



# Intermountain LDS Hospital

8th Avenue and C Street  
Salt Lake City, Utah 84143  
(801) 408-1100

## TEST REPORT

Device: Vitalograph COPD-6

Testing dates: April 2, 2008

Present: LDS Hospital  
Heather Gallo  
Robert O. Crapo, M.D.  
Robert L. Jensen, Ph.D.  
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 (FEV<sub>1</sub>), and FEF<sub>25-75%</sub>, 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 FEV<sub>6</sub> and FEV<sub>1</sub>.

### **Dynamic waveform testing results**

#### **Forced Expired Volume in six seconds (FEV<sub>6</sub>):**

*Standard: The acceptable performance criteria for accuracy are deviation from target  $\pm 3\%$  or  $\pm 0.050$  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 FEV<sub>6</sub>.

**Forced expired volume in one second (FEV<sub>1</sub>):**

*Standard: The acceptable performance criteria for accuracy are deviation from target  $\pm 3\%$  or  $\pm 0.05$  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 FEV<sub>1</sub>.

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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,



Robert O. Crapo, M.D.  
Medical Director, Pulmonary Laboratory



Robert L. Jensen, Ph.D.  
Biophysicist, Pulmonary Laboratory

Telephone: 801-408-1610  
FAX: 801-408-1671  
E-mail: [ldrcrapo@ihc.com](mailto:ldrcrapo@ihc.com)



### Vitalograph COPD-6

### FEV6 Results- ATS 24 Standard Waveforms

Testing date: 04/02/2008

Waveform number	Target Value	Measured FVC Trial 1	Measured FVC Trial 2	Measured FVC Trial 3	Measured FVC Trial 4	Measured FVC Trial 5	Mean FVC	FVC Range	FVC Range %	Deviation From Target	Deviation % from Target
1	6.001	6.03	6.05	6.04	6.05	6.03	6.040	0.02	0.331	0.039	0.650
2	4.989	5.07	5.07	5.04	5.05	5.03	5.052	0.04	0.792	0.063	1.263
3	3.227	3.17	3.17	3.16	3.16	3.14	3.160	0.03	0.949	-0.067	-2.076
4	1.494	1.51	1.52	1.51	1.51	1.41	1.492	0.11	7.373	-0.002	-0.134
5	4.984	4.94	4.98	4.95	4.97	4.94	4.956	0.04	0.807	-0.028	-0.562
6	3.724	3.58	3.59	3.64	3.62	3.59	3.604	0.06	1.665	-0.120	-3.222
7	3.151	3.17	3.18	3.16	3.19	3.19	3.178	0.03	0.944	0.027	0.857
8	1.993	1.89	1.89	1.88	1.86	1.88	1.880	0.03	1.596	0.113	-5.670
9	4.84	4.88	4.88	4.87	4.87	4.85	4.870	0.03	0.616	0.030	0.620
10	3.795	3.75	3.73	3.72	3.75	3.73	3.736	0.03	0.803	-0.059	-1.555
11	2.701	2.66	2.63	2.64	2.61	2.65	2.638	0.05	1.895	-0.063	-2.332
12	1.991	1.89	1.89	1.86	1.88	1.91	1.886	0.05	2.651	-0.105	-5.274
13	4.888	4.88	4.89	4.87	4.87	4.88	4.878	0.02	0.410	-0.010	-0.205
14	3.677	3.66	3.64	3.65	3.65	3.70	3.660	0.06	1.639	-0.017	-0.462
15	5.936	5.98	5.99	5.93	5.97	5.98	5.970	0.06	1.005	0.034	0.573
16	5.454	5.52	5.52	5.52	5.53	5.53	5.524	0.01	0.181	0.070	1.283
17	5.085	4.94	4.97	4.96	4.96	4.97	4.960	0.03	0.605	-0.125	-2.458
18	4.272	4.23	4.23	4.26	4.21	4.27	4.240	0.06	1.415	-0.032	-0.749
19	3.543	3.44	3.47	3.45	3.46	3.46	3.456	0.03	0.868	-0.087	-2.456
20	2.871	2.91	2.93	2.91	2.92	2.90	2.914	0.03	1.030	0.043	1.498
21	4.433	4.40	4.36	4.38	4.39	4.43	4.392	0.07	1.594	-0.041	-0.925
22	3.62	3.64	3.63	3.64	3.60	3.64	3.630	0.04	1.102	0.010	0.276
23	3.075	2.92	3	2.97	2.98	2.98	2.970	0.08	2.694	-0.105	-3.415
24	1.229	1.18	1.17	1.18	1.18	1.16	1.174	0.02	1.704	-0.055	-4.475
<b>Averages</b>							<b>0.04</b>	<b>1.44</b>	<b>-0.03</b>	<b>-1.21</b>	

#### Acceptable Performance Criteria

Accuracy: Deviation from Target +/- 3.5% or +/- 0.100 liters, whichever is greater

Testing was performed using guidelines from the American Thoracic Society's "Standardization of Spirometry" 1994 update.