

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 which better represented realistic patient conditions.

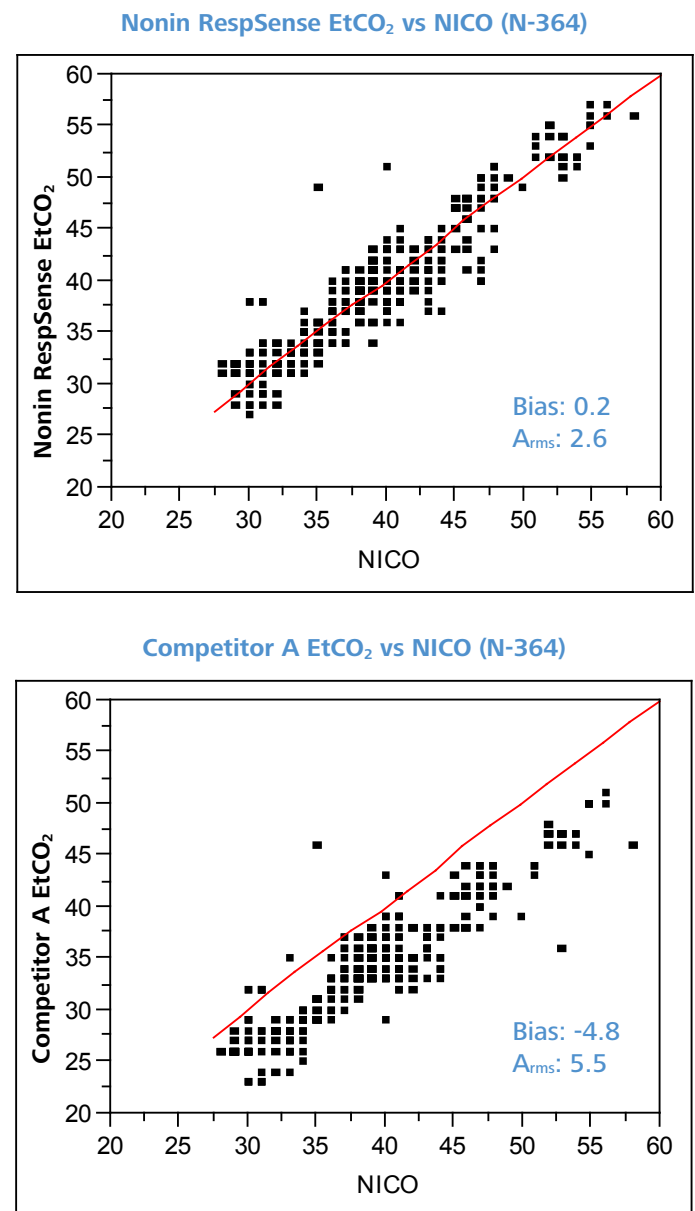
METHODS

To evaluate the accuracy of Nonin’s MedAir™ end-tidal CO₂ technology across challenging breathing conditions, data was collected from the RespSense™ Capnograph with Nonin MedAir EtCO₂ technology and from an internationally known competitor device (Competitor A). Both devices were compared against the Philips Respironics NICO® Mainstream EtCO₂ monitor, a mainstream capnograph chosen for comparison due to its accepted accuracy.

To compliment the findings of the simulation testing, an additional test was performed at a constant flow of 5% CO₂—a value required in medical device testing standards¹—in order to validate the accuracy of the devices at a static CO₂ level.

The tests were performed in a controlled laboratory setting using a Michigan Training Test Lung (TTL). The TTL chamber was insufflated with CO₂ and ventilated with a Draeger Medical, Inc. or Puritan Bennett ventilator. Settings were adjusted to simulate appropriate CO₂ 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



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

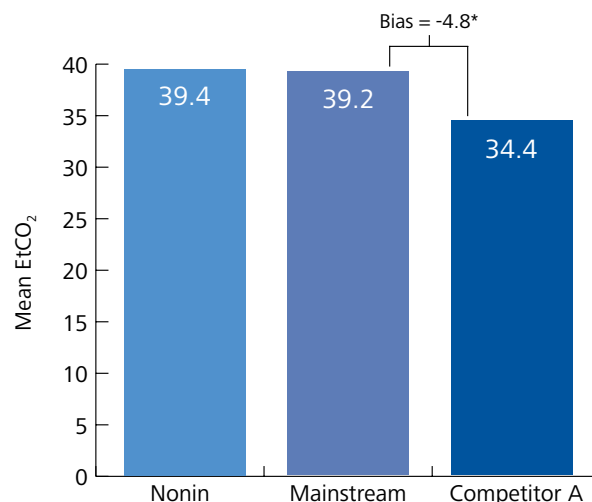
RESULTS

- Nonin’s MedAir side stream technology consistently performed as well as the mainstream technology across all simulated disease models and the range of respiratory rates.
- Nonin’s MedAir side stream technology performed significantly better than Competitor A’s side stream 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 side stream technology compared to the competitor side stream technology was also noted with 5% CO₂ constant flow gas test (See Figure 3).

CONCLUSION

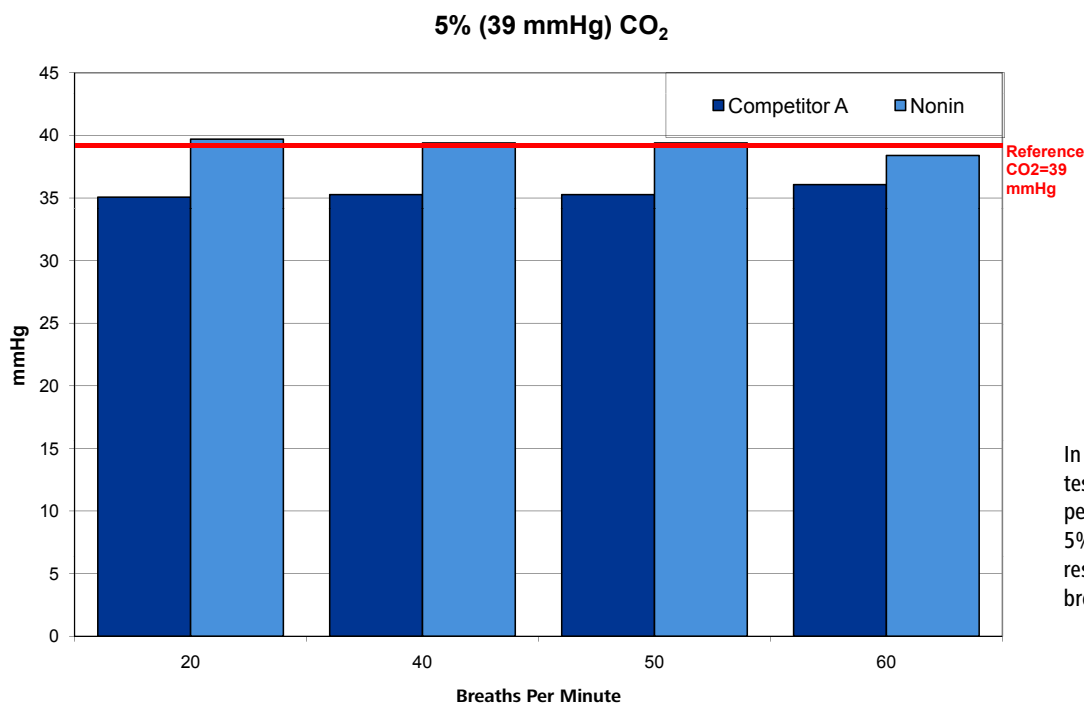
Nonin’s MedAir EtCO₂ technology, with its stable optical bench, is as accurate as the mainstream EtCO₂ reference and significantly more accurate than Competitor A. Nonin’s MedAir technology provides accurate information in a wide range of simulated patient models and disease states.

Figure 2: Mean EtCO₂ by Device



* Statistically significant difference between devices in mean EtCO₂ (paired t-test, p-value <0.05). Data set includes those observations where NICO EtCO₂ <60 mmHg.

Figure 3: Accuracy Compared to Reference 5% CO₂ at Various BPM



In addition to the simulated tests, a calibration test was performed by administering 5% CO₂ (39 mmHg) at respiration rates of 20 to 60 breaths per minute.



Nonin Medical, Inc.

13700 1st Avenue North, Plymouth, MN 55441-5443, USA
 Phone: +1 763.553.9968 | Toll Free: 800.356.8874 | Fax: +1.763.553.7807 | Email: info@nonin.com

www.nonin.com