

Trudell Medical International

Aerosol Laboratory Report

AUTHORS: M.W. Nagel, C.C. Doyle, S.L. Bates, J.P. Mitchell
London, Ontario, Canada

NEBULIZER DOSE COMPARISON

Information derived from the following studies:

Performance of the **AeroEclipse® II**

Breath Actuated Nebulizer (BAN) with

Albuterol Sulphate and Ipratropium Bromide Solutions -
Adult Breathing Simulator



INTRODUCTION

This report describes comparative testing between the breath actuated **AeroEclipse® II** BAN and four other nebulizing devices. Delivery of bronchodilators by small volume jet nebulizer (SVN) is widely practiced for the treatment of obstructive lung diseases 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 (DPI)¹. SVN treatment times are long compared with pMDI and DPI use² leading to interest in reducing them³ and improving nebulizer efficiency⁴. Studies have shown the ideal medical aerosol will be characterized by a Mass Median Aerodynamic Diameter (MMAD) of $2.8\mu\text{m}$ ⁵. Environmental loss of aerosolized medications is an important measure both regarding the impact of data results from the nebulizer and based on the health and safety of healthcare professionals⁶. This report describes comparative testing between the breath-actuated **AeroEclipse® II** BAN and six other SVNs.

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/ml).

All measurements were made with the nebulizer operated with approximately 8.0 ± 0.2 L/min air, delivered at approximately 50.0 ± 0.5 psig. 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 1 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.

Environmental loss values were determined by subtracting the mass of ALB collected on the inspiratory filters combined with the residual ALB collected from the nebulizer following operation from the mass of albuterol that was placed within the SVN at the start of the experiment.



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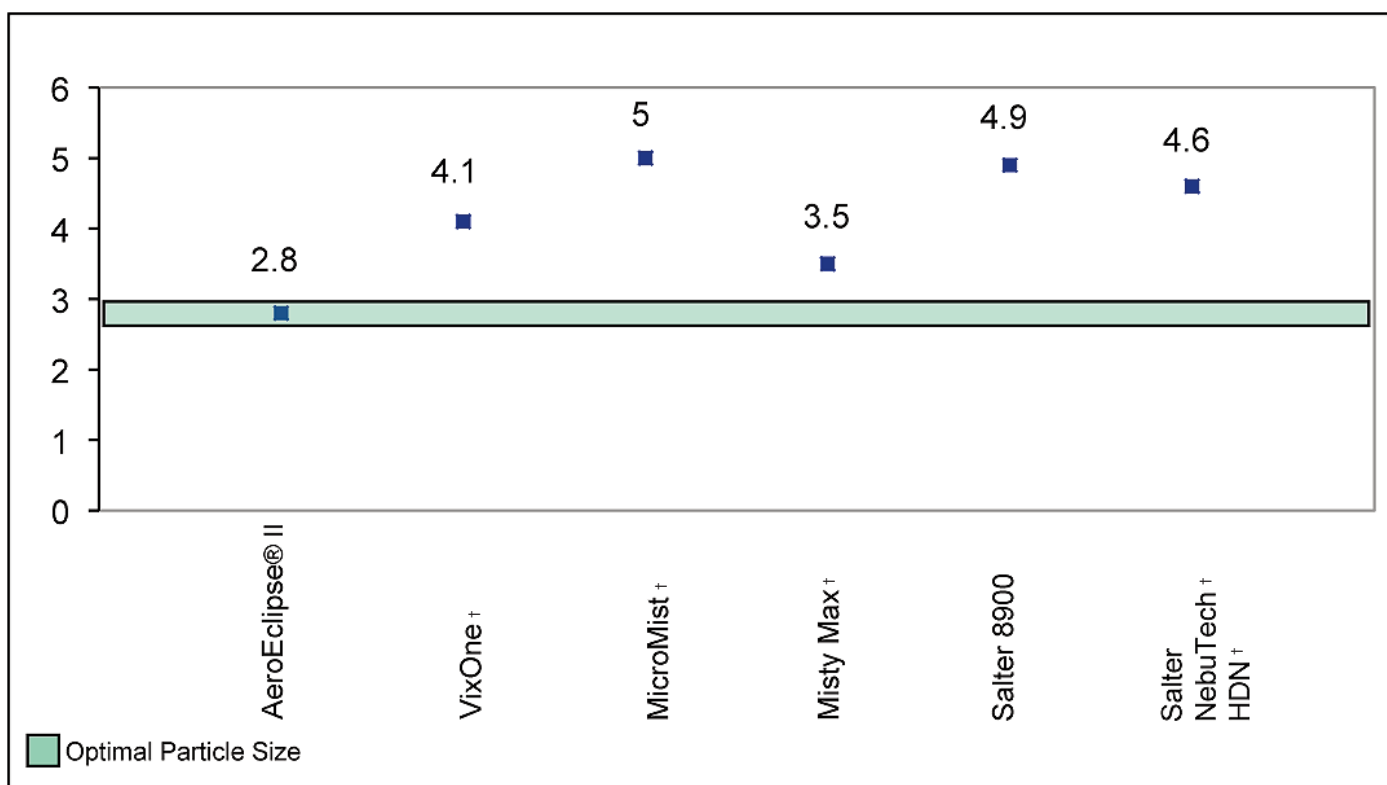
PARTICLE SIZE ANALYSIS

Particle size analysis was performed using the laser diffractometry technique. A 300-mm range lens was used to detect particles between 0.5 μ m- and 2000 μ m-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 ($r_i = 1.000$).

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 μ m- and 180 μ m-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 ($r_i = 1.000$).

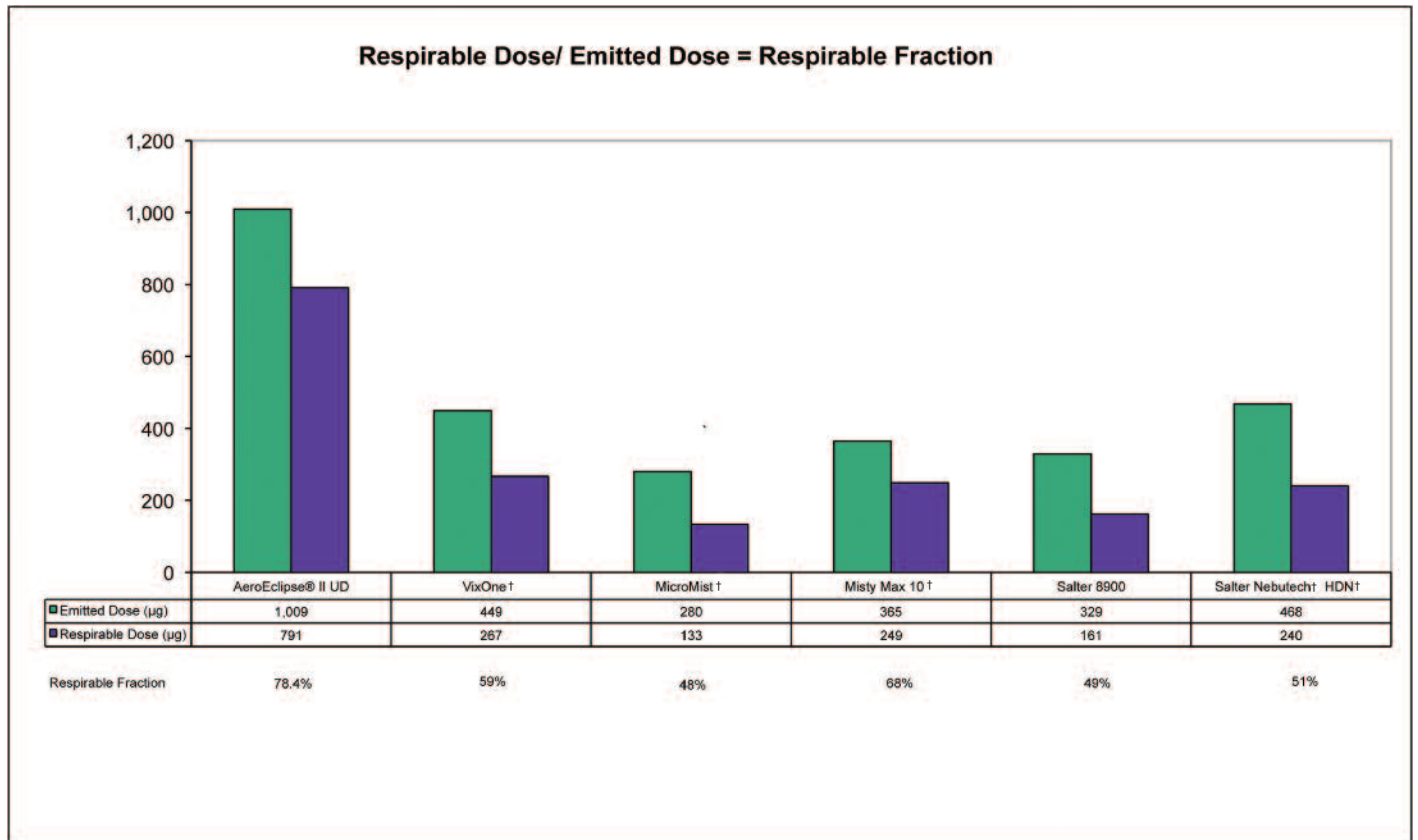
Mass Median Aerodynamic Diameter (MMAD) μ m



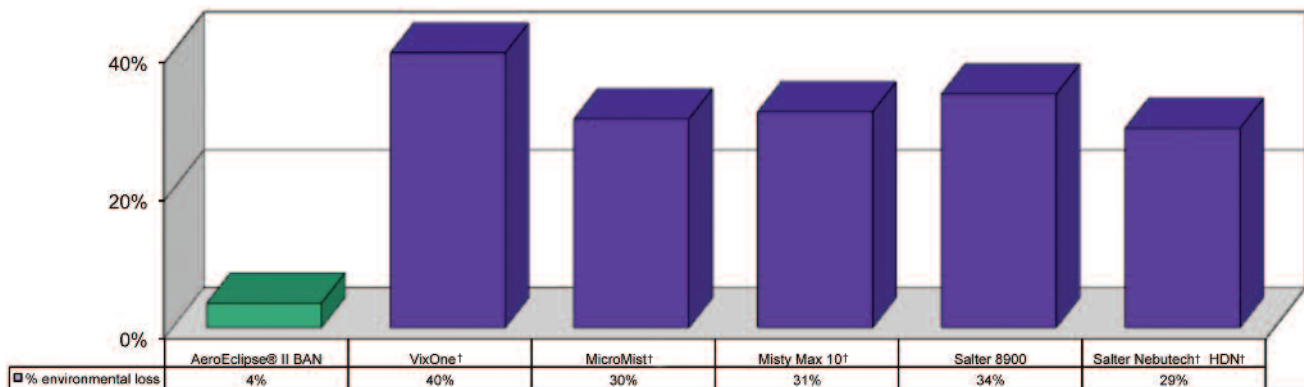
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RESULTS

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.



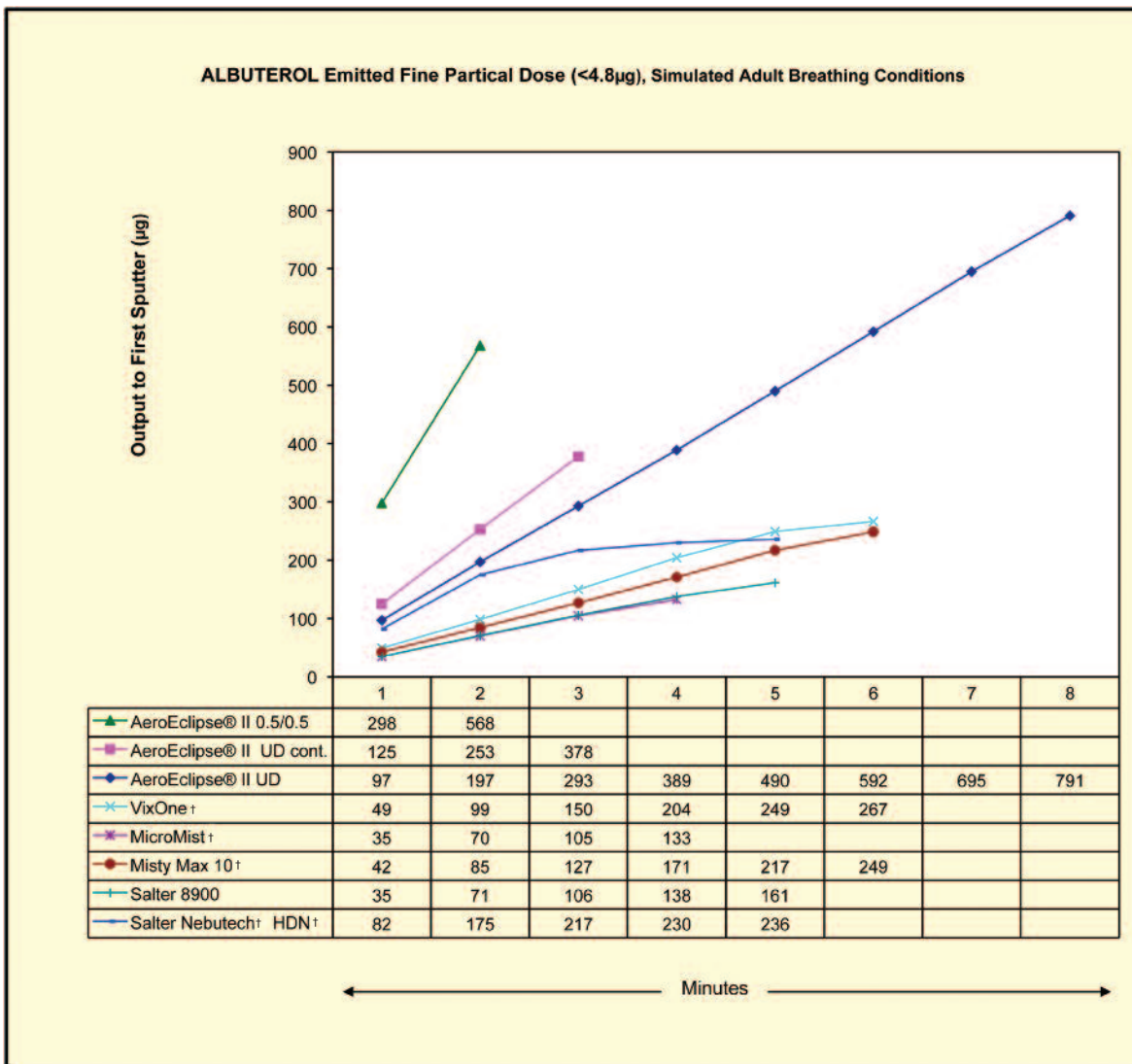
Percent Environmental Loss (%)



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CONCLUSIONS

Based on the data, the clinician can alter the drug concentration, treatment time or volume placed in the reservoir of the **AeroEclipse® II BAN** to achieve a desired dosing regime. The **AeroEclipse® II BAN** also emits minimal environmental loss to the atmosphere thus providing less second-hand aerosols to healthcare providers.



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5 Latour Ave., Suite 1600
Plattsburgh, NY 12901
800-833-9653
www.monaghanmed.com

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