Quantifying Facemask Sealing Efficiency when used on a Valved Holding Chamber During Simulated Breathing

D. von Hollen, E. Lieberman, K. Nikander: Philips Respironics, Respiratory Drug Delivery, Parsippany, NJ, USA.

Introduction
Valved holding chambers (VHCs) are used by patients who are unable to effectively receive pressurized metered dose inhaler treatments using a VHC mouthpiece. A leak between a patient’s face and the facemask of a VHC can reduce the dose of medication delivered to the patient, which makes the design of facemask a critical feature of a VHC. The relevance of in vitro facemask testing to real-life situations has historically been hampered by the complexity of human facial anatomy. Previous attempts to model human facial anatomy in vitro testing have comprised simple hard surface facemasks. The Soft Anatomical Model (SAM) facemask was created to address this issue (Figure 1).

Table 1. Details of facemasks tested.

<table>
<thead>
<tr>
<th>Facemask name</th>
<th>Manufacturer</th>
<th>Seal geometry</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>PhilipsRespivos</td>
<td>Respironics, Respiratory Drug Delivery, Parsippany, NJ</td>
<td>Three dimensional silicone cushion seal</td>
<td>Medium</td>
</tr>
<tr>
<td>Panda facemask</td>
<td>ResMed, Inc., Longmont, CO</td>
<td>Silicone flange</td>
<td>Medium</td>
</tr>
<tr>
<td>ComfortSeal facemask</td>
<td>Respironics, Respiratory Drug Delivery, Parsippany, NJ</td>
<td>Silicone cushion seal</td>
<td>Medium</td>
</tr>
</tbody>
</table>

The test fixture allows for simulated forces to be applied to each facemask to assess the force needed to obtain the best possible seal. Leakage from the facemask to the face replica of a 4-year-old child, using one size of mask. Different face geometries from facemask designs. Leakage from the facemask to the face can significantly reduce the amount of drug that the patient receives.

Method
The test fixture and the SAM face replica were utilized to test and compare three different facemasks for use with VHCs (Table 1). The size of each brand of facemask was selected using an assessment of seal efficiency to the SAM face replica. The test fixture was designed to facilitate reproducible testing of VHC facemasks using directly relevant application forces (Figure 2). We used the test fixture with SAM face replica to test three VHC facemasks with different seal geometries.

Results
There was a wide variation in the leakage among the three facemask designs tested. The design of the facemask had a greater influence upon the percent leakage than the applied force. There was no leakage when testing the Prototype facemask at all amounts of applied force. Leakage from the other two facemasks was affected by the applied force, whereas applied force had only a marginal effect upon leakage from the ComfortSeal facemask.

Discussion
The new purpose-built test fixture offers researchers the opportunity to conduct a wide variety of facemask tests under reproducible conditions and can be a valuable tool in the development of new more effective facemask designs. Leakage from the facemask to the face can significantly reduce the amount of drug that the patient receives. The results of these tests showed that there was a large variation in the effectiveness of seal between different facemask designs and that the effectiveness of increased application force was also facemask design dependent. It should, however, be noted that in vitro tests were only performed on one pediatric facemask of a 4-year-old child, using one size of mask. Different face geometries from facemask designs. Leakage from the facemask to the face is a significant issue (Figure 1).

Conclusions
• The results indicate that facemask design affects the leakage between face and facemask.
• The force required to minimize leakages varies depending on facemask design.
• The Prototype facemask did not leak at any of the applied forces.

References
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Figure 2. Test fixture and connections to flow meters.

Figure 3. Example of Prototype facemask fitted to the test fixture.

Figure 4. Example of Panda facemask fitted to the test fixture.

Figure 5. Example of ComfortSeal facemask fitted to the test fixture.

Figure 6. Leak from each of the facemasks.

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