



Intermountain LDS Hospital

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

TEST REPORT

Device: ndd EasyOne Pro Spirometer

Testing dates: June 26 and 29, 2009

Present: LDS Hospital

Heather Gallo

Robert O. Crapo, M.D.

Robert L. Jensen, Ph.D.

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.

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 -0.09 liters (-2.24%). No errors were observed.

Precision: The average range was 0.02 liters (0.69%). No errors were observed.

Summary: The ndd EasyOne Pro meets ATS recommendations for accuracy and precision in the measurement of FVC.

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.

Results: See attached data sheets.

Accuracy: The average deviation from target was -0.06 liters (-2.13%). No errors were observed.

Precision: The average range was 0.02 liters (0.77%). No errors were observed.

Summary: The ndd EasyOne Pro meets ATS recommendations for accuracy and precision in the measurement of 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 $\pm 5.5\%$ or 0.250 liters/sec with no more than one error.

Results: See attached data sheets

Accuracy: The average deviation from target was -0.04 liters/sec (-1.87%). No errors were observed.

Precision: The average range was 0.04 liters/sec (1.86%). No errors were observed.

Summary: The ndd EasyOne Pro meets ATS recommendations for accuracy and precision in the measurement of 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 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 -0.051 liters/sec (-0.441%). No errors were observed.

Precision: The average range was 0.10 liters/sec (1.506%). No errors were observed.

Summary: The ndd EasyOne Pro meets ATS recommendations for accuracy and precision in the measurement of peak expiratory flow on the 26 standard flow-time waveforms.

Human Subject Testing

Standard: Measurements of FVC and FEV₁ from the test spirometer are compared to measurements done on a standard spirometer and on the ndd EasyOne Pro in two human subjects. The largest of three trials on each spirometer is used for comparisons. The differences for both FVC and FEV₁ must be within 6% or 200 ml, whichever is larger. No errors are allowed.

Method: Two healthy subjects were tested on two devices: a standard horizontal rolling seal spirometer and on the ndd EasyOne Pro. Each subject blew three times into each spirometer, alternating spirometers with each blow. One subject began blowing into the ndd EasyOne Pro spirometer, the other into the standard rolling seal spirometer.

Results: See attached data sheets. For FVC and FEV₁, the largest absolute difference observed was 0.21 liters and the largest percent difference was 6.169%. No errors were observed for FVC or FEV₁. For peak flow, the largest absolute difference observed was 0.19 liters/second and the largest percent difference was 2.045%. No errors were observed.

Summary: The ndd EasyOne Pro meets ATS standards for human subject testing for FVC, FEV₁, and peak flow.

BTPS Testing

Standard: The ATS recommendations require wave forms 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 (36.5°C; relative humidity 95.6%) was injected into the spirometer. Three injections each of wave forms 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 -0.018 liters (-0.836%). For FEV₁, the average deviation from target was 0.014 liters (0.038%). No errors were observed in the measurement of FVC or FEV₁. The average deviation for PEF was 0.078 liters/sec (1.010%).

Summary: The ndd EasyOne Pro meets ATS recommendations for accuracy in the measurement of FVC and FEV₁ under BTPS conditions.

DL_{CO} Simulator Testing

A DL_{CO} simulator, manufactured by Hans Rudolph, Inc., was used to test the accuracy of the ndd EasyOne Pro in measuring DL_{CO}. The device consists of two calibrated syringes used in conjunction with precise gas mixtures. The ndd EasyOne Pro was tested after routine setup and calibration. The DL_{CO} simulator device simulates an inhalation by withdrawing a known volume of DL_{CO} test gas from the device being tested with a calibrated syringe. After the normal 10 second breath hold period for a DL_{CO} maneuver, a valve on the simulator is turned and, using a second syringe, a precision gas mixture is injected into the instrument being tested, simulating a patient's exhalation.

DL_{CO} simulator testing was performed with the following protocol:

Using three inspired volumes (3, 4 and 5 liters) using three sets of simulated alveolar gas concentrations:

- | | |
|---------------|--|
| 1. Low Gas | CO = 0.130%, He = 5.30%, O ₂ = 17.00%, CO ₂ = 5.00%, Bal. N ₂ |
| 2. Medium Gas | CO = 0.100%, He = 6.50%, O ₂ = 17.00%, CO ₂ = 5.00%, Bal. N ₂ |
| 3. High Gas | CO = 0.080%, He = 7.19%, O ₂ = 17.00%, CO ₂ = 5.00%, Bal. N ₂ |

A high precision "test" gas was attached to the ndd EasyOne Pro device that contained the following gas concentrations:

Test Gas: CO = 0.300%, He = 10.00%, O₂ = 20.99%, CO₂ = 0%, Bal. N₂

The unit was tested six times at each volume/concentration level (total 54 simulation tests). The first test of each volume/concentration level was discarded to ensure that all gas lines and the simulator was flushed from the previous simulator gas.

Calculations were made using the EasyOne QC software program to predict the measured DL_{CO} (target) given the inhaled volume, breath hold time and precision gas concentrations used with the simulator. The breath hold times used in this comparison came from the ndd EasyOne Pro.

Results: See the attached data sheets for details of the DL_{CO} comparisons. Summary data are presented in this report.

There are no industry (IEEE or equivalent) or society standards (e.g. American Thoracic Society or European Respiratory Society) for accuracy and precision for the measurement of the DL_{CO} with a DL_{CO} simulator.

Accuracy of the simulator syringes is thought to be excellent. However, no independent validation of the volume calibration has been made. The gases used in the simulator are accurate within known tolerances of gravimetric mixing (< 1% absolute). Differences between the ndd EasyOne Pro reported gas concentrations and the simulator gas values may, in part, be due to small differences between the reported concentrations on the simulator gas tanks and the actual concentrations. Finally,

Test Report: ndd EasyOne Pro Spirometer
Test Date: June 26 and 29, 2009
Page 6

calculation of DL_{CO} by the ndd EasyOne Pro may be slightly different than the calculations made in the Hans Rudolph, Inc. EasyLab QC program.

In a recent publication by Jensen, et al (Chest 2007; 132:388-395) evaluating the accuracy of DL_{CO} instruments, DL_{CO} measurement errors were defined as a difference from the simulator target of +/- 2.0 ml CO/min/mmHg. This definition was based in part on the work of Punjabi et al (Chest 2003; 123:1082-1089). In the study by Jensen et al, all 5 instruments tested had error rates ranging from 2.8% to 78% during simulation testing (> 2.0 ml CO/min/mmHg from simulation target).

The differences between the simulator targets and DL_{CO} values measured by the ndd EasyOne Pro at every volume/simulator-gas combination were all less than 1.25 ml CO/min/mmHg. The device showed no errors in measurement of DL_{CO} using the above definition, performing better than the instruments tested by Jensen, et al.

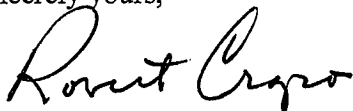
Mean deviations from the target DL_{CO} values were all less than 0.75 ml CO/min/mmHg for each test level. When expressed as a percent of the average target value all were less than 2% except the low simulation gas using 3.0 Liter inspired volumes. For all testing levels, the ranges of the differences were all less than 2.0 ml CO/min/mmHg.

OVERALL SUMMARY

The ndd EasyOne Pro meets ATS recommendations for accuracy and precision in measuring FVC, FEV₁, FEF_{25-75%}, and PEF under ambient and BTPS conditions. The ndd EasyOne Pro performs acceptably in the measurement of DL_{CO}.

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

EasyOne Pro FVC Results- ATS 24 Standard Waveforms

Testing date: June 26, 2009

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	5.83	5.84	5.86	5.84	5.84	5.842	0.03	0.514	-0.159	-2.650
2	5.001	4.86	4.89	4.90	4.90	4.87	4.884	0.04	0.819	-0.117	-2.340
3	3.494	3.42	3.43	3.43	3.43	3.45	3.432	0.03	0.874	-0.062	-1.774
4	1.500	1.49	1.48	1.49	1.47	1.46	1.478	0.03	2.030	-0.022	-1.467
5	5.122	5.04	5.01	5.03	5.01	5.03	5.024	0.03	0.597	-0.098	-1.913
6	4.010	3.97	3.93	3.95	3.94	3.94	3.946	0.04	1.014	-0.064	-1.596
7	3.150	3.08	3.08	3.08	3.07	3.07	3.076	0.01	0.325	-0.074	-2.349
8	1.993	1.93	1.93	1.93	1.93	1.93	1.930	0.00	0.000	-0.063	-3.161
9	4.84	4.76	4.75	4.75	4.74	4.74	4.748	0.02	0.421	-0.092	-1.901
10	3.831	3.79	3.78	3.77	3.77	3.77	3.776	0.02	0.530	-0.055	-1.436
11	2.703	2.64	2.64	2.65	2.64	2.65	2.644	0.01	0.378	-0.059	-2.183
12	1.992	1.94	1.93	1.94	1.93	1.95	1.938	0.02	1.032	-0.054	-2.711
13	4.888	4.80	4.8	4.77	4.75	4.76	4.776	0.05	1.047	-0.112	-2.291
14	3.676	3.60	3.59	3.57	3.61	3.59	3.592	0.04	1.114	-0.084	-2.285
15	5.936	5.79	5.81	5.80	5.79	5.79	5.796	0.02	0.345	-0.140	-2.358
16	5.456	5.33	5.35	5.33	5.33	5.33	5.334	0.02	0.375	-0.122	-2.236
17	5.835	5.73	5.72	5.71	5.71	5.73	5.720	0.02	0.350	-0.115	-1.971
18	4.295	4.20	4.19	4.20	4.19	4.20	4.196	0.01	0.238	-0.099	-2.305
19	3.937	3.86	3.86	3.87	3.87	3.87	3.866	0.01	0.259	-0.071	-1.803
20	2.873	2.82	2.82	2.82	2.83	2.81	2.820	0.02	0.709	-0.053	-1.845
21	4.446	4.32	4.35	4.33	4.34	4.35	4.338	0.03	0.692	-0.108	-2.429
22	3.844	3.75	3.74	3.76	3.78	3.74	3.754	0.04	1.066	-0.090	-2.341
23	3.408	3.31	3.32	3.29	3.31	3.30	3.306	0.03	0.907	-0.102	-2.993
24	1.229	1.19	1.18	1.19	1.18	1.19	1.186	0.01	0.843	-0.043	-3.499
Acceptable Performance Criteria							Averages	0.02	0.69	-0.09	-2.24

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.

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FEV1 Results- ATS 24 Standard Waveforms

Testing date: June 26, 2009

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	4.395	4.29	4.30	4.32	4.31	4.30	4.304	0.03	0.697	-0.091	-2.071
2	4.591	4.47	4.50	4.52	4.51	4.49	4.498	0.05	1.112	-0.093	-2.026
3	1.271	1.24	1.25	1.23	1.24	1.25	1.242	0.02	1.610	-0.029	-2.282
4	1.388	1.35	1.35	1.36	1.35	1.35	1.352	0.01	0.740	-0.036	-2.594
5	3.857	3.8	3.78	3.79	3.79	3.79	3.79	0.02	0.528	-0.067	-1.737
6	3.026	2.98	2.97	2.98	2.98	2.97	2.976	0.01	0.336	-0.050	-1.652
7	2.502	2.46	2.45	2.46	2.46	2.44	2.454	0.02	0.815	-0.048	-1.918
8	1.613	1.57	1.57	1.58	1.57	1.57	1.572	0.01	0.636	-0.041	-2.542
9	3.760	3.70	3.69	3.68	3.68	3.68	3.686	0.02	0.543	-0.074	-1.968
10	3.021	2.98	2.96	2.97	2.96	2.96	2.966	0.02	0.674	-0.055	-1.821
11	1.784	1.75	1.75	1.75	1.75	1.75	1.75	0.00	0.000	-0.034	-1.906
12	1.611	1.56	1.56	1.56	1.56	1.56	1.56	0.00	0.000	-0.051	-3.166
13	3.827	3.78	3.78	3.74	3.73	3.75	3.756	0.05	1.331	-0.071	-1.855
14	3.050	2.99	2.99	2.97	3.00	2.98	2.986	0.03	1.005	-0.064	-2.098
15	5.303	5.18	5.21	5.19	5.17	5.19	5.188	0.04	0.771	-0.115	-2.169
16	3.896	3.81	3.84	3.81	3.82	3.82	3.82	0.03	0.785	-0.076	-1.951
17	2.597	2.55	2.54	2.54	2.54	2.56	2.546	0.02	0.786	-0.051	-1.964
18	3.117	3.07	3.05	3.07	3.05	3.05	3.058	0.02	0.654	-0.059	-1.893
19	2.505	2.46	2.45	2.46	2.46	2.46	2.458	0.01	0.407	-0.047	-1.876
20	2.555	2.52	2.51	2.52	2.53	2.50	2.516	0.03	1.192	-0.039	-1.526
21	3.518	3.43	3.46	3.44	3.45	3.46	3.448	0.03	0.870	-0.070	-1.990
22	2.802	2.73	2.72	2.74	2.75	2.72	2.732	0.03	1.098	-0.070	-2.498
23	1.354	1.33	1.32	1.33	1.32	1.32	1.324	0.01	0.755	-0.030	-2.216
24	0.915	0.89	0.88	0.89	0.88	0.88	0.884	0.01	1.131	-0.031	-3.388
Acceptable Performance Criteria							Averages	0.02	0.77	-0.06	-2.13
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.											

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MMEF Results- ATS 24 Standard Waveforms

Testing date: June 26, 2009

Waveform number	Target Value	Measured MMEF Trial 1	Measured MMEF Trial 2	Measured MMEF Trial 3	Measured MMEF Trial 4	Measured MMEF Trial 5	Mean MMEF	MMEF Range	MMEF Range %	Deviation From Target	Deviation % from Target
1	3.669	3.60	3.60	3.64	3.63	3.62	3.618	0.04	1.106	-0.051	-1.390
2	5.962	5.82	5.90	5.89	5.87	5.87	5.870	0.08	1.363	-0.092	-1.543
3	0.684	0.66	0.66	0.66	0.66	0.66	0.660	0.00	0.000	-0.024	-3.509
4	1.851	1.78	1.80	1.79	1.79	1.83	1.798	0.05	2.781	-0.053	-2.863
5	3.205	3.16	3.15	3.15	3.18	3.15	3.158	0.03	0.950	-0.047	-1.466
6	2.564	2.49	2.52	2.51	2.52	2.52	2.512	0.03	1.194	-0.052	-2.028
7	2.343	2.33	2.32	2.34	2.34	2.31	2.328	0.03	1.289	-0.015	-0.640
8	1.843	1.86	1.83	1.91	1.86	1.83	1.858	0.08	4.306	0.015	0.814
9	3.341	3.31	3.30	3.25	3.29	3.29	3.288	0.06	1.825	-0.053	-1.586
10	2.878	2.84	2.78	2.84	2.82	2.81	2.818	0.06	2.129	-0.060	-2.085
11	1.245	1.21	1.21	1.21	1.22	1.22	1.214	0.01	0.824	-0.031	-2.490
12	1.773	1.72	1.71	1.72	1.73	1.67	1.710	0.06	3.509	-0.063	-3.553
13	3.661	3.66	3.65	3.61	3.59	3.62	3.626	0.07	1.931	-0.035	-0.956
14	3.261	3.21	3.22	3.18	3.23	3.20	3.208	0.05	1.559	-0.053	-1.625
15	6.078	6.00	6.00	5.99	5.96	5.98	5.986	0.04	0.668	-0.092	-1.514
16	2.899	2.85	2.88	2.85	2.87	2.87	2.864	0.03	1.047	-0.035	-1.207
17	1.150	1.11	1.12	1.11	1.11	1.12	1.114	0.01	0.898	-0.036	-3.130
18	2.306	2.29	2.27	2.28	2.25	2.26	2.270	0.04	1.762	-0.036	-1.561
19	1.128	1.09	1.08	1.10	1.07	1.08	1.084	0.03	2.768	-0.044	-3.901
20	2.688	2.68	2.67	2.68	2.68	2.64	2.670	0.04	1.498	-0.018	-0.670
21	3.309	3.29	3.34	3.30	3.30	3.32	3.310	0.05	1.511	0.001	0.030
22	2.192	2.21	2.13	2.13	2.14	2.11	2.145	0.10	4.849	-0.047	-2.153
23	0.529	0.52	0.52	0.52	0.51	0.52	0.518	0.01	1.931	-0.011	-2.079
24	0.704	0.68	0.68	0.69	0.67	0.67	0.678	0.02	2.950	-0.026	-3.693

Acceptable Performance Criteria

Accuracy: Deviation from Target +/- 5.5% or +/- 0.250 liters, whichever is greater

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

Averages	0.04	1.86	-0.04	-1.87
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ndd EasyOne Pro

PEF Results- ATS 24 Standard Waveforms

Testing date: June 26, 2009

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	6.418	6.45	6.41	6.39	6.36	6.27	6.376	0.18	2.823	-0.042	-0.654
2	10.060	9.91	9.89	10.07	9.87	10.06	9.960	0.20	2.008	-0.100	-0.994
3	1.405	1.39	1.40	1.37	1.36	1.39	1.382	0.04	2.894	-0.023	-1.637
4	3.189	3.10	3.07	3.13	3.06	3.12	3.096	0.07	2.261	-0.093	-2.916
5	7.533	7.56	7.49	7.44	7.39	7.39	7.454	0.17	2.281	-0.079	-1.049
6	5.094	5.04	5.03	4.99	5.07	5.03	5.032	0.08	1.590	-0.062	-1.217
7	4.788	4.70	4.70	4.73	4.72	4.60	4.690	0.13	2.772	-0.098	-2.047
8	3.552	3.38	3.48	3.43	3.40	3.45	3.428	0.10	2.917	-0.124	-3.491
9	7.839	7.73	7.74	7.74	7.74	7.56	7.702	0.18	2.337	-0.137	-1.748
10	4.691	4.58	4.67	4.58	4.58	4.58	4.598	0.09	1.957	-0.093	-1.983
11	3.875	3.88	3.84	3.85	3.88	3.84	3.858	0.04	1.037	-0.017	-0.439
12	3.803	3.87	3.81	3.81	3.79	3.83	3.822	0.08	2.093	0.019	0.500
13	5.240	5.18	5.21	5.09	5.13	5.18	5.158	0.12	2.326	-0.082	-1.565
14	4.368	4.39	4.31	4.31	4.36	4.28	4.330	0.11	2.540	-0.038	-0.870
15	12.199	11.78	11.85	11.94	12.03	11.87	11.894	0.25	2.102	-0.305	-2.500
16	7.395	7.36	7.40	7.27	7.29	7.25	7.314	0.15	2.051	-0.081	-1.095
17	5.337	5.39	5.40	5.38	5.36	5.34	5.374	0.06	1.116	0.037	0.693
18	7.670	7.57	7.52	7.74	7.62	7.55	7.600	0.22	2.895	-0.070	-0.913
19	5.458	5.35	5.32	5.27	5.40	5.40	5.348	0.13	2.431	-0.110	-2.015
20	5.934	5.86	5.83	5.90	5.88	5.85	5.864	0.07	1.194	-0.070	-1.180
21	9.470	9.21	9.30	9.25	9.31	9.38	9.290	0.17	1.830	-0.180	-1.901
22	5.111	5.13	5.07	5.11	5.06	5.05	5.084	0.08	1.574	-0.027	-0.528
23	2.971	2.98	3.02	3.02	3.02	3.01	3.010	0.04	1.329	0.039	1.313
24	2.123	2.11	2.10	2.11	2.10	2.10	2.104	0.01	0.475	-0.019	-0.895
							Averages	0.12	2.03	-0.07	-1.21

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" 1994 update.

Indd EasyOne Pro

Testing date: 06/29/2009

Waveform number	Target Value	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	7.476	7.43	7.47	7.48	7.51	7.39	7.456	0.12	1.609	-0.020	-0.268
2	10.907	10.75	10.73	10.86	10.74	10.76	10.768	0.13	1.207	-0.139	-1.274
3	4.836	4.91	4.91	4.86	4.92	4.87	4.894	0.06	1.226	0.058	1.199
4	4.432	4.42	4.46	4.4	4.44	4.42	4.428	0.06	1.355	-0.004	-0.090
5	3.682	3.62	3.60	3.57	3.62	3.56	3.594	0.06	1.669	-0.088	-2.390
6	3.157	3.22	3.22	3.20	3.21	3.21	3.212	0.02	0.623	0.055	1.742
7	2.559	2.59	2.59	2.58	2.61	2.58	2.590	0.03	1.158	0.031	1.211
8	2.341	2.44	2.42	2.42	2.41	2.41	2.420	0.03	1.240	0.079	3.375
9	5.312	5.38	5.45	5.43	5.36	5.40	5.404	0.09	1.665	0.092	1.732
10	4.763	4.82	4.87	4.85	4.86	4.87	4.854	0.05	1.030	0.091	1.911
11	6.871	6.84	6.79	6.88	6.78	6.77	6.812	0.11	1.615	-0.059	-0.859
12	10.714	10.56	10.57	10.52	10.63	10.48	10.552	0.15	1.422	-0.162	-1.512
13	4.828	4.78	4.72	4.83	4.75	4.76	4.768	0.11	2.307	-0.060	-1.243
14	3.875	3.84	3.79	3.83	3.78	3.82	3.812	0.06	1.574	-0.063	-1.626
15	7.977	7.96	7.86	7.81	7.98	7.79	7.880	0.19	2.411	-0.097	-1.216
16	5.272	5.18	5.20	5.21	5.25	5.30	5.228	0.12	2.295	-0.044	-0.835
17	5.869	5.78	5.79	5.82	5.81	5.79	5.798	0.04	0.690	-0.071	-1.210
18	8.614	8.45	8.40	8.50	8.42	8.44	8.442	0.10	1.185	-0.172	-1.997
19	6.984	6.95	6.96	6.93	6.97	6.92	6.946	0.05	0.720	-0.038	-0.544
20	7.428	7.33	7.31	7.36	7.33	7.38	7.342	0.07	0.953	-0.086	-1.158
21	4.004	3.98	3.98	4.00	3.94	3.92	3.964	0.08	2.018	-0.040	-0.999
22	3.455	3.38	3.34	3.35	3.38	3.31	3.352	0.07	2.088	-0.103	-2.981
23	8.154	8.21	8.00	8.00	8.12	8.11	8.088	0.21	2.596	-0.066	-0.809
24	4.190	4.27	4.29	4.29	4.30	4.30	4.290	0.03	0.699	0.100	2.387
25	14.217	13.82	13.93	14.04	14.08	14.02	13.978	0.26	1.860	-0.239	-1.681
26	11.626	11.47	11.40	11.27	11.38	11.25	11.354	0.22	1.938	-0.272	-2.340
Acceptable Performance Criteria							Averages:	0.10	1.506	-0.051	-0.441

Accuracy: Deviation from Target \pm 12% or \pm 0.417 L (25 L/min), whichever is greater
 Precision: Range \pm 7% or \pm 0.420 L/s (25 L/min), whichever is greater

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

EasyOne Pro Human Testing

Testing Date: 06/29/2009											
		Measured FVC									
Subject	Spirometer	Trial 1	Trial 2	Trial 3	Largest FVC	Difference	Difference %				
1	Std. Spirometer	2.51	2.62	2.60	2.62	-0.04	-1.527				
1	EasyOne Pro	2.50	2.58	2.56	2.58						
		Measured FEV1									
Subject	Spirometer	Trial 1	Trial 2	Trial 3	Largest FEV1	Difference	Difference %				
1	Std. Spirometer	2.32	2.42	2.41	2.42	-0.02	-0.826				
1	EasyOne Pro	2.31	2.40	2.34	2.40						
		Measured PEF									
Subject	Spirometer	Trial 1	Trial 2	Trial 3	Largest PEF	Difference	Difference %				
1	Std. Spirometer	8.39	8.26	7.95	8.39	-0.08	-0.954				
1	EasyOne Pro	8.04	8.21	8.31	8.31						
		Measured FVC									
Subject	Spirometer	Trial 1	Trial 2	Trial 3	Largest FVC	Difference	Difference %				
2	Std. Spirometer	4.20	4.07	4.09	4.20	-0.21	-5.000				
2	EasyOne Pro	3.99	3.94	3.90	3.99						
		Measured FEV1									
Subject	Spirometer	Trial 1	Trial 2	Trial 3	Largest FEV1	Difference	Difference %				
2	Std. Spirometer	3.08	2.93	2.95	3.08	-0.19	-6.169				
2	EasyOne Pro	2.81	2.89	2.86	2.89						
		Measured PEF									
Subject	Spirometer	Trial 1	Trial 2	Trial 3	Largest PEF	Difference	Difference %				
2	Std. Spirometer	9.29	8.97	8.92	9.29	0.19	2.045				
2	EasyOne Pro	9.40	9.36	9.48	9.48						
Acceptable Performance Criteria For FVC and FEV1: Difference % < +/- 6% or 200ml, whichever is greater For PEF: Difference % < +/- 15% or 0.5 liters/sec, whichever is greater											

nidd EasyOne Pro				BTPS Testing					
Testing date: 06/29/09									
Waveform number	Target value	Measured FVC Trial 1	Measured FVC Trial 2	Measured FVC Trial 3	Mean FVC	FVC Range	FVC Range %	Deviation from Target	Deviation % from Target
1	6.001	5.99	6.00	6.01	6.000	0.02	0.333	-0.001	-0.017
2	5.001	5.01	5.01	5.03	5.017	0.02	0.399	0.016	0.313
3	3.494	3.43	3.44	3.44	3.437	0.01	0.291	-0.057	-1.641
4	1.500	1.48	1.46	1.47	1.470	0.02	1.361	-0.030	-2.000
					Averages:	0.02	0.596	-0.018	-0.836
Waveform number	Target value	Measured FEV1 Trial 1	Measured FEV1 Trial 2	Measured FEV1 Trial 3	Mean FEV1	FEV1 Range	FEV1 Range %	Deviation from Target	Deviation % from Target
1	4.396	4.41	4.44	4.44	4.430	0.03	0.677	0.034	0.773
2	4.590	4.63	4.63	4.64	4.633	0.01	0.216	0.043	0.944
3	1.271	1.27	1.27	1.26	1.267	0.01	0.789	-0.004	-0.341
4	1.387	1.38	1.36	1.37	1.370	0.02	1.460	-0.017	-1.226
					Averages:	0.02	0.786	0.014	0.038
Waveform number	Target value	Measured PEF Trial 1	Measured PEF Trial 2	Measured PEF Trial 3	Mean PEF	PEF Range	PEF Range %	Deviation from Target	Deviation % from Target
1	6.427	6.49	6.39	6.58	6.487	0.19	2.929	0.060	0.928
2	10.027	10.09	10.40	10.28	10.257	0.31	3.022	0.230	2.290
3	1.405	1.42	1.42	1.38	1.407	0.04	2.844	0.002	0.119
4	3.181	3.24	3.19	3.18	3.203	0.06	1.873	0.022	0.702
					Averages:	0.15	2.667	0.078	1.010
BTPS TESTING NOTES: Temperature of Waveform Generator: 36.5 degrees C Barometric Pressure: 647 mmHg Relative Humidity of Generator: 95.6%									
Acceptable performance criteria For FVC and FEV1: Deviation From Target \pm 4.5 % or \pm 200ml, whichever is greater.									

DLco Results- Simulation Tests									
Testing date:	29-Jun-09								
Volume/ Simulator Gas	Target Value	Measured DLco	Deviation From Target	Absolute Deviation From Target	Deviation % from Target	Mean Deviation from Target	Mean % Deviation from Target	DLCO Deviation Range	DLCO Range %
3L/Low	8.400	9.18	0.780	0.780	9.286	0.792	9.406	1.11	13.183
3L/Low	8.300	8.66	0.360	0.360	4.337				
3L/Low	8.400	9.43	1.030	1.030	12.262				
3L/Low	8.510	9.96	1.450	1.450	17.039				
3L/Low	8.49	8.83	0.340	0.340	4.005				
4L/Low	11.910	11.76	-0.150	0.150	-1.259	0.040	0.343	1.87	16.049
4L/Low	11.650	10.70	-0.950	0.950	-8.155				
4L/Low	11.490	12.41	0.920	0.920	8.007				
4L/Low	11.690	11.38	-0.310	0.310	-2.652				
4L/Low	11.520	12.21	0.690	0.690	5.990				
5L/Low	14.820	14.82	0.000	0.000	0.000	0.050	0.337	1.78	11.993
5L/Low	14.700	13.55	-1.150	1.150	-7.823				
5L/Low	14.730	15.03	0.300	0.300	2.037				
5L/Low	15.040	15.67	0.630	0.630	4.189				
5L/Low	14.920	15.39	0.470	0.470	3.150				
Acceptable Performance Criteria Accuracy: Deviation from Target +/- 2.0 ml CO/min/mmHg Testing was performed using protocol described in "Instrument Accuracy and Reproducibility in Measurements of Pulmonary function. Jensen et al, Chest 2007;132:338-395									

DLCO Results- Simulation Tests										
Testing date:	29-Jun-09	Target Value	Measured DLco	Deviation From Target	Absolute Deviation From Target	Deviation % from Target	Mean Deviation from Target	Mean % Deviation from Target	DLCO Deviation Range	DLCO Range %
Volume/ Simulator Gas										
3L/High	30.790	31.45	0.660	0.660	2.144	0.350	1.142	0.81	2.643	
3L/High	30.210	30.91	0.700	0.700	2.317					
3L/High	31.010	30.90	-0.110	0.110	-0.355					
3L/High	30.570	30.62	0.050	0.050	0.164					
3L/High	30.63	31.08	0.450	0.450	1.469					
4L/High	42.040	42.13	0.090	0.090	0.214	-0.268	-0.634	0.80	1.893	
4L/High	42.790	42.08	-0.710	0.710	-1.659					
4L/High	42.350	42.17	-0.180	0.180	-0.425					
4L/High	42.170	41.79	-0.380	0.380	-0.901					
4L/High	41.910	41.75	-0.160	0.160	-0.382					
5L/High	54.100	53.11	-0.990	0.990	-1.830	-0.388	-0.720	1.76	3.266	
5L/High	53.930	53.87	-0.060	0.060	-0.111					
5L/High	53.050	53.71	0.660	0.660	1.244					
5L/High	54.440	53.99	-0.450	0.450	-0.827					
5L/High	53.930	52.83	-1.100	1.100	-2.040					
Acceptable Performance Criteria Accuracy: Deviation from Target +/- 2.0 ml CO/min/mmHg <i>Testing was performed using protocol described in "Instrument Accuracy and Reproducibility in Measurements of Pulmonary function. Jensen et al, Chest 2007;132:338-395</i>										