PROTOCOL 18-0017

End Tidal CO_2 Measurements for The POM Mask, Product #1003
Adult During Dual Bronchoscope Probe Use

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PROTOCOL: End Tidal CO_2 Measurements for The POM Mask, Product #1003 Adult During Dual Bronchoscope Probe Use

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Tested By:	Rocky Jewell, Cora Piper		**Date:**	01/26/2018- 03/10/2018
Reported By:	Cora Piper		**Date:**	03/11/2018
Approved By:	S. David Piper, PE		**Date:**	03/11/2018

1.0 Objective

1.1 To measure to the end tidal CO_2 values and waveforms of the POM Mask, Product #1003 Adult under simulated patient conditions including dual bronchoscopes use and to compare to previous testing under the same conditions without bronchoscopes.

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

2.5 PIPER PROTOCOL 17-0041 - END TIDAL CO_2 MEASUREMENTS FOR THE POM MASK, PRODUCT #1003 ADULT AND MONITOR MASK CAPNOVUE M1, PRODUCT #1001-A ADULT UNDER SIMULATED PATIENT CONDITIONS, MAY 22, 2017

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 POM Mask, Product #1003, Adult, 3 samples (Piper Medical Sample ID 180125-6, 180125-7, and 180125-8).

4.2 Adult Oral Bronchoscope Probe, having a diameter of 0.625" and a length of 12"

4.3 Adult Nasal Bronchoscope Probe, having a diameter of 0.250" and a length of 12"

4.4 0-100 psig Pressure Gauge (E-008)

4.5 Gilmont glass float type Rotameter (E-015)

4.6 Low Flow Rotameter (E-082)

4.7 AccuLAB Standard Electronic Balance TS series (E-002)

4.8 Vacuum source (in-house)

4.9 Compressed gas source (in-house)

4.10 Oxygen source (in-house)

4.11 CO_2 source (in-house)

4.12 Velleman Digital Oscilloscope (E-154)

4.13 Ohmeda 5200 CO_2 Monitor (E-132)

4.14 Data Acquisition System

4.15 Humidity/Temperature Meter (E-100)

4.16 Oxygen Sensor (E-081)

4.17 Harvard Respiratory Pump (E-053)

4.18 Wright Respirometer (E-004)

4.19 Mannequin Head (oral and nasal passages)

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Testing Procedure

5.1 Sample Preparation

5.1.1 Three samples of the POM Mask, Product #1003 Adult have been received. Sample devices will be set up and used per product instructions during all testing.

5.2 Test Set Up

5.2.1 Connect the Harvard Respirator pump as shown in figure 1. Connect the oxygen supply line of the DUT to the oxygen flow valve. Connect the CO_2 sensing line of the DUT to the CO_2 detector.

5.2.2 Use mannequin head with an oral and nasal passage for a simulated patient head.

5.2.3 Set the Harvard Pump and CO_2 flow to the desired settings per table 1.

5.2.4 Per DUT instructions, insert oral bronchoscope through DUT port and into oral passage of mannequin head to a depth of 6". Similarly, and at the same time, insert nasal bronchoscope though DUT port into nasal passage of mannequin head to a depth of 4".

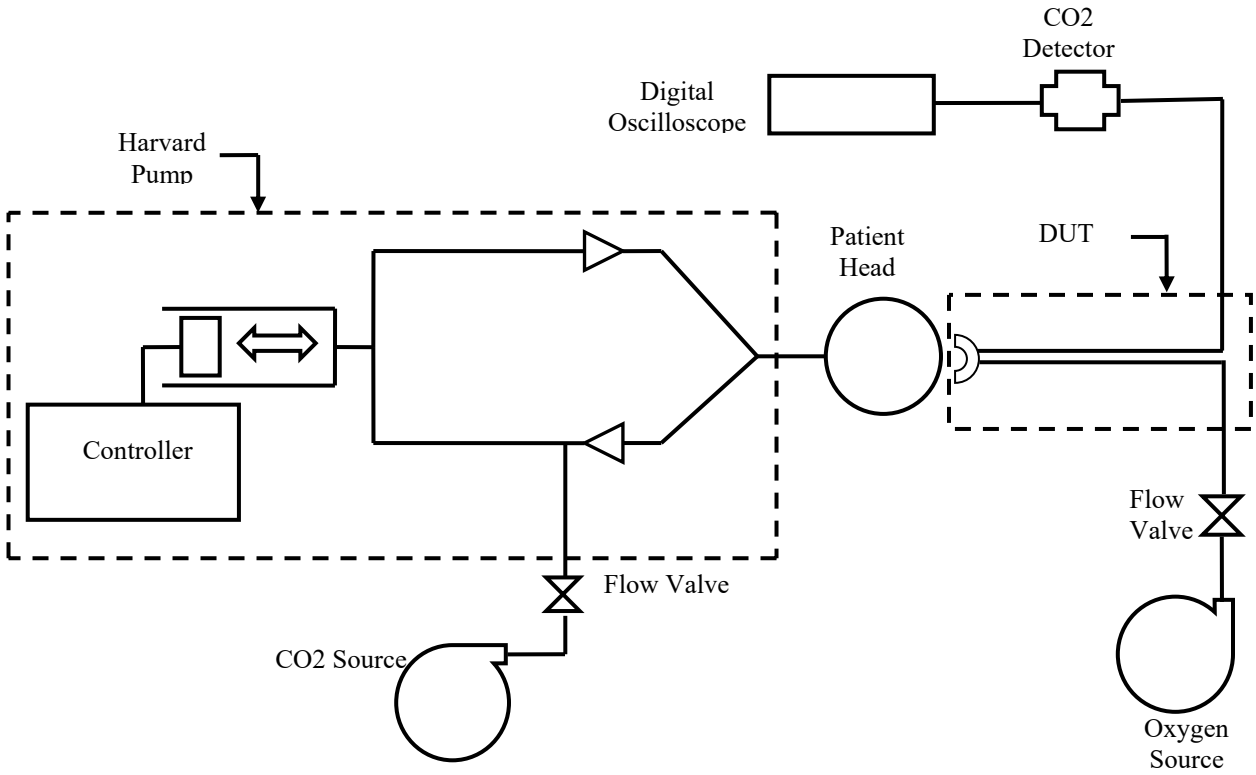

Figure 1 showing the patient simulation setup used for testing

	Simulated Respiratory Settings	
Respiratory Rate	12	20
Tidal Volume	500	300
I:E Ratio	1:1	1:1

Table 1 showing the two respiratory settings used for testing

5.3 Testing

5.3.1 Perform measurements for oxygen source flows through the DUT of 1 and 8 l/min, and at baseline true $ETCO_2$ values 5%. Allow system to equilibrate for at least 3 minutes prior to taking each reading Test each sample DUT once per combination of condition. There shall be a total of 12 tests (1 model of DUT x 3 samples of DUT x 2 respiratory setting x 2 oxygen flow rates x 1 baseline $ETCO_2$ value = 12 tests total)

5.3.2 After allowing each setting 3 minutes to equilibrate capture a full inhalation exhalation CO_2 waveform and take an end tidal CO_2 measurement.

5.3.3 Tabulate combined data and perform a comparison to previous data taken without bronchoscopes in place in Piper Medical Protocol 17-0041.

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RESULTS

Indicated $ETCO_2$ Results for Rate = 12 BPM, TV = 500 ml, I:E Ratio = 1:1

	POM Mask, Product #1003, Adult without Bronchoscopes in place	POM Mask, Product #1003, Adult with Bronchoscopes in place
	Oxygen Flow = 1 l/min, Baseline $ETCO_2$=5%	
Sample 1	7.6%	5.8%
Sample 2	7.2%	6.8%
Sample 3	7.3%	7.1%
Mean	**7.37%**	**6.57%**
Std Dev	**0.21%**	**0.68%**
	Oxygen Flow = 8 l/min, Baseline $ETCO_2$=5%	
Sample 1	5.1%	4.5%
Sample 2	5.1%	4.9%
Sample 3	5.3%	4.8%
Mean	**5.17%**	**4.73%**
Std Dev	**0.12%**	**0.21%**

Table 2 showing the indicated $ETCO_2$ for the POM Mask, Product #1003 Adult Mask with and without bronchoscopes in place.

Indicated Breathing Rate for Rate = 12 BPM, TV = 500 ml, I:E Ratio = 1:1

	POM Mask, Product #1003, Adult without Bronchoscopes in place	POM Mask, Product #1003, Adult with Bronchoscopes in place
	Oxygen Flow = 1 l/min, Baseline $ETCO_2$=5%	
Sample 1	12.0	12.0
Sample 2	12.0	12.0
Sample 3	12.0	12.0
Mean	**12.0**	**12.0**
Std Dev	**0.0**	**0.0**
	Oxygen Flow = 8 l/min, Baseline $ETCO_2$=5%	
Sample 1	12.0	12.0
Sample 2	12.0	12.0
Sample 3	12.0	12.0
Mean	**12.0**	**12.0**
Std Dev	**0.0**	**0.0**

Table 3 showing the indicated respiratory rate for the POM Mask, Product #1003 Adult Mask with and without bronchoscopes in place.

Indicated $ETCO_2$ Results for Rate = 20 BPM, TV = 300 ml, I:E Ratio = 1:1

	POM Mask, Product #1003, Adult without Bronchoscopes in place	POM Mask, Product #1003, Adult with Bronchoscopes in place
	Oxygen Flow = 1 l/min, Baseline $ETCO_2$=5%	
Sample 1	8.2%	6.4%
Sample 2	8.2%	7.0%
Sample 3	8.3%	7.8%
Mean	**8.23%**	**7.07%**
Std Dev	**0.06%**	**0.70%**
	Oxygen Flow = 8 l/min, Baseline $ETCO_2$=5%	
Sample 1	5.8%	4.0%
Sample 2	6.3%	4.8%
Sample 3	6.4%	4.4%
Mean	**6.17%**	**4.40%**
Std Dev	**0.32%**	**0.40%**

Table 4 showing the indicated $ETCO_2$ for the POM Mask, Product #1003 Adult Mask with and without bronchoscopes in place.

Indicated Respiratory Rate for Rate = 20 BPM, TV = 300 ml, I:E Ratio = 1:1

	POM Mask, Product #1003, Adult without Bronchoscopes in place	POM Mask, Product #1003, Adult with Bronchoscopes in place
	Oxygen Flow = 1 l/min, Baseline $ETCO_2$=5%	
Sample 1	20.0	20.0
Sample 2	20.0	20.0
Sample 3	20.0	20.0
Mean	**20.0**	**20.0**
Std Dev	**0.0**	**0.0**
	Oxygen Flow = 8 l/min, Baseline $ETCO_2$=5%	
Sample 1	20.0	20.0
Sample 2	20.0	20.0
Sample 3	20.0	20.0
Mean	**20.0**	**20.0**
Std Dev	**0.0**	**0.0**

Table 5 showing the indicated respiratory rate for the POM Mask, Product #1003 Adult Mask with and without bronchoscopes in place.

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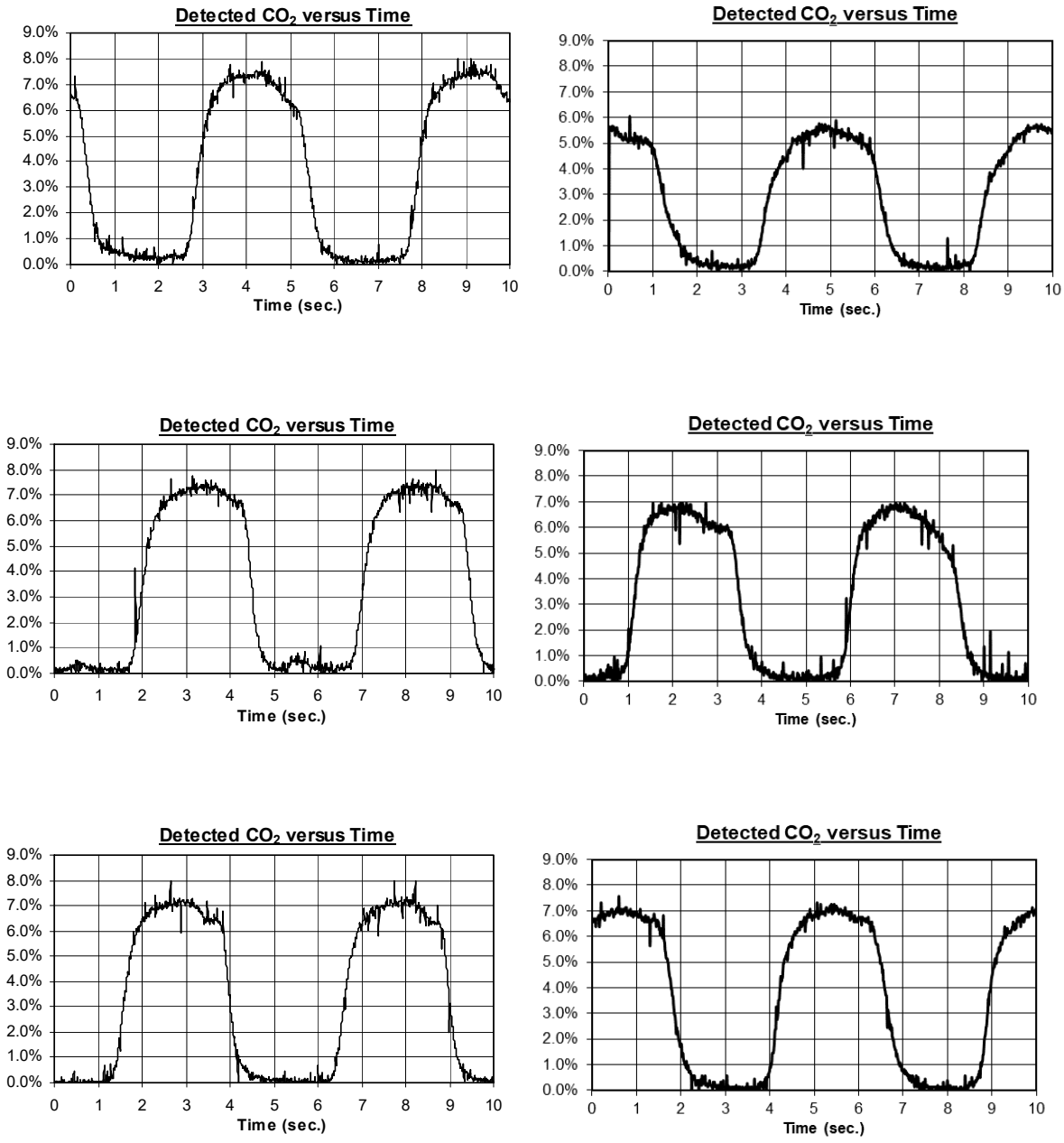

Figure 2 showing the CO_2 waveforms for the POM Mask, Product #1003, Adult without bronchoscopes in place (left column) and with bronchoscopes in place (right column) at breathing rate of 12 bpm, a tidal volume of 500 ml, a I:E of 1:1, an oxygen flow of 1 l/min, and a baseline ET CO_2 of 5%.

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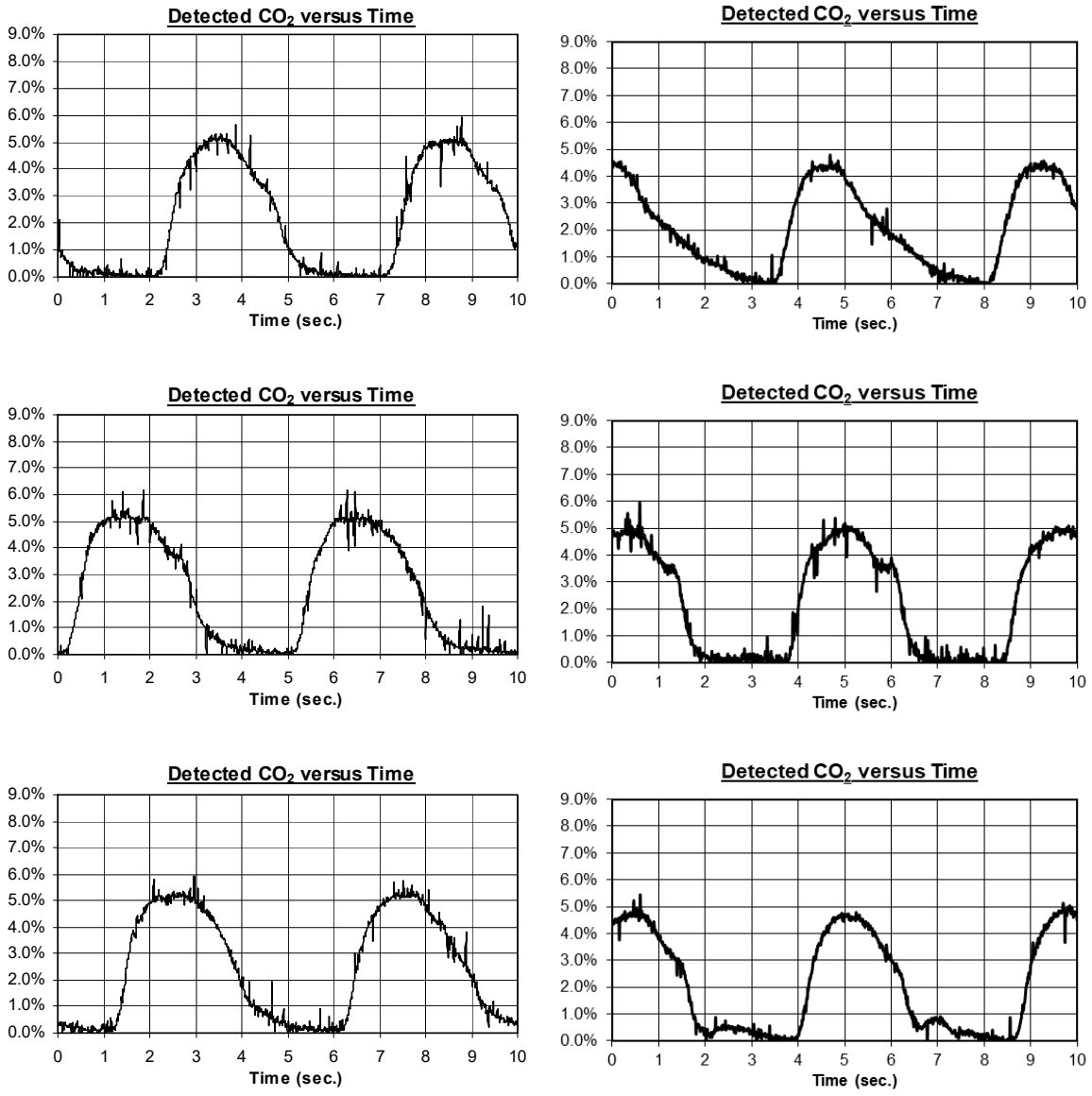

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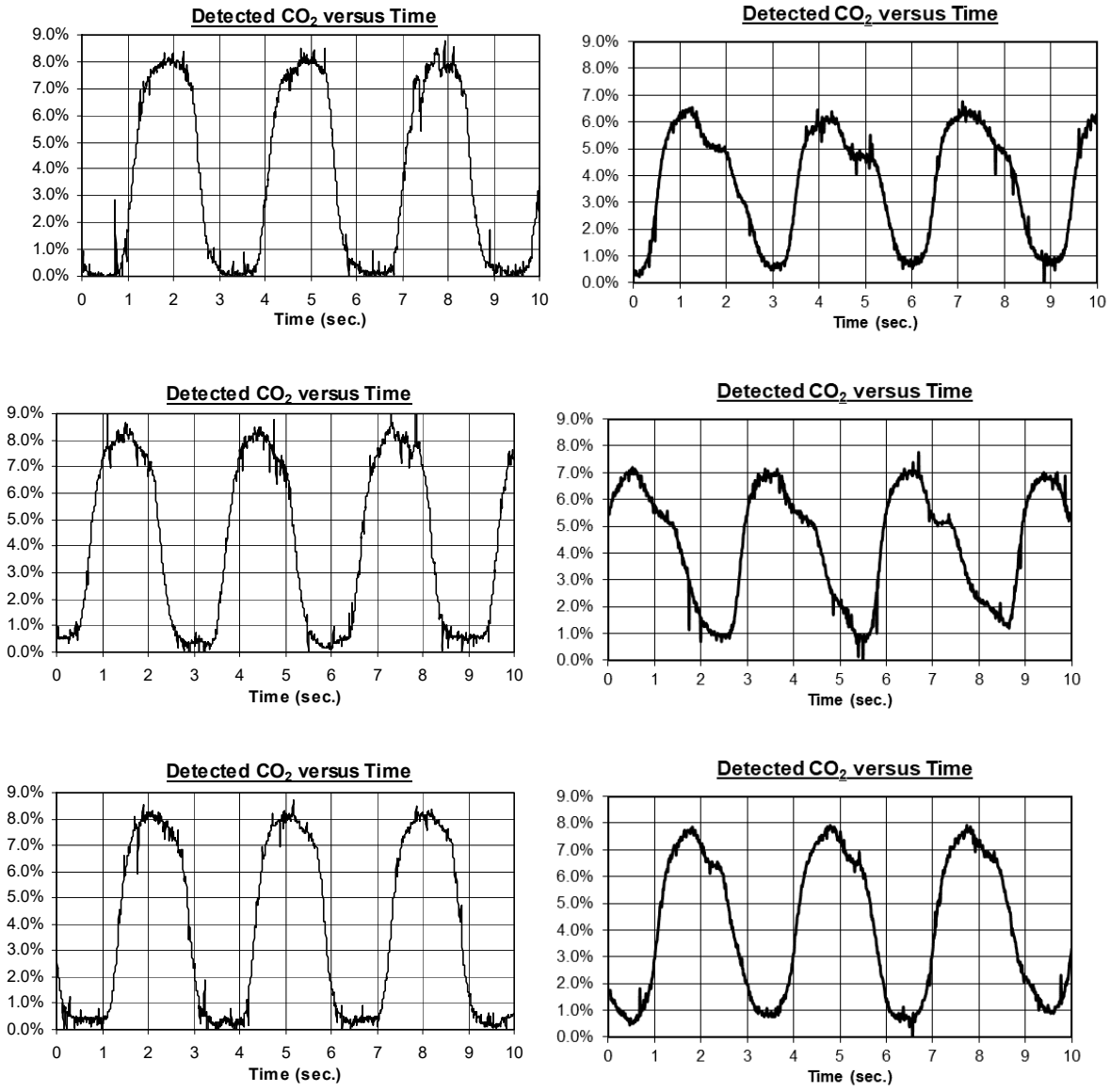

Figure 4 showing the CO_2 waveforms for the POM Mask, Product #1003, Adult without bronchoscopes in place (left column) and with bronchoscopes in place (right column) at breathing rate of 20 bpm, a tidal volume of 300 ml, a I:E of 1:1, an oxygen flow of 1 l/min, and a baseline ET CO_2 of 5%.

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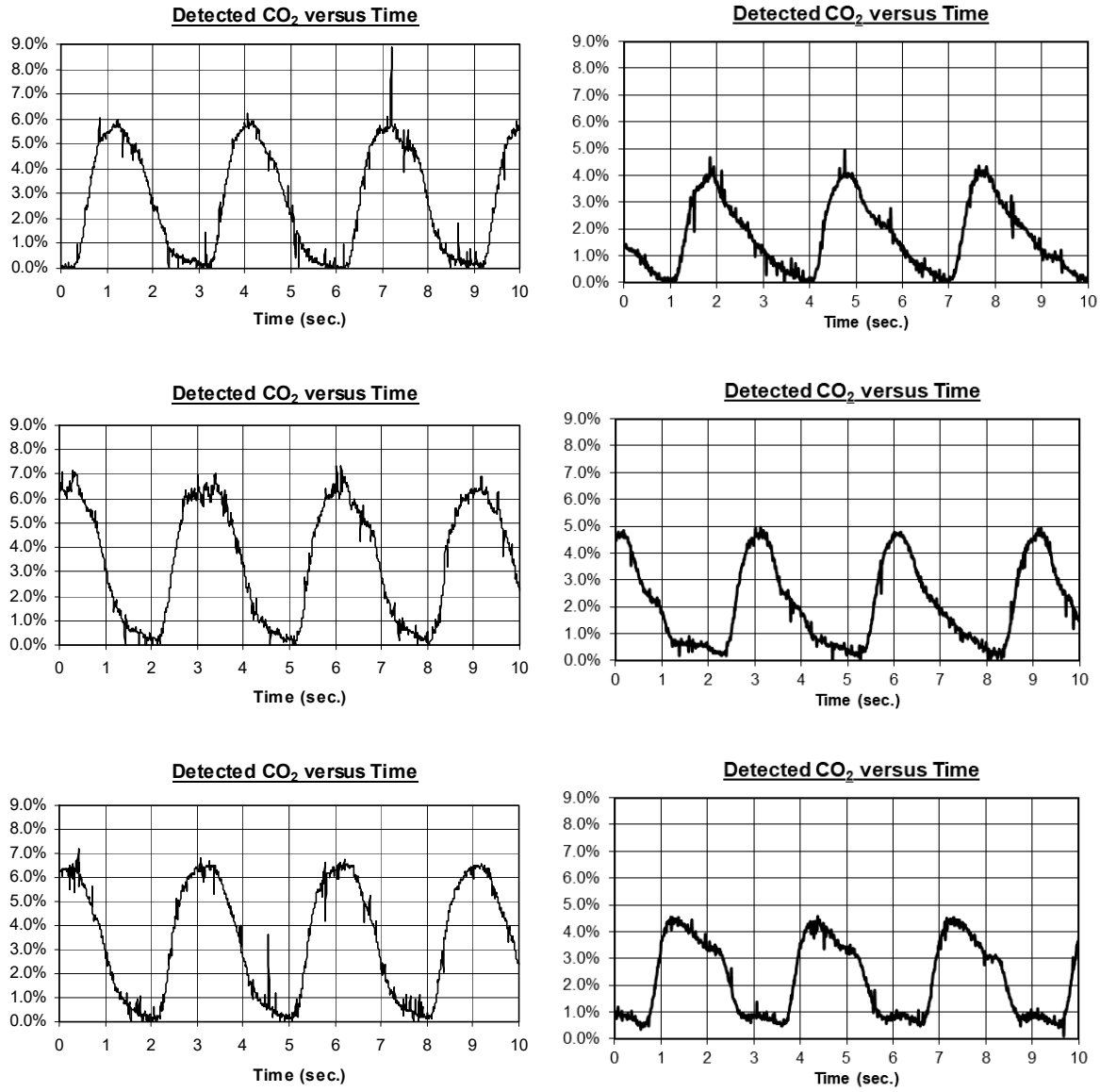

Figure 5 showing the CO_2 waveforms for the POM Mask, Product #1003, Adult without bronchoscopes in place (left column) and with bronchoscopes in place (right column) at breathing rate of 20 bpm, a tidal volume of 300 ml, a I:E of 1:1, an oxygen flow of 8 l/min, and a baseline ET CO_2 of 5%.

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DISCUSSION

All equipment and laboratory processes met their specifications and requirements before and after testing. The system was calibrated before testing. After testing calibration curves were verified. True $ETCO_2$ values were checked after each set of tests and found to be 5% and not to vary from test set to test set. Results were typical for the devices being studied.

End tidal CO_2 values were shown to alter a bit with bronchoscopes in place, as expected, but breathing patterns remained detectable at all oxygen flows. Therefore, all the acceptance criteria of the test were met.