Should spirometer quality control be treated like other laboratory devices?

To the Editor:

Spirometry plays an important role in the diagnosis and management of obstructive and restrictive lung disease [1–4]. To help ensure the accuracy of spirometry testing the American Thoracic Society (ATS)/European Respiratory Society (ERS) recommend that the calibration of spirometers be verified daily with a 3-L syringe and the recorded value should be $3\text{ L} \pm 3.5\%$ [5]. This recommendation is based on expert opinion, not evidence. The following case describes a situation where a significant spirometer malfunction was not detected by the ATS/ERS spirometer calibration limits and offers an alternative approach to spirometer quality control.

Calibration verification of a pressure differential pneumotach with a 3-L calibration syringe produced a value of 3.07 L. This reading falls within the ATS/ERS range of acceptability (2.90–3.10 L), but is historically an unusual reading for this device. Closer inspection of the pneumotach performance including repeat calibration verification, which included pauses between strokes, revealed a positive zero-flow error [6]. A positive zero-flow error can falsely elevate spirometry indices and preclude the achievement of end-of-test criteria [5, 6].

Following this incident, spirometer calibration data from the preceding 6 weeks was used to create a Levey–Jennings chart displaying the $\text{mean} \pm 2\text{SD}$ calibration value (figure 1). Plotting the 3.07 L calibration value showed that the reading was nearly 6SD away from the mean value for this device, while still satisfying the ATS/ERS quality control standard. Using the $\text{mean} \pm 2\text{SD}$ as a quality control range is common in laboratory medicine, but not in pulmonary function laboratories. A value outside of these limits is an unusual finding for a properly functioning analyser and should prompt close inspection and troubleshooting of the device. Indeed, in this case using the $\text{mean} \pm 2\text{SD}$ was sensitive to a significant positive zero-flow error where the ATS/ERS recommended range was not. We believe that the performance of modern spirometers allows for tighter calibration ranges [7], including the use of $\text{mean} \pm 2\text{SD}$. For example, one approach would be stipulating that the mean calibration value should be $3\text{ L} \pm 1.5\%$ (2.95–3.05 L) for accuracy and the 2SD range should not produce a coefficient of variation $>3\%$ for precision. Spirometer calibration limits could be established by the manufacturer and integrated into the software for each model such that continuous statistics for every calibration are recorded. Alternatively, the software could determine calibration limits for each individual device after clinical testing has begun. Measurements used to calculate the mean and SD of spirometer performance should be carried out on different days. If the pneumotach uses single patient use flow sensors, a different sensor should be used for each calibration. If the precision of a device is too narrow to use SD ranges, a fixed error tighter than the current 3.5% should be used. Calibration limits based on performance rather than fixed arbitrary values may provide better quality control of spirometer devices.

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The ATS/ERS spirometer calibration standards may not be adequate <http://ow.ly/Pqdq30nwAmb>

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FIGURE 1 Spirometer calibration data plotted as a Levey-Jennings graph. The final datapoint was the product of a positive zero-flow error. Mean $\pm$ SD value: 2.98 $\pm$ 0.02 L. ATPS: ambient temperature and pressure saturated with water vapour; ATS/ERS: American Thoracic Society/European Respiratory Society calibration limits.

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