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Validation of Novel Completely Sealed Nasal Positive Airway Pressure Device: SuperNO$_2$VA^{TM} EtCO$_2$ Measurement and Pressure Test Performance

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Abstract

Background: SuperNO$_2$VA^{TM} Et Nasal Mask (Vyaire Medical, Inc., United States) is a new nasal mask with an integrated sampling hood to capture exhaled gases and enable accurate measurements of end tidal carbon dioxide (EtCO$_2$). The authors hypothesized that the SuperNO$_2$VA Et design would measure EtCO$_2$ more accurately than a predicate EtCO$_2$ sampling line, the Smart CapnoLine® Plus, Adult/Intermediate CO$_2$ Oral-Nasal Set (Medtronic, United States). **Methods:** A simulated patient setup enabled comparison of the accuracy of CO$_2$ measurements within the SuperNO$_2$VA Et and a predicate device for eight condition combinations of input CO$_2$; breath rate and tidal volume (VT); and O$_2$ flow rates. These tests were repeated with simulating Nasal Breathing and Oral Breathing. **Results:** Testing demonstrated that measurements of 1% and 5% input CO$_2$ within the SuperNO$_2$VA Et were accurate for a range of respiratory rates, VT, O$_2$ flows, and CO$_2$ concentrations. CO$_2$ measurement errors were significantly larger for the Oral-Nasal Set compared to the SuperNO$_2$VA Et for both 1% Input CO$_2$ (−0.12%vol vs. −0.01%vol, $p = 0.0005$) and 5% Input CO$_2$ (−0.93%vol vs. −0.08%vol, $p < 0.0001$). At 5% Input CO$_2$, eight of the 12 trials for the Oral-Nasal Set failed to meet the ISO accuracy specification, while all SuperNO$_2$VA Et measurements met the specification. The accuracy of CO$_2$ measurement within the SuperNO$_2$VA were not different for Oral and Nasal Breathing trials for both CO$_2$ concentration (1%: $p = 0.33$, 5%: $p = 0.064$). With the Oral-Nasal Set, CO$_2$ measurements were lower during Oral compared to Nasal Breathing (1%: $p = 0.0005$, 5%: $p = 0.0091$). **Conclusions:** Based on performance outcomes, use of the SuperNO$_2$VA Et offers significantly more accurate measurement of

$EtCO_2$ than the predicate $EtCO_2$ sampling line. Measurements of $EtCO_2$ within the SuperNO_2VA Et are accurate over a range of CO_2, breathing rates, tidal volumes, and O_2 flows, as well as for nasal and oral breathing.

Keywords

Capnography, Sedation, Hypoxemia, Hypoventilation, Ventilation

1. Introduction

Moderate and deep sedation have long been associated with high rates of respiratory complications such as hypoxemia and hypoventilation [1] [2] [3]. These complications arise from sedation medications and inadequate monitoring that contribute to or cause upper airway obstruction (UAO), central respiratory depression, or both [1] [2] [3]. Ventilation monitoring and supplemental oxygenation can mitigate respiratory complications in both sedation settings.

1.1. Monitoring

Traditionally, pulse oximetry had enabled limited and indirect respiratory monitoring. Because such devices measure only peripheral oxygen saturation, their use created the potential for delaying complication detection, with possible subsequent health risks for the patient. For example, pulse oximetry is unable to directly detect hypoventilation or apnea, especially in patients undergoing procedural sedation while receiving supplemental oxygen [4] [5].

A superior monitoring approach involves the breath-to-breath measurement of the concentration of carbon dioxide (CO_2) in exhaled respiratory gas, which has gained ready acceptance, particularly with endorsement from the American Society of Anesthesiologists (ASA) for use of end-tidal capnography ($EtCO_2$) as a standard of care for moderate and deep procedural sedation [6] [7].

Although capnography has greater efficiency than pulse oximetry for effective detection of hypoventilation and apnea, accurate and consistent measurements of the $EtCO_2$ during minimally invasive procedures under deep sedation have historically been challenging [8]. This difficulty results from the capnography port of the nasal cannula being open to air, causing atmospheric gases to be entrained and sampled [9]. Additionally, delivery of supplemental oxygen to patients, particularly at flows >5 liters per minute (L/min), causes a "wash-out" or dilution of the sample of exhaled CO_2 and results in either a falsely low reading or no reading at all [10].

1.2. Supplemental Oxygenation

Recent prospective randomized controlled trials (RCTs) report up to 54% of all patients experience severe hypoxemia secondary to sedation-related UAO and respiratory depression [11]. Although passive oxygenating devices can provide

higher concentrations of oxygen, they are incapable of generating positive pressure to maintain airway patency. Continuous Positive Airway Pressure (CPAP) equipment has been shown to relieve UAO by creating a pneumatic stent [12]. However, their utility is limited by the machine's very large size and relatively greater expense, and the high oxygen flows required to maintain pressure also dilute $EtCO_2$ sampling [13] [14].

A recent RCT comparing the SuperNO$_2$VA^{TM} nasal PAP ventilation device (Vyaire Medical, Inc., United States) vs. nasal cannula with capnography during deep sedation documented a significantly higher minute ventilation and reduction in the incidence of severe hypoxemia in the SuperNO$_2$VA^{TM} nasal PAP ventilation device cohort compared to the nasal cannula with capnography cohort [15]. However, the design of the SuperNO$_2$VA nasal PAP ventilation device had the disadvantage of being unable to capture $EtCO_2$, especially in patients who exhale from their mouths, which also results in false apnea alarms.

1.3. SuperNO$_2$VA™ Et Nasal Mask

A solution that offers the ability to monitor $EtCO_2$ and deliver supplemental oxygen is the novel SuperNO$_2$VA^{TM} Et Nasal Mask (Vyaire Medical, Inc., United States). This completely sealed nasal PAP device provides positive pressure to maintain upper airway patency without the use of capital equipment. The SuperNO$_2$VA^{TM} Et Nasal Mask (**Figure 1**) also is designed to capture $EtCO_2$ exhaled from both the patient's mouth and nose. Combining capnography with positive pressure in a single device may prove to be a methodology to further improve patient outcomes in deep sedation as opposed to passive oxygenation techniques with capnography.

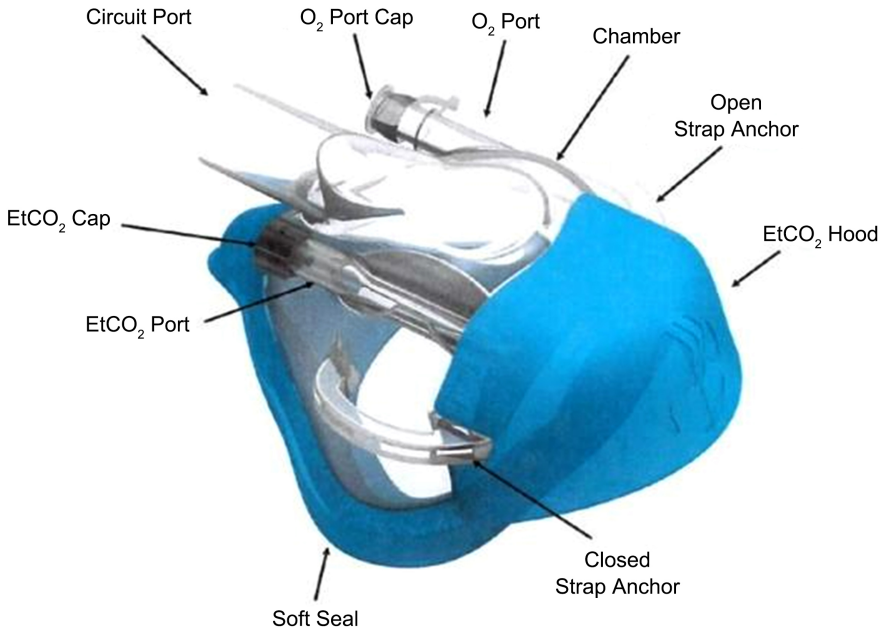

Figure 1. SuperNO$_2$VA Et Nasal Mask features an $EtCO_2$ Hood and $EtCO_2$ nasal sampling port (Source: Vyaire Medical).

The objectives of this study were to validate the capability of the Super-NO_2VA^{TM} Et to capture $EtCO_2$ exhaled from the nose and the mouth, provide 20 cm H_2O positive pressure, quantify leak rates, and summarize the performance testing compared to a predicate device.

2. Methods

2.1. Experimental Setup and Methods

A simulated patient setup was used to compare the accuracy of CO_2 measurements within the SuperNO_2VA Et Nasal Mask and a predicate device, the Smart CapnoLine® Plus, Adult/Intermediate CO_2 Oral-Nasal Set (Medtronic, United States).

The Device Under Test (DUT), either the SuperNO_2VA Et or Oral-Nasal Set, was placed on a face surrogate and breathing simulation was provided by a Large Animal Volume Controlled Ventilator Model 613 (Harvard Apparatus, United States). This device is suitable for humans up to 50 kg (110 lb) and enables an adjustable VT from 30 to 700 milliliters (ml) per stroke and an adjustable respiratory rate from 7 to 50 breaths per minute (BPM). The concentration of CO_2 flowing through the surrogate nose and mouth was set using a digitally controlled flow meter and CO_2 source, and verified using a CO_2 monitor (Dräger Narkomed 6400). A Datex-Ohmeda 5250 Respiratory Gas Anesthesia Monitor (General Electric Healthcare, United States) connected to the $EtCO_2$ sampling port was used to monitor CO_2. Testing assessed eight combinations of Input CO_2 (1% ± 0.25%; 5% ± 0.5%); breath rate and VT (12 BPM/500 ml; 20 BPM/300 ml); and O_2 flow rates (1 L/min; 5 L/min). Table 1 lists the combinations of Input CO_2, Breath Rate/VT, and O_2 Flows that were tested. After a 3-min stabilization period to reach steady-state, the CO_2 waveform of the sensor connected to the $EtCO_2$ sampling port was recorded for 16 seconds via an analog port of an oscilloscope (Tektronix TBS2000, United States).

Table 1. Test matrix listing the eight combinations of input CO_2, breath rate, tidal volume, and O_2 flow. Each test was repeated three times for the SuperNO_2VA Et and Oral/Nasal Sampling Set.

Test Number	Input CO_2	Breath Rate (BPM)	Tidal Volume (ml)	O_2 Flow (L/min)
1	1%	12	500	1
2	1%	12	500	5
3	1%	20	300	1
4	1%	20	300	5
5	5%	12	500	1
6	5%	12	500	5
7	5%	20	300	1
8	5%	20	300	5

To evaluate the performance of the Oral-Nasal Set and SuperNO_2VA Et when a patient is breathing exclusively nasally or orally, the same set of eight tests were repeated while simulating nasal breathing and oral breathing. Three trials were performed for each of the eight test conditions and breathing type (*i.e.*, nasal or oral).

In addition, leak rate and ability to hold a positive pressure for five minutes were tested for three SuperNO_2VA Et Nasal Masks and, as a comparator, a full-face anesthesia mask (Ventlab™ inflatable anesthesia mask VR5100; SunMed, United States). The DUT was placed on a surrogate face and sealed with 10 pounds of force. To determine the leak flow rate, the O_2 flow rate was slowly reduced until a minimum flow was achieved while still maintaining a positive pressure of 20 cm H_2O.

2.2. Statistical Analysis

Absolute and relative errors between the CO_2Max, defined as maximum CO_2 during the 16-second trial, and the Input CO_2 were quantified for each DUT.

$$\text{Absolute Error} = CO_2\text{MaxDUT} - \text{Input}CO_2$$

$$\text{Relative Error} = \frac{\left(CO_2\text{MaxDUT} - \text{Input}CO_2\right)}{\text{Input}CO_2} * 100\%.$$

Negative errors correspond to an underestimation of CO_2. Unpaired t-tests compared CO_2Max errors between the two devices for tests with Input CO_2 of 1% and 5%. Unpaired t-tests were also performed to compare CO_2Max errors between the two devices at O_2 Flows of 1 L/min and 5 L/min. Paired t-tests were performed to compare CO_2Max errors during Nasal Breathing and Oral Breathing trials for each of the two devices. As a comparator, DUT accuracy was measured against the specifications of the International Organization for Standardization (ISO 80601-2-55:2018) requirements for the basic safety and essential performance of a respiratory gas monitor intended for continuous operation with a patient, defined as ± (0.43%vol + 8% of gas level) [16].

3. Results

3.1. Accuracy of CO_2 Measurement

The SuperNO_2VA Et Nasal Mask had lower CO_2Max errors than the Oral-Nasal Set for all eight conditions (**Figure 2**).

For 1% Input CO_2, CO_2Max errors were significantly larger for the Oral-Nasal Set, −0.12%Vol ± 0.03%Vol (−12.2%Vol ± 3.3%Vol, mean ± SD), compared to the SuperNO_2VA Et Nasal Mask, −0.01%Vol ± 0.02%Vol (−1.3%Vol ± 2.2%Vol) ($p = 0.0005$). All 12 trials for the Oral-Nasal Set and the SuperNO_2VA Et Nasal Mask met the ISO accuracy specification.

For 5% Input CO_2, the Oral-Nasal Set significantly underestimated CO_2Max error, −0.93%Vol ± 0.16%Vol (−18.6%Vol ± 3.2%Vol), compared to the SuperNO_2VA Et Nasal Mask, −0.08%Vol ± 0.06%Vol (−1.5%Vol ± 1.2%Vol) ($p <$

0.0001). At 5% Input CO_2, eight of the 12 trials for the Oral-Nasal Set failed to meet the ISO accuracy specification, while all SuperNO_2VA Et Nasal Mask met the specification.

3.2. Effect of Supplemental Oxygen Flow Rate

To examine the effect of O_2 Flow on performance of the two devices, results from trials with O_2 Flow of 1 L/min were compared to trials with O_2 Flow of 5 L/min (Figure 3). Trials with the SuperNO_2VA Et had significantly lower errors than the Oral-Nasal Set with O_2 Flows of 1 L/min (0.01%vol vs. 0.11%vol, p = 0.0032) and 5 L/min (−0.03%vol vs. −0.14%vol, p = 0.0032). The difference in performance was even larger with an Input CO_2 of 5%. Specifically, the Super-NO_2VA Et errors were significantly less at both 1 L/min (−0.04%vol vs. 0.91%vol, p < 0.0001) and 5 L/min (−0.11%vol vs. −0.95%vol, p = 0.0002).

3.3. Nasal Breathing vs. Oral Breathing

The same set of eight tests were repeated while simulating Nasal Breathing and Oral Breathing for each of the two devices (See Figure 4). For the Oral-Nasal Set, CO_2Max measurements were significantly lower for the Oral Breathing compared to Nasal Breathing trials for Input CO_2 concentrations of 1% (paired t-test, p = 0.0005) and 5% (p = 0.0091). For the SuperNO_2VA Et, there was no

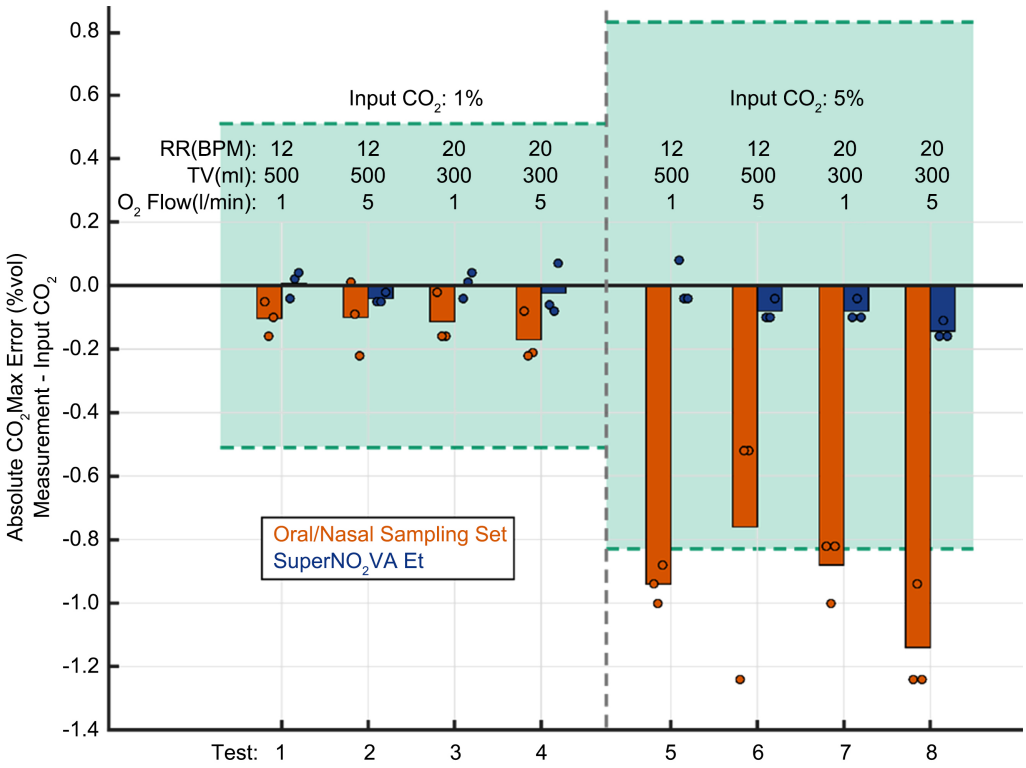

Figure 2. CO_2Max Error (in %vol) for the eight condition performance tests for Oral-Nasal Set (orange) and SuperNO_2VA Et Nasal Mask (blue). Horizontal shaded green areas correspond to the ISO 80601-2-55:2018 error limit (0.51% and 0.83% for 1% and 5% input CO_2 respectively). Filled circles are individual trials and bars represent mean error across the three trials for each condition test.

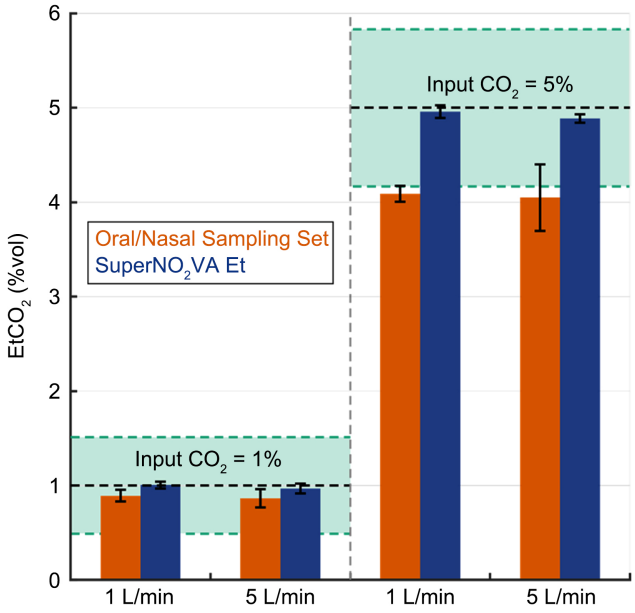

Figure 3. Comparison of maximum CO_2 measurements (*i.e.*, CO_2Max) measurements during trials with O_2 Flow of 1 L/min and 5 L/min. CO_2Max with Oral-Nasal Set (orange) and SuperNO_2VA Et (blue) are compared to known Input CO_2 concentrations of 1% or 5% (horizontal dashed black lines). Shaded green areas correspond to the ISO 80601-2-55:2018 error limit (0.51% and 0.83% for 1% and 5% Input CO_2, respectively). Bars are the average measurements across all trials performed under those conditions and error bars are the standard deviation of measurements across these trials.

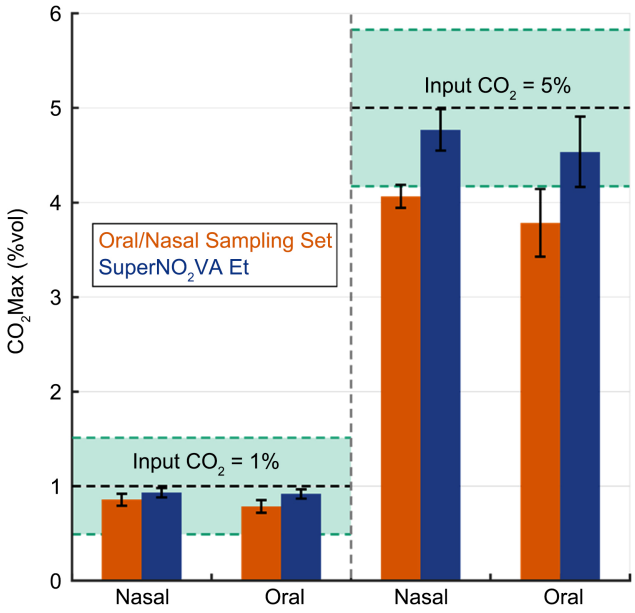

Figure 4. Comparison of maximum CO_2 measurements (*i.e.*, CO_2Max) measurements during Nasal Breathing and Oral Breathing trials. CO_2Max with Oral-Nasal Set (orange) and SuperNO_2VA Et (blue) are compared to known Input CO_2 concentrations of 1% or 5% (horizontal dashed black lines). Shaded green areas correspond to the ISO 80601-2-55:2018 error limit (0.51% and 0.83% for 1% and 5% Input CO_2, respectively). Bars are the average measurements across all trials performed under each condition and error bars are the standard deviation of measurements across these trials.

significant difference in CO_2Max measurements for Nasal Breathing and Oral Breathing trials for both Input CO_2 concentrations (1%: p = 0.33, 5%: p = 0.064). At an Input CO_2 of 5%, the Oral-Nasal Set had 10 out of the 12 Nasal Breathing trials and 9 out of 12 Oral Breathing trials outside of the ISO error bound (shaded green region).

3.4. Flow Leak Rate

Both the SuperNO_2VA Et Nasal Mask and the full-face anesthesia mask successfully held a pressure of 20 cm H_2O for three, 5-minute trials. The SuperNO_2VA Et Nasal Mask had a leak rate of 2.0 L/min for all three samples compared to the mean leak rate of 2.7 (range: 2.5 - 3.0 L/min) for the anesthesia mask (**Table 2**).

4. Discussion

This performance test study compared the functionality of the SuperNO_2VA Et Nasal Mask and Oral-Nasal capnography in eight condition combinations with binary variations of input CO_2; respiratory rate and VT; and O_2 flow rates. Our results indicate that SuperNO_2VA Et Nasal Mask provided significantly greater accuracy in measuring $EtCO_2$ across a range of typical respiratory rates, tidal volume, O_2 flow, and CO_2 concentration, well within the error bounds specified by ISO (**Figure 2**). The error of CO_2 measurements within the SuperNO_2VA Et mask was less than 0.1%vol at both 1% and 5% CO_2 concentrations. In contrast, measurements from the Oral-Nasal Set did not meet the ISO standard for eight out of the twelve trials at a physiological CO_2 level of 5% (*i.e.*, 38 mmHg) and underestimated CO_2 by −0.93%vol (−18.6%). Clinically, this dramatic underestimation of CO_2 could result in false positives of hypocapnia or apnea or missing true hypercapnic events.

Capnography has become standard-of-care during moderate and deep sedation in order to provide real-time feedback of the patient's respiratory status and early detection of respiratory depression [6] [7] [17]. With good quality CO_2 sampling, capnography has been shown to significantly reduce adverse events, such as apnea and desaturation, during moderate and deep sedation [18] [19] [20]. However, $EtCO_2$ measurements using nasal cannula sampling are often not accurate during minimally invasive procedures under deep sedation [8]. The inaccuracy of $EtCO_2$ using nasal cannulas arises because they are exposed to

Table 2. Flow leak rate results for Full-Face Anesthesia Mask and SuperNO_2VA Et.

	Flow Leak Rate (L/min)	
Sample Number	Full-Face Anesthesia Mask	SuperNO_2VA Et
1	3.0	2.0
2	2.5	2.0
3	2.5	2.0
Mean	2.7	2.0

atmospheric gas [8] and supplemental O_2 washes out CO_2 in the sample [10] [21]. Both of these effects result in an underestimation in CO_2 measurements.

The SuperNO_2VA Et offers a solution to this CO_2 sampling problem by capturing all expired gases from the patient's mouth and nose using an integrated flexible sampling hood over the patient's mouth. The SuperNO_2VA Et also provides positive pressure to maintain upper airway patency. Use of the SuperNO_2VA results in increased minute ventilation and a reduction in severe hypoxemia compared to a nasal cannula [15]. Furthermore, in contrast to traditional anesthesia masks, the SuperNO_2VA Et does not cover the full face and therefore allows the clinician access to the oral cavity during a procedure while delivering air, oxygen, or anesthesia gases and simultaneously sampling expired gases.

Delivery of supplemental oxygen using traditional nasal cannulas results in an underestimation of CO_2 [10] and the error increases with the flow rate as more of the sampled gas is washed out with O_2 when using traditional nasal cannulas [21]. In this study, we saw no decrease in accuracy of CO_2 measurements when using the SuperNO_2VA Et (**Figure 3**). There was also no significant difference between 1 and 5 L/min O_2 flow rates using the Oral-Nasal Set. However, this dilution effect is typically observed for nasal cannulas at flow rates greater than 5 L/min which were not tested in this study.

Another source of capnography error arises when the patient breathes orally, which is common during respiratory distress and sedation, especially in obese patients with obstructive sleep apnea (OSA) [10]. For example, in non-intubated volunteers, mouth breathing resulted in a 2 mmHg decrease in $EtCO_2$ compared to nasal breathing [22]. In the present study, the accuracy of the CO_2 measurements within the SuperNO_2VA Et was similar for Nasal and Oral Breathing (**Figure 4**). The Nasal-Oral Set used in this study was engineered with an oral scoop intended to obtain gas samples from the mouth as well as the nose. Despite this design, CO_2 measurements were significantly lower during Oral Breathing compared to Nasal Breathing when using the Oral-Nasal Set.

Furthermore, the SuperNO_2VA Et Nasal Mask maintained a positive pressure of 20 cm H_2O within the mask with a low leak rate of 2.0 L/min, demonstrating superior fit to a full-face anesthesia mask. The majority of the leak from the SuperNO_2VA Et masks comes from the $EtCO_2$ sampling port. In order to achieve a sufficient seal for the full-face anesthesia mask, the balloon had to deflated and inflated in order to achieve a maximum seal.

The SuperNO_2VA Et Nasal mask is a sealed system around the nose that keeps all expired CO_2 within the system, preventing atmospheric dilution. The larger hood over the mouth increases capture of exhaled CO_2 from mouth. The size of the SuperNO_2VA Et nasal and oral apertures for $EtCO_2$ capture was designed based on fluid dynamic calculations to allow for an equal amount of capture.

5. Limitations

This study was conducted to determine specific performance features of the Su-

perNO$_2$VA Et Nasal Mask in a controlled setting using a face surrogate. The study results document the significantly better accuracy of the device and its potential to aid in providing optimal patient care during sedation. Future clinical work should be conducted to confirm if the use of the SuperNO$_2$VA Et improves clinical outcomes and decreases adverse events in patients under sedation.

6. Conclusions

The testing described in this report demonstrated that measurements of CO_2 within the SuperNO$_2$VA Et Nasal Mask are accurate for a range of respiratory rates, tidal volumes, O_2 flows, and CO_2 concentrations and meet ISO standards. The design of the SuperNO$_2$VA Et Nasal Mask allows for a good seal against a patient's face to maintain positive pressure with minimal leak.

This performance and the positive pressure mechanism of the SuperNO$_2$VA Et Nasal mask to improve upper airway obstruction without sacrificing end-tidal measurements differentiate the device favorably from other methods of airway management. Additionally, its design and function improved airway management comparatively to passive devices that, because they cannot provide positive pressure to force airways open, lack the ability to maintain airway patency.

In practice, the performance of SuperNO$_2$VA Et Nasal Mask may help prevent patients from becoming hypoxemic and improve their overall outcomes in the settings of moderate or moderate and deep sedation.

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Declarations of Interest

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Author Contributions

MJP: Conceptualization; Investigation; Data curation; Formal analysis, Methodology.

SHC: Writing—original draft, Writing—review & editing.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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