Medtronic

White paper

Not all cannulas are created equal: the influence of sampling line design on capnography performance

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Introduction to capnography

A capnograph is a monitoring device that measures exhaled carbon dioxide (CO_2) in a patient's breath. In addition to measuring end-tidal carbon dioxide ($etCO_2$), capnography provides information about inspiration and expiration. Capnography was introduced to the United States in 1978.[1] Since then, capnography has become an integral part of patient respiratory monitoring and is considered the standard of care for all patients receiving general anesthesia.[2] Capnography is also an essential part of routine monitoring in pre-hospital and acute care settings, and has been shown to provide earlier detection of changes in respiration rate and apneic events than pulse oximetry and clinical observations during procedural sedation.[3] As the use of capnography continues to expand to more clinical settings as a monitoring tool, there is a need for increased awareness on the appropriate way to obtain accurate $etCO_2$ measurements from patients undergoing procedural sedation as well as those in the post-operative setting.[4-6]

Measurement of $etCO_2$ is a non-invasive and convenient way to measure changes in circulation, airway status and the respiratory system.[7] These parameters provide early indicators of respiratory compromise and can indicate patient distress; therefore, it is imperative that the monitor and disposable gas sampling components (i.e. sampling line) provide accurate and meaningful measurements, trends, and waveform data. A key to obtaining accurate measurements largely depends on the quality and design of the sampling line, as the monitor requires an optimal ventilation gas sample to provide true and accurate readings. Quality components are critical to ensure that healthcare providers who use capnography have confidence in the information provided by the monitoring equipment.

Why sampling lines matter

Many clinicians may consider all sampling lines equal in that they provide similar performance and measurements. However, sampling lines from different manufactures can vary in quality of materials and functionality. A significant amount of research and development goes into the manufacturing and design of each of the sampling ports. Studies have noted subtle details and variations in sampling line design can have a substantial impact on both the sample line indications for use as well as on the performance of the sampling line in real-world clinical setting. Variations in sampling line designs may include different nasal and oral cannula shapes, pressure systems, lengths, tubing volumes, filters, luer inputs, manufacturing materials, sampling systems and connection points, all of which can affect the accuracy of $etCO_2$ sampling and O_2 delivery. All of these features can impact capnography performance.[8,9] Medtronic performed internal bench testing to determine the compatibility and performance of commercially available capnography sampling lines. They were compared using a series of bench tests designed to simulate common clinical situations using the Medtronic Capnostream™ 35 portable respiratory monitor.

In addition, results from the Restrepo et al. study on the accuracy of sampling lines and performance of capnography are included.[10]

Competitive analysis overview

Study design and objective

Three specifically designed and validated benchside tests were conducted to compare the performance of commercially available capnography side-stream sampling lines using the Capnostream™ 35 portable respiratory monitor. Performance of all sampling lines was compared on the same monitor to minimize variations and ensure that all the lines were tested with the same algorithms. The primary objective of these benchside analyses was to compare the sampling accuracy and performance of Medtronic capnography sampling lines to commercially available competitors, under conditions emulating real-world clinical ventilation scenarios with variations of respiratory rates and tidal volumes. The study outcomes included (1) $etCO_2$ sampling accuracy with and without supplemental O_2 (2) $etCO_2$ accuracy as a function of respiratory rate; and (3) rise time.

Competitive samples

The following sampling lines were compared: Smart Capnoline™ Plus sampling line (Medtronic Inc, USA), O_2/CO_2 Nasal FilterLine™ sampling line (Medtronic Inc, USA), Divided Adult Capnography Cannula, (Salter Labs, USA), RCI Softech™* Bi-Flo $EtCO_2$/O_2 Cannula (Hudson RCI, USA), Adult CO_2 Oral/Nasal Cannula, (Respironics, USA), Adult Dual Nasal Cannula (Flexicare Medical Ltd, USA), CO_2/O_2 Adult Cannula (Westmed, USA). All tests were conducted on the Capnostream™ 35 portable respiratory monitor (Medtronic, USA). A complete listing of competitive samples can be found in the **Appendix**.

Benchside test overview and results

1. $etCO_2$ sampling accuracy with and without supplemental O_2

Overview

In this test, we investigated the effect of CO_2 cannula sample port design and oxygen flow on expired $etCO_2$ accuracy during constant respiratory rate conditions of 10 BPM (breaths per minute). This test mimics a common clinical situation in which a patient receives supplemental oxygen; between 2 to 4 L/min of O_2 is typical for patients in the recovery and sedation suites.[11] In this scenario, $etCO_2$ accuracy is critical to understanding the pulmonary function of a patient, as supplemental oxygen can mask ventilation challenges due to high oxygen saturation readings.[12,13] The greater the O_2 delivery rate, the more likely it is to affect the accuracy of the CO_2/$etCO_2$ readings, as O_2 may dilute the ventilation gas sample.[14] Traditional cannulas are designed to deliver O_2 through one prong and sample through the other, therefore, when high O_2 levels are delivered, the exhaled CO_2sample is diluted, ultimately affecting capnography accuracy, waveforms, and readings.[14] Newer sampling lines, such as Microstream™ Advance filter lines, have been designed to sample CO_2 from both nares and the mouth, improving the separation between the delivery of O_2 and the CO_2 sampling ports.

In this test, supplemental O_2 (100%) and CO_2 (5%) were connected to a manikin head and respiratory rate controller used to simulate a spontaneously breathing adult **(Figure 1)**. Oxygen was delivered to the manikin at varying flow rates, from 0 to 4 liters per minute (LPM). Accuracy of $etCO_2$ (mmHg) in the gas sample was compared to the known CO_2 percent. A target $etCO_2$ value of 34 mmHg was considered a true and accurate reading based on the following equation:

$$\textit{Ambient pressure} \times CO_2\% \times 0.97$$

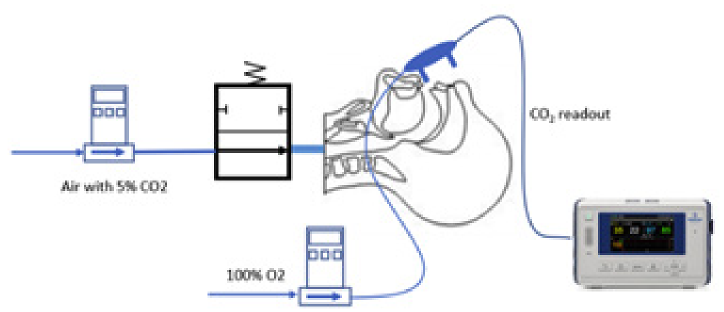
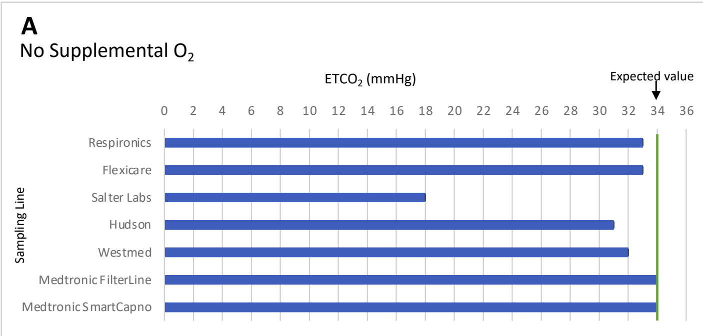
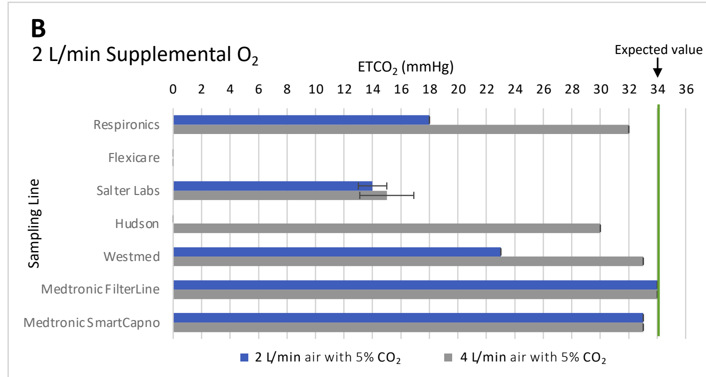


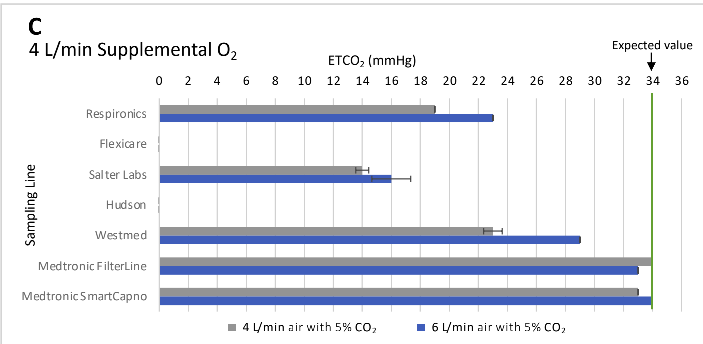
Figure 1. Schematic representation of the $etCO_2$ accuracy test design

Results

In the control reading without supplemental O_2 (flow rate = 0 LPM), we observed that the Salter Labs sampling lines failed to report the expected $etCO_2$ value, while the Medtronic and Respironics sampling lines were accurate. However, when supplemental O_2 was added at 2 and 4 L/min, a majority of the sampling lines exhibited reduced $etCO_2$ accuracy, with the exception of the Medtronic sampling lines **(Table 1, Figures 2A-C)**. In particular, the $etCO_2$ readings from Flexicare and Hudson sampling lines dropped to 0 mmHg in the presence of supplemental O_2. These results were alarming, suggesting that the $etCO_2$ accuracy of Flexicare and Hudson were compromised during supplemental O_2 delivery, which is







Figures 2A-C. $EtCO_2$ Sampling accuracy with and without supplemental O_2 at varying levels of CO_2. NOTE: Figure extracted and modified from Restrepo et al. 2020 to denote sampling line names and manufacturers.

likely due to their incompatibility with the Capnostream™ 35 portable respiratory monitor and inability to provide a representative gas sample for measurement.[2]

Restrepo et al reported additional results using variable O_2 rates from 0 to 4L/min and CO_2 rates from 2 to 6L/min **(Figures 2A-C)**.[10] All sampling lines were consistent when no supplemental O_2 was introduced, with the exception of Salter Labs. Flexicare and Hudson sampling lines dropped to 0 mmHg in the presence of supplemental O_2. While Medtronic sampling lines demonstrated consistent performance across varying O_2 rates, almost all competitive sampling lines tested showed variable performance. These results demonstrate that as flow of supplemental O_2 increases, the accuracy of competitive sampling lines is affected. Therefore, cross-pairing different manufacturer lines with the Capnostream portable respiratory monitor could result in frequent dropouts or inaccurate readings while monitoring patients.

2. $etCO_2$ accuracy as a function of respiratory rate

Overview

Respiration rate is a critical vital sign that provides early detection of respiratory compromise and patient distress.[15] Patients that receive sedation or postoperative opioid administration are at risk for potentially fatal respiratory depression.[16] Therefore, continuous monitoring of CO_2 derived respiratory rates and accurate $etCO_2$ readings are essential in order to help detect life-threatening conditions.

In this test, we looked at the influence of respiration rate on accuracy of $etCO_2$ at varying breaths per minute (BPM). Each sampling line was tested at respiration rates between 10 and 150 BPM using a validated respiratory rate controller, and $etCO_2$ was measured using the capnography device. The expected $etCO_2$ value in the presence of 5% CO_2 was 34 mmHg, and the predefined acceptable accuracy range was ±2 mmHg for readings between 0-38 mmHg.

Results

We found that only Medtronic and Respironics sampling lines met the expected $etCO_2$ value of 34 mmHg at all respiratory rates **(Table 1)**. Salter Labs, Flexicare, and Westmed dropped to 0 mmHg and did not report accurate $etCO_2$ readings in at least one respiratory rate setting when paired with the Capnostream™ 35 portable respiratory monitor. The differences in performance could be attributed to the design of the sampling lines, or due to a larger dead space volume within these lines.

3. Rise time

Overview

Rise time is an important technical feature of capnography sampling lines and determines their ability to provide a timely, high resolution reading of CO_2 in exhaled breath.[8,17] Rise time is the time required for the displayed $etCO_2$ value to rise from 10% to 90% and is a direct indicator of the system response (separation between breaths) and the system accuracy ($etCO_2$ and background noise, **Figure 3**).

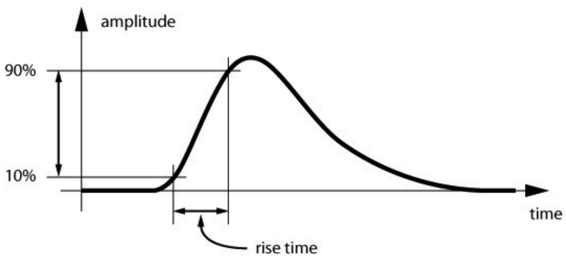


Figure 3. Diagram of measurable rise time in capnography

An ideal measurement of $etCO_2$ is taken from the peak of the CO_2 sample which must be reached quickly (i.e. rise time) before gas mixing occurs in the sampling line. Therefore, a shorter rise time is desirable and considered more accurate. The rise time is lengthened by impedance of air flow, which may be related to friction along the tubing and filters.

In this test, rise time was defined as time required for the measured CO_2 concentration value to increase from 10% to 90% of the final value. A validated rise time measurement device was utilized, enabling the calculation of maximum respiratory rate and exhalation time. The maximum respiratory rate and exhalation time at inhalation:exhalation ratios equal to 1:1 and 1:2 were calculated and used to determine the accuracy threshold respiratory rate of 150 breaths per minute (BPM).

		Rise Time	$etCO_2$ Accuracy with Supplementary O_2	$etCO_2$ Accuracy with Varied Respiration Rate
MEDTRONIC	Smart Capnoline™ Plus Sampling Line	✓	✓	✓
	O_2/CO_2 Nasal FilterLine™ Sampling Line	✓	✓	✓
	Microstream™ Advance oral/nasal filter line	-	✓	✓
	Microstream™ Advance nasal filter line	-	✓	✓
MASIMO	NomoLine™* O LH Adult Nasal/Oral CO_2 Cannula with O_2	-	X	✓
	NomoLine™* O LH Adult Nasal CO_2 Cannula with O_2	-	X	X
SALTER LABS	Divided Adult Capnography Cannula	X	X	X
	$O_2/etCO_2$ Filtered Oral/Nasal Divided Cannula	-	X	✓
	$O_2/etCO_2$ Filtered Nasal Divided Cannula	-	X	X
RESPIRONICS	Adult CO_2 Oral/Nasal Cannula	✓	X	✓
FLEXICARE	Adult Dual Nasal Cannula	X	X	X
HUDSON	RCI Softech™* Bi-Flo ET CO_2/O_2 Cannula	✓	X	X
WESTMED	CO_2/O_2 Adult Cannula	X	X	X

GREEN CHECKMARK: Passed all test parameters; ORANGE X MARK: Failed in at least one test parameter (predefined as error >2 mmHg in $etCO_2$ readings). Rise time data was not collected for new sampling lines.

Table 1. Comparison of overall performance of sampling lines by manufacturer when used in combination with Medtronic Capnostream™ 35 portable respiratory monitor.

Results

We demonstrated that the sampling lines from Flexicare, Salter Labs, and Westmed failed to achieve the accuracy standard up to 150 BPM using either inhalation:exhalation ratios of 1:1 and/or 1:2 **(Table 1)**. This could be due to a larger dead space within the sampling lines, which results in a longer rise time and a mixing of breath samples. In contrast, both Medtronic and Respironics sampling lines were determined to be accurate up to the 150 BPM respiratory rate threshold.

4. Performance of new sampling lines

Overview

Additional testing was performed using new sampling lines recently introduced to the market, including the Microstream™ Advance nasal and oral-nasal filter lines (Medtronic), the NomoLine-O LH Adult Nasal/Oral CO_2 Cannula with O_2 and Nasal CO_2 Cannula with O_2 sampling lines (Masimo), and the adult O_2/etCO_2 Filtered Oral/Nasal Divided Cannula and O_2/etCO_2 Filtered Nasal Divided Cannula sampling lines (Salter Labs).

Bench testing was performed to measure etCO_2 accuracy across a clinical range of respiratory rates (10-50 breaths per minute) and supplemental oxygen delivery (0-5 LPM) using a mechanical lung setup. The expected etCO_2 value in the presence of 5% CO_2 was 34 mmHg, and the predefined acceptable accuracy range was ± 2 mmHg for readings between 0-38 mmHg. Using the lung simulation test results, a mathematical model was created to extrapolate the accuracy of each sampling line in a broad range of conditions.

Results

The Medtronic sampling lines achieved accuracy of ± 2 mmHg in all conditions tested, whereas the Masimo and Salter Labs sampling lines had several readings with error >2 mmHg as respiratory rate, supplemental oxygen flow, or both variables changed (**Table 1**). This indicates the Microstream™ Advance lines provide more accurate etCO_2 readings than competitor third party sampling lines, particularly when supplemental oxygen is used.

Modeling of the bench testing results portrays a similar pattern in which the Medtronic Microstream™ Advance sampling lines achieved etCO_2 accuracy across all respiratory rates and supplemental oxygen flow rates, but the Masimo and Salter Labs sampling lines exhibit errors of >2 mmHg for a broad range of conditions. For example, the results suggest that in a patient with a respiratory rate of 20 BPM and receiving 4 LPM supplemental oxygen, the Medtronic Microstream™ Advance sampling lines will measure etCO_2 equal to 34 mmHg, but the Masimo nasal, Masimo oral-nasal, and Salter Labs oral-nasal sampling lines all exhibit errors between 2-4 mmHg and the Salter Labs nasal sampling line has errors between 4-6 mmHg.

Conclusions

An increasing number of professional organizations recommend use of capnography monitoring to ensure patient safety, including The Joint Commission, which requires hospitals to monitor patients at high risk for opioid-related adverse events. This includes having a policy or protocol to assess patient risk and to manage and monitor the patient according to the risk level.[18]

Our bench test results suggest that varying oxygen flow rates and sampling line design impact the accuracy of etCO_2 and respiratory rate measurements when using Microstream™-enabled capnography technology, inclusive of standalone and OEM partner (multiparameter) monitors. Only Medtronic sampling lines met or surpassed all performance measures. The results demonstrate that non-Medtronic sampling lines, that were not designed and validated for use with the Capnostream™ 35 monitor, had poor etCO_2 measurement accuracy during supplemental oxygen delivery. Thus, cross-pairing sampling lines from third-party manufacturers with the Capnostream™ 35 portable respiratory monitor may result in poor measurement accuracy, and may not be sufficient to meet the monitoring standards necessary to ensure patient safety.

Appendix

All sampling lines tested

MANUFACTURER		INDICATION	CATALOG #
MEDTRONIC	Smart CapnoLine™ Plus sampling line	Adult	9826
	Microstream™ Advance oral/nasal filter line	Adult	MVAO
	Microstream™ Advance nasal filter line	Adult	MVANO
	FilterLine™ H Set sampling line	Infant/Neonate	6324
	O_2/CO_2 Nasal FilterLine™ sampling line	Adult	6912
	O_2/CO_2 Nasal FilterLine™ sampling line	Pediatric	6913
	VitaLine™ H sampling line set	Adult and Pediatric	10787
	Smart CapnoLine™ H Plus sampling line	Adult	12463
	Smart CapnoLine™ sampling line	Pediatric	7269
	Smart CapnoLine™ sampling line with Guardian bite block	N/A	12530
	CapnoLine™ H sampling line	Adult	8180
	Smart CapnoLine™ Plus sampling line	Adult	9822
	Smart CapnoLine™ H Plus sampling line	Adult	10433; 10625
	CapnoLine™ H sampling line	Medtronic	8181
	CapnoLine™ H sampling line	Medtronic	10582
MASIMO	NomoLine™* O LH Adult Nasal/Oral CO_2 Cannula with O_2	Adult	4459
	NomoLine™* O LH Adult Nasal CO_2 Cannula with O_2	Adult	4456
SALTER LABS	Divided adult capnography cannula	Adult	4707FTG-7-7
	Divided pediatric capnography cannula	Pediatric	4703F-7-7
	Divided adult capnography cannula	Adult	4797F-7-7
	Adult O_2/etCO_2 Filtered Oral/Nasal Divided Cannula	Adult	4MSF1-7-6-25
	Adult O_2/etCO_2 Filtered Nasal Divided Cannula	Adult	4MSF3-7-6-25
RESPIRONICS	Adult CO_2 oral/nasal cannula	Adult	M2756A
	Pediatric CO_2 oral/nasal cannula	Pediatric	M2757A
	Infant CO_2 nasal cannula	Infant	M2746A
	Adult CO_2 nasal cannula	Adult	M2744A
	Pediatric CO_2 nasal cannula	Pediatric	M2745A
	Airway Adapter Set H (ET Tube ≤4.0mm)	N/A	M2773A
	Airway Adapter Set H (ET Tube >4.0mm)	N/A	M2772A
	Airway Adapter Set (ET Tube >4.0mm)	N/A	M2768A
	Straight sample line	N/A	M2776A
	Adult O_2/CO_2 oral/nasal cannula	Adult	M2760A
	Pediatric O_2/CO_2 nasal cannula	Pediatric	M2751A
	Pediatric O_2/CO_2 oral/nasal cannula	Pediatric	M2761A
	Adult O_2/CO_2 nasal cannula	Adult	M2750A

FLEXICARE	Adult dual nasal cannula	Adult	032-10-125U
	Adult dual nasal cannula with filter	Adult	032-10-125AU
	Adult dual nasal cannula	Adult	032-10-126U
HUDSON	RCI Softech™* Bi-Flo etCO_2/O_2 cannula	N/A	1844
	RCI Softech™* Bi-Flo etCO_2/O_2 cannula	N/A	1845
	RCI Softech™* Plus pediatric divided nasal cannula	Pediatric	2850
WESTMED	CO_2/O_2 adult cannula	Adult	539
	Adult oral/nasal cannula CO_2/O_2 sampling line	Adult	913
	Adult nasal cannula CO_2/O_2 sampling line	Adult	912
VENTLAB	Adult etCO_2 cannula	Adult	4707
MEDLINE	SuperSoft™* oxygen cannula with universal connector	Pediatric	HCSU4518S

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The Microstream™ capnography monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

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