

**[2365] Spirometry quality control - documentation of random variability**

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One of two pneumotachograph spirometers, in repeated use during a single day's testing of subjects in the field, appeared to have some drift in readings during testing. No change in temperature had occurred. As the machines were new, the company was contacted. It was suggested that: a) The flow head may not have been at ambient temperature when calibrated

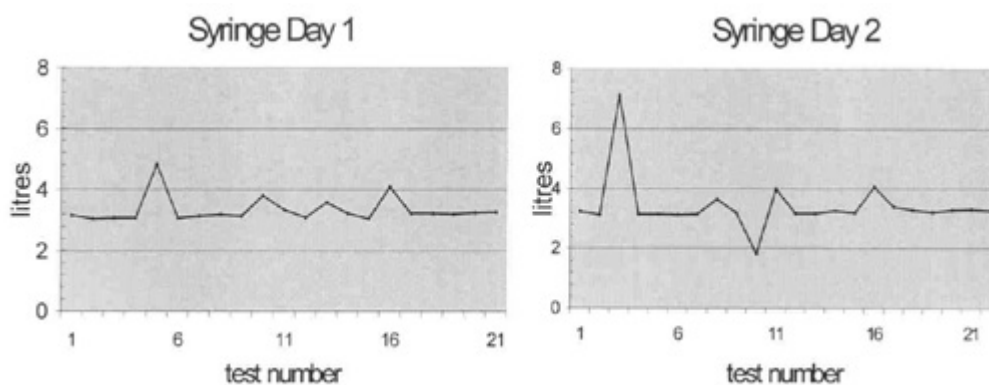
b) The head required drying after every 10 blows

A two day study was instigated to investigate the problem.

Day 1. Four subjects underwent spirometric testing more than 20 times each under constant conditions. On each occasion, the subject performed three blows. Testing was according to ARTP protocols, excepting the highest result was recorded whether or not it was within 100 mL of the nearest blow. A single operator used a 3L syringe as a regular verification.

Day 2. The procedure was repeated with the spirometer head being dried in between each subject/syringe. (Click to see figure 1) Results demonstrated unacceptable variability for both syringe and subjects on both days. This variability appeared randomly and independently distributed throughout the course of testing.

Drying had thus not solved the problem. The study demonstrates the importance of careful monitoring of quality control mechanisms for individual spirometers.



Figure