

PROTOCOL 14-0022

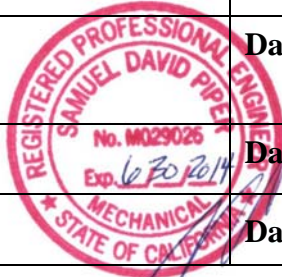
Oxygen Delivery Testing of the POM Panoramic Oxygen Mask
Under Simulated Patient Conditions

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1.0 Objective

- 1.1 To measure the delivered FiO2 for the POM Panoramic Oxygen Mask under simulated patient conditions

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-131 – PRESSURE FLOW MEASUREMENT OPERATION
- 2.4 PIPER MEDICAL SOP-E-133 – OXYGEN SENSOR OPERATION

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.

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4.0 Equipment List

- 4.1 POM Medical, LLC Panoramic Oxygen Mask with Medium and High concentration adapters, REF 1001 – Piper Sample ID 140317-1, 140317-2, and 140317-3
- 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 source (in-house)
- 4.7 Compressed gas source (in-house)
- 4.8 Oxygen source (in-house)
- 4.9 CO2 source (in-house)
- 4.10 Velleman Digital Oscilloscope (E-154)
- 4.11 Ohmeda 5200 CO2 Monitor (E-132)
- 4.12 Data Acquisition System
- 4.13 Humidity/Temperature Meter (E-100)
- 4.14 Oxygen Sensor (E-081)
- 4.15 Harvard Respiratory Pump (E-053)
- 4.16 Wright Respirometer (E-004)
- 4.17 Mannequin Head (0.875” ID oral cavity, head width = 6.0”)

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Testing Procedure

5.1 Set Up

- 5.1.1 Connect the Harvard Respirator pump as shown in figure 1. Run a line from the CO2 source to the inhalation limb of the Harvard Pump on the piston side of the inhalation check valve as shown.
- 5.1.2 Use mannequin head for a simulated patient head.
- 5.1.3 Set the Harvard Pump and oxygen flow to the desired settings per table 1. Prior to placing each sample set the ETCO2 level to 3%. Take FiO2 measurements.

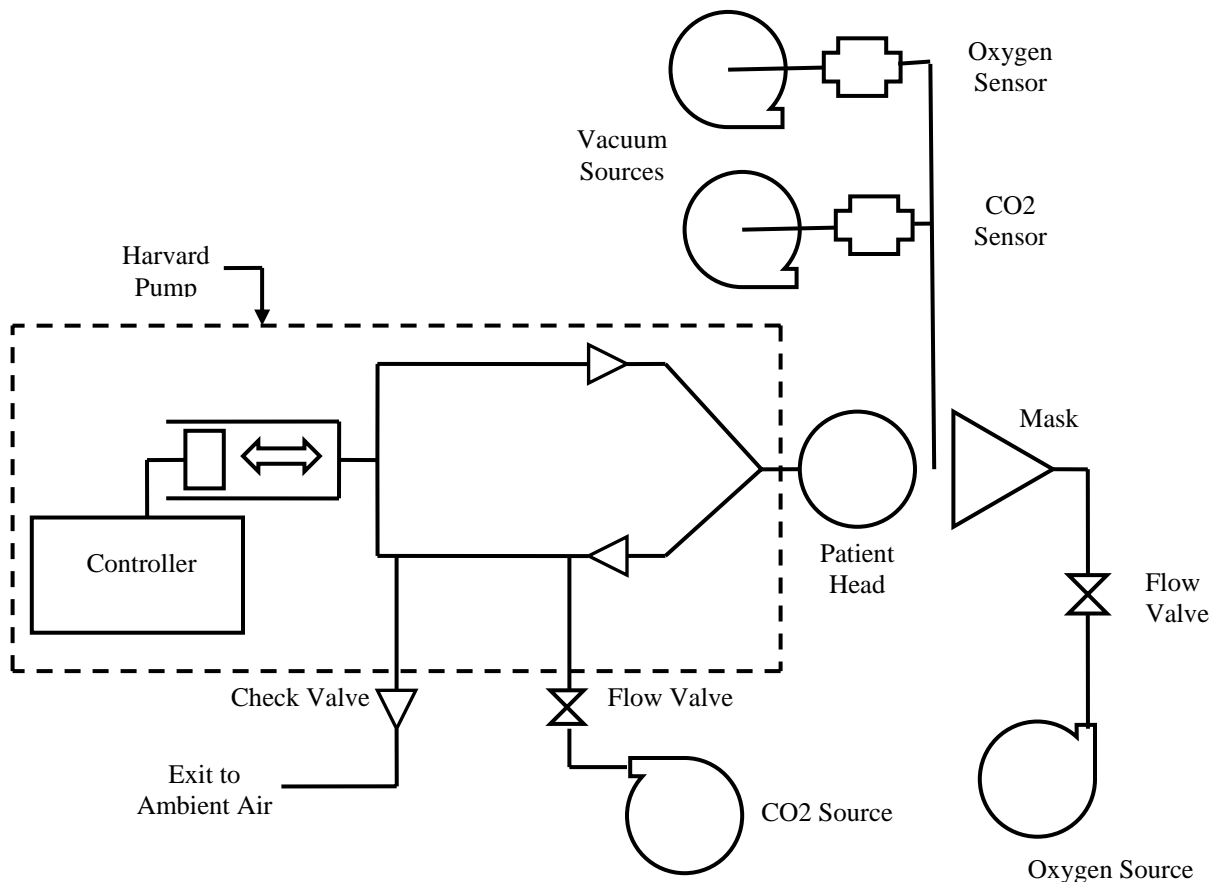


Figure 1 showing the patient simulation setup used for testing

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Simulated Respiratory Settings	
Respiratory Rate	12 bpm
Tidal Volume	400 ml
I:E Ratio	1:1
End Tidal CO2	3%

Table 1 showing the respiratory settings used for testing.



Figure 2 showing a picture of the set ups used during testing. The medium concentration adapter configuration is showed on the left, the high concentration adapter configuration is showed on the right.

- 5.1.4 Attach a 0.125" OD sensing oxygen line to mannequin head and position the sensing end directly centered over the 0.875" ID simulated oral cavity of the mannequin head. Sample through the line to the oxygen and CO2 sensor (10 ml/min each) using a vacuum source. End tidal CO2 values shall be set with out the mask in place so as to simulate normal expected breathing.
- 5.1.5 Once CO2 flow has been set to the desired end tidal CO2 value, the mask will be adjusted to the desired oxygen flow rate and placed on mannequin head.
- 5.1.6 Two sets of measurements will be performed, one set will be with the sample masks equipped with a medium concentration adapter as described in the production instructions. The other identical set of tests will be performed on the same sample masks equipped with a high concentration adapter as described in the product instructions. Testing of the medium concentration adapter configuration will occur at 8, 10, and 12 l/min oxygen flow provided as described in product instructions. Testing of the high concentration adapter configuration will occur at 10, 12, and 15 l/min oxygen flow as described in the product instructions.
- 5.1.7 Each sample will be tested once in each configuration at each oxygen flow rate.

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- 5.2 Testing
 - 5.2.1 Allow system to equilibrate for at least 3 minutes prior to taking each reading. Test each sample once for FiO₂.
 - 5.2.2 After allowing each setting 3 minutes to equilibrate obtaining an FiO₂ measurement.
 - 5.2.3 Tabulate combined data and perform a comparison. Discuss results and reference results to acceptance criteria.

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6.0 RESULTS

POM (Panoramic Oxygen Mask) FiO2 Results

Rate = 12 BPM, TV = 400 ml, I:E Ratio = 1:1, ETCO2 % = 3%

Medium Oxygen Flow Adaptor			
	O2 Flow = 8 l/min	O2 Flow = 10 l/min	O2 Flow = 12 l/min
1	78.4%	84.4%	87.6%
2	76.8%	83.8%	88.1%
3	77.5%	82.0%	85.2%
Mean	77.6%	83.4%	87.0%
Std Dev	0.8%	1.2%	1.6%

High Oxygen Flow Adaptor			
	O2 Flow = 10 l/min	O2 Flow = 12 l/min	O2 Flow = 15 l/min
1	89.2%	91.6%	95.6%
2	88.4%	92.2%	97.1%
3	87.0%	90.1%	93.8%
Mean	88.2%	91.3%	95.5%
Std Dev	1.1%	1.1%	1.7%

Table 2 showing the oxygen (FiO2) delivery results for the two device configurations.

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7.0 DISCUSSION

All equipment and laboratory processes met there specifications and requirements before and after testing. Oxygen measurements were calibrated at 21% and 100% before testing. After testing calibration curves were verified. The acceptance criteria of the test were met.