

Assessment of the AirWatch lung function monitoring system

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Home monitoring of lung function in asthmatic patients is used extensively in both clinical and research settings¹⁻⁶; however, little attention is given to device quality control. We describe the relative accuracy, preci-

Abbreviations used

ACRN: Asthma Clinical Research Network
AW: AirWatch
IQR: Interquartile range
MRB: Median relative bias
PEF: Peak expiratory flow

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sion, and durability of a new device, the AirWatch (AW) system, by using a modified calibrating method.⁷

METHODS

Accuracy is defined by the median relative bias (MRB), with the initial acceptable range of $\pm 15\%$ and repeat testing within $\pm 5\%$ of the initial value.⁷ Precision is defined by the interquartile range (IQR), with the initial acceptable range less than 10% and repeat testing less than 5% greater than the initial value.⁷

Different peak expiratory flow (PEF) rates were created by 12 compressions of a Jones calibrating syringe connected in series to a pneumotachograph (standard) and 12 separate AW devices (Fig 1). This allowed for simultaneous recorded measurements of PEF and calculation of accuracy and precision. For FEV₁ accuracy and precision, each of the 20 AW devices was placed in an airtight chamber in series between a spirometer and 3 different sources of flow generation: the Jones syringe, a 4-L syringe, and a wave form generator.

AW durability was assessed by determining the MRB and IQR for 5 different flow rates at each of 6 clinic visits over a 10-week

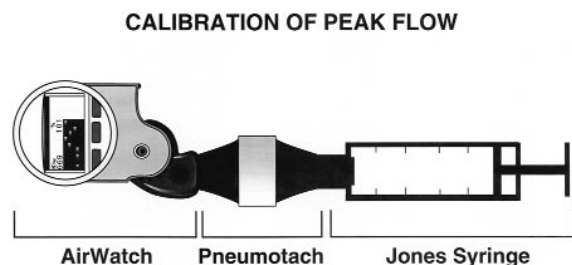


FIG 1. AW system PEF was calibrated against the pneumotachograph ("gold standard") and Jones calibrating syringe in series as shown (not drawn to scale).

period in the 71 subjects enrolled in a clinical trial.⁸ Only PEF was evaluated in this trial.

Because the AW may fail because of electronic problems with the housing case or the mouthpiece-rotor measuring component, the following steps were used to identify the underlying mechanism. If the MRB and IQR criteria were not met, the mouthpiece-rotor unit was replaced. If the criteria were then met, the initial mouthpiece-rotor system was deemed to have failed. If the criteria were still not met, a final test was performed with another mouthpiece before deciding the storage unit had failed.

RESULTS

There was a high degree of PEF correlation between the pneumotachograph and Jones calibrating syringe ($r = 0.98$ [95% CI, 0.96, 0.99]), the AW and pneumotachograph ($r = 0.98$ [95% CI, 0.95, 0.99]), and the AW and Jones syringe ($r = 0.97$ [95% CI, 0.93, 0.99]). Similarly, there was an excellent correlation between the spirometer and AW FEV₁, combining the 3 sources of flow ($r = 0.98$ [95% CI, 0.95, 0.98]). Individually, the AW correlation was as follows: versus Jones syringe, $r = 0.92$ (95% CI, 0.85, 0.96); versus wave form generator, $r = 0.75$ (95% CI, 0.62, 0.89); and versus the calibrating syringe, $r = 0.40$ (95% CI, 0.24, 0.56).

The range for the PEF MRB was -17.0% to $+0.8\%$. One device fell outside the acceptable range. The PEF IQR had 3 devices outside the acceptable range at 12%, 13%, and 16%. The range of the FEV₁ MRB was -13.5% to $+7.9\%$. Two devices fell outside the acceptable range (IQR of 17.9% and 11.1%), but failure was only at higher flows from the wave form generator.

For the 71 subjects, 101 AW units were used. Seventeen units were immediately recalled because of possible electronic problems. Four additional units were replaced for unknown reasons but not because of accuracy or precision failure. Therefore a total of 80 AW units were evaluated for durability.

Table I demonstrates the number (%) of AW units that failed during field testing. Seven mouthpiece-rotor components were replaced because of quality control failure. However, another 11 component failures were later identified by retrospective forms review. Therefore a total of 18 mouthpiece-rotor components (20.7%) failed. Seventeen failed accuracy standards (10 below and 7 above the defined range), and 1 failed precision

TABLE I. Failures of the AW monitoring system

Mouthpiece/rotor	18 (20.7%)
Electronic housing device	
Display	5 (6.25%)
Low battery	1 (1.25%)
Data recording/uploading	2 (2.50%)
Dead unit	1 (1.25%)
Total	9 (11.25%)

standards. The number of weeks from issuance to failure varied.

DISCUSSION

In a previous publication⁷ we described a technique to measure the accuracy, precision, and durability of peak flow meters. This is important for clinical trials and patient care because interpretations of clinical status and adjustment of therapy are based on portable measurements. Indeed, we previously found that the MiniWright peak flow meter had a field trial failure rate of 20%, mainly because of loss of accuracy.⁸

In this study the AW PEF correlated well to the pneumotachograph and Jones calibrating syringe. In addition, there was good FEV₁ correlation between the AW and spirometer. On repeated clinical trial assessment, a failure rate of 20.7% of the mouthpiece-rotor component occurred. Although there was an 11.25% failure rate of the electronic housing device, this was easily detected by the subject.

Our present study reinforces the need for interim quality control measures of home lung function measuring devices. Nonetheless, the potential benefits of the AW system, specifically its capability for date/time electronic storage and rapid retrieval of PEF and FEV₁, as well as its high patient acceptability, make it an important addition to home monitoring of respiratory disease.

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