

# Assessing Different Valved Holding Chambers with Facemask for Delivered Mass to Carina with Inhaled Corticosteroid by Pressurized Metered Dose Inhaler

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## RATIONALE

- To effectively evaluate pressurized metered dose inhaler + Valved Holding Chamber (VHC) delivery systems with a mask, the most appropriate laboratory method is to use a face model that includes soft tissue simulation and an anatomically realistic oro-naso-pharynx airway
- We report a study in which both two types of infant and child mask VHCs were evaluated using the ADAM III anatomical models of an infant and small child
  - $n = 3$  devices per group



Infant



Child

**AeroChamber Plus<sup>®</sup> Flow-Vu<sup>®</sup>** Anti-Static VHC  
Trudell Medical International



Infant

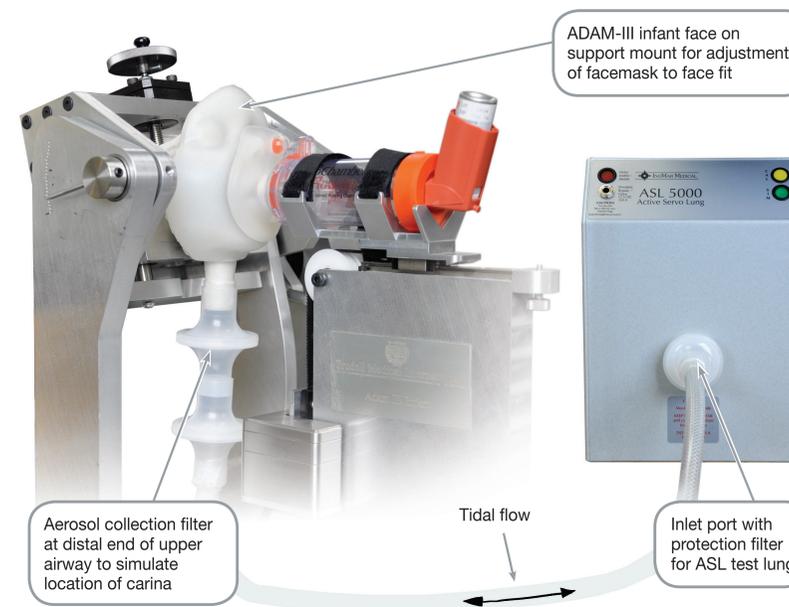


Child

**Free-Breath<sup>†</sup> Spacer**  
Taian Character Polymer Co., Ltd.

## METHODS

- Each VHC was evaluated by breathing simulator
  - ASL5000, IngMar Medical, Pittsburgh, PA
- Tidal breathing – **Infant**
  - Tidal volume = 50-mL
  - Inspiratory: Expiratory ratio = 1:3
  - Rate/min = 30 cycles
- Tidal breathing – **Child**
  - Tidal volume = 155-mL
  - Inspiratory: Expiratory ratio = 1:2
  - Rate/min = 25 cycles
- A 2-s delay was introduced before initiating the first respiration cycle to mimic a short coordination delay
- The test chamber with mask was attached to the anatomical model (ADAM III) of a 7 month old infant and a 4 year old child face equipped with modelled airway
- The airway was coupled to the breathing simulator via an electret filter located at the exit to capture drug particles that penetrated as far as the modelled carina
- 5 actuations of Fluticasone Propionate (FP, Flovent 50) were delivered at 30-s intervals
- FP recovered from specific locations in the aerosol pathway was subsequently assayed by HPLC-UV spectrophotometry



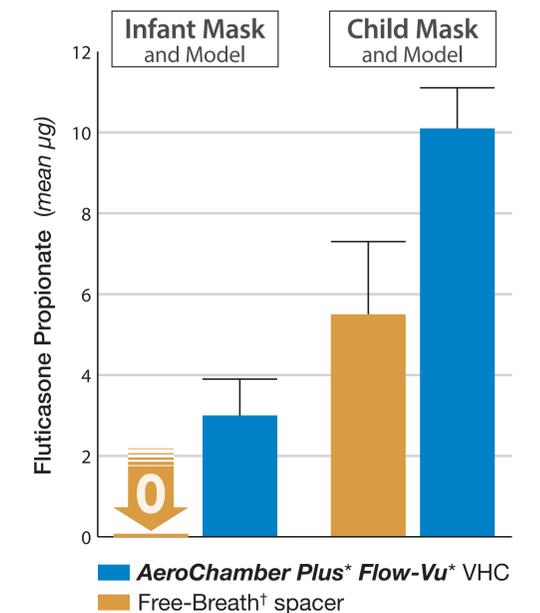
## RESULTS

### FP Recovered from VHCs and Models Following Tidal Breathing

(mean  $\mu\text{g} \pm \text{SD}/\text{actuation}$ )

	Infant Pattern		Child Pattern	
	Free-Breath <sup>†</sup>	AeroChamber Plus <sup>®</sup> Flow-Vu <sup>®</sup>	Free-Breath <sup>†</sup>	AeroChamber Plus <sup>®</sup> Flow-Vu <sup>®</sup>
VHC	40.5 $\pm$ 3.7	20.3 $\pm$ 1.8	34.2 $\pm$ 2.8	17.5 $\pm$ 1.6
Facemask	0.0 $\pm$ 0.0	1.4 $\pm$ 0.2	1.1 $\pm$ 0.6	1.4 $\pm$ 0.2
Airway	0.0 $\pm$ 0.0	0.5 $\pm$ 0.1	0.3 $\pm$ 0.2	1.1 $\pm$ 0.2
Filter at <i>Carina</i>	0.0 $\pm$ 0.0	3.0 $\pm$ 0.9	5.5 $\pm$ 1.8	10.1 $\pm$ 1.0

### FP Recovered at “Carina” (mean $\mu\text{g}$ )



## CONCLUSIONS

- Significantly more FP was delivered to filter/carina with the **AeroChamber Plus<sup>®</sup> Flow-Vu<sup>®</sup>** VHC versus the Free-Breath<sup>†</sup> spacer for both child and infant models
  - Un-paired t-test,  $p < 0.001$
- As the Free-Breath<sup>†</sup> spacer delivered no medication at all in infant form, this would clearly be a safety concern if replicated in an *in vivo* setting
- Clinicians need to be aware that not all VHCs are the same and that large differences in delivery may exist when a facemask is present



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