# Air*Life*™ brand Misty Max 10™ nebulizer

## Respiratory care products and services

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## Technical data

The purpose of this document is to provide the in vitro performance characteristics of the Air*Life*™ brand Misty Max 10™ nebulizer. In vitro measurements will help guide the end user as to the likelihood of effective delivery of inhaled medication to the lower respiratory tract.[1]

### Particle size

#### Methods

An Andersen eight-stage cascade impactor (ACI) with USP inlet[2] was used and assayed with a spectrophotometer (224 nm). Particle size characterization was performed using 3 mL of 0.083% albuterol sulfate in normal saline. Cascade impaction was chosen for the following reasons:

1. 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]
2. 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.
3. Cascade impaction is one of the USP methods for characterization of particle distributions.[2]

| Performance characteristics | 7 L/min flow | 8 L/min flow | 10 L/min flow |
|---|---|---|---|
| **MMAD** Mass median aerodynamic diameter (µm) | 1.66 ±0.06 | 1.48 ±0.02 | 1.35 ±0.04 |
| **GSD** Geometric standard deviation | 1.45 ±0.04 | 1.44 ±0.02 | 1.45 ±0.03 |
| **Respirable fraction** % < 4.7µm (by mass) | 85.2 ±4 | 91.4 ±5 | 93.9 ±6 |
| **Output rate** (g/min) | 0.313 ±0.022 | 0.312 ±0.017 | 0.338 ±0.014 |
| **Treatment time** 3 mL albuterol solution (min) | 8.66 ±0.60 | 8.77 ±0.55 | 8.24 ±0.71 |
| **Residual** (g) | 0.84 ±0.06 | 0.84 ±0.07 | 0.84 ±0.07 |
| **Operating pressure** (psi) | 20.8 ±0.2 | 25.8 ±0.3 | 36.0 ±0.0 |

Data presented: Mean ±standard deviation.

Sufficient sample sizes were tested to obtain a 95% confidence interval on the mean less than or equal to: ±9% respirable fraction and ±4% for all other characteristics.

#### Test conditions

Particle size testing was conducted with components included with Air*Life* brand Misty Max 10 nebulizer 002438: T-adapter, mouthpiece, 7′ oxygen tubing and 6″ flex tube. The nebulizer was driven by compressed air (regulated to 50 psi) at 7, 8 and 10 L/min. flow. Ambient air, which flows through the open end of the T-adapter, was controlled at 50% ±10% relative humidity.

## Definition of parameters measured

1. 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.
2. 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]

### Respirable fraction

Respirable fraction is the percent of aerosol generated by mass that falls below 5µ MMAD. It has been reported that particles less than 5µ 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 4.7µ was utilized to quantify the mass below 5µ.

### Output rate

#### Methods

Nebulizers were weighed before and after aerosolizing a fill volume of 5 mL normal saline for 3 min. Performance was reported in the average weight loss per minute (g/min).

#### Test conditions

Testing was done with nebulizers randomly pulled from production lots. The nebulizer was operated with compressed air, and normal saline was the nebulized solution.

### Residual and treatment time

#### Methods

The measurements of residual and treatment time will depend on the criteria used to end the treatment. In clinical practice, it is common to tap the nebulizer near the end of the treatment to maximize the amount of drug nebulized. To simulate this practice, the nebulizer was periodically tapped until tapping resulted in an aerosol production of less than 5 sec.

Residual was calculated by subtracting the weight of the nebulizer after the trial from the weight of the nebulizer empty. Treatment time was the total time required to nebulize 3 mL of solution.

#### Test conditions

Residual and treatment time testing was done with nebulizers randomly pulled from production lots. The nebulizer was operated with compressed air, and normal saline was the nebulized solution.

### Operating pressure

#### Methods

Pressure was obtained from a T-connection between the compressed air flow meter and the nebulizer.

#### Test conditions

Testing was done with nebulizers randomly pulled from production lots. Pressures at 7, 8 and 10 L/min. flow were evaluated while nebulizing 3 mL of normal saline.


**References**

1 Consensus Statement: Aerosols and Delivery Devices. *Respiratory Care*, 2000, 45(6).

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4 Laube, B. In vivo measurements of aerosol dose and distribution: Clinical relevance. *Journal of Aerosol Medicine*, 1996, 9(1).

5 Dolovich, M. Influences of inspiratory flow rate, particle size and airway caliber on aerosolized drug delivery to the lung. *Respiratory Care*, 2000, 45(6).



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