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Title: Assessment of facemask seal leakage from six VHC systems on two pediatric simulated anatomical models under simulated breathing conditions

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Body: Facemasks establish the vital patient-device interface to facilitate drug delivery from a pressurized metered dose inhaler (pMDI) with an attached valved holding chamber (VHC). Leakage from a VHC facemask seal can reduce the delivered dose. We used two pediatric simulated anatomical models (SAMs, Figure 1 Right) to test the leakage from six VHC facemasks. Testing was conducted using an apparatus which allowed reproducible facemask placement with a constant applied force of 1.9kg.¹ Each facemask with associated VHC (Figure 1 Left) was applied to each SAM in turn. A constant flow of 15 L/min was extracted from the rear of the SAM. The difference (Δ TSI, L/min) between flow into the VHC and flow exiting the SAM was measured using two flow meters (TSI Inc, Shoreview, MN). The vertical location of the SAM in relation to the VHC was altered by 1 mm increments until the minimum Δ TSI (leakage) was found. Figure 1 Left shows the minimum leakage for each VHC/facemask combination with each SAM.

Figure 1. Left - Facemask seal leakage (%), Top Right - SAM 0, Bottom Right - SAM 1. There was a wide variation in leakage from different VHC facemasks and also between SAMs. The smallest amount of leakage for both SAMs was seen with the OptiChamber Diamond VHC with LiteTouch facemask. 1) Hsu et al. Proceedings of Respiratory Drug Delivery Europe 2011; www.rddonline.com.