PROTOCOL 07-0086

Oxygen Delivery Performance of the Southmedic Infant Mask under Simulated Patient Conditions

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1.0 Objective

1.1 To measure the oxygen delivery of the Southmedic Infant oxygen mask when delivering 250, 500, 750, 1000, 1500, 2000, 2500, 3000 ml per minute of oxygen for a simulated patient condition of 50 ml tidal volume, 30 bpm breathing rate, and an IE 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
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 Infant Oxygen Masks — One sample as supplied by manufacturer.
4.2 0-100 psig Pressure Gauge (E-008)
4.3 Gilmore glass float type Rotameter (E-015)
4.4 Low Flow Rotameter (E-082)
4.5 AccuLAB Standard Electronic Balance TS series (E-002)
4.6 Vacuum pump (E-009)
4.7 Compressed gas source (in-house)
4.8 Data Acquisition System
4.9 CAHN Model C-31 Microbalance (E-031)
4.10 Humidity/Temperature Meter (E-100)
4.11 Oxygen Sensor (E-081)
4.12 Valve Controller (E-090)
4.13 Frequency Generator (E-065)
4.14 Infant Mannequin Head
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Testing Procedure

5.1 Set Up
5.1.1 Connect the valve controller to the frequency generator as shown in figure 1. Connect Inhalation Valve to a vacuum source set to 3 l/min. Connect Exhalation Valve to a compressed air source set to 3 l/min.
5.1.2 Use the infant mannequin head for a simulated patient head (width of head at eye position is 2.75").

5.1.3 Set the frequency generator to a rate of 30 bpm and an I/E ratio of 1:1.
5.1.4 Attach a sensing oxygen line to infant head for sampling immediately proximal to the mouth. Sample 10 ml/min through the line to the oxygen sensor using a vacuum source.
5.1.5 Place Southmedic Infant Mask on patient head. Connect mask oxygen tubing to oxygen source.
5.2 Testing

5.2.1 Set oxygen source flow setting to 250 ml/min. Allow system to equilibrate for 5 minutes. Take an oxygen reading. Repeat for a total of 5 times. Take off mask and replace on simulated patient after each measurement.

5.2.2 Repeat step 5.2.1 for 500, 750, 1000, 1500, 2000, 2500, and 3000 ml/min of oxygen source flow.

5.2.3 Tabulate combined data and perform a comparison.
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RESULTS

Oxygen Concentration Delivery

<table>
<thead>
<tr>
<th>Oxygen Flow (ml/min)</th>
<th>250</th>
<th>500</th>
<th>750</th>
<th>1000</th>
<th>1500</th>
<th>2000</th>
<th>2500</th>
<th>3000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen Concentration Measurements</td>
<td>22</td>
<td>25</td>
<td>31</td>
<td>34</td>
<td>40</td>
<td>42</td>
<td>48</td>
<td>52</td>
</tr>
<tr>
<td>Mean</td>
<td>22.4</td>
<td>25.2</td>
<td>29.4</td>
<td>33.6</td>
<td>42.3</td>
<td>47.0</td>
<td>49.8</td>
<td>50.0</td>
</tr>
</tbody>
</table>

Table 1 showing the oxygen concentration measurements for the Southmedic Infant mask at each of the oxygen flow settings, and the resulting mean and standard deviation.

Oxygen Concentration Versus Oxygen Flow

![Graph showing oxygen concentration versus oxygen flow](image)

Figure 2 showing the delivered oxygen concentration of the Southmedic Infant mask for varying oxygen flow rates.
DISCUSSION

All equipment and laboratory processes met their specifications and requirements before and after testing. The system was calibrated at 21% and 100% before testing. After testing, calibration curves were verified. Oxygen concentration varied between 21% and 50% for oxygen flow rate of 250 ml/min to 3,000 ml/min.