Final Report for MTHE 393

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1 Executive Summary

In the United States and other countries, medical patients are often administered insufficient or excess amounts of anaesthesia during medical procedures, which can lead to complications, and in some cases death. Furthermore, anesthesiologists are expensive to employ to perform a task which could be performed by a machine governed by a control system.

The course MTHE 393 requires the determination of a linear, time-invariant state-space or transfer function that heuristically models a black box system, or in other words, an unknown system. This system has a known input and known output, however, the system itself is unknown. The black box system was first shown to be linear by testing the output of a variety of input signals, and then shown to be time invariant by observing the output when a variety of sinusoidal input signals were used. The noise was then determined to be white noise after observing the difference between the averaged signals and original signals. The Savitzky-Golay filter was chosen to reduce the noise at is performed better than the other filters tested. In order to develop a heuristic transfer function, a Bode plot also had to be generated, and the zeros and poles of the transfer function were found by applying piecewise linear approximations to this bode magnitude plot. A PID controller was developed, and it exceeded the specified performance requirements.

In terms of control systems, this report examines the feasibility of implementing a control system to regulate anaesthesia doses to hospital patients. A linear and time invariant heuristic transfer function was developed to model this application of a control system.

To examine the application further the following steps were taken. A cost savings analysis was performed to demonstrate that employing such a system would reduce operational costs greatly - the break-even period would be less than a year. A rigorous analysis was also performed to examine the environmental, social, and economic impact of such a system on key stakeholders such as hospital staff, patients, anesthesia manufacturers, and the hospital organizations, to demonstrate that this implementation would yield an overall positive impact on the stakeholders. Regulatory, ethical and safety concerns were also considered to conclude that this application would allow for an ethical, safe, and legal implementation of a control system. Metrics to gauge the application's implementation success were also established.

2 Introduction

2.1 Problem Definition

As computational power has made tremendous progress in recent history, control theory has been able to be applied to various applications to model and control black box systems. As stated earlier, the goal of this project is the determination of a linear, time-invariant state-space or transfer function that heuristically models a black box system. The system must be proved to be linear as well as time-invariant. The nature of the noise must also be identified, and an optimal filter must be selected to reduce this noise. A PID controller must then be developed based off of the corresponding Bode plots that must be generated. This controller must also meet the required performance criteria.

An application of such a control system must also be developed. It must first be determined which of the considered application options should be chosen based on their relation to the black box system and their impact on key stakeholders. To gauge the feasibility of such an implementation, the economic, environmental and social impact have to be determined on key stakeholders. Ethical, safety and regulatory concerns of the chosen application will also have to be analyzed in order to ensure that the application does not violate any of these considerations.

2.2 Approach

The problem solving approach first consisted of creating an equation representative of the scenario in the application, and passing it through the black box as an input. The following report will outline the process by which the black box was examined in relation to various inputs to conclude that the system is linear and time-invariant. The report will also discuss the various filtering methods that were considered, and quantitative justification as to which one was most effective. A bode plot based on the filtered data will also be demonstrated, from which a transfer function will be developed. The PID controller parameters were first developed using guidelines from references, and fine tuned using matlab integrated libraries. A mind-map was used to determine that this application was the most beneficial and practical, and further analysis was performed on key stakeholders to determine the net benefit of the application. Finally, a yearly cost savings analysis was performed and was compared to the initial costs to determine that the system would be economically favourable.

3 Methodology and Results

3.1 LTI Justification

An LTI system is a system that is both linear and time invariant.

For a control system to be linear, the following must hold: for u_1 and u_2 and for some real constant α, it must be that $f(\alpha u_1 + u_2) = \alpha f(u_1) + f(u_2)$. For a control system to be time invariant, the output at any shift of time in input must be equal identical to the original output, only shifted.

However, the system provided is a black box system therefore, the proper mathematical proofs could not be conducted. Thus, LTI was shown as follows below.

Linearity was justified by using a number of inputs such as polynomial functions, sinusoidal inputs, and exponential functions and capturing the output. Linear combinations of such functions were then entered as inputs and compared to the linear combinations of the output of the same functions to reflect the mathematical definition described above. In all cases, the linear combinations of inputs produced outputs equal to the combination of the outputs thus it could be concluded for the purposes of our project that the system is linear. Below is one such example, comparing the outputs of $f(3t + t^{3)}$ and $3f(t) + f(t^3)$.

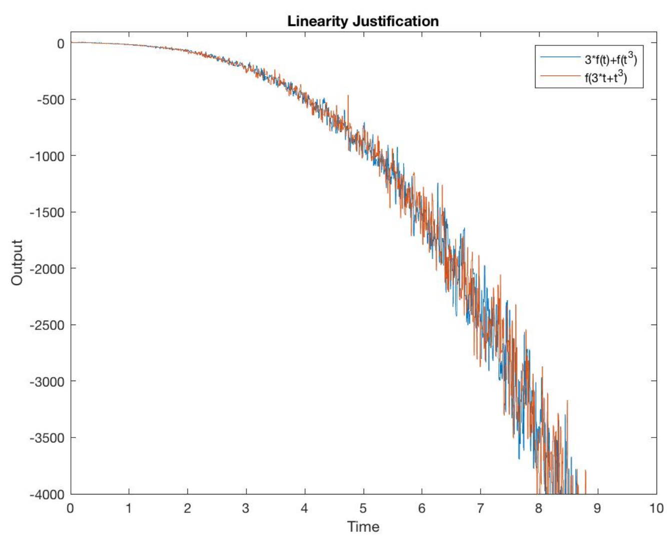

Figure 1: Justification of linearity through the comparison of the outputs of$f(3t + t^3)$ and $3f(t) + f(t^3)$.

From the figure above it is clear that the outputs are almost identical, however we can also quantitatively analyze the outputs through the root-mean-square error (RMSE) and the root-mean-squared error as a percentage of the maximum amplitude (pRMSE). For this project, an acceptable error for the pRMSE is $< 5\%$.

$$RMSE = 2.8652e + 03$$

$$pRMSE = \frac{2.8652e + 03}{5.4099e + 04} = 5.3\%$$

While the pRMSE is not quite under the limit for the acceptable error, given the differences in length of amount data plots for the two functions and the amount of noise that still exists in the data, 5.3% is a sufficient pRMSE for the justification of linearity.

Time in-variance was justified use of sinusoidal functions at different shifts in time. For a time invariant system it would be expected that the same output was produced just shifted on the graph according to the shift in time. For all such cases, the aforementioned result was found. See below a plot of sin(t) and sin(t+4), where it is clear that the outputs the two functions are the same, just shifted.

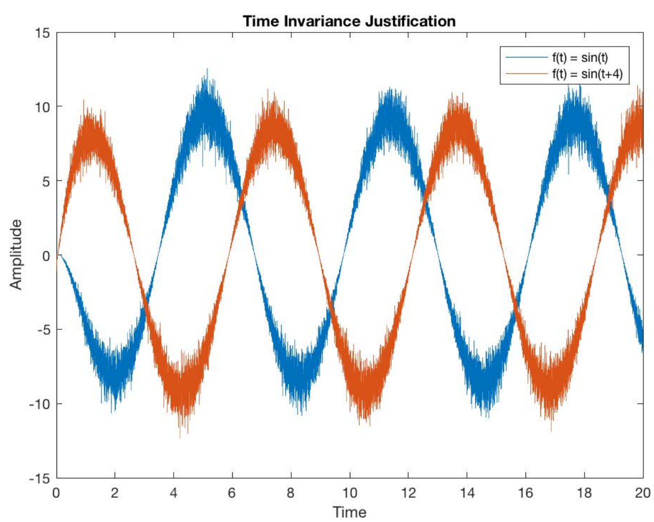

Figure 2: Justification of time in-variance through the comparison of the outputs of sin(t) and sin(t+4).

Similarly, the outputs can be compared quantitatively using RMSE and pRMSE. Using Matlab, the RMSE was found to be 0.6567 and the maximum amplitude to be 14.2755.

$$RMSE = 0.6567$$

$$pRMSE = \frac{0.6567}{14.2755} = 4.6\%$$

4.6% is within the acceptable error, and like the error in the justification for linearity, is likely due to the noise in the system. Thus, we can conclude for this projects research that the system is Linear and Time-Invariant (LTI).

3.2 Determining the Type of Noise

The difference between the averaged signals and the original signal was determined to find the largest amplitude. From Figure 3, we can see that the largest amplitude is -2.8, implying insignificant noise on the signal.

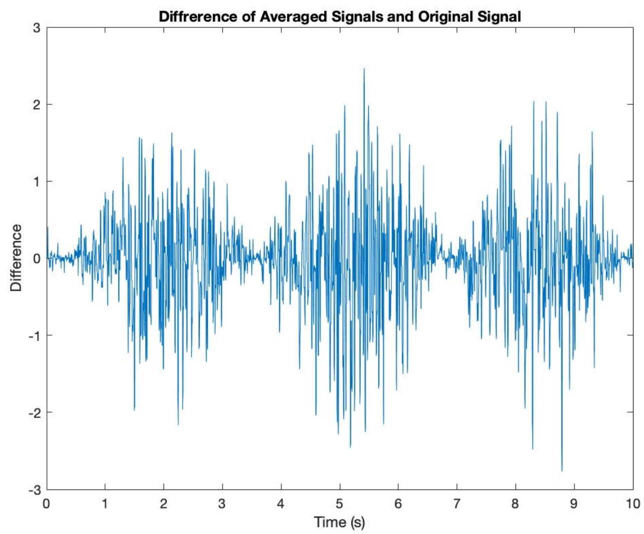

Figure 3: Graph of Difference of averaged signals and original signal

This can be further exemplified by the following histogram:

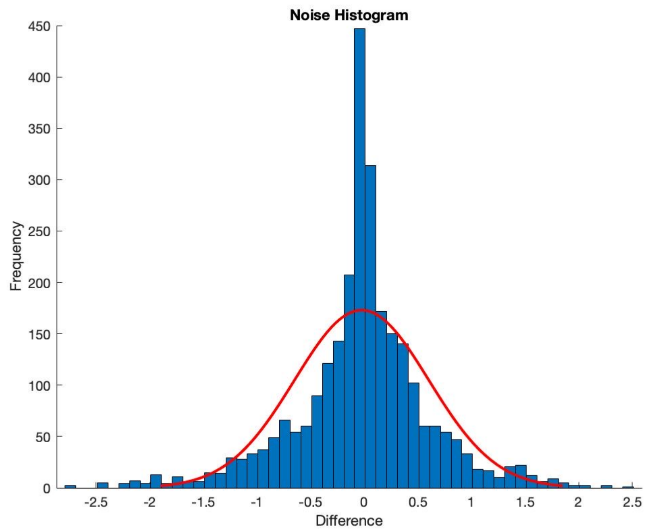

Figure 4: Histogram of the noise

Fig. 4 clearly displays a normal distribution with a median approximately equal to zero. As the mean is also approximately equal to zero, it can be concluded that the noise the system is experiencing is white noise.

3.3 Filter Comparisons

Our group first generated a list of potential noise filtration methods possible on MATLAB. This consisted of the smooth and hampel functions. After initial trials in the workshop, we attempted using the Gaussian, Mean, Median and Savitzky-Golay filters. From Fig. 5, the Savistky-Golay method is clearly the most effective smoothing function. At the peaks and troughs of the sinusoidal signal, the other filtering methods greatly reduce the magnitude of the output signal, while the Savitsky-Golay method does not. The Savitsky-Golay method is accomplished by fitting successive subsets of adjacent data points to low degree polynomials by applying the method of linear least squares. This filtering method is most effective at reducing high-frequency noise in a signal, which is why it is highly effective for our output signal – Fig. 5 depicts high frequency noise in our signal.

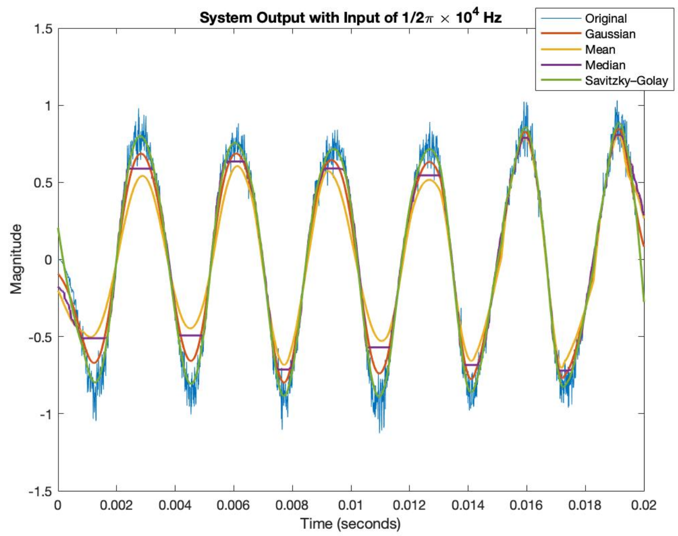

Figure 5: Output signal as well as output signal with Gaussian, median, mean, and Savistky-Golay filtering methods applied.

3.4 Bode Plot Generation

In order to model the system with a transfer function, a magnitude Bode plot has been constructed as seen in Figure 6. A corollary of the system being both linear and time-invariant is that for input sinusoids, the system always outputs sinusoids. Output sinusoids have the same frequency as input sinusoids but may have a different amplitude and phase shift. Using this fact, 33 sinusoids of varying frequency have been provided as input to the system. The output data was filtered using the filtering method explained earlier, and their magnitudes have been collected and plotted against the corresponding sinusoid frequency in Figure 6.

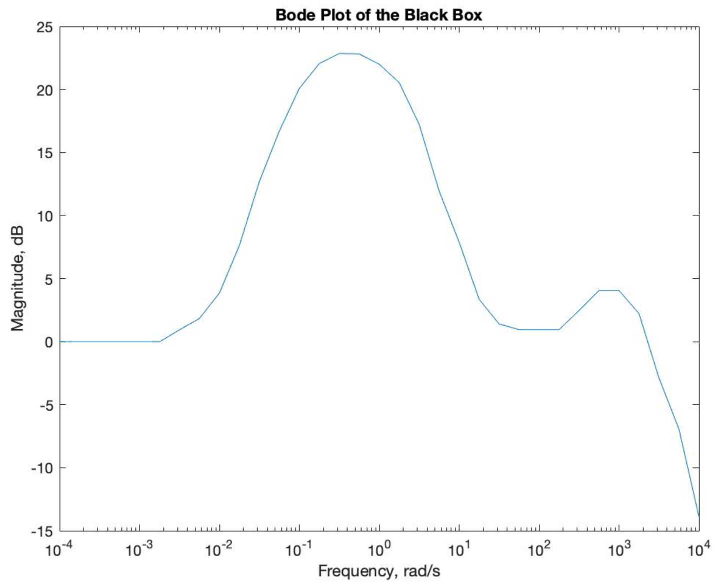

Figure 6: Magnitude Bode plot of the system; $A =$ amplitude and $w =$ frequency on the axes.

The key assumption in measuring amplitudes of outputs to sinusoids was that outputs should be sinusoidal. The transient response of some frequencies led to outputs that were not sinusoidal across the output domain. For instance, very large frequency inputs (i.e. inputs in the set $\{\sin(wt) : w \geq 3162\}$), the first period of the output sinusoid had a vertical shift that the remaining periods of the output did not have. This is shown in Figure 7. Note that the first period does not oscillate about the horizontal axis, while the remaining periods all vary from about -0.5 to $+0.5$ magnitude (about the horizontal axis).

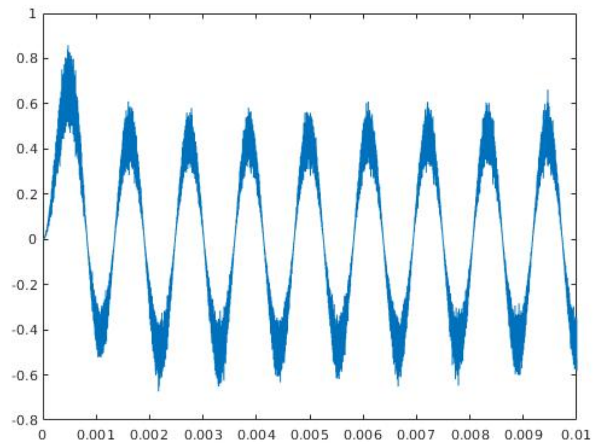

Figure 7: System output to an input of $\sin(5623t)$ (with noise).

To combat this, the amplitudes of output sinusoids were calculated using only the steady-state response. From the remaining periods of the output in Figure 7, the magnitude was then computed to be the half maximum distance between any two points in the filtered signal. This calculation resulted in a magnitude of about 0.5 for this signal. Incorporating the transient response into the magnitude calculation would have resulted in an amplitude of about 0.6.

Due to the transient response of the system, finding the phase shift of output sinusoids presented a problem. To develop the magnitude plot only the steady-state response was considered, however to develop a phase plot, it is the transient response that is crucial since this is where the phase shift is determined. For instance, in Figure 8, the transient response produced a small peak near the origin, from which it made difficult to calculate a phase shift.

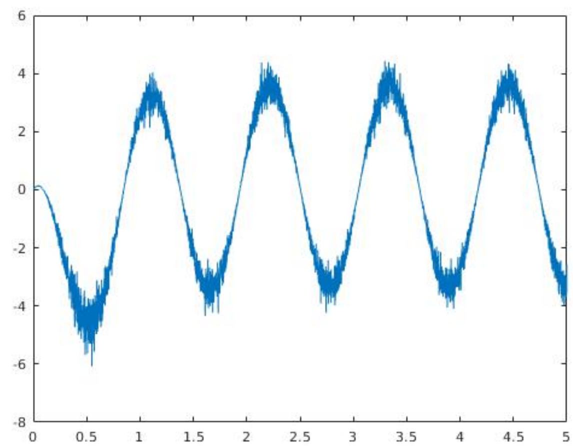

Figure 8: System output to an input of $\sin(5.6234)$ (with noise).

Since the poles and zeros of the transfer function can be heuristically determined from the magnitude plot, the use of the phase plot is to find the gain of the transfer function. Instead of pursuing the Bode phase plot method of finding the gain, the steady-state step response was used, as is described in section 3.6

3.5 Transfer Function

3.5.1 Zeros and Poles

Zeros and poles of the model transfer function were found by applying piece-wise linear approximations to the Bode magnitude plot in Figure 6. The intersections of the piece-wise linear approximations gave the break frequencies: the frequencies were there was a change in slope in the linear approximation. Using the break frequencies and changes in slope, zeros and poles of the transfer function were found. The results of this procedure are recorded in Table1.

Break Frequency (rad/s)	Change in Slope (dB/decade)	Pole or Zero
0.002	$+20$	Zero
0.3	-20	Pole
0.5	-20	Pole
50	$+20$	Zero
200	$+20$	Zero
600	-20	Pole
1000	-20	Pole

Table 1: Poles and zeros of the heuristic transfer function modelling the black box.

These poles and zeros were further adjusted to better model the black box. This analysis is discussed in section 3.6. Applying these adjustments, for gain K, the transfer function is given by

$$H(s) = K\frac{(s+0.0055)(s+25)(s+190)}{(s+0.1)(s+1.5)(s+500)(s+1000)}.$$

3.5.2 Gain

Rather than using the Bode plot, the gain of the model transfer function was found using the steady-state of the step response. The Laplace transform of the step input is $U(s) = 1/s$, so when applying a step input, the output in the Laplace domain is given by

$$Y(s) = H(s)U(s) = K\frac{(s+0.0055)(s+25)(s+190)}{s(s+0.1)(s+1.5)(s+500)(s+1000)}$$

where K is the unknown gain. This rational function has a partial fraction expansion of the form

$$Y(s) = K\left(\frac{\alpha_0}{s} + \frac{\alpha_1}{s+0.1} + \frac{\alpha_2}{s+1.5} + \frac{\alpha_3}{s+500} + \frac{\alpha_4}{s+1000}\right)$$

for some constants α_0, α_1, α_2, α_3, and α_4. Taking the inverse Laplace transform of the above expression gives the output in the time domain as

$$y(t) = K\left(\alpha_0 + \alpha_1 e^{-0.1t} + \alpha_2 e^{-1.5t} + \alpha_3 e^{-500t} + \alpha_4 e^{-1000t}\right).$$

As t gets large in the above expression, all the exponential terms decay to 0, leaving the equation

$$y(t) = K\alpha_0.$$

However, for large t, the step response approaches its steady-state value, which for the black box is $y(t) = 1$. Therefore the gain K of the model transfer function is

$$K = \frac{1}{\alpha_0}.$$

Since α_0 is just a function of the zeros and poles of the transfer function, it can directly be computed as $\alpha_0 \approx 0.00034$. Hence $K \approx 2900$. To better match the Bode magnitude plot, the gain of the model was reduced to $K = 2500$. The final transfer function is then given by the equation

$$H(s) = 2500\frac{(s+0.0055)(s+25)(s+190)}{(s+0.1)(s+1.5)(s+500)(s+1000)} \tag{1}$$

.

3.6 Efficacy of Model

The effectiveness of the transfer function can be seen in the comparison of its Bode plot to the experimental Bode plot and its predicted step response. In comparing against the experimental Bode plot, the zeros, poles, and gain of the model transfer function were heuristically adjusted so that the model's transfer function would match the experimental data. In Figure 9, this relationship is clearly visible. The largest difference between an experimental data point and the model's predicted output magnitude is for very small frequencies: a difference of about 1.2dB. Therefore, the average is much less than 1.2dB, which is also clearly apparent in the figure.

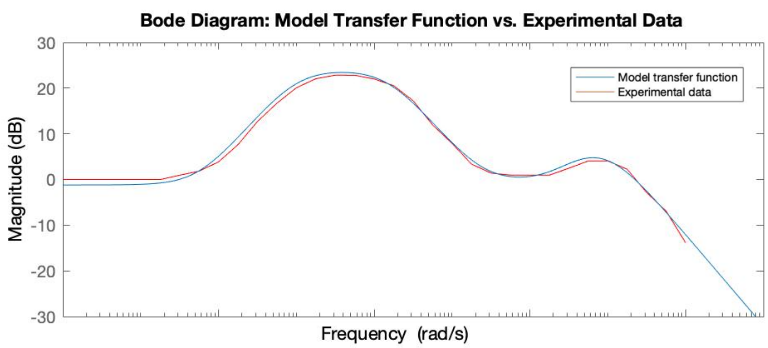

Figure 9: Magnitude Bode plot of experimental data versus the Bode plot given by the model transfer function.

The second method of comparison for analysis of the efficacy of the transfer function is how it predicts the step response. These two outputs are presented in Figure 10. There is a large error from the median of the actual transient step response, of over 2 in magnitude. However, the system presents a large amount of noise in the transient response so this is expected. The error of the steady-state response is much smaller at less than 0.15 in magnitude.

3.7 Controller Design

The process of designing a controller for the system began with determining the effects that altering PID values had on the system. A PID controller is a proportional–integral–derivative controller and is used to tune the controller parameters of a system [1]. The proportional control, integral control, and derivative control each affect the system differently, so the proper tuning of the PID controller was found to be crucial to the success of the system. After some research, the table below was found to help determine how to properly tune the controller on a closed loop system.

CL Response	Rise Time	Overshoot	Settling Time	S-S Error

P	Decrease	Increase	Small Change	Decrease
I	Decrease	Increase	Increase	Eliminate
D	Small Change	Decrease	Decrease	Small Change

Table 2: Effects of the proportional control (P), integral control (I), and derivative control (D) on a closed loop system[2]

This table was a useful reference in determining the starting values of the PID controller. The MATLAB PID Tuner Extension was also used finely tune the controller. This application allowed the group to adjust for response time speed as well as for a more robust or aggressive transient behaviour. The process of finding the right PID values took a lot of trial and error and this application helped the process by finding the right ratios between the different controls. A proper filter was also needed in order to smooth out the noise acting on the system. The process of finding a proper filter took some trial and error, but it was determined that a Savitzky-Golay filter was most effective at reducing the noise. This type of filter was then added to our state space system. The design for the controller was done in Simulink, with the full system shown below.

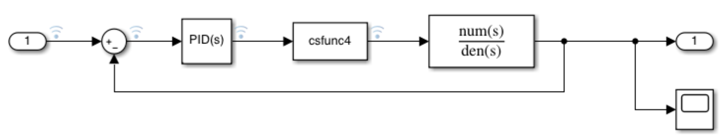

Figure 11: Model of the system

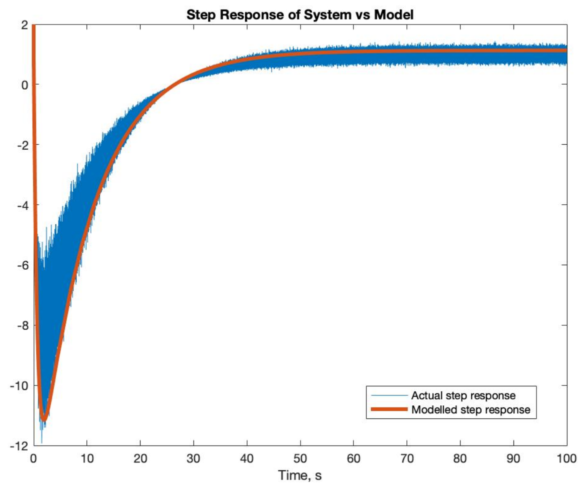

Figure 10: Step response of the black box versus the step response of the model.

3.7.1 Evaluating Controller Performance

Shown below is the plot of the signal after the controller was used on the system.

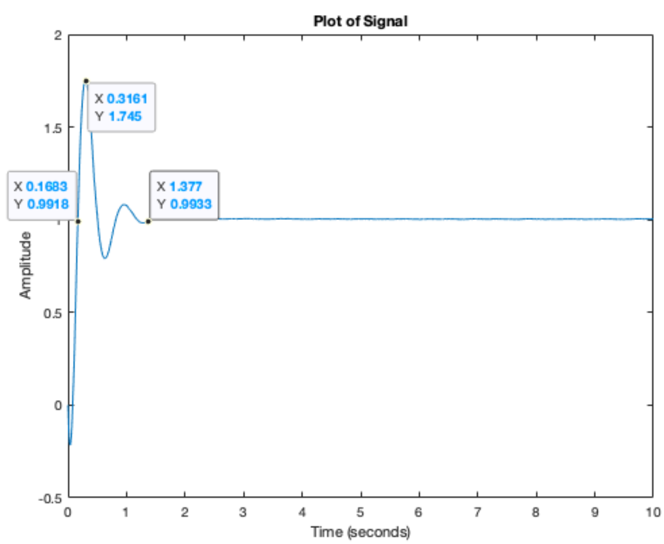

Figure 12: Signal after controller

The controller used in this system was able to exceed the required targets for the group. From the table shown below, one can see that each value was demonstrated to be under the system targets.

	System Targets	Actual Values
Steady State Error	± 0.08	± 0.004
Rise Time (s)	2	0.1683
Overshoot	1.8	0.745
Settling Time (s)	1.6	1.377
Settling Time(ϵ)	0.08	0.07

Table 3: System Targets compared with Actual Values of the system

3.7.2 Closed-Loop Stability

For the closed-loop system, the overall transfer function H is given by

$$H(s) = \frac{C(s)P(s)}{1 + P(s)C(s)}$$

where P is the plant's transfer function given in Equation 1 and C is the controller's transfer function. The function $s \mapsto C(s)P(s)$ has only one pole in the right-half of the complex plane, so by Nyquist's stability criterion the closed-loop system is stable if the Nyquist contour encircles -1 once. However, the Nyquist contour illustrated in Figure 13 does not encircle -1, so the closed-loop system is not stable.

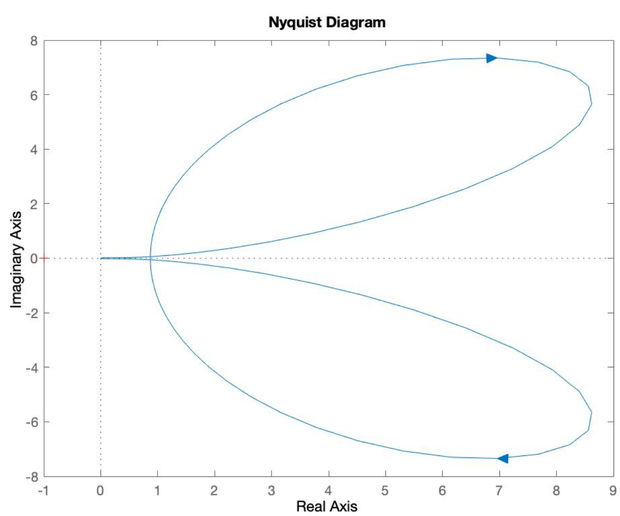

Figure 13: Nyquist plot of the closed-loop system incorporating the controller.

Unfortunately, this instability is not desirable of the closed-loop system. This instability was achieved through only designing the controller such that the step-response was optimized.

4 Application: Regulation of Anesthesia Administration

Regulating the Administration of Anesthesia is the incredibly difficult task that is prescribed to anesthesiologists. They are considered experts in their field, and have one of the most difficult professions due to the nature and required precision of anesthesia. This project will cover the positives and negatives of implementing such a system in the United States, and then in the future, in other countries as well.

Through utilizing a model which can determine the amount of anesthesia individuals need, the amount required for the appropriate level of consciousness can be better determined.

The issue that arises is that due to the difficulty of their profession and the costs of employing an anesthesiologist, there is often no way of ensuring that an appropriate quantity of anesthesia is being administered. Often times the effects of this are minimal, but patients would have benefited from a decrease or increase in anesthesia. However, other times, the situation can be disastrous. Through employing a machine which can check the dosage, patients can be delivered better suited amounts of anesthesia.

4.1 Stakeholders

A stakeholder table is available to reference in the appendix. The stakeholders examined in this table, are the same stakeholders discussed in the Triple Bottom Line Analysis.

4.2 Mathematical Modelling

To complete the mathematical modelling section, the questions which were provided in Week 9 were used as to provide guidance. These questions aided in ensuring that the chosen application was able to be modelled through a control system.

State Variable	The state variable is level of consciousness. The level of consciousness can be determined through using bispectral index monitoring. A bispectral index (BIS) monitor is utilized to assess the depth of sedation when administering anesthesia during surgical and medical procedures; the depth of sedation is calculated through measuring cerebral electric activity using an electroencephalogram (EEG) [18]. Thus, using a BIS monitor would allow for the depth of sedation, or in other words, level of consciousness, to be assessed in a quantitative manner.
Why	The patient should be asleep and unable to feel pain during surgery. If the state remains uncontrolled, patients can stay asleep for an indefinite amount of time or wake up mid-surgery. The state can be measured based upon the hours required for surgery, and may take into consideration a short duration post-surgery to limit pain.
Control Input	Control input is the amount of anesthesia provided. The amount of anesthesia administered directly controls the level of consciousness of the patients. This means that it impacts how long the patient will be asleep and when they will wake up.

Table 4: Mathematical Modelling Requirements for Application 1

A visual depiction of the closed loop model is also shown below for more clarity.

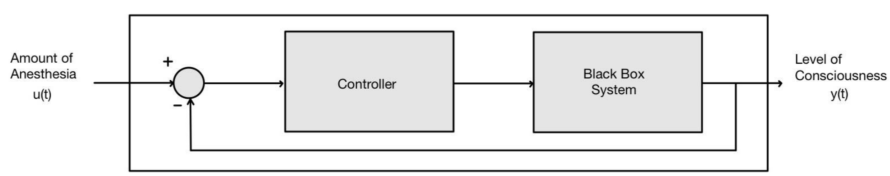

Figure 14: Closed loop model representation.

4.3 Brainstorming

To determine what application to pursue, the group utilized the mind-map method. The mind-map contains the thought process behind the chosen two applications, and the applications which were discarded.

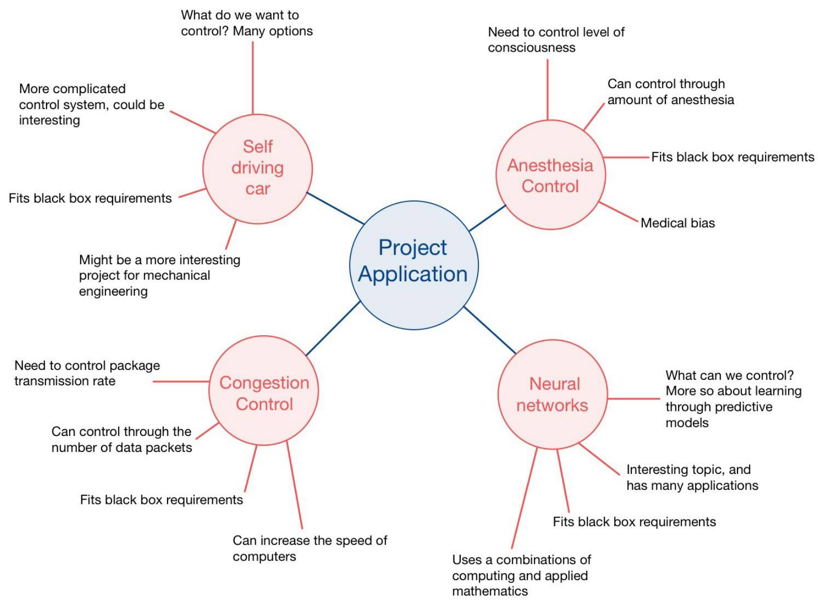

Figure 15: Mind-map of potential applications and their relations to control.

As can be seen in the mind-map, the chosen applications picked are due to their relation to the black box system and control systems. The self-driving car and neural networks did not have clear state spaces and control variables which made them less suited for this project.

Between the applications of Congestion Control and Anesthesia Control, Anesthesia Control was chosen due to its positive impact on its stakeholders (patients, anesthesia hospital staff, hospitals, manufacturers and government) in terms of the economical, social and environmental aspects. Once the application of Anesthesia Control was chosen, the group then had to brainstorm and research the application to determine the necessary components for its success.

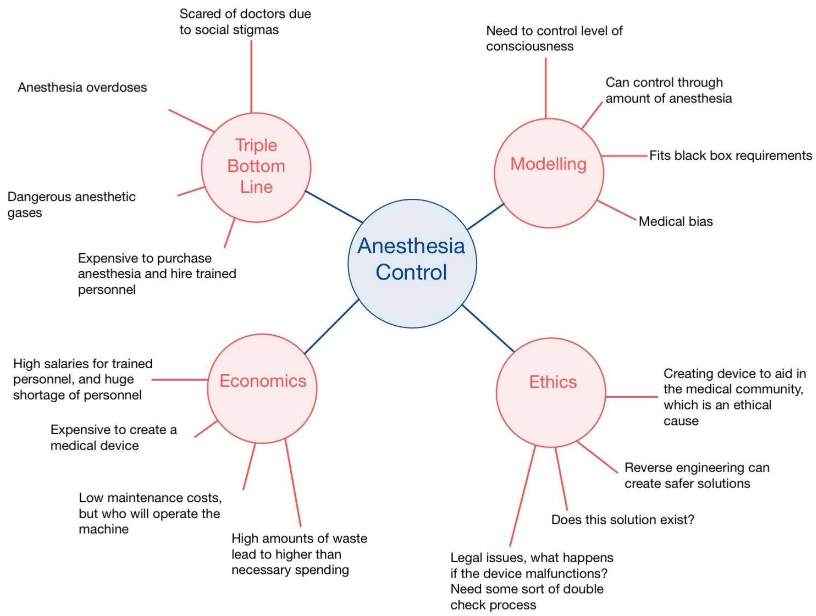

Figure 16: Mind-map of anesthesia control application and its various sections.

The branches of this mind map were then expanded on and researched in the sections of the final report.

4.4 Triple Bottom Line Analysis

It is essential that the impacts economically, socially and environmentally on the stakeholders of this project are all examined. In parallel to the Professional Engineers of Ontario's Code of Ethics, it is essential that the project that is being introduced does not harm society and the stakeholder involved. The goal is that the application will provide an overall benefit and improve people's lives.

Economically, healthcare procedures involving anesthesia can be quite expensive. "For patients without health insurance, the cost of anesthesia can range from less than $\$500$ for a local anesthetic administered in an office setting to $\$500$-$\$3,500$ or more for regional anesthesia and/or general anesthesia administered by an anesthesiologist and/or certified registered nurse anesthetist"[3]. These rates are unaffordable and can deter individuals from seeking procedures they need. Hospitals also pay large amounts to be able to have anesthesia, "average anesthesia-related cost reductions of US $\$13 - 30$ per cases multiplied by 25 million anesthetics administered annually in the USA has the potential to yield savings of US $\$350 - 750$ million"[4].

Unfortunately, there are inherent issues in the healthcare system that is utilized. There is bias in medicine, which is prevalent as it is human nature. In addition to this, most medical studies are not conducted on a diverse group of individuals, which leads to doctors diagnosing on the basis of one group. As stated by Dr. Keisha Ray "Research suggests that women and minority patients are more likely to receive less effective care than white males. But it's not as simple as personal bias or stereotypes. It's that physicians are still relying on longstanding research, clinical trials and medical training"[5]. Furthermore, there are many patients who fear surgery. This fear is referred to as tomophobia [6]. It is often a result of individuals fearing anesthesia, and having to be unconscious for surgery. While anesthesia and surgery are relatively safe nowadays, many individuals have deep seated fears which stem from discrimination and prejudice in medical procedures. For instance, "J. Marion Sims, the so-called 'father of gynecology'...developed his technique by operating on female slaves without anesthesia" [27]. These horrendous experiences lead to word-of-mouth stories, that cause a fear of surgeries, doctors and medicine overall.

One of the largest areas of environmental detriment concerning anesthesia is anesthetic gases. "Waste anesthetic gases are small amounts of volatile anesthetic gases that leak from the patient's anesthetic breathing circuit into the air of operating rooms during delivery of anesthesia. These gases may also be exhaled by patients recovering from anesthesia"[7]. WAGS (waste anesthetic gases) harm the environment, and they harm patients and doctors. Furthermore, "All volatile anesthetics are halogenated chlorofluorocarbons (halothane, enflurane, isoflurane) or fluorinated hydrocarbons (sevoflurane and desflurane) and are thus potentially damaging to the earth's ozone layer"[8]. They also contribute to climate change.

Stakeholders	Economic	Social	Environmental
Patients	In countries which do not have free healthcare, they can face large bills for medical procedures ($500 to $3,500 [3]). Through decreasing costs associated with anesthesia, ideally patients will also benefit economically through lower medical rates.	The majority of studies conducted on anesthesia are conducted on white males, which can make it more difficult to correctly determine amounts for other groups [5]. By using a device, individuals will be able to receive a higher level of health regardless of factors such as gender, race, age and others.	Patients will be decreasing their own environmental footprint by utilizing technology which correctly determines the amounts of anesthesia required. In addition to this, there will be a decreased amount of anesthetic gases which can harm the environment and humans.
Anesthesia Hospital Staff (Includes Anesthesiologists, Nurse Anesthetists and Anesthetic Assistants)	Anesthesia hospital staff may be worried about economic implications this may have, particularly anesthesiologists. However, at this stage, this would simply be aiding in calculating anesthesia quantities, not taking the position of a anesthesiologist. Thus, anesthesia hospital staff would not suffer economically.	Anesthesia hospital staff will be able to more comfortably deliver dosages to individuals whom may not have studies conducted on them, or are underrepresented in medical trials. Furthermore, “it has been estimated that more than 250,000 health care professionals in the United States…are potentially exposed to WAGs and are at risk of an occupational illness”[21]. Through decreasing anesthesia quantities, this number will decrease.	There will be a decrease in anesthetic gases in hospitals, which aids the environment and the working environment of the hospital. “The global warming potential (GWP) of a halogenated anesthetic is up to 2,000 times greater than CO2” [22]. These gases have a detrimental impact on the ozone layer [8] and also on the health of health care workers, as was touched upon in the social section.

Hospitals	If hospitals are more accurately determining anesthesia quantities that are required for surgeries, they will benefit economically [4]. This is because it will be less likely that there is an excess amount of anesthesia. Currently, “the estimated yearly cost of preventable anesthetic drug waste was $185,250” [23]. This study was conducted over 543 separate surgical cases, however, there were 217,778,00 surgeries in the United States in 2014 [24], which calculates to $7,429,719,061 of preventable waste.	If hospitals can better determine anesthesia amounts it can decrease the stigma around anesthesia being dangerous. While many sources cite anesthesia as being completely safe, there is fear in many communities [6] which are disproportionately affected by errors in anesthesia calculations.	The environmental implications of anesthesia are tremendous [7]. Through using a system which can aid in determining an appropriate amount of anesthesia, the environmental detriments caused by Anesthesia can be decreased. “It has been calculated that up to 20% of anesthetics enter the atmosphere,” [22], thus these gases have a large environmental impact.
Manufacturers of Anesthesia and Anesthesia Related Devices	Manufacturers may suffer economically if the quantities of anesthesia required are decreased. Manufacturers benefit from over-producing anesthesia. However, they also benefit economically through advances in anesthesia technology [25].	Through the environmental implications of anesthesia, manufacturers have a poor social standing. Through producing a decreased quantity, they can improve their contributions to society.	Manufacturers of anesthesia will be able to decrease their environmental footprint and their contributions to climate change, through only producing the required quantities of anesthesia.

Government	In the United States, hospitals are partially funded by the government. Through better determining the required amounts of anesthesia, the government will be saving money in the long term, and its allocated hospital budget can be used towards other projects in healthcare. As was calculated in the hospital section, there is currently $7,429,719,061 of preventable waste, thus, there is a large portion of the budget that could be applied to better causes.	This will aid in the government's reputation of supporting minority groups and their rights to equal healthcare. As has been touched upon earlier, many minority groups do not have studies conducted on them [4] which has lead to fear of anesthesia in various communities. Supporting and aiding these communities in medical procedures can result in broadening the support base of the political party in power.	Through decreasing and better determining required amounts of anesthesia, the government will support reducing the toxic waste which is produced through anesthesia. Currently, "the climate impact of anesthetic gases corresponds to about one-third of the climate impact of the use of electricity and district heating." [22] Thus, decreasing the impact of anesthetic gases would make a great different in the environmental footprint of the United States.

Table 5: Triple Bottom Line Analysis for Regulation of Anesthesia Administration

4.5 Design Criteria

It is essential that a success criteria or design criteria is created to guide the solution to the problem of anesthesia administration. In the below table, the criteria for a successful design has been outlined in a quantitative manner.

Category	Failure	Marginal Pass	Pass
Medical Procedure Safety	The safety of patients is either decreased or not impacted by the implementation of the anesthesia control device. Roughly 1 in every 100,000 to 200,000 will continue to face death as a result of anesthesia administration [9].	The safety of patients is marginally increased through the implementation of an anesthesia device. This will be considered a 25% decrease in death due to anesthesia.	Through the use of this device there is a 50% increase in the quality healthcare which can be quantified through the number of deaths as a result of anesthesia.
Medical Procedure Comfort	It does not improve their comfort level or decreases their confidence in their healthcare system.	The level of comfort marginally increases. To quantitatively determine the increase in comfort a survey will be conducted and improvement of 25% will be considered marginal.	Patients feel significantly more confident in their healthcare system and there is a 50% increase in confidence in the healthcare system.
Healthcare Professionals Safety	There are still up to 250,000 professionals exposed to toxic waste each year [21].	There is a decrease in professionals exposed to toxic waste by 25%.	The amount of healthcare workers exposed to toxic waste is decreased by 50%.
Economic Benefits	There is no significant economic benefit from implementing this device. There is either a loss or the benefit is less than $2,500,000,000 which is less than 25% of the projected benefit.	The device either results in savings from anesthesiologist costs or waste costs, but not both. The economic benefit seem from the device is greater than $2,500,000,000 (approximately 25% of the projected economic benefit in accordance to the economic analysis).	The device results in an economic benefit in terms of both anesthesiologist costs and waste costs. The economic benefit as a result of the anesthesia device is greater than $5,000,000,000 (approximately 50% of the projected economic savings according to the conducted economic analysis).

Environmental Benefits	There are still 20% of anesthetic gases entering the atmosphere [22].	Only 15% of anesthetic gases are entering the atmosphere.	There is a significant reduction in the amount of anesthetic gases entering the atmosphere, less than 10% are entering the atmosphere.

Table 6: Table outlining the design criteria and metrics for success

4.6 Economic Analysis

The costs which will be associated with this project can be divided into initial and operational categories. Initial costs will consist of research, development and employment costs. Operational costs will consist of employment costs and the cost of the used anesthesia will also be considered. In this analysis, there will be no profit considered, however, the costs avoided will be considered in the Operational Cost section.

4.6.1 Initial Costs

Initial costs for a medical device are generally quite high. As this project would be considered a medical device, it can be estimated that a “Class II 510(k) cleared medical device is approximately $30 million CAD. The development and engineering costs comprise approximately $2-5 million CAD of this total” [16]. Class II devices, are considered devices that have an intermediate risk to life [17], since the anesthesia regulation device will be working in conjunction with another professional, this classification is appropriate. If in the future, the device is to work independently, the cost of clearance for a Class III device would need to be examined [18]. These values are from a Canadian study, however, the provided statistics are for FDA Class II approval, as desired. To mitigate the cost of clinical trials, as the United States is significantly more expensive in this regard, clinical trials will be conducted in Canada, which will make these costs comparable [19].

4.6.2 Operational Costs

In general, for the administration of anesthesia, there is a trained individual. There are three main groups involved with administering anesthesia, Anesthesiologists, Nurse Anesthetists (CRNAs) or Anesthesia Assistants. Anesthesiologists typically supervise Nurse Anesthetists and Anesthesia Assistants [10].

The median salary of an Anesthesiologist is $208,000 USD [11], Nurse Anesthetists is $ 183,580 USD [10] and Anesthesia Assistants (estimated from physician assistant) is $115,390 USD [13]. Currently, there are 6,090 [14] hospitals in the United States, however, according to the U.S. Bureau of Labor Statistics, only 3,920 [11] anesthesiologists. This means that is impossible for there to be an anesthesiologist available to measure anesthesia for every surgery, or even one per hospital. Similarly, for Canada, "Anesthesia services are essential for providing surgical, obstetric and emergency services in the remote and rural areas of Canada, but there is currently a lack of adequate anesthesia services in these regions," says Dr. Beverley Orser. It is clear, that the implementation of any machine, would cost significantly lower, than to bridge even the gap between the number of hospitals and anesthesiologists in the United States, as that would cost $451,360,000 USD. To have an anesthesiologist available at all times for surgery, would cost a significantly higher amount. If it assumed that all doctors work 40 hours a week, it would cost $4,504,864,000 USD.

The costs of hiring and working to bridge the gap between number anesthesiologists and hospitals can be avoided or at least mitigated through the process of implementing a control system that can estimate anesthesia amounts. There are currently 14,030 [12] Nurse Anesthetists in the United States, which is significantly more comparable to the number of hospitals and hours needed to be worked for anesthesia administration. The system implemented can work alongside the Nurse Anesthetists and Anesthesia Assistants, and they can be trained in its operation. This eliminates any costs of having to hire new personnel to operate the system, while maintaining its social and environmental benefits. This dual system of having a control system and Nurse Anesthetists or Anesthesia Assistant, can perform similarly to the method that an anesthesiologist would be supervising anesthesia administration, in the sense that there would be at least two individuals ensuring the safety of the patient.

As was calculated in the Triple Bottom Line Table, in the Hospital Section, there is currently $7,429,719,061 of preventable waste related to anesthesia use in surgeries. For the economic analysis, it will be assumed that the device will able to decrease waste by 80%. 80% is the lower limit of generic to brand name for bio-equivalence [26]. This can also be thought of the requirement to be able to successfully release a generic drug. Thus, while a medical device is being released, since this is a direct medical benefit a similar success factor will be used, where it will be aimed to decrease 80% preventable anesthetic waste that is contributing to both environmental waste and an unsafe work environment. Through decreasing by 80% the anesthesia device will be able to decrease the cost of waste by $5,943,775,249.

The last cost that will be considered is maintenance costs. To estimate this cost, the maintenance costs for the Primus and the Zeus were used, these are both anesthetic machines, and thus, the created device can be expected to have similar maintenance rates. The Primus has a total cost of €1752.90 and the Zeus of €2322.28 [28]. The estimate that will be used is an average of these two rates, at €2037.59 or 2,433.80 USD.

Overall, this system is a faster solution than increasing the number of anesthesiologists, and is also the more economically friendly option.

4.6.3 Summary of Costs

The following table will summarize the costs explained above. Please note that all the costs in this table have been converted to United States Dollars for consistency and accurate calculations. Furthermore, the total savings assume that the initial costs are paid back in Year 1 and the entire table is representative only of the costs in the first year of operation. It is important to recognize that the first year is the most expensive year of operation, and any year where the device must be replaced, which is why it is the represented year of operation.

Initial Costs	
Development and Engineering Costs	-$1,596,125-3,990,312
Other Costs	-$22,347,086-19,952,755
Total Costs	-$23,943,306
Operational Costs (For Anesthesiologist at Each Hospital)	
Employment	$0 (will be operated by existing employees)
Maintenance	$2,434
Anesthesiologist Savings	+$451,360,000
Waste Savings	+$5,943,775,249
Total Savings	**+$6,371,189,509**
Operational Costs (For Anesthesiologist for all Hours)	
Employment	$0 (will be operated by existing employees)
Maintenance	$2,434
Anesthesiologist Savings	+$4,504,864,000
Waste Savings	+$5,943,775,249
Total Savings	**+$10,448,636,815**

Table 7: Summary of the costs regarding creating a medical device to regulate the administration of anesthesia in USD, rounded to the nearest dollar.

4.7 Regulatory, Safety and Ethical Concerns

4.7.1 Safety and Regulation

Anaesthesiologists undergo approximately ten years of post-graduate education and training before receiving their licence; it is an extremely rigorous process as doctors must be trained in every aspect of the human body on a very technical and chemical level. They must be knowledgeable of all types of potential surgeries and complications as the consequences due to too much or too little anesthesia are fatal [29]. Administering anesthesia is one of the most complicated tasks, particularly in the event of a sudden change of the patient or a complication in a procedure. In different situations, depending on the type of surgery or procedure the patient is undergoing, the change of status of the patient, procedural mistakes, unforeseen complications, the amount of anesthesia the patient requires can change immediately. As such, it is required that the patient is being monitored by a physician or anesthesia assistance fully trained under the direct supervision of an anaesthesiologist, also equipped with mechanical and electronic devices [29].

As this regulation pertains to the using a system to regulate anesthesia, it must be made clear that such a system is not to replace the role of an anesthesiologist. In many cases, machinery is able to perform better than people, and in this case while that remains true for the most part (i.e. more consistent dose, immediate reaction to changes), the system would not be able to address all potential procedural complications and the surgeons plans for how to proceed, replace physicians discretion in complicated matters, or react according to ethical reasoning about the patient's wishes or the medical code of ethics. Therefore, if the system is presented in such a way that it appears to fully replace the role of anesthesiologists it will likely not pass this regulation. This also poses safety concerns if the training of anaesthesiologists begins to diminish to save time and costs because people begin to rely too much on the control system. The years of schooling are put in place mainly to protect against any possible edge case, which also are the cases the system is the least reliable. Administration of anesthesia via a control system is also complicated as it pertains to the law, particularly if the job and training of anaesthesiologists were to change. If a patient were to not make it through a procedure due to a complication related to the anesthesia, is the liability on the anaesthesiologist, the hospital, or the company who put in place the control system? Questions like this must be thoroughly addressed before implementing such a system so that all parties are protected and aware of the risks.

Another crucial safety and regulatory concern in the implementation of such a system is the testing phase. In order to determine whether the control system is properly regulating the anaesthesia and reacting to changes in the patient, medical trials would have to be run with live patients. Although simulations are now incredibly advanced and could be used up to a point with testing, if the device is going to act as replacement for anaesthesiologist than it would require testing on live patients with the device as the sole indicator of anaesthesia levels. However, this testing would likely be deemed unethical if there is no support staff given the life or death consequences of a complication. The aforementioned regulation would even inhibit this level of testing as the regulation states the patient is under direct super vision of a fully trained assistant under supervision of an anaesthesiologist. To combat this regulation in testing and to ensure safety to the patient throughout testing and implementation, the device is to be implemented as a "Class 2" medical device. This means that it must work along side of physician assistants and not as a stand alone device, in keeping with the current regulations,

4.7.2 Ethics

Reverse engineering someone elses system is a complicated matter that walks a fine line between violating intellectual property rights and providing many benefits for future innovation, under the argument that the system has been made publicly available. It will be argued here that reverse engineering someone elses devices is unethical and despite whatever goal that you are looking to accomplish that there is a way to do so that doesn't undermine the initial engineering. For example, three reasons someone would want to reverse engineer a system is to 1) recreate the system in a more affordable way to benefit from it 2) for future innovation 3) educational purposes. If reason one was the case, then the purpose for reverse engineering is strictly to undermine the people who created the initial product which is unethical in itself. For the second case, there is potential in terms of innovation which could go towards extremely beneficial causes that the system proprietors hadn't otherwise thought of. However, in this case the more ethical approach would be to try to work with the original engineers, or pitch the idea for a stake of the monetary or another form of outcome. Lastly, for educational purposes the original engineers can be made aware and provide limitations to the reverse engineering that takes place. The fundamental part of reverse engineering is that whatever new idea or application is born from it could not take place without both the original engineer and whomever wants to reverse engineer. Therefore, if the goal of reverse engineering is not of the benefit of the original engineers then it should strictly not be done, but if it does then the ethical approach is to ensure both parties get involved and both benefit from the outcome according to their share of the work that results in end product.

5 Summary and Next Steps

The black box system was first shown to be linear by testing the output of a variety of inputs, and then shown to be time invariant by observing the output when a variety of sinusoidal inputs were used. The noise was then determined to be white noise after observing the difference between the averaged signals and original signals. The Savitzky-Golay filter was used to reduce this noise as it was determined to be the most suitable filter. After determining the poles and zeros of the Bode magnitude plot, a PID controller was developed which met the target performance values set out.

The application of such a control system to regulate anaesthesia administration was analyzed. This application was chosen over the other options considered due to it's relation to the black box system and it's high positive impact on key stakeholders. The economic analysis demonstrated that the operational cost reductions resulting from this implementation would result in a break-even period of less than one year, indicating that this implementation is economically favourable. It was also shown that the key stakeholders in this implementation would also benefit from the implementation, and that the implementation would cause no safety, ethical or regulatory issues.

Several steps must be taken to finalize the implementation of such a control application. A machine that performs the tasks dictated by the controller must be developed to carry out the implementation. Furthermore, to expand the product to be international, thorough research must be conducted on the regulatory laws of each country. Even though the control system automates the administration, a brief training program would also need to be developed to ensure the hospital can use the system effectively and safely.

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7 Appendix

Stakeholders	Stakeholder Needs	Effect on Solutions
Patients	The right to equal healthcare. Require a safe environment, that is free of anesthetic gases during their stay at the hospital.	The system will be able to provide a second consultation on the administration of anesthesia. Marginalized groups will be represented in the learning process of this system. Possibly decreased healthcare costs (for countries without free healthcare) and negative impacts of anesthesia.
Anesthesia Hospital Staff (Includes Anesthesiologists, Nurse Anesthetists and Anesthetic Assistants)	The right to continuing practicing in their fields without threat. Require a safe work environment which does not contain anesthetic gases.	Will have a second opinion on the administration of anesthesia. May need training to learn how to operate the system.
Hospitals	Need assurance that the system provided is safe and effective. Require there to always be a reliable system and professional to administer anesthesia.	The system will decrease hospital costs through reduction in the amount of anesthesia, decrease the requirements of anesthesiologists (of which there is a shortage). Improved air quality through reduction of anesthetic gases.
Manufacturers	Assurance that they will be continue to operate their business.	May be impacted by a decrease in sales of anesthesia.
Government	Require a safe healthcare system for citizens of their country. Costs associated with the product must be within the healthcare budget (37 billion in Canada [16], which is below the costs of creating the device, if funded through the government).	Will experience an improved healthcare system, thorough a decreased impact of the anesthesiologist shortage. Will benefit economically in comparison to working to decrease the gap in the current anesthesiologist shortage.

Table 8: Table representing the needs and effect of the solution on stakeholders