

PROTOCOL 07-0086

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

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Dave Piper, PE
Piper Medical Products
PO Box 993
Carmichael, CA 95609
Tel 916-834-3283
Dave@PiperMedical.com
www.PiperMedical.com

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Prepared By:	S. David Piper, PE	Date:	12/18/2007
Approved By:	S. David Piper, PE	Date:	12/18/2007
Tested By:	Lindsay Kniasly, S. David Piper, PE	Date:	12/21/2007- 01/15/2008
Reported By:	S. David Piper, PE	Date:	01/16/2008
Approved By:	S. David Piper, PE	Date:	01/16/2008



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 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

**PROTOCOL: Oxygen Delivery Performance of the Southmedic Infant Mask
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3.0 Acceptance Criteria

- 3.1** All equipment and laboratory processes used and specified will meet their pre-determined 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** Gilmont 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 Mennocquin Head

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

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

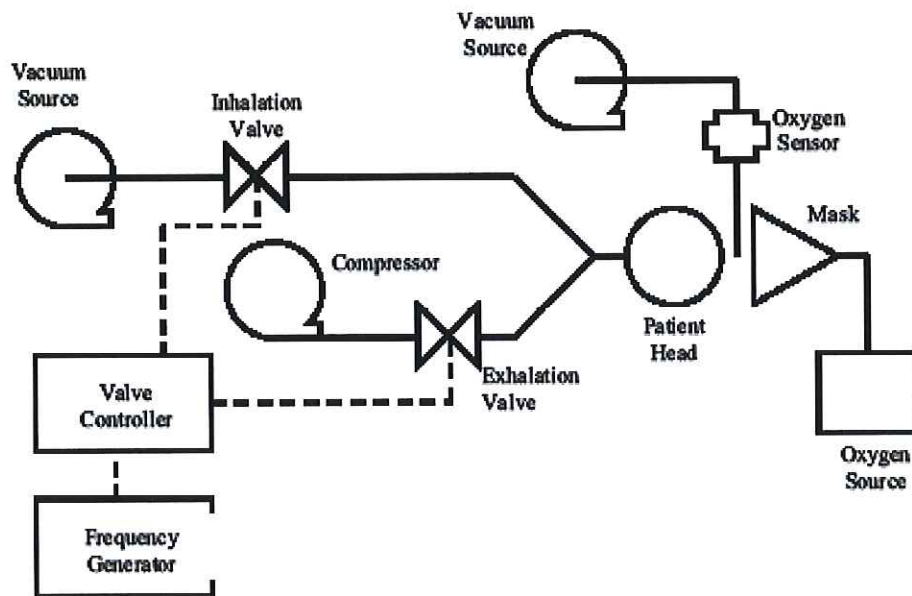


Figure 1 showing the patient simulation setup used for testing

- 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.

PIPER MEDICAL

Protocol 07-0086

**PROTOCOL: Oxygen Delivery Performance of the Southmedic Infant Mask
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5.2 Testing

- 5.2.1 Set oxygen source flow setting to 250 ml/min. Allow system to equilibrate for 3 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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Protocol 07-0086

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RESULTS

Oxygen Concentration Delivery

Oxygen Flow	250	500	750	1000	1500	2000	2500	3000
	ml/min	ml/min	ml/min	ml/min	ml/min	ml/min	ml/min	ml/min
Oxygen Concentration	22	24	29	33	43	52	50	58
Measurements	22	25	31	34	48	48	48	50
	22	26	31	40	42	48	52	48
	24	25	27	30	44	48	48	50
	22	26	29	31	39	43	53	45
Mean	22.4	25.2	29.4	33.6	42.6	47.0	49.6	49.6
St. Dev.	0.9	0.6	1.7	3.9	2.6	3.3	2.9	4.0

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

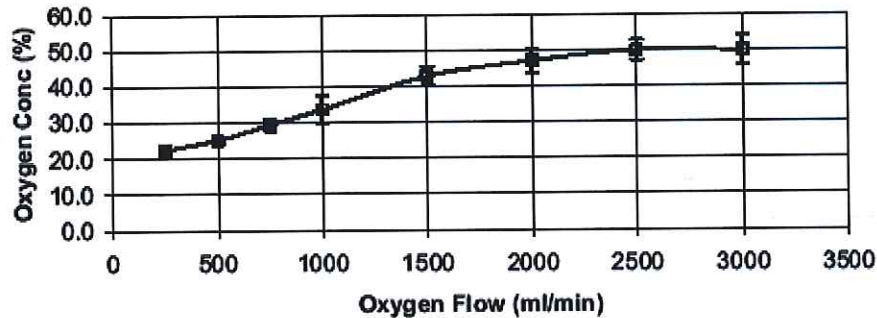


Figure 2 showing the delivered oxygen concentration of the Southmedic Infant mask for varying oxygen flow rates.

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Protocol 07-0086

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

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.