

## Inspiratory Efforts Achieved in Use of the Technosphere® Insulin Inhalation System

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### Abstract

#### *Objective:*

The Technosphere® Insulin (TI) inhalation system comprises TI powder premetered into unit dose cartridges and the patient-friendly, reusable, breath-powered MedTone® inhaler. This high-resistance system uses a patient's inspiratory effort to effect TI powder de-agglomeration and promote subsequent deep-lung delivery. This study reports on flow and pressure data achieved by patients with diabetes using the MedTone system.

#### *Method:*

MedTone inhalers containing empty cartridges were adapted with pneumotach measuring devices to capture inhalation profiles. The measuring apparatuses had negligible impact on the nominal MedTone system resistance level of 0.117 kPa<sup>0.5</sup>/liters/min. Each of 56 subjects inhaled twice to mimic TI clinical study dosing instructions.

Achieved inhalation profiles were characterized by peak inspiratory flow (PIF), peak inspiratory pressure (PIP), and average pressure drop from the time of PIP to 4 s ( $P_{avg}$ ).

#### *Results:*

The achieved mean PIF ( $\pm$  standard deviation [SD]) in all subjects was 26.74 ( $\pm 6.06$ ) liters/min after the first inhalation and was similar to the mean PIF of 26.25 ( $\pm 6.23$ ) liters/min achieved after the second inhalation. Mean PIP ( $\pm$ SD) achieved by subjects was 8.49 ( $\pm 2.86$ ) and 8.1 ( $\pm 2.99$ ) kPa, and mean  $P_{avg}$  drop ( $\pm$ SD) in all subjects was 6.53 ( $\pm 2.24$ ) and 6.09 ( $\pm 2.08$ ) kPa after the respective inhalations.

#### *Conclusion:*

Patients with diabetes demonstrated consistent inhalation efforts over two inhalations using the MedTone system. The achieved PIFs and PIPs demonstrate the capacity of this population to obtain sufficient inspiratory effort necessary for delivery of TI using the MedTone inhaler. Adequate postpeak pressures were also revealed, further supporting reliable and sustained inhalation efforts.

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**Abbreviations:** (NHANES III) National Health and Nutrition Examination Survey, ( $P_{avg}$ ) average pressure, (PIF) peak inspiratory flow, (PIP) peak inspiratory pressure, (SD) standard deviation, (TI) Technosphere Insulin

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