Subject: Evaluation of MedGraphics CPX-Express for Breath-by-Breath Analysis of Cardiopulmonary Exercise Testing

Evaluators:
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I. Volume and flow

Studies were done for stability, reproducibility and precision from 8/18/2009 to 12/4/2009 almost on a daily basis. We performed 36 volume calibration studies with a 3-Liter syringe using low, medium and high inspiratory and expiratory flow rates. See Tables 2 and 3, below. Quality control requirements were consistently met except on one occasion (8/28/2009, 4:34pm) when the volume difference from expected was 0.13L. The flow-volume calibration passed after recalibration. Details available if requested.

Table 1. Laboratory conditions: Mean, standard deviation (SD), minimum (Min), and maximum (Max) for temperature, barometric pressure and relative humidity

		Measured				Reference	
	Unit	Mean	SD	Min	Max	Min	Max
Room Temperature	C	21.0	1.0	18.9	22.3	**15.0**	**35.0**
Barometric Pressure	mmHg	756.1	1.3	755	759	**500.0**	**800.0**
Relative Humidity	%	52	6.4	38	64	**0.0**	**100.0**

Table 2. Mean expiratory volume, SD, minimum, maximum, and range around mean of calibration volume.

		Measured				Reference	
	Unit	Mean	SD	Min	Max	Min	Max
Volume	L	3.00	0.02	2.96	3.04	**2.94**	**3.06**
Volume range	L	0.03	0.03	0.00	0.13*	**-0.09**	**0.09**
Error	%	-0.01	0.58	-1.22	1.31	**-2.01**	**2.01**

*only one failure - 8/28/2009, 4:34pm. Calibration passed after recalibration.

Table 3. Mean inspiratory volume, SD, minimum, maximum, and range around mean of calibration volume.

		Measured				Reference	
	Unit	Mean	SD	Min	Max	Min	Max
Volume	L	3.00	0.01	2.98	3.04	**2.94**	**3.06**
Volume range	L	0.02	0.01	0.00	0.06	**-0.09**	**0.09**
Error	%	0.13	0.41	-0.58	1.39	**-2.01**	**2.01**

Conclusion:

Expiratory and inspiratory volume calibration, reproducibility, precision and stability are excellent over three months of study, without the need for replacement parts.

II. Oxygen and Carbon Dioxide Analyzers

Forty studies of voltage readings of reference and calibration gases were determined for the O_2 and CO_2 analyzers. Also, the phase delay and response time of each analyzer was determined. The goal was to assess the accuracy, reproducibility and stability of the O_2 and CO_2 analyzers. The reference gas was 21.00% O_2 (±0.02%) and 79.00% N_2 and 0.00% CO_2. The Calibration gas was 12.00% O_2(±0.02%), 5.00% CO_2(±0.02%) and 83.00% N_2. Phase delay = transit delay + instrument response time.

Table 4. O_2 analyzer: Voltages (V=Volts**) for reference and calibration gases, transit delays and instrument response times, SD, and minimum, and maximum differences from mean values.**

		Measured				Reference	
	Unit	Mean	SD	Min	Max	Min	Max
Cal gas	V	9.10	0.04	9.02	9.20	**5.00**	**20.00**
Ref. gas at 0 % O2	V	0.02	0.00	0.02	0.03	**-0.10**	**0.10**
Phase Delay	Sec	0.49	0.01	0.45	0.51	**0.10**	**1.50**
Response Time (2-90%)	Sec	0.12	0.01	0.11	0.13	**0.02**	**0.25**

Table 5. CO_2 analyzer: Voltages (V=Volts**) for reference and calibration gases, transit delays and instrument response times, SD, and minimum, and maximum differences from mean values.**

		Measured				Reference	
	Unit	Mean	SD	Min	Max	Min	Max
Cal gas	V	0.70	0.00	0.70	0.70	**0.40**	**2.00**
Ref. gas 0 % CO_2	V	-6.64	0.02	-6.67	-6.60	**-9.99**	**-5.50**
Phase Delay	Sec	0.34	0.01	0.32	0.37	**0.10**	**1.50**
Response Time (2-90%)	Sec	0.15	0.00	0.14	0.16	**0.02**	**0.25**

Conclusion

O_2 and CO_2 analyzer calibrations were highly reproducible and stable (> 3 months). There were no failures in the CO_2 or O_2 calibrations and no need to replace equipment parts.

III. System assessment

Validation studies were performed on "CPX Express" using the Gas Exchange Validator: 14 valid sets of data were obtained using 3 breathing frequencies (10, 20, and 40 breaths /min) 6 different tidal volumes (0.50, 1.00, 1.50, 2.00, 2.50, and 3.00L) and 3 metabolic rates (low, medium, and high). The 30-second averaged data were printed and electronically exported. The resultant data are shown in Tables 6, 7, and 8 and Figures 1, 2, 3, and 4.

Table 6. Mean $\dot{V}O_2$ (ml/min) at three metabolic rates, SD, minimum, maximum values and percentage variability, and reference values. See figure 1 for the effect of varying minute ventilation, breathing frequency and tidal volume on $\dot{V}O_2$.

		Measured					Reference		
Metabolic Rate	Unit	Mean	SD	Min	Max	**% Var.***	**Target**	Min-accepted	Max-accepted
Low	mL/min	277	10	260	321	3.6	**284**	270	298
Middle	mL/min	1659	52	1550	1790	2.4	**1725**	1638	1811
High	mL/min	2778	77	2640	2943	2.9	**2937**	2482	3084

*Note: %Var. (Average percent difference of the individual measurements from the mean of the group)

Table 7. Mean $\dot{V}CO_2$ (ml/min) at three metabolic rates, SD, minimum, maximum values and percent variability, and reference values. See figure 2 for the effect of varying minute ventilation, breathing frequency and tidal volume on $\dot{V}CO_2$

		Measured					Reference		
Metabolic Rate	Unit	Mean	SD	Min	Max	% Var.*	**Target**	Min-accepted	Max-accepted
Low	mL/min	286	9	266	328	3.2	**284**	270	298
Middle	mL/min	1698	47	1593	1845	1.3	**1727**	1641	1814
High	mL/min	2824	62	2661	2983	1.6	**2941**	2794	3088

*Note: %Var. (Average percent difference of the individual measurements from the mean of the group)

Table 8. Mean respiratory exchange ratio (RER, i.e. $\dot{V}CO_2/\dot{V}O_2$) at three metabolic rates, SD, minimum, maximum values and percent variability, and reference values. See figure 3 for the effect of varying minute ventilation, breathing frequency and tidal volume on RER

		Measured					Reference		
Metabolic Rate	Unit	Mean	SD	Min	Max	**% Var.***	**Target**	Min-accepted	Max-accepted
Low	ratio	1.03	0.01	0.98	1.07	2.1	**1.00**	0.941	1.062

							1		
	ratio						**1.00**		
Middle		1.02	0.02	0.98	1.05	1.5	**1**	0.941	1.062
	ratio						**1.00**		
High		1.01	0.02	0.98	1.05	1.7	**1**	0.941	1.062

**Note: %Var. (Average percent difference of the individual measurements from the mean of the group)

Conclusion O_2 and CO_2 analyzers are stable, reproducible and precise (see figures 1-3). Response times of gas analyzers are fast enough to give linear outputs over range of minute ventilation, tidal volumes and breathing frequencies studied.

Figure 1. Effect of varying tidal volume, breathing frequency and minute ventilation on three levels of $\dot{V}O_2$

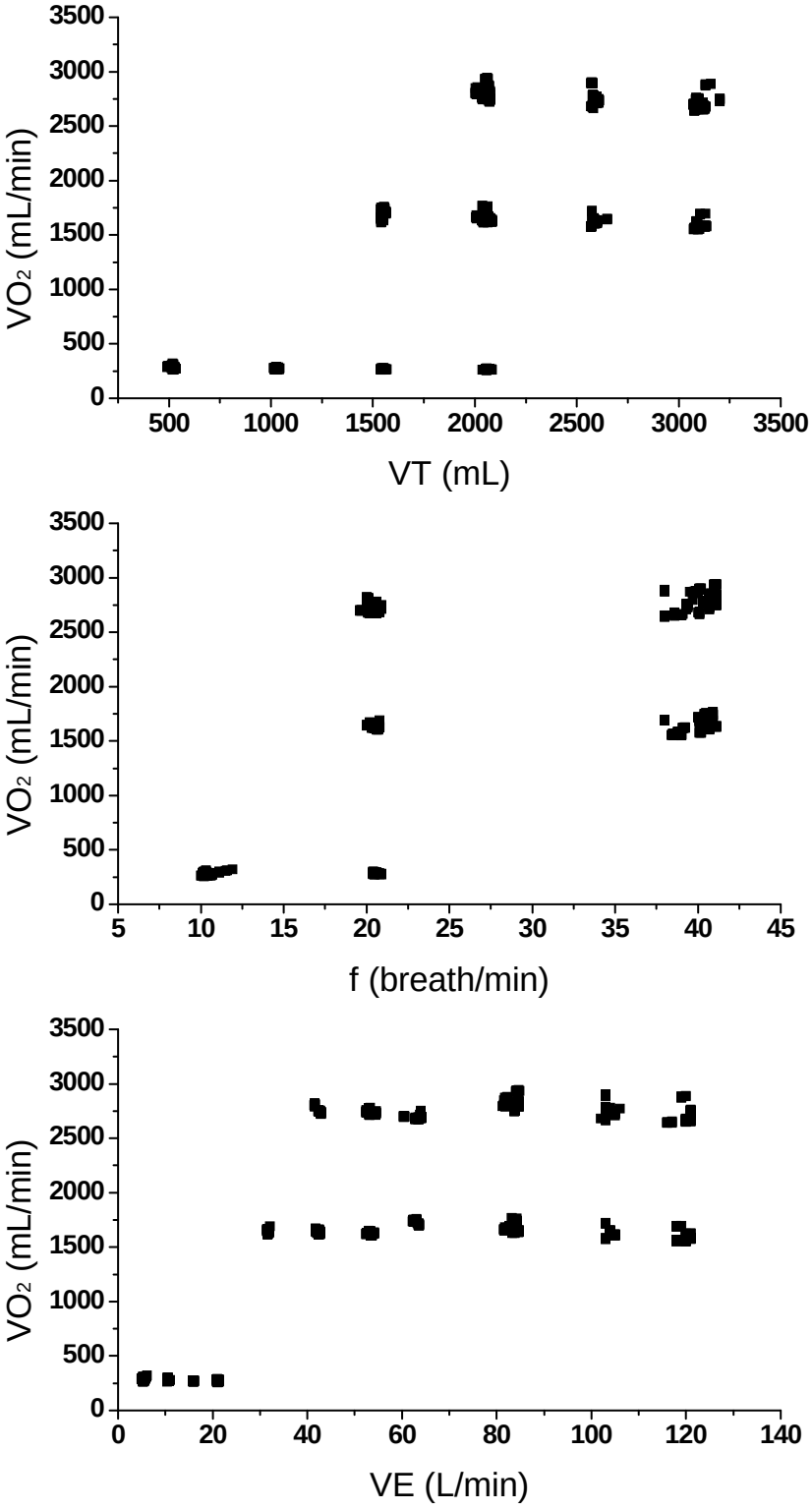


Figure 2. Effect of varying tidal volume, breathing frequency and minute ventilation on three levels of $\dot{V}_{CO_2}$

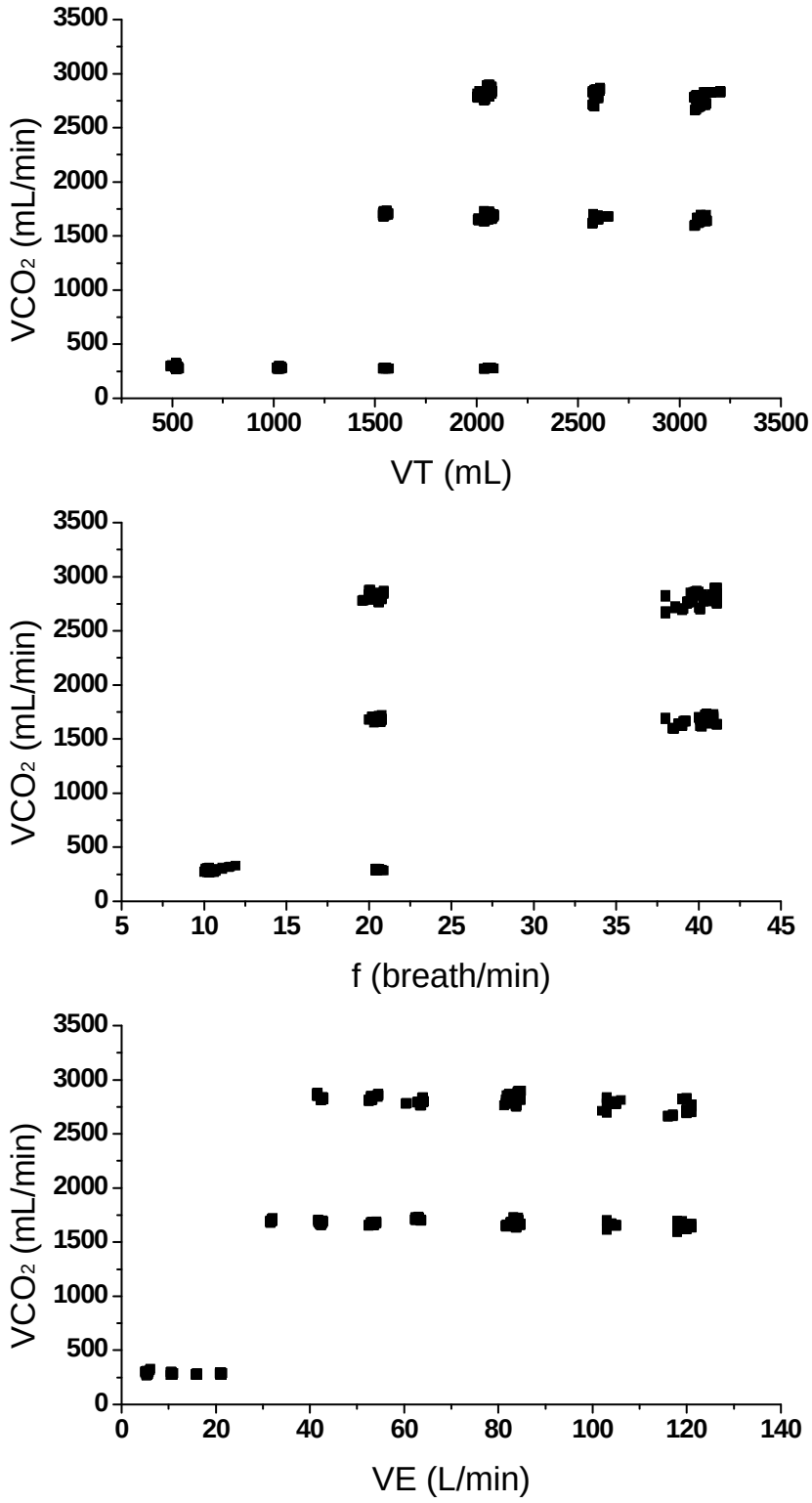


Figure 3. Effect of varying tidal volume, breathing frequency and minute ventilation on respiratory Exchange Ratio (RER, i.e. $\dot{V}CO_2/\dot{V}O_2$)

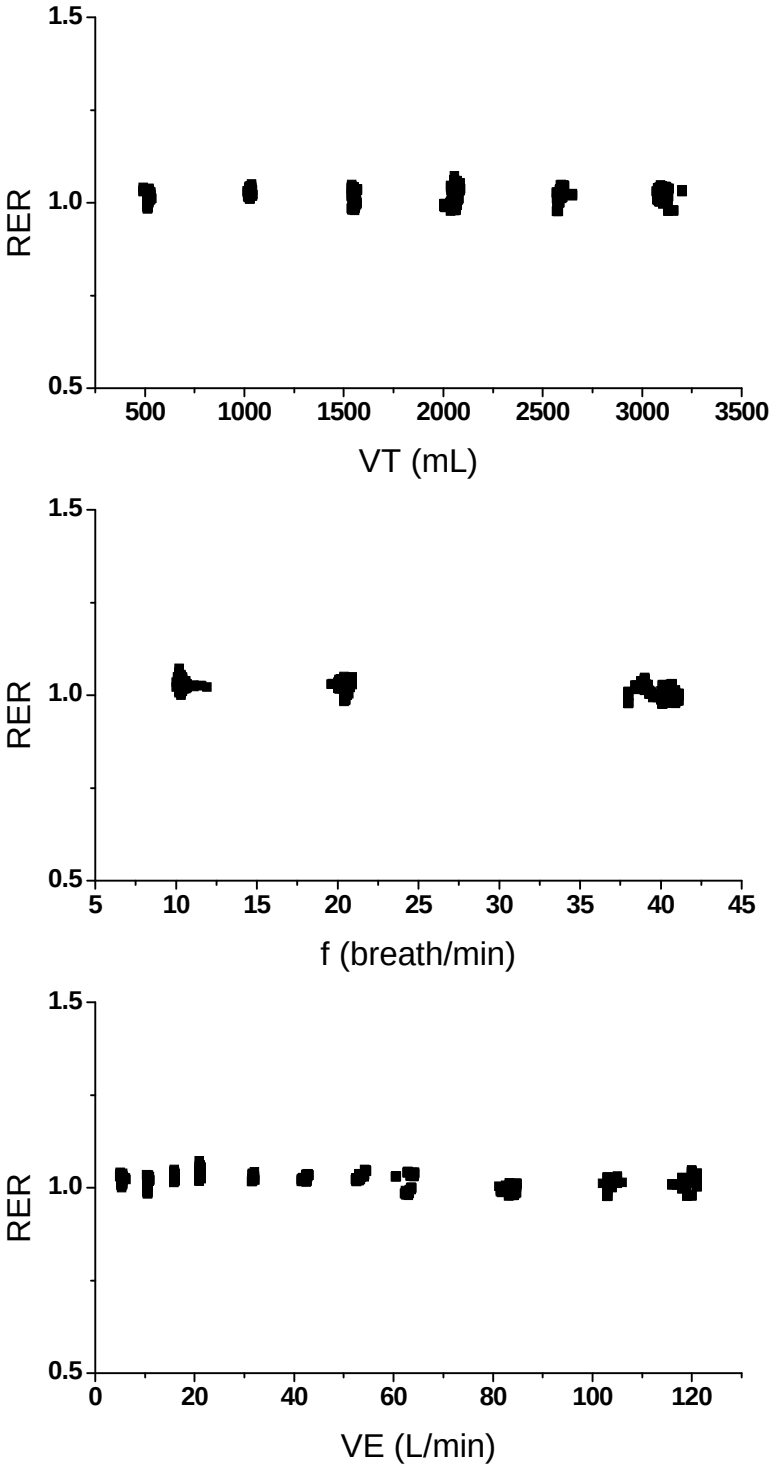
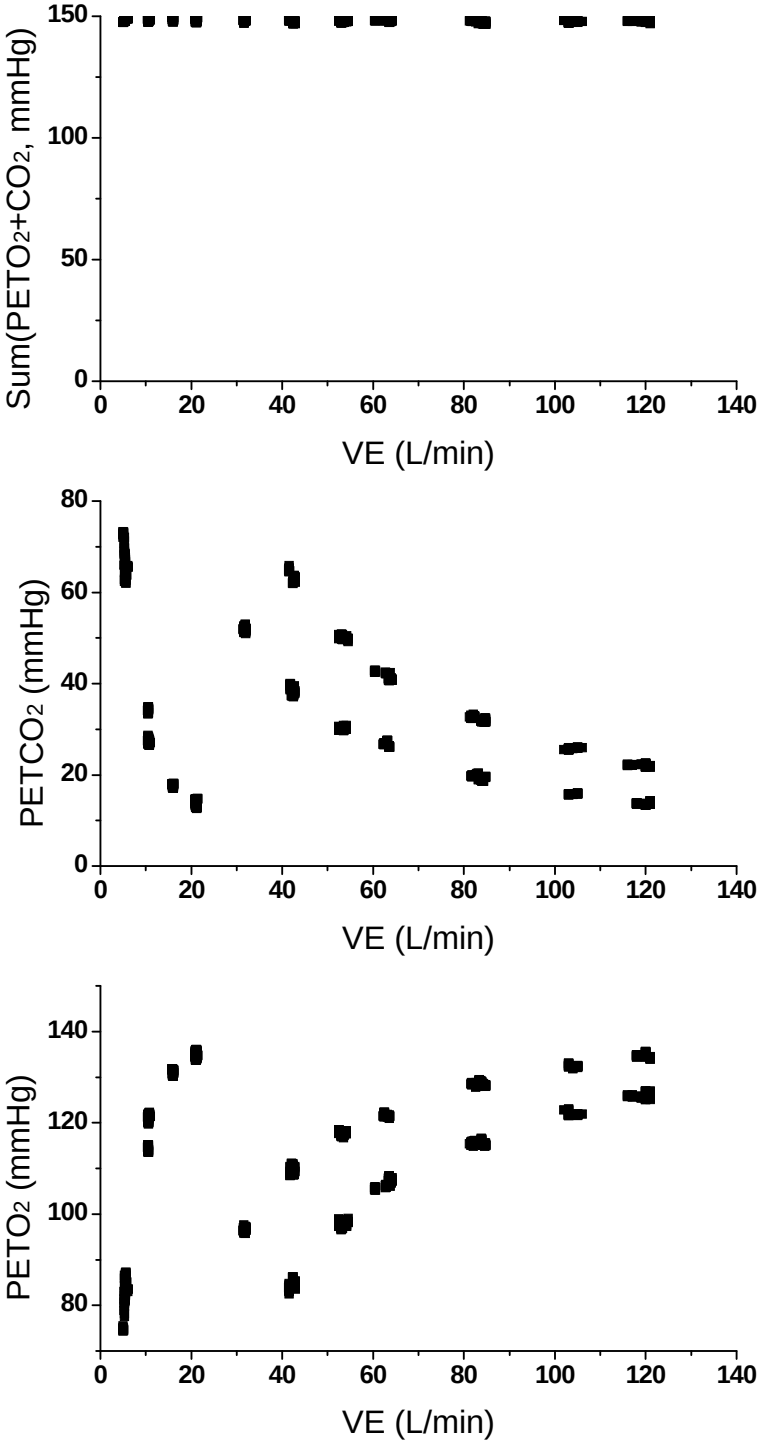


Figure 4: Effect of increasing ventilation on $P_{ET}O_2$, $P_{ET}CO_2$ and Sum of $P_{ET}O_2$ and $P_{ET}CO_2$ for three different metabolic rates



Conclusion

The CPX Express performed exceptionally well in stability, reproducibility and accuracy for gas exchange measurements ($\dot{V}_E$, $\dot{V}_{O_2}$, $\dot{V}_{CO_2}$, RER, PO_2 , PCO_2 and sum of end-tidal PO_2 and PCO_2) Studies were done with tidal volumes that ranged from 0.5 to 3.0 L, frequencies from 10 to 40 breaths/min, $\dot{V}_E$ from 5 to 120 L/min, PCO_2 from 10 to 80 mmHg, PO_2 from 70 to 140 and $\dot{V}_{O_2}$ and $\dot{V}_{CO_2}$ over a ten-fold metabolic rate range (260 to 2943ml/min). All analyzers responded linearly over the full range of study. The plan is to extend the observations to metabolic rates of athletes.