

SPECIFICATIONS

TABLE 1 - WITHOUT VALVED TEE ADAPTER

PARAMETERS	FLOW RATE		
	10 lpm	20 lpm	40 lpm
Average Pressure (cmH ₂ O) across all settings	10-13	18-21	27-41
Average Pressure Amplitude (cmH ₂ O) across all settings	7-17	22-28	51-76
Frequency (Hz) across all settings	8-16	12-17	19-22

WITH VALVED TEE ADAPTER

PARAMETERS	FLOW RATE		
	10 lpm	20 lpm	40 lpm
Average Pressure (cmH ₂ O) across all settings	9-13	18-21	29-40
Average Pressure Amplitude (cmH ₂ O) across all settings	5-13	19-24	46-58
Frequency (Hz) across all settings	8-15	13-17	18-21

Note: Testing was performed at a fixed flow rate. Actual values are dependent upon individual effort.

The following specifications were established via performance test using an eight-stage cascade impactor at a flow rate of 28 L/min equipped with USP <601> induction port throat. Three (3) device samples were tested with 3 runs each, for a total of 9 samples points per each drug for a total of 27 data points. Aerosol was sampled directly from the outlet. The specifications are listed below based upon a 95% confidence level.

TABLE 2 - AEROSOL ONLY MODE AT 28 LPM - PARTICLE SPECIFICATIONS

Measurement (Mean)	Standalone Configuration	with Valved Tee Adapter	Standalone Configuration	with Valved Tee Adapter	Standalone Configuration	with Valved Tee Adapter
Westmed - VixOne®						
	Albuterol		Cromolyn Sodium		Ipratropium Bromide	
MMAD (um)	1.7	1.37	1.67	1.43	1.53	1.37
GSD	2.24	2.21	2.04	1.75	2.11	2.09
Total Dose (ug)	1256	1050	6295	5212	262	252
Total Respirable Dose (0.5-5 um)	896	790	4939	4106	174	147
Coarse Particle > (4.7 um)	266	154	881	555	72	83
Fine Particle	990	896	5413	4657	190	169
Ultra-Fine Particle (< 1.0 um)	347	351	1804	2460	64	69
Statistical analysis Significant differences	No		No		No	
Hudson RCI Micro Mist®						
	Albuterol		Cromolyn Sodium		Ipratropium Bromide	
MMAD (um)	1.77	1.40	1.60	1.43	1.53	1.47
GSD	2.94	2.28	2.69	2.75	2.74	2.83
Total Dose (ug)	863	779	2803	2482	127	119
Total Respirable Dose (0.5-5 um)	497	493	1696	1556	62	60
Coarse Particle > (4.7 um)	277	193	782	564	52	44
Fine Particle	586	586	2022	1918	75	75
Ultra-Fine Particle (< 1.0 um)	231	250	828	878	31	34
Statistical analysis Significant differences	No		No		No	

Note: Course particles (oropharyngeal deposition) and ultrafine particles (exhaled) are not likely to deposit in the patient's airway and thus provide clinical benefit.