

Therapist Exposure Risk and the Potential Impact of Device Selection.

*A Brief Review of the Literature on Second-hand Aerosols and the Effects of Occupational Exposure

- **Danger in the Air**, Proctor S., *Advance for Respiratory Care Practitioners*, January 24, 2005.

In a review and expansion of the 2004 *Chest* article this publication states “respiratory therapists are at an increased risk of developing asthma and asthma-related symptoms due to their involvement in the diagnosis and treatment of patients with respiratory conditions.” In separate communications with the lead author, *Advance* reports “Routine monitoring and care of patients can expose therapists to trace amounts of airborne agents that can trigger respiratory symptoms and cause exacerbations of acute asthma;” and “Under current conditions, control of exhaust aerosols is paramount. ... this includes use of scavengers, developing shut-off devices for nebulizers...”

- **Respiratory Health Survey of Respiratory Therapists**, Dimich-Ward, et al. *Chest* 2004; 126: 1048-1053

Study showed that RTs have an elevated prevalence of asthma diagnosis after they enter into the profession, and when compared to a control group of Physical Therapists, are more than twice as likely to develop respiratory symptoms. The study also found that the administration of specific aerosolized medications was associated with an increased risk of asthma.

- **Respiratory Therapists Twice as Likely to Have Asthma Than Other Therapists – Exposure to Patient Treatments May Increase Therapists’ Asthma Risk**, *Canadian Society of Respiratory Therapists News*, Oct. 2004

R.S. Irwin MD, FCCP, President of the American College of Chest Physicians, quoted in the article states, “It is important for respiratory therapists and other medical professionals to recognize and understand the possible respiratory effects related to the administration of aerosolized substances and take appropriate steps to minimize their exposure to these medications during patient diagnostic procedures and treatments.”

- **Mist-ical Problem—Aerosolized Patient Exhaust May Jeopardize Practitioner Airways**, *Advance for Respiratory Care Practitioners*, March 24, 2003.

“... evidence suggests some RTs are at risk of developing occupational asthma when treating asthmatics. At issue is an unintended consequence of liquid nebulization.” Patrick Dunn, quoted in the article speculates, “The higher than average occupational asthma rate is probably related to passive inhalation of the exhaust of patients’ aerosolized medications. The reality is we need to change the way nebulizers are designed. You are giving the room a treatment.” Manufacturers have responded to this emerging need with filter attachments and nebulizers designed for low environmental loss such as the **AeroEclipse®** breath-actuated nebulizer that produces aerosol in response to the patient’s inspiratory flow.

- **Second-hand (S)-Albuterol: RT Exposure Risk Following Racemic Albuterol**, Carnathan, et al. *Respiratory Care*, October 2001, V46, No. 10.

Whether exposure to nebulized medications such as Racemic Albuterol (RAC) contribute to increased incidence of asthma among respiratory therapists is unknown. This *in vivo* study was designed to determine if the S and R isomers in RAC are detectable in the plasma of RTs. After a two-day work holiday blood was drawn at baseline, 2, 4, and 8 hours after exposure on days 1 and 4. Subjects were exposed to an average of 31mg of RAC for 4.3 hours each day. Results indicate RAC isomers increased with exposure. The study concludes S isomer (proinflammatory effects) achieves higher plasma levels (1.6 to 2.5 fold) than R isomer (confers all off the bronchodilatory effects) and stays in the systemic circulation for a longer period of time.

- **Asthma Risk and Occupation as a Respiratory Therapist**, Christiana DC, Kern DG. *American Review Respiratory Disease* 1993, Sept; 148(3): 671-674

A study of 2,086 respiratory therapists and 2,030 physical therapists found a history of physician diagnosed asthma in 16% of respiratory therapists and 8% of control subjects. When analysis was restricted to those who developed asthma after entry into the profession, RTs still had a significant excess, 7.4% versus 2.8%. This article concludes efforts should be directed to identifying potential agents responsible for this form of occupational asthma.



AeroEclipse® II BAN – Breath actuation proven to reduce exposure to second-hand aerosol

These studies used the AeroEclipse® Breath Actuated Nebulizer, not the AeroEclipse® II Breath Actuated Nebulizer (BAN) which is currently on the market. The AeroEclipse® BAN and AeroEclipse® II BAN are equivalent in regards to in vitro performance.¹

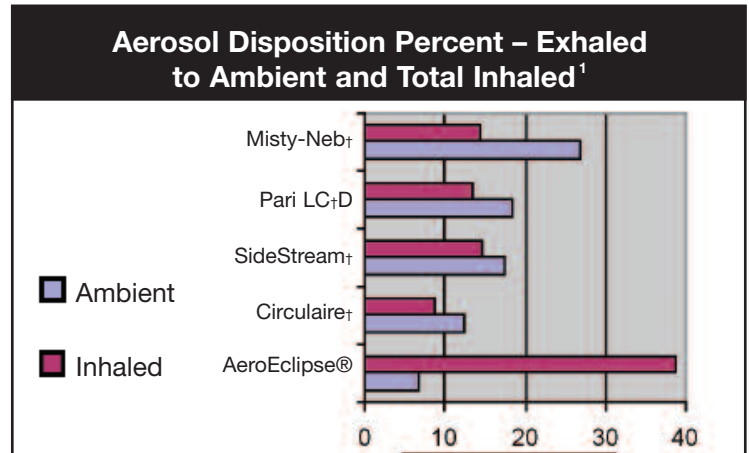
Changing the way nebulizers are designed can reduce the risk of second-hand aerosols.

The **AeroEclipse® II Breath Actuated Nebulizer (BAN)** is engineered to reduce the environmental loss of aerosol. The literature supports the unique benefit of this SVN to reduce occupational exposure to second-hand aerosols.

Performance Comparison of Nebulizer Designs: Constant-Output, Breath-Enhanced, and Dosimetric.

Rau, et al. *Respiratory Care*, February 2004, Vol 49 No 2, page 174–179.

- This study (also mass balance) evaluated the *in vitro* dose disposition (delivered to patient, lost to the equipment and lost to ambient) with 5 different nebulizer models representing 3 product types—constant output, breath-enhanced and dosimetric—using simulated normal, adult breathing. The results concluded, “The nebulizers we tested differ significantly in overall drug disposition. The dosimetric **AeroEclipse®** provided the largest inhaled drug mass and the lowest loss to the ambient air ...” (See chart at right.)

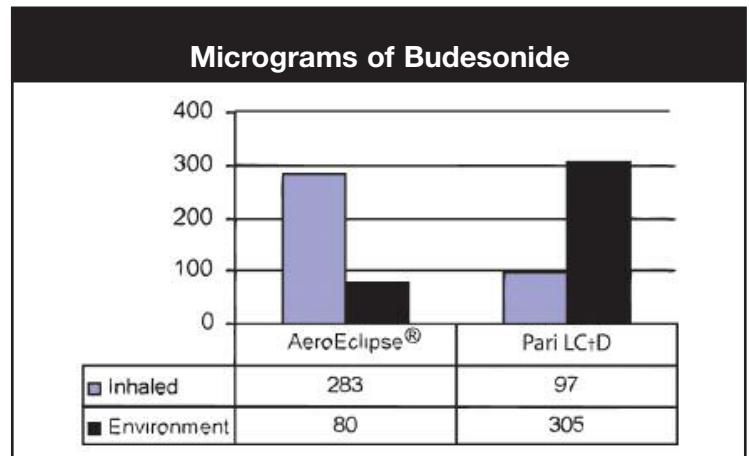


¹ Study used 2.5mg Albuterol in 3ml fill volume.

Delivery of a Suspension Corticosteroid Formulation by Small Volume Nebulizers: A Comparative Bench Study.

Mitchell, et al. ERS Congress, September 2001, Abstract #290.

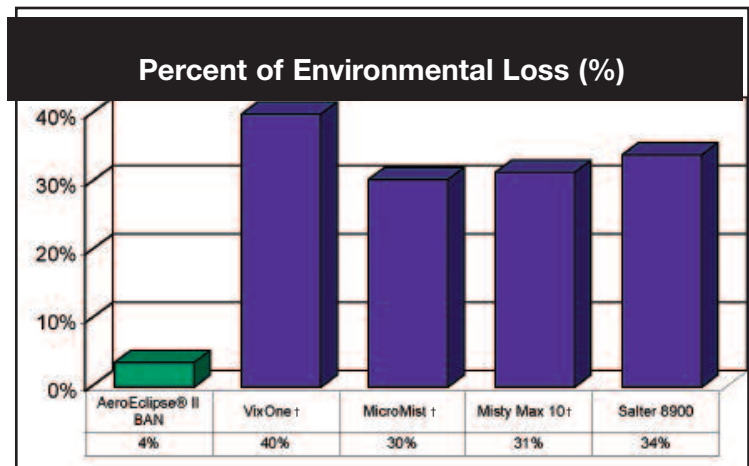
- This study reports the *in vitro* delivery of 0.25% mg/ml Budesonide suspension in two types of SVNs including the **AeroEclipse®** and Pari LC®D under simulated adult breathing conditions. The study reported total drug mass delivered to the patient and the environment. (See chart at right.) The authors conclude “The breath-actuation feature of the **AeroEclipse®** SVN minimizes aerosol release to the environment during exhalation, which may cause adverse effects to both patient and health care provider.”



Breath Actuated AeroEclipse® II Nebulizer: Performance Validation and Comparison to Competitive Products.

J. Schmidt and J. Pevler

- This study measures the *in vitro* environmental loss of the **AeroEclipse® II BAN** and competitive other small volume nebulizers including: Hudson MicroMist®, VixOne™, AirLife™ Brand Misty Max 10™ and the Salter 8900 Series. The study reported total environmental loss for each nebulizer based on 2.5mg Albuterol dosing. (See chart at right.) The findings conclude the **AeroEclipse® II BAN** delivers far less aerosol to the environment. As the **AeroEclipse® II BAN** delivers aerosol only on patient inspiration, the vast majority of the aerosolized drug goes to the patient and not into the environment.



¹ ARE FIRST AND SECOND GENERATION, MECHANICALLY-OPERATED BREATH-ACTUATED NEBULIZERS (BAN) COMPARABLE BASED ON IN VITRO PERFORMANCE?

J. Schmidt, J. Pevler, C. Doyle, K. Wiersema, M. Nagel, J. Mitchell; *Respiratory Drug Delivery*, 2006: 817-819.

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