

TEST REPORT

Device: Cosmed Pony FX
Testing dates: August 24, 2004
Present: LDS Hospital
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Dynamic Waveform 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 waveforms were used. Each waveform was delivered into the device five times. Mean values were used to score performance. A temperature adjustment was made to correct measured values to ambient conditions.

Dynamic waveform testing results

Forced Vital Capacity (FVC):

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.

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 0.034 liters (1.00%). One error was observed (Waveform 3).

Precision: The average range was 0.03 liters (0.80%). One error was observed (Waveform 19).

Summary: The Cosmed Pony FX meets ATS recommendations for accuracy and precision in measuring FVC.

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Results: See the attached data sheets. Only the 26 standard flow-time waveforms were scored. The data sheet with results for the 24 standard volume-time waveforms is included for your information only.

Accuracy: The average deviation from target was -0.014 liters/sec (-0.75%). No errors were observed.

Precision: The average range was 0.03 liters/sec (0.53%). No errors were observed.

Summary: The Cosmed Pony FX meets ATS recommendations on accuracy and precision in measuring peak flow on the 26 standard flow-time waveforms.

Human Subject Testing

Standard: Measurements of FVC, FEV1 and peak flow from the test spirometer are compared to those from a standard spirometer in two human subjects. The largest of three trials on each spirometer is used for comparisons. For FVC and FEV1, the differences must be within 6% or 200 ml, whichever is larger. For peak flow, the differences must be less than 15% or 0.5 liters/second, whichever is larger. No errors are allowed.

Method: Two healthy subjects were tested on two devices: a validated flow based spirometer and on the Cosmed Pony FX. Each subject blew three times into each spirometer, alternating spirometers with each blow. One subject began blowing into the Cosmed Pony FX, the other into the "standard" spirometer.

Results: See attached data sheets. For FVC and FEV1, the largest absolute difference observed was 0.27 liters and the largest percent difference was 5.67%. No errors were observed for FVC or FEV1. For peak flow, the largest absolute difference observed was 0.71 liters/second and the largest percent difference was 5.91%. No errors were observed.

Summary: The Cosmed Pony FX meets ATS criteria for human testing for FVC, FEV1, and peak flow.

BTPS Testing

Standard: The ATS recommendations require waveforms 1-4 of the 24 standard waveforms be injected with heated (temp 37 °C ±1 °C), humidified air. Three trials are made and the average used for scoring. Only FVC and FEV1 are scored. Comparisons are made with the ATS target values. Acceptable accuracy is defined as ±4.5% or 200 ml; no errors are allowed. Peak Flows are reported for your information only.

Method: Heated humidified air (36.8°C; relative humidity 93.9%) was injected into the Cosmed Pony FX. Three injections each of waveforms 1, 2, 3, and 4 were made. Average measured values were compared to ATS target values.

Results: See attached data sheet. The average deviation from target for FVC was -0.044 liters (-0.80%). No errors were observed in the measurement of FVC. For FEV1, the average

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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 -0.005 liters (-0.15%). No errors were observed.

Precision: The average range was 0.01 liters (0.49%). No errors were observed.

Summary: The Cosmed Pony FX meets ATS recommendations for accuracy and precision in measuring FEV₁.

Midflows (FEF_{25-75%} or MMEF)

Standard: The criteria for accuracy are $\pm 5.5\%$ or ± 0.250 liters/sec of target value, with no more than one error.

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 0.250 liters/sec or range(%) less than 5.5% with no more than one error.

Results: See attached data sheets

Accuracy: The average deviation from target was -0.085 liters/sec (-3.84%). No errors were observed.

Precision: The average range was 0.06 liters/sec (3.39%). One error was observed (Waveform 19).

Summary: The Cosmed Pony FX meets ATS recommendations for accuracy and precision in measuring FEF_{25-75%}.

Peak Flow (PEF):

Standard: The criteria for accuracy are ± 25 liters/minute (0.42 liters/second) or $\pm 12\%$ with no more than one error.

Precision Testing: The ATS standards do not specifically address intra-device precision testing for peak flow measured by diagnostic devices. We therefore chose the inter-device criteria applied to peak flow meters. Specifically, range must be within 25 liters/minute (0.42 liters/second) or range (%) must be within 12% , whichever is larger. One error is allowed.

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deviation from target was -0.016 liters (-0.21%). No errors were observed in the measurement FEV1. The average deviation for PEF was 0.012 L/sec (-0.11%).

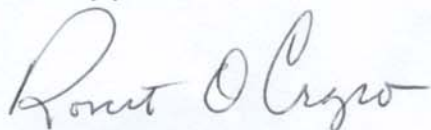
Summary: The Cosmed Pony FX meets ATS recommendations for accuracy under BTPS conditions.

OVERALL SUMMARY

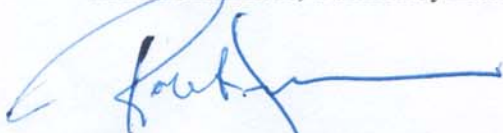
The Cosmed Pony FX meets ATS recommendations for accuracy and precision in measuring FVC, FEV1, FEF25-75%, and peak expiratory flow under ambient and BTPS conditions.

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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