



TEST REPORT

Devices: Vitalograph 2120 Spirometer
With revised BTPS software
Testing dates: 15 July 1997
Present: LDS Hospital
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Dynamic Wave Form Testing

Dynamic testing was performed by injecting each of the 24 standard wave forms recommended 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. Each wave form was delivered into the device five times and the average value was used to score spirometer performance. The spirometry simulator and computer algorithm have been improved; the target values we use represent our best estimate of the actual flow delivered by the simulator.

Forced Vital Capacity:

Standard: The acceptable performance criteria for accuracy are deviation from target $\pm 3.5\%$ or ± 100 ml, whichever is greater with no more than one error. For precision testing, the range of values for each wave form must be within $\pm 3.5\%$ or 100 ml, whichever is greater; one error is allowed.

Results: See the attached data sheets.

Accuracy: The average deviation from target, calculated as value measured by the spirometer minus ATS target value, was +0.003 liters (+0.10%). No errors were observed in measuring any of the 24 standard wave forms.

Precision: The average range was 0.06 liters (1.87%). No precision errors were observed.

Summary: The Vitalograph 2120 spirometer meets ATS recommendations for accuracy and precision in measuring vital capacity.

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Forced expired volume in one second (FEV1):

Standard: The acceptable performance criteria for accuracy are deviation from target $\pm 3.5\%$ or ± 100 ml, whichever is greater with no more than one error. For precision testing, the range of values for each wave form must be within $\pm 3.5\%$ or 100 ml, whichever is greater; one error is allowed.

Results: see attached data sheets

Accuracy: The average deviation from target was +0.033 liters (+1.29%). No errors were observed in measuring FEV1

Precision: The average range was 0.01 liters (0.52%). No precision errors were observed.

Summary: The Vitalograph 2120 spirometer meets ATS recommendations for accuracy and precision in measuring FEV1.

Midflows (FEF25-75%):

Standard: The criteria for accuracy are $\pm 5.5\%$ or 0.250 liters/second of target value, with no more than one error. For precision, the criteria are range must be within $\pm 5.5\%$ or 0.250 liters/second with no more than one error.

Results: see attached data sheets

Accuracy: The mean deviation from target was +0.002 l/sec (+0.588%). No errors were observed in measuring FEF25-75%.

Precision: The average range was 0.06 liters/second (3.2%). No precision errors were observed.

Summary: The Vitalograph 2120 spirometer meets ATS recommendations for accuracy and precision in measuring FEF25-75%.

Peak Flow

Standard: There are no specific recommendations for accuracy in measuring peak flow using the 24 standard wave forms. The information provided here is for your information.

Results: See attached data sheets.

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Accuracy: The PEF average deviation from target was +23.43 liters/minute (+7.23%). No errors were observed.

Summary: The Vitalograph 2120 spirometer measures peak flows slightly higher than the target flow in the 24 standard wave forms. The reason for this is most likely that the ATS wave forms use a 80 msec average technique for estimating FEV₁ while most newer instruments use either instantaneous peak flow or a 40 msec averaging, both of these techniques will result in slightly higher estimates of peak flow.

Dynamic Testing of Peak Flow using the 26 Flow Time Wave Forms

Dynamic testing was performed by injecting 26 standard wave forms recommended by the American thoracic society for assessing peak expiratory flow (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. Each wave form was delivered into the device five times and the average value was used to score spirometer performance. The target value reported is that of the instantaneously measured peak expiratory flow.

Accuracy and precision were scored using instantaneous peak flows calculated by piston displacement as our best estimate of target peak flow.

Peak Flow (PEF) using 26 standard flow time wave forms

Standard: The acceptable performance criteria for accuracy are average deviation from target $\pm 12\%$ or ± 25 liters/minute (± 0.42 liters/second) whichever is larger with less than three errors. For intradevice precision testing, the criteria require the average of values for each wave form to be within $\pm 6\%$ or ± 15 liters/minute (0.25 liters/second) whichever is greater. A 5% error rate (2 errors) is allowed. The ATS recommendations do not include a specific technique for measuring precision in peak flow on the 26 standard wave forms when a single spirometer is being tested. We used the general ATS guidelines for accuracy and precision (5% error rate).

Results: See attached data sheets (PEF Results - ATS 26 Standard Wave Forms)

Accuracy: The average deviation from target was +15.22 liters/minute (+4.39%). No errors were observed in measuring the 26 standard wave forms.

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Precision: The average range was 2.8 liters/minute (0.73%). No errors in precision were observed.

Summary: The Vitalograph 2120 spirometer meets ATS recommendations for accuracy and precision in measuring peak flow on the 26 flow time wave forms.

BTPS TESTING

Standard: *The ATS recommendations require wave forms 1-4 of the 24 standard waveforms be injected with heated (temp $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$) humidified air. Three trials are made and the average used for scoring. Comparisons are made with the ATS target values. Acceptable accuracy is defined as $\pm 4.5\%$ or 200 ml; no errors are allowed.*

Method: Using headed humidified air, wave forms 1-4 were each injected five times into the spirometer; the average was used for comparison.

Results: See attached data sheets (BTPS Testing)

FVC: The average deviation from target was -0.049 liters (-0.73%). No errors were observed in the measurement of FVC at BTPS conditions.

FEV₁: The average deviation from target was -0.042 liters (-0.88%). No errors were observed in the measurement of FEV₁ under BTPS conditions.

Peak Expiratory Flow: The average deviation from target was -0.5 liters/minute (+0.332%). No errors were observed in measuring peak flow under BTPS conditions.

RESISTANCE TESTING

Standard: *Instrument resistance should be less than 1.5 cm H₂O/liter/second.*

Method: Continuous flows of 10, 12 and 14 liters/second were put through the flow sensor three times each. Average pressures were used to calculate resistance.

Results: See attached data sheets. Resistance measured at 14 liters/second was 0.71 cm H₂O/L/sec.

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Summary: The Vitalograph 2120 spirometer meets ATS criteria for resistance testing.

HUMAN TESTING

Standard: The difference between the largest values measured in three trials for each subject for each device should be within $\pm 6\%$ or 200 ml, whichever is greater, for FVC and FEV₁ and within 15% or 30 L/minute, whichever is greater, for PEF.

Method: Two healthy human subjects performed three maneuvers alternating between the standard spirometer and the Vitalograph 2120. One began with the standard spirometer, the other with the Vitalograph 2120. Each subjects performed three maneuvers on each device.

Results: See attached data sheets.

Summary: The Vitalograph 2120 meets ATS criteria for testing with healthy human subjects.

OVERALL SUMMARY

The Vitalograph 2120 meets recommendations for accuracy and reproducibility in measuring spirometric parameters on both the 24 and 26 standard wave forms and meets ATS resistance and comparability standards using healthy human subjects.

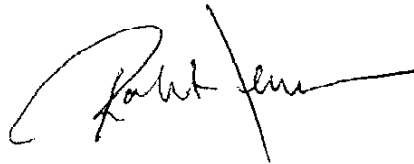
Testing done at the LDS Hospital measures devices against recommendations published by the American Thoracic Society. It does not imply an endorsement or certification by the ATS.

We appreciate the opportunity of working with you on this testing. If you have questions, please do not hesitate to ask.

Sincerely yours,



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