

TEST REPORT

Device: Vitalograph COPD-6

Testing dates: April 2, 2008

Present: LDS Hospital

Heather Gallo

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Vitalograph

Phil Hemes

Dynamic Wave Form Testing

Dynamic testing was performed using standards published by the American Thoracic Society (Crapo RO, Chair. Standardization of spirometry: 1994 Update. Official Statement of the American Thoracic Society. Am J Respir Crit Care Med 1995; 152:1107-1136) using a computer driven spirometry simulator. The standards used were those for diagnostic devices. For forced vital capacity (FVC), forced expired volume in one second (FEV₁), and FEF_{25-75%}, the 24 standard volume-time waveforms were used. For peak flow (PEF), the 26 standard flow-time forms were used. Each waveform was delivered into the device five times. Mean values were used to score performance.

The COPD-6 records FEV₆ and FEV₁.

Dynamic waveform testing results

Forced Expired Volume in six seconds (FEV₆):

Standard: The acceptable performance criteria for accuracy are deviation from target $\pm 3\%$ or ± 0.050 liters, whichever is greater with no more than one error. The criteria were increased to $\pm 3.5\%$ or 0.100 liters to account for the estimated inaccuracy and imprecision of the waveform generator.

Precision testing: Only intra-device testing is required for diagnostic devices. The criteria for acceptable performance are that, for each waveform, the range of values must be less than 0.10 liters or range (%) less than 3.5% with no more than one error.

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Results: See the attached data sheets.

Accuracy: The average deviation from target, calculated as the value measured by the spirometer minus the ATS target value, is -0.03 liters (-1.21%). Two errors were observed.

Precision: The average range was 0.04 liters (1.44%). One error was observed.

Summary: The Vitalograph COPD-6 meets ATS recommendations for accuracy and precision in the measurement of FEV₆.

Forced expired volume in one second (FEV₁):

Standard: The acceptable performance criteria for accuracy are deviation from target $\pm 3\%$ or ± 0.05 liters, whichever is greater with no more than one error. The criteria were increased to $\pm 3.5\%$ or 0.100 liters to account for the estimated inaccuracy and imprecision of the waveform generator.

Precision testing: Only intra-device testing is required for diagnostic devices. The criteria for acceptable performance are that, for each waveform, the range of values must be less than 0.10 liters or range (%) less than 3.5%. With no more than one error.

Results: See attached data sheets.

Accuracy: The average deviation from target was 0.04 liters (0.93 %). No errors were observed.

Precision: The average range was 0.03 liters (1.29%). No errors were observed.

Summary: The Vitalograph COPD-6 meets ATS recommendations for accuracy and precision in the measurement of FEV₁.

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OVERALL SUMMARY

The Vitalograph COPD-6 meets ATS recommendations for accuracy and precision in measuring FEV6 and FEV1 under ambient conditions.

The testing done in the LDS Hospital laboratory uses criteria published by the American Thoracic Society. Meeting the criteria does not imply endorsement or acceptance by the ATS.

Sincerely yours,



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