Final Report for MTHE 393

Group 17

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Executive Summary

At the beginning of this project, the team was provided with an unknown black box system and was tasked with modelling the system with the aim of designing a suitable controller that achieves prescribed system targets. Additionally, an application of this controller was to be chosen and researched, focusing on the potential stakeholders and a triple bottom line analysis of the project.

The chosen area of application is in the medical/healthcare industry, specifically the regulation of blood pressure during intraoperative anaesthesia. Since over 25% of patients under anesthesia experience hypertension or hypotension during surgery, there were clear social, ethical, safety, and economic factors influencing the decision to pursue this area of application. Additionally, the input-output nature of administering anaesthetic medications and monitoring a patients blood pressure during surgical operations is a compelling and largely unprecedented application of control theory. The stakeholders for this project were identified as patients, doctors, anaesthesiologists, families, hospitals, governments, and tax payers. An analysis of the interests of different stakeholders along with a detailed triple bottom line analysis was performed led to the creation of design criteria and constraints to be considered in the controller design process.

To model the black-box system, several assumptions were made and quantitatively justified. Linearity and time invariance was justifiably assumed to enable the use of many frequency-based methods of determining a heuristic transfer function. Also, the system was observed to be impacted by inherent noise, which was verified through mean and distribution analysis to be white noise. A Stavitzky-Golay filter was chosen, with filter order 5 and frame length 501, as the most effective filter. The team was then able to evaluate the gain and phase different of sinusoidal inputs at 50 different angular frequencies, which were used to create Bode plots. By locating the break frequencies on the plots a heuristic transfer function was determined and iterated to closely match the system bode plots and step response.

Following the modelling process, the team designed a PID controller on the heuristic transfer function using a deliberate methodology that incorporated Nyquist stability analysis and other frequency-based control concepts. Using only proportional and integral control the controller exceeded system targets on the heuristic transfer function. A closed-loop model of the black-box system was created, incorporating an analog Butterworth filter to perform real-time noise filtration. The PID controller was further tuned to have gain values of 0.32, 1.5, and 0.016 for proportional, integral, and derivative control respectively.

The success of the designed controller was assessed using the system's output behavior for a step response input, specifically the steady-state error, rise time, overshoot, and settling time. For this system, the design objectives were a steady-state error of ± 0.02, rise time of 38 seconds, overshoot of 0.4 and a settling time of 57 seconds within an $\epsilon = 0.02$ band. Upon implementing the final controller and evaluating the step response of the system, the design accomplished a steady state error of ± 0.01, rise time of 0.0668 seconds, overshoot of 0.0667 and a settling time of 0.4833 seconds, which all fall well within the targeted values for the system. The controller was also tested against different input functions to verify its robustness and effectiveness.

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1 Introduction

This project aims to determine a linear and time-invariant (LTI) transfer function that heuristically models an unknown system and design a robust controller that meets provided performance specifications. Such a problem mimics the real-world challenge of designing a controller for an application that cannot be precisely mathematically modelled. Specific to the provided system, the designed controller must achieve a steady-state error of ± 0.02, rise time of 38 seconds, overshoot of 0.4 and a settling time of 57 seconds within an $\epsilon = 0.02$ band.

The design of such a controller requires the use of frequency-based methods, which can only be applied to LTI systems. Therefore, the first step was to justify the assumption that the system, despite its unknown dynamics, is LTI. This was done through the quantitative comparison of scaled, summed, and time-shifted system outputs, which were shown to be sufficiently close for specific sinusoidal inputs. Based on this analysis, it was assumed that the system was LTI for all possible input signals.

As in most real-world systems, there is noise present in the measurement of the output. In order to accurately evaluate system properties using the bode plot and heuristic transfer function, this noise must be filtered to reconstruct the true output signal. By repeatedly measuring the sinusoidal output of the system an average signal was constructed, which was used to analyze the system noise and conclude that it had 0 mean, implying it is white noise. A Savitzky-Golay filter with polynomial order 5 and frame length 501 was determined, through research and quantitative analysis, to be the most suitable filter for this system.

To better understand the behaviour of the black box system, gain and phase Bode Plots were created. From these plots, the various break frequencies were analyzed to create a heuristic transfer function. The location of the zeros and poles and the gain of this transfer function were tuned so the transfer function bode plots and step response matched that of the black box system.

Research was conducted into controller design methodologies, focusing specifically on ones that utilize a derived plant transfer function or characteristics. Using the chosen methodology, gain values were tuned to meet and exceed performance specifications on the heuristic transfer function. Then, through research and testing the Butterworth filter was selected for real-time noise reduction of the black-box system. The PID values were further tuned to the black-box system and the final controller was tested for robustness.

In addition to the project methodology, this report will outline the chosen applications of the designed controller. Specifically, the idea generation and decision-making process will be described, which resulted in the application of blood pressure regulation under anesthesia. For this application, the relevant stakeholders and needs will be outlined, including a concrete analysis of the environmental, social, and economic benefits of this solution. The additional constraints and design specifications imposed by this application will also be analyzed, focusing specifically on their effect on the design process.

2 Modelling

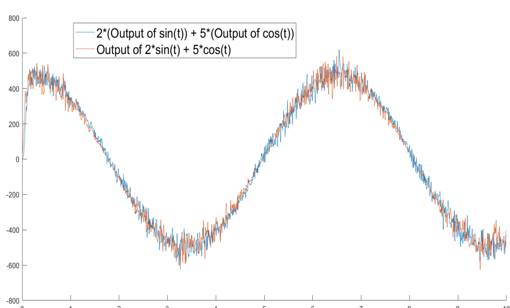
The goal of this project was to design a robust and effective controller for a black box system of unknown dynamics. Such a controller should be robust in its invariance to disturbances and have qualities such as rise time and settling time within provided system targets. This section will describe the various techniques, mathematical models, and assumptions that have been used to characterize the black box system in pursuit of designing such a controller.

2.1 Assumptions

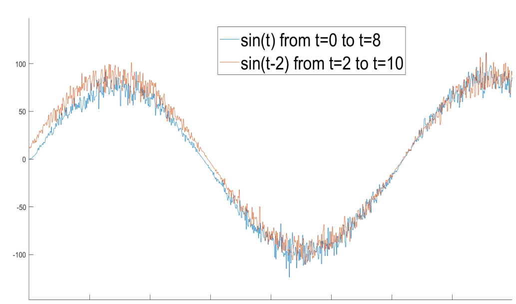
Prior to any attempt at modelling the unknown system, crucial assumptions were made to enable the use many of the frequency-based response methods of determining a heuristic transfer function. Many of the classical frequency-based methods rely on the assumption that the system is linear and time-invariant (LTI). Therefore, it is important to verify whether the system, despite its unknown dynamics, can be assumed to be LTI. If the system was non-linear or non-time invariant, the frequency-based methods of determining a transfer function would be ineffective.

The assumption of linearity was justified by observing closure under addition and multiplication by a scalar. Two output plots were produced for input signals: $u_1(t) = sin(t)$ and $u_2(t) = cos(t)$. The respective output signals, $y_1(t)$ and $y_2(t)$, were summed to produce the output signal $y(t) = 2y_1(t)+5y_2(t)$, and plotted against time. On the same plot, the system output for an input of $u(t) = 2u_1(t) + 5u_2(t) = 2sin(t) + 5cos(t)$ was also plotted. Figure 1a shows the overlapping of the two signals previously described. It is immediately clear that the two plots are qualitatively similar.

Time invariance was similarly verified by applying a time-shift to the input signal $sin(t)$, and analyzing the output when shifted by the same amount. The system output for an input of $sin(t)$ was plotted from $t = 0$ to $t = 8$. On the same plot, the output for an input of $sin(t - 2)$ was plotted from $t = 2$ to $t = 10$ and shifted by subtracting 2 from each entry of the output time vector. The resulting plot of the two signals demonstrates clear qualitative similarity, as shown in Figure 1b.



(a) Linearity



(b) Time Invariance

Figure 1: Qualitative Justification that the System is Linear and Time Invariant

To verify equivalence of signals quantitatively, the root mean square error (RMSE) between the output signals was computed. Quantitative justification is crucial in validating the assumption that the system is

LTI. The RMSE was calculated in Matlab by

$$RMSE(x, y) = \sqrt{\frac{\sum_{i=1}^{N}(x_i - y_i)^2}{N}}$$

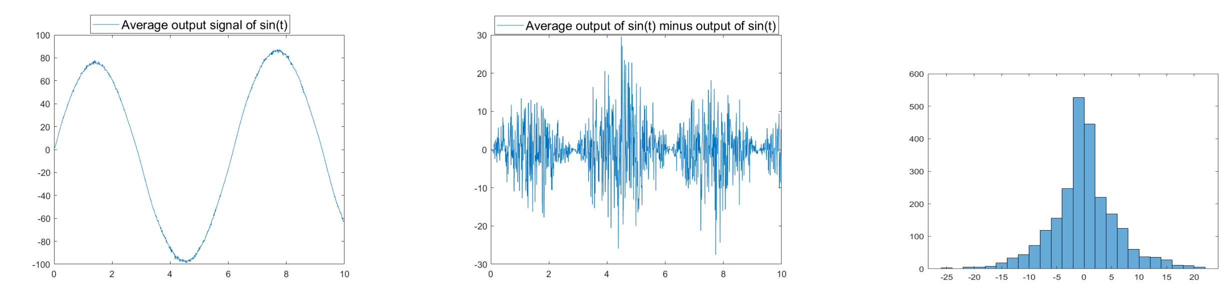
Where x_i and y_i are the values of the respective output signals at index i and N is the length of the output vectors.

Following initial computations, the RMSE between the signals in Figure 1a, was found to be 48.8370. Though, upon filtering the output signals using the Savitzky-Golay filter (described further in 2.2), the RMSE was recalculated to eliminate random white noise errors and was found to be 7.6395. Similarly, the RMSE between the output signals in figure 1b was initially found to be 14.9156, however upon noise filtration, the RMSE was recalculated to be 11.9585. Based on the qualitative analysis and sufficiently low RMSE demonstrated, it was concluded that the black box system is LTI for basic sinusoidal inputs. This validates the assumption that the system is LTI for all inputs, which cannot be proven conclusively but will allow for meaningful frequency-based response analysis.

2.2 Noise Filtration

The output of the system was also observed to be affected by measurement noise. The system output for an input of $sin(t)$ was measured twice, and the two output signals had a relative RMSE of 8.5633. This is clear proof of noise within the system, as otherwise the output would be identical for a shared input. To address this, the team designed a noise filter for the system to get a more accurate and readable output signal that can be implemented for constructing Bode plots (described further in 2.3).

To design an effective filter, the nature of the noise first had to be determined. This was accomplished by producing a smooth reference signal to compare the noise to in Matlab. The input signal $u(t) = sin(t)$ was ran through the black box 100 different times. The output signals where then summed together and divided by 100, to produce an average smooth output signal of $sin(t)$, as shown in Figure 2a.



(a) Average output for input $sin(t)$ (b) Average minus noisy output (c) Noise Histogram

Figure 2: Noise affecting system

It was observed qualitatively that the noise is indeed white noise, as seen in Figure 2b. The noise histogram in 2c displays a normal distribution with a mean zero, which research showed is a clear indicator of white noise [1]. Further, the mean of the measured noise was computed to be 0.0345, providing sufficient quantitative justification that the system noise is white noise, leading to the filter design process.

Following research and experimentation of various different white noise filtering techniques, it was determined that the Savitzky-Golay filter worked optimally for the filtering of sinusoidal outputs. The Savitzky-Golay filter works by defining a polynomial of specified degree over a given subset of data points of specified frame-length [2]. The purpose of the filter is to eliminate the noise in the system while maintaining the general trend of the output to a high degree of precision [3]. While experimenting with the Savitsky-Golay filter, it was determined that the optimal polynomial order is 5, with a corresponding frame-length of 501 data points. Noise filtration for an input signal of $sin(t)$ is observed qualitatively in Figure 3, with the both the unfiltered and filtered outputs plotted.

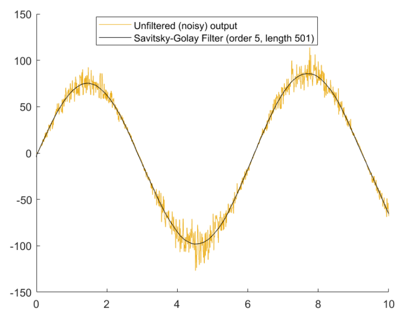


Figure 3: Unfiltered sinusoidal output vs. Savitzky-Golay filtered output

The limitation of this filter is that it is non-causal, meaning it cannot be used to filter the system in real-time. Therefore, when implementing the controller another filter will be required to smooth the output signal of the system. However, the superiority in filtering on the Savitzky-Golay filter relative to this system caused the team to make the design decision to implement it for the post-processing of system data during the construction of Bode plots, despite its limitations.

2.3 Bode Plots

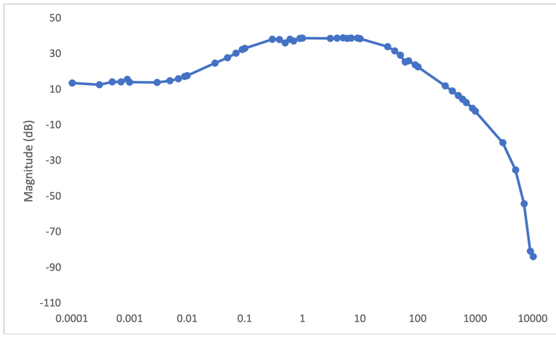
Having determined an appropriate noise filter, the aim became deriving a transfer function that could accurately model the black box system. To do this, Bode Plots of the system were prepared, which could then be used to determine the transfer function and other important properties of the system. The following procedure was used to determine the Bode Plot of the black box system. For a frequency $\omega \in [10^{-4}, 10^{4}]$, the team

a) simulated the system response of $sin(\omega t)$,

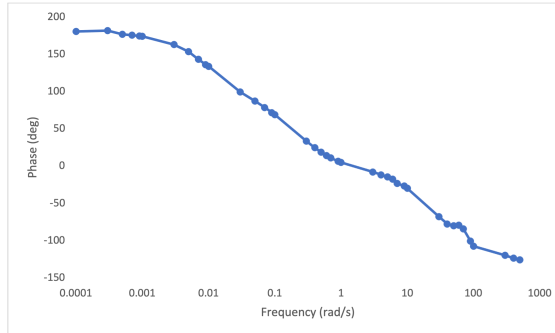
b) determined the magnitude of the output sinusoid by recording its peak amplitude, then computing the gain (dB) as gain $= 20 \log_{10}$magnitude, and

c) calculated the phase difference ($\Delta\theta$) by identifying a zero of the input sinusoid (t_i) and the corresponding zero of the output (t_o) and computing $\Delta\theta = \frac{180}{\pi}\omega(t_i - t_o)$.

The phase and gains were then plotted against the logarithmic-scale frequency to create the Bode Plot for our black-box system, shown in Figure 4.



(a) Gain Bode Plot



(b) Phase Bode Plot

Figure 4: Computed Bode Plots for the black box system

2.4 Determining Heuristic Transfer Function

The Bode Plots were used to determine a heuristic transfer function, $H(s)$, that accurately models the black box system. By examining the break points of the gain plot and the relative changes in slope, the location of the zeros and poles of the transfer function were determined. Table 1 shows the qualitatively determined location and order of the zeros and poles of the transfer function.

Table 1: Break frequencies and the corresponding zero or pole

Break Frequency	Change in Slope	Zero or Pole	Order
$\omega = 0.005$	$+20$	Zero	1
$\omega = 0.3$	-20	Pole	1
$\omega = 9$	-20	Pole	1
$\omega = 1000$	-40	Pole	2

These values give a transfer function of

$$H(s) = K\frac{s+0.005}{(s+0.3)(s+9)(s+1000)^2}.$$

By comparing the step response and bode plots of this transfer function to that of the black box system, the location of the zeros and poles and gain were optimized to reduce error. Specifically, understanding the limitations of the transfer function model when generated from break frequencies, the location and sign of the zeros and poles were altered until the shape of the Bode Plots closely matched. This tuning process resulted in a system transfer function of

$$H(s) = K\frac{s-0.006}{(s+0.25)(s+10)(s+1000)^2}.$$

To find the system gain, the Final Value Theorem was used to relate the black box system step response $y(t)$ to the transfer function by

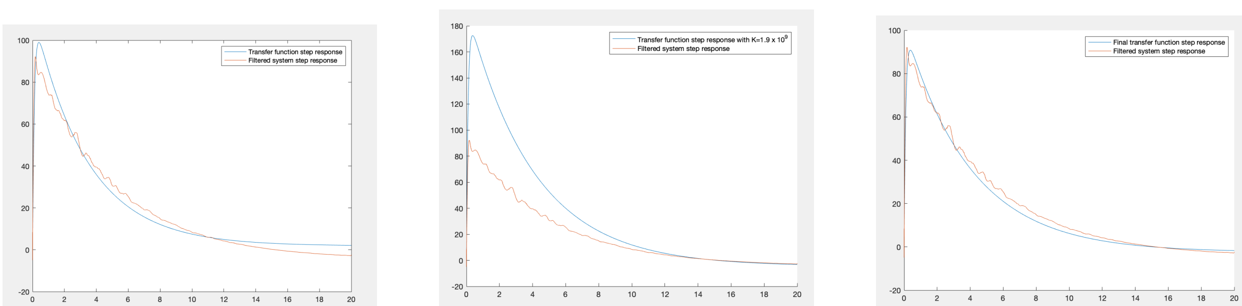
$$\lim_{t\to\infty} y(t) = \lim_{s\to 0} sY(s) = \lim_{s\to 0} K\frac{1}{s}s\frac{s-0.006}{(s+0.25)(s+10)(s+1000)^2} = -2.4\times 10^9 K.$$

The black box system step response has a limit value of -4.6, which was determined by running the simulation until the response stabilized—meaning the average over multiple periods of 10 seconds remained constant—and taking the mean value to get

$$\lim_{t \to \infty} y(t) \approx -4.60 \implies K \approx 1.9 \times 10^9.$$

This procedure is limited by the imprecision of the transfer function and the inherent noise in the step response of the system. However, this does give an approximate value of K that can be further refined to best match the Bode Plots and step response of the black box system. Indeed, this starting value of $K = 1.9 \times 10^9$ gives a mean absolute error of 15.1597 between the transfer function and system step response, while a gain of $K = 10^9$ gives a mean absolute error of 2.1363. Using this gain of $K = 10^9$, we also quantitatively evaluated the transfer function tuning previously completed, which reduced the mean absolute error between the transfer function step response and black box system step response from 3.469 to 2.1363.

Figure 5 shows the system step response plotted against the transfer function step response at each step of the tuning process. Examining these plots, it is immediately clear the qualitative improvements caused by this tuning process. Other values of K and pole locations were tried, but this transfer function resulted in the lowest RMSE of the step response while also producing Bode Plots that matched those computed.



(a) Step response of the original H(s)

(b) Step response of the computed gain $K = 1.9 \times 10^9$

(c) Step response of the tuned transfer function

Figure 5: Step responses of the transfer function and system during the tuning process

The Bode Plots for the final transfer are shown in Figure 6, which when compared to Figure 4 are nearly identical.

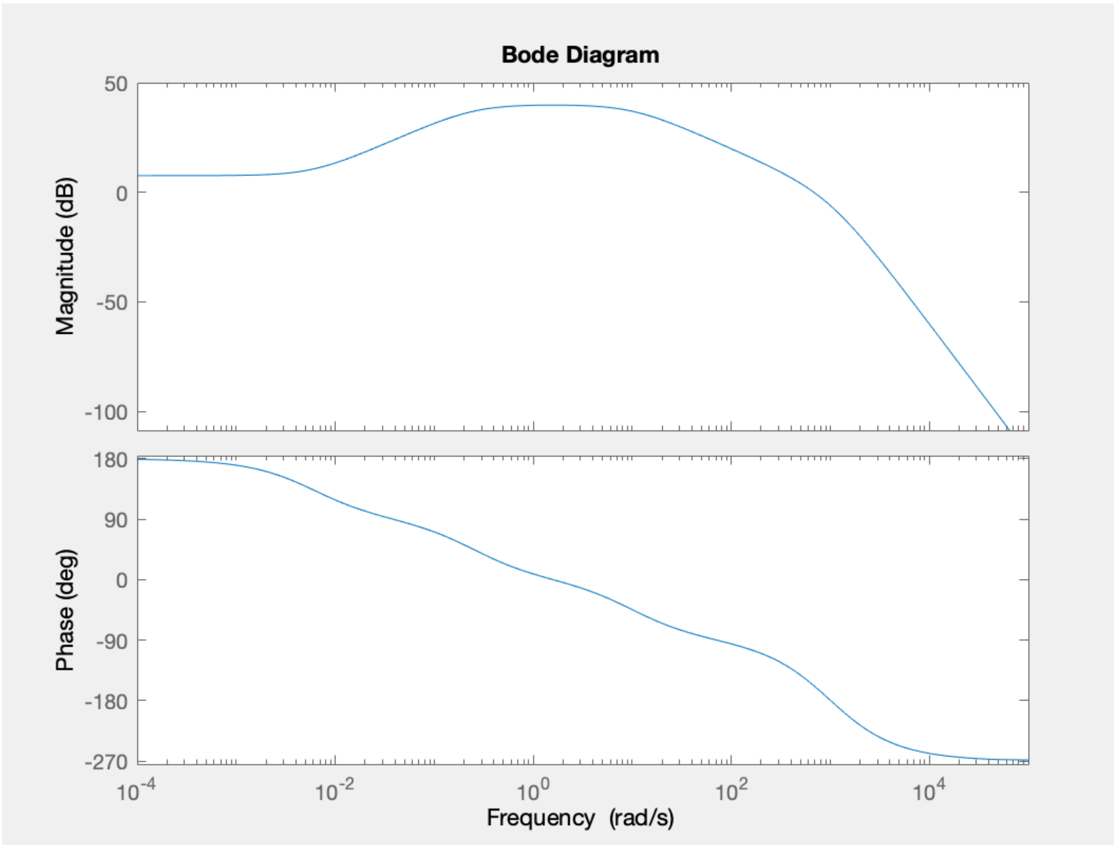


Figure 6: Bode Plots generated from the heuristic transfer function

3 Control Design

The goal of this project is to design a robust controller that meets specified system targets. Using the derived mathematical model of the system dynamics, deliberate tuning methods can be applied to a proportional, integral, and derivative (PID) controller. There are several established classical tuning techniques that can be applied to this problem. For instance, the Ziegler Nichols and Cohen Coon Methods both assign gain values based on characteristics of the step response [4]. These heuristics were applied to the system without success. Instead, the technique applied follows incremental iteration of the proportional, integral, and derivative gains (K_P, K_I, and K_D respectively) based on knowledge of their effect on system response. Specifically, the team

a) set $K_P = K_I = K_D = 0$,

b) increased K_P until the system rise time targets was achieved and the response exhibited consistent oscillation,

c) fixed K_P and increased K_I until system targets of rise time, settling time, and steady-state error were achieved, and

d) increased K_D to decrease overshoot and improve overall system stability and robustness.

This heuristic was chosen based literature reviews and an understanding of the impact of each gain parameter on the system response. Further, this paradigm is advantageous as it permits stability analysis to be performed using Nyquist Diagrams and the heuristic transfer function, giving a range of permissible gain values. Using this analysis the stability of different configurations can be determined without requiring lengthy or computational simulations. The limitation of this tuning method is that it can be time-consuming, particularly if the transfer function does not closely model the black-box dynamics. However, because of the small difference between the step responses and bode plots of the transfer function and black-box system, it was assumed that the transfer function is an excellent model of the system and this problem would not be encountered.

3.1 Heuristic Transfer Function Controller Tuning

The closed-loop system is shown in Figure 7. The $\frac{\text{zero(s)}}{\text{pole(s)}}$ block was defined using the heuristic transfer

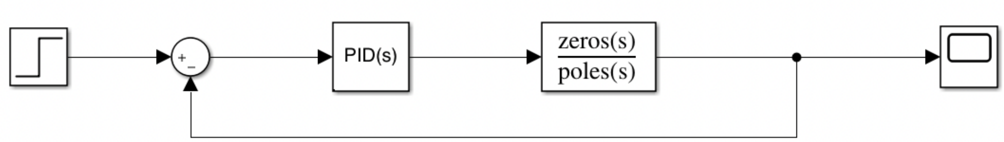


Figure 7: Simulink Diagram of the closed loop system

function determined in Section 2.4. Applying the PID controller yields a control and plant transfer function of

$$C(s) = K_P + \frac{K_I}{s} + K_D s \quad \text{and} \quad P(s) = 10^9 \frac{s - 0.006}{(s+0.25)(s+10)(s+1000)^2}$$

respectively. The entire closed-loop transfer function can then be expressed as

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

Beginning with $K_I = 0$ and $K_D = 0$, Nyquist Diagrams were used to determine that the system is stable for $0 < K_P < 2.07$. Figure 8 shows the Nyquist Diagram for the marginally stable system with $K_P = 2.07$, as there are no poles in the right-half plane there cannot be any encirclements of -1. When $K_P = 0.3$ the

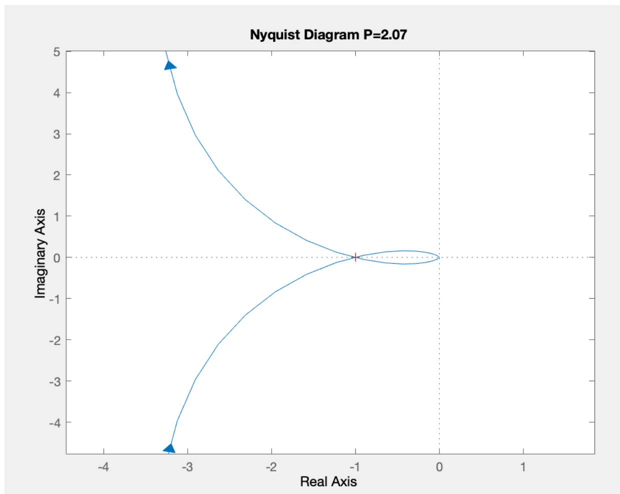


Figure 8: Nyquist Diagram when $K_P = 2.07$ and the system is marginally stable

system response achieved the desired rise time properties and increasing the gain further caused the step response to exhibit oscillations. Thus, being cognizant of making the system as stable as possible, K_P was set to 0.3. Similar Nyquist analysis was conducted on the integral gain K_I, and Figure 9 shows the system is stable for $K_P = 0.3$, $0 < K_I < 2.5$. K_I was increased until system targets were met, which occurred once

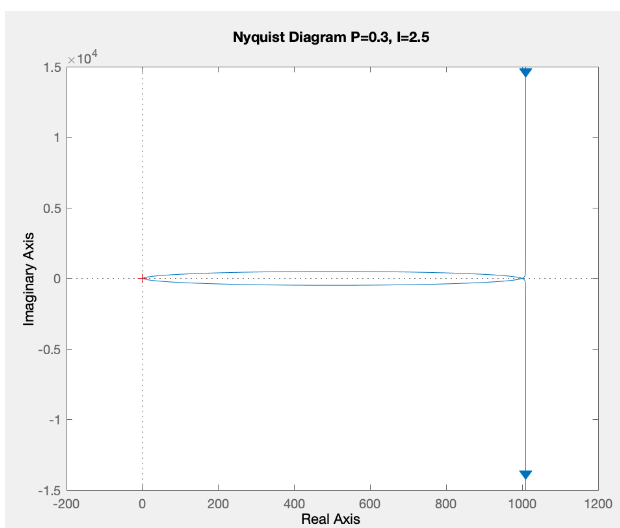
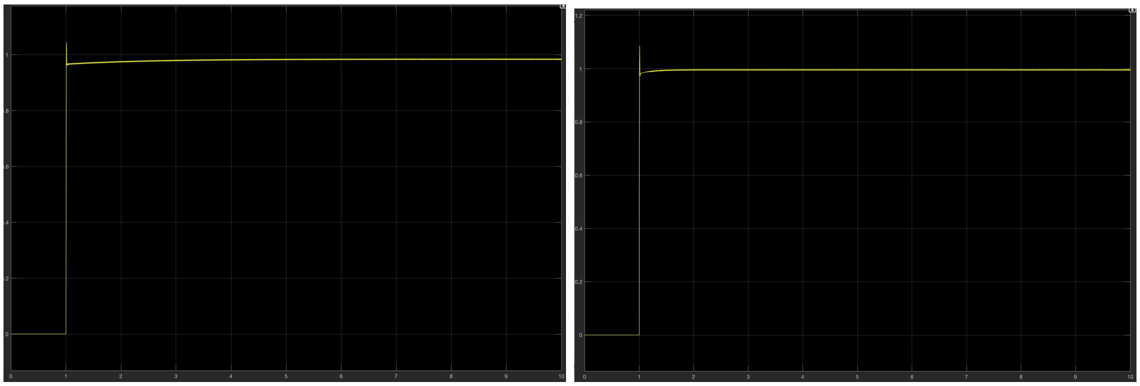


Figure 9: Nyquist Diagram when $K_P = 0.3$, $K_I = 2.5$ and the system is marginally stable

$K_I = 0.2$. At these parameters there was a steady-state error of 0.019, which was not comfortably within the system target of ±0.02. Thus, K_I was incrementally increased to a gain of 1.5, reducing the steady-state error while keeping the overshoot within the maximum of 0.4. The closed-loop step responses for $K_I = 0.2$ and $K_I = 1.5$ are compared in Figure 10.



(a) Step response with $K_P = 0.3$, $K_I = 0.2$ (b) Step response with $K_P = 0.3$, $K_I = 1.5$

Figure 10: Step responses of the closed-loop system during the PID Controller tuning process

As the system targets were already met on the idealized transfer function, derivative control was set to zero, understanding that it would be necessary when applied to the black-box system to dampen the effect of noise and increase system stability.

3.2 Black-Box Controller Tuning

The closed-loop system was created in Simulink using the black-box provided, as shown in Figure 11.

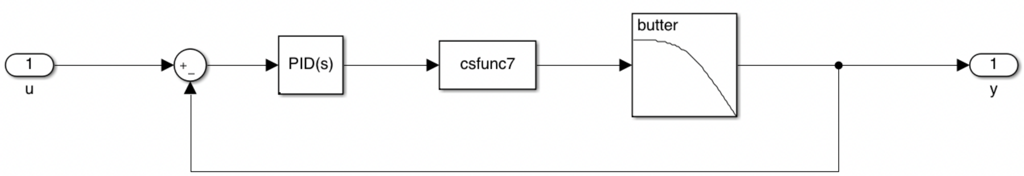


Figure 11: Simulink Diagram of the closed loop system

Prior to testing the PID controller, it was necessary to design a noise filter that could be used for real-time noise filtration. The Savitzky-Golay filter previously used is non-causal and not suitable for real-time applications [3]. A literature review of signal filters demonstrated that analog filters analog were the superior choice because of processing speed and no introduction of latency [5]. Of these, the Butterworth filter was selected, as it produces the smoothest filtered signals of these options [6]. Having a smooth output signal is crucial is being able to apply derivative control without destabilizing the system. The Butterworth filter is a frequency domain filter that is designed to have a maximally flat frequency response [7]. It has parameters of order and cutoff frequency, where the filter smooths the noise of the signal for frequencies greater than the cutoff frequency [7]. The filter was designed to be first-order with a cutoff frequency of 1 rad/s, as it resulted in the smoothest step response. Further testing demonstrated that the tuned PID gains only produced a stable system response under these filter settings, further justifying this decision. The open-loop step-response of the black-box system under this filter paradigm is shown in Figure 12.

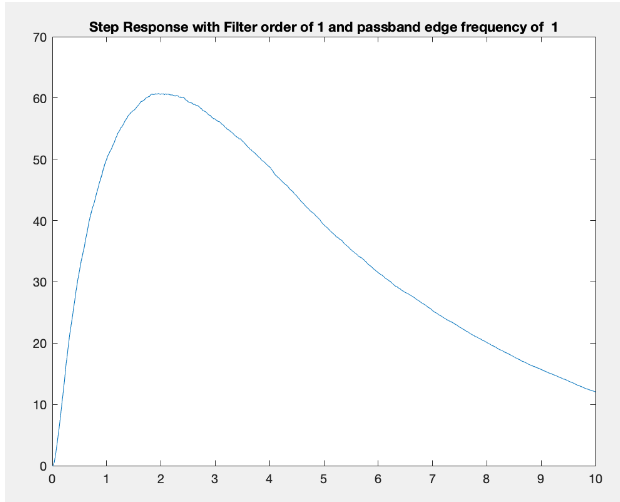
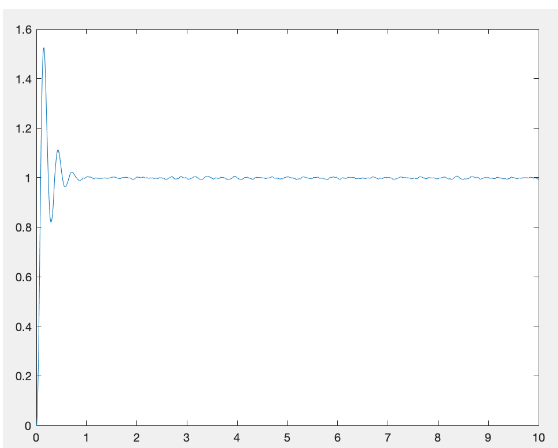
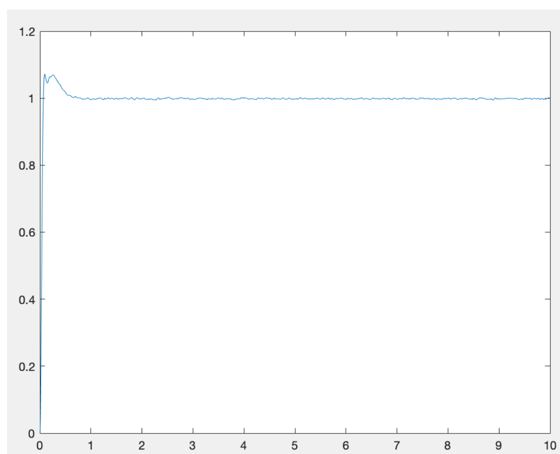


Figure 12: Step-Response of open-loop system with Butterworth Filter applied

Applying the PID Controller previously tuned to gains of $K_P = 0.3$ and $K_I = 1.5$ yielded the step-response shown in Figure 13a. The derivative gain was increased to reduce overshoot and oscillations and improve system stability, with a final value of $K_D = 0.016$. The values of K_P and K_I were also further tuned to reduce rise time and steady-state error, resulting in final values of $K_P = 0.32$ and $K_I = 1.5$. The step-response under this PID Controller is shown in Figure 13b.



(a) Step response of closed-loops system with $K_P = 0.3$, $K_I = 1.5$



(b) Step response with tuned PID control applied, $K_P = 0.32$, $K_I = 1.5$, and $K_D = 0.016$

Figure 13: Step responses of the closed-loop black-box system during the final tuning process

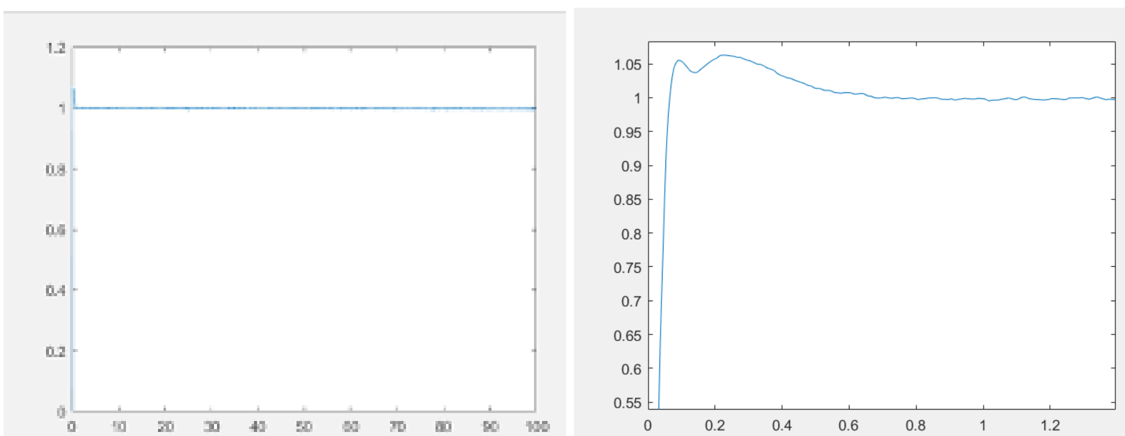
3.3 Evaluating Controller Performance

The performance of the final controller design was compared against prescribed system targets specifically the rise time, settling time, overshoot, and steady-state error. For system 7, the system targets were ± 0.02 for steady state error, a rise time of 38 seconds, a settle time of 57 seconds to within an $\epsilon = 0.02$ band, and an overshoot of 0.4. and a 0.02 epsilon band around the settled system. Essentially, the controller must be extremely precise in its steady-state error without needing to rise or settle quickly. As shown in Table 2,

Table 2: Controller Performance

Performance Metrics	System Targets	System Performance
Overshoot	0.4	0.0667
Rise Time (s)	38	0.0668
Settling Time (s)	57	0.4833
Steady State Error	± 0.02	$< \pm 0.01$

the tuned controller exceeded every prescribed target, often by a significant amount. The system response, shown in Figure 14, had a rise time of 0.0668 seconds, a settle time of 0.4833 seconds, an overshoot of 0.0667, and remains within 0.01 of the target state once settled. The settling time and steady-state error were determined by running the system for 100 seconds and computing the maximum absolute error between the system response and 1.



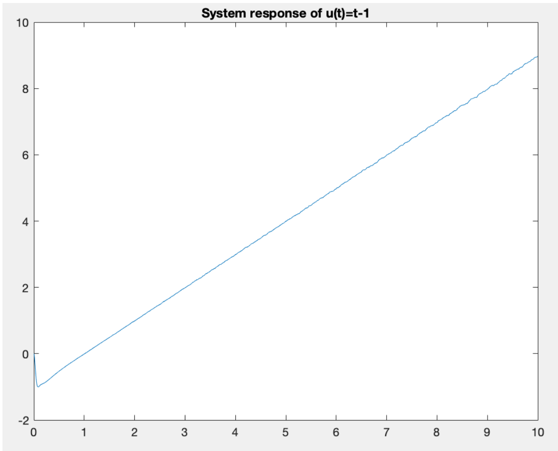
(a) Full 100-second system response

(b) First 1.4 seconds of system response

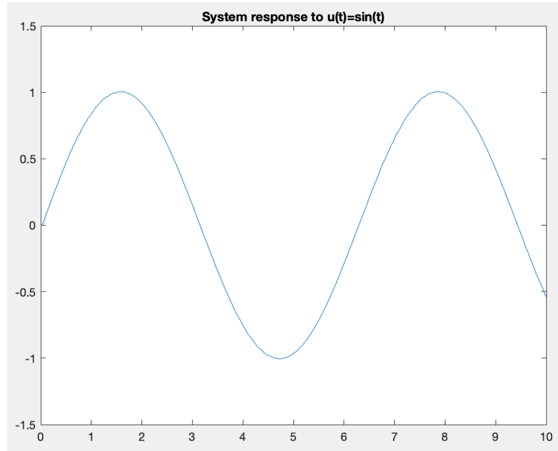
Figure 14: Simulation response to step function input to the PID controller with P=0.32, I=1.5, D=0.016 using a Butterworth filter

The controller was also tested against other input functions to confirm its robustness and rejection of disturbances. Select system responses are shown in Figure 15 and demonstrate the tuned controller's effectiveness beyond just a step response input signal. For an input signal of $u(t) = t - 1$, the controller achieved a RMSE of 0.0896 between the input and output, similarly for $u(t) = \sin(\mathrm{t})$ the controller achieved a RMSE of 0.0082. It is evident that the tuned controller is robust for various and diverse input signals.

Overall, the tuned PID controller can be deemed a tremendous success. It achieved and exceeded all of the prescribed system targets and has been demonstrated to be robust to different input functions. This indicates that the team has found excellent PID gain values and that the heuristic transfer function closely models the black-box system dynamics. While further iteration could likely be conducted to marginally improve the controller performance, exceeding the system targets by this much indicates the tuned values are close to optimal.



(a) System response of $u(t) = t - 1$



(b) System response of $u(t) = \sin(t)$

Figure 15: Robustness of tuned controller against various input functions

4 Regulating Blood Pressure Under Anesthesia

To generate a variety of potential applications, each team member individually researched and prepared 3 viable applications of a control system. These applications were compiled and the researcher presented the control input and outputs, high-level social and economic impacts, and how well the application fit the black-box system and system targets provided. Applications were sorted into three categories: medical, environmental, and robotic applications, a technique that allowed further research and generation of ideas based on similar applications within that domain. After discussion, team members gave each idea a rating out of 5 based on the criteria previously outlined. Appendix A shows the Padlet used to facilitate this process, the ratings given to each idea, and other ideas proposed but not further researched.

From this analysis, four applications were chosen for further research, which included a literature review of competing mathematical models and existing control methods and a partial Triple Bottom Line (TBL) analysis: blood pressure control under anesthesia, water level control in a canal system, indoor garden temperature and humidity control, and control of community water fluoridation. To evaluate each application, the team considered the financial, social and environmental impacts of each, how well the application fit the system and system targets, and the robustness of existing solutions. The pros and cons of each application, when analyzed according to these criteria, are shown in Table 3.

Based on this analysis, blood pressure control under anesthesia and community water fluoridation were chosen as the two potential applications. These presented the highest potential economic, social, and environmental impact while also best matching the system constraints and targets presented by this project. Following the testing of the controller, blood pressure control under anesthesia was chosen as the most impactful application. The sub 1-second rise time and low steady-state error achieved meant that the controller fit this application best.

4.1 Application Description

The designed controller will be used to regulate patient blood pressure while under anesthesia. While a patient is under anesthetics, they wear a blood pressure cuff that continuously measures their blood pressure.

Table 3: Pros and cons of considered applications

Application	Pros	Cons
Blood Pressure under Anesthesia	Large social benefit to patients and other stakeholders. Complex physiological system that is difficult to model mathematically [8].	Ideal response time is slightly faster than provided system targets, increasing the design constraints on the controller.
Water Level Canal System	Natural phenomenon that is difficult to linearly model, making contributions more significant as it is an active area of research. Time required for settling and rise time align well with the system targets of 38 and 57 seconds, respectively.	Prevailing mathematical models use decentralized controllers, opposed to the SISO black box system provided [9].
Indoor Garden Temperature and Humidity	Variety of environmental and financial benefits if properly implemented.	The established control models of this system are MIMO, not SISO models [10].
Community Water Fluoridation	Immense social and financial benefits as a control system. Complex system that is difficult to accurately model mathematically.	Automatically measuring fluoride levels is difficult and an area of active research [11]

Measuring blood pressure is the main sign of the patient's depth of anesthesia and is the method used in clinical practice [12]. If the patient's blood pressure exits a certain range and is critically low or critically high, the amount of anesthesia they are receiving is altered. It is important to monitor and control a patient's blood pressure while they are on anesthetics, as anesthesia commonly leads to hypotension (low blood pressure) during surgery [13]. Additionally, after a patient's surgery anesthesia can lead to hypertension (high blood pressure). [13]

A closed loop system integrating a blood pressure cuff will be used to control the blood pressure of the patient, as shown in Figure 16. The input to the system will be the desired blood pressure and the output will be the resulting blood pressure of the patient, both measured in mmHg. When developing the technology, the team must keep in mind that the system will have two types of noise. Specifically, skin incisions can significantly decrease the patient's blood pressure while measurement devices used in the operation will have inherent noise. [8].

While creating this technology, a primary consideration is the reaction time that the controller must have. A patient's blood pressure can rise or drop very rapidly, which can cause further problems such as cardiac arrest. Thus, the technology must respond quickly to any changes. The controller's rise and settling times of 0.0668 and 0.4833 seconds, respectively, mean that the patient's blood pressure will theoretically stabilize almost immediately, creating minimal risk for adverse effects. Another design challenge is being aware of the bounds that a patient's blood pressure must stay within. The average adult should has systolic pressure less than 120 and diastolic pressure less than 80; however, the desired blood pressure range varies widely based on age and weight [14]. As well, the technology must know how much anesthesia is safe to inject into the patient, which is dependent on their weight [8]. To ensure the safety of the patient this controller would

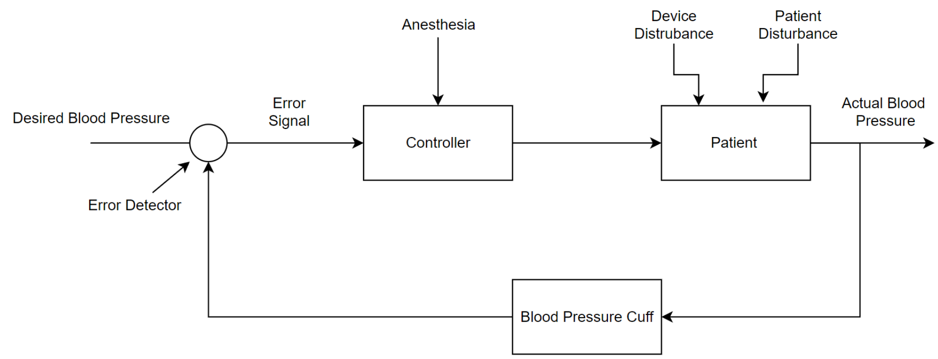


Figure 16: Closed Loop System Regulating Blood Pressure While Under Anesthesia

have to undergo thorough supervised safety trials before being used without anesthesiologist supervision.

4.2 Stakeholders

The stakeholders considered for the chosen application include patients, anesthesiologists, families of patients, hospitals, the government, and tax payers. A further analysis on the needs and effects of the application on these stakeholders can be seen in Table 6 in Appendix B. Based on this analysis, the following stakeholder criteria and constraints were developed. Patient blood pressure must be continuously monitored and any sudden change in their blood pressure must be responded to within minutes so that the deviation does not cause any adverse effects [14]. Additionally, a small overshoot is necessary, as over-injecting anesthesia would cause further problems. This criteria is also relevant for families of patients, as their interest in the application is the health of the patient. Hospitals must be confident in the control system being implemented. This means that they have the criteria that the system must have gone through a long clinical trial to prove the success of the system. Further information about the requirements of the clinical trial can be seen in Section 4.5. The government is also interested in the success of a clinical trial as they will have to approve the use of the system in hospitals as well. Lastly, the criteria that taxpayers in countries with public healthcare are looking for is that the control system will decrease costs in hospitals related to hyper and hypo-tension and thus decrease the amount of taxes spent on healthcare annually. These constraints are summarized in Table 4 and must be met, in addition to the prescribed system targets, for this project to be considered a success.

Table 4: Stakeholder Constraints

Stakeholder(s)	Constraints/Criteria
Patients, Families of Patients, Anesthesiologists	Rise time, settling time, and overshoot
Hospitals, The Government	Success of clinical trial
Taxpayers	Decrease in hospital costs and thus their taxes spent on healthcare

4.3 Triple Bottom Line

Table 5: TBL Analysis

Stakeholder	Economic	Social	Environmental
Patients (Consumers)	If the patient is in a country that does not have public healthcare, they might have to pay additional costs for treatment of hypertension or hypotension if this occurs. In the US, it is predicted that a patient with hyper or hypotension will pay almost $2000 more annually on healthcare than those without [15].	Hyper and hypotension are dangerous conditions that can lead to death. 25% of patients under anesthesia experience hyper or hypotension, thus we need a good control to prevent this.	
Anesthesiologists	If anesthesiologists are replaced by control technology, they will lose their jobs. This will mean that they will have to find a new job, that will probably be less specialized and thus they will probably receive a lower salary. In Canada, the average salary of a medical specialist is $360,000 whereas the average salary of a doctor is $281,000 [16].	Implementing a controller will leave the anesthesiologist more time to monitor other vitals during surgery. To measure these vitals, they must monitor a pulse oximeter, electrocardiography, and a temperature monitor [14]. If any of these vitals exit a certain range, they will also lead to further health problems. If other vitals are automatized as well, anesthesiologists might lose their jobs. Patients might feel uncomfortable that they do not have someone monitoring them.	
Families of Patients	The effects of hyper or hypo tension can leave large economic burdens on the families of the patient due to further treatment or longer stays at the hospital, as stated above in the patient section.	Families can feel confident with their loved ones going under anesthesia knowing there will be good control over their blood pressure. A successful surgery without the need will decrease the amount of care and attention the family needs to give their loved one after surgery, and also will reduce their concern that further problems will occur after surgery.	
Hospitals	Hyper and hypo tension cause further treatment and prolonged hospital stays, costing hospitals more money. In the US, hospitals face $ 131 billion costs due to hypo and hypertension annually [15].	Need to have good control over their patient's blood pressure to minimize the risk in their hospital. If the job of an anesthesiologist is taken over by control technology, the hospital will be able to redistribute medical help to other areas of need.	Hospitals generate about 29 pounds of waste per bed per day [17]. Improved medical intervention for hyper and hypo tension will reduce waste from injection tools and medication containers, hopefully aiding the hospital to reduce their overall waste.

Government	If further automation is completed for other vitals, the government will not have to pay for anesthesiologists. An anesthesiologist makes $288,294 annually, and there are over 1,300 anesthesiologists working in Ontario [18]. Thus, this could save the government a lot of money. The government will also have to pay for the new technology. While the cost of the technology is unknown, this would be a large upfront cost. However, the fixed cost of new technology will eventually pay off with the reduced salary costs.	If the hospitals don't need anesthesiologists anymore, there will be a many trained medical professionals that can be allocated to other jobs in the hospitals. This will help with the very prevalent staffing shortages in hospitals.
Tax Payers (only relevant for countries with public healthcare)	On average, a Canadian tax payer pays about $5,789 annually for public healthcare [19]. A decrease in post-op treatment needed for hypertension will decrease the total costs of healthcare in Canada, and thus will decrease how much taxpayers must pay for public healthcare.	Would like to spend less on taxes.

4.4 Economic Analysis

Prior to any attempt at implementing this controller design and acquiring the necessary technology, relevant economic considerations such as projecting expected costs and potential revenues must first be assessed. The results of these estimations will be used to evaluate the overall economic feasibility of this project, specifically whether this design solution is viable in practice and will generate future economic value. For the scope of this analysis, costs and revenues will be approximated per unit, though it is noted that on a larger scale of implementation these estimations may vary significantly.

4.4.1 Cost Estimation

Having a reasonably accurate estimation of expected capital and operational costs is imperative in the process of evaluating a project's economic feasibility. Capital costs include all costs associated with the initial implementation of the system, while operational costs reflect the cost to maintain the system over a given time period.

The capital costs related to implementation consist of the cost of the required medical equipment and the cost of developing the necessary software to integrate with the equipment. The two pieces of medical equipment required for this application include a blood pressure monitoring system and an infusion pump for the administration of anaesthetics intravenously to the patient. As of current market prices, a clinical grade blood pressure monitoring system can cost upwards of $1000 per unit depending on the precision of measurement required [20]. The current cost of an infusion pump used for IV administration during surgery can range between $2,184 to over $6,865 depending on the volume of administration required [21]. Given the extreme safety and ethical consequences of this area of application, it is assumed that a high precision monitor and a large volume pump will be required for implementation, meaning the total equipment cost is estimated to be $8000 per unit. Additionally, there will be significant capital costs relating to the integration of the PID controller with the blood pressure monitoring system and infusion pump. Current outsourced healthcare and medical software development projects range in cost between $50,000 to upwards of $500,000, depending on the complexity and nature of the application [22]. For the scope of this application it is assumed that a relatively complex software package will be required, as any small error could cause the system to become unbounded, which would result in extreme safety and ethical consequences. It is assumed that the initial software development and testing will cost $500,000, however given the scalability of software this could be implemented across multiple systems without increasing costs significantly. For simplicity of analysis, it is therefore assumed that the per-unit software cost is $1000 per system. This consequently estimates that each blood pressure regulation system has a capital cost of $9,000.

Estimating operational expenditures is another useful consideration when evaluating costs and economic feasibility. In the healthcare industry, routine equipment maintenance and repairing is indispensable in ensuring the safety of their patients [23]. In 2006, a survey of 19 large hospital across the U.S. recorded an average ratio of equipment repair/maintenance cost to acquisition cost of 7.4% [24]. Using this average ratio, along with the estimated acquisition cost of $8,000 for equipment, the annual maintenance and repair costs are projected to be $592 annually. Additionally, software upgrades and repairs will be likely be required as the system develops. Since it is difficult to accurately estimate future development costs, it is assumed that 12% of initial software costs will be required for updating the system each year, which is consistent with industry standards [25]. Therefore, it is estimated that total annual operational cost of each blood pressure regulation system will be $712 per system per year, approximately 7.12% of the initial investment.

4.4.2 Projected Revenues

Similar to cost estimation, projecting revenues is essential in the assessment of a given projects economic feasibility. Projects that do not generate sufficient revenues would be considered unfeasible as the project would become unsustainable to operate provided the costs described above. For this medical application, revenues are observed by decreasing the current operational costs to perform surgery, as fewer Anesthesiologists will be required on staff, instead automating the process with this controller design. Current intraoperative anesthesia costs during surgical operations account for 5.6% of total hospital costs [26]. In 2020, the average U.S. hospital costs was estimated to be $2,607 per day, which is approximately $1 million annually [27]. The annual costs for intraoperative anaesthesia can thus be estimated to be around $56,000 for the average hospital each year. Given the difficulty of projecting future revenues, it was conservatively estimated for simplicity that the implementation of this control system will decrease the average dependence on Anesthesiologists by 15%. This implies that on average, a hospital will observe $8,400 in revenues generated annually from this application. It is noted that initial revenues will likely be less than this estimate, however as the technology develops and when implemented on a larger scale, a continuous reduction in costs could be experienced, resulting in revenues potentially far greater than $8,400 annually.

4.4.3 Economic Feasibility

Having determined reasonable estimates for the expected costs and revenues concerning the implementation of this control system, the economic feasibility can thus be evaluated. Assuming current federal interest rates of 1.25%, a present worth analysis was performed to determine a payback period, and to quantify economic feasibility [28]. It was assumed that the average hospital will implement 5 units of this system, implying a $45,000 capital investment and $3,560 annuity. Revenues generated are assumed to be $8,400 as previously stated. The payback period was calculated equating the present worth to 0 as follows:

$$PW = (-\$45,000) + (\$8,400 - \$3,560)(\frac{P}{A}, 1.25\%, N) = 0$$

Where $(\frac{P}{A}, 1.25\%, N)$ is the present worth compound interest factor, with payback period N. Hence,

$$(\frac{P}{A}, 1.25\%, N) = \frac{(1.0125)^N - 1}{0.0125(1.0125)^N} = \frac{\$45,000}{\$4,840} = 9.2975$$

Solving for the payback period, N, it was concluded that it will take approximately 10 years for the present worth of this project to become positive, under the assumptions previously stated. This implies that implementation of this controller would be feasible for stakeholders looking for an investment lifetime greater than 10 years, which is reasonably low. Conversely, implementation would be unfeasible for stakeholders looking for a return on investment sooner than 10 years.

4.5 Regulatory, Ethical and Safety Concerns

Due to the complex and life-altering nature of surgery, when it comes to implementing new technology within procedures, there are many ethical, and safety concerns that must be addressed. Before implementing new technology, it is necessary that thorough testing, and controlled trials be completed to ensure the reliability of the technology. The Food and Drug Administration (FDA) requires pre-market approval when a new technology or process, that is not like anything else on the market, is proposed. This approval process includes a large clinical trial with many patients and usually takes 4-5 years to complete. Additionally, the clinical trial is an expensive process. [29]

The adoption of control systems and other technologies such as machine learning in the healthcare sector is a relatively new advancement. Thus, organizations such as the FDA do not have a concrete framework outlining regulations and criteria for approval of new technologies. However, the FDA is working on developing a framework and the following are criteria that will be included in their regulations:

- Adequate risk assessment and mitigation systems;
- High quality of data sets feeding the system to reduce risks and discriminatory outcomes
- Logging of activity to ensure traceability of results;
- Detailed documentation providing all information necessary on the system and its purpose for authorities to assess its compliance;
- Clear and adequate information to the user;
- Appropriate human oversight measures to reduces risk;

- A high level of robustness, security, and accuracy [30].

The new control system must meet the regulations that an anesthesiologist must meet. For example, blood pressure must be recorded at least every five minutes, however, must be continuously monitored while the patient is under anesthesia [31]. Additionally, the technology must respond quickly to drastic changes in blood pressure. With the team's achieved rise and settling times, it is clear that the technology will respond in a much quicker time frame than an anesthesiologist could respond in.

Since the implementation of surgical technology is contingent on passing clinical trials, safety concerns from patients regarding the technology should be reduced. However, while the adoption of technology in many medical applications has shown to improve efficacy and accuracy, many individuals are still skeptical about receiving diagnosis and care from a machine. For example, artificial intelligence used in breast cancer detection has improved diagnosis by 9.4%. Nevertheless, many patients still want to be examined and diagnosed by a doctor [32]. Thus, there will most likely be ethical and safety concerns about the control system being developed. Patients and their loved ones might be worried about not being monitored by a human throughout the surgery and relying solely on a machine.

Many people consider reverse engineering someone else's system or device to not be ethical. They believe that it allows others to violate their copyright and steal their hard work. However, reverse engineering can also be an incredibly valuable method to enhance a product or system. Reverse engineering allows the engineer to understand the original design and add on other functionality or enhance the existing functionality. For example, software engineers reverse engineer software to find any security issues. If they find any vulnerabilities, they can rewrite the code to fix the issues they found, making the software much more secure. When it comes to healthcare, reverse engineering a design could help to expose risks in the processes currently used [33]. Thus, depending on how reverse engineering is used, it could be ethical. However, if used in a malicious way, reverse engineering can allow others to take credit for work that isn't theirs.

Clearly, if what is being reverse engineered is patented, then there will be limitations on what can be done. If there aren't any patent issues, reverse engineering should be limited to uses that will help the greater good and that won't damage the original design. Using reverse engineering for purposes such as improving software security and health care processes as discussed as should be allowed. However, using reverse engineering for purposes such as to sell fake goods for a lower price or hacking into a system with intentions to corrupt the system are not ethical and should not be allowed.

5 Summary and Direction for Further Work

Over this project, the team has worked to determine the dynamics of a black-box system and design a feedback controller to meet provided performance metrics. To utilize frequency-based design methods the team made justified assumptions about linearity and time-invariance, identified and filtered the white noise present in the system, and produced accurate bode plots of the black-box system. From the bode plots, break frequencies were identified and used to construct a heuristic transfer function, which was iterated until its step response and bode plots closely matched those of the black-box system. A PID controller was then tuned on this heuristic transfer function using a deliberate methodology justified by research and testing. After achieving the prescribed system targets using only proportional and integral control, the tuned PID controller was applied to the black-box system. This required designing a real-time Butterworth filter capable of creating a smooth de-noised output signal. After iterating the PID values, reaching final gains of $K_P = 0.32$, $K_I = 1.5$, and $K_D = 0.016$, the controller exceeded all of the prescribed targets. Specifically, the controller had rise time of 0.0668 seconds, overshoot of 0.0667, settling time of 0.4833 seconds, and a steady state error of less than 0.01. Further testing of the controller on various input signals confirmed its robustness.

The application of blood pressure regulation under anesthesia was chosen for the designed controller. In Table 6, a thorough analysis of the stakeholders and their needs was conducted. This analysis imposed further constraints on the project, which were outlined in Table 4. Rise time, settling time, and overshoot of the system will primarily impact the patients, but also secondary stakeholders such as families of patients and anesthesiologists. The controller has demonstrated minimal rise and settling time, meaning this constraint has been fulfilled. The overshoot is also minimal to ensure that the patient has no adverse effects related to the over-application of anesthesia. Hospitals and the government also require that the system pass a series of clinical trials. This is mentioned below in the next steps, but should the government see a positive physiological response in most candidates, then barring economic or other social concerns the device would likely receive approval. Finally, evaluating the system based on a taxpayer's point of view is contingent on the success of the clinical trials the reduction in costs caused by the reduction of the number of staffed anesthesiologists.

Given more time, the team would iterate the PID controller on the heuristic transfer function to further improve the system response. The transfer function has been shown to be an excellent model of the system dynamics, meaning applying classical tuning methods would be effective in improving the controller. Recommendations for future teams include dedicating sufficient time to fully understand how to construct precise Bode plots. Properly estimating the heuristic transfer function leads to a strong basis for the remainder of the project. If the transfer function is improperly estimated early in the project, it can set a team back by several weeks and will negatively affect the controller tuning process.

The application has several next steps which could be undertaken to further develop the concept of a blood pressure regulation device. Seeing as the theoretical functioning of the system has been justified through many mathematical tools, the next step is to translate the system to a physical device. Going through the design process to conceptualize and create multiple prototypes is crucial to verifying that the simulated system could be translated to the desired real-world scenario. According to the FDA, the next step after prototyping is the approval pathway, which depends on its risk classification [34]. Devices can be assigned either Class I, II, or III, which depends on the level of control and regulations needed for said device. Once approval has been granted for the prototype, clinical trials can begin where safety information is recorded and further submitted to the FDA for approval to move to market. The final step in the device development process is the market release where information is continually collected to ensure the device's long-term efficiency and safety. This entire process is known to take between three to seven years from the conceptual phase to the approval phase [35]. Furthermore, it would be necessary to investigate the marketing aspect of this medical device, which would increase its ability to reach hospitals nationwide.

References

[1] M. Moffat, "White Noise Process Definition," ThoughtCo., 1 April 2018. [Online]. [Accessed 24 March 2022].

[2] MathWorks, "Savitsky-Golay Filtering," 2022. [Online]. Available: https://www.mathworks.com/help/signal/ref/sgolayfilt.html. [Accessed 24 March 2022].

[3] Deepshika Acharya, "Application of adaptive Savitsky-Golay filter for EEG signal processing," Perspectives in Science, vol. 8, p. 679, 2016.

[4] H. O. Bansal, "PID Controller Tuning Techniques: A Review," Journal of Control Engineering and Technology, vol. 2, no. 4, pp. 168-176, 2012.

[5] H. Lam, Analog and Digital Filters: Design and Realization, Englewood Cliffs: Prentice Hall, 1979.

[6] G. Ellis, "Butterworth Low-Pass Filters," ScienceDirect, 4 March 2012. [Online]. Available: https://www.sciencedirect.com/topics/engineering/butterworth-filters. [Accessed 6 April 2022].

[7] MathWorks, "Butterworth Filter Design," MathWorks, [Online]. Available: https://www.mathworks.com/help/signal/ref/butter.html?s-tid=doc-ta. [Accessed 6 April 2022].

[8] Lonjaret, L., Lairez, O., Minville, V., & Geeraerts, T. (2014, September 12). Optimal perioperative management of arterial blood pressure. Retrieved from PubMed Central: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4178624/

[9] J. Schuurmans, A. Hof, O. Bosgra and R. Brouwer, "Simple Water Level Controller for Irrigation and Drainage Canals," Journal of Irrigation and Drainage Engineering, vol. 125, pp. 189-195, 1999.

[10] O. Olaniyan, M. Adegboye, O. Isife and O. Bolaji, "Design and Implementation of a Temperature and Humidity Control System for a Poultry House Prototype," Journal of Science, Technology and Education, vol. 6, no. 1, 2018.

[11] Lihong Li, Min Zhang, Lei Ding, Guodong Ren, Xiaoyu Hou, Wen Liu, Haojiang Wang, Bin Wang, Lili Yan, Haipeng Diao. (2021). Ultrafast fluorescent probe with near-infrared analytical wavelength for fluoride ion detection in real samples. Retrieved from Science Direct: https://www.sciencedirect.com/science/article/abs/pii/S1386142521000949

[12] K. Bartels, "Blood Pressure Monitoring for the Anesthesiologist: A Practical Review," Aneshtesia Analgesia, vol. 122, no. 6, pp. 1866-1879, 2016.

[13] Kirkland, E. B., Schumann, S. O., & Morgan, W. P. (2018). Trends in Healthcare Expenditures Among US Adults With Hypertension: National Estimates, 2003–2014. Journal of the American Heart Association, 1.

[14] Iohom, G.. (2022). Monitoring during anesthesia. Retrieved from UpToDate: https://www.uptodate.com/contents/monitoring-during-anesthesia

[15] Nieuwland, J., Meier, R., Zbinden, R., & Hacisalihzade, S. (2016). Fuzzy Logic Control of Blood Pressure During Anesthesia . Zurich: Research Gate.

[16] Campbell, K.. (2020, April 24). The average medical doctor salary in Canada. Retrieved from DrBill: https://www.dr-bill.ca/blog/practice-management/average-medical-doctor-salary-canada/

[17] Practice GreenHealth (2020). Understand hospital waste streams, how to measure them, and how to reduce waste at your facility. Retrieved from Practice GreenHealth: https://practicegreenhealth.org/topics/waste/waste-0

[18] Indeed Editorial Team. (2021, June 21). How Much Does an Anesthesiologist Make? (With Salaries by Province). Retrieved from Indeed: https://ca.indeed.com/career-advice/pay-salary/how-much-do-anesthesiologist-make#: :text=Ontario%3A%20%24288%2C294%20per%20year

[19] Warnica, R.. (2017, August 2). How much does the 'average' Canadian pay in a year for public health care? Retrieved from National Post: https://nationalpost.com/health/how-much-does-the-average-canadian-pay-for-public-health

[20] Hypertension Canada, "Blood Pressure Devices," Hypertension Canada, [Online]. Available: https://hypertension.ca/bpdevices. [Accessed 10 April 2022].

[21] J. Laskaris, "Purchasing Insight: Watch infusion pump prices as market surges for intraveneous therapy," Healthcare Finance, 23 January 2015. [Online]. Available: https://www.healthcarefinancenews.com/blog/purchasing-insight-infusion-pump-prices-market-surges-intraveneous-drug-therapy: :text=To [Accessed 10 April 2022].

[22] D. V. Kamani, "How To Estimate The Overall Cost For A Healthcare Software Development Project," Arkenea, 2020. [Online]. Available: https://arkenea.com/blog/estimate-overall-cost-for-healthcare-software-development-project/: :text=Depending [Accessed 10 April 2022].

[23] V. Laktash, "Medical equipment maintenance," Health Facilities Management, 4 March 2015. [Online]. Available: https://www.hfmmagazine.com/articles/1493-medical-equipment-maintenance. [Accessed 10 April 2022].

[24] T. Cohen, "The cost of biomedical equipment repair and maintenance: results of a survey," National Library of Medicine, September 2006. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/7176994/. [Accessed 10 April 2022].

[25] D. Burkett, "Operational Expenses for Software Application Projects," 19 Febuary 2020. [Online]. Available: https://workingmouse.com.au/software-development/what-are-the-monthly-operational-expenses-to-budget-for-a-software-application-project/. [Accessed 10 April 2022].

[26] T. S. V. B. D. T. M. A Macario, "Where are the costs in perioperative care? Analysis of hospital costs and charges for inpatient surgical care," National Library of Medicine, December 2004. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/8533904/. [Accessed 10 April 2022].

[27] B. Fay, "Hospital and Surgery Costs," 12 October 2021. [Online]. Available: https://www.debt.org/medical/hospital-surgery-costs/. [Accessed 10 April 2022].

[28] Board of Governors of the Federal Reserve, "Selected Interest Rates," Federal Reserve of the United States of America, 8 April 2022. [Online]. Available: https://www.federalreserve.gov/releases/h15/. [Accessed 10 April 2022].

[29] Herdon, J., Hwang, R., Bozic, K. H.. (2007, April 11). Healthcare technology and technology assessment. Retrieved from PubMed: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2200774/

[30] Dettling, H. (2021, November 1). Artificial intelligence is forcing healthcare regulators to play catch-up and reimagine the regulation rule book. Retrieved from Ernst Young: https://www.ey.com/en$_k z/law/how-the-challenge-of-regulating-ai-in-healthcare-is-escalating$

[31] College of Physicians and Surgeons British Columbia. (2019, March 25). Accreditation Standards Anesthesia. Retrieved from College of Physicians and Surgeons British Columbia: https://www.cpsbc.ca/files/pdf/NHMSFAP-AS-Anesthesia.pdf

[32] Amethia, Y., Pipariya, P., Patel, S., Shah, M.. (2021, October 21). Comparative analysis of breast cancer detection using machine learning and biosensors. Retrieved from ScienceDirect: https://www.sciencedirect.com/science/article/pii/S2667102621000887: :text=Machine

[33] Tawde, S.. (2021, January 6). Reverse Engineering. Retrieved from EduCBA: https://www.educba.com/reverse-engineering/

[34] FDA. (2018, September 2). Step 3: Pathway to Approval. Retrieved from FDA: https://www.fda.gov/patients/device-development-process/step-3-pathway-approval

[35] TWI. (2022). What is the Medical Device Development Process?. Retrieved from TWI Global:https://www.twi-global.com/technical-knowledge/faqs/what-is-the-medical-device-development-process: :text=How%20long%20does%20it%20take,device%20from%20concept%20to%20approval.

A Idea Generation Padlet

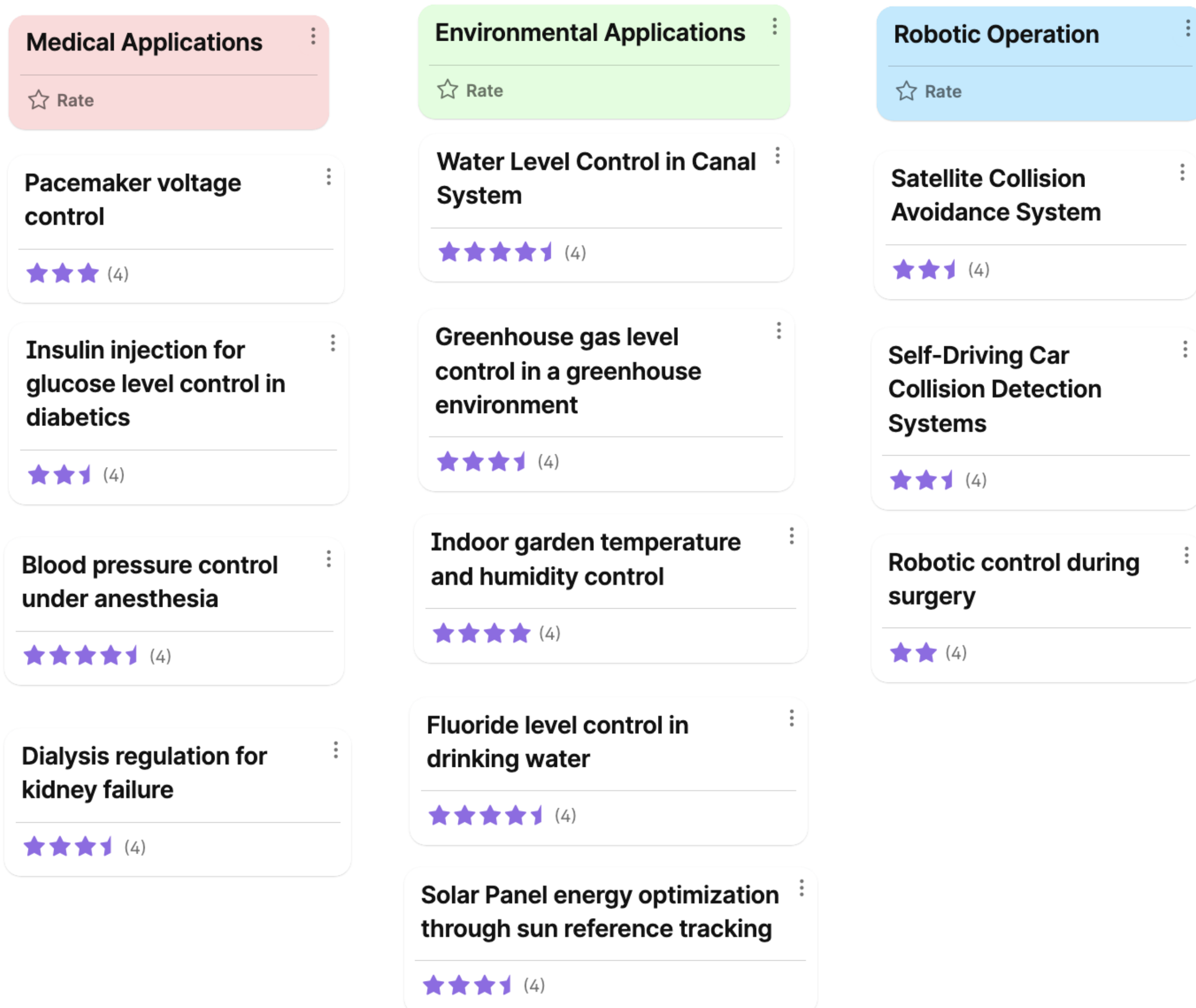


Figure 17: Padlet used for idea generation and preliminary decision-making

B Stakeholder Analysis Table

Table 6: Stakeholder Analysis

Stakeholder	Stakeholder Level	Needs	How they are Affected	Estimated Impact (High, Medium, Low)	Estimated Priority
Patients (Consumers)	Primary	The patient needs the best care that they can get. They are already in a vulnerable condition given that they are in a surgery under anesthesia. They need to be educated and have confidence in the surgery that they are receiving and the technology and processes that are going to be used throughout the surgery. Physiologically their needs related to blood pressure include: -A controlled blood pressure (systolic blood pressure of less than 120, and diastolic pressure of less than 80) [14] -Oxygen flow throughout their body	The patient is directly affected by the control of their blood pressure, their life depends on whether their blood pressure can be controlled while they are under anesthesia.	High	1
Anesthesiologists	Primary	The anesthesiologist's job is to survey the patient's blood pressure while they are under anesthesia throughout surgery. They also need to survey other vitals throughout the surgery. They need to be confident in the care that is being given to patients and that the control being implemented can adequately replace the integrity of their job.	The application of a blood pressure control will reduce the amount of work an anesthesiologist needs to do throughout a surgery. If controls are created for other vitals, they might lose their job.	High	2
Families of patients	Primary	Families must be confident that their loved ones will be safe while in surgery. They must be educated about what processes and technology will be used during the surgery. Additionally, surgery is expensive and thus they need to avoid any extra further treatment that will cause a larger economic burden.	The lives of their loved ones depend on the regulation of their blood pressure while anesthesia. The use of technology instead of a human watching blood pressure may cause stress to the family while the patient is in surgery.	High	3

Hospitals	Secondary	Hospitals need to have a good reputation and be confident in the care that they are giving. They need to see successful clinical trials with the new technology to be sure of the reliability of the new method before taking this job away from anesthesiologists.	Hospitals will have to purchase this new technology which could be a high cost as there are many surgeries that go on at a hospital per day, and they would need to purchase controls for each operating room. However, if controls are implemented for other vitals, they will save costs as they will not have to pay for anesthesiologists anymore.	Medium	4
Government	Tertiary	The government needs to have highly recognized hospitals in their region. They need to approve of the new technology by conducting trials and providing evidence of the success and reliability of this technology. They must provide everyone with confidence in the technology.	The government will need to conduct a lot of research and complete many clinical trials to show evidence of the success of the new technology. This will impose a lot of costs for them, however it will also create jobs in the government.	Medium	5
Tax Payers (only relevant for countries with public healthcare)	Tertiary	They need their taxes to be as low as possible.	The more attention and treatment patients need, the higher their taxes will be. The use of the control will prevent further treatment from being needed and thus lower taxes.	Low	6