

PROTOCOL 18-0018

End Tidal CO₂ Measurements for The POM Mask, Product #1003-
PED Pediatric During Dual Bronchoscope Probe Use

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1.0 Objective

- 1.1 To measure to the end tidal CO₂ and FiO₂ values and waveforms of the POM Mask, Product #1003-PED Pediatric 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 MEDICAL PROTOCOL 17-0044 - END TIDAL CO₂ MEASUREMENTS FOR THE POM MASK, PRODUCT #1003-PED PEDIATRIC AND MONITOR MASK CAPNOVUE M1, PRODUCT #1001-P PEDIATRIC UNDER SIMULATED PATIENT CONDITIONS

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.

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4.0 Equipment List

- 4.1 POM Mask, Product #1003-PED Pediatric, 3 samples (Piper Medical Sample ID 180125-9, 180125-10, and 180125-11).
- 4.2 Pediatric Oral Bronchoscope Probe, having a diameter of 0.325” and a length of 12”
- 4.3 Pediatric Nasal Bronchoscope Probe, having a diameter of 0.188” 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 CO₂ source (in-house)
- 4.12 Velleman Digital Oscilloscope (E-154)
- 4.13 Ohmeda 5200 CO₂ 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-PED Pediatric 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 CO₂ sensing line of the DUT to the CO₂ detector.

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

5.2.3 Set the Harvard Pump and CO₂ 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".

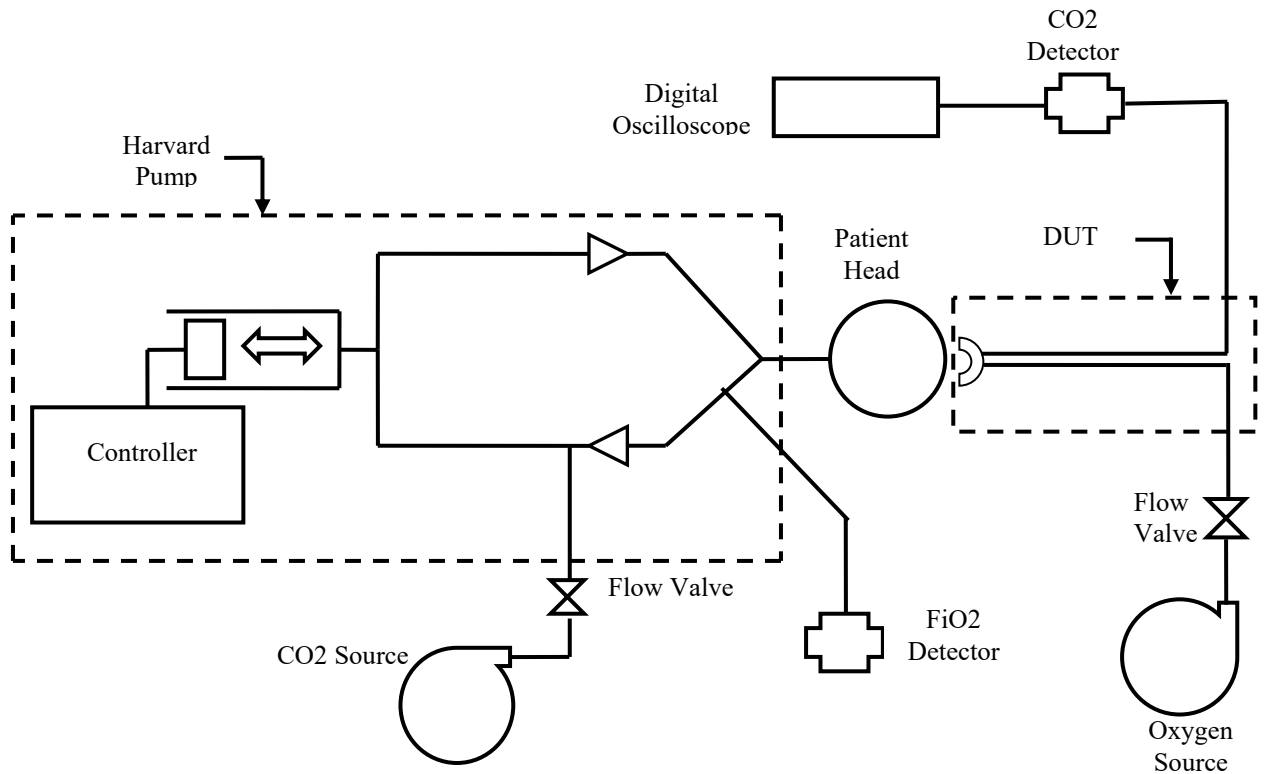


Figure 1 showing the patient simulation setup used for testing

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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 ET_{CO}₂ values of 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 per model x 2 respiratory setting x 2 oxygen flow rates x 1 baseline ET_{CO}₂ value = 12 tests total)
 - 5.3.2 After allowing each setting 3 minutes to equilibrate capture a full inhalation exhalation CO₂ waveform and take an FiO₂ and end tidal CO₂ measurement.
 - 5.3.3 Tabulate combined data and perform a comparison to previous data taken without bronchoscopes in place in Piper Medical Protocol 17-0044.

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RESULTS

Indicated ETCO₂ Results for Rate = 12 BPM, TV = 500 ml, I:E Ratio = 1:1

	POM Mask, Product #1003-PED, Pediatric without Bronchoscopes in place	POM Mask, Product #1003-PED, Pediatric with Bronchoscopes in place
	<u>Oxygen Flow = 1 l/min, Baseline ETCO₂=5%</u>	
Sample 1	6.4%	6.0%
Sample 2	6.4%	6.2%
Sample 3	6.4%	6.2%
Mean	6.40%	6.13%
Std Dev	0.00%	0.12%
	<u>Oxygen Flow = 8 l/min, Baseline ETCO₂=5%</u>	
Sample 1	3.6%	2.8%
Sample 2	3.2%	3.8%
Sample 3	3.4%	2.9%
Mean	3.40%	3.17%
Std Dev	0.20%	0.55%

Table 2 showing the indicated ETCO₂ for the POM Mask, Product #1003-PED Pediatric Mask with and without bronchoscopes in place.

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

	POM Mask, Product #1003-PED, Pediatric without Bronchoscopes in place	POM Mask, Product #1003-PED, Pediatric with Bronchoscopes in place
	<u>Oxygen Flow = 1 l/min, Baseline ETCO₂=5%</u>	
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
	<u>Oxygen Flow = 8 l/min, Baseline ETCO₂=5%</u>	
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-PED Pediatric Mask with and without bronchoscopes in place.

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Indicated FiO₂ Results for Rate = 12 BPM, TV = 500 ml, I:E Ratio = 1:1

	POM Mask, Product #1003-PED, Pediatric without Bronchoscopes in place	POM Mask, Product #1003-PED, Pediatric with Bronchoscopes in place
	<u>Oxygen Flow = 1 l/min, Baseline ETCO₂=5%</u>	
Sample 1	25.0%	24.0%
Sample 2	26.0%	25.0%
Sample 3	24.0%	24.0%
Mean	25.00%	24.33%
Std Dev	1.00%	0.58%
	<u>Oxygen Flow = 8 l/min, Baseline ETCO₂=5%</u>	
Sample 1	46.0%	49.0%
Sample 2	52.0%	47.0%
Sample 3	48.0%	51.0%
Mean	48.67%	49.00%
Std Dev	3.06%	2.00%

Table 4 showing the indicated FiO₂ for the POM Mask, Product #1003-PED Pediatric Mask with and without bronchoscopes in place.

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Indicated ETCO₂ Results for Rate = 20 BPM, TV = 300 ml, I:E Ratio = 1:1

	POM Mask, Product #1003-PED, Pediatric without Bronchoscopes in place	POM Mask, Product #1003-PED, Pediatric with Bronchoscopes in place
	<u>Oxygen Flow = 1 l/min, Baseline ETCO₂=5%</u>	
Sample 1	6.5%	6.0%
Sample 2	6.4%	6.6%
Sample 3	6.3%	6.1%
Mean	6.40%	6.23%
Std Dev	0.10%	0.32%
	<u>Oxygen Flow = 8 l/min, Baseline ETCO₂=5%</u>	
Sample 1	3.0%	2.2%
Sample 2	3.3%	2.3%
Sample 3	3.0%	2.2%
Mean	3.10%	2.23%
Std Dev	0.17%	0.06%

Table 5 showing the indicated ETCO₂ for the POM Mask, Product #1003-PED Pediatric Mask with and without bronchoscopes in place.

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

	POM Mask, Product #1003-PED, Pediatric without Bronchoscopes in place	POM Mask, Product #1003-PED, Pediatric with Bronchoscopes in place
	<u>Oxygen Flow = 1 l/min, Baseline ETCO₂=5%</u>	
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
	<u>Oxygen Flow = 8 l/min, Baseline ETCO₂=5%</u>	
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 6 showing the indicated ETCO₂ for the POM Mask, Product #1003-PED Pediatric Mask with and without bronchoscopes in place.

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Indicated FiO₂ Results for Rate = 20 BPM, TV = 300 ml, I:E Ratio = 1:1

	POM Mask, Product #1003-PED, Pediatric without Bronchoscopes in place	POM Mask, Product #1003-PED, Pediatric with Bronchoscopes in place
	<u>Oxygen Flow = 1 l/min, Baseline ETCO₂=5%</u>	
Sample 1	23.0%	24.0%
Sample 2	23.0%	25.0%
Sample 3	25.0%	25.0%
Mean	23.67%	24.67%
Std Dev	1.15%	0.58%
	<u>Oxygen Flow = 8 l/min, Baseline ETCO₂=5%</u>	
Sample 1	59.0%	56.0%
Sample 2	54.0%	54.0%
Sample 3	55.0%	59.0%
Mean	56.00%	56.33%
Std Dev	2.65%	2.52%

Table 7 showing the indicated FiO₂ for the POM Mask, Product #1003-PED Pediatric Mask with and without bronchoscopes in place.

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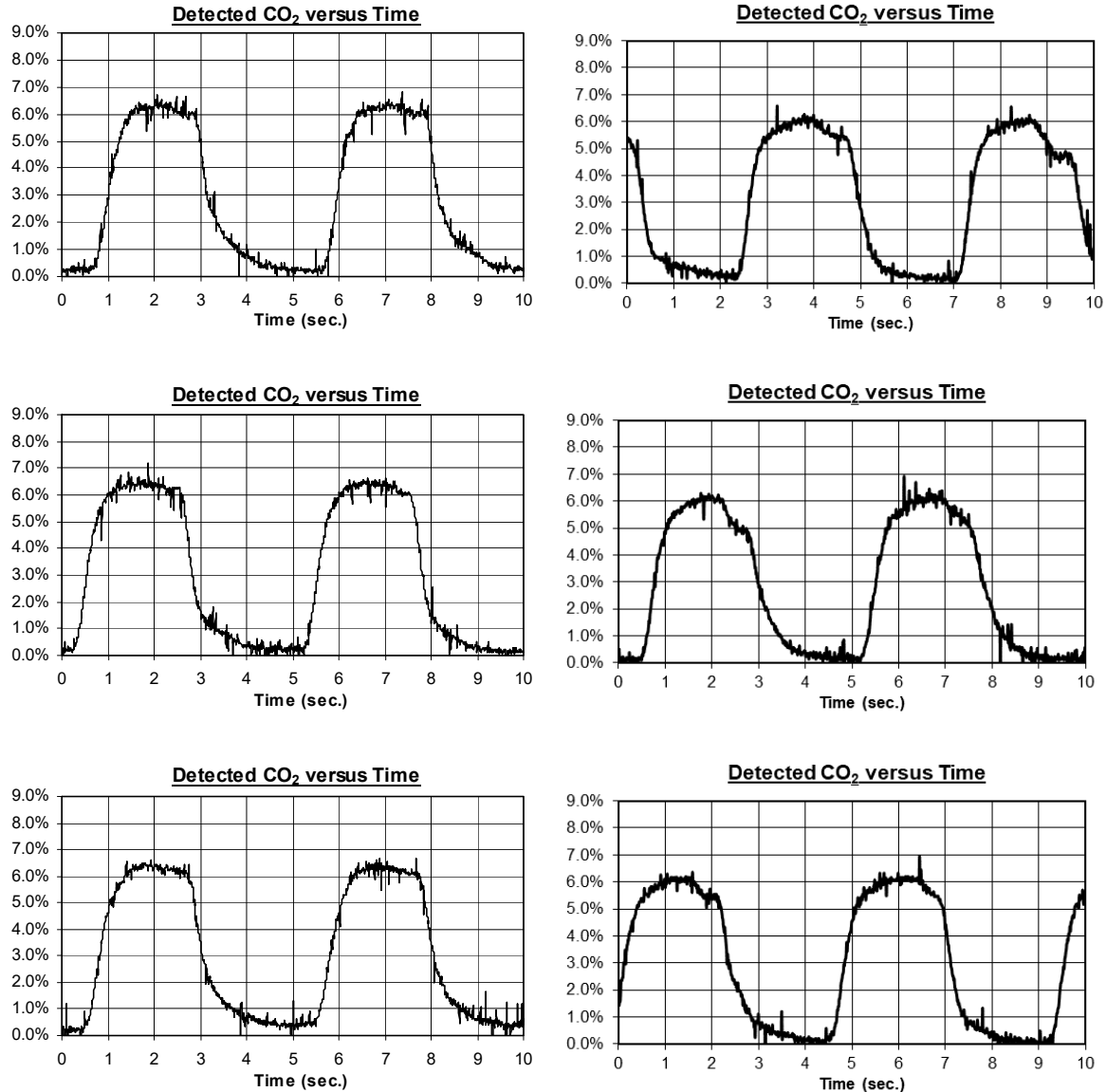


Figure 2 showing the CO₂ waveforms for the POM Mask, Product #1003-PED Pediatric without bronchoscopes (left hand column) and with bronchoscopes (right hand column) at breathing rate of 12 bpm, a tidal volume of 500 ml, a I:E of 1:1, an oxygen flow of 1 l/min, and a baseline ET CO₂ of 5%.

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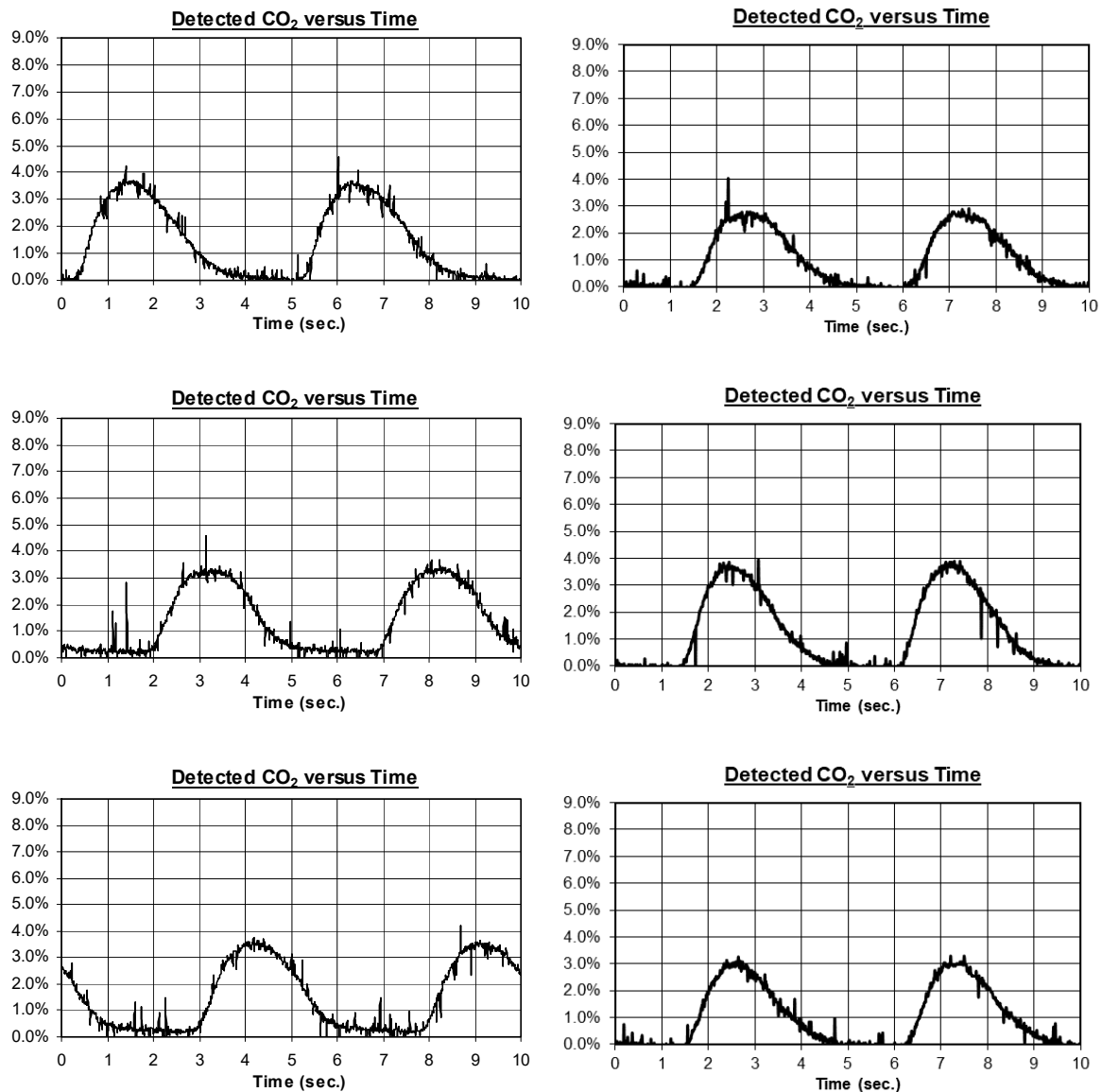


Figure 3 showing the CO₂ waveforms for the POM Mask, Product #1003-PED Pediatric without bronchoscopes (left hand column) and with bronchoscopes (right hand column) at breathing rate of 12 bpm, a tidal volume of 500 ml, a I:E of 1:1, an oxygen flow of 8 l/min, and a baseline ET CO₂ of 5%.

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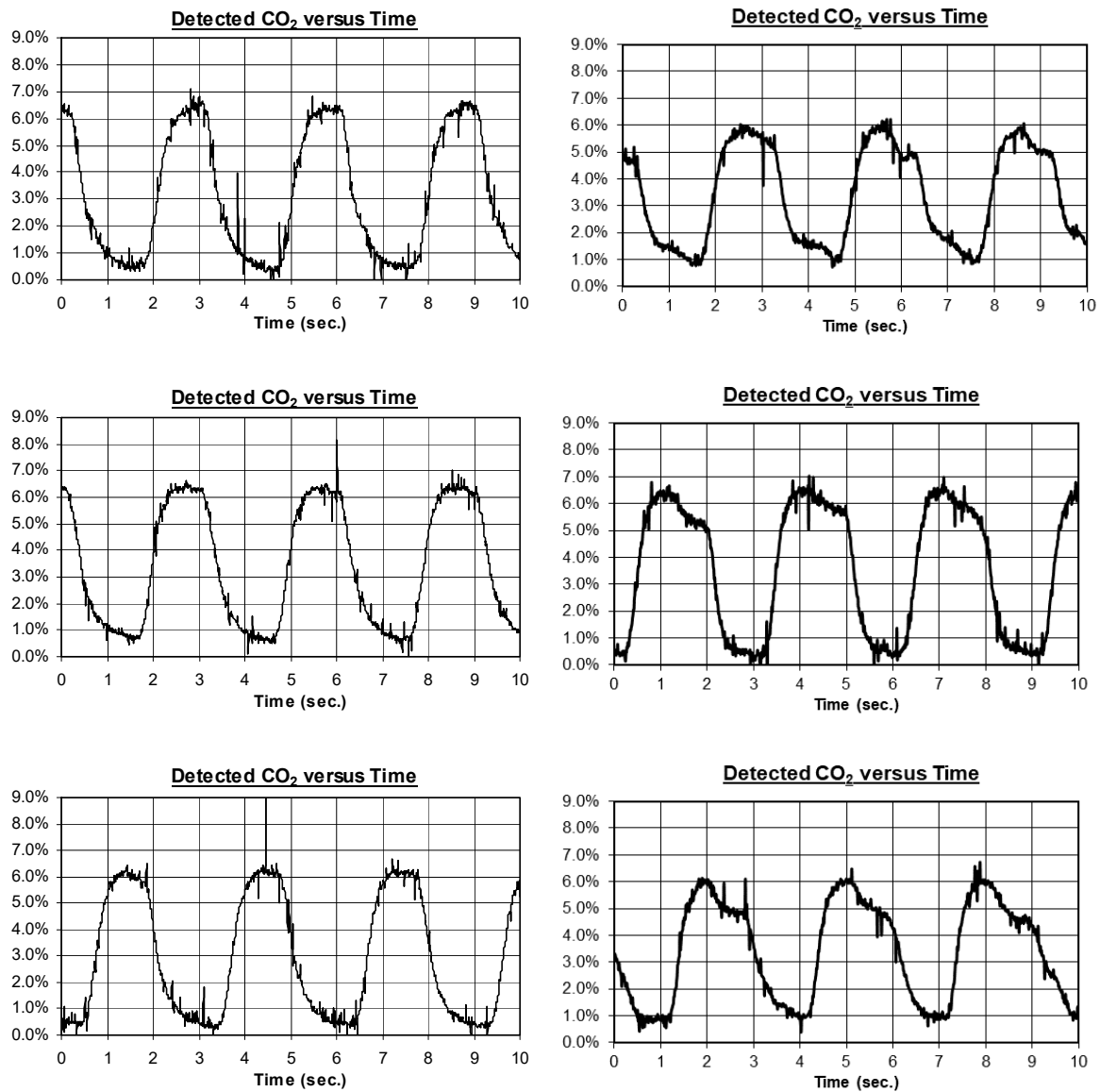


Figure 4 showing the CO₂ waveforms for the POM Mask, Product #1003-PED Pediatric without bronchoscopes (left hand column) and with bronchoscopes (right hand column) at breathing rate of 20 bpm, a tidal volume of 300 ml, a I:E of 1:1, an oxygen flow of 1 l/min, and a baseline ET CO₂ of 5%.

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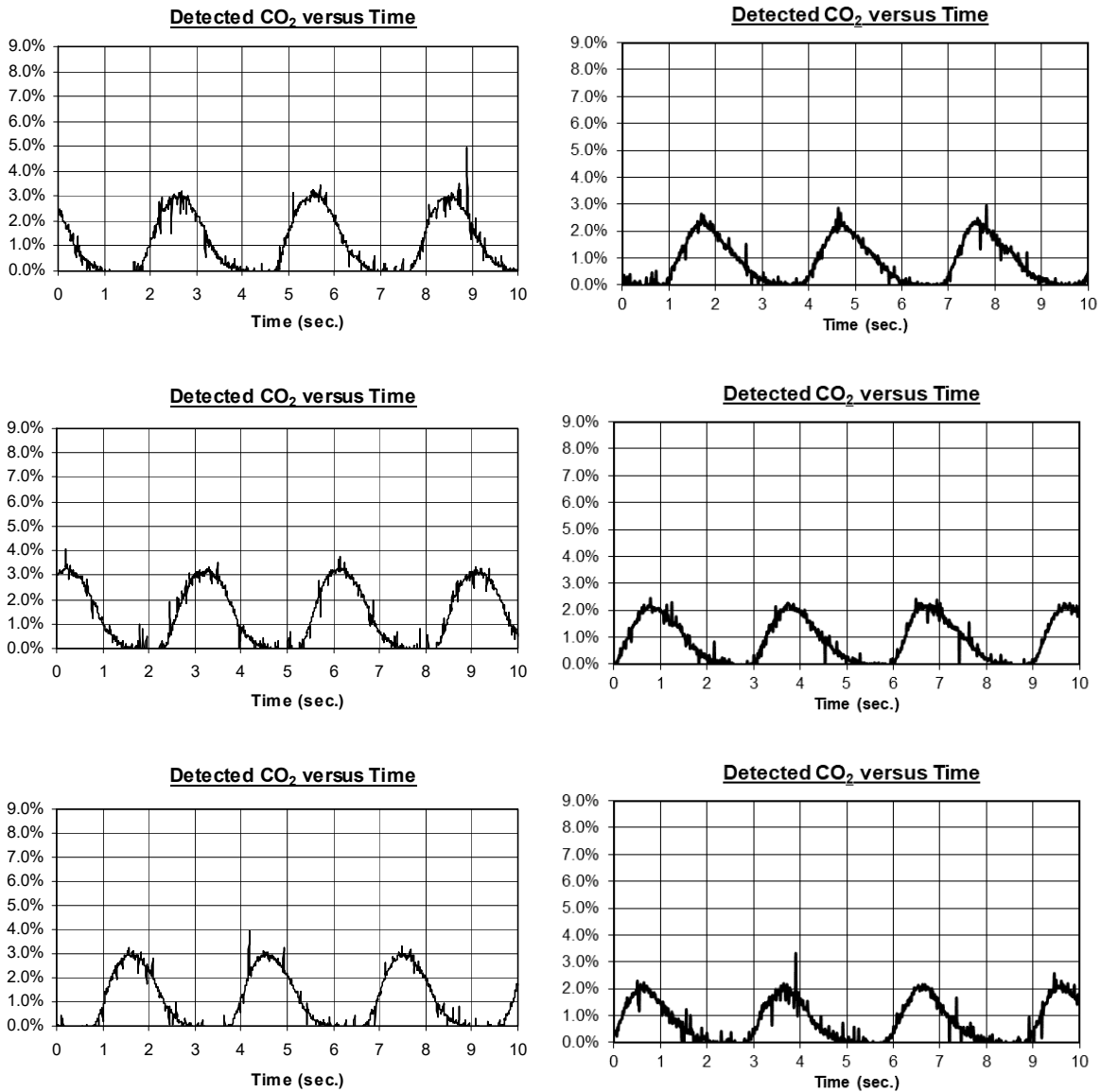


Figure 5 showing the CO₂ waveforms for the POM Mask, Product #1003-PED Pediatric without bronchoscopes (left hand column) and with bronchoscopes (right hand column) at breathing rate of 20 bpm, a tidal volume of 300 ml, a I:E of 1:1, an oxygen flow of 8 l/min, and a baseline ET CO₂ of 5%.

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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 ETCO₂ 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 CO₂ values were shown to alter a bit with bronchoscopes in place, as expected, but breathing patterns remained detectable at all oxygen flows. FiO₂ values were similar with and without bronchoscopes in place. Therefore, all the acceptance criteria of the test were met.