

A CO₂ Waveform Simulator For Evaluation and Testing of Respiratory Gas Analyzers

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Abstract

Introduction: This paper describes a carbon dioxide (CO₂) waveform simulator designed to evaluate and test the performance of capnographs, which are clinically used respiratory gas analyzers that continuously measure CO₂. Currently, capnographs are tested for minimum performance standards according to guidelines specified by the International Organization for Standardization (ISO) and the American Society for Testing and Materials (ASTM). However, capnographs that meet these guidelines are not guaranteed to perform to a high caliber in a dynamic clinical environment.

Methods: We designed a simulator that overcomes the limitations of current testing protocols by reproducing real-time capnography waveforms (called capnograms) recorded in clinical settings. At each time point in the capnogram, the desired CO₂ partial pressure (mmHg) is simulated by controlling a proportional solenoid valve to mix various flow rates of CO₂ into a constant flow of oxygen (O₂).

Results: The simulator was tested using five different capnography waveforms. Four out of five files had mean squared errors (MSE) under 5mmHg. All five files had R² values greater than .97.

Conclusion: After further research and optimization, this device has the potential to standardize and improve the testing methods used for capnographs.

I. INTRODUCTION

Capnographs are devices used in clinical settings to continuously measure CO₂ concentrations (%) or partial pressures (mmHg) that transpire during respiration. These devices can provide clinicians with graphical and

numerical information about CO₂ production and respiratory patterns. The graphical display of the CO₂ data over time is called a capnogram (Figure 1a)¹. Abnormal capnograms can represent many things, including respiratory changes, such as airway obstruction, or technical problems, such as an endotracheal tube not positioned correctly (Figure 1b and 1c)¹. A capnogram can also show cardiogenic oscillations, which are small oscillations in the CO₂ signal caused by the heart beating against the lung.

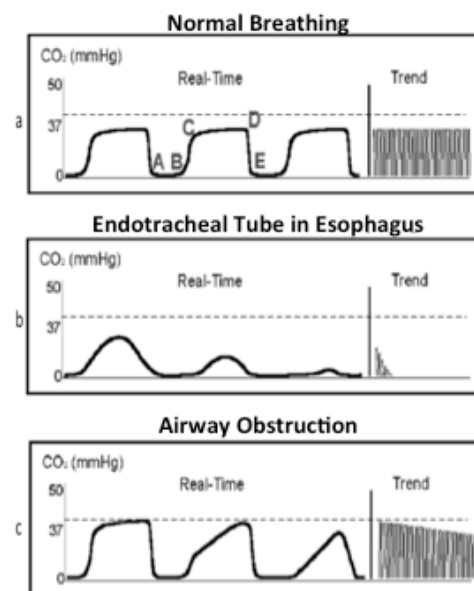


Figure 1: Capnogram Waveforms (A-B: Baseline, B-C: Expiratory Uptake, C-D: Expiratory Plateau, D: End-Tidal Concentration, D-E: Inspiration)

Capnographs are currently tested for minimum performance standards using single tanks of calibration mixtures fixed at a constant flow rate. For example, ASTM standards require that a capnograph be able to accurately measure 0, 2.5, 5 and 10% CO₂ (balance Nitrogen) twice over a 24-hour period². ISO specifies similar standards, and both require manufacturers to report the range of CO₂ that can be measured, the accuracy of measurements, the minimum flow

rate, stability over time, average rise-time, and total transit time in their specifications²⁻⁴.

These testing protocols are far from the environment in which a capnograph would be expected to perform to a high standard. In addition, the test methods are inconsistent from manufacturer to manufacturer and are only required to be reported to ISO and ASTM upon request². Ideal standards would test for a capnograph's ability to respond to changing flow rates and frequencies of respiration, as well as to account for the complex shapes and patterns that can occur as part of the capnography waveform. Also, these testing methods would be standardized for all manufacturers.

In 2005, an EtCO₂ simulator was designed to overcome the limitations of current testing procedures and evaluate the dynamic performance of capnographs. Their finds were concerning: older capnographs' performances had deteriorated over time and most no longer met their initially reported specifications⁵. However, there is still more that could be done to test a capnograph's clinical behavior. For example, the EtCO₂ simulator design is still limited in that it uses only two calibration gasses (room air and 5% CO₂) and only creates square-wave capnograms of different frequencies⁵.

Our simulator aims to improve capnography testing standards by analyzing the dynamic response of gas analyzers through simulations of capnograms recorded in clinical settings. By simulating these waveforms, capnographs can be tested for the parameters required by ISO and ASTM, and be evaluated for their performance on realistic waveforms. Our device functions by using a variable solenoid valve that dynamically controls the CO₂ flow rate that is mixed with a constant flow rate of O₂, resulting in varying partial pressures of CO₂. The capnograms tested on the simulator include waveforms from intensive care unit (ICU) and operating room (OR) patients, as well as new born and pediatric patients. The system presented, after further research, has the potential to become a standard for testing new capnographs, as well as verifying existing capnographs' reported specifications.

II. METHODS

Design

The CO₂ waveform simulator consists of: 1) 100% CO₂ and 100% O₂ gas sources, 2) a simulator enclosure, 2) a reference capnograph, 3) a test capnograph, and 4) a computer loaded with capnograms (**Figure 2**).

The computer is the control point for the simulator. A C++ (Borland, Austin, TX) program was written to control data collection from the capnographs and communication with the valves in the simulator enclosure. It also controls the calibration and simulation algorithms, and contains a library of capnography files that can be simulated. The simulator enclosure (**Figure 3**) consists of all the hardware needed to create the varying levels of CO₂, including two pressure regulators for the gasses (both regulated to 25 psi), a proportional solenoid valve (EVP-10-0925, Clippard) for CO₂, a Data Acquisition Board (DAQ) (USB-1208FS, Measurement Computing), a valve driver circuit board, and four on/off O₂ valves.

The CO₂ flow rate is controlled by analog output voltage from the DAQ. The proportional solenoid valve's response is proportional to input current and not voltage, so the known voltage is output to a non-inverting amplifier circuit (on valve driver circuit board) to convert it to a known current. The current is then amplified using an NPN transistor, since the amount of current from the first portion of the circuit is small. An example of the valve's response is shown in **Figure 4**. The valve outputs higher flow rates for higher input currents, but it is important to note that the valve's response is not linear and exhibits a significant amount of hysteresis (which is compensated for in the algorithm).

The O₂ flow rate is controlled by digital outputs from the DAQ that go to the circuit board, which contains a comparator circuit for each of the four on/off valves. When the digital output is high (+5V), the output to the valve is +12V and the valve is opened. When the digital output is low (0V), the output to the valve is 0V and the valve is closed. Each valve has a different orifice resistor attached, causing each valve to output O₂ at a different flow rate (ranging from 3 to 14LPM) when turned on. By turning on different combinations of the valves flow rates from 3 to 25 LPM can be used (similar to a binary number system).

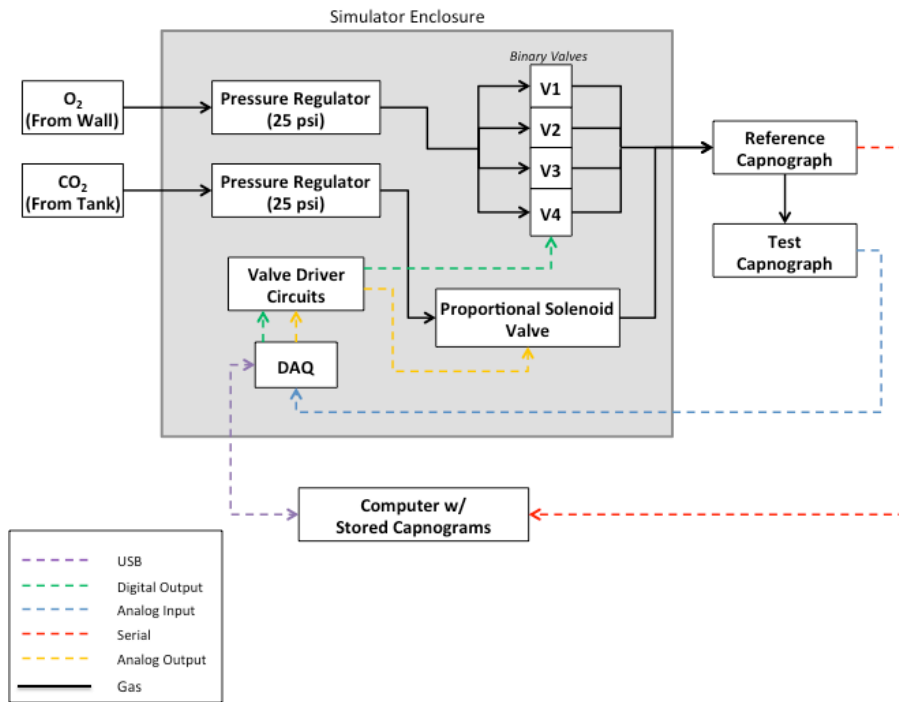


Figure 2: Block Diagram of Simulator Design

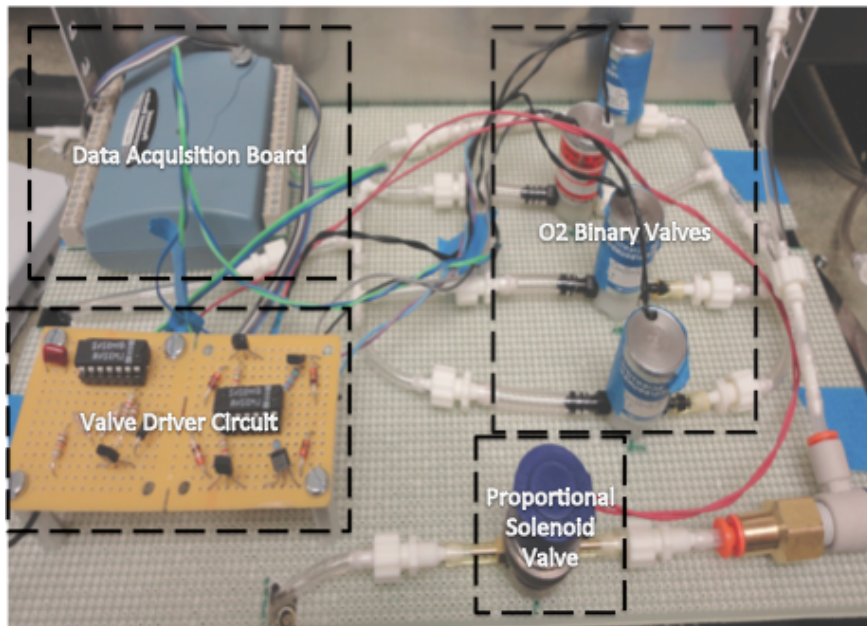


Figure 3: Picture of Interior of Simulator Enclosure

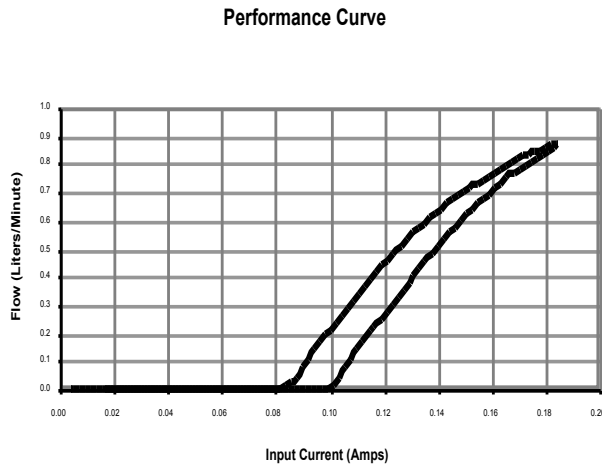


Figure 4: Proportional Solenoid Valve’s Performance Curve

The reference capnograph is a mainstream capnograph used for calibrations and as a reference for comparison during simulations. For our design a NICO₂ (Phillips Respironics, Wallingford, CT) was used as the reference capnograph. The computer collects CO₂ values over time from the capnograph through serial communication at 100Hz sampling frequency.

The test capnograph can be any capnograph that the user wishes to evaluate for dynamic performance. The computer collects relevant data from the test capnograph through analog input to the DAQ at the manufacturer’s specified sampling frequency. The test capnograph’s performance would be compared to the reference capnograph’s performance for differences in sensitivity and specificity in breath detection, as well as accuracy and precision in detecting changing CO₂ levels.

Algorithm

A block diagram for the current algorithm is shown in **Figure 5**.

(1) The program begins by asking the user to select a stored CO₂ waveform file from a library. These files are comma delimited text files containing CO₂ waveform data recorded at 100Hz. The recorded values in these files include times, flow (LPM), pressure (cmH₂O), CO₂ (mmHg), volume (mL), and breath markers. Once a file is selected, the times, CO₂ values, and breath markers are stored to arrays. The CO₂ levels are the setpoint values that need to be mixed during the simulation. The setpoints will be used to

guide the simulation. **(2)** The maximum and minimum CO₂ levels are also recorded from the downloaded file, since they represent the highest and lowest levels of CO₂ the simulator needs to be able to create.

(3) Based on the maximum level of CO₂ needed, a constant O₂ flow rate is selected from a stored table within the program. The selected O₂ flow rate, when added to the maximum CO₂ flow rate (~1LPM), needs to simulate the maximum CO₂ setpoint from the downloaded file.

(4) Once the file has been downloaded and the O₂ flow rate has been selected, the calibration begins. **(5a)** The user has the option to upload an existing calibration or to **(6a)** begin a new calibration. **(5b)** If the former is selected, the user will be prompted to select a calibration file to download. The values from this file will be stored into calibration arrays that will serve as a lookup table for voltage/CO₂ during the simulation. **(6b)** If the latter option is selected, the program begins

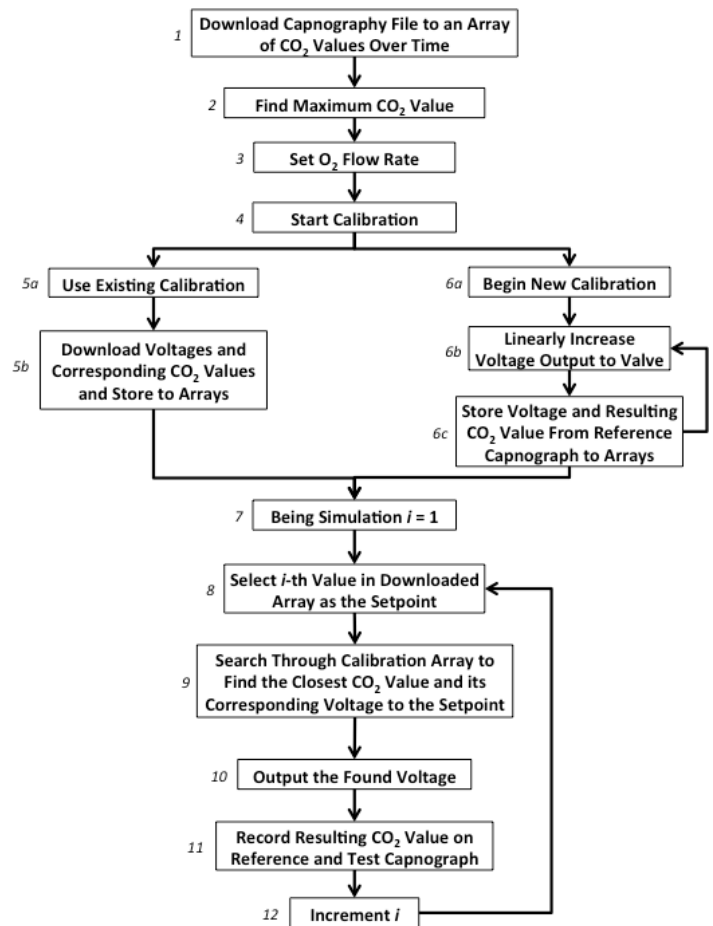


Figure 5: Block Diagram of Algorithm

its standard calibration by connecting the reference capnometer for data collection. The calibration utilizes a pulsing scheme to minimize the valve's stiction and hysteresis. Each voltage has an associated pulse sequence that lasts .02 seconds. The voltage is pulsed high (+.05V above the value) in the first .01 seconds and then is pulsed low (-.05V below the value) in the second .01 seconds. Then the voltage is incremented by .001 V. For example, if the voltage value were .351V, the voltage output would be .401V in the first .01 seconds and .301 in the second .01 seconds. Then the voltage value would be incremented to .352. **(6c)** After every voltage output, the resulting CO₂ value is recorded to an array and file. The array serves as a lookup file for the simulation, and the file can be saved and reused later. An example calibration is shown in **Figure 6**.

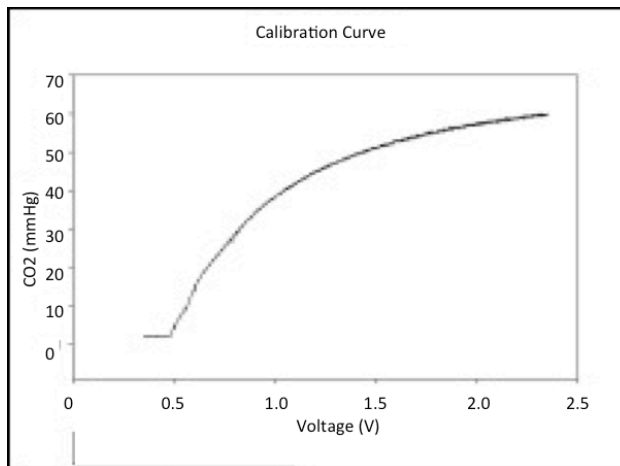


Figure 6: Sample Calibration Curve

(7) Once the calibration is complete, the simulation begins. **(8)** It begins by selecting the first CO₂ value in the downloaded array to be the setpoint (the value trying to be simulated). **(9)** Next, the program searches through the lookup table to pick the CO₂ value, and its corresponding voltage, that is closest to the setpoint. **(10)** Once found, that voltage value is output to the proportional solenoid valve using the same pulse sequence described in the calibration. **(11)** As the simulation occurs, all data from the reference and test capnometer is recorded to a data file for future processing. **(12)** A new CO₂ setpoint is selected every .02 seconds (after the previous pulse is completed). This is repeated until the

user ends the simulation or the end of the simulation file is reached.

Testing

The simulator was tested using five different capnography files: 1) Adult ICU, 2) Adult OR, 3) New Born, 4) Pediatric, and 5) Noisy Waveform. These five files are a good representation of capnograms because they include fast and slow respiration rates, different levels of CO₂, and different shapes in the waveforms. Simulation data was collected for each file over five minutes. After collecting, data from the reference capnograph was compared with the expected waveform using cross correlation coefficients (CC), R² values, and mean squared errors (MSE). No data using the test capnograph was collected for this paper, since the current goal is to optimize the simulator before testing the performance of multiple capnographs.

III. RESULTS

The results of the five simulations are shown in **Figure 7**. The red trace is the simulator's response and the black trace is the expected response (from the downloaded file). The statistics calculated are shown in **Table 1**.

IV. DISCUSSION

The initial results from the simulations were very promising. Four out of five files had mean squared errors lower than 5 mmHg and all five files had R² values greater than .97.

Parameters

Although the initial results are very promising, there are many parameters in the model that can still be optimized to minimize the valve's nonlinearity and hysteresis, while maximizing the simulator's performance.

One thing that can be changed during the calibration is how long to hold each voltage value until a corresponding CO₂ value is recorded. The reason for doing this is that there are a number of components of the simulator that can cause a delay before a steady state CO₂ value is reached. There is a small delay from the proportional solenoid valve (<10ms) and the reference capnograph (<20ms).

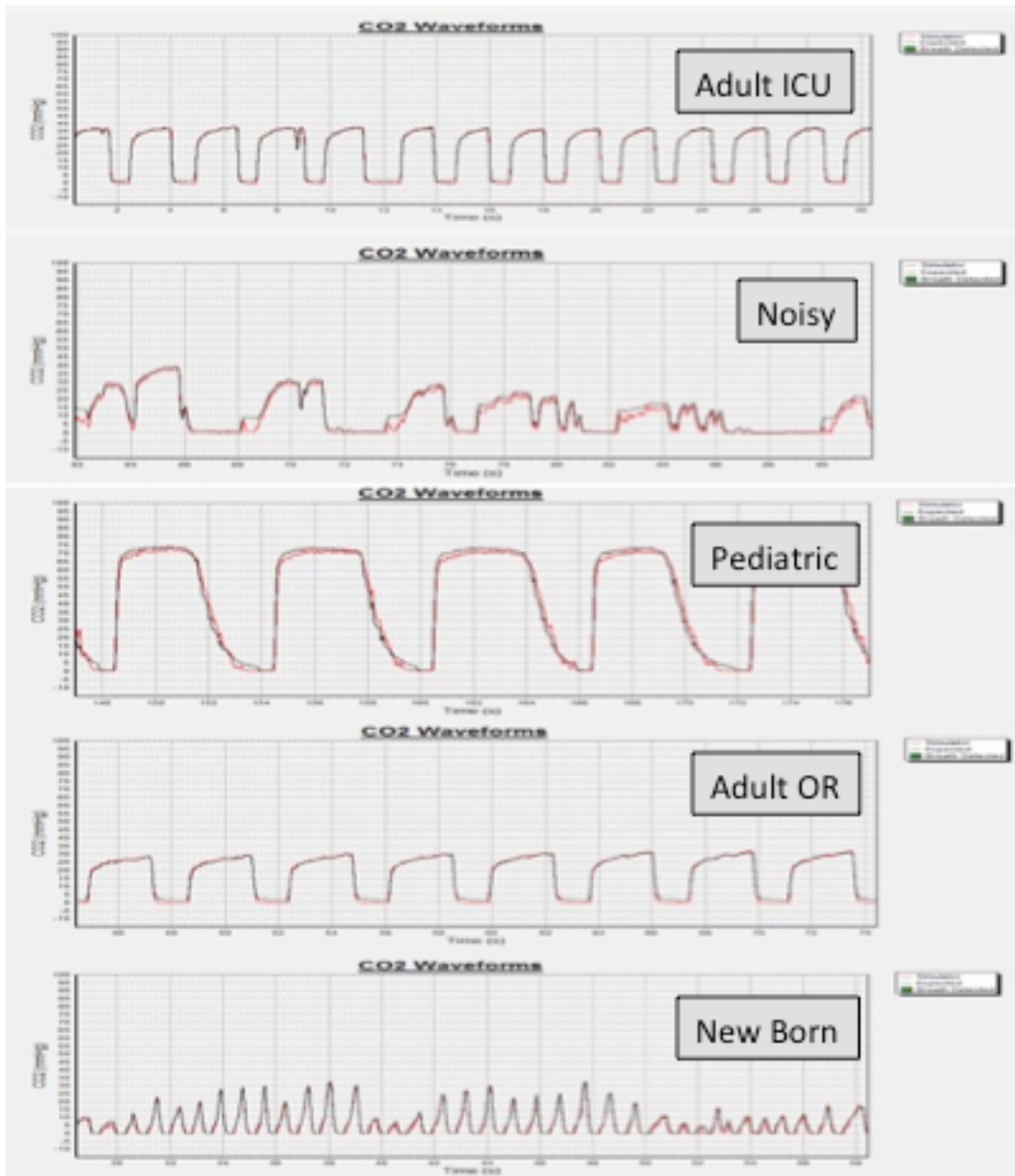


Figure 7: Screen Shot of Simulations (black trace – expected; red trace - simulator). Y-axis shows CO₂ partial pressure and ranges from -10 to 100 mmHg. X-axis shows time and ranges from 0 to 30 seconds.

	<i>MSE</i>	<i>CC</i>	<i>R²</i>
Adult ICU	1.8026	0.9977	0.9954
Noisy Data	4.2879	0.9941	0.9882
Pediatric	15.1139	0.9921	0.98420
Adult OR	1.8735	0.9979	0.9957
New Born	1.5835	0.9899	0.9800

Table 1: Statistics From Simulations

There is also a delay factor that results from the length of time it takes the gas to travel from the proportional solenoid valve to the reference capnometer (via the tubing). Another factor that can be changed during the calibration is the voltage step size (which is currently set to .001). This means that a CO₂ value is recorded for every .001 V increment. It is unclear at this point if this voltage increment can be increased to result in a quicker calibration, without compromising the simulator's performance.

The simulation portion of the algorithm also contains a number of parameters that can be optimized. The first thing that can be changed is how often a new setpoint is selected and how far ahead in the file a value is chosen. The reason for doing this is because of the delay factors mentioned earlier. Another change that can be made is to turn the valve off below some level of CO₂ (ex. 1mmHg). This can be done to avoid a slow drop off time and maximize the simulator's performance. The last thing that needs to be evaluated is whether a threshold needs to be passed before a new voltage is output. For example, at the top of the calibration curve a small change in voltage results in a very small change in CO₂. However below that region, a small change in voltage result in very large change in CO₂. It is possible that the sensitivity could be changed in these different regions of the curve to optimize the simulator.

Finally the last thing that can be optimized is the pulsing scheme used in both the calibration and the simulation. The factors mentioned should all be optimized over the five files that were tested to choose the factors that work the best for the most files. A model that minimizes mean squared errors (MSE) will probably be selected.

Future Work

In addition to optimizing the algorithm used for the simulator, a number of other tests will need to be performed to evaluate the strength of the simulator in testing capnometers.

The resulting simulator's response should be compared to the originally recorded response for sensitivity and specificity in terms of breath detection. It is important that the simulator is still eliciting the same breath detection response (the

same number of breaths at the same time points) recorded in the original file to ensure this is an accurate and valuable simulator. In addition, tests will need to be done on test capnometers to see how their response compares to the reference capnometer before building a standard testing protocol.

V. CONCLUSION

The capnogram waveform simulator presented has the potential to integrally change the way capnographs are tested and compared. Our device improves upon current testing protocols by testing capnographs with clinically relevant waveforms. With further research and optimization this could be a very useful tool. In addition to testing capnographs, it could also be used as an educational tool for training residents to understand and recognize different capnograms.

VI. REFERENCES

- [1] Capnography Reference Handbook. Respironics, Inc. 2004. Available http://www.orsupply.com/docuploads/1023317_CapnogRef_Hndbk.pdf.
- [2] Standard Specification for Minimum Performance and Safety Requirements for Capnometers. F1456-01: American Society for Testing and Materials. 2001.
- [3] Medical Electrical Equipment — Part 2-55: Particular requirements for basic safety and essential performance of respiratory gas monitors. ISO/FDIS 80601-2-55: International Organization for Standardization. 2010.
- [4] Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors. ISO 21647: International Organization for Standardization. 2004.
- [5] Shakya, K., Deegan, C., Hegarty, F., & Markham, C. Dynamic response measurement of clinical gas analyzers." Proceedings - IEEE Symposium on Computer-Based Medical Systems. 2005: 165-170.