ATS® standard 24 and 26 dynamic waveform test results for new Vyntus™ ultrasonic sensor

Joachim Schwertberger
Dr. Herman Groepenhoff

Introduction

International guidelines[1,2] recommend to validate clinical diagnostic spirometry systems against a known and accepted standard. The most reasonable test signals are those that represent actual patients. The diversity of flow-volume curve (FVC) maneuvers encountered in clinical practice is currently best simulated by the 24 standard volume–time waveforms developed by the ATS[1] and Hankinson and Gardner[3].

26 flow-time waveform are recommended to test peak flow (PEF) results[1,2].

Therefore, we used these 24 and 26 dynamic waveforms according to previous publications[4,5] to drive a computer-controlled mechanical syringe, for validating our new Vyntus™ ultrasonic sensor with the latest and future oriented software platform SentrySuite®.

Method

24 Volume-time wave forms to test FEV1 and FVC

A production spirometry device was connected to the pump system for testing, orientated as it would be to test human subjects. Each of the 24 ATS waveforms was discharged into the spirometry device five times under ambient conditions, all of the readings were recorded.

BTPS conditions are simulated by discharging waveforms 1–4 to the spirometry device three times, using air heated to 37 ± 1°C and at > 98% relative humidity.

Accuracy test

The average of the five tests under ambient conditions (three for BTPS conditions) is compared with the standard value in the following way:

- Deviation = average – standard
- Percentage deviation = 100* (average-standard)/ standard

The accuracy validation limits for volumes, which include the waveform generator inaccuracy, are ± 3.5% of reading or ± 0.100L whichever is greater. The validation limits for these tests under BTPS conditions are ± 4.5% or ± 0.200 L, whichever is greater, and these limits include the allowable inaccuracy for the pump system.

Acceptable spirometer performance for ambient conditions is defined as fewer than three accuracy errors for either FVC or FEV1 across the 24 waveforms (< 5% error rate).

Acceptable spirometer performance under BTPS conditions is defined as the accuracy requirement being met for all of the four profiles used (0% error rate).

Repeatability test

The FEV1 and FVC data from the accuracy test are used to derive the span of the five recordings:

- Span = maximum - minimum
- Percentage span = 100 * span / average

The repeatability validation limits for the volume measured at ambient conditions are ± 3.5% or ± 0.100 L, whichever is greater and, for BTPS conditions, ± 4.5% or ± 0.200 L, whichever is greater. A repeatability error occurs if the span or percentage span exceeds these limits.

Acceptable spirometer performance for repeatability is defined as fewer than three accuracy errors for either FVC or FEV1 across the 24 profiles (< 5% error rate).

26 flow-time wave forms to test PEF

Two randomly chosen sprirometry devices were connected to the pump system for testing, orientated as it would be to test human subjects. Each of the 26 ATS waveforms was discharged into the spirometry device five times under ambient conditions, all of the readings were recorded.

Accuracy test:

The accuracy validation limits are ± 12% or ± 0.47 $L*s^{-1}$, whichever is the larger, and these limits include the 2% inaccuracy limit for the waveform generator.

Acceptable performance is defined as ≤ 5% error rate.

Repeatability test

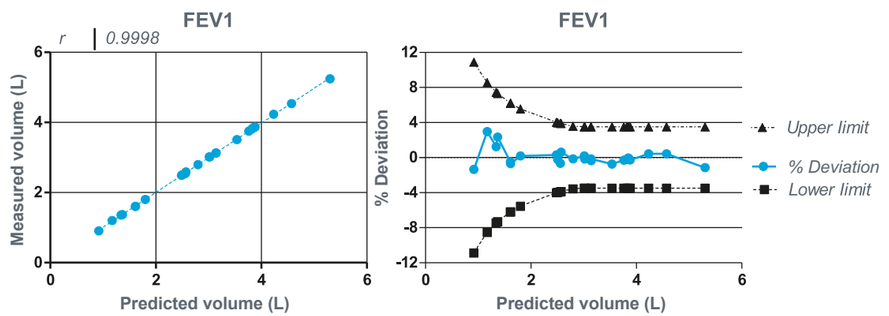
The PEF data from the accuracy test are used to derive the span of the five recordings.

The repeatability validation limits are ± 6% or ±15 $L*min^{-1}$, whichever is the greater, and these limits include 1% for waveform-generator variability.

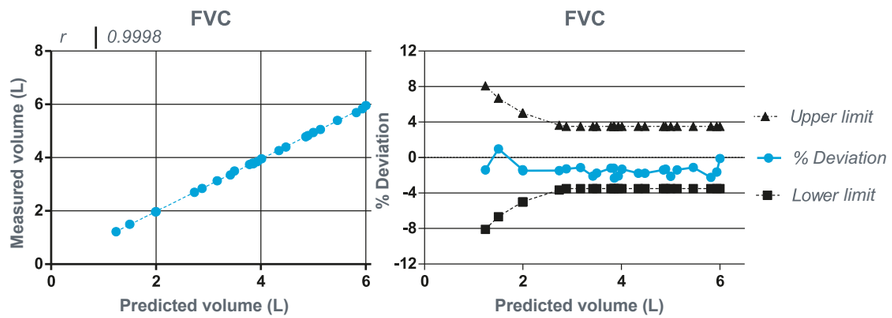
Acceptable performance is defined as ≤ 5% error rate.

24 waveform results for FEV1 and FVC: **BTPS condition*

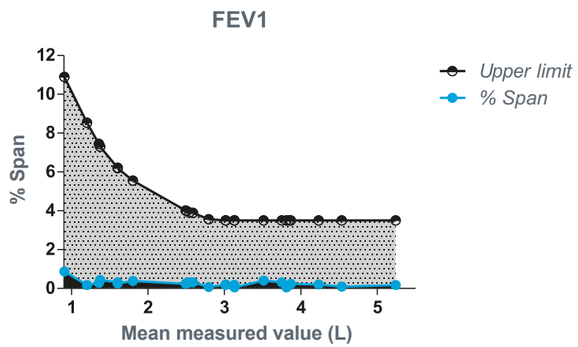
Accuracy of FEV1							
ATS waveform	Volume pred.	Volume abs.	L Deviation	% Deviation	Lower limit	Upper limit	Pass/Fail
24	0.918	0.906	0.012	-1.34%	-10.89%	10.89%	PASS
3*	1.188	1.22	-0.035	2.97%	-16.84%	16.84%	PASS
23	1.343	1.359	-0.017	1.25%	-7.45%	7.45%	PASS
4*	1.371	1.40	-0.032	2.36%	-14.59%	14.59%	PASS
8	1.611	1.603	0.008	-0.50%	-6.21%	6.21%	PASS
12	1.616	1.605	0.011	-0.70%	-6.19%	6.19%	PASS
11	1.801	1.804	-0.003	0.18%	-5.55%	5.55%	PASS
19	2.486	2.494	-0.008	0.31%	-4.02%	4.02%	PASS
7	2.510	2.505	0.006	-0.23%	-3.98%	3.98%	PASS
20	2.558	2.541	0.017	-0.65%	-3.91%	3.91%	PASS
17	2.571	2.587	-0.016	0.60%	-3.89%	3.89%	PASS
22	2.799	2.795	0.004	-0.15%	-3.57%	3.57%	PASS
6	3.012	3.018	-0.005	0.18%	-3.50%	3.50%	PASS
10	3.022	3.017	0.005	-0.17%	-3.50%	3.50%	PASS
14	3.140	3.129	0.011	-0.35%	-3.50%	3.50%	PASS
18	3.137	3.132	0.005	-0.16%	-3.50%	3.50%	PASS
21	3.539	3.513	0.026	-0.72%	-3.50%	3.50%	PASS
9	3.761	3.751	0.011	-0.29%	-3.50%	3.50%	PASS
13	3.820	3.813	0.007	-0.18%	-3.50%	3.50%	PASS
5	3.848	3.846	0.002	-0.05%	-3.50%	3.50%	PASS
16	3.880	3.869	0.011	-0.28%	-3.50%	3.50%	PASS
1*	4.262	4.28	-0.018	0.42%	-4.69%	4.69%	PASS
2*	4.574	4.50	0.074	-1.62%	-4.50%	4.50%	PASS
15	5.302	5.241	0.061	-1.15%	-3.50%	3.50%	PASS



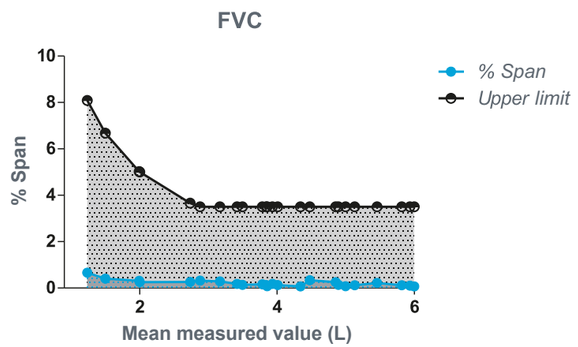
Accuracy of FVC							
ATS waveform	Volume pred.	Volume abs.	L Deviation	% Deviation	Lower limit	Upper limit	Pass/Fail
24	1.237	1.219	0.017	-1.39%	-8.09%	8.09%	**PASS**
4*	1.499	1.51	-0.014	0.96%	-13.34%	13.34%	**PASS**
8	1.992	1.965	0.027	-1.37%	-5.02%	5.02%	**PASS**
12	2.000	1.970	0.030	-1.49%	-5.00%	5.00%	**PASS**
11	2.734	2.694	0.040	-1.47%	-3.66%	3.66%	**PASS**
20	2.880	2.844	0.036	-1.26%	-3.50%	3.50%	**PASS**
7	3.168	3.132	0.036	-1.13%	-3.50%	3.50%	**PASS**
23	3.418	3.347	0.071	-2.09%	-3.50%	3.50%	**PASS**
3*	3.498	3.44	0.061	-1.75%	-5.72%	5.72%	**PASS**
14	3.785	3.740	0.045	-1.19%	-3.50%	3.50%	**PASS**
10	3.842	3.796	0.046	-1.19%	-3.50%	3.50%	**PASS**
22	3.856	3.767	0.089	-2.32%	-3.50%	3.50%	**PASS**
19	3.934	3.853	0.081	-2.07%	-3.50%	3.50%	**PASS**
6	4.010	3.958	0.052	-1.31%	-3.50%	3.50%	**PASS**
18	4.342	4.265	0.077	-1.77%	-3.50%	3.50%	**PASS**
21	4.476	4.396	0.080	-1.78%	-3.50%	3.50%	**PASS**
9	4.853	4.785	0.068	-1.40%	-3.50%	3.50%	**PASS**
13	4.894	4.829	0.065	-1.32%	-3.50%	3.50%	**PASS**
2*	4.999	4.89	0.106	-2.11%	-4.50%	4.50%	**PASS**
5	5.131	5.060	0.071	-1.38%	-3.50%	3.50%	**PASS**
16	5.457	5.397	0.060	-1.10%	-3.50%	3.50%	**PASS**
17	5.817	5.687	0.130	-2.23%	-3.50%	3.50%	**PASS**
15	5.936	5.839	0.097	-1.63%	-3.50%	3.50%	**PASS**
1*	6.000	5.99	0.007	-0.11%	-4.50%	4.50%	**PASS**



Repeatability of FEV1								
ATS waveform	Volume pred.	Volume mean	Min	Max	Span	% Span	Upper limit	Pass/Fail
24	0.918	0.906	0.901	0.909	**0.008**	**0.88**	10.89%	**PASS**
3*	1.171	1.204	1.203	1.205	**0.002**	**0.17**	8.54%	**PASS**
23	1.343	1.359	1.358	1.362	**0.004**	**0.29**	7.45%	**PASS**
4*	1.368	1.374	1.370	1.376	**0.006**	**0.67**	13.34%	**PASS**
8	1.611	1.603	1.601	1.606	**0.005**	**0.31**	6.21%	**PASS**
12	1.616	1.605	1.603	1.607	**0.004**	**0.25**	6.19%	**PASS**
11	1.801	1.804	1.800	1.807	**0.007**	**0.39**	5.55%	**PASS**
19	2.486	2.494	2.490	2.496	**0.006**	**0.24**	4.02%	**PASS**
7	2.510	2.505	2.502	2.509	**0.007**	**0.28**	3.98%	**PASS**
20	2.558	2.541	2.539	2.547	**0.008**	**0.31**	3.91%	**PASS**
17	2.571	2.587	2.583	2.591	**0.008**	**0.31**	3.89%	**PASS**
22	2.799	2.795	2.794	2.796	**0.002**	**0.07**	3.57%	**PASS**
6	3.012	3.018	3.015	3.021	**0.006**	**0.20**	3.50%	**PASS**
10	3.022	3.017	3.015	3.02	**0.005**	**0.17**	3.50%	**PASS**
14	3.140	3.129	3.126	3.132	**0.006**	**0.19**	3.50%	**PASS**
18	3.137	3.132	3.131	3.133	**0.002**	**0.06**	3.50%	**PASS**
21	3.539	3.513	3.505	3.519	**0.014**	**0.40**	3.50%	**PASS**
9	3.761	3.751	3.745	3.757	**0.012**	**0.32**	3.50%	**PASS**
13	3.820	3.813	3.812	3.814	**0.002**	**0.05**	3.50%	**PASS**
5	3.848	3.846	3.843	3.849	**0.006**	**0.16**	3.50%	**PASS**
16	3.880	3.869	3.864	3.873	**0.009**	**0.23**	3.50%	**PASS**
1*	4.231	4.233	4.229	4.238	**0.009**	**0.21**	3.50%	**PASS**
2*	4.571	4.536	4.533	4.537	**0.004**	**0.09**	3.50%	**PASS**
15	5.302	5.241	5.237	5.246	**0.009**	**0.17**	3.50%	**PASS**

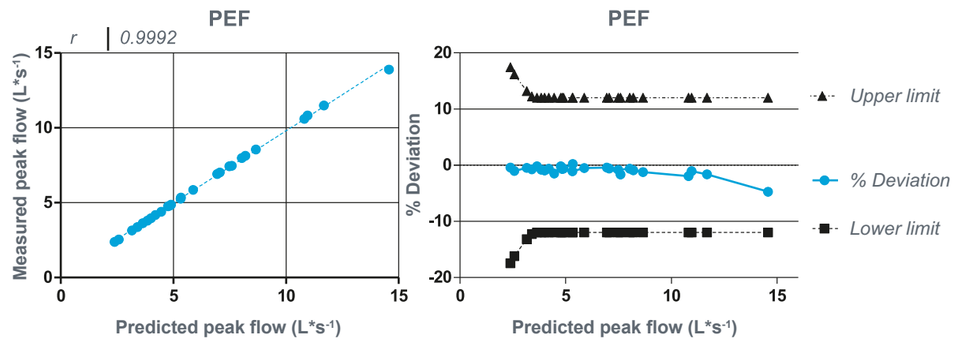


Repeatability FVC								
ATS waveform	Volume pred.	Volume mean	Min	Max	Span	% Span	Upper limit	Pass/Fail
24	1.237	1.219	1.214	1.222	**0.008**	**0.66**	8.09%	**PASS**
4*	1.498	1.495	1.491	1.497	**0.006**	**0.67**	13.34%	**PASS**
8	1.992	1.965	1.962	1.968	**0.006**	**0.31**	5.02%	**PASS**
12	2.000	1.970	1.968	1.973	**0.005**	**0.25**	5.00%	**PASS**
11	2.734	2.694	2.689	2.696	**0.007**	**0.26**	3.66%	**PASS**
20	2.880	2.844	2.841	2.850	**0.009**	**0.32**	3.50%	**PASS**
7	3.168	3.132	3.129	3.138	**0.009**	**0.29**	3.50%	**PASS**
23	3.418	3.347	3.345	3.351	**0.006**	**0.18**	3.50%	**PASS**
3*	3.497	3.494	3.492	3.497	**0.005**	**0.86**	5.72%	**PASS**
14	3.785	3.740	3.737	3.743	**0.006**	**0.16**	3.50%	**PASS**
10	3.842	3.796	3.794	3.799	**0.005**	**0.13**	3.50%	**PASS**
22	3.856	3.767	3.765	3.768	**0.003**	**0.08**	3.50%	**PASS**
19	3.934	3.853	3.849	3.856	**0.007**	**0.18**	3.50%	**PASS**
6	4.010	3.958	3.955	3.960	**0.005**	**0.13**	3.50%	**PASS**
18	4.342	4.265	4.263	4.266	**0.003**	**0.07**	3.50%	**PASS**
21	4.476	4.396	4.387	4.402	**0.015**	**0.34**	3.50%	**PASS**
9	4.853	4.785	4.780	4.792	**0.012**	**0.25**	3.50%	**PASS**
13	4.894	4.829	4.827	4.834	**0.007**	**0.14**	3.50%	**PASS**
2*	4.998	4.943	4.941	4.945	**0.004**	**0.08**	4.50%	**PASS**
5	5.131	5.060	5.058	5.064	**0.006**	**0.12**	3.50%	**PASS**
16	5.457	5.397	5.391	5.403	**0.012**	**0.22**	3.50%	**PASS**
17	5.817	5.687	5.684	5.691	**0.007**	**0.12**	3.50%	**PASS**
15	5.936	5.839	5.835	5.841	**0.006**	**0.10**	3.50%	**PASS**
1*	5.999	5.957	5.955	5.959	**0.004**	**0.07**	4.50%	**PASS**

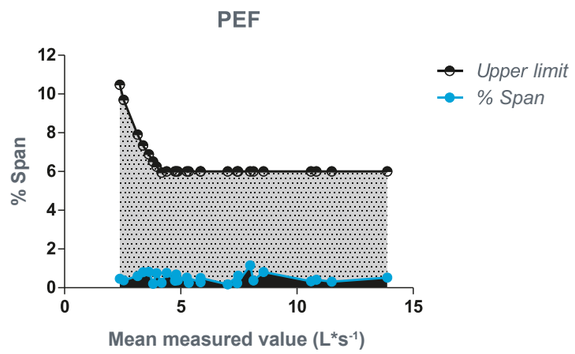


26 Waveform results for PEF

Accuracy of PEF							
ATS waveform	Flow pred. $L*s^{-1}$	Flow abs. $L*s^{-1}$	Deviation $L*s^{-1}$	% Deviation	% Lower limit	% Upper limit	Pass/Fail
8	2.386	2.3762	0.0098	-0.41	-17	17	**PASS**
7	2.576	2.5494	0.0266	-1.03	-16	16	**PASS**
6	3.16	3.1446	0.0154	-0.49	-13	13	**PASS**
22	3.4	3.3746	0.0254	-0.75	-12	12	**PASS**
5	3.636	3.629	0.007	-0.19	-12	12	**PASS**
14	3.842	3.8112	0.0308	-0.80	-12	12	**PASS**
21	4.002	3.9638	0.0382	-0.95	-12	12	**PASS**
24	4.202	4.1758	0.0262	-0.62	-12	12	**PASS**
4	4.462	4.3958	0.0662	-1.48	-12	12	**PASS**
10	4.766	4.7578	0.0082	-0.17	-12	12	**PASS**
3	4.898	4.8698	0.0282	-0.58	-12	12	**PASS**
13	4.836	4.8034	0.0326	-0.67	-12	12	**PASS**
9	5.338	5.3498	-0.0118	0.22	-12	12	**PASS**
16	5.324	5.266	0.058	-1.09	-12	12	**PASS**
17	5.882	5.851	0.031	-0.53	-12	12	**PASS**
11	6.944	6.9142	0.0298	-0.43	-12	12	**PASS**
19	7.062	7.0218	0.0402	-0.57	-12	12	**PASS**
1	7.594	7.4684	0.1256	-1.65	-12	12	**PASS**
20	7.488	7.4262	0.0618	-0.83	-12	12	**PASS**
15	8.034	7.9838	0.0502	-0.62	-12	12	**PASS**
23	8.200	8.1254	0.0746	-0.91	-12	12	**PASS**
18	8.664	8.5586	0.1054	-1.22	-12	12	**PASS**
12	10.812	10.6014	0.2106	-1.95	-12	12	**PASS**
2	10.952	10.8372	0.1148	-1.05	-12	12	**PASS**
26	11.682	11.4922	0.1898	-1.62	-12	12	**PASS**
25	14.574	13.8876	0.6864	-4.71	-12	12	**PASS**



Repeatability PEF								
ATS waveform	Flow pred.	Flow mean	Min	Max	Span	% Span	Upper limit	Pass/Fail
8	2.386	2.376	2.369	2.380	0.011	0.46	10.48%	**PASS**
7	2.576	2.549	2.545	2.555	0.010	0.39	9.70%	**PASS**
6	3.160	3.145	3.135	3.154	0.019	0.60	7.91%	**PASS**
22	3.400	3.375	3.365	3.392	0.027	0.80	7.35%	**PASS**
5	3.636	3.629	3.616	3.646	0.030	0.83	6.88%	**PASS**
14	3.842	3.811	3.804	3.812	0.008	0.21	6.51%	**PASS**
21	4.002	3.964	3.945	3.975	0.030	0.76	6.25%	**PASS**
24	4.202	4.176	4.170	4.181	0.011	0.26	5.95%	**PASS**
4	4.462	4.396	4.379	4.413	0.034	0.77	6.00%	**PASS**
10	4.766	4.758	4.750	4.767	0.017	0.36	6.00%	**PASS**
3	4.898	4.870	4.858	4.877	0.019	0.39	6.00%	**PASS**
13	4.836	4.803	4.787	4.820	0.033	0.69	6.00%	**PASS**
9	5.338	5.350	5.341	5.355	0.014	0.26	6.00%	**PASS**
16	5.324	5.266	5.252	5.280	0.028	0.53	6.00%	**PASS**
17	5.882	5.854	5.841	5.858	0.017	0.29	6.00%	**PASS**
11	6.944	5.851	6.896	6.926	0.030	0.51	6.00%	**PASS**
19	7.062	7.022	7.016	7.028	0.012	0.17	6.00%	**PASS**
1	7.594	7.468	7.442	7.489	0.047	0.63	6.00%	**PASS**
20	7.488	7.426	7.416	7.433	0.017	0.23	6.00%	**PASS**
15	8.034	7.984	7.906	7.999	0.093	1.16	6.00%	**PASS**
23	8.200	8.125	8.109	8.140	0.031	0.38	6.00%	**PASS**
18	8.664	8.559	8.521	8.590	0.069	0.81	6.00%	**PASS**
12	10.812	10.601	10.578	10.613	0.035	0.33	6.00%	**PASS**
2	10.952	10.837	10.817	10.862	0.045	0.42	6.00%	**PASS**
26	11.682	11.492	11.478	11.514	0.036	0.31	6.00%	**PASS**
25	14.574	13.888	13.856	13.930	0.074	0.53	6.00%	**PASS**



Conclusion

These validation results show that new Vyntus ultrasonic sensor in combination with the SentrySuite software platform, meet all 24 and 26 waveform requirements with no failure **(100% passing)**.

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GLOBAL HEADQUARTERS

Vyaire Medical, Inc.
26125 North Riverwoods Blvd
Mettawa, IL 60045
USA

CareFusion Germany 234 GmbH
Leibnizstrasse 7
97204 Hoechberg
Germany

vyaire.com

vyaire™ MEDICAL