A Novel Method of Low Cost Capnometry

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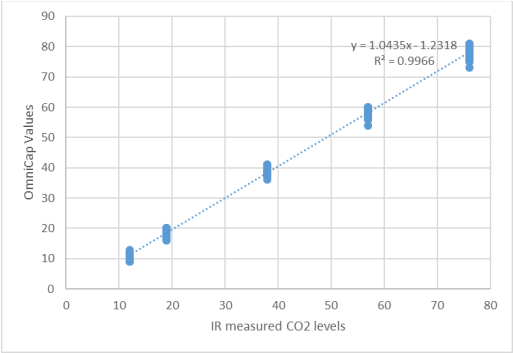
The use of ventilation monitoring using end tidal carbon dioxide (CO_2) has expanded considerably since the publication of the first set of anesthesia monitoring guidelines in 1986[1]. Since that time, disciplines outside of anesthesia continue to explore and recognize the value of CO_2 monitoring during procedural sedation and narcotic administration[2-4]. However, the cost, complexity and fragility of the current infrared (IR) based CO_2 monitors has slowed their widespread implementation outside of the operating room. We describe a novel CO_2 monitoring technology in a patented[5], FDA approved platform[6] that could greatly expand the use of CO_2 monitoring.

Colorimetric end tidal CO_2 detection technology employed in the new device relies on pH-sensitive color change of indicator dyes embedded within the detector. Carbon dioxide is absorbed within a matrix exposed to the respiratory stream, causing a transient drop in pH via formation of carbonic acid. During inhalation, the carbonic acid is rapidly neutralized by alkaline components within the matrix. The pH sensitive indicator thereby cycles between two distinct colors representing the extremes of the breath by breath excursions in pH. The color change is followed via reflectometry using embedded LEDs and color-selective photodiodes sampling every 25 msec. The sensor chemistry is optimized such that the amplitude of color excursions can be quantitatively calibrated to end tidal CO_2.

As part of the required FDA bench testing, the new device was tested against a Nellcor N-85® infrared capnograph using a series of tests referenced from ANSI/AAMI/ES 60601-1, IEC 60601-1-2, and ISO 80601-2-55[6]. Sensor cartridges were stored at temperatures of either 5°C, 24°C, and 38°C for up to 180 days before being exposed to increasing levels of CO_2 at different simulated respiratory rates. The experimental readings were then compared against simultaneous measurements from the N-85® and then compared against prescribed performance standards, as per ISO 80601-2-55. Bland Altman analysis of this data is illustrated in Figure 1. The pass rate of the test device and all tested cartridges was 100% out to eight hours of continuous exposure.

The new, novel capnometric device is accurate, robust, and portable. It is also much less expensive to manufacture than the corresponding IR technology. However, it does have its limitations. The chemical reaction is not as rapid as IR detection, and therefore, it can not produce the same sort of capnographic waveforms. There is a warmup time that averages just over 30 seconds. It does use a disposable sensor cartridge, but the cartridge will be RFID protected as to prevent protracted use above the certified accurate continuous 8 hours. It measures 5.75” L x 3.75” W x 1.25” H, weighs slightly less than 8 ounces and is expected to retail for a tenth of the list price of the N-85®.

The size and lower cost of the novel device would allow for expansion of CO_2 monitoring into a myriad of non-operating room locations, such as the post anesthesia care unit and other areas in the hospital where sedatives and/or narcotics are administered. Other potential areas of use are in dentistry, free standing clinics, sports medicine, military applications, developing world medicine, and even veterinary medicine. Having the ability to expand the use of CO_2 monitoring so that it is ubiquitous and pervasive in any location where ventilation can be monitored can provide an extra layer of patient safety.



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