Air*Life*™ brand Misty Finity® large-volume nebulizer

Misty Finity FiO_2 and particle size analysis

Neil A. Korneff, Research and Development

Introduction

Delivery of nebulized medication to the lungs is a complex process dependent upon a variety of device-related and clinical variables. Patient breathing patterns, the choice and dilution of drug, nebulizer flow rate and device selection all have the potential to affect the amount of drug delivered to the patient. In vitro (bench) testing can provide the clinician with useful information regarding nebulizer performance.

The purpose of this document is to provide in vitro FiO_2 performance of the Air*Life* brand Misty Finity large volume continuous nebulizer when using the auxiliary gas port and to compare particle size performance to Westmed's HEART and B&B's HOPE large volume nebulizers. In vitro measurements will help guide the clinician as to the likelihood of effective delivery of inhaled medication to the lower respiratory tract.[1]

Products tested

All testing was conducted with components included in the following catalog numbers:

- Air*Life* brand Misty Finity nebulizer, 002500
- HEART nebulizer, manufactured by Westmed, 100609, (002200)
- HOPE nebulizer, manufactured by B&B, 11310, (BBM11310)

Conclusions

The Misty Finity large volume continuous nebulizer creates finer particles (MMAD) with a tighter distribution (GSD) within the respirable range (% < 4.7 µm) than the HEART and HOPE continuous nebulizers (differences are statistically significant, $P < 0.05$).

	MMAD (µm)	GSD (µm)	Respirable fraction (% < 4.7 µm)
Misty Finity large-volume nebulizer *(at recommended 11 L/min. flow rate)*	2.78	2.54	71.2%
HEART large-volume nebulizer *(at recommended 10 L/min. flow rate)*	3.87	2.64	54.4%
HOPE large-volume nebulizer *(at recommended 10 L/min. flow rate)*	3.17	3.04	51.7%

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Particle size test method

An Andersen eight-stage cascade impactor (ACI) with USP inlet[3] was used and assayed with a spectrophotometer (277 nm). Particle size characterization was performed using albuterol/saline solution. Drug concentrations used were the maximum dosage in accordance with label copy dosing charts provided by the manufacturer. Cascade impaction was chosen for the following reasons:

- Cascade impaction measures aerodynamic diameter directly, which accounts for the density and irregular shape of drug particles. It is believed that aerodynamic diameter more accurately predicts the behavior of aerosol as it is delivered into the patient's lungs.[3]
- There is more historical data on particle size measurement using cascade data than any other method. Relative comparison with historical data can be readily made.
- Cascade impaction is one of the USP methods for characterization of particle distributions.[2]

Particle size test conditions

All nebulizers were driven by compressed air, with flow meters regulated to 50 psi. Flow rates used were in accordance with label copy provided by the manufacturer. Ambient air was controlled at 22° C, 50% relative humidity (±10%).

Definition of parameters measured

MMAD: Mass Median Aerodynamic Diameter

This is a measure of central tendency of the size distribution of aerosol particles. It is the diameter, in micrometers, of which 50% of the mass of aerosol is larger and 50% is smaller.

GSD: Geometric Standard Deviation

This is a measure of the width of the size distribution of aerosol. For log normal distributions, it is calculated as follows:[2] GSD = (84.13% diameter/15.87% diameter).[1, 2]

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FiO_2 chart Use oxygen analyzer to verify FiO_2	
Primary gas: Air @ 11 L/min. Secondary gas: Oxygen	
L/min. oxygen	FiO_2
1	28
4	42
7	52
9	57
Primary gas: Oxygen @ 11 L/min. Secondary gas: Air	
L/min. air	FiO_2
1	93
4	79
7	69
9	64

Respirable fraction

Respirable fraction is the percent of aerosol generated, by mass, that falls below an aerodynamic diameter of 5 µm. It has been reported that particles less than 5 µm will penetrate beyond the upper airways and deposit into the tracheobronchial and pulmonary regions of the lung.[4] This measurement is often used to describe the quality of aerosol.[5] The closest cascade plate cutoff point of 4.7 µm was utilized to quantify the mass below 5 µm.

FiO_2 test method

USP-grade oxygen and air were used, and the flow rates were confirmed using a mass flow meter. The nebulizer was run without liquid, and an oxygen analyzer was used to verify FiO_2 in the corrugated tubing leaving the nebulizer. Printed values are rounded and are within 1% FiO_2 of the values obtained from testing.

Patient inspiratory flows in excess of total gas flow (primary + secondary) will influence delivered FiO_2.

References
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