manufacturer immediately returned the results by facsimile, enabling the investigator to verify the accuracy of the system.



**Fig. 2.** Correlation between Diagnosa and Jaeger for: FVC ( $r = 0.99$ ), FEV<sub>1</sub> ( $r = 0.99$ ), FIVC ( $r = 0.99$ ) and PEF ( $r = 0.98$ ) of all 45 subjects. Regression lines are shown.

#### Statistical Analysis

The curves from both devices were assessed for acceptability and reproducibility according to the standards established by the ATS. The best value for the following parameters from all acceptable curves for both devices were compared: FVC, FEV<sub>1</sub>, FIVC and PEF. FEF<sub>25</sub>, FEF<sub>50</sub> and FEF<sub>75</sub> were also compared but from the test with the highest sum of FVC and FEV<sub>1</sub>, on each device.

In order to test whether the measurements of the Diagnosa correlated with those of the Jaeger, the correlation coefficient ( $r$ ) between the data obtained with both apparatuses was calculated. A significance level of  $\alpha < 5\%$  was chosen. The mean of the differences was analyzed using the paired  $t$  test. To further elucidate whether the measurements of both spirometers could be used interchangeably, the mean of the differences between the indices measured by both devices was calculated as described by Bland and Altman [6].

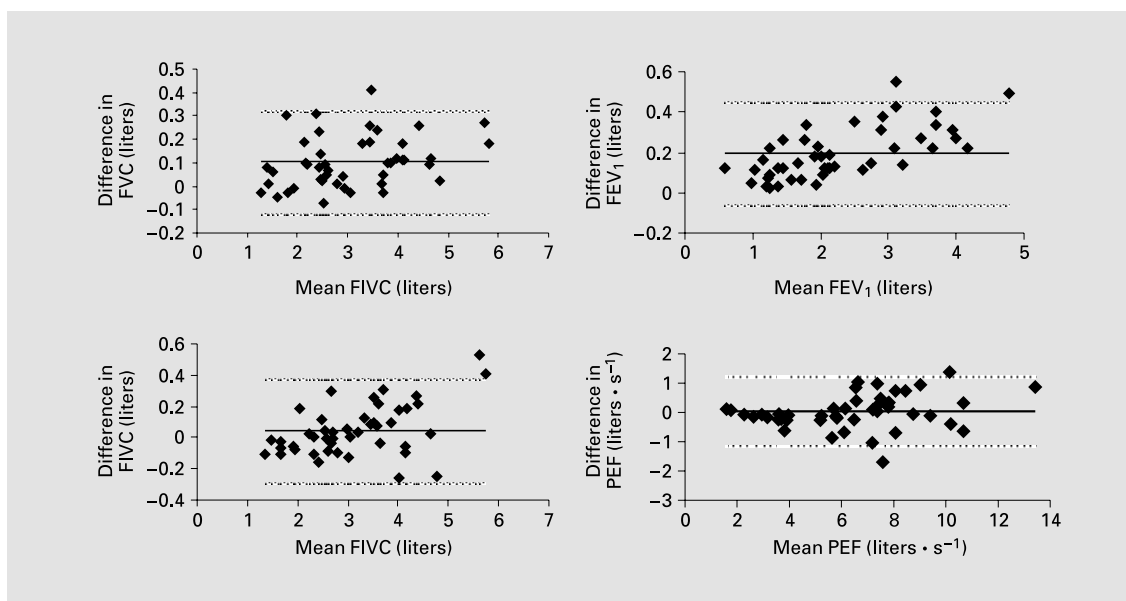
## Results

The Diagnosa was stable with respect to the accuracy of the measurements throughout the day after calibration of the system. All tests recorded met ATS acceptability criteria for both devices. The ATS reproducibility criteria (FEV<sub>1</sub> and FVC of the two best curves of each device differing by  $< 5\%$  or  $< 200$  ml) were met by 37 (82%) of the subjects on the Jaeger and by 39 (87%) subjects on the Diagnosa. The Diagnosa correlated very well with the Jaeger ( $r$  values for all parameters 0.92–0.99) (table 1) for the following parameters: FVC, FEV<sub>1</sub>, FIVC, PEF, FEF<sub>25</sub>,

FEF<sub>50</sub> and FEF<sub>75</sub>. Figure 2 shows the correlation between the Diagnosa and the Jaeger measurements for FVC, FEV<sub>1</sub>, FIVC and PEF for all subjects. Figure 3 shows the plots of the differences between the readings of the two spirometers against their mean, as described by Bland and Altman [6], for FVC, FEV<sub>1</sub>, FIVC and PEF. Analysis of the different subgroups (normal, obstructive and restrictive) for correlation and differences between the readings of the apparatuses did not show worse results for a particular type of airflow limitation in comparison to the overall results. Significant differences between the means were found for FVC, FEV<sub>1</sub>, FEF<sub>25</sub> and FEF<sub>75</sub> using the paired  $t$  test, with all measurements reading higher with the Jaeger, with the exception of PEF and FEF<sub>75</sub> (table 1). All 45 subjects' results were transmitted to the manufacturer via the Internet and immediately returned via facsimile; all 45 results were received without any inaccuracies.

## Discussion

The results of our study show that the Diagnosa spirometer correlated very well with the standard spirometer for all measured parameters. Although the difference between the means (Diagnosa versus Jaeger) was significant for 4 parameters, they were small in absolute values,



**Fig. 3.** Plots of the differences between Diagnosa and Jaeger against their mean for: FVC, FEV<sub>1</sub>, FIVC and PEF. The mean difference (—) and upper and lower limits of agreement ( $\pm 2$  SD; ..... ) are indicated.

**Table 1.** Comparison of measurements between Diagnosa® and a standard spirometer (Jaeger Masterlab 4.0)

Parameters	Diagnosa	Jaeger	Correlation coefficient	Differences <sup>1</sup>	Limits of agreement
FVC, liters	3.02 (1.10)	3.12 (1.40)	0.99	-0.10*	-0.12–0.32
FIVC liters	3.12 (1.02)	3.16 (1.10)	0.99	-0.04	-0.06–0.45
FEV <sub>1</sub> liters	2.17 (0.97)	2.37 (1.06)	0.99	-0.20*	-0.29–0.38
PEF, liters·s <sup>-1</sup>	6.44 (2.56)	6.47 (2.72)	0.98	-0.03	-1.15–1.21
FEF <sub>25</sub> , liters·s <sup>-1</sup>	4.94 (2.47)	5.16 (2.73)	0.98	-0.12*	-0.87–1.30
FEF <sub>50</sub> , liters·s <sup>-1</sup>	2.73 (1.53)	2.82 (1.76)	0.96	-0.09	-0.92–1.11
FEF <sub>75</sub> , liters·s <sup>-1</sup>	0.99 (0.69)	0.87 (0.73)	0.92	0.12*	-0.70–0.48

All data are presented as mean  $\pm$  SD (in parentheses).

<sup>1</sup> Mean Diagnosa reading – mean Jaeger reading. \*  $p < 0.05$  (paired t test).

the largest being 0.2 liter for FEV<sub>1</sub>. This difference is acceptable for clinical practice, all the more so that the real value of the measurement lies somewhere between the 2 measurements. Furthermore, analysis of the limits of agreement for all 7 parameters showed that only 2 out of 45 (4%) measurements lay outside 2 standard deviations, which is generally accepted as a criterion of good agreement.

The Diagnosa was also tested for its reliability in electronically transmitting the test results via the Internet

from the test site to the manufacturer's offices. Additionally, the capability of Diagnosa of storing and transmitting secure patient results is useful in clinical trials and epidemiological studies.

In an industrial medicine setting or in epidemiological surveys, measurement of flow-volume loops on site is expected to produce superior data to the often-prescribed and unsupervised use of PEF measurements, which have been shown to be unreliable [7, 8]. Another spirometer with telemedicine features, which we tested previously,

was different in its concept in that the device was handed out to individuals who would directly report to a remote receiving center [3, 9]. The Diagnosa as a multifunctional unit is designed for use in a general practice or industrial set-up. The data would be screened and secondarily transmitted by the practice personnel and not by the patient.

In conclusion, the Diagnosa is deemed comparable to standard laboratory spirometry for the determination of forced flow-volume curves in clinical practice. The quality of the results can be assessed on location in real time and where required, expert advice can be sought immediately via the Internet.

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