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 to 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, 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 there pre-determined 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)

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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. 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

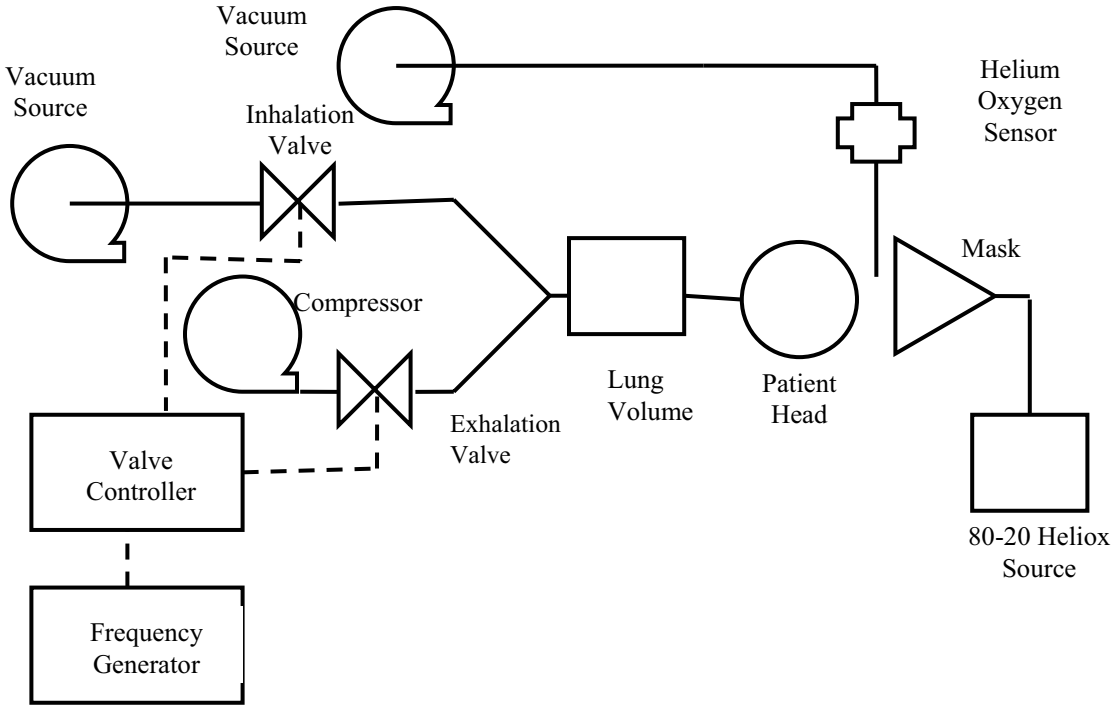

Figure 1 showing the patient simulation setup used for testing

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.

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

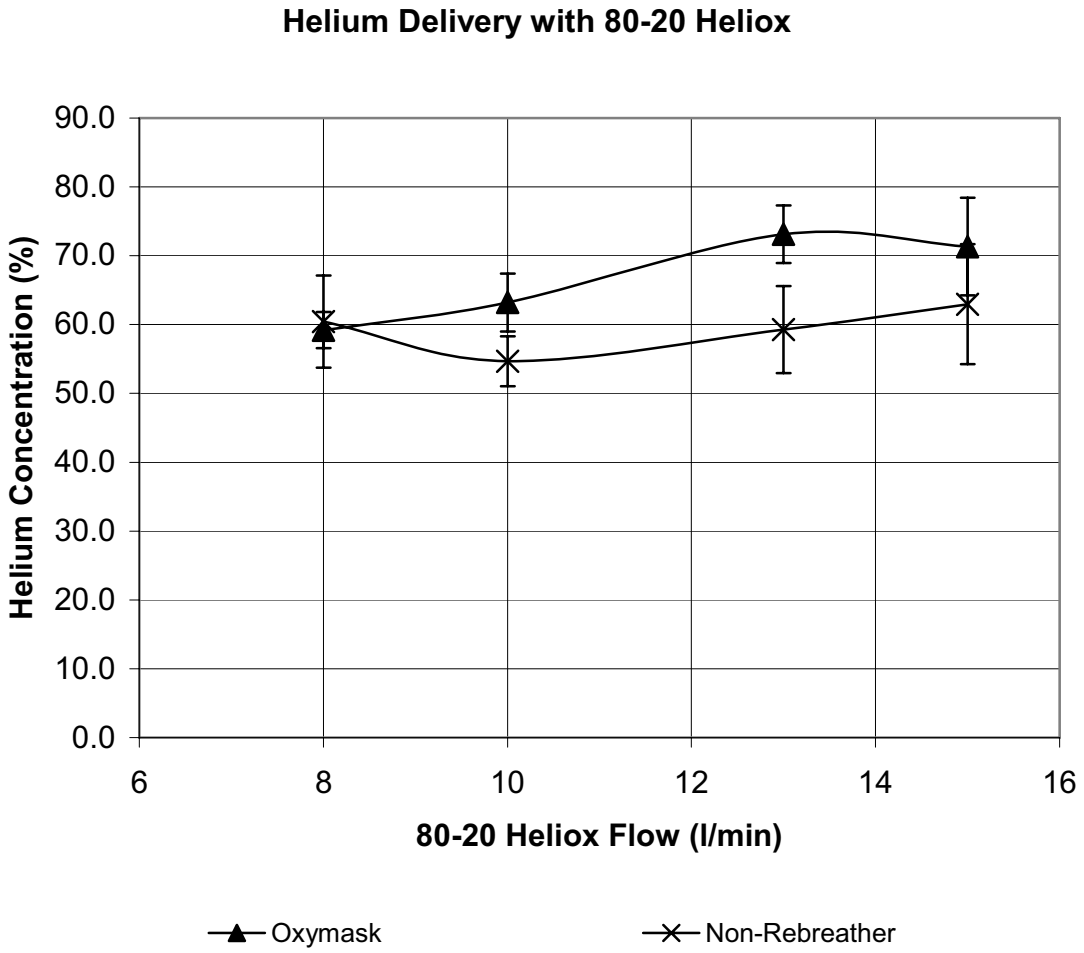

Figure 2 showing the delivered helium concentration for the Oxymask and Non-Rebreather Mask while delivering various flowrates of 80-20 heliox. Indicated error bars represent 1 standard deviation. Measurements were done immediately at the mouth.

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Helium and Oxygen Concentrations

Heliox Flow (L/min)		Oxymask % He	Oxymask % O_2	Non-Rebreather % He	Non-Rebreather % O_2
15		76.8	21.4	58.3	20.9
		63.3	21.3	57.6	21.1
		73.9	21.3	73.0	21.3
	Mean	**71.3**	**21.3**	**63.0**	**21.1**
	Std Dev	**7.1**	**0.1**	**8.7**	**0.2**
13		75.7	21.4	53.1	20.8
		75.4	21.1	65.7	21.2
		68.3	20.9	59.0	20.9
	Mean	**73.1**	**21.1**	**59.3**	**21.0**
	Std Dev	**4.2**	**0.3**	**6.3**	**0.2**
10		58.8	20.5	50.5	20.7
		63.6	20.7	56.5	20.8
		67.2	20.8	57.0	20.8
	Mean	**63.2**	**20.7**	**54.7**	**20.8**
	Std Dev	**4.2**	**0.2**	**3.6**	**0.1**
8		61.2	20.7	59.8	21.6
		56.2	20.1	54.1	21.3
		60.2	20.5	67.4	21.7
	Mean	**59.2**	**20.4**	**60.4**	**21.5**
	Std Dev	**2.6**	**0.3**	**6.7**	**0.2**

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%.