Technical Bulletin

July 2009

Nonin® MedAir™ Capnography Technology is Consistently Accurate Across Challenging Breathing Conditions

INTRODUCTION

Current standards for evaluating accuracy of capnographs includes simple, steady flow gas validation in which a known percent gas is delivered to the device. Such testing does not allow evaluation of the effects of complexities due to breathing and diseased lungs. This study sought to create a more complex system to evaluate device performance in conditions that better represented realistic patient conditions.

METHODS

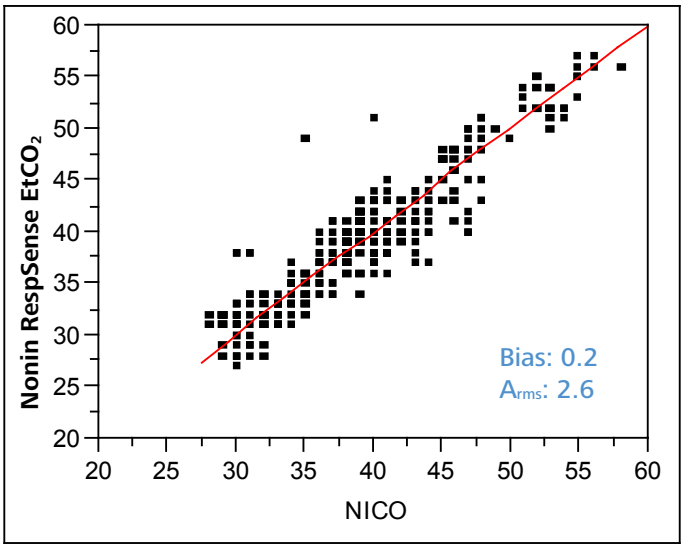
To evaluate the accuracy of Nonin's MedAir™ end-tidal CO_2 technology across challenging breathing conditions, data was collected from the RespSense™ Capnograph with Nonin MedAir $EtCO_2$ technology and from an internationally known competitor device (Competitor A). Both devices were compared against the Philips Respironics NICO® Mainstream $EtCO_2$ monitor, a mainstream capnograph chosen for comparison due to its accepted accuracy.

To complement the findings of the simulation testing, an additional test was performed at a constant flow of 5% CO_2, a value required in medical device testing standards[1], in order to validate the accuracy of the devices at a static CO_2 level.

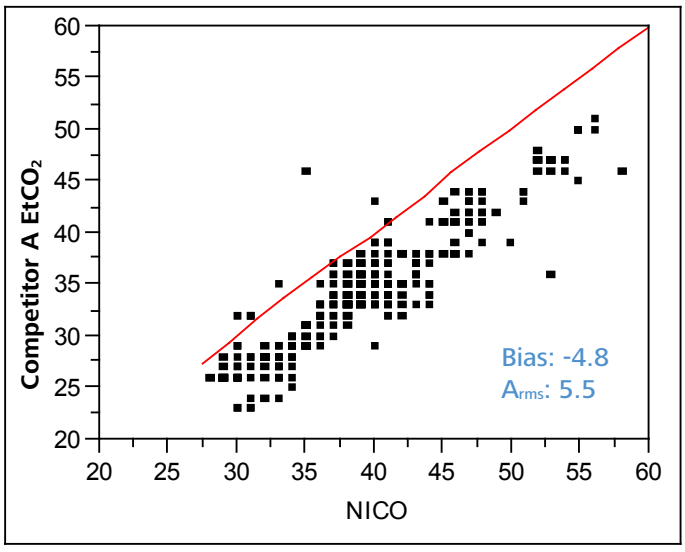
The tests were performed in a controlled laboratory setting using a Michigan Training Test Lung (TTL). The TTL chamber was insufflated with CO_2 and ventilated with a Draeger Medical, Inc. or Puritan Bennett ventilator. Settings were adjusted to simulate appropriate CO_2 output and upper airway flow/leak dynamics of various clinical models, including Restricted, COPD, Normal, Obstructive, COPD-Obstructed, Infant, and Child. Respiratory rates from 6 to 82 breaths per minute were tested to evaluate device performance in changing environments.

Figure 1: Product Comparison – Accuracy

Nonin RespSense $EtCO_2$ vs NICO (N-364)



Competitor A $EtCO_2$ vs NICO (N-364)



[1]*ISO 21647:2004 Medical electrical equipment – particular requirements for the basic safety and essential performance of respiratory gas monitors.*

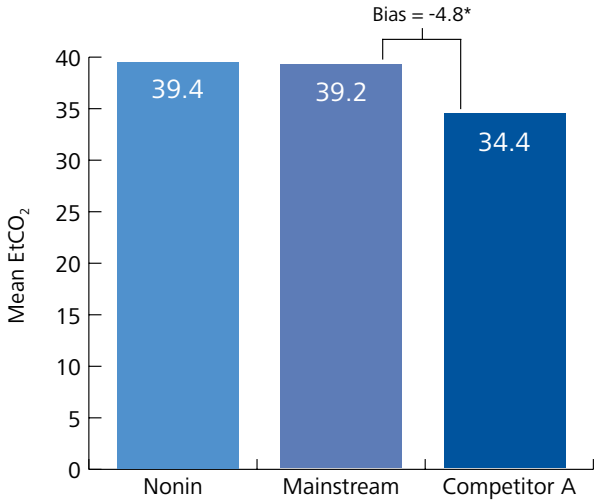
RESULTS

- Nonin's MedAir sidestream technology consistently performed as well as the mainstream technology across all simulated disease models and the range of respiratory rates.
- Nonin's MedAir sidestream technology performed significantly better than Competitor A's sidestream device (Accuracy as compared to mainstream: Nonin 0.2 mmHg bias; Competitor A –4.8 mmHg bias) *(See Figure 2)*.
- The superior accuracy of the Nonin's MedAir sidestream technology compared to the competitor sidestream technology was also noted with 5% CO_2 constant flow gas test *(See Figure 3)*.

CONCLUSION

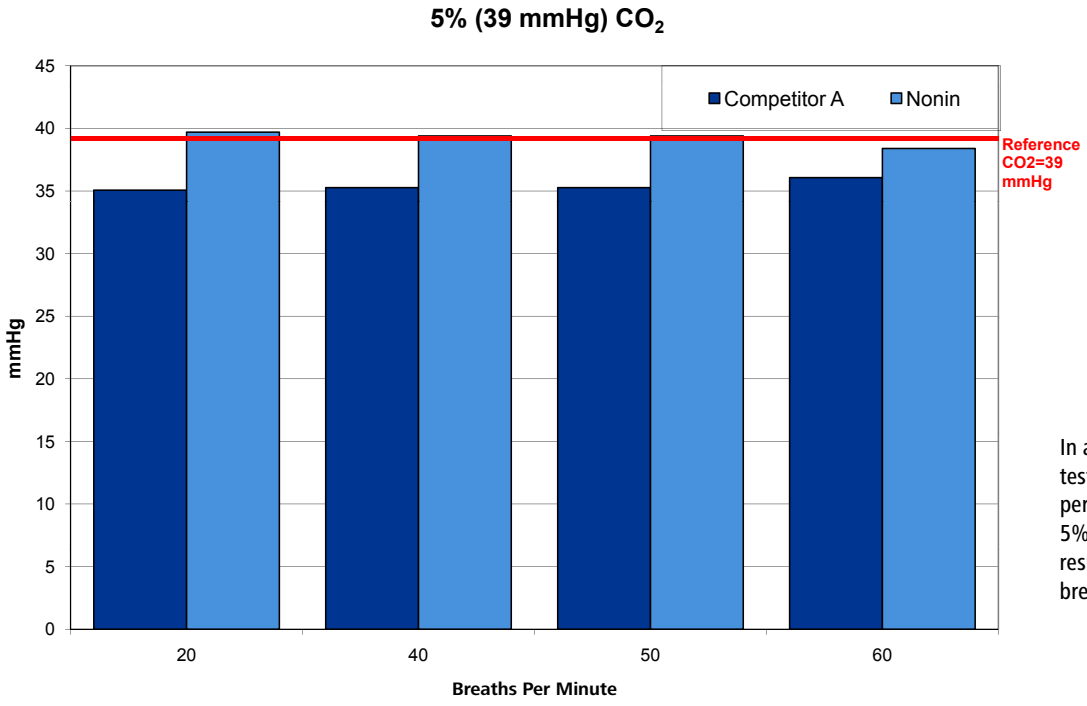
Nonin's MedAir $EtCO_2$ technology, with its stable optical bench, is as accurate as the mainstream $EtCO_2$ reference and significantly more accurate than Competitor A. Nonin's MedAir technology provides accurate information in a wide range of simulated patient models and disease states.

Figure 2: Mean EtCO2 by Device



* Statistically significant difference between devices in mean $EtCO_2$ (paired t-test, p-value <0.05). Data set includes those observations where NICO $EtCO_2$ <60 mmHg.

Figure 3: Accuracy Compared to Reference 5% CO_2 at Various BPM



In addition to the simulated tests, a calibration test was performed by administering 5% CO_2 (39 mmHg) at respiration rates of 20 to 60 breaths per minute.

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