

Remote Euthanasia System

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<u>Abstract</u>

Decompression sickness is an illness that humans can get while under extreme external pressure like sailors trapped in sunken submarines under 5 atmospheres of pressure. The clients, Dr. Sobakin and Dr. Eldridge, were contracted by the Navy to determine how long humans could survive under this pressure while being rescued to evaluate the Navy's rescue protocol for sailors in a sunken submarine. The clients will be monitoring sheep in a hyperbaric chamber set to five atmospheres of pressure over the course of a 172 hour period. The sheep within the chamber have the possibility of getting decompression sickness which would cause great trauma and can ultimately lead to death. In order to prevent this traumatic end, the team has been tasked with producing a remote euthanasia system. There are commercially available syringe pumps that can serve this purpose; however, the pumps won't operate correctly under such high pressures. After careful consideration with the help of a design matrix, the team decided to use a lead screw/stepper motor design. The team's design will utilize a lead screw and stepper motor to generate linear motion to force the euthanasia solution from the syringe, which can be activated remotely from outside the chamber. Following initial testing, the team will create the housing out of wood and the 3D printable parts out of carbon fiber PLA. In the future, the team plans to test the device in 5 atmospheres of pressure to ensure the device's functionality and reliability.

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I. INTRODUCTION

A. <u>Motivation</u>

It takes around 172 hours or 7 days to rescue every sailor from a disabled submarine through the use of rescue submarines. This is a lengthy process and can take a serious toll on the health of the sailors' who are required to stay for extended periods in the sunken submarine until help arrives. At the bottom of the ocean, the sunken submarine is typically at almost 5 atmospheres of pressure, so sailors experience a

wide variety of pressure and oxygen changes which often results in decompression sickness. Decompression sickness is also known as the "bends" when bubbles of air form in the blood vessels and cause immense pain in addition to other symptoms [1]. This is often a result of the uptake of nitrogen into the blood when air is breathed at increased ambient pressure [2]. Some symptoms of decompression sickness include: pain, neurological injury, cardiopulmonary collapse, and possibly death.

The Navy has tasked the clients of this project to test the Navy's standard operation to rescue sailors in a disabled submarine at the bottom of the ocean. To simulate the high pressure environment, the clients make use of a hyperbaric chamber. In typical clinical settings, hyperbaric chambers are often utilized to help fight infection or minimize injury [3]; however, too much exposure in a hyperbaric chamber may result in [4]:

- Lung collapse caused by air pressure changes (barotrauma)
- Seizures as a result of too much oxygen (oxygen toxicity)

The clients will be testing the Navy's protocols using sheep due to their physiological similarities to humans. Sheep have a similar cardiovascular system compared to humans, so testing the cardiovascular systems of sheep can help determine what would happen to humans under the same circumstance [1]. The clients will be using female sheep, as they have similar fat compositions to humans. Past research has utilized pigs, which has caused error due to the lack of psychological similarities between pigs and humans which has led to unreliable results according to the clients.

During these trials, some sheep are likely to get very sick while in the chamber. As a result, the IACUC have required the clients to have a manner to euthanize the sheep humanely prior to a rapid drop-out decompression if necessary. The clients do not have quick access to them in case of emergency, so a device that can remotely inject the solution in the vein is required.

B. <u>Existing Devices</u>

Hyperbaric chambers

Hyperbaric chambers are often utilized to help fight infection or minimize injury. They are typically set to induce a pressure of around 1.5 atm, which simulates what it would be like to be around 15-18 m of underwater [4]. In a hyperbaric oxygen therapy chamber, the air pressure is increased to three times higher than normal air pressure. Under these conditions, lungs can gather more oxygen than would be possible breathing pure oxygen at normal air pressure [4]. As a result, blood carries this oxygen throughout your body. This helps fight bacteria and stimulate the release of substances called growth factors and stem cells, which promote healing [4].

Depending on the chamber used, typical chambers are:

- A unit designed for 1 person. In an individual (monoplace) unit, the patient lies down on a table that slides into a clear plastic tube (Figure 1).
- A room designed to accommodate several people. In a multi person hyperbaric oxygen room, which typically looks like an open hospital room, a patient may sit or lie down.



Figure 1: An example of an individual (monoplace) hyperbaric chamber unit [4].

Infusion Pumps

Infusion pumps are pumps that are designed to inject fluid for prolonged periods of time, such as the Baxter Sigma Spectrum [5] (Figure 2). This device sells for north of \$1000, and is designed to be robust and last for decades. The pump draws fluid from a reservoir and then feeds that fluid through a tube into the patient's vein. The pump has the functionality that the rate and pressure with which it pumps the solution can be modified on the unit. However, pumps like the Baxter Sigma Spectrum are not rated for use in above 1.4 atmospheres of pressure. This poses a significant problem as the experiment where the device is to be used is being performed at up to 5 atmospheres of pressure.

While infusion pumps are designed to pump large amounts of fluid over long periods of time, syringe pumps are designed to pump fluid out of one or more syringes mounted inside the pump [6]. Although syringe pumps are typically used for research purposes, there are some commercially available units; however, these commercially available units are not usable in this project. Syringe pumps are usually operated via a keypad mounted directly on the unit, which would not work for this experiment as it would require the operator to be in the hyperbaric chamber. Furthermore, syringe pumps are not rated for anywhere near the pressure induced by the hyperbaric chamber which the device must withstand.



Figure 2: An image of the Baxter Sigma Spectrum Infusion Pump [5].

HOSPIRA Infusion Pumps

Hospira's Plum A+ hyperbaric infusion pump is the only FDA approved infusion pump for high pressure environments (Figure 3). Hospira manufactures various infusion pumps that are customizable for specific applications [7]. For IV infusions delivered to patients in monoplace chambers, the infusion pump is located adjacent to the chamber. The infusion pump administration set is connected to a specialized fitting in a port in the chamber hatch, which forms a seal. Inside the chamber, tubing from the specialized fitting is connected to the patient's IV catheter. The infusion pump's occlusion pressure is set to maximum. In order to deliver the IV solution into the pressurized environment, the pump must be able to generate 30 psi or more without alarming and stopping the infusion [7]. This device was the only FDA approved infusion pump on the market for hyperbaric environments; however, Hospira recently announced that it would be discontinuing the manufacture, sale, leasing, service, and support of the Plum A+ hyperbaric infusion pump.



Figure 3: An image of the Hospira's Plum A+ Hyperbaric Infusion Pump [7].

C. Problem Statement

Due to a new contract with the Navy, Dr. Aleksey Sobakin and Dr. Marlowe Eldridge are testing the Navy's standard operation to rescue sailors in a disabled submarine at the bottom of the ocean. In order to examine their standard operation, the team's clients will be using sheep and a hyperbaric chamber. This hyperbaric chamber will be putting the sheep through a variety of pressures that can be fatal. However, IACUC has asked the clients to institute a method to euthanize the sheep humanely prior to a rapid drop-out decompression if necessary. As the sheep are sealed away in a chamber, the client has asked the team to devise a method to remotely euthanize the sheep when they are inside the hyperbaric chamber. This euthanasia system will have three main subsystems. For the housing subsystem, There must be a way to secure the syringe within the device and to prevent it from moving or being accidentally discharged. For the injection subsystem, there must be a way to pump the euthanasia solution out of the syringe and into the vein in a timely, complete manner. Finally, there must be a remote control subsystem that enables the device to perform the injection protocol upon a button press by a researcher outside of the hyperbaric chamber.

II. BACKGROUND

A. Background research

The client will be injecting euthansia solution into a major vein of the sheep. The sheep will have a catheter inserted and sutured in order to allow direct access to this vein. Intravenous injections are often given through the jugular vein, but great caution needs to be taken when injecting in order to ensure that no other major arteries or veins are nicked, causing a more painful and less humane death [8]. In sheep, the jugular vein can be found lying in a line starting at the base of the ear running down the neck to the thoracic inlet. It is often necessary to part the wool to give adequate visualization of the vein. Adequate restraint is critical to avoid inadvertent puncture of other structures such as the trachea or esophagus. A 4-cm, 20-gauge needle can be used for venipuncture [9].

Pentobarbital is the most common medication to administer for animal euthanization [10]. It can be used in smaller doses as it is used as an anti seizure medication. Size of the animal being euthanized is a crucial part in how much they need to administer, and as a result, the client will be using similar sized female sheep in order to consistently use a similar dosage. Typically, a dosage of 100 mg per kilogram of body mass of the sheep is required to adequately dispatch a sheep [11]. Pentobarbital behaves as an incompressible fluid much like water. The shelf life of sodium pentobarbital is rated at 3 years when unopened, and 28 days after opening the package [11].

B. Research required to design and build your prototype

The device will be utilizing a lead-screw. This device will harness a form of a leadscrew coupled with a stepper motor that force feeds the leadscrew forward (the stepper motor "walks" in a direction away from the syringe) into the plunger of the syringe. This stepper motor is electrically controlled which would enable an interface with a microcontroller that can control its function (after some calibration) after a remote signal is sensed.

Choosing the correct motor relies on many factors. There are three main motor devices that the team is investigating, which include the DC Stepper Motor, DC Brush Servo Motor, and DC Brushless Servo Motor [12]. First, the DC Stepper Motor (Figure 4) has open loop positioning so no encoder is required. It utilizes a simple "pulse and direction" signal needed for rotation and has a high torque density at low speeds. However, there is no position correction in the event the load exceeds the output torque. It has a low power density meaning that the torque drops off dramatically at higher speed and the motor draws continuous current, even at standstill and experiences high iron losses above 3000 RPM [12].

Second, the DC Brush Servo Motor has linear speed/torque curve and low-cost drive electronics. In addition to having many different motor configurations available, it is highly customizable and is easy to control and integrate [12]. The DC Brush Servo Motor has a very smooth operating system which enables low speeds (depends on the number of slots and commutator bars) and a high power density. However, the motor will draw high current in an overload condition, and the angular velocity is more limited due to mechanical factors in the armature design and brush system [12].

Third, the DC Brushless Servo Motor has a high power density. This motor has the highest move response, acceleration, and smooth operation possible when compared to the other two motor options. That being said, the DC Brushless Servo Motor is also the most expensive of the three motors mentioned. The motor will draw high current in an overload condition and will use the method of feedback needed for closed-loop positioning. Furthermore, the DC Brushless Servo Motor has a high drive circuit complexity and cost.



Figure 4: An example of a DC Stepper Motor that can be paired with a lead-screw [12].

In addition to choosing the motor based on functionality and cost, it must also meet the required load acceleration, overcome friction in the system, overcome the effect of gravity, and maintain a safe maximum operating temperature [12]. After selecting our motor and ensuring that it can work well for our application, a lead screw is to be chosen that can work in tandem with the chosen motor.

A lead screw uses a thread to convert the rotary motion of the stepper motor into linear motion. The performance of a lead screw depends on the coefficient of friction between the nut and the screw, which in turn depends on the material used for the nut and screw [13].

When utilizing a lead screw device, the correct nut must be chosen. To do this, one must look at the required load capacity. Plastic nuts are typically used for light loads of less than 100 lbs, although plastic nut designs for 300 lbs and beyond are possible [14]. Bronze nuts can be used for applications in excess of several thousand pounds. This project will most likely use a plastic nut, but a bronze nut may be considered if it's in the price range.

The pressure-velocity factor is also a determinant when choosing the correct lead screw device [14] (Figure 5). The pressure-velocity, or PV factor, is the product of the pressure and velocity between the nut and lead screw. It helps determine the load, speed and duty cycle that the nut can handle. Plastic materials have an intrinsic PV rating, the point at which frictional heat causes permanent deformation of the plastic. So the more load applied to a lead screw assembly, the slower it must be turned to avoid exceeding the nut's PV limit.

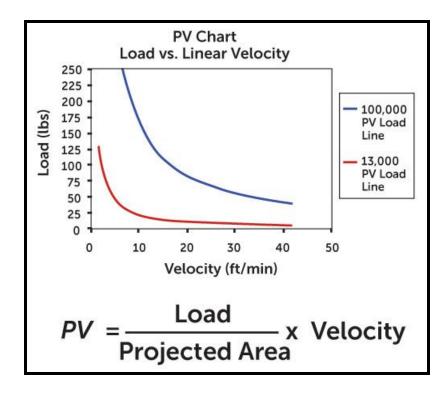


Figure 5: A graph expressing the pressure-velocity factor when choosing the correct lead-screw [14].

C. Client information

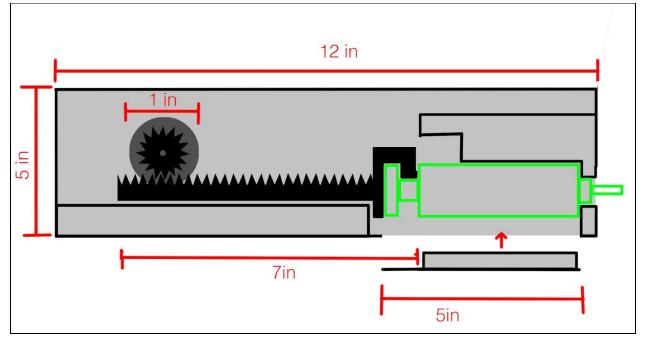
The clients for this project are Dr. Aleksey Sobakin and Dr. Marlowe Eldridge. Dr. Aleksey Sobakin is an associate scientist in the UW Department of Pediatrics. Dr. Aleksey does research in Orthopedic Surgery, Sports Medicine and Emergency Medicine. Dr. Marlowe Eldridge is a professor and chief of the Division of Pediatric Critical Care. Dr. Eldridge's research broadly involves cardiopulmonary interactions in congenital and acquired heart and lung diseases.

D. Design Specifications

This device's system must be able to operate in a system with a pressure of 5 atmospheres, it must also be able to withstand the pressure inside the hyperbaric chamber. Since there will be two sheep in the chamber at a time, the client is requesting two devices. The device will most likely be controlled wirelessly using a radio transmitter, there would also be the option of wiring in a controller from the outside. The main goal is for the researcher on the outside to be able to press a button and cause the device to activate on the inside of the chamber. It must be a slow, controlled release of the solution in order to ensure a complete release of the euthanasia solution from the syringe

III. Preliminary Designs

Although three distinct designs were produced, they all possessed two distinct commonalities. First, the syringe was constant across all three designs, as this part was supplied by the client. The syringe is a 20cc Kendall Monoject Syringe with a Luer Lock Tip. Additionally, the devices each needed a control module to actuate the method by which they depress the syringe plunger. The team working on this project has decided to use a PCB to power the device, for its functionality, low cost and ease of use.



A. Rack and Pinion

Figure 6: A side view of the Rack and Pinion design with dimensions labeled in inches

The Rack and Pinion design utilized a small direct current motor to drive a pinion gear which was fixed to the motor's output shaft (Figure 6). The pinion gear was in constant contact with a linear rack gear that was pinned against a smooth surface by the pinion gear. This gearing was able to translate the rotational motion of the motor into linear motion. The linear motion generated by this assembly was then used to depress the plunger of the syringe, since the syringe and rack gear were in constant contact. The rack gear was attached to the plunger of the syringe via a hook-like protrusion on the gear's end, which the end of the plunger slotted into (Figure 6). This protrusion's purpose was twofold: prevent accidental depression caused by the air pressure and prevent the syringe from shifting in its chamber. The high air pressure within the chamber could have depressed the plunger, since the liquid inside was filled at 1 ATM, and thus a pressure differential existed around the syringe. The protrusion on the rack gear locked the plunger in place, preventing this accidental discharge. Additionally, the protrusion kept the syringe in place by stabilizing it from the back. Other directional stabilization was provided by chocks molded into the device's housing, and the chock attached to the removable trapdoor (Figure 6). The syringe was to be loaded and removed from the device through this removable trapdoor located on the underside of the device housing. The syringe was loaded in a similar manner to a shotgun shell, in that the nose is pushed up and into the chamber, which then allows it to slide forward as the back slides up and in. Once in, it is completely encased by chocks, locking it in place.

This device had two advantages over the other designs, namely efficiency and cost. It would have been made primarily out of 3D printed carbon fiber reinforced PLA, which costs around \$33 per kilogram [15], and approximately 700 grams would have been needed to print this design. This would have been cheaper than the other designs, which would have been made out of metal or wood. It also used a small DC motor which had a relatively low power draw, and the nature of the rack and pinion gear assembly would have allowed the motor to depress the syringe with relatively little energy.

B. Linear Actuator

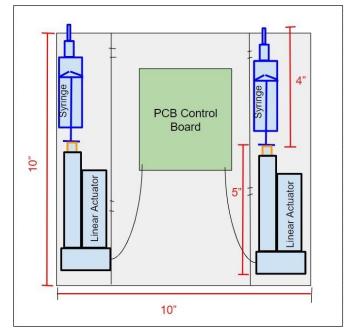
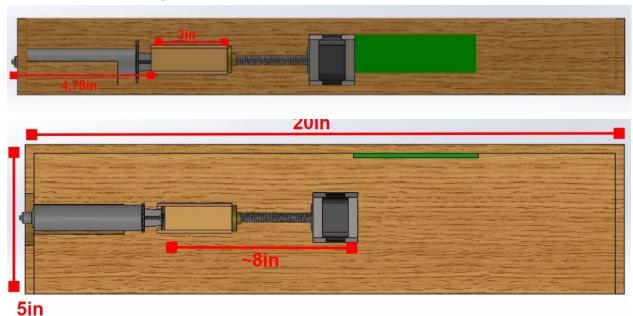


Figure 7: A top view of the Linear Actuator design with dimensions labeled in inches

The Linear Actuator design utilized two commercial linear actuator systems placed within a housing with their respective plunger arms interfacing with syringes (Figure 7). This design offers three key functionalities. First, the syringe would be able to be easily inserted into the box with the flat side of its plunger interfacing with the arm of the linear actuator where a holding apparatus keeps the syringe plunger from depressing prematurely due to the high pressures of the hyperbaric chamber. Subsequently, once used, the syringes are easily removable from the apparatus as to facilitate its use for the client. Second, the design made use of robust, consistent linear actuators to drive the plunging motion of the syringe when required by the user (Figure 7). These linear actuators are able to be purchased from commercial vendors with the specific function of translating an object linearly. As these are commercial systems, this would give confidence that the system would work consistently and without fail for many cycles. These linear actuators would be capable of being wired to a control board PCB that can interface and read the input of a receiver that can direct function. Once activated, linear actuators can generate high forces; however, they tend to act very slowly over their defined displacement. That being said, this function provided confidence that the linear actuator would be able to depress the plunger into the syringe without obstacle. Third, this design acts to incorporate two linear

actuators within one housing that is controlled by a central control PCB (Figure 7). This PCB would read inputs from the user controller that could specify which linear actuator, and by extension, which syringe is required to be depressed. This would enable only one system to be built that includes selectivity for which syringe is to be activated depending on the sheeps' conditions within the chamber and to the discretion of the user.

Although this design offered consistency, selectivity, and robustness, the linear actuators are often very expensive in comparison to other linear motion motors. That being said, the pressure induced by the hyperbaric chamber also presents challenges in finding a linear actuator that can hold up to the pressures. As the linear actuators are often closed systems, the high pressure induced by the hyperbaric chamber may pose risks in disrupting function of the design over repeated use. Furthermore, linear actuators tend to be heavy, and large which would put undue strain on the housing and those that move the apparatus.



C. Lead Screw Plunge

Figure 8: A side and top view of the Lead Screw Plunge design with dimensions labeled in inches.

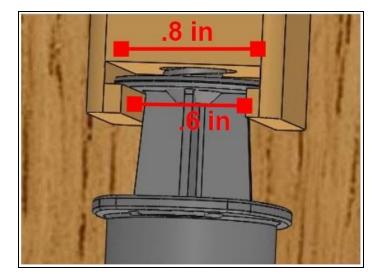


Figure 9: A closeup view of the interface between the plunger of the syringe and the slot in the holding cap with dimensions labeled in inches. The leadscrew is fed through the holding cap so it is still able to interface with the plunger to depress it upon controller activation.

The Lead Screw Plunge utilized a lead screw coupled with a stepper motor in order to generate the linear motion required to depress the plunger of the syringe (Figure 8). The Lead Screw Plunge has three key parts that enable its function. First, the syringe was able to be easily slotted in the top of the apparatus such that the plunger of the syringe was able to interface with the holding cap (Figure 9) on the leadscrew and also be secured within the housing. The syringe would rest on a guide built into the housing that would pin the syringe between the front opening of the housing (where the tubing feeds through) and the holding cap (Figure 8). By enabling this functionality, this would enable the user to easily insert the syringe into the box without worrying about accidental discharge or rupturing the tubing. This is key as the device is to be used many times which would require reloading of the syringe and accidental discharge of the syringe would be detrimental for the client's experiment. Second, there is a holding cap that is capable of being threaded onto the leadscrew such that it holds the plunger of the syringe in place (just in case the 5 atm pressure of the chamber causes the syringe to naturally depress) and will also allow for the forced plunging of the syringe as the leadscrew is in contact with the top of the syringe through the holding cap (Figure 9). As the top of plunger is held in place within the holding cap, the holding cap prevents the syringe from prematurely discharging euthanasia solution as the chamber is is pressurized. Finally, the main linear pushing mechanism comes in the form of a leadscrew coupled with a stepper motor that essentially force feeds the leadscrew forward (the stepper motor "walks" away in a direction away from the syringe) into the plunger of the syringe. This motion causes the release of the euthanasia solution from the syringe into the sheep. Luckily, the stepper motor and lead screw set is highly customizable to the design considerations at hand in terms of depression speed and strength; thus, this system can be made to fit under any depression speed requirements defined by the client. This stepper motor is electrically controlled via a PCB control board which would enable an interface with a microcontroller that can control its function (after some calibration) after a remote signal is sensed.

Although this design offers customizability, ease-of-use, and robustness, this design requires a fair amount of moving parts to work harmoniously which will require careful, patient

calibration. Next, the stepper motor chosen may be loud which could startle the sheep; however, this was taken into consideration when choosing the stepper motor to use.

Designs	Rack and Pinion		Linear Actuator		Lead Screw Plunge	
Reliability (30)	3	18	4	24	5	30
Efficiency (25)	5	25	3	15	4	20
Robustness (20)	4	16	3	12	5	20
Feasibility (15)	4	12	5	15	3	9
Ease of Use (10)	4	8	4	8	5	10
Cost (5)	5	5	1	1	3	3
Total (100)	84		75		92	

IV. Preliminary Design Evaluation

Table 1: Design matrix

The team defined 6 criteria to analyze the effectiveness of the proposed designs (Table 1). First, Reliability was defined as consistent delivery of expected results, such that all the solution is consistently forced from the syringe and speed of injection is consistent. In terms of Reliability, the team decided that the Lead Screw Plunge (with a score of 5/5) won the Reliability category due to its customizability in terms of force induced and speed as well as lead screw/stepper motor tandems being built to last. The Rack and Pinion design scored the lowest (with a score of 3/5) due to it having the least inherent customizability and that there may be issues with ensuring that the teeth of the pinion align with the rack over many uses.

Second, Efficiency was defined as how effectively and speedily the device can administer the euthanasia. The team chose the Rack and Pinion design to win the category (with a score of 5/5) because the design takes the least amount of time to depress the syringe, and also takes the least amount of power to do so. On the other hand, a lead screw/stepper motor and commercially available linear actuators tend to be slower with linear actuators being the slowest possible option (which is why it was scored 3/5 in this category).

Third, Robustness was defined as the ability for the design to be able to withstand repeated use and withstand the high pressure environment induced by the hyperbaric chamber. The team chose the Lead Screw plunge design to win the Robustness category (with a score of 5/5) due to it being manufactured out of metal components that can withstand repeated use and mechanical components that can withstand the high pressure environment. On the other hand, it was tough to find commercial linear actuators that can withstand the high pressure environment due to the nature of their closed system. The Rack and Pinion designed scored low in Robustness due to its components being made out of plastic which is inherently less strong and more prone to being destroyed over repeated use than metal.

Fourth, Feasibility was defined as how straight forward the design would be to complete in the given time frame of one semester. This category was won by the Linear Actuator (with a score of 5/5) because it can be just purchased and slotted into the design; however, the other designs will give the team a better engineering opportunity in the future. That being said, the Rack and Pinion designed scored higher (with a score of 4/5) than the Lead Screw Plunge (with a score of 3/5) in this category due to the main mechanisms being able to be 3D printed instead of order or manufactured from a third party like the components of the Lead Screw Plunge.

Fifth, Ease Of Use was defined as how easy the clients can interact with the design in order to activate it and reload syringes between experiments. The Lead Screw Plunge design won the category (with a score of 5/5) due to its slot-in method that makes it very easy and intuitive to replace the syringe between trials when compared to the other two designs, namely the shotgun loading method of the Rack and Pinion.

Sixth, the cost category was given a very low weight in the matrix because the team was not given a budget, but they still chose to keep spending at a minimum. The Rack and Pinion design won (with a score of 5/5) this category because it is made of plastic, and is therefore relatively inexpensive to produce. The Linear Actuator scored lowest in this category (with a score of 1/5) due to the high price tag associated with purchasing commercial systems.

Based on the criteria and the scores that the team gave the designs on the various criteria, the team decided to move forward with the Lead Screw Plunge design, and will begin production in the coming weeks.

V. Fabrication/Development Process

A. Materials

Carbon fiber reinforced 1.75 mm PLA was used for all of the 3D printed components (Appendix A). The experiment will be performed at 20-22°C, which is well within the range of temperatures for which PLA retains its structural integrity. Carbon fiber reinforced PLA was used because it is significantly stronger than traditional PLA. Additionally, a metal lead screw and an accompanying stepper motor was used. These components are very robust, and capable of withstanding the necessary pressures. Additionally, metal was used for the lead screw because it was strong enough to not deform under the compressive forces that it was under within the device. A PCB was used to control the stepper motor because of its ease of use, functionality and cost.

B. Methods

Several components of the device were 3D printed in carbon fiber reinforced PLA with a Fused Deposition Modeling (FDM) 3D printer (Appendix A). These components included the device housing, threaded holding cap, and mounting for the stepper motor and PCB. The lead screw was fed into the center of the stepper motor, and one end was fed into the threaded holding cap. The stepper motor was then fastened to the housing with its mounting bracket. Next, the PCB was mounted to the housing with its mounting bracket, and was then connected to the stepper motor.

C. Testing

Due to the high-stakes nature of this device, the design team felt it was necessary to rigorously test its functionality, ensuring that it would work every time it needed to. First, they tested the stepper motor and lead screw by actuating it and measuring its speed. This was done by recording the time it took to move a certain distance and using that information to calculate its

speed. The test was performed in 1 ATM and 5 ATM with ten trials in each pressure. This was done on a 95% confidence interval. Next, the team needed to verify that all of the euthanasia solution contained within the syringe was expelled. This was done by actuating the device five times and observing the syringe to determine if any solution remained after each trial. The final test that the design team performed was done with the intended purpose of determining whether the device's battery would last for the entire duration of the experiment, which is 7 days. This test was performed in two different ways. First, the theoretical life of the battery while the device is powered on and in use was calculated. Second, the device was powered on and ran continuously until the battery was drained to the point where the device could no longer function. These values were then compared to the minimum required life of the battery, 7 days. The experimentally determined battery life needed to be at least 20% longer than the required 7 days in order for the device to pass the test.

VI. Discussion

At this time, there was not a prototype created to test, so no results were collected for comparison. There were many possible ethical considerations that were discovered through research and through the process of designing the end product. A major ethical consideration that the team worked with was how to justify the euthanization of the sheep. Since the euthanization of the sheep would be for when the sheep got sick and to prevent further suffering, the team felt that the device was a benefit to the sheep that are to undergo the experiment within the hyperbaric chamber. Furthermore, the experimental data has the possibility of saving hundreds of human lives.

The team also had to consider the impacts the device had in settings outside the experiment. There were other places that the device could have been used such as in assisted suicide (in a clinical setting) which raised many other ethical concerns. The team's ultimate use of the device was to give the researchers a humane way to continue their experiments for the Navy. The most important aspect the team drew from the design evaluation was the device's reliability. The reliability of the device determined whether or not the device would be capable to consistently perform humane euthanization when activated. The team achieved this by accounting for external pressures at each aspect of the device.

Throughout the duration of the sheep experiment, there were a couple possible sources of error, and these sources were things outside of the team's control. A major source of error could be the variability of the pressure in the chamber. The team's calculations were based around a certain pressure range, and if the pressure falls out of that range, the device has the possibility to fail. On the other hand, another small source of error could be human error from the researchers. There is a chance that the researchers missed the jugular vein when suturing, or the researchers accidentally put the wrong amount of Pentobarbital in the syringes. These small human errors could impact the performance of the team's device.

VII. Conclusions

Time is a critical factor when a submarine is disabled and decompression sickness is quite fatal to sailors depending on the depth of the submarine. The clients have taken to using sheep in the experiments in order to gauge the survivability time and to observe physiological response of being exposed to five atmospheres of pressure for 172 hours or 7 days. In light of this, it is possible that the sheep get very sick from their time in the hyperbaric chamber; thus, IACUC has instructed the clients to develop a method to remote euthanasia system to humanely euthanize the sheep if necessary. A remote euthanasia system is a critical tool to providing a humane euthanization of a sheep test subject in the case of any harmful changes inside the hyperbaric chamber. Additionally, it ensures that the researcher is able to quickly deliver the euthanasia solution instead of having to wait for the chamber to depressurize and open which could put the sheep through unnecessary trauma.

The team formulated three designs that all fit the qualifications set by the client, but after some discussion and creation of a design matrix, the team found that the Lead Screw Plunge design would best fit the client's needs and team's abilities. Upon consideration of final designs, the team realized that the high pressures of the chamber would create a need for a very sturdy housing container for the system, so the team will need to test the chosen material of the housing under different pressure scenarios. The team plans to move forward by testing multiple aspects of the Lead Screw Plunge design, including injection speed and completeness, as well as determining whether a wired or wireless setup, and a mirrored or multi system setup will better facilitate the euthanization process.

The team's design fit the qualities of efficiency and reliability when it came to activation of the device by researchers outside the chamber. Due to its inherent customizability, the Lead Screw Plunge design excels in providing streamlined plunger depression, which ensures that the euthansia solution is able to be delivered to the sheep at a constant rate that was defined by the client. It is assumed that the device has to fight against variable pressure differences inside the chamber during actual testing conditions. To amend this, the team plans to take special care when developing the mechanical components and which components make up the final design. More work pertaining to increasing the pressure range of the device to ensure dependable results was planned by the team. With these considerations in mind, the team is confident that a usable, robust prototype can be developed to satisfy the requirements of the clients.

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IX. Appendix

Appendix A - 3D Printing Protocol

There are 4 components to any 3D printed part: the ceiling, floor, infill, and shell. The shell consists of a set number of concentric and conjoined walls that runs along the vertical axis of the print. The ceiling and floor consist of a set number of completely solid layers of material, and sit on top of and below the shell. Together, the shell, ceiling, and floor form a complete and connected surface. This surface bounds the infill, which is a three dimensional grid with hollow cells. Infill is calculated as a percentage of interior volume. Since the components all needed to withstand 5 ATM of pressure, resistance to deformation from pressure was the key parameter that was optimized during the printing process.

Each part was printed with the following settings:

1. A 0.4 mm extruder nozzle was used because it offered a good balance between horizontal adhesion and precision.

2. A layer height of 0.12 mm was used because it promoted strong vertical adhesion and minimized layer lines on slanted top/bottom surfaces.

3. A shell width of 1.6 mm (4 passes) was used, since it provided a good balance between weight and resistance to deformation.

4. A ceiling and roof thickness of 1.08mm (9 layers) was used since it provided a top and bottom with a similar strength to the shell, to maintain uniformity.

5. An infill density of 40% was used. Although a much lower infill density, as low as 15%, would have sufficed, the design team felt it was important to "over-build" the components due to the catastrophic events that could have occurred if this device had failed.

6. A hotend temperature of 210°C was used as per the filament manufacturer's recommended settings.

7. A heated bed and enclosure were not used, as PLA does not require either.

Appendix B -- PDS

Function:

Due to a new contract with the Navy, Dr. Aleksey Sobakin and Dr. Marlowe Eldridge are testing the Navy's standard operation to rescue sailors in a disabled submarine at the bottom of

the ocean. In order to examine their standard operation, the clients will be using sheep and a hyperbaric chamber. This hyperbaric chamber will be putting the sheep through a variety of pressures that can lead to various health risks like pulmonary barotrauma or decompression sickness [1]. In fact, decompression sickness has the capacity to result in neurological injury or even death [1]. In order to avoid these traumatic health complications, IACUC has asked the clients to institute a method to euthanize the sheep humanely prior to a rapid drop-out decompression if necessary. As the sheep are sealed away in a chamber, the client has asked the team to devise a method to remotely euthanize the sheep when they are inside the hyperbaric chamber. This euthanasia system will have three main subsystems. For the housing subsystem, There must be a way to secure the syringe within the device and to prevent it from moving or being accidentally discharged. For the injection subsystem, there must be a way to pump the euthanasia solution out of the syringe and into the vein in a timely, complete manner. Finally, there must be a remote control subsystem that enables the device to perform the injection protocol upon a button press by a researcher outside of the hyperbaric chamber.

<u>Client requirements:</u>

- Housing materials, motor, and leadscrew must be capable of withstanding pressure differential caused by hyperbaric chamber
- Remote-controlled system to allow for activation of the system from outside the hyperbaric chamber based on the researcher's evaluation of the sheep's condition
- Method required to expel the euthanasia solution from the needle in a humane, timely manner
 - It must be a slow, controlled release of the solution in order to ensure a complete release of the euthanasia solution from the syringe

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

The remote euthanasia system must be ready and usable each time a sheep is placed into the hyperbaric chamber for the experiment. In general, the remote euthanasia system is not expected to have to carry a load larger than the components that make it up; however, the system must be capable of withstanding and function within the pressure differentials induced by the hyperbaric chamber (5 atm). In terms of specifics, the remote euthanasia system that is to be developed will need to be able to perform three key tasks repeatedly and without fail.

First, the system must be capable of expelling the euthanasia solution from the syringe through a sutured catheter inserted into the jugular vein of the sheep.

This tubing must be short, allowing the solution to enter the sheep's bloodstream quickly after activation of the system. This expelling step must be timed properly in order to ensure the sheep is correctly euthanized. Second, the syringe must be able to be replaced and "reloaded" after use in order to ensure reusability of the remote euthanasia system. Third, the system must be able to be controlled remotely via a wireless signalling system (RF or Bluetooth) or through a wired signalling system depending on cost and feasibility. This will enable researchers to control the system outside of the hyperbaric chamber if any rapid sheep health degradation occurs. These three key capabilities will enable the remote euthanasia system to operate and to meet the client's requirements.

b. *Safety:*

This product is being made with the intention of humanely euthanizing animal test subjects, and the safety of those animals actually lies in assuring that their death is humane, because if they suffer, the device is no longer safe. It is important that the lead screw plunge system doesn't activate at unexpected times when handling. Although meant to dispatch animal test subjects, it is also important that this product euthanizes the animal test subjects in a timely manner in order to prevent them from succumbing to the medical issues of the hyperbaric chamber. This device needs to perform a humane euthanization, and it needs to be able to be activated when the researchers decide the time is right to reduce suffering of the animal.

c. Accuracy and Reliability:

Using a lead screw, the team needs to assure that it moves at a given speed to assure that the euthanization happens at the right rate. The syringe is approximately 9 cm long, and the client has requested that the injection happen in 10-20 seconds. Therefore the team needs the lead screw to move at anywhere between .5 and 1 cm/second. This can be achieved by calculating the teeth ratio of the gears used in the motor and using the appropriate thread size on the lead screw.

d. Life in Service:

The client requests that the device lasts as long as the hyperbaric sheep experiment lasts. This is roughly 172 hours. The experiments will be going all day and night, so the device must stay in service during this time. The client stated that the device must be able to function under 5 atm (73 psi) which has the possibility of impairing the function of the device[4].

e. Shelf Life:

Euthanasia will be performed using sodium pentobarbital. Typically, a dosage of 100 mg per kilogram of body mass of the sheep is required to adequately dispatch a sheep [5]. The shelf life of sodium pentobarbital is rated at 3 years when unopened, and 28 days after opening the package [5].

Batteries will need to be utilized in the project, as the device must be fully self-contained, and thus must rely on batteries within the device housing. Batteries are labeled with an expiration date on the packaging.

f. Operating Environment:

This device is going to be subjected to very high pressures (5 atm) due to the hyperbaric chamber environment [4]; thus, all components of the device, including the housing material and the containers of the medications will have to be able to withstand large pressures. The wireless signal will need to go through multiple inches of steel or glass in order to move the lead screw inside the chamber, so the team will need to test whether the signal can pass through those barriers.

g. Ergonomics:

The product will not interact directly with the sheep, as it will be positioned on the top of the housing that is securing the head of the sheep in the hyperbaric chamber. The syringe tubing will be the only aspect attached directly to the sheep. As a result, the device should not cause tangling of this tubing. No part of the device should induce any discomfort to the sheep.

h. Size:

The device must be compact, yet robust. The product must be large enough to fit a 20 cc Kendall monoject syringe with a luer lock tip and a lead screw/stepper motor to control the expelling rate of the sodium pentobarbital from the syringe [2]. This device will consist of electrical components, the injection system housing, and motorized components, which reach no more than 20 inches long. As a result, the device will be less than a cubic foot, measuring around 4 inches x 20 inches x 4 inches.

i. Weight:

Weight is not an integral factor in the design process due to the fact that the device will be attached to the top of the housing that is securing the head of the sheep in the hyperbaric chamber. However, the weight should not be too light so the device is not easily jostled from its resting position.

j. Materials:

It will be very important to choose materials that can withstand the pressure differentials induced by the hyperbaric chamber that is to be used in the experiment. Outside of the closed system of the syringe, the pressure changes will need to be considered in terms of the electrical components of the PCB, the injection system housing, and the motorized components. When possible, it will be important to avoid closed systems as this will mitigate the risk of having a closed system failing under pressure changes.

The materials utilized in this design should facilitate the creation of a lightweight, sturdy system that is capable of repeated use without disrupting the experimental design of the clients. When materials are chosen, it will be important to keep the pressure, the sheep's health, the overall structural integrity of the system, and the weight of the system in mind.

k. Aesthetics, Appearance, and Finish:

As the device's function is most important in the project, the device can have a very simple appearance. The client has not specified a color or type of finish; however, the device will be designed to be as professional and compact as possible while still functioning efficiently and effectively.

2. Production Characteristics

a. Quantity:

As the client is expecting that two sheep will be in the hyperbaric chamber at any given time, it is expected that two devices will need to be manufactured. It should be noted that the client expressed interest in integrating two injection systems in one box which would require only one device to be produced.

b. Target Product Cost:

The client has money built into their yearly budget for laboratory maintenance that they are using for this project. The client also does not have a specified amount, but the team has a goal of staying under \$250.

3. Miscellaneous

a. Standards and Specifications:

For any application, the team will not need FDA approval or any governmental approval. The client conducting the experiment already has the necessary IACUC approval.

b. Customer:

The client would prefer for the device to be wirelessly actuated and dispense the euthanasia solution at a moderate pace in order to avoid rupturing a blood vessel and/or prolonging suffering. Additionally, the client would like the device to be able to euthanize two sheep either simultaneously or in rapid succession.

c. Patient-related concerns:

The most important part of a humane euthanasia is a quick and relatively painless death. Assuring death is very important, and if the animal doesn't die the decompression sickness, and the side effects of the injected medication cause the animal to suffer, which is contrary to the purpose of the project. Over the course of the experiment, the device will need to be removed from the chamber between trials, sterilized, reloaded with syringes filled with sodium pentobarbital, and then placed back in the hyperbaric chamber before the next test begins. Due to this expected use, old syringes need to be easily removable from the device and new syringes must be able to be reloaded with ease.

d. *Competition:*

There are similar items/patents that will compete with the design. A competing design for fluid injection in human patients was patented in the European Patent Office in 2016 [7][Appendix A]. This device injects insulin into the patient by leaving a permanent needle in the patient and using a pump to inject insulin into the patient.

Infusion pumps are pumps that are designed to inject fluid for prolonged periods of time, such as the Baxter Sigma Spectrum[9]. This device sells for north of \$1000, and is designed to be extremely robust and last for decades. The pump draws fluid from a reservoir and then feeds that fluid through a tube into the patient's vein. It can vary the rate and pressure with which it pumps the solution. However, it is not rated for use in above 1.4 atmospheres of pressure, which would pose a significant problem, as this experiment is being performed at up to 5 atmospheres of pressure.

While infusion pumps are designed to pump large amounts of fluid over long periods of time, syringe pumps are designed to pump fluid out of one or more syringes mounted inside of the device. They are used primarily for research purposes, and while there are some commercially available, none meet the needs of this experiment. They are usually operated via a keypad mounted directly on the unit, which would not work for this experiment. However, the design of these would likely cause these syringe pumps to function better under the air pressure of this experiment than the infusion pump would.

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