

# IN VITRO PERFORMANCE OF THE MyNeb™ NEBULIZER: A NEW PORTABLE AEROSOL DELIVERY SYSTEM

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## INTRODUCTION

MyNeb™ (Figure 1, Respironics Respiratory Drug Delivery) is a new handheld, portable (h 4.96" × w 2.80" × d 1.46") ultrasonic nebulizer utilizing a novel aerosol generating technology (Respironics Respiratory Drug Delivery). Without the use of moving parts or impediments to flow, this new technology uses focused energy to separate liquid medication into a fine particle aerosol stream and impel that stream through the device. The objective of this study was to compare the *in vitro* performance of the MyNeb with three drugs commonly used in the treatment of patients with asthma and COPD.

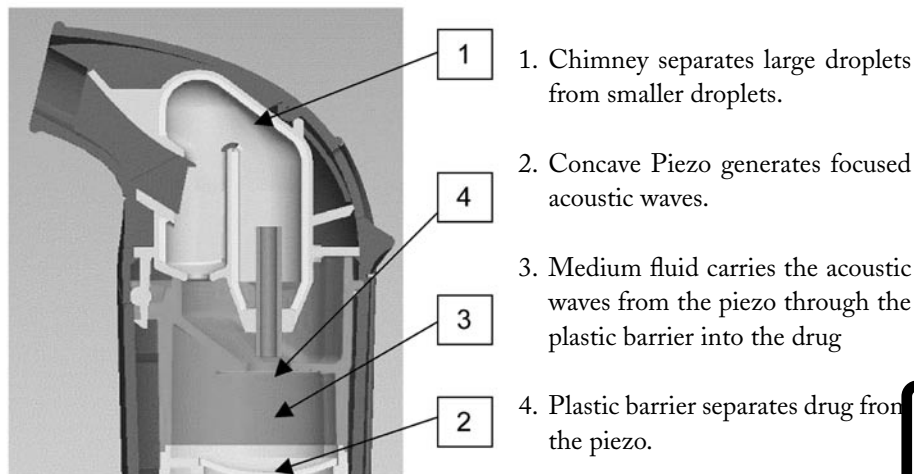


Figure 1. The MyNeb™ nebulizer.

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## METHODS AND RESULTS

The three drug solutions for inhalation used in the study were: albuterol sulfate 2.5 mg/3 mL (Proventil® Inhalation Solution 0.083%, Schering-Plough), cromolyn sodium 20 mg/2 mL (In-tal® Nebulizer Solution 20mg/2mL, Aventis), and ipratropium bromide 0.5 mg/2.5 mL (Ipratropium Bromide Inhalation Solution 0.02%, RxElite). A pre-production MyNeb was filled with one ampoule of the drug solution and connected via the USP throat to a Marple-Miller Model 150 Cascade Impactor (MMI), operated at 30 L/min. The total nebulization time for each MMI run was determined by sensors within the MyNeb unit. The effective cut-off diameters for the different Marple-Miller Impactor stages were: 10.00  $\mu\text{m}$  (Stage 2), 5.00  $\mu\text{m}$  (Stage 3), 2.50  $\mu\text{m}$  (Stage 4), 1.25  $\mu\text{m}$  (Stage 5), and 0.63  $\mu\text{m}$  (Filter). MyNeb was activated after the device had been filled, and produced a constant stream of aerosol until the end of the treatment (detected automatically as a function of the fluid level in the nebulizer medication chamber). The amount of drug recovered from each stage of the Marple-Miller Impactor was determined by high performance liquid chromatography (HPLC). Three separate ampoules of each drug solution ( $n=3$ ) were evaluated in the same MyNeb device. The aerosol output characteristics were defined in terms of delivered dose, fine particle fraction ( $\text{FPF}_{0.5-5\mu\text{m}}$ , % of drug in particles between 0.5–5.0 $\mu\text{m}$ ), mass median aerodynamic diameter (MMAD), and geometric standard deviation (GSD).

Figure 2 shows the mean amount of all three drugs recovered from the Marple-Miller Impactor stages, filter, and USP Throat.

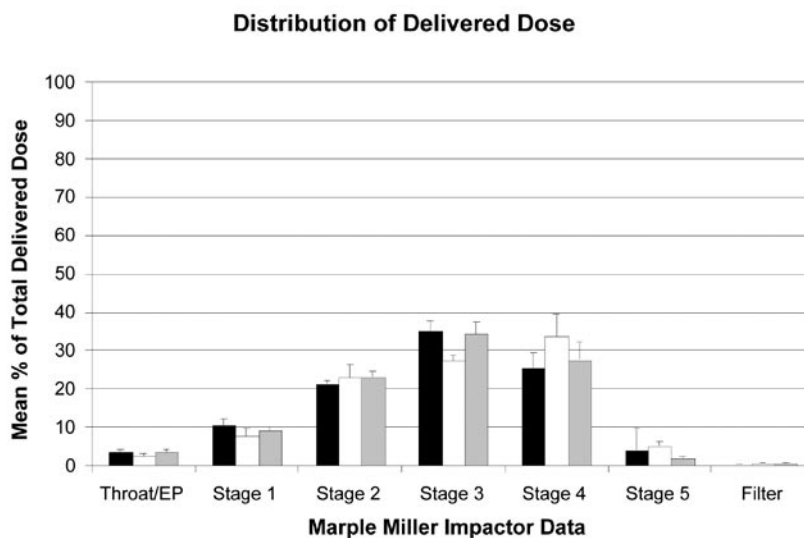


Figure 2. The particle size distributions for the MyNeb nebulizer with albuterol sulfate (black), cromolyn sodium (white), and ipratropium bromide (grey). The amount of drug is represented as a percentage of the total amount of drug recovered from the USP Throat, MMI stages and filter.

The majority of particles were deposited on Stages 2 to 4 of the MMI. The overall particle size distributions for albuterol sulfate, cromolyn sodium, and ipratropium bromide appear to be similar as seen in Figure 2.

Refer to Table 1 for the overall performance of MyNeb with the three drug products tested. The delivered doses, defined as the amount of drug exiting the nebulizer mouthpiece, were 1.7 mg (albuterol), 10.3 mg (cromolyn), and 0.3 mg (ipratropium). The delivered fine particle fractions (FPF<sub>0.5-5µm</sub>), expressed as a percent of the label claims, were approximately 64%, 66%, and 64% for albuterol, cromolyn, and ipratropium, respectively. The MMADs for the MyNeb nebulizer with the three drug solutions ranged from 3.11 µm to 3.39 µm.

Table 1

MyNeb™ Performance.

	Albuterol Sulfate			Cromolyn Sodium			Ipratropium Bromide		
	Mean (mg)	SD (mg)	% CV	Mean (mg)	SD (mg)	% CV	Mean (mg)	SD (mg)	% CV
Amount of Drug Exiting Nebulizer (mg)	1.73	0.07	4.04	10.3	0.3	2.63	0.3	0.03	8.32
Amount in Fine Particle Dose (mg)	1.11	0.01	1.11	6.8	0.7	9.63	0.2	0.02	12.08
% Drug in Fine Particle Dose	64.43	1.95	3.02	66.32	5.67	8.55	63.77	2.86	4.49
MMAD	3.28	0.21	6.46	3.11	0.27	8.74	3.39	0.20	5.75
GSD	1.75	0.05	2.86	1.90	0.05	2.79	1.86	0.02	0.82

## CONCLUSIONS

The results of the characterization of the aerosols of albuterol sulfate, cromolyn sodium, and ipratropium bromide delivered with the MyNeb nebulizer indicate that the main aerosol descriptors were similar for the three drug solutions evaluated. The uniformity of results, based on FPF<sub>0.5-5µm</sub> and MMAD, demonstrates that the moving stream of aerosol produced by this new technology is well-suited for nebulizing various inhalation solutions. The aerosol produced by MyNeb has characteristics suitable for patients with chronic airway obstruction (1).

## REFERENCE

1. Johnson, M.A. et al. (1989), "Delivery of albuterol and ipratropium bromide from two nebulizer systems in chronic stable asthma," *Chest*, 96:1-10.

*Notes*