WHITE PAPER

Clinical Testing of the LoFlo C5 Module – Inter-device Comparisons

Michael B. Jaffe, Ph.D., and Technical Staff, Respironics (Hospital Respiratory Care Business Unit)

ABSTRACT

We compared the performance of the LoFlo C5 CO_2 capnography module to its predecessor, the LoFlo C3 CO_2 module. The end-tidal CO_2 and respiratory rate measurements from the LoFlo C5 CO_2 and LoFlo C3 CO_2 modules obtained from 23 OR and ICU patients were substantially equivalent. Data from three patients in particular exemplify this clinical equivalence and illustrate the clinical utility of capnography for lesser known applications. The objective of this clinical testing was to compare the performance of the LoFlo C5 CO_2 capnography module to its predecessor, the LoFlo C3 CO_2 module.

INTRODUCTION

We have previously described the advantages of the LoFlo Sidestream Gas Monitoring System.[1-3] The LoFlo Series of capnography devices include a removable and disposable sample cell that effectively eliminates the need for preventive maintenance of the sample cell required for conventional systems. The LoFlo C5 system is an integrated gas monitoring system. Its predecessor, the LoFlo C3 system, is a sidestream gas monitoring front end device that interfaces to a connector for a mainstream Capnostat 3 CO_2 sensor on standard physiological monitors offered by vendors such as GE and Zoll. The LoFlo C5 system is the next step in our evolution of sidestream capnography and, in conjunction with the Capnostat 5 CO_2 sensor, offers the clinician the capability to conveniently and quickly switch between mainstream and sidestream capnography, as dictated by the dynamic clinical situation.

Figure 1 – LoFlo C5 Module

METHODS

We conducted a clinical evaluation under IRB-approved protocols at Hartford Hospital (Hartford, CT), and Sacred Heart Medical Center (Eugene, OR). We collected data from 14 ICU and 9 OR patients (see Table 1). For each patient, we compared the end-tidal CO_2 ($PetCO_2$) and respiratory rate (RR) values obtained from a LoFlo C5 sidestream CO_2 module connected to a pediatric/adult sample set to the $PetCO_2$ and RR values obtained from a LoFlo C3 sidestream module interfaced to a CO_2SMO Plus! monitor using the Capnostat 3 CO_2 sample set. All OR study patients studied were ventilated via an endotracheal tube (ETT) or a laryngeal mask airway (LMA) using an Ohmeda Anesthesia Ventilator, with general anesthesia using Desflurane or Sevoflurane. We placed the LoFlo sidestream sampling adapters (for both LoFlo C5 and LoFlo C3) and a sampling adapter for the anesthesia gas monitor between the ETT or LMA and the wye. Likewise we placed the LoFlo sidestream sampling adapters (for both LoFlo C5 and LoFlo C3) between the ETT and the wye in ICU patients, who all were mechanically ventilated.

We saved the data from each patient to a laptop computer using proprietary software. We then imported the recorded breath-to-breath $PetCO_2$ and RR values to spreadsheet software (Excel®, Microsoft, Inc., Redmond, WA) for data analysis. We calculated bias, precision and aRMS* for each individual patient for both $PetCO_2$ and RR (see Table 1). We also calculated the average bias and precision for patients aggregated into OR and ICU groups. We identified patients to represent three known and potential clinical uses of capnography: laparoscopic CO_2 insufflation, sepsis, and diabetic ketoacidosis. For each representative patient, we created a time plot, a scatterplot, and a Bland-Altman plot to compare end-tidal values generated by each of the two LoFlo modules.

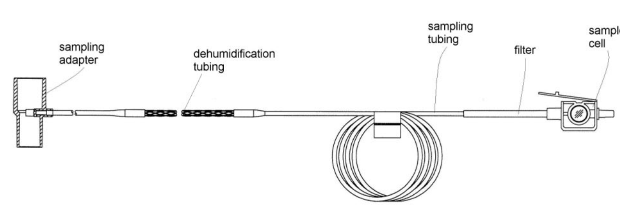

Figure 2 – Pediatric/adult sampling set for use with a humidified breathing circuit, which includes a sample cell, filter, dehumidification tubing, and an airway adapter.

**aRMS is the square root of the sum of the squares of bias and precision.*

RESULTS

Case Studies

We begin by presenting the data from three patients, one for each of the following clinical situations: laparoscopic CO_2 insufflation, sepsis, and diabetic ketoacidosis.

Case 1, Laparoscopic CO_2 Insufflation

Laparoscopic cholecystectomy (Patient #21, Table 1) is a minimally invasive surgical procedure in which the gallbladder is removed with the aid of a laparoscope. After gaining access to the peritoneal space, the surgeon inflates the abdominal cavity with carbon dioxide. Capnography during this procedure can monitor the resulting CO_2 resorption and guide adjustments of the ventilator, such as increasing the minute ventilation to maintain appropriate CO_2 levels in the blood.[4] Note that the $PetCO_2$ values from the two LoFlo modules closely track each other over time in Figure 3. Note also the increase in $PetCO_2$ 23 minutes into the case, which signaled the need to increase ventilation, bringing $PetCO_2$ levels down closer to baseline values. The scatterplot (Figure 4) and Bland-Altman plot (Figure 5) show excellent agreement between the two LoFlo modules.

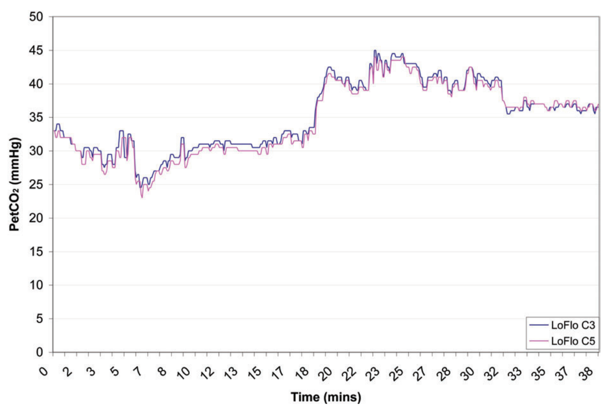

Figure 3 – Time Plot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a female patient during a laparoscopic cholycystectomy

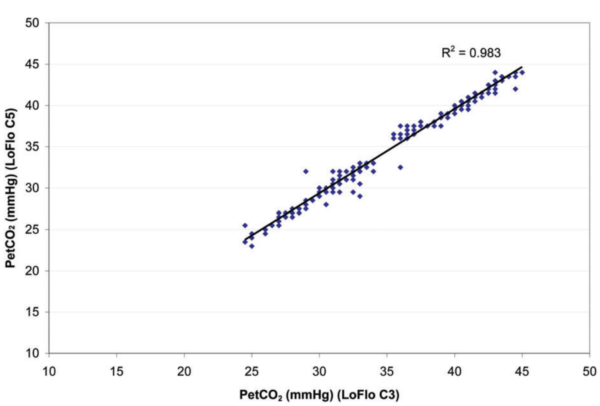

Figure 4 – Scatterplot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a female patient during a laparoscopic cholycystectomy (r^2=0.983, n=461)

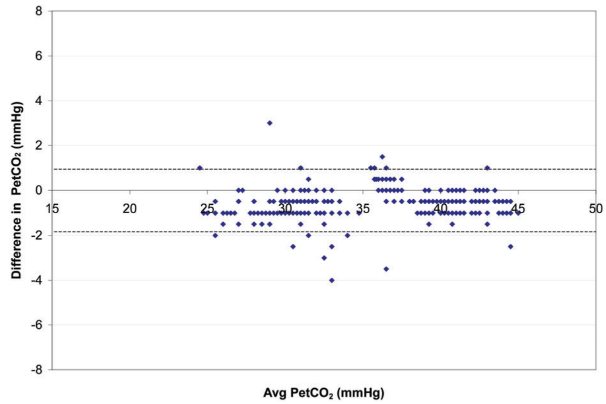

Figure 5 – Bland-Altman Plot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a female patient during a laparoscopic cholycystectomy (limits of agreement shown)

Case 2, Sepsis

In patients with constant minute ventilation and carbon dioxide production, $PetCO_2$ can serve as a surrogate for cardiac output, reflecting the rate at which CO_2 is transported from the tissues for presentation to the lungs. The plot in Figure 6 from a patient (Patient #9, Table 1) with abdominal sepsis due to a perforated colon shows time-varying levels of $PetCO_2$ and illustrates how PetCO2 can be used as a surrogate for cardiac output.[5] Again, the scatterplot (Figure 7) and Bland-Altman plot (Figure 8) show excellent agreement between the two LoFlo modules. Given the constancy of ventilation (SIMV, FiO2=80%) in this patient and that it has been shown that the variability in $PetCO_2$ can be highly correlated with cardiac index during septic shock,[5] it is reasonable to assume that $PetCO_2$ in this patient can be used as a surrogate for changes in cardiac output.[7]

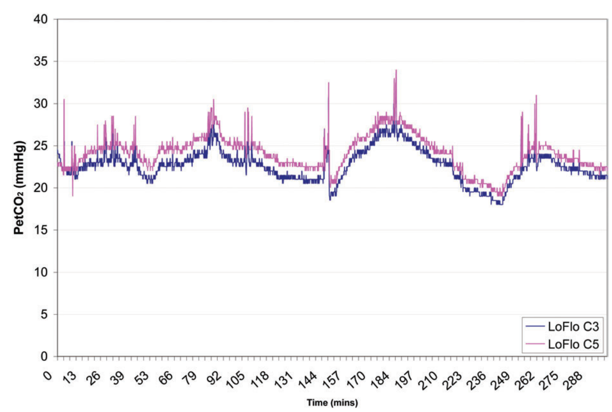

Figure 6 – Time Plot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a female patient with abdominal sepsis

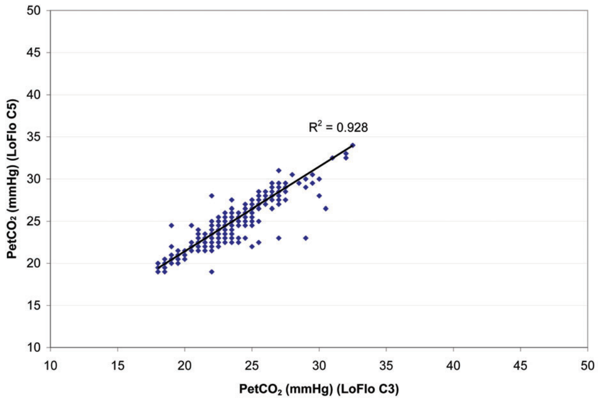

Figure 7 – Scatterplot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a female patient with abdominal sepsis (r^2=0.928, n=3580)

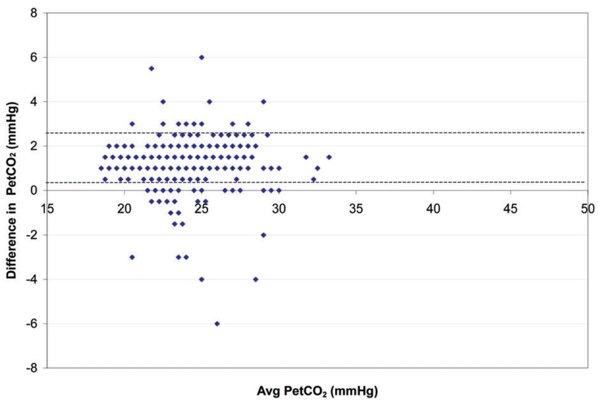

Figure 8 – Bland-Altman Plot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a female patient with abdominal sepsis (limits of agreement shown)

Diabetic Ketoacidosis, Case 3

Diabetic ketoacidosis (DKA) is a life-threatening metabolic complication that may be the presenting condition for patients with juvenile-onset diabetes. It can also occur when a patient with diabetes (Patient #1, Table 1) fails to take adequate insulin either because of noncompliance with a prescribed regimen or because infection or other stress increases the insulin requirement. Patients with DKA hyperventilate to lower $PaCO_2$ to compensate for a metabolic acidosis. Garcia and colleagues have suggested that $PetCO_2$ might approximate $PaCO_2$ and thus serve as an important tool to guide therapy.[6] Note in Figure 9 the decrease in $PetCO_2$ associated with mechanical ventilation at settings (A/C f 12, Vt 590, PEEP12, FiO_2=70%) that achieved the compensatory hyperventilation required to manage the severe metabolic acidosis. Figure 10 illustrates the dynamic change in the patient's respiratory rate which increased to a high level (at minute 125) until mechanical ventilation partially relieves patient effort (after minute 150). Figures 11 and 12 again show agreement of the LoFlo modules by scatterplot and Bland-Altman plot, respectively.

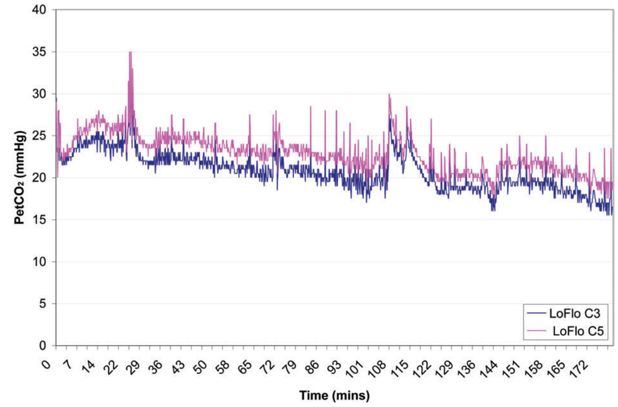

Figure 9 – Time Plot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a male patient with DKA

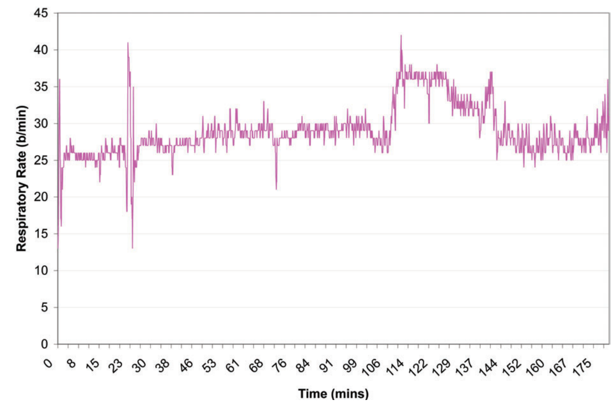

Figure 10 – Time Plot of respiratory rate for LoFlo C5 module in a male patient with DKA

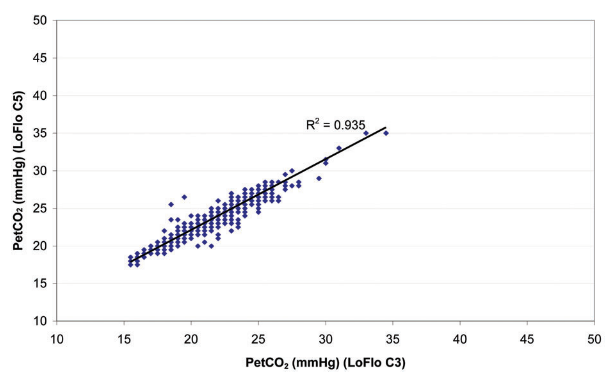

Figure 11 – Scatterplot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a male patient with DKA (r^2=0.935, n=2142)

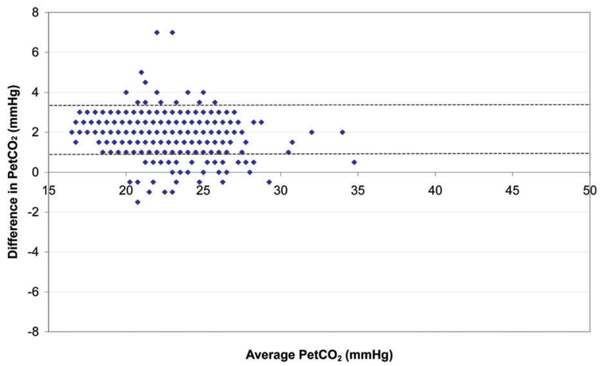

Figure 12 – Bland-Altman Plot of end-tidal CO_2 for LoFlo C5 and LoFlo C3 modules in a male patient with DKA (limits of agreement shown)

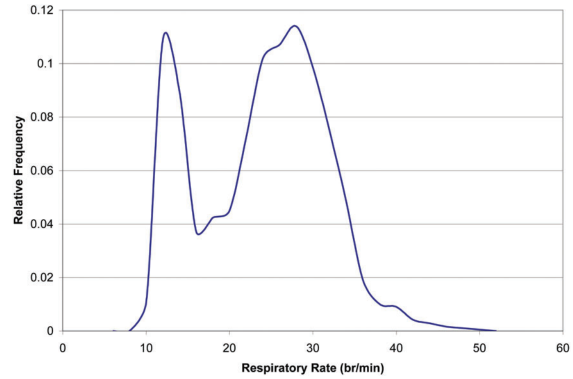

Figure 13 – Relative Frequency of Respiratory Rate for Patient #6

AGGREGATE DATA

Table 1 presents the data for each of the patients in the study, with separate tables for the OR and ICU groups. The aggregated bias, precision, and aRMS values are given as averages for these groups.

DISCUSSION

We use time plots, scatterplots, and Bland-Altman plots to assess the agreement between the new (LoFlo C5) and predicate (LoFlo C3) capnography devices. The bias and precision values for respiratory rate between the LoFlo C5 and LoFlo C3 devices are quite low showing excellent clinical performance. The only exception is found with patient #6, who had respiratory failure. An examination of the record for patient #6 suggests that this decrease in performance may be an artifact of the extremely high temporal variability in breath-by-breath respiratory rate as well as the wide range of values for the rates (see Figure 13).

In general, the bias and precision for end-tidal CO_2 were low and clinically acceptable. Precision values for end-tidal CO_2 were not as low as those for respiratory rate due to small and clinically insignificant differences relating to calibration, relative position of airway adapter in breathing circuit, patient asynchrony and rapidly varying breathing patterns.

Data analysis of measurements for inter-device comparisons in the critically ill patient can often be challenging because of dynamic patient clinical condition as well as variable breathing circuit conditions. Despite these challenges, our testing showed the new LoFlo C5 module shows performance clinically equivalent to its predecessor module, the LoFlo C3 module.

CONCLUSION

Inter-device comparison between the LoFlo C5 module and its predecessor LoFlo C3 module demonstrates clinical equivalence for end-tidal CO_2 and respiratory rate measurement in the tested patient population.

Table 1 – Summary Statistics for ICU and OR Patients

	ICU Patients			n	RR			$PetCO_2$		
#	Age	Sex	Dx (Hx)		Bias	Prec	aRMS	Bias	Prec	aRMS
1	36	M	DKA (Diabetes)	2142	-0.03	0.54	0.54	2.07	0.60	2.15
2	67	M	Resp. Failure (CA)	2060	0.00	0.37	0.37	1.87	0.84	2.05
3	67	F	Resp. Failure (COPD)	1823	-0.02	0.73	0.73	2.09	0.47	2.14
4	36	F	Resp. Failure	1671	0.05	1.73	1.73	2.93	1.58	3.33
5	85	M	Resp. Insuff. (post-op HTN, AAA repair)	2579	0.00	1.15	1.15	1.43	1.33	1.96
6	78	M	Resp. Failure	3774	3.01	5.41	6.19	-0.58	1.07	1.21
7	48	F	GSW abd	2532	0.09	0.90	0.91	-0.76	1.02	1.27
8	78	M	Resp. Failure (HTN)	3773	-0.02	0.37	0.37	1.06	0.53	1.18
9	80	F	Abd sepsis	3580	-0.01	0.30	0.30	1.42	0.56	1.53
10	78	F	Resp. Failure, RLL mass	1694	-0.22	1.79	1.81	-1.45	1.25	1.92
11	45	M	ARF	2801	0.02	0.61	0.61	-1.67	1.27	2.10
12	52	F	Post op CABGx4	2086	-0.01	0.19	0.19	0.47	0.74	0.87
13	62	F	Resp. Failure	2493	0.10	1.73	1.73	-1.29	1.14	1.72
14	60	F	mech vent. A/C 26	2097	0.05	0.83	0.83	-4.07	2.22	4.64
			Average		0.22	1.19	1.25	0.25	1.04	2.01
	OR Patients									
	Age/Range	Sex	Dx		Bias	Prec	aRMS	Bias	Prec	aRMS
15	50-60	F	Bilateral Prophylactic Mastectomy	726	0.01	0.10	0.10	-1.11	0.77	1.35
16	45-55	M	Lumbar Laminectomy	717	-0.01	0.11	0.11	-0.55	0.79	0.96
17	25-35	M	Laparoscopic Appendectomy	580	0.02	0.42	0.42	-2.22	0.67	2.32
18	60-70	F	Prolapsed Uterus; Urethral Repair	929	0.03	0.78	0.78	1.22	2.33	2.63
19	65-75	F	Total Hysterectomy	1554	0.00	0.03	0.03	-0.41	0.78	0.88
20	26	F	Kidney Stones; Lithotripsy	158	-0.28	1.48	1.51	-2.08	0.58	2.16
21	47	F	Cholycystitis;Laparoscopic Cholycystectomy	461	-0.09	0.36	0.37	-0.53	0.69	0.87
22	25-35	F	Kidney Stones; Rt. Ureteroscopy/Lithotripsy	657	0.13	1.67	1.68	1.47	3.06	3.39
23	73	M	Prostectomy Retropubic Radical w/ Bilat. Pelvic	862	0.00	0.03	0.03	1.03	0.51	1.15
			Average		-0.02	0.55	0.56	-0.35	1.13	1.75

Key:

n = number of breaths

AAA = abdominal aortic aneurysm

ARF = acute respiratory failure

CA = cancer

CABG = coronary artery bypass graft

COPD = chronic obstructive pulmonary disease

DKA = diabetic ketoacidosis

GSW = gun shot wound

HTN = hypertension

REFERENCES

1. Technical Staff. 21st Century CO_2 Technology Sidestream Monitoring – The LoFlo System. Respironics White Paper.

2. Jaffe, MB. Respironics LoFlo™ and Oridion Microstream® Technologies Contrasted. Respironics White Paper.

3. Jaffe, MB. Sidestream Gas Monitoring with a Detachable Sample Cell – The LoFlo™ System. Respironics White Paper.

4. Blobner M, Felber AR, Gögler S, Feussner H, Weigl EM, Jelen G, Jelen-Esselborn S. [The resorption of carbon dioxide from the pneumoperitoneum in laparoscopic cholecystectomy] *Anaesthesist*. 1993 May;42(5):288-94

5. Jin X, Weil MH, Tang W, Povoas H, Pernat A, Xie J, Bisera J. End-tidal carbon dioxide as a noninvasive indicator of cardiac index during circulatory shock. *Crit Care Med.* 2000 Jul;28(7):2415-9

6. Garcia, E., Abramo, T.J., Okada, P., Guzman, D.D., Reisch, J.S. & Wiebe, R.A. (2003). Capnometry for noninvasive continuous monitoring of metabolic status in pediatric diabetic ketoacidosis. *Crit. Care Med.,* 31: 2539–2543.

7. Gravenstein, JS, DA Paulus and MB Jaffe. *Capnography: Clinical Aspects.* Cambridge University Press, London, 2004.

RESPIRONICS®

Customer Service: 800-345-6443 or 724-387-4000
Respironics Europe, Africa, Middle East: +33-1-47-52-30-00
Respironics Asia Pacific: +852-3194-2280
www.respironics.com

MCI 4101939