CONCLUSIONS

According to the data the ***AeroEclipse***® R BAN takes comparable time to run to sputter as the Salter Nebutech† and the Pari LC Sprint† (See Box 1).

The ***AeroEclipse***® R BAN* delivers more respirable dose as compared to the other nebulizers and compressor sets tested (See Box 2). To further increase respirable dose the ***AeroEclipse***® R BAN can be run in breath actuated mode.

In breath actuated mode the ***AeroEclipse***® R BAN takes longer to run to sputter but delivers considerably more medication.

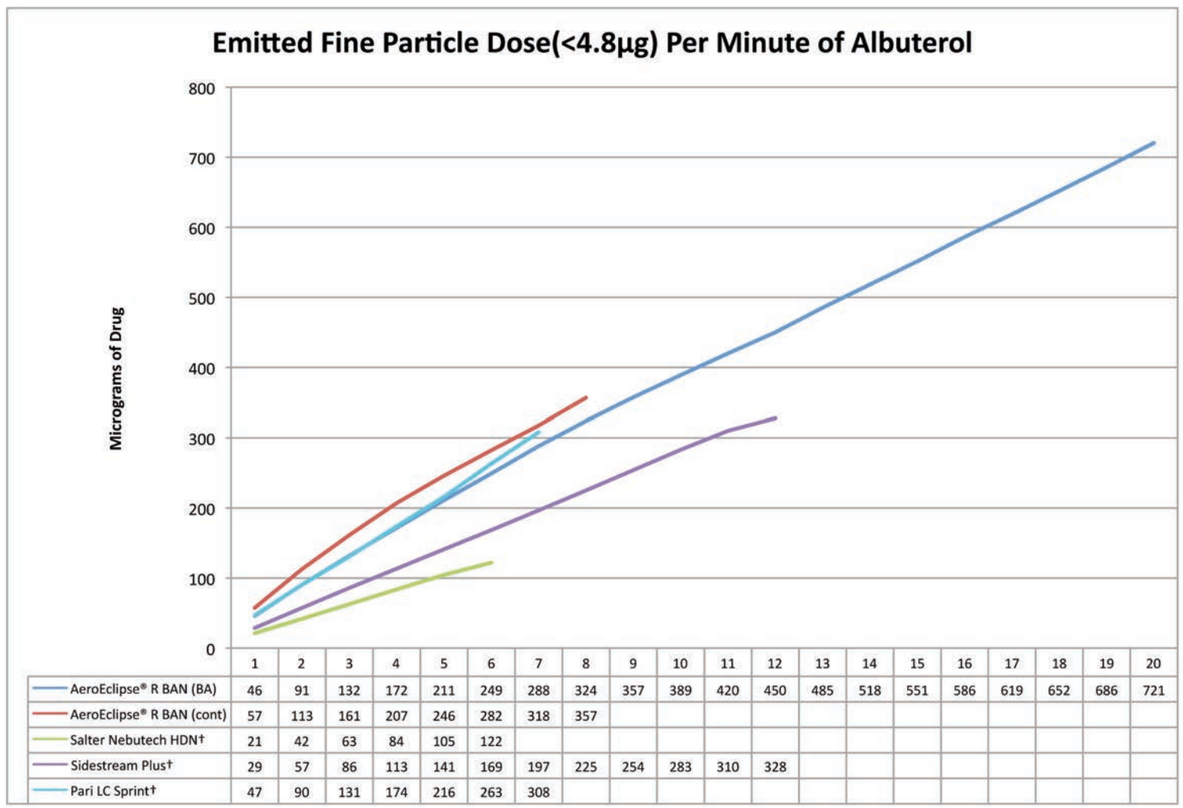
*AE R BAN in continuous mode

Box 1: Average Run Time to Sputter

Device	Average Run Time
AeroEclipse® R BAN (cont)	8 min
Salter NebuTech HDN†	6 min
Pari LC Sprint†	7 min
Sidestream Plus†	12 min

Box 2: Competitive Nebulizers Deliver Less RD as Compared to the AeroEclispe® R BAN*

Competitive Device	% *LESS* RD Delivered
Sidestream Plus†	-8%
Pari LC Sprint†	-14%
Salter NebuTech HDN†	-66%



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
AeroEclipse® R BAN (BA)	46	91	132	172	211	249	288	324	357	389	420	450	485	518	551	586	619	652	686	721
AeroEclipse® R BAN (cont)	57	113	161	207	246	282	318	357												
Salter Nebutech HDN†	21	42	63	84	105	122														
Sidestream Plus†	29	57	86	113	141	169	197	225	254	283	310	328								
Pari LC Sprint†	47	90	131	174	216	263	308													

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Monaghan Medical Corporation, 5 Latour Ave., Suite 1600,
Plattsburgh, NY 12901, Customer Service 800-833-9653
www.monaghanmed.com

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Trudell Medical International
Aerosol Laboratory Report

NEBULIZER/COMPRESSOR DOSE COMPARISON
Information derived from the following study:
Performance of the ***AeroEclipse***® Reusable Breath Actuated Nebulizer (R BAN) with Albuterol Sulphate - Adult Breathing Simulator

INTRODUCTION

Traditionally, delivery of bronchodilators by small volume jet nebulizer (SVN) is widely practiced for the treatment of obstructive lung disease because certain drugs are only available as inhalation solutions and some patients are unable to master the correct use of either pressurized metered-dose inhalers (pMDIs) or dry powered inhalers (DPIs). Delivery of bronchodilators by SVN on a compressor is widely practiced for the treatment of COPD due to the existing reimbursement practices and other economic considerations when compared to MDIs and DPIs. SVN treatment times are long as compared to pMDI and DPI use leading to interest in reducing overall time and improving nebulizer efficiency; however, SVN treatment times vary based on SVN and compressor combinations. Studies have shown the ideal medical aerosol will be characterized by a Mass Median Aerodynamic Diameter (MMAD) of 2.8μm.

This report describes comparative testing among:

- ***AeroEclipse***® R BAN/Sport Neb eXPRESS† compressor
- PARI LC Sprint† SVN/Vios† compressor
- Salter Nebutech HDN† SVN/Salter AIRE Plus† compressor
- Sidestream Plus† SVN/Mini Elite† compressor

METHODS

Five devices of each type were tested using an in-vitro model breath simulator to evaluate the effect of a representative breathing pattern. A bacterial/viral filter (Respirgard II†, Marquest Medical, Englewood, CO.) was located to cover the mouthpiece of each nebulizer. The mouthpiece was coupled to the PARI breathing simulator, which was set to replay a breathing pattern with the following parameters:

- Tidal Volume: 600 ml I:E Ratio 1:2 BPM 10
- Each nebulizer was filled with 3ml of a standard solution of 2.5mg generic Albuterol sulfate (ALB) (2.5 mg/ 3 ml).
- All measurements were made with the nebulizer operated per the specific parameters of the paired compressor.

Compressor	Flow (LPM)	Pressure (PSI)
Sport Neb eXPRESS†	2.5 - 6	30
Vios†	4.5 - 8.5	18 - 34
Salter AIRE Plus†	6 - 10	25
MiniElite†	3.5 - 8	29

Each nebulizer was allowed to operate until first sputter (defined to be the point at which nebulization changed [audibly or visibly] or became intermittent). At one minute intervals the bacterial/viral (sample) filter was replaced with a fresh filter. The sample filter was filled with pure methanol to a constant volume (20 ml), from which an aliquot was removed for analysis. Drug assay was undertaken by HPLC-UV spectrophotometry to determine the mass of ALB.

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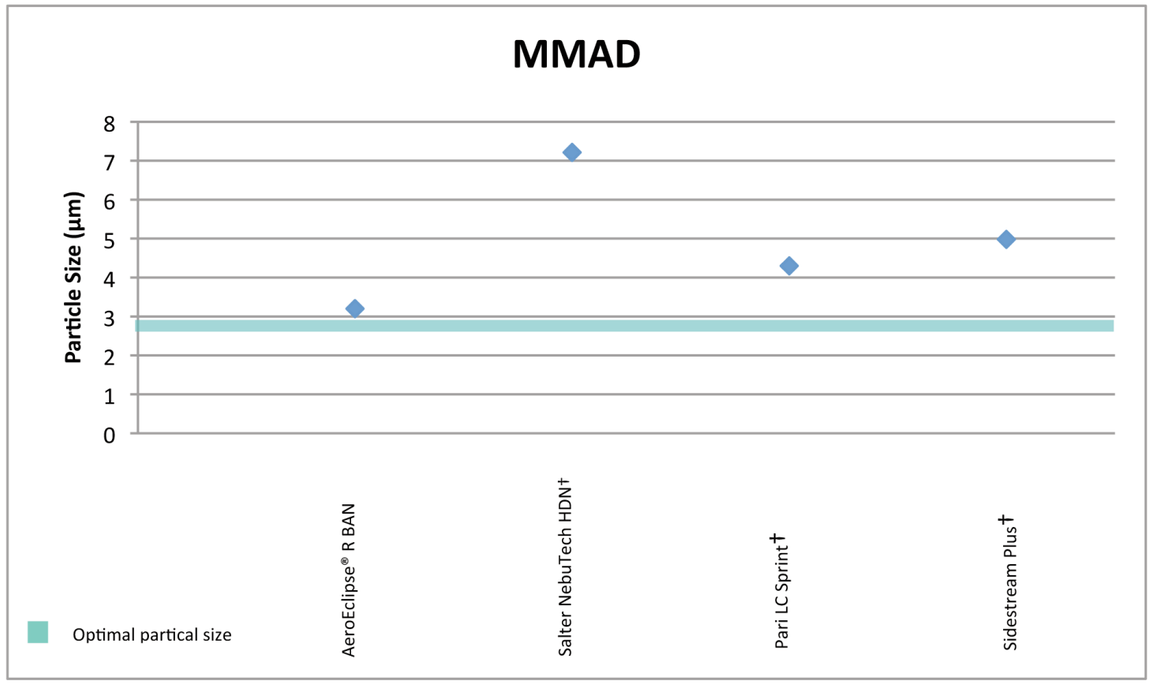
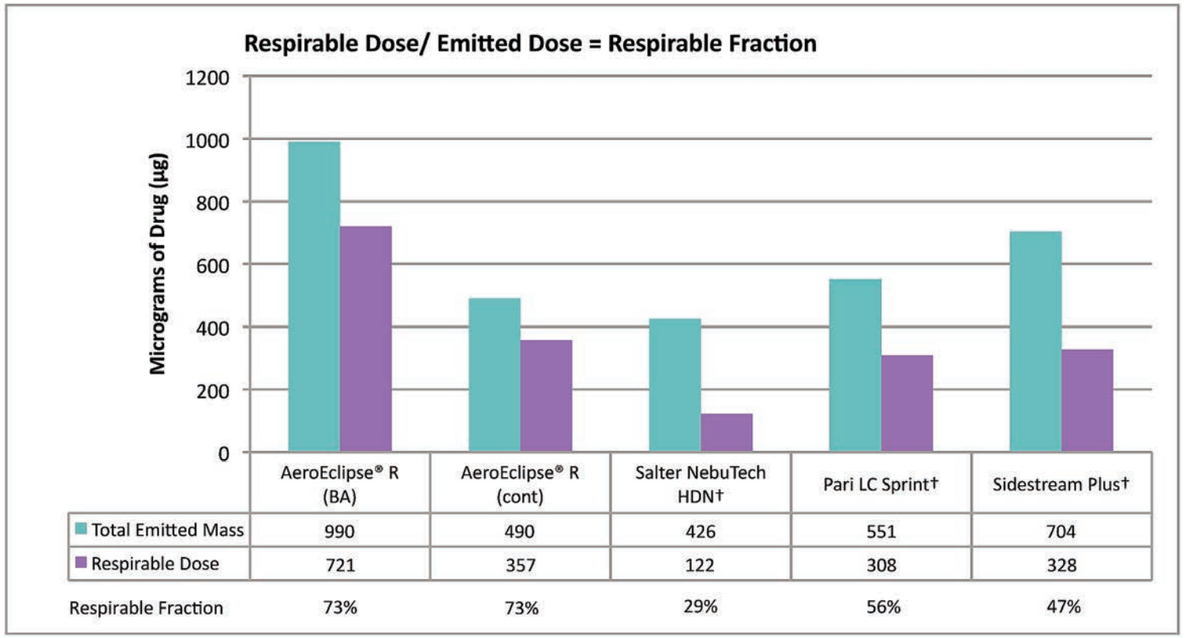
PARTICLE SIZE ANALYSIS

Particle size analysis was performed using the laser diffractometry technique. A 300-mm range lens was used to detect particles between 0.5µm- and 2000 µm-calculated diameter. The average particle size from each nebulizer replicate was determined based on a 30 second sample period. The presentation code corresponded to water (refractive index of 1.333) dispersed in air (ri = 1.000). The position of the nebulizer and presentation of the aerosol to the laser are important to obtain reproducible results. The mouthpiece of the nebulizer was placed 1-2 cm from the detector lens and 1 cm from the edge of the laser beam for these experiments. Aerosol was pushed across the laser beam by flow from a compressed air source at 28.3 lpm to simulate the conditions of cascade impaction. A vacuum source was placed opposite the nebulizer mouthpiece to collect the emitted aerosol, avoiding recirculation of aerosol droplets; the vacuum inlet was located <3 cm from the laser beam. A 100-mm range lens was used to detect particles between 0.5 µm- and 180 µm-calculated diameter. The detector was programmed to make 5 replicates of 2,000 measurements each requiring a 4-second time period. The presentation code corresponded to water (refractive index of 1.333) dispersed in air (ri = 1.000).



RESULTS

The following charts and tables summarize the data collected during the study. All output data are presented as fine particle dose (FPD) which was calculated by multiplying fine particle fraction (FPF) by the mass of medication captured on the sample filter.



	AeroEclipse® R (BA)	AeroEclipse® R (cont)	Salter NebuTech HDN†	Pari LC Sprint†	Sidestream Plus†
Total Emitted Mass	990	490	426	551	704
Respirable Dose	721	357	122	308	328
Respirable Fraction	73%	73%	29%	56%	47%

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