PROTOCOL 08-0002

Oxygen and Helium Delivery Concentrations for the SouthMedic Oxymask and a Non-Rebreather Mask with 80-20 Heliox as Measured at the Mouth

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1.0 Objective

1.1 To measure the oxygen and helium delivery of the Southmedic Oxymask and a standard non-rebreather mask when used to deliver 80-20 heliox under simulated patient conditions of a respiratory rate of 15 bpm, a minute ventilation of 10 l/min, and a I:E ratio of 1:1.

2.0 Reference

2.1 DRAFT VERSION “REVIEWER GUIDANCE FOR PREMARKET NOTIFICATION SUBMISSIONS” November 1993.
2.2 GOOD LABORATORY PRACTICE REGULATIONS, USFDA (21 CFR PART 58)
2.3 PIPER MEDICAL SOP-E-133 – OXYGEN SENSOR OPERATION
2.4 PIPER MEDICAL SOP-E-131 – PRESSURE FLOW MEASUREMENT OPERATION
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3.0 Acceptance Criteria
3.1 All equipment and laboratory processes used and specified will meet their predetermined operation and calibration requirements before and after testing. All testing shall be performed per GLP.

4.0 Equipment List
4.1 Southmedic Oxymask - One sample as supplied by Southmedic.
4.2 Hudson RCI Non-Rebreather Mask
4.3 0-100 psig Pressure Gauge (E-008)
4.4 Gilmont glass float type Rotameter (E-015)
4.5 Low Flow Rotameter (E-082)
4.6 AccuLAB Standard Electronic Balance TS series (E-002)
4.7 Vacuum pump (E-009)
4.8 Compressed gas source (in-house)
4.9 Data Acquisition System
4.10 CAHN Model C-31 Microbalance (E-031)
4.11 Humidity/Temperature Meter (E-100)
4.12 Oxygen Sensor (E-081)
4.13 Valve Controller (E-090)
4.14 Frequency Generator (E-065)
4.15 Adult Mannequin Head
4.16 Helium Oxygen Sensor (E-107)
5.1 Set Up

5.1.1 Connect the valve controller to the frequency generator as shown in figure 1. Use a lung volume of at least 1.5 liters to insure that the simulated patient exhales the same gas it inhales. Connect Inhalation Valve to a vacuum source set to 20.0 l/min. Connect Exhalation Valve to a compressed air source set to 20.0 l/min.

5.1.2 Use the adult mannequin head for a simulated patient head.

5.1.3 Set the frequency generator to a rate of 15 bpm and an I:E ratio of 1:1.

5.1.4 Attach a sensing oxygen/helium line immediately proximal to the mouth. Sample 10 ml/min through the line to the helium/oxygen sensor using a vacuum source.

5.1.5 Place mask on patient head.

Figure 1 showing the patient simulation setup used for testing
5.2 Testing

5.2.1 Set heliox flow to 15 l/min (indicated flow of 8.8 l/min). Confirm flow by measuring with a rotameter and correcting for difference in molecular weight (the square root of the Mw, so a reading of 10 l/min for a flowmeter calibrated for air is actually 17.1 l/min for 80-20 heliox). Allow system to equilibrate for 3 minutes. Take an oxygen and helium concentration reading. Repeat for a total of 3 times. Between each measurement, remove and replace mask back onto patient head.

5.2.2 Repeat step 5.2.1 for 13, 10, and 8 l/min of heliox (indicated flows of 7.6, 5.8, and 4.7 l/min of heliox respectively) and both masks.

5.2.3 Tabulate combined data and perform a comparison.
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RESULTS

Helium Delivery with 80-20 Heliox

Figure 2 showing the delivered helium concentration for the Oxymask and Non-Rebreather Mask while delivering various flowrates of 80-20 heliox. Indicated error bars represent 1 standard deviation. Measurements were done immediately at the mouth.
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<table>
<thead>
<tr>
<th>Heliox Flow (L/min)</th>
<th>Oxymask</th>
<th>Non-Rebreather</th>
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<tbody>
<tr>
<td></td>
<td>% He</td>
<td>% O2</td>
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<tr>
<td>15</td>
<td>76.8</td>
<td>21.4</td>
</tr>
<tr>
<td></td>
<td>63.3</td>
<td>21.3</td>
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<td>73.9</td>
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<td>Std Dev</td>
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<td>13</td>
<td>75.7</td>
<td>21.4</td>
</tr>
<tr>
<td></td>
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<tr>
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<td>Std Dev</td>
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<td>0.3</td>
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</table>

Table 1 showing the measured oxygen and helium concentrations for various 80-20 heliox flows. All measurements were done at the mouth.
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DISCUSSION

All equipment and laboratory processes met there specifications and requirements before and after testing. The system was calibrated at 21% and 100% oxygen, and 0% and 80% helium before testing. After testing calibration curves were verified and no drift was detected greater than 1%.