



Intermountain LDS Hospital

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TEST REPORT

Device: Vitalograph Asma-1

Testing date: 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 Asma-1 device records FEV₁ and PEF.

Dynamic waveform testing results

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 wave form 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 attached data sheets.

Accuracy: The average deviation from target was 0.03 liters (0.81%). No errors were observed.

Precision: The average range was 0.03 liters (1.17%). No errors were observed.

Summary: The Vitalograph Asma-1 meets ATS recommendations for accuracy and precision in the measurement of FEV₁.

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 11%, whichever is larger. One error is allowed.

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 0.475 liters/min (-0.77%). One error was observed.

Precision: The average range was 4.31 liters/min (1.15%). No errors were observed.

Summary: The Vitalograph Asma-1 meets ATS recommendations for accuracy and precision in the measurement of peak flow on the 26 standard flow-time waveforms.

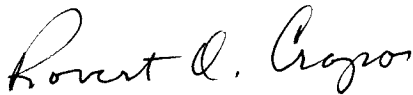
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OVERALL SUMMARY

The Vitalograph Asma-1 meets ATS recommendations for accuracy and precision in measuring FEV₁ and PEF 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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Vitalograph Asma-1

Testing date: 04-02-2008

FEV1 Results- ATS 24 Standard Waveforms

Waveform number	Target Value	Measured FEV1 Trial 1	Measured FEV1 Trial 2	Measured FEV1 Trial 3	Measured FEV1 Trial 4	Measured FEV1 Trial 5	Mean FEV1	FEV1 Range	FEV1 Range %	Deviation From Target	Deviation % from Target
1	4.396	4.48	4.49	4.48	4.47	4.50	4.484	0.03	0.669	0.088	2.002
2	4.591	4.71	4.71	4.59	4.63	4.71	4.67	0.12	2.570	0.079	1.721
3	1.271	1.27	1.28	1.27	1.27	1.27	1.272	0.01	0.786	0.001	0.079
4	1.387	1.42	1.44	1.44	1.45	1.46	1.442	0.04	2.774	0.055	3.965
5	3.857	3.91	3.91	3.92	3.89	3.91	3.908	0.03	0.768	0.051	1.322
6	3.026	3.03	3.05	3.02	3.02	3.02	3.028	0.03	0.991	0.002	0.066
7	2.502	2.52	2.53	2.51	2.52	2.50	2.516	0.03	1.192	0.014	0.560
8	1.613	1.64	1.63	1.65	1.64	1.65	1.642	0.02	1.218	0.029	1.798
9	3.760	3.84	3.80	3.84	3.84	3.84	3.832	0.04	1.044	0.072	1.915
10	3.021	3.01	3.01	3.01	3.01	3.01	3.01	0.00	0.000	-0.011	-0.364
11	1.784	1.76	1.74	1.76	1.77	1.75	1.756	0.03	1.708	-0.028	-1.570
12	1.611	1.62	1.61	1.61	1.61	1.62	1.614	0.01	0.620	0.003	0.186
13	3.826	3.86	3.88	3.86	3.87	3.87	3.868	0.02	0.517	0.042	1.098
14	3.051	3.03	3.04	3.03	3.04	3.03	3.034	0.01	0.330	-0.017	-0.557
15	5.303	5.42	5.43	5.39	5.42	5.42	5.416	0.04	0.739	0.113	2.131
16	3.896	3.96	3.96	3.95	3.85	3.92	3.928	0.11	2.800	0.032	0.821
17	2.597	2.58	2.58	2.59	2.58	2.54	2.574	0.05	1.943	-0.023	-0.886
18	3.117	3.11	3.15	3.14	3.11	3.15	3.132	0.04	1.277	0.015	0.481
19	2.505	2.53	2.53	2.54	2.54	2.53	2.534	0.01	0.395	0.029	1.158
20	2.555	2.59	2.58	2.59	2.53	2.57	2.572	0.06	2.333	0.017	0.665
21	3.518	3.61	3.60	3.60	3.58	3.59	3.596	0.03	0.834	0.078	2.217
22	2.802	2.87	2.87	2.87	2.87	2.87	2.87	0.00	0.000	0.068	2.427
23	1.354	1.36	1.35	1.36	1.34	1.34	1.35	0.02	1.481	-0.004	-0.295
24	0.915	0.90	0.90	0.90	0.91	0.90	0.902	0.01	1.109	-0.013	-1.421
Averages							Averages	0.03	1.17	0.03	0.81

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.

Vitalograph Asma-1

Testing date: 04/02/2008

PEF Results- ATS 26 Standard Waveforms

Waveform number	Target Value (L/min)	Measured PEF					Mean PEF	PEF Range	PEF Range %	Deviation From Target	Deviation % from Target
		Trial 1	Trial 2	Trial 3	Trial 4	Trial 5					
1	448.08	456	455	458	457	455	456	3.00	0.658	8.120	1.812
2	654.44	673	674	672	675	676	674	4.00	0.593	19.560	2.989
3	290.16	281	280	279	282	280	280	3.00	1.070	-9.760	-3.364
4	266.43	260	261	263	262	263	262	3.00	1.146	-4.630	-1.738
5	221.38	217	216	215	214	216	216	3.00	1.391	-5.780	-2.611
6	168.10	164	162	162	163	162	163	2.00	1.230	-5.500	-3.272
7	137.61	128	129	129	128	130	129	2.00	1.553	-8.810	-6.402
8	125.07	114	114	114	113	113	114	1.00	0.880	-11.470	-9.171
9	318.74	312	314	314	312	315	313	3.00	0.957	-5.340	-1.675
10	285.80	286	286	285	284	284	285	2.00	0.702	-0.800	-0.280
11	414.17	416	422	421	417	419	419	6.00	1.432	4.830	1.166
12	641.84	674	674	671	669	670	672	5.00	0.744	29.760	4.637
13	290.16	291	288	290	290	289	290	3.00	1.036	-0.560	-0.193
14	232.52	228	227	226	226	226	227	2.00	0.883	-5.920	-2.546
15	479.08	490	492	491	491	493	491	3.00	0.611	12.320	2.572
16	316.80	320	317	316	321	317	318	5.00	1.571	1.400	0.442
17	352.65	355	357	355	354	353	355	4.00	1.127	2.150	0.610
18	516.87	534	536	536	536	530	534	6.00	1.123	17.530	3.392
19	419.01	427	421	426	426	426	425	6.00	1.411	6.190	1.477
20	449.05	455	455	452	455	453	454	3.00	0.661	4.950	1.102
21	240.27	232	232	232	234	236	233	4.00	1.715	-7.070	-2.943
22	207.33	200	198	201	201	200	200	3.00	1.500	-7.330	-3.535
23	489.25	505	499	505	503	503	503	6.00	1.193	13.750	2.810
24	250.92	247	245	244	245	244	245	3.00	1.224	-5.920	-2.359
25	842.85	793	794	791	804	797	796	13.00	1.634	-47.050	-5.582
26	697.07	708	717	711	716	722	715	14.00	1.959	17.730	2.544
Acceptable Performance Criteria							Averages:	4.31	1.154	0.475	-0.774

Accuracy: Deviation from Target +/- 12% or +/- 0.417 liters/sec (25 liters/min), whichever is greater
 Testing was performed using guidelines from the American Thoracic Society's "Standardization of Spirometry" 1994 update.

Vitalograph Asma-1 PEF Results- ATS 24 Standard Waveforms

Testing date: 04-02-2008

Waveform number	Target Value	Measured PEF Trial 1	Measured PEF Trial 2	Measured PEF Trial 3	Measured PEF Trial 4	Measured PEF Trial 5	Mean PEF	PEF Range	PEF Range %	Deviation From Target	Deviation % from Target
1	386.07	395	393	393	388	391	392.0	7.00	1.786	5.930	1.536
2	603.57	624	632	631	628	627	628.4	8.00	1.273	24.830	4.114
3	84.77	86	86	86	86	85	85.8	1.00	1.166	1.030	1.215
4	191.83	183	183	184	182	184	183.2	2.00	1.092	-8.630	-4.499
5	454.86	461	462	464	466	462	463.0	5.00	1.080	8.140	1.790
6	305.66	306	309	306	307	307	307.0	3.00	0.977	1.340	0.438
7	287.26	285	286	286	284	283	284.8	3.00	1.053	-2.460	-0.856
8	212.17	204	201	203	203	202	202.6	3.00	1.481	-9.570	-4.511
9	469.39	483	479	480	480	478	480.0	5.00	1.042	10.610	2.260
10	281.44	277	278	279	277	277	277.6	2.00	0.720	-3.840	-1.364
11	234.45	213	214	213	214	215	213.8	2.00	0.935	-20.650	-8.808
12	231.06	226	226	225	226	227	226.0	2.00	0.885	-5.060	-2.190
13	314.87	315	319	316	317	316	316.6	4.00	1.263	1.730	0.549
14	264.49	259	261	261	260	261	260.4	2.00	0.768	-4.090	-1.546
15	732.43	782	768	772	776	770	773.6	14.00	1.810	41.170	5.621
16	446.83	456	452	455	456	455	454.8	4.00	0.880	7.970	1.784
17	319.71	312	313	314	312	313	312.8	2.00	0.639	-6.910	-2.161
18	461.64	462	464	466	465	463	464.0	4.00	0.862	2.360	0.511
19	326.49	328	324	323	324	324	324.6	5.00	1.540	-1.890	-0.579
20	355.56	354	351	356	351	352	352.8	5.00	1.417	-2.760	-0.776
21	567.24	584	582	582	582	582	582.4	2.00	0.343	15.160	2.673
22	308.08	302	303	306	305	302	303.6	4.00	1.318	-4.480	-1.454
23	177.78	157	158	158	157	157	157.4	1.00	0.635	-20.380	-11.464
24	126.92	118	117	117	120	119	118.2	3.00	2.538	-8.720	-6.870
Averages							118.2	3.88	1.15	0.87	-1.02

Acceptable Performance Criteria

Accuracy: Deviation from Target +/- 12% or +/- 0.417 liters/sec (25 liters/min), whichever is greater
 Testing was performed using guidelines from the American Thoracic Society's "Standardization of Spirometry" 2005 update.