# Assessment of One-way Valve Efficiency in the OptiChamber Diamond VHC During Exhalation

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#### Introduction

Spacers and valved holding chambers (VHCs) are used to provide space for the deceleration of droplets, to reduce droplet size, and to evaporate propellant from the plume of aerosol emitted from a pressurized metered dose inhaler (pMDI). <sup>1-3</sup> Unlike spacers, VHCs include valves to allow the chamber to be used with patients who are breathing tidally or who have difficulty with coordination. These valves open and close based on the pressure on either side of the valve, generated by the patient's tidal breathing. Figures 1 and 2 demonstrate the operation of an example VHC and show how the valves open during inhalation and close during exhalation, thus ensuring that the aerosol within the chamber is not disturbed by exhaled gases. This design is particularly advantageous for patients who breathe tidally when using a VHC, as, otherwise, exhaled gas could mix with the aerosol in the chamber.<sup>4</sup>

Any leak in the inhalation valve of a VHC would allow exhaled air back into the VHC. This could dilute the aerosol, and reduce the efficiency of the VHC in holding the aerosol cloud ready for the next inhalation. There are a range of different valve types, all of which are designed to work with a variety of patients, including adults and infants, who will each have different inhalation patterns. The valves must therefore work with a wide range of flow rates, while providing the lowest possible resistance, so they are often manufactured

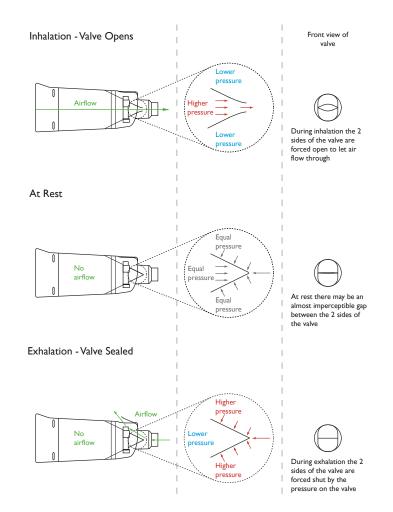
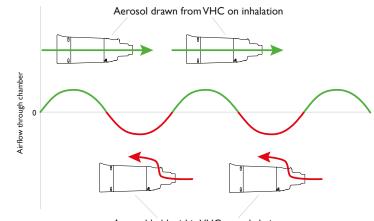


Figure 1. Valve operation inside an example VHC (OptiChamber Diamond, Respironics Respiratory Drug Delivery (UK) Ltd).



Aerosol held within VHC on exhalation

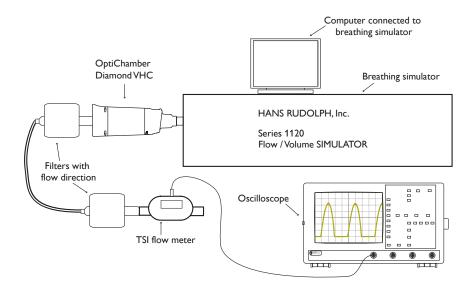
Figure 2. Example breathing pattern showing valve operation during inhalation and exhalation in an OptiChamber Diamond VHC.

from very thin material. Because the valves are only in their operating positions when airflow is applied to the chamber, visual inspection is not sufficient to determine performance; instead, testing with various breathing patterns is required. Tests were conducted using 4 different breathing patterns and valves to determine the efficiency of the different valves in stopping the flow of gas back into the chamber during simulated exhalation.

## <u>Method</u>

Five different VHCs were tested for valve efficiency: OptiChamber Diamond VHC (Respironics Respiratory Drug Delivery (UK) Ltd, a business of Philips Electronics UK Limited, Chichester, UK), which features a duckbill valve; AeroChamber Plus Z-Stat VHC, AeroChamber Plus Flow-Vu VHC (both with identical doughnut-shaped valves), and AeroChamber with FLOWSIGnal VHC, which has a flap valve (Monaghan Medical Corp., Plattsburgh, NY, USA); and ACE VHC (Smiths Medical International Limited, Hythe, Kent, UK), which features a different design of duckbill valve. The VHCs were each attached to a breathing simulator (Series 1120 Flow/Volume Simulator, Hans Rudolph, Inc., Kansas City, MO, USA), which was connected to a computer. The computer was loaded with software to control the airflow (breaths per minute; BPM) and tidal volume (breath volume) produced by the breathing simulator (see Figure 3).

A TSI flow meter (TSI, Inc., Shoreview, MN, USA) was attached and sealed to the end of the VHCs to measure any exhaled air flowing past the valve and through the chamber. An oscilloscope (Teledyne LeCroy, NY, USA) connected to the TSI flow meter displayed the airflow through the chamber over time.





The breathing patterns tested were: tidal volumes of 0.1 L and 1.0 L, at a frequency of 15 BPM, for children; tidal volumes of 0.5 L and 0.75 L, at a frequency of 25 BPM, for adults. These breathing patterns were derived from the CAN/ CSA-Z264.1-02 standard, <sup>5</sup> and are outside the range of normal breathing patterns. The breathing patterns were used to evaluate the efficiency of the valves under very high and very low flow rates. All the VHCs were tested with these breathing patterns under the same conditions. The results shown below and in the linked online-only appendices are for 1 VHC of each brand.

#### **Results**

The graphs below (Figures 4-8) show the amount of air that flowed through the VHC. The initial horizontal red line at the left side of each graph represents 0 airflow. This line indicates airflow prior to the breathing simulator being activated, and can therefore be used as a baseline for 0 airflow with which to compare exhalation. The green curve immediately following the baseline is the simulated inhalation. After the peaks in airflow during inhalation, the airflow returned to the baseline level if no exhaled air flowed through the chamber. Any elevation to this baseline between inhalation peaks (i.e., during exhalation) indicates that exhaled air was not being blocked by the valve, and could therefore pass into the chamber.

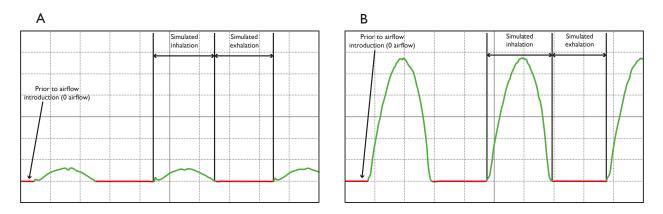


Figure 4. Flow rate through the OptiChamber Diamond VHC, during inhalation and exhalation at a flow rate of 15 BPM and with: (A) a tidal volume of 0.1 L; (B) a tidal volume of 1.0 L. The Y axis represents airflow and the X axis represents time.

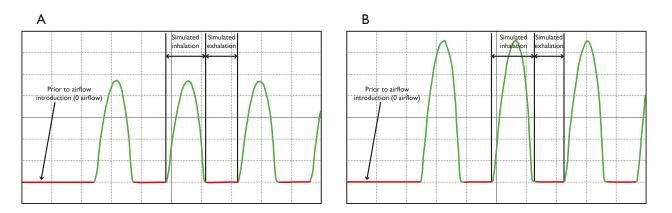


Figure 5. Flow rate through the OptiChamber Diamond VHC, during inhalation  $\blacksquare$  and exhalation  $\blacksquare$ , at a flow rate of 25 BPM and with: (A) a tidal volume of 0.5 L; (B) a tidal volume of 0.75 L. The Y axis represents airflow and the X axis represents time.

With all of the breathing patterns tested on the OptiChamber Diamond VHC, results indicated that no exhaled air flowed through the chamber under either very low or very high flow rates. This suggests that the valves worked correctly to prevent exhaled air from flowing into the chamber.

The valve efficiency of each VHC did not differ greatly between the breathing patterns (i.e., a valve that leaked at 15 BPM with a volume of 1.0 L also leaked with the other patterns); Figures 6-8 are therefore representative of the valve

leakage with these VHCs across the breathing patterns tested. The results from these VHCs with the other breathing patterns tested, and results from the AeroChamber Plus Flow-Vu VHC, are located in the online-only appendices. [link]

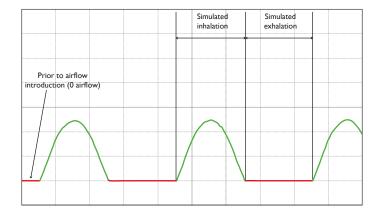


Figure 6. Flow rate through the AeroChamber Plus Z-Stat VHC, during inhalation and exhalation at a rate of 15 BPM and with a tidal volume of 1.0 L. The Y axis represents airflow and the X axis represents time.

There was no airflow through the chamber of the AeroChamber Plus Z-Stat VHC during exhalation under the 15 BPM and 1.0 L breathing pattern. This indicates that the valve was working correctly to prevent exhaled air from flowing through the chamber.

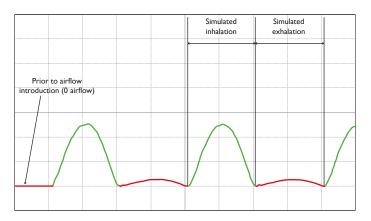


Figure 7. Flow rate through the AeroChamber with FLOWSIGnal VHC, during inhalation and exhalation , at a rate of 15 BPM and with a tidal volume of 1.0 L. The Y axis represents airflow and the X axis represents time.

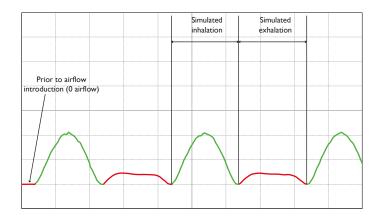


Figure 8. Flow rate through the ACE VHC, during inhalation and exhalation at a rate of 15 BPM and with a tidal volume of 1.0 L. The Y axis represents airflow and the X axis represents time.

Considerable airflow through the chamber was found with the AeroChamber with FLOWSIGnal VHC and the ACE VHC during exhalation, which suggests that the valves of both of these VHCs were not fully closed during exhalation.

# **Discussion**

Both the OptiChamber Diamond VHC and the AeroChamber Plus Z-Stat VHC were found to prevent exhaled air from entering the chamber in all breathing patterns tested, indicating that their newer valve designs work correctly under both very low and very high flow rates, and may therefore be suitable for use by a wide range of patients. These results also suggest that these VHCs may be efficient at preventing medication dilution, because the exhaled air is rerouted away from the chamber. Conversely, exhaled airflow through the chamber was found in the AeroChamber FLOWSIGnal VHC and the ACE VHC. These VHCs feature older valve designs, and may therefore be less efficient at delivering the full amount of medication than the other VHCs tested. The inhalation peaks for some of the devices were higher than those seen with the other devices, which may be a result of mouthpiece leakage; however, this does not affect data comparison of the exhausted airflow.

## <u>Conclusions</u>

The valves of the OptiChamber Diamond VHC and the AeroChamber Plus Z-Stat VHC prevented exhaled air from entering the chamber, but, with the AeroChamber FLOWSIGnal VHC and the ACE VHC, exhaled air flowed past the valves and into the chamber. The OptiChamber Diamond VHC was also found to prevent exhaled air from entering the chamber under all the breathing patterns tested, indicating successful valve operation with both very high and very low flow rates.

### <u>References</u>

- 1. Fink JB. Metered-dose inhalers, dry powder inhalers, and transitions. Respir Care. 2000;45(6):623-635.
- 2. Rubin BK, Fink JB. Optimizing aerosol delivery by pressurized metered-dose inhalers. Respir Care. 2005;50(9):1191-1200.
- 3. Amirav I, Newhouse MT. Review of optimal characteristics of face-masks for valved-holding chambers (VHCs). Pediatr Pulmonol. 2008;43:26-274.
- 4. Morton RW, Mitchell JP. Design of facemasks for delivery of aerosol-based medication via pressurized metered dose inhaler with valved holding chamber: key issues that affect performance. J Aerosol Med. 2007;20(1):29-45.
- 5. Canadian Standards Association. CAN/CSA-Z264.1-02 (R2011) Spacers and Holding Chambers for Use with Metered-Dose Inhalers. Toronto, Canada: Canadian Standards Association; 2002.

### Additional information

Online-only appendices, containing the remaining valve leakage results, can be accessed via this [OptiChamber Diamond Valve Appendix link], or by scanning the QR code below.



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