

## Efficacy and Variability of Aerosol Delivery from Portable DC-Powered Compressor/Nebulizer Systems.

### Correspondence author:

**Norman H. Tiffin**, BSc, RRT, MSA

Tiffin Consulting, Chesterfield, VA 23838

**Kirby L. Zeman**, PhD

UNC Center for Environmental Medicine, Asthma, and Lung Biology, Chapel Hill, NC

**William D. Bennett**, PhD

UNC Center for Environmental Medicine, Asthma, and Lung Biology, Chapel Hill, NC

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### ABSTRACT

#### Background

The use of portable DC-powered compressor/nebulizer systems has become more prevalent because of their convenient size and weight. However, no evidence exists to evaluate their efficacy. We compared four common portable DC-powered nebulizer/compressor systems to compare efficacy in aerosol delivery using albuterol and budesonide.

#### Method

We compared the MiniElite and MicroElite (Philips/Respironics, Murrysville, PA), Traveler (DeVilbiss, Somerset, PA) and Trek S (Pari Respiratory Equipment, Midlothian, VA) using 200 uL of radiolabelled  $^{99m}\text{Tc}$  as sodium pertechnetate in normal saline, added to either a 3 mL ampule of 2.5 mg albuterol and .25 mg in 2.0 mL of budesonide in separate tests. Particle size was measured by cascade impaction. Output characteristics were determined by measuring the  $^{99m}\text{Tc}$  on an inspiratory filter and on a filter capturing flow from the nebulizer exhalation valve. A Harvard pump simulated breathing patterns using 500 ml, 15 breaths min, and 0.5 duty cycle. Nebulizers were timed until dry. Prior testing by cascade impaction confirmed homogeneity for co-location of  $^{99m}\text{Tc}$  and albuterol. In addition to measuring particle size, inhaled mass, time to sputter and time to dry, respiratory dose (RD) and respiratory drug delivery rate (RDDR) were calculated.

Tests were performed in triplicate and analyzed with ANOVA using Fisher's post hoc analysis with significance level set at 0.05. All tests were performed in the Center for Environmental Medicine, Asthma and Lung Biology laboratories at the University of North Carolina.

#### Results

Differences up to 7.9 times respiratory dose (RD) and 7 times respiratory drug delivery rate (RDDR) were found between nebulizer/compressor systems. The PariTrek nebulizer/compressor system performed with highest RD and RDDR,

### RÉSUMÉ

#### Contexte

L'utilisation de compresseurs/nébuliseurs portatifs alimentés par courant continu (CC) se répand de plus en plus, en raison de la commodité de leur taille et de leur poids. Cependant, il n'existe pas de données permettant d'en évaluer l'efficacité. Nous avons comparé quatre compresseurs/nébuliseurs portatifs CC couramment utilisés afin de comparer leur efficacité à générer des aérosols, en utilisant l'albutérol et le budésonide.

#### Méthode

Nous avons comparé les appareils MiniElite et MicroElite (Philips/Respironics, Murrysville, PA), Traveler (DeVilbiss, Somerset, PA) et Trek S (Pari Respiratory Equipment, Midlothian, VA) en utilisant 200 uL de pertechnétate de sodium radiomarqué au  $^{99m}\text{Tc}$  as en solution saline normale, ajouté à une ampoule de 3 mL d'albutérol 2,5 mg ou à 0,25 mg dans 2,0 mL de budésonide, dans des tests séparés. La taille des particules a été mesurée par impactation cascade. Les caractéristiques de sortie ont été déterminées en mesurant le  $^{99m}\text{Tc}$  sur un filtre inspiratoire et sur un filtre capturant le flux du robinet d'exhalation du nébuliseur. Une pompe Harvard simulait le flux respiratoire à raison cycle de 500 ml par inspiration, 15 inspirations/min et un cycle de service de 0,5. Les mesures ont été prises jusqu'à l'assèchement du nébuliseur. Les tests préliminaires par impactation cascade ont confirmé l'homogénéité pour la colocation du  $^{99m}\text{Tc}$  et de l'albutérol. En plus de mesurer la taille des particules, la masse inhalée, le temps avant la pulvérisation et le temps d'assèchement, la dose respiratoire (DR) et le taux de débit du médicament respiratoire (TDMR) ont été calculés.

Les essais ont été réalisés en triple et analysés avec ANOVA à l'aide de l'analyse à postériori de Fisher, le seuil de signification étant fixé à 0,05. Tous les tests ont été effectués dans les laboratoires du Center for Environmental Medicine, Asthma and Lung Biology de l'Université de la Caroline du Nord.

and the DeVilbiss Traveler performed lowest. Only the MicroElite exhibited differences in drug delivery between medications.

### Conclusions

The large variability and dosing abilities of portable DC-powered nebulizer/compressor systems are large enough to be of clinical importance and may negatively influence the perceived efficacy of medications.

*Keywords: aerosol, nebulizer, respiratory dose, pulmonary drug delivery*

## INTRODUCTION

Portable DC-powered compressor/nebulizer systems are compact, convenient and often preferred alternatives to larger, more powerful tabletop compressors. We hypothesize that smaller compressors, although attractive to the user, may not create an aerosol that is required for optimal inhalational drug delivery because they may not generate driving pressures and gas flows required to adequately drive the nebulizer. Portable DC-powered compressor/nebulizer systems attempt to overcome this in one of two ways. Some attempt to generate similar gas pressures and flows using evolving pump and battery technology. These systems use the same nebulizers as desktop compressors; however, less driving pressure and flow may lead to less favorable aerosol characteristics, potentially less drug delivered and longer treatments. Other portable DC-powered systems engineer a nebulizer that is designed to function with less pressure and flow. These nebulizers can only be used with the dedicated compressor which is designed specifically for it.

Although one previous study investigated variability in compressor/nebulizer systems using adult breathing patterns that study, published in 1998, included only two DC capable compressors, neither of which were tested on DC power and only one of which is still available today. A second study, in 2009, tested 30 combinations of jet nebulizers and compressors, four of which were DC capable. This study from Sweden included models not widely available in North America. Two of the models we used are included in that study but testing was done on AC power only. Both of these studies used budesonide only. A third study, reported in abstract only in 2009, compared the MicroElite and Trek systems only using budesonide and found similar aerosol characterization and performance.

To our knowledge none of the portable DC-powered systems have been systematically tested on DC power to determine if there are differences in aerosol characterization between them.

### Résultats

Des écarts allant jusqu'à 7,9 fois la dose respiratoire (DR) et sept fois le taux de débit du médicament respiratoire (TDMR) ont été constatés entre les systèmes de compresseur/nebuliseur. Le système de compresseur/nebuliseur Pari Trek a présenté les résultats DR et TDMR les plus élevés, alors que l'appareil DeVilbiss Traveler offrait le rendement le plus faible. Seul l'appareil MicroElite a affiché des variations de débit entre les deux médicaments.

### Conclusions

La variabilité et les capacités de dosage des compresseurs/nebuliseurs portatifs CC sont suffisamment élevées pour avoir une importance clinique et peuvent avoir une incidence négative sur l'efficacité perçue des médicaments.

*Mots clés : aérosol, nébuliseur, dose respiratoire, libération de médicament pulmonaire*

We tested four popular portable DC-powered nebulizer systems using battery power only to determine if there were differences in efficiency and aerosol characteristics within and between systems. Parameters measured were aerosol droplet size and distribution, time of nebulization, rate of delivery. Respirable dose (RD) and respiratory drug delivery rate (RDDR) were calculated. While gravimetric or HPLC techniques have been used to determine delivered dose from nebulizers, the former is not very sensitive and the latter is very complicated. Therefore we, and others, have utilized radiolabel techniques to assess delivery and droplet sizes associated with nebulizers. By first showing that the radiolabel suitably colocalizes with the nebulized drug, the label can then be used to provide accurate assessments of delivered dose under a variety of conditions.

## METHODS AND MATERIALS

Four different portable DC-powered compressor/nebulizer models were used directly out of the box and included the Trek S compressor with LC Sprint nebulizer (Pari Respiratory Equipment, Midlothian, VA, USA), Traveler Compressor with 800 series reusable nebulizer (DeVilbiss Healthcare, Somerset, PA, USA), the Mini-Elite with the Sidestream Plus reusable nebulizer and MicroElite with dedicated nebulizer (both Respironics, Murraysville, PA, USA). Each compressor/nebulizer model was tested in triplicate using different nebulizer/compressor systems for each trial with albuterol solution (2.5 mg in 3 mL ampoules, Nephron Pharmaceuticals Corporation, Orlando, FL, USA) and a second test with a suspension of budesonide (.25 mg in 2 mL ampoules as Pulmicort, AstraZenica LP, Wilmington, DE, USA). All tests used only battery power after the compressor was fully charged according to manufacturer's instruction.

### Verification of Radiolabeling and Droplet Sizing

The nebulizer mouthpiece was fitted with tubing that directed the output of the nebulizer mouthpiece to a T-piece

ending in a high flow/high efficiency filter or through a Sierra Series 210 eight stage cascade impactor (Sierra Instruments, Inc, Carmel Valley, CA). A vacuum source was connected to the impactor with flow controlled at a constant 5 L/minute by a critical orifice downstream of the impactor, with flow at the inlet of the impactor measured at 4.1 L/minute at atmospheric pressure. The fiberglass substrates of the impactor stages were pre-humidified except for the last filter stage and the impactor was cooled to 4 degrees C.

The nebulizer reservoir was loaded with the contents of the medication. To radiolabel the solutions, a small volume of <sup>99m</sup>Tc-pertechnetate in normal saline, typically less than or equal to 200 uL was added to the contents of the nebulized solution. The nebulized medication was run directly into the impactor for a length of time to collect enough activity and mass on the stages. The nebulizers were cleaned, without sterilizing, prior to each run according to the manufacturer's instructions.

For the aerosol sizing, three replicate runs on new systems were made with each of the four compressor/nebulizer systems for each medication. The particles were captured on the cascade impactor stages, and activity counted. Activity of the radiolabel on each stage was measured at the end of each run and analyzed for mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD) by probability of the cumulative distribution. The fraction collected within the impactor that was less than 5 um was calculated from the MMAD and GSD assuming a standard normal cumulative distribution.

For the verification of homogenous radiolabeling of the solutions, the nebulizer output was captured on pre-weighed stages of the impactor and analyzed for the mass of medication solution and the radioactivity of the <sup>99m</sup>Tc in triplicate for each combination. The results of the mass and radiocounting methods were compared for differences that would verify that the drug and label were co-localized in the droplets during the operation of the device.

### Mass Output and Rate

The nebulizer mouthpiece was fitted with tubing that directed the output of the nebulizer mouthpiece to a high flow/high efficiency filter during the inhalation phase (the simulated lung). The exhalation ports were attached to another high volume/high efficiency filter capturing the medication that would be lost to environment during the exhalation phase of the cycle. A Harvard Apparatus Respirator (Harvard Apparatus, Hollister, MA) was connected to the distal outlet of the inhalation filter with the stroke volume set at 500 mL, 15 cycles/minute, with a duty cycle of 0.5. Vacuum was applied to the distal connection of the exhalation phase filter to provide a 30 L/minute flow through the filter.

For each case, the nebulizer was charged with the medication and a small amount of radiolabel, less than 200 µL, and operated to discharge the contents in its normal mode until the observation of sputtering, recording the time. The nebulizer was tapped periodically to deposit suspended solution into the reservoir. Tapping continued until less than

three breaths would be observed before sputtering (dryness). The time to dryness and sputter were recorded.

Activity was counted on the inhalation filter and its adaptor to the mouthpiece; the exhalation filter and its adaptor; the mouthpiece if appropriate; and the residual activity left in the nebulizer at the end of the run. Total residual activity was defined as the activity remaining in the nebulizer plus mouthpiece. Occasionally, drops would form on the exterior mouthpiece surface around the exhalation valve and the activity associated with this portion would be added to the exhalation counts.

### Aerosol Characterization

In addition to particle size reported as MMAD and GSD we compared systems using respiratory dose (RD) and respiratory drug delivery rate (RDDR). Respiratory dose is the product of respirable fraction, inhaled mass (%) and charge dose. Respiratory drug delivery rate (RDDR) is the amount of drug delivered in the respirable range (ie. < 5 ug particle size) per minute calculated as respiratory dose divided by time.

### Statistical Analysis

The co-localization of medication mass and radiolabel were analyzed by Pearson moment correlation of the mass versus activity fractions on each stage to show association. Significance was set at p<0.05. To show a statistically significant positive correlation using a sample size of 3 a correlation coefficient of 0.71 or higher is required for a confidence level of 95% and alpha value less than 0.05. To compare respirable drug delivery rate and respirable dose we used one way analysis of variance with a post hoc Fisher's LSD. Again significance was set at p<0.05. Mean and standard deviation are reported.

## RESULTS

### Mass and Radioactivity Co-Localization

The average correlation for aerosol mass and activity for the three runs with each nebulizer system and medication combination are shown in Table 1. The mass and activity in each fraction were significantly associated since a confidence value of at least 95% (p<0.05) requires a correlation coefficient of at least 0.71. All correlations showed a high, positive value and had statistically significant associations.

**TABLE 1** Verification of radiolabeling and droplet sizing.

	Albuterol	Budesonide
Trek	0.94	0.88
Traveller	0.96	0.75
MiniElite	0.98	0.98
MicroElite	0.93	0.86

**TABLE 2** Aerosol characterization results by nebulizer and medication.

Aerosol characterization for each of four portable DC-powered nebulizer/compressor systems for both albuterol (alb) and budesonide (bud). MMAD is reported from radiometric method. Respirable fraction is the percent of particles less than 5 ug. Inhaled mass is the mass of drug delivered to the inhalation filter as a percent of the total charge.

	Trek S		Traveler		MiniElite		MicroElite	
	alb	bud	alb	bud	alb	bud	alb	bud
particle size (um, MMAD)	3.9	4.1	5.8	5.2	4.7	4.3	4.0	3.8
GSD (um)	1.9	2.0	2.1	2.0	2.0	2.1	1.9	2.0
respirable fraction (%)	64	62	42	48	57	59	63	66
Inhaled mass (%)	41	39	16	14	36	29	15	27
time to sputter (min)	8.0	4.6	9.8	7.7	9.4	4.2	5.9	6.5
time to dryness (min)	10.3	5.7	19.3	9.3	10.8	5.2	6.6	7.0

### Aerosol Characterization

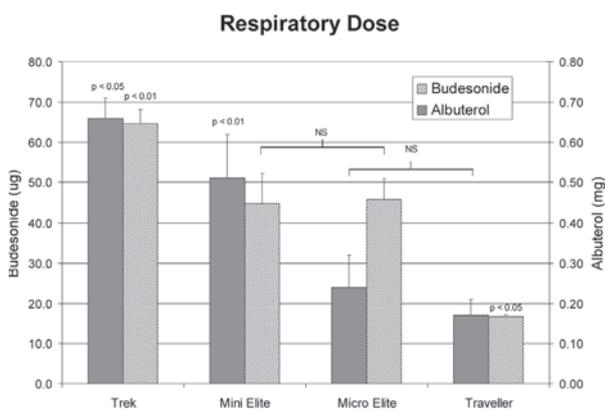
Aerosol characterization including calculations of respirable fraction which is the percent of particles less than 5 ug and inhaled mass which is the percent of the total charge solution that is nebulized and delivered out of the nebulizer are shown in Table 2. Post hoc analysis comparing each system is displayed in Figure 1 for RD and in Figure 2 for RDDR.

Variability of RD (RDV) is provided in Table 4 for both budesonide and albuterol. The RDV is calculated from the standard deviation of the RD as a percentage of the RD mean. See discussion for an explanation of RDV.

### DISCUSSION

This study was performed to determine the variability and differences in efficiency between portable DC-powered nebulizer/compressor systems on DC power. We found wide variances both within and between four portable DC-powered nebulizer/compressor systems using the measures of respiratory dose (RD) and respiratory drug delivery rate (RDDR).

**FIGURE 1:** Respiratory dose (RD) for each portable nebulizer/compressor system for budesonide (solid) and albuterol (hatched) given as mean with standard deviation bars. Albuterol is given in mg on the right axis and budesonide in ug on the left axis. The only statistically non-significant relationships are indicated by NS.

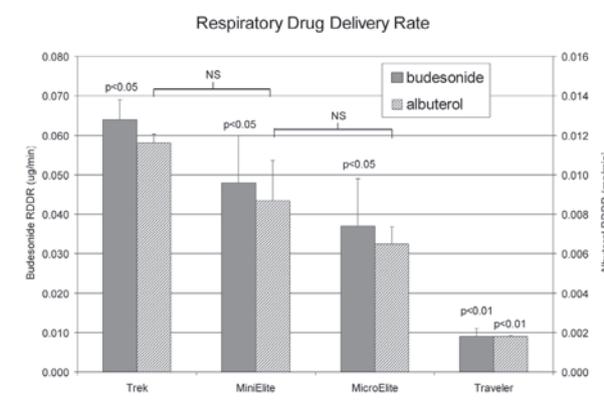


### Respiratory Dose (RD)

Respiratory dose is a measure of the dosage of drug delivered to the mouth in the respirable range (<0.05 ug) as measured in mass. RD and RDDR have used to characterize aerosol performance previously. RD can be calculated as a percentage of the charge dose to enable comparison between medications (RD%). We believe it is a better measure of inhaled mass which has been used previously because RD includes only the mass in the respirable range whereas inhaled mass includes all particle sizes. Standard deviation is a measure of variability within a data set. The standard deviation would be expected to be less with lower RDs so we control for the amount of respiratory drug delivered by comparing systems using the standard deviation of RD divided by the mean of RD. We call this measure the variability of RD (RDV) and report it as a percentage. See Table 3.

Respiratory Dose compared between nebulizers varied widely with both drugs. The Trek delivered the highest RD with both drugs with 0.66 mg albuterol ( $p > 0.05$ ) and

**FIGURE 2:** Respiratory drug delivery rate (RDDR) for each portable nebulizer/compressor system for budesonide (solid) and albuterol (hatched) given as mean with standard deviation bars. Albuterol is given in mg on the right axis and budesonide in ug on the left axis. The only statistically non-significant relationships are indicated by NS.



**TABLE 3** Respiratory Dose Variability (RD<sub>v</sub>)

The variability of RD is calculated from the standard deviation of the RD divided by the RD mean and given as a percentage. This corrects for relativity of standard deviation to the means where lower means would be expected to exhibit lower standard deviations and vice versa.

	Trek	Traveler	MiniElite	MicroElite
albuterol	7.6%	23.5%	21.6%	23.5%
budesonide	5.3%	2.1%	16.4%	2.1%

0.60 mg budesonide ( $p > 0.01$ ) with RD% of 26.4% and 25.9%, respectively. The Traveller delivered the least with 0.17 mg ( $p < 0.01$ ) of albuterol and 0.016 mg ( $p < 0.01$ ) of budesonide with RD% of 6.7% and 6.8%, respectively. The MicroElite had the highest difference between albuterol and budesonide in RD% at 9.6% and 18.3%, respectively. This would indicate that the MicroElite is less efficient in delivering budesonide by 47%. The other three did not have RD% within system differences between drugs of more than 2.5%.

The difference in RDV between the nebulizer system with the lowest variability (Trek; 7.6%) and the highest variability (Traveler; 33.3%) yields a 4.4 fold difference with albuterol and 7.9 fold increase using budesonide (Traveler 2.1% and MiniElite 16.4%). These are potentially significant clinical difference in drug administration between nebulizer systems. The largest difference in nebulizers measured by percentage of budesonide nebulizer charge on the inhalation filter for the 30 jet nebulizer systems tested by Berg is a 4 fold difference (20% and 5%).<sup>3</sup> Although this is not the same measure as RD or RDV it is an indicator of variability between systems. Interestingly, the most efficient system measured in the Berg et al study was the Pari system which uses the same nebulizer as the Trek in our study (Pari LC Sprint reusable nebulizer). The lowest charge percentage was the Medel Clenny which is a portable compressor which can be used on AC power. Smaldone et al found more than an eightfold difference in inhaled mass using budesonide between the highest nebulizer system (Pari LC Plus nebulizer and DeVilbiss Pulmo-Aide nebulizer) and the lowest combination (Hudson ISO-NEB with Hudson compressor).<sup>2</sup> This study measured 27 combinations, only two of which used portable compressors but not using battery power. Some of the combinations of nebulizers and compressors in this study are not available as a pair commercially.

Lieberman et al compared the MicroElite directly to the Trek in both adult and pediatric breathing patterns and measured MMAD, respirable fraction (0.5 - 5.0  $\mu$ m), time and drug output for budesonide only at the same charge dose as our study.<sup>4</sup> They calculated RD and reported the MicroElite RD at 23.6 and Trek at 24.6 using adult breathing pattern. It was not reported if they performed multiple runs and no standard deviations are provided. Lieberman's results

are not in accord with our results when comparing numerical results directly. Given they used a different technique (HPLC) this is not unusual. However, Lieberman reports that the RD for the MicroElite and Trek are not different yet our study found that the Trek delivered a higher RD ( $64.6 \pm 3.5$ ) than the MicroElite ( $45.7 \pm 5.2$ ;  $p < 0.01$ ).

### Respiratory Drug Delivery Rate (RDDR)

Respiratory drug delivery rate (RDDR) is a measure of rate of delivery of respiratory dose measured in mass/time units typically mg/min or  $\mu$ g/min. Treatment time is an important variable for compliance but, by itself, may not represent optimal drug delivery unless the aerosol is in the respirable range. RDDR is a measure that incorporates both the speed of treatment and the aerosol particle characterization. It is calculated by dividing the respiratory dose by the treatment time to sputter. Using time to dryness does not represent the nebulizer's optimal output since after sputtering begins the output is reduced.

Our testing revealed that there are no differences in RDDR when using budesonide or albuterol within the same system. RDDR followed the same ranking as RD when comparing systems with Trek as the highest and Traveler as the lowest. However, the variability between these two systems is even greater with Trek delivering 7 times the RDDR of Traveler using albuterol and over 6 times with budesonide. The MicroElite had the highest standard deviation and the Trek the lowest. Since standard deviation represents the variability in RDDR the variability with all but the Trek are high. The MicroElite's standard deviation is 0.012 mg/min (32% of the mean) which would indicate that 68% of the treatments range from 0.025 mg/min to 0.049 mg/min according to the empirical rule.<sup>7</sup> This represents a potential of nearly doubling or halving the RDDR from treatment to treatment. Should patients use the treatment for a defined time, that is not finish the treatment, they could then potentially receive either double or half dose with any two random treatments.

This study suffers from a small sample size that will affect the standard deviation. Nevertheless, we believe that our methods of data collection were sound, performed in a dedicated lab with experienced personnel and the trends we report are meaningful. We tested only four portable DC-powered nebulizer/compressor systems out of a possible eight or more. However, these four make up the majority of current market share in North America and are from the major manufacturers of aerosol devices and can be accessed almost anywhere in the US and Canada.

The batteries we tested were new and fully charged. It is possible that batteries used over several weeks or which are not optimally charged may not deliver as consistent or high RD or RDDR as we measured which may increase variability within and between systems even further. This warrants further study.

This study indicates that there is a wide variability in drug delivered between and within nebulizer/compressor systems. This study found the Pari Trek nebulizer/compressor

system performed the best using RD, RDV and RD% and RDDR with the DeVilbiss Traveler least efficient of the four systems studied. Other battery powered systems not studied may be equally efficient. Changing nebulizer systems can potentially change delivered dosage by up to 14 fold difference considering both between and within system variability. This has important clinically implications particularly for aerosol drug delivery with children or drugs with a small to moderate therapeutic range. There is potential that using poorly performing DC powered nebulizer/compressor systems may lead to incorrect clinical drug efficacy assessment or incorrect perceived patient compliance. Since the use of these more portable systems is increasing further studies with a larger sample size and a wider range of models is warranted.

#### AUTHOR DISCLOSURE STATEMENT

Norm Tiffin is a paid contributor to this manuscript by Pari Respiratory Equipment, Inc.

Kirby Zeman and William Bennett performed work under contract from Pari Respiratory Equipment, Inc.

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*Correspondence to:*

**Norman Tiffin**

3560 Pine Grove Ave #549

Port Huron, Michigan 48060

Telephone: 804-432-4174

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**Rita Hansen**

CSRT Communications Manager

400-331 Cooper St.,

Ottawa ON K2P 0G5

rhansen@csrt.com

800-267-3422