LifeWatch

The First Wearable Auto-Injector

Final Project Report

Team EpiPenn

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Team Members

BSE Candidates in Mechanical Engineering and Applied Mechanics

Benjamin Bernstein
Spencer Fox
Alexander Garcia
Reed Ginsberg
Daniel Orol
Jacob Snipes

Faculty Advisor

Dr. Kevin Turner
Professor and MEAM Associate Chair for Graduate Affairs and Graduate Group Chair

Technical Advisor

Dr. Paulo Arratia
Professor and MEAM Associate Chair for Undergraduate Affairs

Abstract

Anaphylaxis is a life threatening allergic reaction that affects 1 in 50 Americans, for which the necessary treatment is an immediate injection of epinephrine. Only a quarter of respondents to a survey stated that they remember to have their epinephrine auto-injector with them at all times. After investigating the cumbersome solutions that exist on the market today, Team EpiPenn developed a wearable auto-injector in the profile of a watch. LifeWatch is a slim, lightweight, and easy-to-remember solution to a life-threatening problem faced by millions every day.

The core design challenge of LifeWatch was volumetric optimization. That is, fitting all of the complex mechanisms into the bounding volume of a standard wristwatch proved to be quite difficult. This process included design of a custom syringe, finite-element analysis of structural components, computational fluid dynamics analysis of flow within the drug delivery subsystem, and design for manufacturability.

Results of our work can be seen in our compact product, which fits within a 55 mm x 48 mm x 15 mm bounding box. The needle extends 16 mm out of the device to inject 0.3 mL of fluid with a standard deviation lower than or equal to that of the EpiPen. Potential future improvements include increasing overall reliability, adding a watch face, and improving ease of assembly.

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1. Executive Summary

Anaphylaxis is defined as "a severe, potentially life-threatening reaction" to antigens to which the body has become hypersensitive; it can be fatal if not treated immediately [1]. Between 1997 and 2011, there was a 50% increase in the number of children suffering from anaphylactic allergies in the US [2]. Clearly, anaphylaxis is a rapidly growing problem in the world today. First-response solutions, known as auto-injectors, allow users to self-administer a small dosage of epinephrine to temporarily suppress the reaction until they can receive proper medical treatment. The current market leader, EpiPen, controls most of the market with over 70% market share [3]. However, the EpiPen is rather bulky with a volume of 70.8 cm^3 and a length-to-width aspect ratio of 5.5 (see Fig. 1.0).

Figure 1.0: EpiPen [4]

The team conducted a survey and found that, due to its bulkiness, many EpiPen users leave their auto-injector at home (both accidentally and intentionally), leaving them at risk of death should they have an allergic reaction. Survey respondents indicated that they were either unable or unwilling to carry their EpiPen in a pocket or bag due to its size and awkward form factor. As such, a need exists for a sleek solution that can be passively remembered. That is, a solution that users only have to remember once (e.g. - when leaving home) and stays on their person in an easily accessible location for the rest of the day. Furthermore, the aforementioned respondents indicated that they would find a watch-shaped auto-injector more convenient than an EpiPen and numerous other wearable form factors.

Consequently, the team began a heavily iterative design process to create LifeWatch. The team began by examining the dimensions and mass of larger watches available on the market today, thus setting the product's bounding volume and mass limits. The prototypes began with an open-faced design, evolved into a completely enclosed model, and finally streamlined to the current form with a volume of 33.6 cm^3 and a height-to-width aspect ratio of only 1.15 (see Fig. 1.1).

Figure 1.1: LifeWatch's major design iterations

LifeWatch retains the same overall function of the EpiPen but has less than half the physical volume. To activate the system, a user must first remove the device from the outer case then push it against their thigh. The internals of the device then activate as follows: the activation button is pushed up, the activation flexures are bent backwards, the injection springs are released, the needle is pushed 16 mm

into the thigh, the quick release pin is pulled, the syringe springs are released, the plunger is pushed down, and 0.3 mL of epinephrine is administered. The above internal activation process occurs within approximately 0.25 s.

Final system validation included five types of quantitative tests: drop tests, activation force tests, needle length tests, injection volume tests, and fluid velocity tests. Drop tests were conducted by dropping the device from a height of 1 m onto each of its sides. A drop test was deemed "passed" when the device did not activate after hitting the ground and could successfully activate after the drop. The team found that the final device passed 50 of 50 tests with the safety case on and 25 of 30 tests without the case.

Activation force tests were conducted by injecting the device into silicone rubber, a commonly used human flesh analog, on a scale. No formal pass/fail metrics were defined, but observations were made to ensure the force of injection was on the same order of magnitude as that of the EpiPen. The team ultimately found that our device injected with a force of around 30 N.

Needle length tests were conducted by activating the device and measuring the length of the needle that was exposed. A needle length test was deemed "passed" when the exposed needle length was within a small margin of 16.0 mm (the nominal needle length); this is the proper length required to reach the correct dermal layer for intramuscular injection. The device passed 50 of 50 tests with an average injection depth of 16.30 mm and a standard deviation of 0.03 mm.

Injection volume tests were conducted by filling the syringe and injecting water into a block of imitation flesh, measuring the mass of each before and after the injection. These tests were not given a pass/fail metric but were deemed valid when the device successfully activated, seal integrity was preserved, and no water leakage was observed from beyond the test setup (e.g. - from fluid ricochets). After 50 valid tests with the initial batch of plungers, we found our device injected an average volume of 0.22 mL of fluid; a further 5 valid tests with an improved manufacturing method showed an average volume of 0.28 mL of fluid. Both plungers showed an average standard deviation of 0.015 mL. Note that the EpiPen injects 0.30 mL of fluid with a standard deviation of 0.016 mL.

Fluid velocity tests were conducted by laying the device horizontally on a tabletop, recording video with a high-speed camera, and measuring the distance and time of the fluid (dyed water) motion. Similar to other tests, no strict pass/fail metric was defined; only the outlet velocity was recorded. Using high-speed video, we found that the outlet velocity of our device was approximately 12 m/s while that of the EpiPen was about 11.8 m/s.

LifeWatch is the winner of the 2018 SEAS Senior Design Competition, the winner of the 2018 Couloucoundis Prize at MEAM Senior Design day, the winner of the inaugural M&T Summit, and a 2018 recipient of the Berkman Fund for Undergraduate Innovation. The team has filed a provisional patent on the device and plans to continue developing LifeWatch as a startup in the coming months. The image below, Figure 1.2, is a render of LifeWatch's final iteration as of the date of submission.

Figure 1.2: Internal components of the final LifeWatch product as of submission

2. Roles and External Contributions

2.1: Team EpiPenn

Benjamin Bernstein
Ben served as one of the primary mechanical designers and led the various manufacturing efforts. His design efforts were concentrated on the activation subsystem and the quick release subsystem while also considering the manufacturability and assemblability of all components. Ben carried out significant machining and assembly efforts as well as developing and performing validation tests.

Spencer Fox
Spencer worked assisting across all aspects of the project whenever necessary. He primarily assisted with mechanism testing, system integration, and some earlier components of the design.

Alexander Garcia
Alex worked primarily on validation and testing. He worked alongside Reed to complete structural FEA in SolidWorks and CFD simulations in COMSOL, as well as planning and assisting with testing in the spring semester.

Reed Ginsberg
Reed served as the primary business strategy and intellectual property researcher, as well as constructing the structural FEA analysis and playing a role in the system validation efforts. He focused his efforts on the design of testing fixtures for system validation. Many external competitions required strategic planning and applications that Reed worked on to gain more funding for the project.

Daniel Orol
Daniel served as one of the primary designers on the project. He focused on mechanism design and volumetric optimization of critical subsystems such as the activation system, the quick release system, and the revolve sheath subsystem. He also carried out significant portions of the manufacturing, assembly, integration, and testing for the project.

Jacob Snipes
Jake served as the project manager. He planned out the project timeline, kept the team on track from week to week, handled purchase orders, managed team finances, and wrote external funding applications. He also assisted with CAD and testing when needed and oversaw the aesthetic aspects of the project.

2.2: External Contributions

Faculty Advisor
The team was advised by Dr. Kevin Turner, Professor and MEAM Associate Chair for Graduate Affairs and Graduate Group Chair. Dr. Turner provided the team with external perspective on the design as well as insight into previously unconsidered modes of material failure such as thermal stresses, fatigue, and creep.

Technical Advisor
The team's technical advisor was Dr. Paulo Arratia, Professor and MEAM Associate Chair for Undergraduate Affairs. Dr. Arratia's expertise in fluid mechanics was invaluable to the team in the early stages of the project when performing CFD analysis and calculating the forces and pressures needed to ensure the fluid would achieve the proper exit velocity.

Manufacturing
Over the course of this project, the team made use of RPL, AddLab, the Penn Biomedical Library, and Shapeways for 3D printed parts. The PML was utilized for machined parts.

Software Packages
The team used SolidWorks for CAD and FEA, COMSOL for CFD, and GrabCAD for version control.

Funding
The team received $1000.00 from the Berkman Fund for Undergraduate Innovation, $2000.00 as part of the first place prize at the 2018 M&T Summit, $400.00 from the 2018 Couloucoundis Prize at MEAM Senior Design Day, and $800.00 as part of the first place prize at SEAS Design Day 2018. Note that the funds from the Couloucoundis Prize and SEAS Design Day will not be put towards the project.

3. Background

More than 1 in 50 people in the United States are affected by allergies that may cause anaphylactic shock, a life-threatening condition that results in a restricted airway [5]. These allergic reactions can come from exposure to common items such as nuts, bees, shellfish, and dairy. In the event that an individual suffers an anaphylactic reaction, that person needs to immediately receive a 0.3 mL dose of epinephrine solution at a concentration of 1 mg/mL (small children require the same volume of solution but at half the concentration) [6] [7]. The patient should then be brought to a hospital for further treatment and observation.

The most effective injection location is beneath the thigh muscle [8], which requires devices that can provide significant force on an injection needle. However, manually injecting a solution using a normal syringe and needle can cause complications if done incorrectly. Users are often not close to a trained medical professional when they need an injection, so auto-injectors have been developed that allow the user to safely and rapidly self-administer epinephrine.

The current market leader of epinephrine auto-injectors is Mylan's EpiPen, which still controls over 70% of the market despite decreasing market share [9]. The EpiPen contains a prefilled syringe containing 2 mL of epinephrine solution (1.7 mL remains after injection) and two springs: one to drive the syringe and plunger, and the other to extend a safety shroud that covers the exposed needle [10]. There is also a safety lock, and all of these components are held within a plastic case.

Alternatives to the EpiPen exist and are gaining popularity but are still only used by a minority of patients with anaphylactic allergies. These include generic forms of the EpiPen that generally cost less than the brand name version. The most popular alternative is the Auvi-Q, which works similarly to the EpiPen but has a smaller form factor [11]. The Auvi-Q uses pressurized gas to drive the syringe and plunger during injection and springs to retract the needle after. It also has a speaker that gives voice instructions to orally guide the patient through the injection process. The Auvi-Q was recalled over concerns that the device was not reliably delivering the correct dose of epinephrine [12] but is now back on the market.

Though these devices are effective when used, it is clear that people who require epinephrine auto-injectors do not have access to them at all times. Two surveys showed that 63% of adults and 51% of parents (57% overall) do not carry auto-injectors [13]. An additional survey, carried out by our team, showed similar results with 95 responses. The questionnaire asked how often auto-injectors are not carried when out of the house, both intentionally and unintentionally. Figures 3.0 and 3.1 show the quantified answers to those questions, with 0% meaning "never" and 100% meaning "always."

When asked how often they intentionally do not carry their auto-injector (see Fig. 3.0), only 49 respondents (54%) said that they never consciously leave it at home. 19 respondents (21%) said that they often leave it at home on purpose (frequency greater than 50%). The main reason given for this was not wanting or being able to carry a bag big enough to hold the auto-injector.

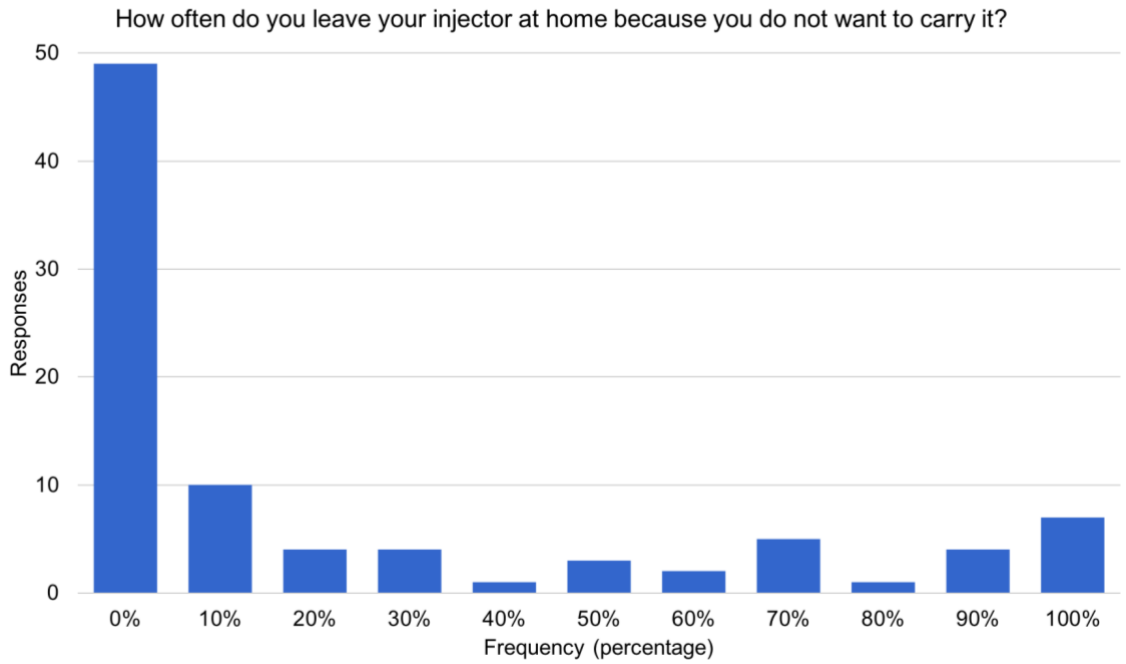

Figure 3.0: Frequency with which an auto-injector is intentionally left at home (0% = never, 100% = always)

Unfortunately, the EpiPen is bulky and cumbersome to carry. Other devices such as the Auvi-Q are gaining market share because of their improved size, but still require a bag or some other container. While it can fit in some large pockets, many pants do not have pockets large enough to comfortably hold the Auvi-Q. No device currently available meets the needs of users who require a product that can be comfortably carried without a bag. Multiple parents of auto-injector users stated that they take bags with them for the sole purpose of carrying the auto-injector. The need to carry an extra bag inconveniences users and is simply not feasible for situations where the user may not have immediate access to a bag. For example, runners, bikers, kayakers, and rock climbers may all forgo carrying an extra bag for convenience, despite the risk this poses. Our research shows that there is a strong need among users for a smaller, more portable auto-injector that could solve this problem.

Additionally, current users and caregivers must actively remember to bring their auto-injector with them. While people with anaphylactic allergies often keep auto-injectors in the house, few other locations keep usable epinephrine on hand at all times, with the exception of a hospital or a nurse's office in a school.

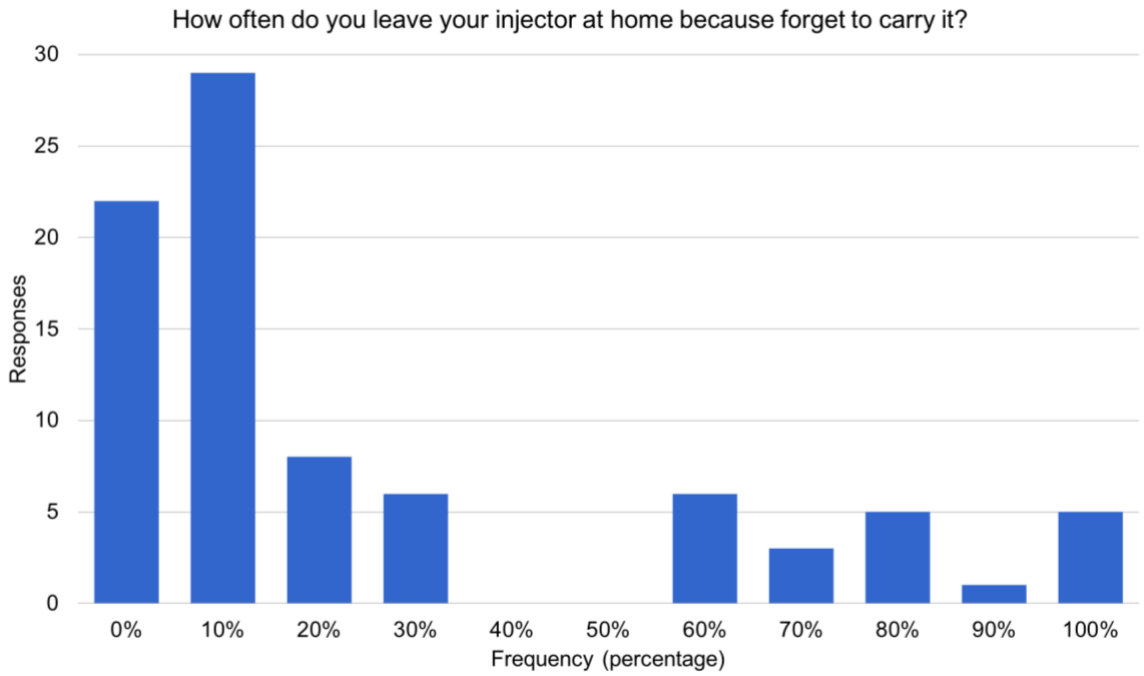

Figure 3.1: Frequency with which an auto-injector is unintentionally left at home (0% = never, 100% = always)

When asked how often they unintentionally do not carry their auto-injector, as seen in Fig. 3.1, only 24% of respondents said "never" (frequency of 0%) and 32% said "rarely" (frequency of 10% or 20%). Thus, 44% of our respondents are at risk of anaphylaxis on a daily basis; assuming this is a representative sample of the United States population, this equates to nearly three million people. People sometimes forget to take their auto-injector when leaving the house, or they gradually lose the habit of taking it everywhere. This significantly reduces the likelihood that an auto-injector would be available during an emergency.

Our research shows that many auto-injector users do not carry their device with them at all times, intentionally and/or unintentionally. This is because current solutions are large and bulky, meaning they require a bag or case, and because users sometimes forget to take their device. Current injector devices can also easily be misplaced or lost. This set of problems is serious even in cases where the user carries their auto-injector most of the time: not having the device in an emergency situation, which often arises without warning, is life-threatening.

A solution that makes people more likely to constantly carry an auto-injector will save lives. Ideally, the device would be carried somewhere that provides the user easy access all of the time and would be unobtrusive. A wearable device fits this description perfectly, as it travels with the user, does not require a bag or container, and does not need to be remembered more than once.

While there are currently multiple options for wearables on the market, each has negative characteristics that prevent their widespread adoption. The most common body-worn solutions are fanny-packs and belt systems that are large enough to hold an auto-injector, usually an EpiPen. These include products such as the SPIbelt and the epiBelt (see Figs. 3.2, 3.3). Arm and thigh bands also exist with compartments to hold auto-injectors. While these can help reduce the chance of accidentally leaving the device at home and help users forgo carrying a bag, they are bulky, obtrusive, and often

unstylish. Consequently, the vast majority of patients do not wear a device holster; less than 5% of survey respondents said they wore some sort of auto-injector case.

Figure 3.2: SPIbelt [14]

Figure 3.3: epiBelt [15]

4. Objectives

4.1: System Characteristics

At the beginning of the fall semester, the team conducted a survey in order to help narrow down what system characteristics were important to our consumers. Using this survey in conjunction with previously established standards, we developed a series of characteristics that our solution would need to meet. Ultimately, our system-level goal was that LifeWatch would be slim, lightweight, and easily remembered.

We thus defined a set of characteristics and features for our ideal system that were then divided into two categories: "basic" and "reach." Basic characteristics are those that are essential for the device to meet customer needs, whereas reach characteristics are optional but would still add value to the product. The attributes are summarized in Table 4.0 below.

Table 4.0: Basic and reach system characteristics

Characteristic	Level	Justification
Inject 16 mm into thigh	Basic	This is a medical requirement for efficacy of the system. Although some studies suggest longer needles, we follow the example of EpiPen, the FDA approved market standard [16].
Dispense 0.3 mL epinephrine in solution	Basic	This is a medical requirement for efficacy of the system [17].
0 accidental injections	Basic	This is a requirement for user and bystander safety. The needle cannot eject at the wrong time.
0 misfire injections	Basic	The system must never fail to inject when desired or the user can be seriously harmed.
Fit in pocket or on wrist (Portable)	Basic	This is a requirement by stakeholders. Current solutions are too bulky, so we need to decrease the form factor size.
Mass produced product < $600	Basic	Our device should not be more expensive than existing solutions [18].Ideally, it will cost much less.
Dimensions ≤ 50 mm x 50 mm x 15 mm	Basic	Ideally, our device will be not much larger than a watch so that it is comfortable and portable.
Mass < 150 g	Basic	Our device should not be so heavy as to be a burden to the wearer. This number comes from the mass of large watches.
~100 N force at injection	Basic	This requirement comes from the EpiPen, which uses that amount of force. The device needs to be able to break the skin, insert the needle to the proper depth, and inject the fluid against internal resistance from the body.

Characteristic	Level	Justification
No electronic activation	Basic	Having a battery component adds needless complexity and sources of failure.
Impact resistant	Basic	Stakeholders require the device to be durable enough to avoid damage during normal operation, especially if it is worn on a wrist. An average person during reasonable physical activity should not risk damaging the device [19].
At most 30 seconds to remove device and be ready to inject	Basic	This is a medical requirement to ensure safety in emergency situations.
Solution temperature between 15-35 °C with allowance for brief deviations	Reach	This is a common specification given by EpiPen and Auvi-Q, but it does not have confirmed medical basis [20].
Waterproof	Reach	This device will be exposed to the elements, so it should have protection against damage. However, it is not a primary goal for the project.
Two injections per device	Reach	This comes from stakeholder desires. Sometimes people need two injections, but there is mixed feedback about whether they should be in the same device.
Incorporation of watch functionality	Reach	Stemming from stakeholder desires, incorporating a watch face is an important reach goal. This would serve a second purpose beyond actually functioning as a watch, as it would also provide some camouflage for what the user was carrying on their wrist.
Voice instructions	Reach	Stakeholders agreed that the Auvi-Q voice instructions were extremely helpful and potentially life-saving in an emergency situation. Ideally, we would have liked to incorporate something similar into our device.

4.2: Design Impact of Standards

LifeWatch is a medical device that will be used in real-world environments by patients with limited training. As such, it is essential to ensure that the device is safe, reliable, and effective. Many standards, codes, and guidelines exist for medical devices, some of which are specifically relevant to auto-injectors.

While we would have been unable to constrain our development to meet the full set of regulations for an FDA-approved medical device, consideration of the most important standards and guidelines allowed us to develop a device that can likely gain approval with reduced redesign work. These standards include ISO 11608 sections 1 and 5 as well as the FDA guidance issued for injectors. Additionally, standards relevant to sharps injury prevention allowed us to verify that our design is safe to use.

The FDA's document "Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products" was released to serve as an all-in-one guide to designing and testing

auto-injectors as well as submitting devices to the agency for approval [21]. Pulling from various relevant standards and the agency's history of medical device approval, the FDA listed the features, characteristics, and tests that it will check for when considering an auto-injector.

The first set of requirements are those regarding the dose of medicine administered to the user. These include ensuring that the volume of injectate matches the prescribed dose, that the needle delivers the medicine to the correct tissue layer (in the case of epinephrine, this is to the intramuscular layer [17]), as well as validating the flow rate and corresponding injection time. The guidelines also suggest measuring and testing the various mechanical aspects of the device such as the forces required to activate the device, to defeat the needle shield, to disconnect the needle from the syringe, and to push the needle into the user's body. Our system validation was heavily influenced by these specifications, as they confirm the core functionality of our system and can be tested using simple equipment and flesh analogs.

Along with the functional requirements, the FDA recommends considering "human factors" in the design and testing process; this encompasses every characteristic of the target audience members and their interactions with the device. Examples include the form of the device, the steps of operation, the physical demands placed on the user, and the emotional and mental states of the user. Speaking with stakeholders, including two of our own team members, provided tremendous insight into the way that patients use the device. We have consulted children, adults, parents, caretakers, and clinicians to learn about our target customers and, by extension, the relevant human factors. Our user research has deeply influenced the project progression, from the main idea to the finest details.

The FDA guidelines also include standards for maintaining a sterile manufacturing facility, performing biocompatibility tests relevant to drug efficacy, labeling information on the device, and FDA application suggestions. While these regulatory checks are very important for any device that reaches the FDA approval process, they fall outside of the scope of this course. As such, these guidelines generally informed our design decisions but were not explicitly taken into consideration.

Chief among the standards that the FDA recommends following is ISO 11608, which governs needle-based injection systems [19]. Most of the standard is reiterated in the FDA guidelines described above. There are specific sets of tests that an auto-injector must pass in order to be verified under the standard. These include ensuring proper device functionality after exposure to extreme temperature, free-fall drop tests, cyclic loading, and vibration. Many of these tests require long periods of time and/or specialized equipment to perform, while drop tests are simple and quickly provide a critical measure of the device's ability to survive real-world use. The user will wear the device on their wrist at all times, and thus the device must be able to withstand impacts that may be encountered with everyday use. The standard specifies that the drop tests should be completed from a height of 1 m and that the device must be dropped on each relevant face. Our drop tests were developed to match this specification.

The FDA also published a set of guidelines for medical devices with "Sharps Injury Prevention (SIP) Features," components of a device that protect the user from coming in contact with a hazardous sharp object like a needle [22]. Because our device would have an exposed needle after injection, SIP is crucial to protect user health and safety. It also helps the user feel more comfortable with the device after injection, reducing stress during an already tense situation. The guidelines recommend making abundantly clear to the user when the SIP feature has activated. Labels should contain instructions explaining SIP and how to activate it. Furthermore, the FDA requires that an SIP feature "completely enclose the needle and prevent finger access." Tests should determine the forces required to activate the SIP feature and those required to break or defeat it. Acceptable values should be based in human factors research. Inclusion of a SIP feature was a major goal during development as a result of these

requirements. Though there was little room for additional features, an external shield was added that requires very little force to activate (see Section 5.9: Revolve Lock Design). Though the needle shield does not completely enclose the needle, it prevents access to the needle tip without interfering with the injection process. Force testing determined that a shield made entirely of plastic would bend too far under loads, so a thin steel insert was added to increase rigidity.

Table 4.1: Requirements from FDA's "Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products"

Requirement or Recommendation	LifeWatch Compliance
Volume of medicine administered should match the required amount.	Perform injection tests to ensure that fluid volume added to flesh analog matched the medically approved dose.
Injection depth should reach correct layer of flesh	Activation tests confirm that needle reaches intramuscular layer
Fluid flow rate should administer dose quickly without causing harm due to high force	Run CFD simulations and high-speed video tests to match fluid flow to that of an EpiPen (which has been approved by the FDA)
Activation force should be low enough to activate reliably	Perform activation force tests and repeated prototype "real-life" experiments
Needle should easily penetrate flesh	Penetration force tests ensure that activation system is powerful enough to puncture skin
User should feel comfortable holding and carrying the device	User testing and feedback improve the physical device
User should easily know/learn how to operate the device	Printed instructions and guided training to increase patient compliance
User knows that the device is safe and effective	Sturdy construction and adequate safety features

Table 4.2: Requirements from ISO 11608 "Needle-based injection systems for medical use — Requirements and test methods"

Requirement or Recommendation	LifeWatch Compliance
Device must withstand a free-fall drop from 1 meter	Perform drop tests from 1 meter height on each face of the device, check operation after each test.
Determine dose mean and standard deviation	Injection tests with measured volume of fluid added, determine the SD from sample

Table 4.3: Requirements from FDA's "Medical Devices with Sharps Injury Prevention Features"

Requirement or Recommendation	LifeWatch compliance
SIP feature activation should be clear to the user	Needle shield changes physical configuration in a visible way
Device should include instructions for activation of the SIP feature	Labeling on the device explains activation of SIP to user
SIP feature should "enclose the needle and prevent finger access"	Needle shield restricts finger access to needle tip
Forces to activate and defeat the SIP should allow for safe, easy usage	Needle shield lock mechanism must be easy to activate and hard to break

5. Design and Realization

5.1 System Level Concept Selection

5.1.1: System-Level Solutions for a Wearable Epinephrine Auto-Injector

To differentiate itself from existing devices, our auto-injector must be worn on the body. We considered a series of potential locations to wear the device. We devised possible solutions based on reasonable body part locations and existing wearable fashion accessories.

For many of these areas, we considered one or two promising solutions, limiting ourselves to semi-practical implementations. One solution is a hat. In this idea, a thin, flexible syringe would wrap all the way around the brim of the hat, minimizing the profile. The needle would eject from the center of the hat brim to inject the patient. A similar solution is a sleeve that has a long, thin syringe running up the arm and a needle that can eject from the lower end. Next, we looked at other ways to carry a standard EpiPen or Auvi-Q. Four potential solutions to this are a chest holster, a necklace, a shoe compartment, or an armband similar to those designed to hold an MP3 while running. Sketches of all these concepts can be seen in Figure 5.0a.

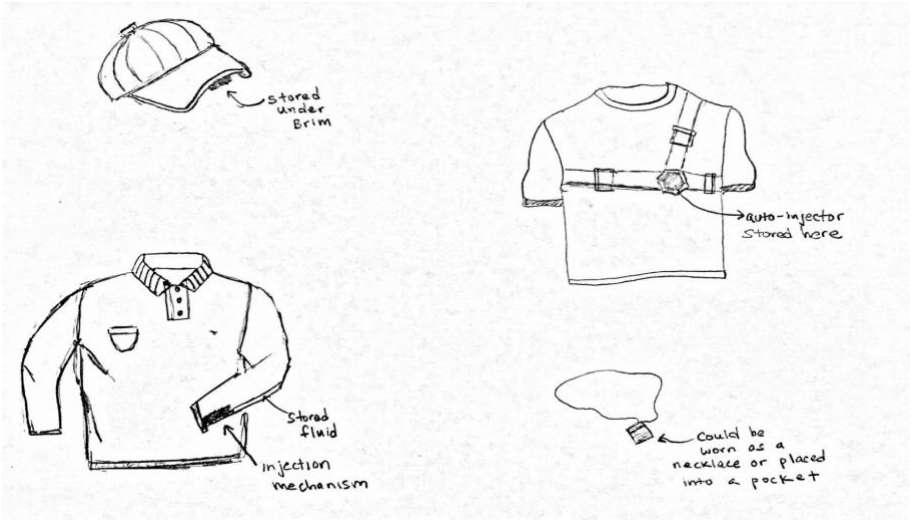

Figure 5.0a: Sketches of apparel-based solutions

Our most promising ideas involved redesigning the actual injection mechanism. Since users need to inject intramuscularly in the thigh [17], a natural solution is a device that sits directly on the thigh, capable of injecting in-place (see Fig. 5.0b). If the user pushes the activation button, it will directly insert the needle and release the medication.

Finally, we looked at items that people commonly carry that could hold an injection device. We considered creating a phone case to hold our device. Since phones are so ubiquitous, this would ensure that the user would always have access in case of emergencies. The other option in this category is a watch or bracelet. Again, this is an easily portable method of carrying an auto-injector that uses an already-popular form factor; the major difficulty of this implementation would be fitting all of the components into a relatively small form factor. Sketches of these concepts can also be seen in Figure 5.0b.

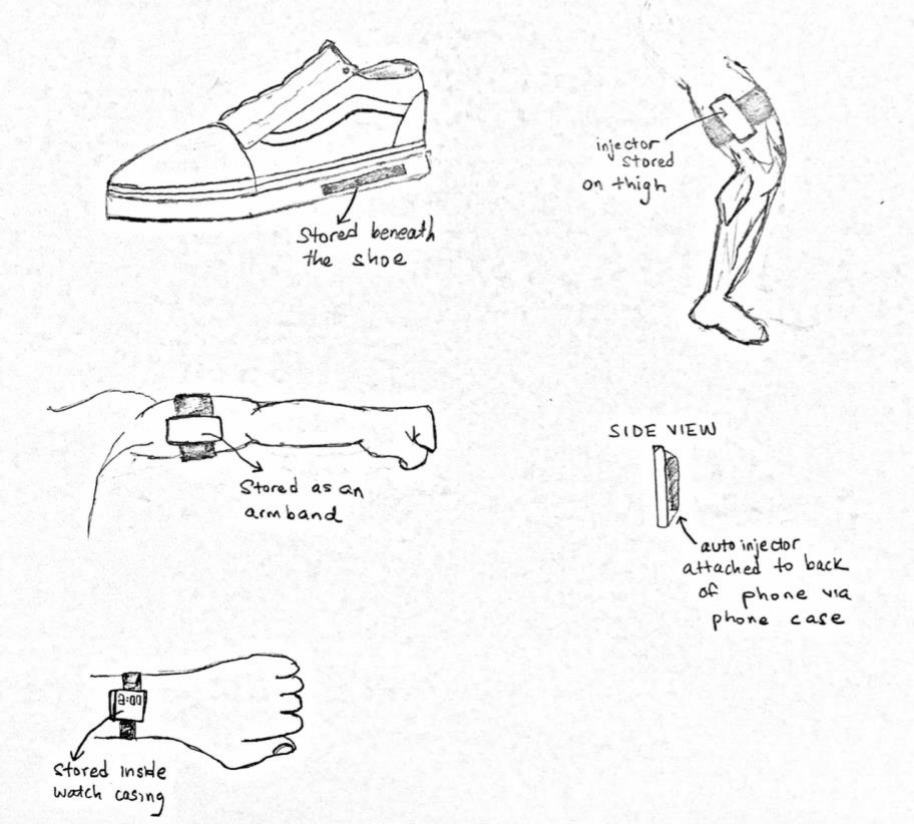

Figure 5.0b: Sketches of accessory-based solutions

5.1.2: Down-Selection

One key element in an emergency is accessibility, which factored heavily into the down-selection. Any system-level solutions that prevented access to the device within thirty seconds of a reaction starting or that would be difficult to access should the primary user fall unconscious were ruled out. This eliminates the chest holster, as it would be worn under clothing and therefore extremely hard to access quickly in an emergency situation. Additionally, it would likely be uncomfortable for the user. The sleeve idea was eliminated for the same reason; it would be too hard to remove in a timely fashion.

Another primary consideration was the convenience of the solution. If there are many instances where the user would not want to be wearing the device, then that form factor is not useful. Epinephrine injectors must be constantly available. From this consideration, we can eliminate the hat idea. Many people do not wear hats, and there are many situations such as playing sports, sitting in meetings, or eating dinner at a restaurant where the average user would be unlikely to want a hat on.

The thigh injector is particularly intriguing because users can inject directly at that location. Our primary concern with this idea is the lifestyle change associated with it. Few potential users, if any, wear a thigh band currently. Unlike devices such as insulin pumps, an epinephrine injector is not a daily use device, so the person would have to adjust to wearing a thigh band without an immediate daily need. Moreover, this would likely interfere with comfort, ability to wear pants, and potentially even simple activities like sitting on a chair. Therefore, we removed this idea from our list.

We re-examined the remaining five items on our list - watch, phone case, necklace, armband, and shoe. All of these meet the criteria of accessibility and comfort without necessitating a significant lifestyle change. To help us through the final down-selection process, we polled current epinephrine auto-injector users or family members to receive valuable stakeholder feedback. We received feedback from 95 stakeholders on our survey.

First, looking at our baseline numbers, we examined the potential five solutions, the EpiPen, the Auvi-Q, and a general "other primary injector" option on a scale from 1 to 10, with 1 being the worst. Key results are summarized in Table 5.0 below.

Table 5.0: Survey responses from stakeholders rating options from 1 to 10, with 1 being the worst. Extremely satisfied was characterized as a response of 8 or above out of the total number of responses. Extremely dissatisfied was characterized as a response 3 or below out of the total number of responses.

Solution	Average satisfaction	Extremely Satisfied	Extremely Dissatisfied
Auvi-Q	7.0	48.4%	6.5%
Phone Case	6.6	50.0%	17.8%
Watch	6.0	43.3%	30.0%
EpiPen	5.1	12.2%	23.3%
Other Existing	5.0	16.7%	26.7%
Necklace	4.7	21.1%	40.0%
Armband	4.4	22.2%	47.8%
Sneaker	3.6	13.3%	56.7%

It is clear from the table that the watch and the phone case are the only two of our solutions that stakeholders feel are valuable. The other solutions are all at or slightly below the average rating of the EpiPen itself.

Besides the ratings, we have a few other concerns about the other three solutions. A necklace would either have to sit uncomfortably underneath clothing - with a relatively large form factor compared to most necklaces - or above clothing in an inconvenient spot. Any sort of physical activity would make this pendant bounce, which would be uncomfortable and potentially dangerous since there is a needle inside. The armband could potentially be useful for runners who want to carry an Auvi-Q with them, but the stakeholders expressed a strong need for a solution that allows anyone to carry the device everywhere they go, not just on runs. Moreover, wearing an armband at all times would be a significant lifestyle change on a day-to-day basis. Finally, the shoe idea was eliminated. Although shoes can be easily reached, the shoe with the auto-injector could become trapped underneath the individual, preventing a bystander from accessing it. Further, shoes undergo regular high-stress loads and impacts as people walk and run, which makes them a suboptimal platform from an engineering perspective. A shoe is also in contact with dirt and water very often, making it harder to keep the device sterile.

Ultimately, we chose to move forward with the watch. From a stakeholder perspective, the phone case and watch form factors were almost equally popular. Although the phone case had a slight edge on the watch numerically, a lot of the stakeholder written feedback involved the need to always carry and remember this device. We believe that, although phones are ubiquitous among our age group, there are many demographics (e.g. - children, elderly people, low-income individuals, etc.) who do not own or regularly carry phones. Moreover, people frequently leave their phones at home or lose them, which is harder to do with a watch that is physically attached to a user's wrist. This watch can easily be worn while working out, whereas a phone needs to be held in a bag or pocket, similar to the EpiPen.

Last, we considered the long-term use of our device. Phone cases are very specific to brand and model of phone, and users would not want to have to buy a new phone case if they used their injection. Additionally, if a user bought a new phone with a different form factor, they would not want to buy a new case that costs more than most. Finally, phones often undergo intense shock loading when dropped. This would increase the risk of damaging the injection device or triggering an activation upon impact, which is dangerous to the user. Although the watch idea does not appeal to everyone, we think it is the best choice after looking at all of the stakeholder feedback and considering the engineering opportunities within our down-selected solutions.

5.1.3: Selected Solution Details

Our final selected solution is a watch that contains an epinephrine auto-injector device. This will need to fit in a 50 mm x 50 mm square device up to 15 mm thick. Ideally, the auto-injector will be smaller than that, but this form factor would be within a few cubic millimeters of the largest standard watches on the market [23]. Inside this package, the device must store a minimum of 0.3 mL container [24], as well as any additional fluid required for accurate dosing. We need a medical-grade needle that is 16 mm long and 22 gauge, identical to the one found in current EpiPens [25]. Finally, we need to provide ~100 N of force on the plunger when the device is triggered to ensure that the injection is completed properly [26].

5.2: Spring Selection

After researching how current auto-injectors store the energy required to power their internal components, three options emerged as feasible for our system: compressed gas, rubber bands, and springs.

Though compressed gas would provide certain design benefits, such as a small footprint and the ability to channel and direct its pressure dynamically, it posed many challenges that would have prolonged the project schedule. First-order calculations and initial experiments (see Section 6: Validation for details) showed that, based on the syringe and needle geometry described below, the epinephrine would require pressures around 500 kPa at the fluid interface. Obtaining compressed gas in high pressure capsules would have cost significantly more than springs or rubber bands, and there were fewer options and reputable suppliers available. Additionally, the analysis required to design for compressed gas and ensure that the device operated consistently is far more complex than that required for linear elastic energy storage. Computational fluid dynamics simulations would be necessary to accurately simulate the gas flow and pressure, which is far more complex than applying Hooke's Law. Finally, though the device is intended to be single-use, our prototypes would need to be easily reset for repeated testing. A punctured capsule and released gas cannot be returned to their initial configuration, so a new activation system would be required for each test. Springs or bands, however, can simply be returned to their initial configuration.

Rubber bands also had issues that made them less than ideal as a form of energy storage. Though they have very small profiles and can be easily combined in series and parallel to achieve required force and deflection values, rubbers and other elastic materials degrade over time. The bands gradually lose their capability to hold a certain force and could potentially fail altogether. In a device where there must be energy stored for months at a time, material degradation ruled out rubber as an option. Metal springs, on the other hand, do not lose their effectiveness on these time scales.

Initial designs for the activation system, described below, used extension springs in a pulley system to drive the syringe. However, extension springs have hooks or loops on their ends to which cables or other elements can be attached. These appendages occupied valuable space within the body of the device, so the extension springs were replaced by compression springs to optimize internal volume use. Determining the optimal compression springs for the two powered subsystems required analyzing the necessary force profiles and selecting springs that matched. All available options were subsequently plotted on a force vs. displacement graph (see Fig. 5.1).

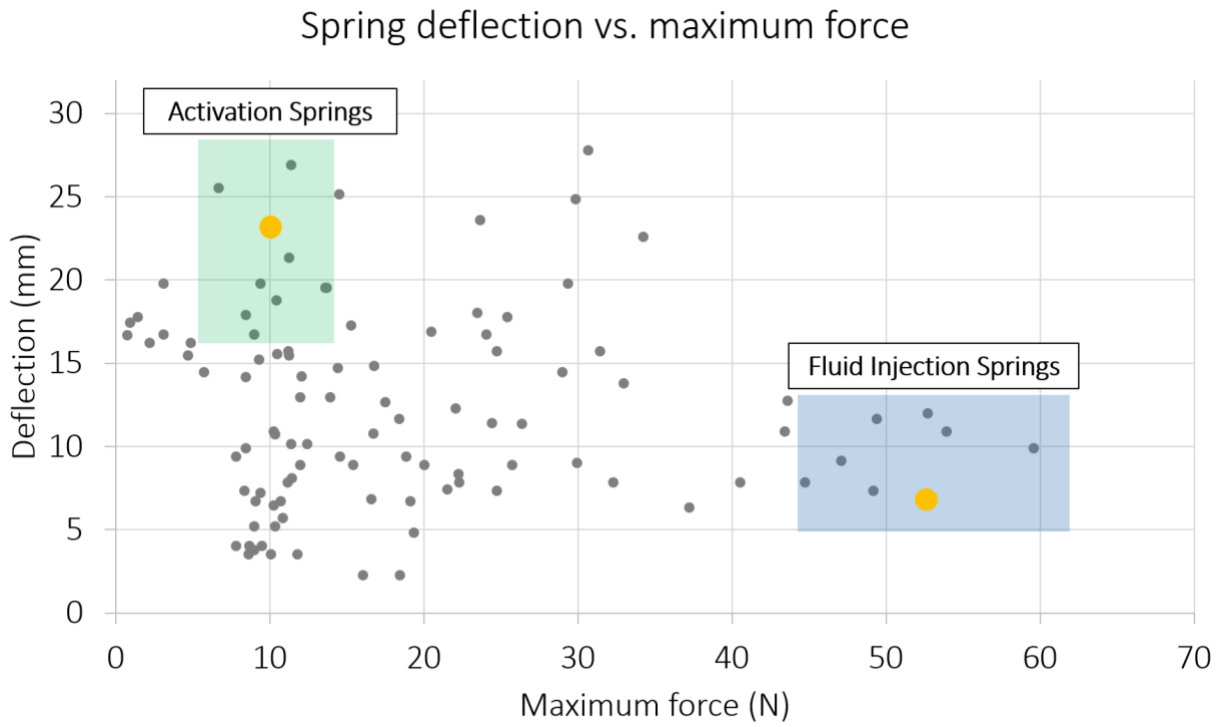

Figure 5.1: Comparing the maximum deflections of various springs with their maximum forces. The two selected springs are marked with large gold circles.

The activation system, further described below, incorporates two springs that are initially held in a locked position. They continually push on the syringe and, when it is released, must force it downwards to drive the needle into the user's thigh. Because the needle is pushed 16 mm into flesh, the activation springs must deflect at least as much while providing at least 2 N of force throughout their expansion (see Section 6: Validation for quantitative analysis). After surveying the options available, a spring made from 302 stainless steel that has an uncompressed length of 31.75 mm, a fully compressed length of 8.9 mm, a spring force constant of 0.45 N/mm, and an outer diameter of 6.35 mm was chosen. When fully compressed, the spring applies a force of

$$(31.75\ -\ 8.9)\ mm \times 0.45\ N/mm = 10.3\ N \quad \text{(Eq. 5.0)}$$

prior to injection. During activation, the spring extends to a length of 24.9 mm. At the end of activation, the spring remains partially compressed and continues to apply a force of

$$(31.75 - 24.9)\ mm \times 0.45\ N/mm = 3.08\ N \quad \text{(Eq. 5.1)}$$

One spring is therefore sufficient to drive a needle into the user's thigh. The inclusion of a second identical spring opposite the first prevents the creation of a rotational moment on the syringe, reduces the time required to eject the needle by doubling the force and therefore the acceleration, and adds an additional safety factor to the driving force to improve reliability. Additionally, this spring's outer diameter is small enough to fit within the main body and leave room for the other components.

The injection system, also described below, required two springs with different characteristics. Their deflections must be very small, only 4.25 mm (see Section 5.3: Syringe Design), but the high fluid pressure required demands high forces during injection. The springs chosen are made of zinc-plated music-wire steel and have an uncompressed length of 12.7 mm, a fully compressed length of 5.84 mm, a spring force constant of 7.62 N/mm, and an outer diameter of 4.76 mm. Each spring would provide a force of

$$(12.7 - 5.84)\ mm \times 7.62\ N/mm = 52.3\ N \quad \text{(Eq. 5.2)}$$

at full compression in its initial state. The two springs together, pushing on a plunger with a surface area of 82 mm^2 would yield an initial fluid pressure

$$(52.3\ N \times 2) \div 82\ mm^2 = 1.28\ N/mm^2 = 1.28\ MPa \quad \text{(Eq. 5.3)}$$

During injection, the springs will extend 4.25 mm to a length of 10.09 mm. At the end of the injection sequence, each spring will apply a force of

$$(12.7 - 10.09)\ mm\ \times 7.62\ N/mm = 19.9\ N \quad \text{(Eq. 5.4)}$$

and the fluid pressure will be

$$(19.9\ N \times 2) \div 82\ mm^2 = 0.49\ N/mm^2 = 490\ kPa \quad \text{(Eq. 5.5)}$$

This shows that the springs will provide enough force throughout their expansion to drive the full volume of fluid out of the syringe. The symmetric placement of the two springs further ensures that the plunger will be pushed on evenly. Asymmetric loading of the plunger could cause its seal with the inner walls to break. The spring's outer diameter of 4.76mm is small enough to comfortably fit within the syringe without interfering with the walls.

5.3 Custom Syringe

5.3.1: Syringe Design Process

At the beginning of the design process, the team created an initial prototype in order to get a better sense of the scale of the device. The open-faced design allowed for easy analysis of the contents, despite not being a realistic solution due to sterility concerns. As we had committed to a maximum height of 15 mm, we had to determine the optimal layout for storing the medicine. For comparison, measurements the team conducted found the outer diameter of a generic auto-injector to be 20.5 mm.

We discussed using a cylindrical syringe, akin to those in traditional auto-injectors. However, the available width (50 mm) was much larger than the available thickness (15 mm), so a circular cross section did not seem to be a valuable use of space. Consequently, a flatter and wider syringe concept was proposed. We found this was a much better solution for our form factor; the first version can be seen in Figure 5.2 below.

Developing a custom syringe allowed the team to design around the volume it would be carrying and minimize excess volume in numerous places. The original length stackup in the binding project proposal allocated a 13.0 mm outer diameter to the syringe. Using the flat profile, the cross-sectional area becomes 88.2 mm^2 meaning that we are able to meet the volume requirement with a syringe that is only 3.66 mm long. This is a 70% reduction in length of the subsystem from the original allocation and provided much needed flexibility that was utilized in the rest of the design.

A major concern of the team was dispensing the appropriate dosage every time, particularly after reading about the recall of Auvi-Q due to dosage inconsistencies [12]. Part of the solution was that the plunger would only be able to travel the distance necessary before hitting the tapered section of the syringe, which served as a mechanical stop. Thus, the dosage is based on the volume of the non-tapered section, while the tapered section serves as excess, similar to the Auvi-Q and EpiPen, in an effort to prevent air bubbles from being injected.

Other features include attempting to create a needle interface at the outlet (this was not ultimately incorporated in the final design due to time constraints; needles were glued into place during testing), flat sections extending from either side that interface with the activation springs (see Section 5.2: Spring Selection), and small cylindrical guides that extend from the primary face of the syringe. The flat surfaces provided a good surface for the springs to push against during activation. The guides interface with the activation button (see Section 5.4: Activation System Design) and are intended to provide lateral stability as they sit in guide rails within the button (see Figs. 5.2a, b). This stability and guidance is required, as the subsystem must translate with only one degree of freedom after the system is activated. Early tests demonstrated that this was not a simple matter as the springs did not initially displace and apply force on the syringe symmetrically.

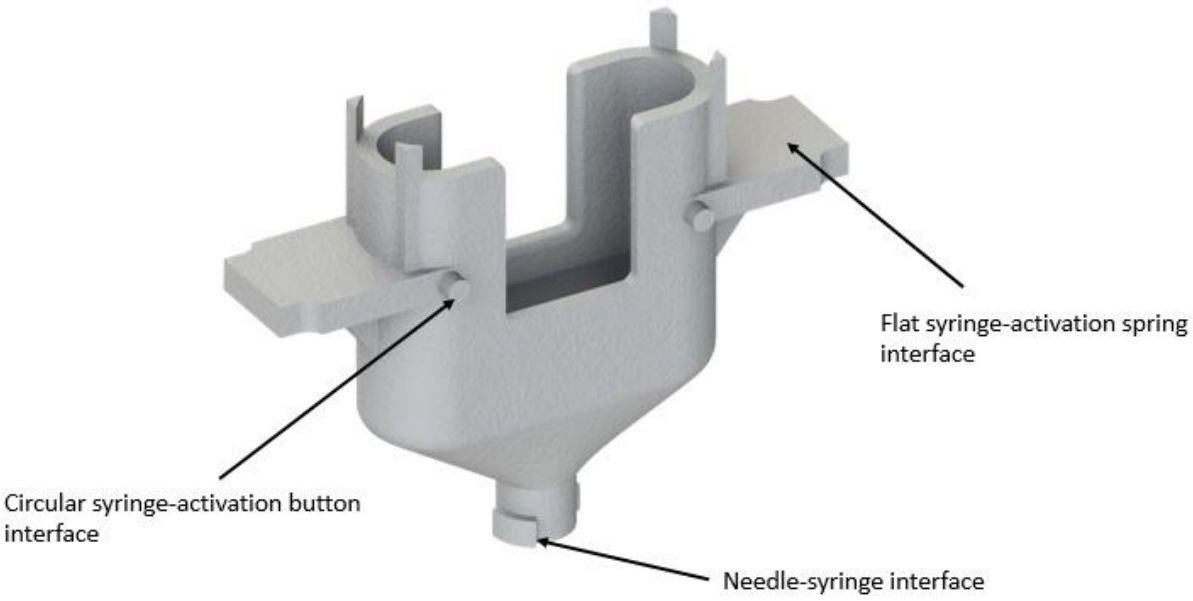

Figure 5.2a: First custom syringe iteration

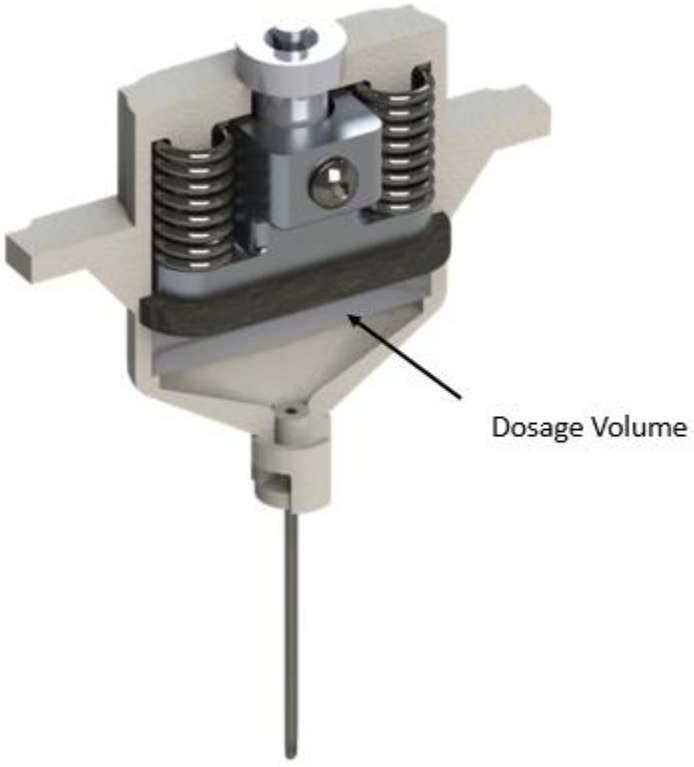

Figure 5.2b: Section view of first-iteration syringe

5.3.2: Computational Fluid Dynamics Analysis

In the second half of the fall semester, the team wanted to begin validating the system but did not have a fully system ready for testing. As such, the team utilized COMSOL Multiphysics as a first step in the analysis. The goal was to demonstrate that the team was on the right path, and that the flat syringe that was being designed would not prevent the team from being able to produce the same output as other auto-injectors. We determined that the Reynolds number of the flow is

$$Re = \left(\frac{u \times D}{v}\right) = \left(\frac{12 \times 0.000413}{0.000001004}\right) = 4936 \quad \text{(Eq. 5.6)}$$

where u is the fluid velocity, D is the inner diameter of the needle, and v is the kinematic viscosity. This is greater than 4000, the Reynold's number at which flow becomes turbulent. After trialing several different modes of turbulent flow analysis, the team used the Turbulent Flow, k-ω study, as it was the only model that was able to consistently find a solution. Additionally, in order to have the simulation converge, the component had to be rendered with a fine mesh setting, as seen in Fig. 5.3, the combination of which resulted in run times longer than 24 hours.

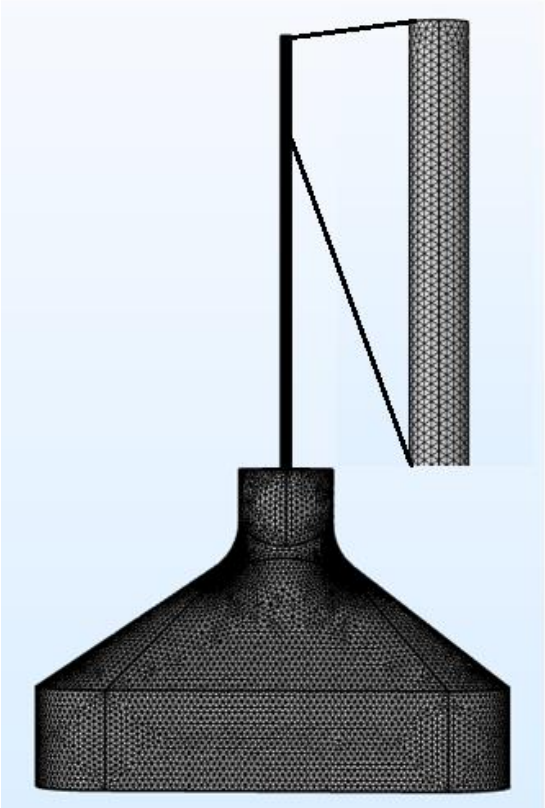

Figure 5.3: COMSOL fine mesh of internal syringe geometry

Research showed that the EpiPen had an average injection time of 0.19 s [27]. The area of the needle was calculated as follows in Eq. 5.7 below.

$$(\frac{0.413\ mm}{2} \times \frac{1\ m}{1000\ mm})^2 \times \pi = 1.34 \times 10^{-7} m^2 \quad \text{(Eq. 5.7)}$$

Using this area and the EpiPen's dosage volume (0.300 mL), the approximate exit velocity of the fluid can be calculated as follows (see Eq. 5.8).

$$0.3\ mL \times \frac{1\ L}{1000\ mL} \times \frac{1\ m^3}{1000\ L} \times \frac{1}{1.34 \times 10^{-7} m^2} \times \frac{1}{0.19\ s} = 11.8\ m/s \quad \text{(Eq. 5.8)}$$

To ensure our custom syringe geometry would be able to reach the same exit velocity, the team used CAD of the interior of the flat syringe prototype to run the COMSOL simulation described above; this simulation was set up to be pressure-driven, as pressure is a known input to our syringe subsystem. Based on the strength of the springs (see Section 5.2: Spring Selection), the inlet pressure to the syringe was set as 500 kPa gauge. The inlet pressure was based off of the force output by the springs (39.8 N) and the area of the syringe inlet (81.91 mm^2), while the outlet pressure was set to 0 kPa gauge (atmospheric pressure). The simulation showed the exit velocity would be approximately 22 - 23 m/s (see Fig. 5.4).

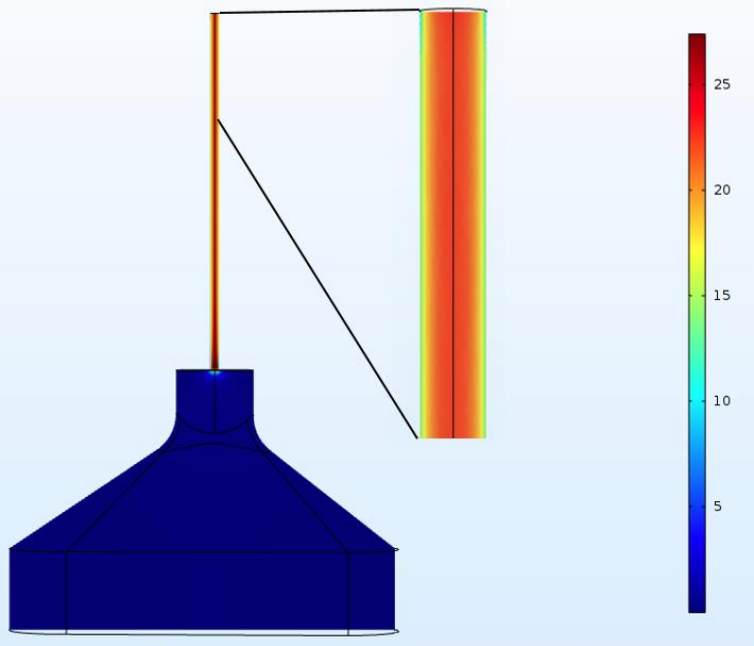

Figure 5.4: 500 kPa Turbulent flow COMSOL simulation showing velocity with close up of needle outlet (values in m/s)

This value is twice as high as both the minimum required exit velocity and the exit velocity that was measured using high speed cameras (see Section 6.4: Fluid Velocity). Therefore, 500 kPa is a sufficient inlet pressure.

5.3.3: Final Syringe

As the team began more rigorous testing of the system, it became clear that the injection guides were not providing sufficient stability; preliminary tests found the syringe jamming after activation. This

jamming was likely caused by an imperfection in how activation spring forces were transferred to the syringe, resulting in a moment and a twisting motion. To help combat this, the team expanded the cylindrical profile of the guides into a slot-shaped profile that would reduce rotational slop. This geometry change also provided the necessary guidance for the syringe to move linearly through the entire translation process of the injection.

The final form (see Figs. 5.5a, b) also featured further iteration to the interface with the activation springs. During assembly for early tests, it was difficult to keep the springs flush with the faces. We implemented a solution whereby the activation springs would fit around two extruded cylinders. Additionally, the sides directly adjacent to the spring-syringe interface were cut away based on the springs' outer diameter. These two features provided sufficient bracing both during assembly and after activation, resulting in better force translation from the springs to the syringe.

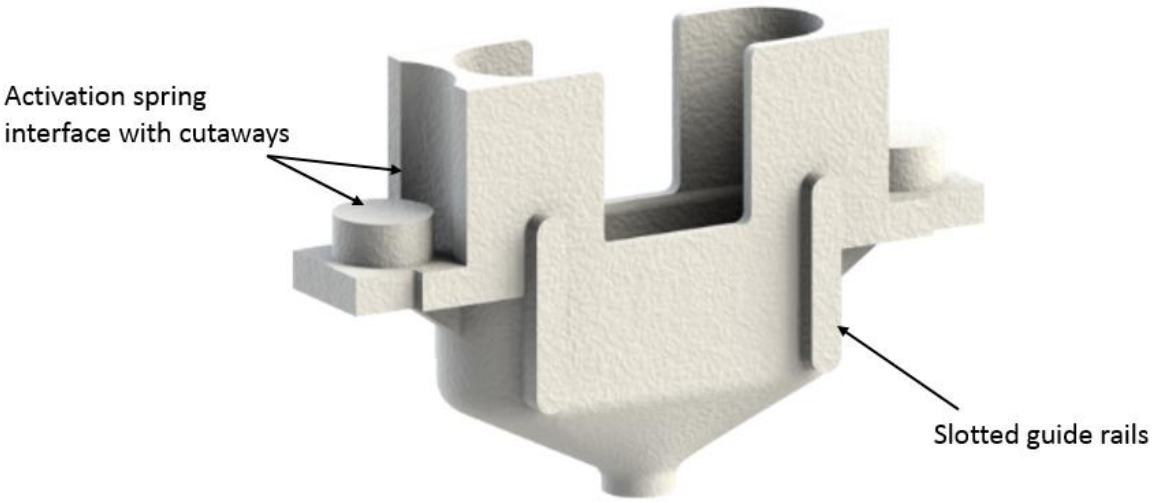

Figure 5.5a: Final syringe

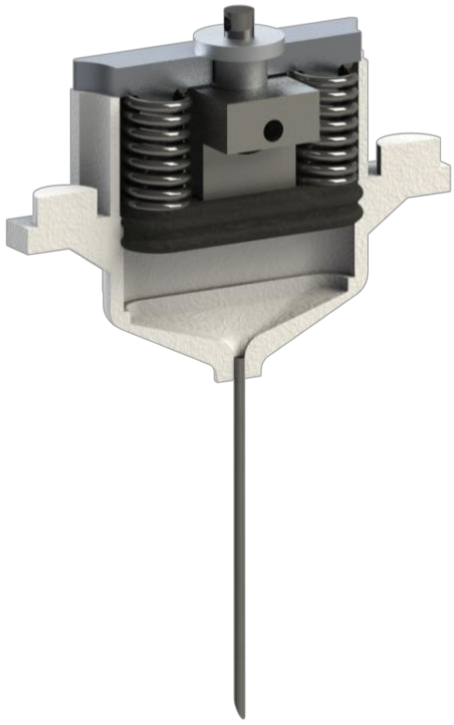

Figure 5.5b: Section view of final syringe

5.4: Activation System Design

One of the primary features of an auto-injector is its ability to carry out the full needle insertion and fluid injection sequence without user interaction once the device is activated. As such, the activation system needs to be extremely reliable and intuitive to use.

Initially, we began by developing a pulley-based system for the extension springs we wanted to use. In this system, a cylindrical button protruded from the face of the device. When pushed, a string attached to this button would pull a small pin holding the spring in its extended position. This spring and its symmetric counterpart on the opposite side would pull down on the syringe via a string and pulley system until the syringe reached a mechanical stop as it entered the activation button. We 3D printed an early prototype of this version but did not test it because we transitioned to compression springs for the reasons outlined above. This mechanism is visible in Figure 5.6 below.

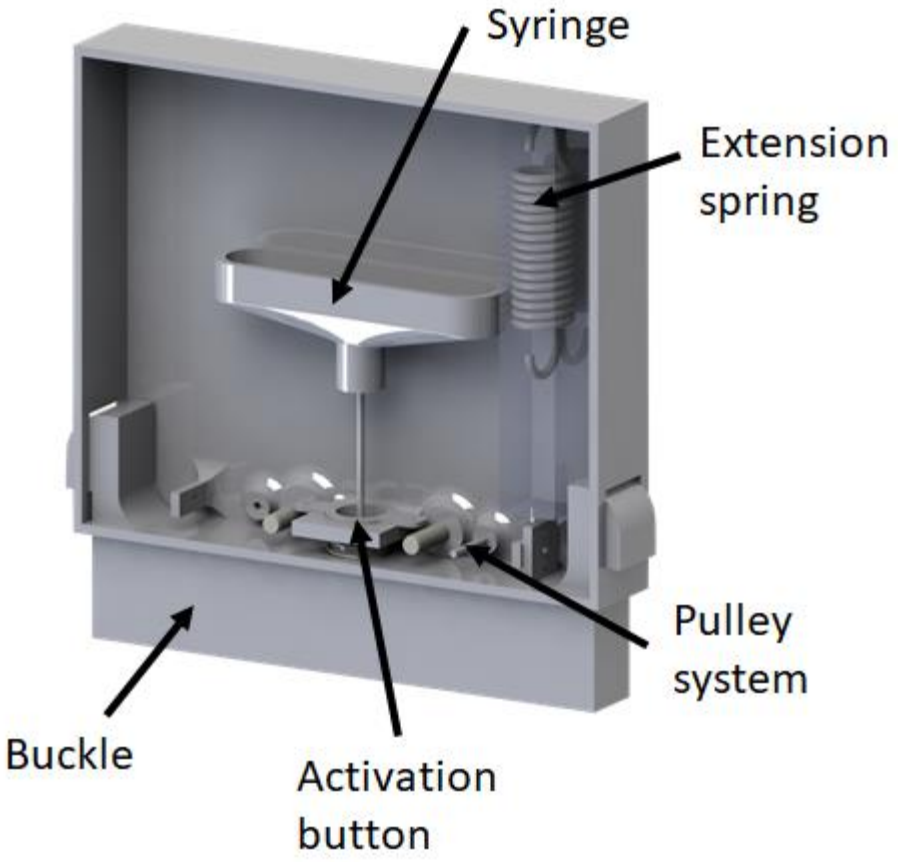

Figure 5.6: Initial CAD of internals with main components labeled

Once we transitioned to compression springs, we redesigned the activation system. To minimize space, we decided to use the inherent material flexibility of plastic and design flexible beams to lock everything in place prior to activation. By using this material property, we avoided the need to implement an additional subsystem and reduced our part count. The activation button had a similar outward facing interface, remaining a cylindrical button, but had extensions to push on the flexible beams instead of attaching to strings. These beams, termed flexures, taper where they interface with the activation button, redirecting part of the axial force of the activation button towards the walls. The user applies enough force on the activation button to bend the flexures until they reach hard stops at the wall, overcoming the spring forces and frictional forces opposing this bending motion. Figure 5.7 shows the main case and the activation button. The detail view shows the taper on the flexure and its interface with the activation button.

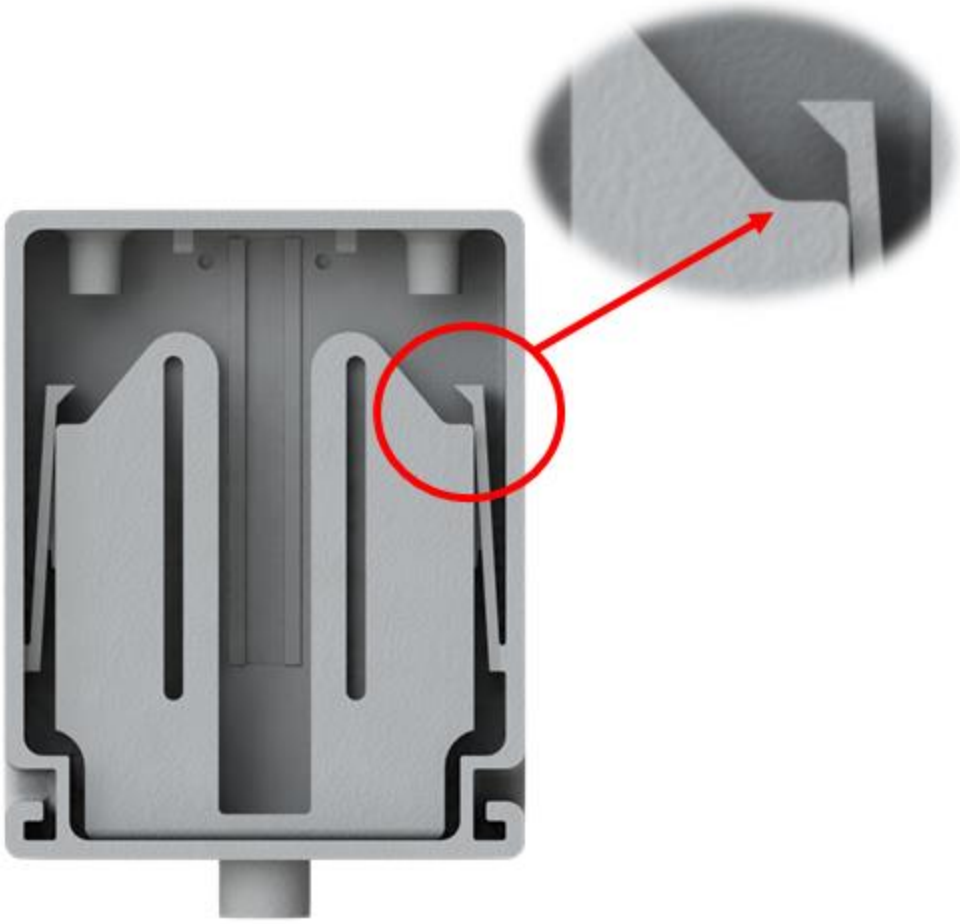

Figure 5.7: Activation button and flexures, with detailed view

Through user testing within the group and the class, we determined that the contact area on the protruding section of the activation button was too small. Rather than working against our primary design dimensions, we modified the cylindrical button to be a slot, increasing the contact area by a factor of 2.67. This allowed the system to activate on the thigh of every user in the group, the TA, and the flesh analogs we tested on. For manufacturing, assembly, and rigidity reasons, further minor modifications to the activation button protrusion geometry were made throughout the year. Specifically, fillets were added to save space and increase manufacturability, the length of the center slot was reduced to increase the rigidity of the system, and the syringe guide slots were extended to allow for easier assembly (see. Fig. 5.8).

Figure 5.8: Final activation button in final case

To ensure that the flexures would not break, we conducted finite element analysis (FEA) in SolidWorks, simulating the applied loads on these components. A load of 10 N, the max load applied by the springs pushing on the flexures in their compressed state, was applied to each beam. The sides of the case were fixed, simulating the user holding the device properly, and virtual planes were added to simulate the physical interference constraints from the other components in the system like the syringe. We set the mesh size to the smallest possible mesh to maximize our resolution and result accuracy. Figure 5.9 shows the mesh and Figure 5.10 shows that the max von Mises stress in the final design is around 12 MPa. The yield stress of injection molded ABS is around 40 MPa [28], resulting in a safety factor of 3.3 on these components. Similar results were obtained for all iterations of the flexures which we validated to ensure that they did not break. Experimentally, these results were validated when we tried using a stronger set of springs with a max force of 24 N each and did not see any material failure. Although analytically we could have reduced the thickness of the flexures without risking their structural integrity, our prototypes showed that with the manufacturing tolerances on the 3D printers we used, we could not reliably decrease this dimension.

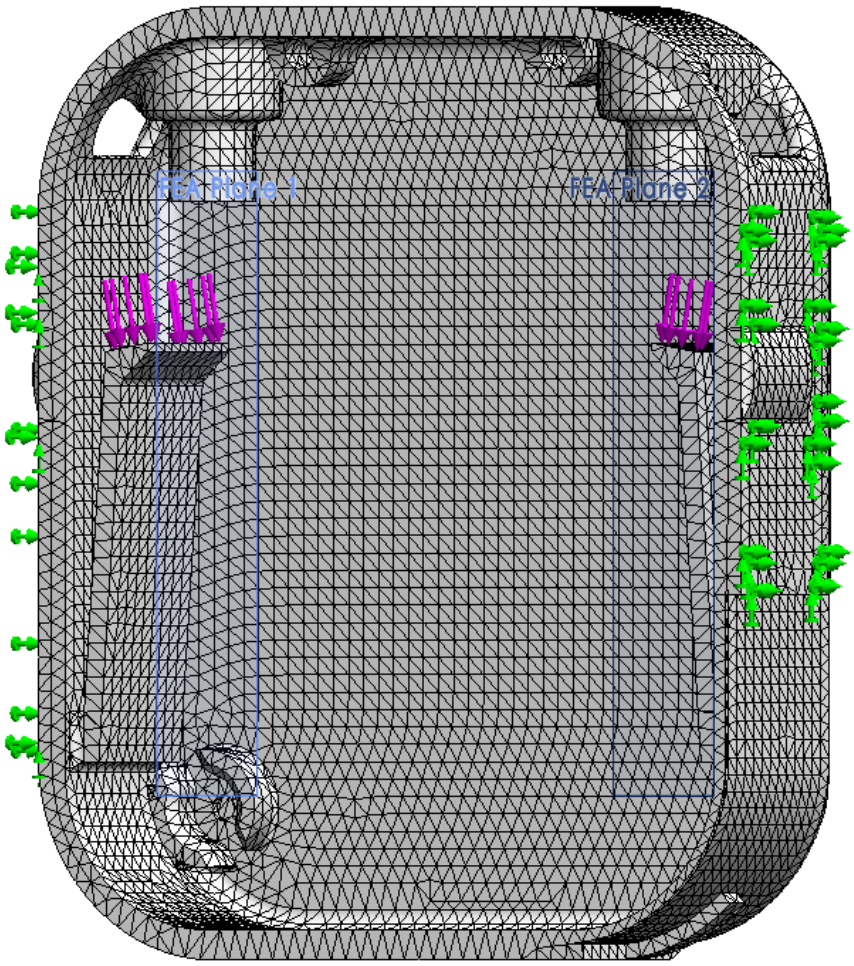

Figure 5.9: SolidWorks mesh of activation flexure loading FEA

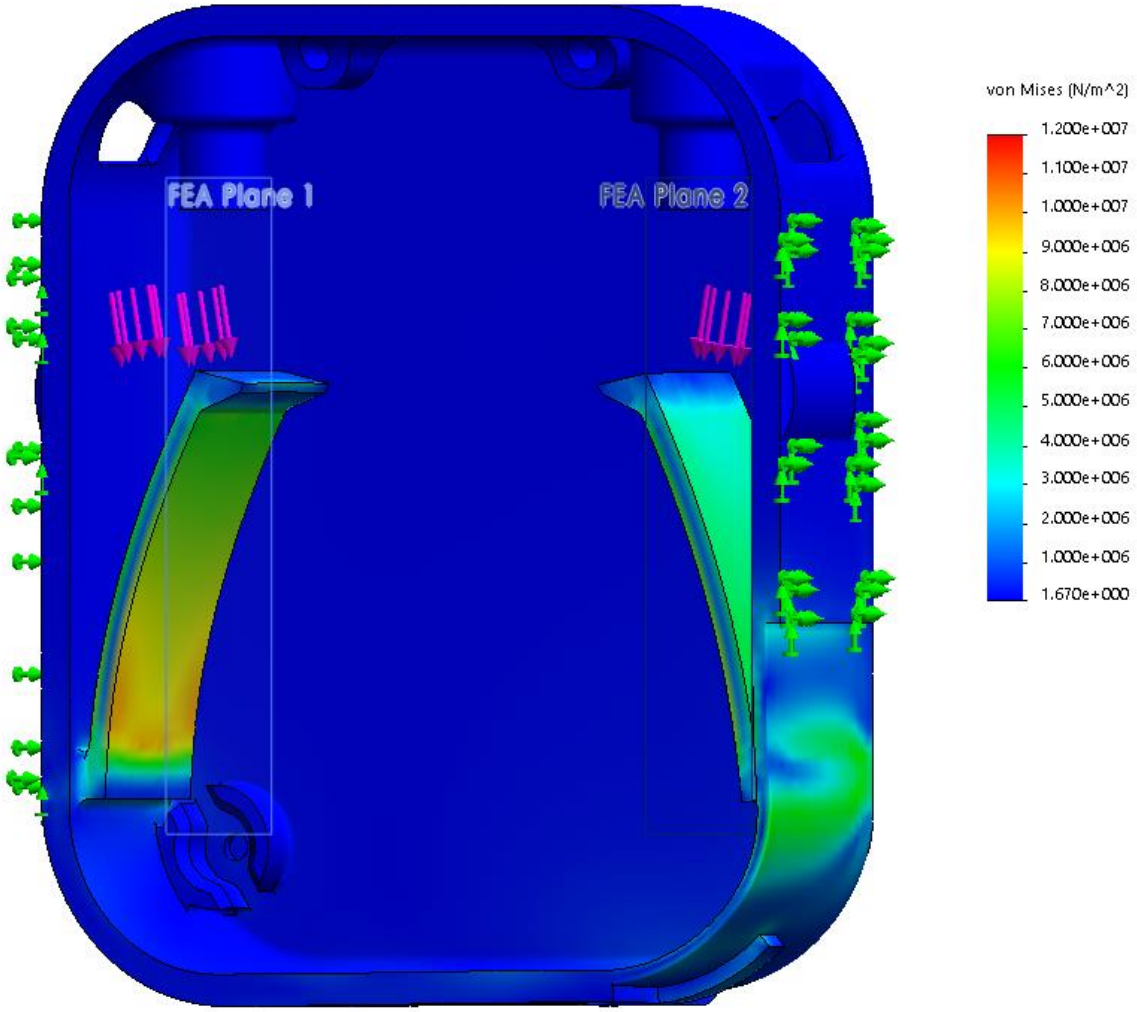

Figure 5.10: FEA on main case flexures shown in deformed position. Green arrows are fixtures, purple arrows are applied loads

5.5: Main Housing Design

The main housings, named the top body and bottom body, primarily serve to constrain everything together besides the main functional elements of the flexures described above. The main elements are indicated in Figure 5.11 below. They are explained briefly here and in more detail in their respective sections. The string holes rigidly constrain the string used to pull the quick release pin, explained in the quick release section. The spring nubs constrain the activation spring, with the smaller nub diameter fitting inside the springs. This prevents the springs from sliding anywhere. The case nubs match with slots on the safety cases, preventing the main assembly from sliding out from its spot on the user's wrist. The revolve key slot interfaces with the revolve lock key as explained in the revolve lock section. The revolve shield cutout allows the revolve shield to fit snugly as explained in the revolve lock section. The general shape and function of the bottom body have stayed generally the same throughout the design process since it just needs to act as an enclosure and have locating features for other parts. However, for reference, one of the original bottom body designs is shown in Figure 5.12. The various design changes are explained throughout this section. Additionally, significant effort was put towards the visual

appearance of the device, causing us to move towards rounded edges and less boxy profiles. The top body simply serves as an enclosure and a source of locating features for other components. Figure 5.13 shows a labeled image of the top body in the final form.

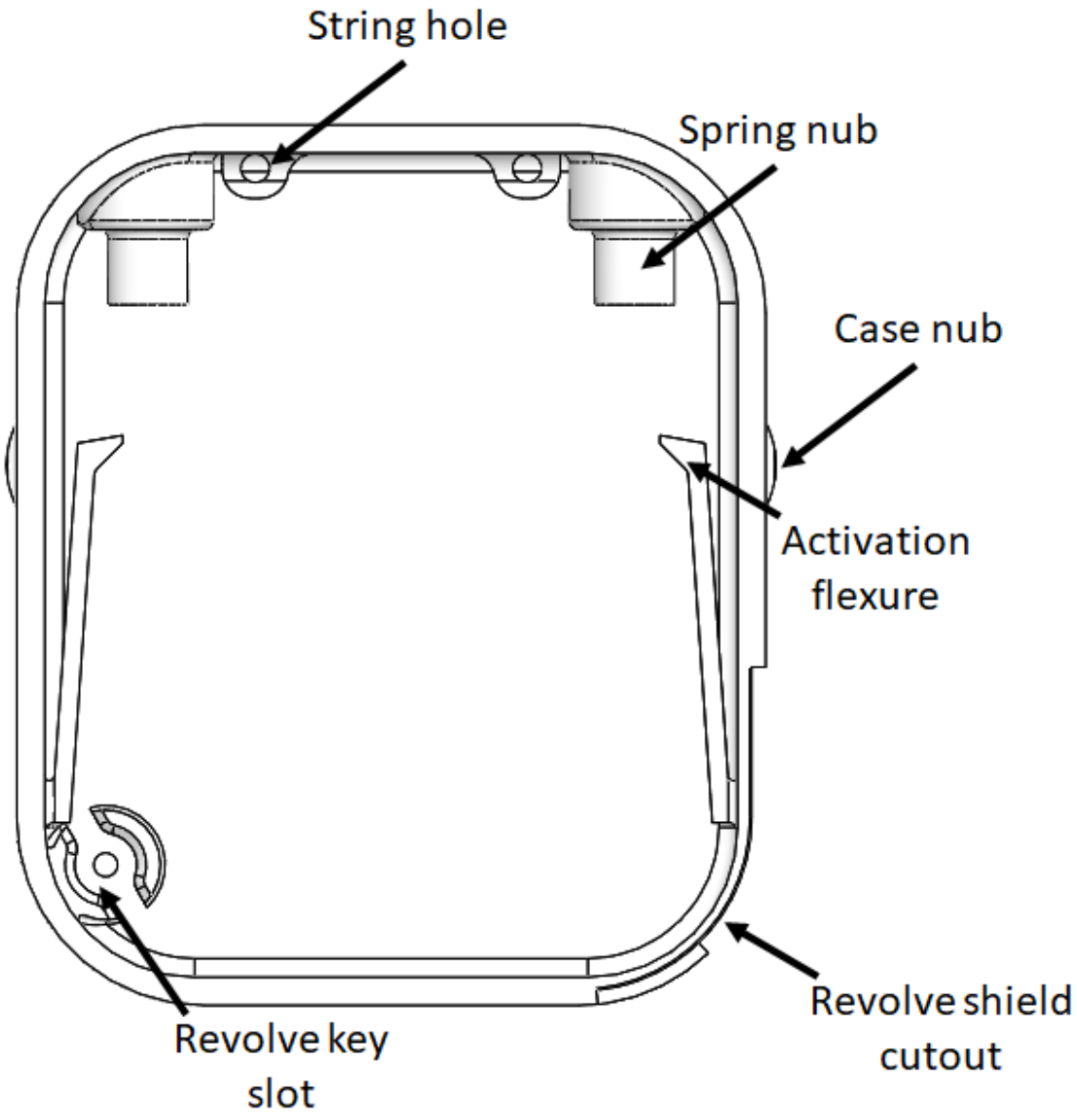

Figure 5.11: Labeled view of final bottom body

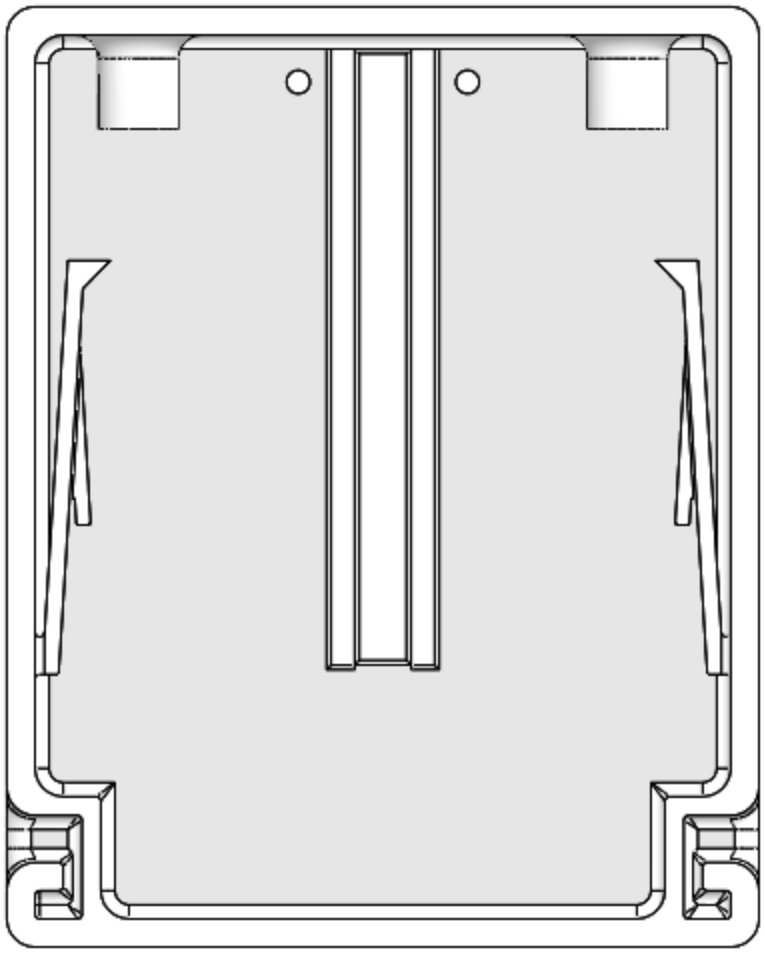

Figure 5.12: Original bottom body design

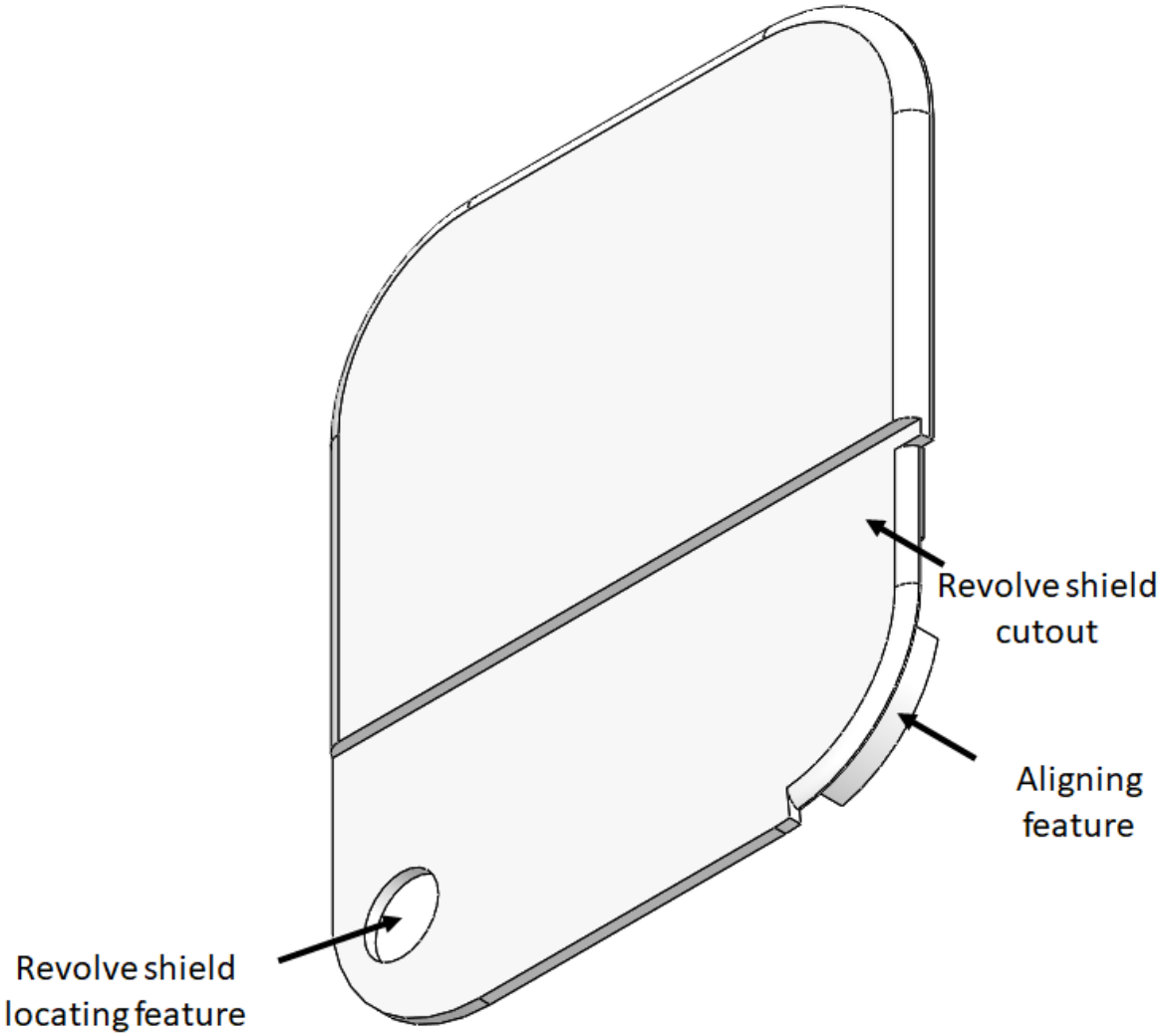

Figure 5.13: Labeled view of final top body

5.6: Quick Release System Design

From the start, we wanted the fluid to be released as part of the activation sequence. This meant that there needed to be a mechanism linked to a position on the body or a displacement of the syringe that activated the fluid injection springs. Initially, we planned on using a snap-fit design in which the springs were held in a compressed state by a pair of plastic clips. As the syringe subsystem travelled axially along the main body, these clips would contact matching protrusions and bend, releasing the springs from their compressed states (see Fig. 5.14). However, after briefly prototyping this mechanism, we realized that to meet all of the required geometric constraints, these clips would not withstand the force of the injection springs, which each exert 52.90 N.

Figure 5.14: Initial quick release design with snap-fit interface

Building off of the initial idea, we continued to use material interference to lock the injection springs in their compressed state. In the new design, the springs push on the syringe cap on one end and the plunger block on the other end. In the center of the syringe cap is a tube with a cross hole that holds two spheres. This cross-hole matches with a smaller one in the plunger block, and when a pin is inserted into the tube, the locking spheres are forced partially out into the plunger block cross holes, materially constraining everything. A diagram of this system is shown in Figure 5.15 below. This whole mechanism sits inside the syringe, and when that subassembly bottoms out along its motion, a string rigidly attached to the main body and connected through a hole on the pin becomes taut. The spring force and syringe subsystem momentum exert enough force to pull the pin, freeing the locking spheres and allowing the syringe springs to push the plunger block.

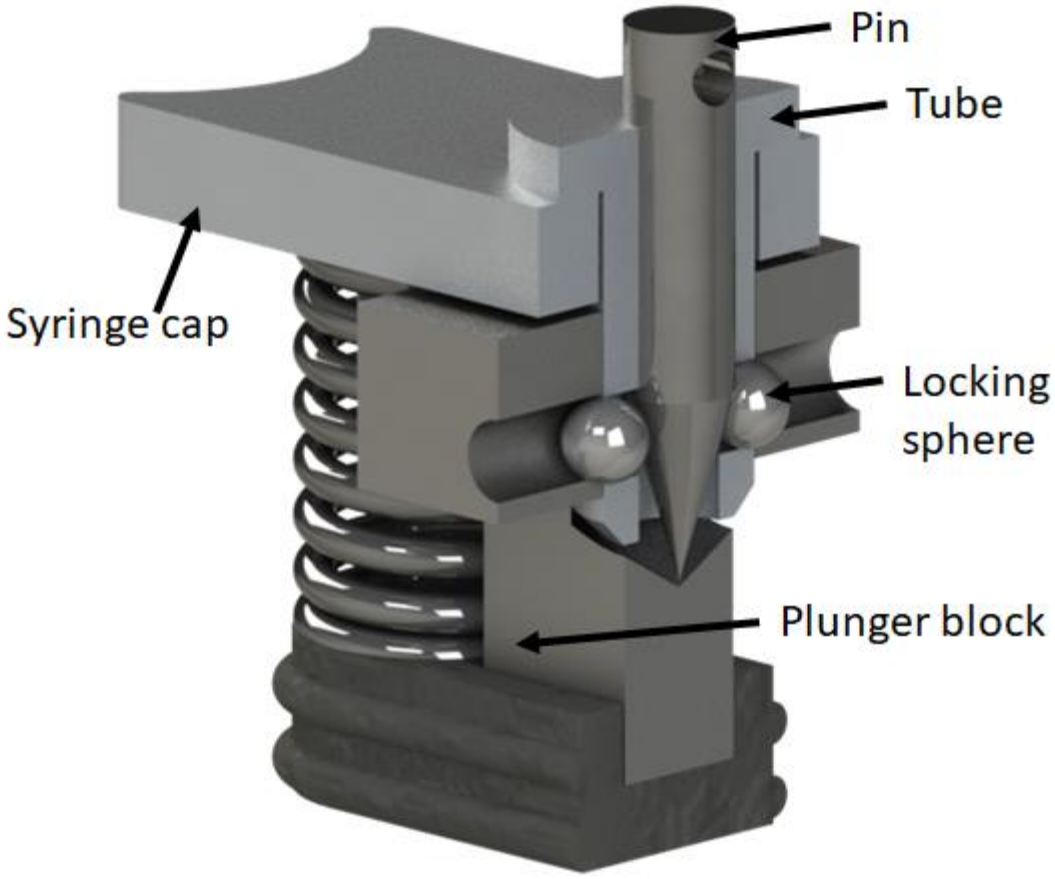

Figure 5.15: Quick release mechanism

The locking spheres originally contacted a flat surface on the pin. Analysis of the system free body diagram indicated that the activation springs, which exert the pull force on the pin, could not overcome the effective frictional force that holds the pin in place. At the location along the syringe motion where the string becomes taut, the springs are pushing down (and therefore pulling the pin that is rigidly anchored above) with a combined force of just under 2 lb. We chose to neglect momentum in this calculation since the frictional losses to that are extremely variable and dependent on the final manufacturing materials and tolerance stackup. The syringe momentum acts in the same direction of the spring force, so this adds in an additional safety buffer. By switching from steel to stainless steel, we reduced the resistive coefficient "μ" between the spheres and the pin. This is a mostly experimentally determined measure of the frictional coefficient and pin material deformation caused by the locking sphere contact.

Figure 5.16 below shows the graph of pin pull force versus angle for the original and modified geometry. The minimum taper angle is the point where the force from the spheres pushes axially along the pin, preventing locking from occurring. The target angle is the point where 0.5 lb of pull force is required. This number was chosen so that, on the optimized design, even with a reasonable manufacturing tolerance of 1-2 degrees, there was still a safety factor of 2 on this system. Originally, we were at the Y axis of the plot on the left, which shows a required pull force of over 10 lb. By reducing the resistive coefficient as explained above and modifying the tube outer diameter / plunger block inner diameter, we

were able to shift to the plot shown on the right of Figure 5.16. The maximum pull force is significantly decreased from the original, and the slope is shallower, reducing the impact of manufacturing tolerances (seen as taper angle changes) on the required pin pull force.

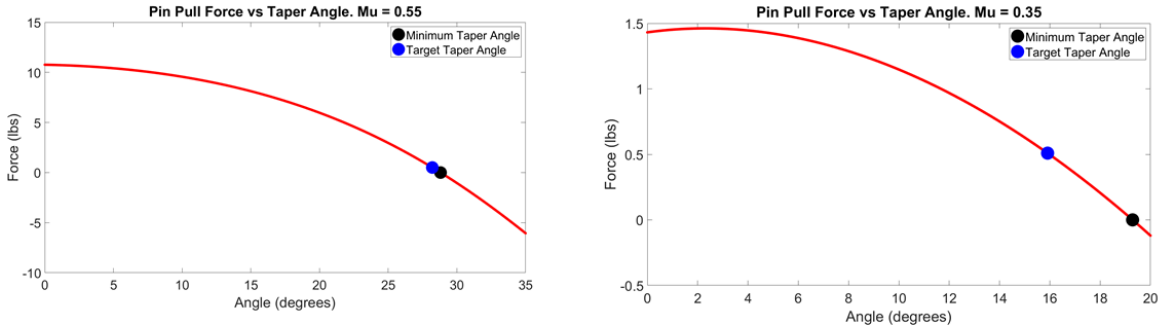

Figure 5.16: Pin taper angle plots. Original (left) with high pull force and steep slope. Modified (right) with low pull force and shallower slope

5.7: Rubber Seal Design

Sealing the fluid chamber proved to be a much harder problem than anticipated. We incorrectly assumed that a flat piece of rubber between the plunger block and the fluid chamber, oversized so that it was squeezed between the syringe wall and the plunger block, would form an adequate seal. However, after prototyping on various thickness, hardness, and overlap geometries with a flat piece of rubber, we realized that we needed a more sophisticated seal design.

To solve this sealing problem, we looked at commercial syringes and plungers that we had and noticed that they used a double-ribbed design, with the rib outer diameter extending past the nominal inner diameter of the syringe. The rubber was squeezed against the side of the syringe, forming a seal. We researched standard values for this overlap parameter and found that, in the relevant syringe size range, they were on the order of 0.35-0.45 mm oversized diametrically [29]. We created a slot-shaped plunger with ribs to match our syringe shape, as shown in Figure 5.17 below. We experimentally tested 0.35, 0.45, and 0.55 mm overlap. However, the other main parameter involved is material hardness. Researching this value indicated that most standard plungers are made of materials in the 45-70 Shore A hardness range [30]. We had 45A hardness rubber available to us, so we tested with that. It was too compliant and did not form a seal, so we moved to 60A rubber, which worked. With our 60A rubber, we found that the 0.45 mm overlap seal was the minimum tested value that consistently provided an effective seal, so we used this geometry for our tests. Larger overlap values are undesirable because they increase the frictional interference of the system, which means less spring kinetic energy is translated into fluid outlet velocity and pressure.

Figure 5.17: Final rubber seal geometry

5.8: Safety Case Design

The safety case is intended to prevent the user from being injected if the device activates while on the wrist as well as to prevent the device from activating if dropped while the case is on. It also needs to interface between the device and a wristband or watch strap so that the user can wear LifeWatch as intended. We started by focusing on the wristband interface. Initially, as shown with the buckle in Figure 5.6 above, we designed a standard push buckle to clip into the base of the device. However, in the transition from extension springs to compression springs detailed above, we realized that an open-faced bottom would be dangerous and unsterile, so we transitioned to a closed-face design with a different type of buckle as seen in Figure 5.18 below. The clips are attached to dowel pins that they can rotate on and are pushed on by extension springs that are compressed by the user through the buckle when it needs to be released as shown in Figure 5.19 below. This mechanism worked well, but the user experience as rated by our group was not ideal. While on the wrist, there was no way to hold the main body of the device and squeeze the buckle, so the injection cartridge would often fall off once the buckle was released.

Figure 5.18: Buckle on closed-faced design

Figure 5.19: Cross-section of buckle shown in Figure 5.18

To solve this, we redesigned the entire safety case and injection cartridge removal interface. In the new design, shown in Figure 5.20, the injection cartridge sits within a section of the case which stays on the user's wrist, and another section of the case can be removed. Then the entire injection cartridge can be removed from the part of the case that remains on the wrist and the device can be used to inject into the user's thigh per medical requirements. The two parts of the case are held together by a set of clips that are part of the case that stays on the wrist. These clips can be easily squeezed by the user, allowing the removable case section to be pulled off.

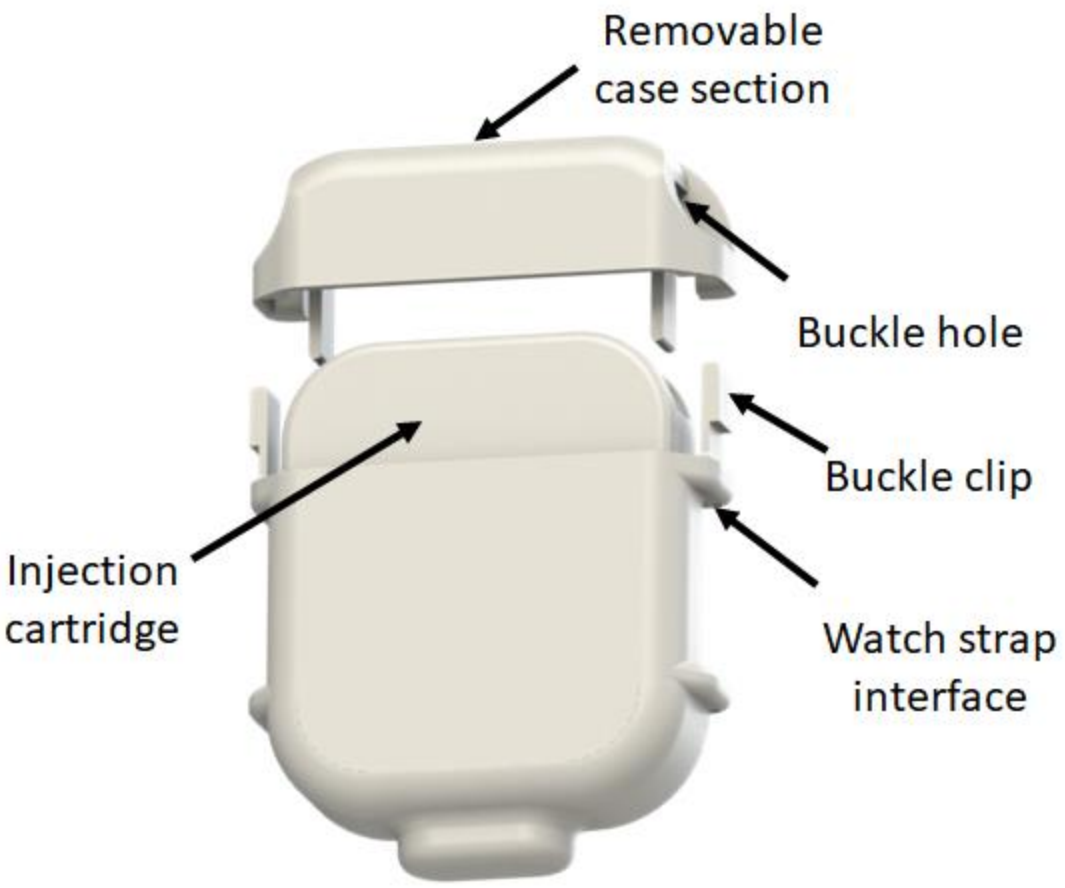

Figure 5.20: Final case version

To address the other two goals of the safety caps, protecting the user and preventing activation upon physical case impacts, two features were added to this final case version. First, a slot-shaped extrusion, at the bottom of Figure 5.20 above, prevents the activation button from being pressed when the device is in its case and stops the needle if the device is somehow activated while in its case. The second goal is solved by the removable safety cap which has two straight extrusions visible in Figures 5.20 above and 5.21 below. These fit behind the activation flexures when the case is closed, preventing them from moving. In this configuration, when the activation button is pressed, it cannot move anywhere, so everything stays in its locked configuration and the device cannot be activated even when it otherwise would be.

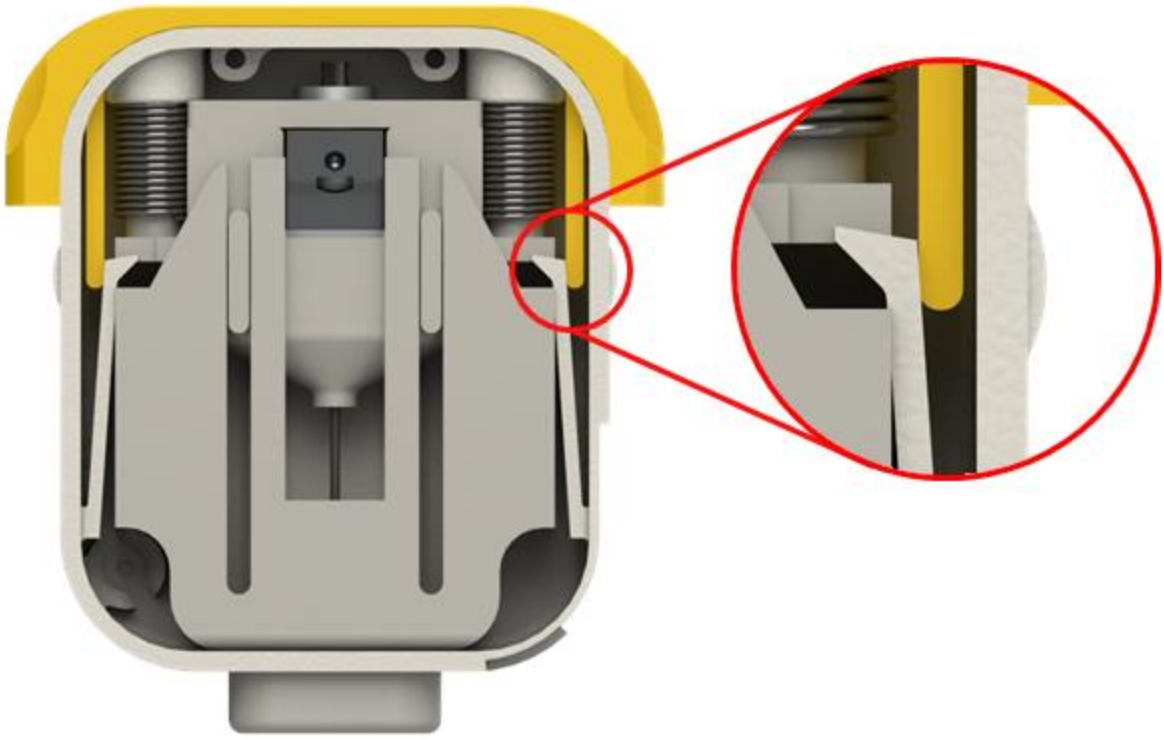

Figure 5.21: Safety cap keeping activation flexures in place

5.9: Revolve Lock Design

To ensure that there are no accidental needle pricks post-injection, we developed a locking mechanism to shield the needle. The most space-efficient mechanism we devised was using a keyed slot to lock a revolvable shield in place. After injection, the shield must be rotated out manually by the user since there was inadequate room for a sufficiently high spring constant torsional spring. We also considered making sections of the top and bottom case slide out to cover the needle, but there was simply not enough room to enable to these to extend fully and still lock in place over the needle, so they were never fully implemented.

In the final design, inside the case, a custom-made brass tube with a D-shaft on one end and a slot on the other rotates with the shield. The D transmits the torque. At a certain point along the rotation, a spring pushes a key into a slot in the main case that matches the slot on the brass tube. The key engages both pieces simultaneously, locking the shield in place over the needle. An exploded view of the subassembly is shown in Figure 5.22. Figure 5.23 shows the internals in a locked configuration, and Figure 5.24 shows the needle in reference to the locked revolve sheath.

The revolve shield itself, the part that locks over the needle, has a complex geometry to enable all of its functionality. First, it has a D feature that allows it to transmit torque to the internal mechanism and aligns the shield during assembly and operation. Second, it is made of thin plastic, half the thickness of the top body (which it sits on). The flat top of the revolve shield joins the primary needle cover section, which is the same thickness, at a 90-degree angle. This specific wall thickness allows the shield to sit within the matching cavities of the top and bottom bodies without changing the device profile as described above. However, by making this piece long and thin, it became extremely flexible, reducing its

safety value. To compensate for this, since we could not make a custom sheet metal part in small batches, we inserted a 0.030" sheet metal plate into the devices shields that we tested on needles (see Fig. 5.25). This flat top of the shield covers the top of the needle, and the other section wraps around to cover the needle point on three sides as shown in Figure 5.24. This section also has a slot that allows the needle to pass through when moving between initial to locked configurations. Although one side of the needle is still exposed, we were unable to touch the point of the needle on our final prototype with the shield locked, even while actively trying. It therefore successfully minimizes the chances of accidental needle pricks.

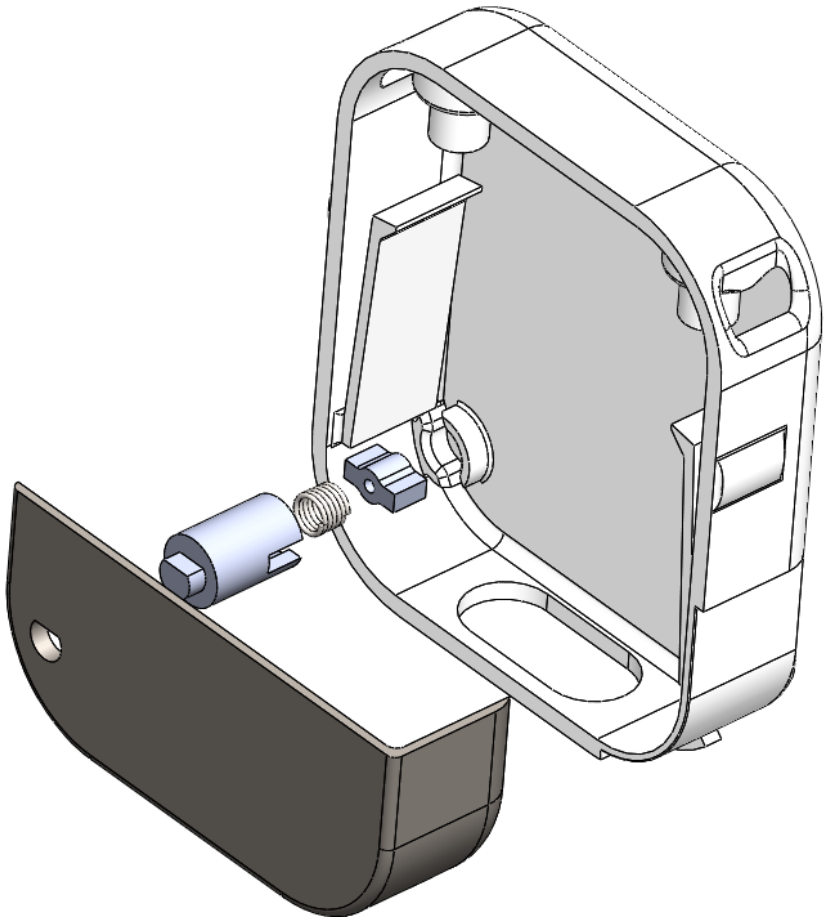

Figure 5.22: Exploded view of revolve sheath subassembly

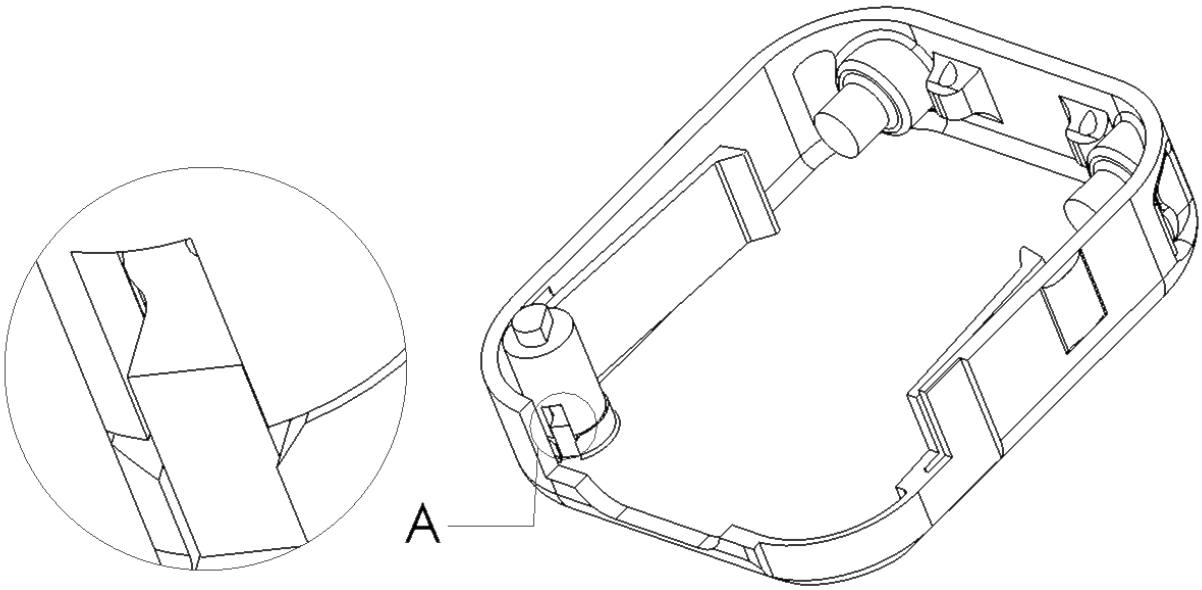

Figure 5.23: Partial cutaway view of internal part of revolve sheath mechanism and detail view A in locked configuration

Figure 5.24: Bottom view of needle in revolve sheath in locked configuration

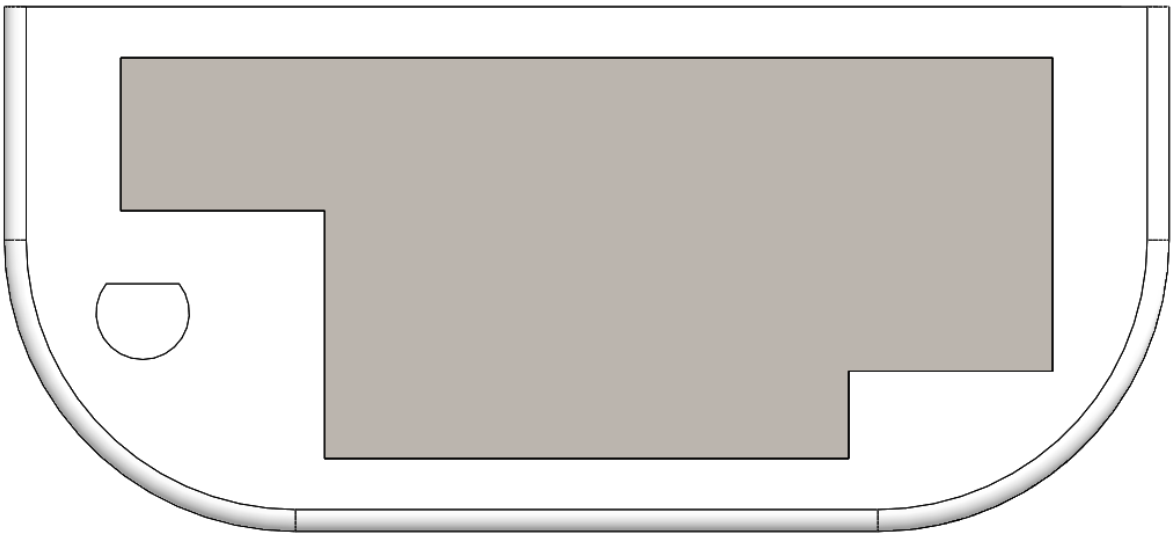

Figure 5.25: Revolve shield top view with plastic section shown in white and sheet metal insert in grey

5.10: Sterility Considerations

One area that we looked into but did not fully develop was a sterility enclosure for the system. Current market solutions either have a sterile enclosure until the safety is removed or cover the needle with a sterile enclosure that is penetrated and compressed upon activation. We tried coating the needle in liquid latex as a proof of concept of the latter. It worked reasonably well, bunching up and allowing the needle to penetrate into our flesh analog test material, but we did not fully implement this. In terms of the other path, we partially designed it in CAD but were unable to manufacture with available tolerances. Our intention was to have rubber seals that covered all device openings, particularly the holes that the rear safety cap sits in, allowing the internal to remain sterile. When the rear safety cap is removed, it would break this sterility, but this should only occur when the user is ready to inject (see Fig. 5.26).

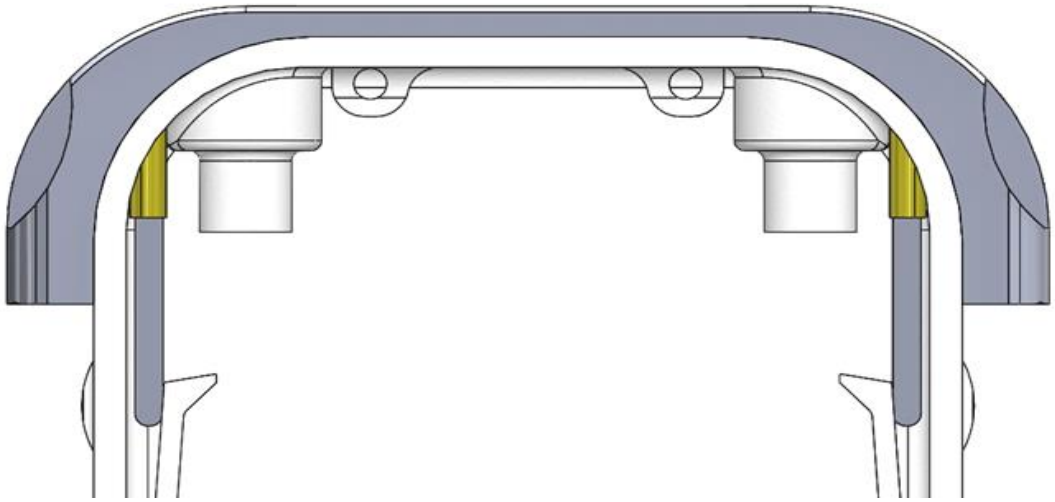

Figure 5.26: Sterility caps shown in gold, penetrated by the rear safety cap in grey

5.11: Watch Considerations

Although the team did not have time to fully implement the reach goal of integrating an actual watch into the device, we began working towards it. To this end, we dissected an existing digital watch, extracted the components, and fit them within our case profile. However, the electronics were damaged during this process; as such, we would like to create a custom circuit board to make this design into a reality. Figure 5.27 shows the initial prototype with the physical watch components in place as a proof-of-concept. All components fit within the existing outer case with laser-cut holes, and the injection cartridge could still be inserted into its housing. This demonstrates the technological feasibility of adding a watch to the case with little to no changes to the dimensional profile.

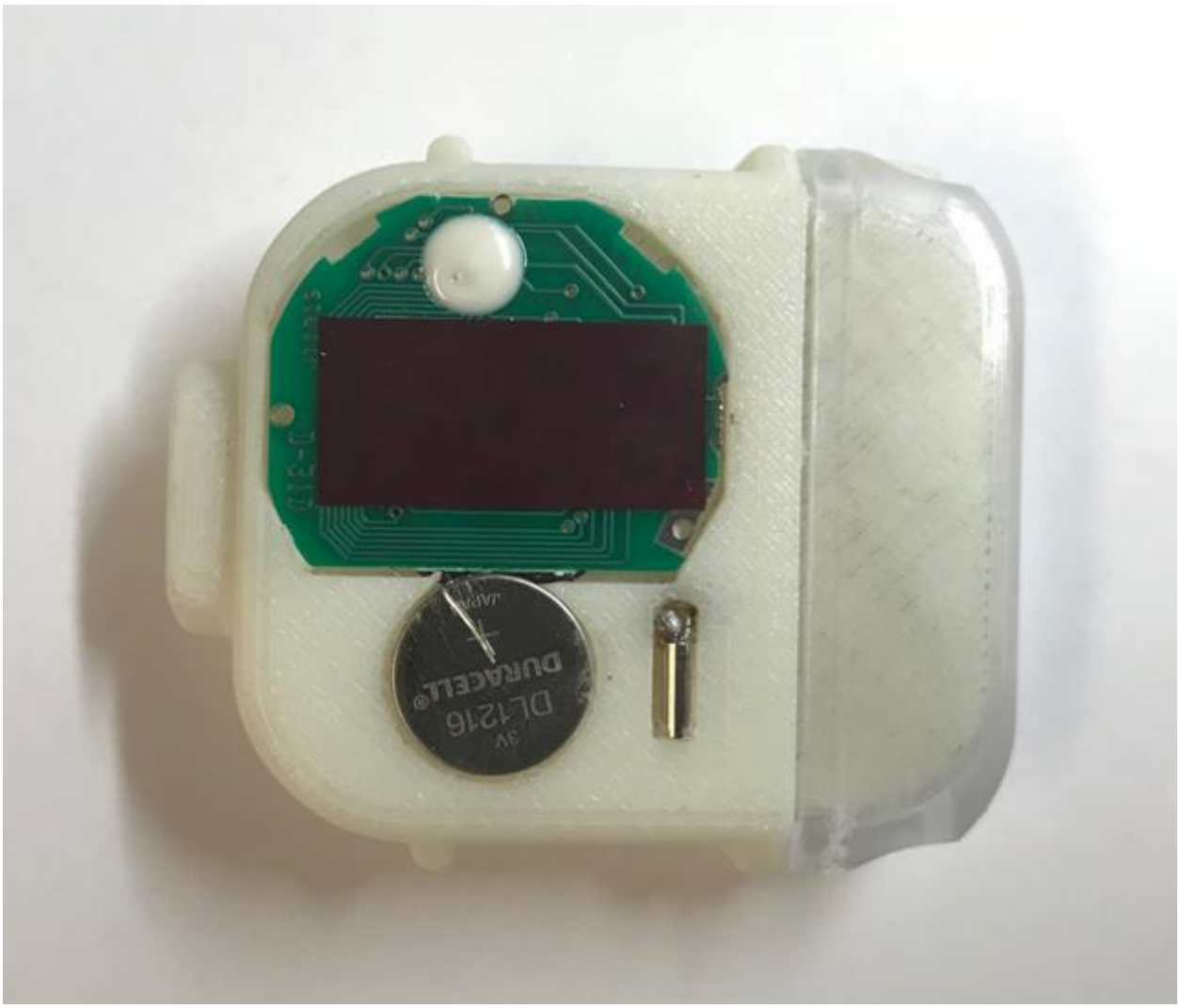

Figure 5.27: Picture of initial prototype of watch in device case

5.12: Design for Manufacturability Considerations

One area of improvement for the future is the manufacturability of the device for mass production. The initial prototype was developed with this in mind, and thus the majority of components were designed such that they could be easily injection molded and assembled without major modifications. Injection molding was chosen since it is one of the most common methods of mass producing structurally sound ABS components. The one component that needed special design attention was the bottom body. Due to the cutouts below the activation flexures that allow them to bend, this part can't be easily molded. To solve this issue we designed, but did not implement, a two-part bottom body. The internals with the spring nubs and activation flexures would be injected molded as a separate piece from the external casing that these sit in. These two pieces of the case could then be assembled to create a new subassembly that would be functionally equivalent to the original bottom body. As a proof of concept, we laser-cut a partial two-part case, and the flexures on that design were able to successfully hold the loaded activation springs and syringe in place, demonstrating the design feasibility of this modification (see Fig. 5.28).

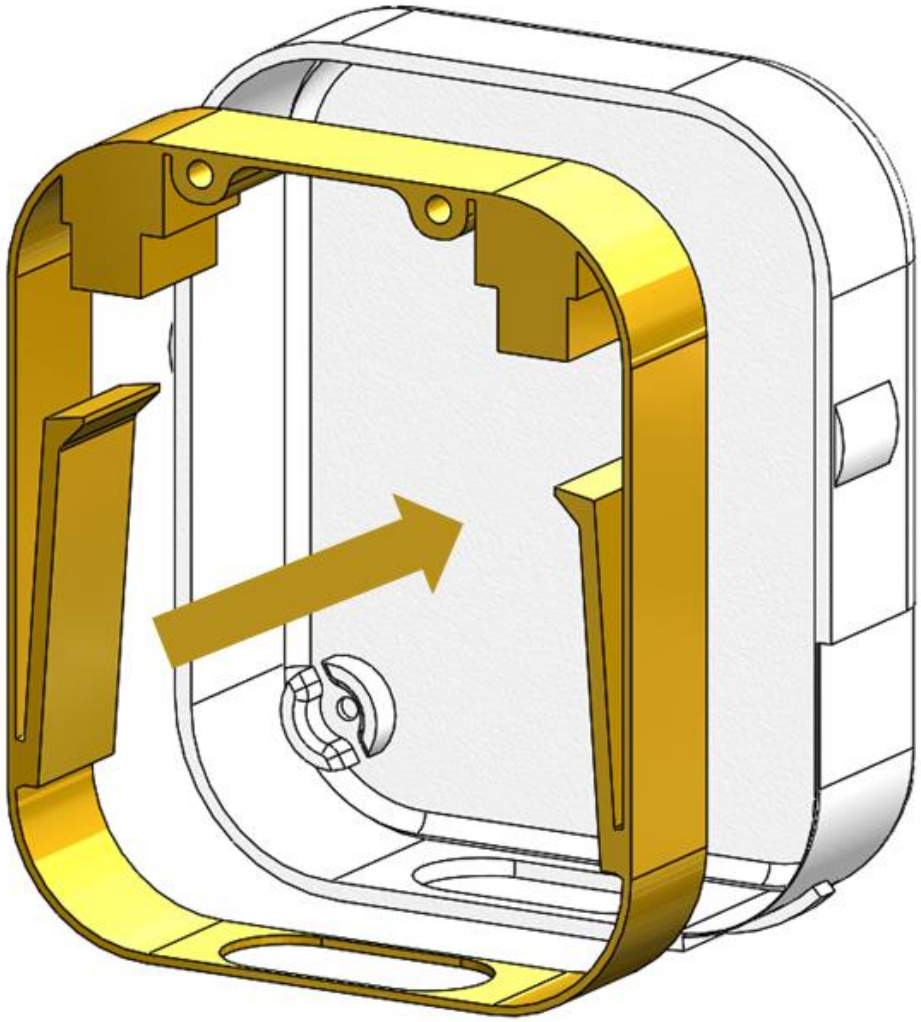

Figure 5.28: Two-part bottom body design for injection molding

5.13: Manufacturing Processes

The majority of the parts were manufactured using 3D printers for most of the project. However, in the final prototype, most of the quick release subsystem parts were precision machined using the in-house machine shop lathes and mills for structural integrity reasons. For prints where tolerance was not crucial, particularly those used to contextualize size, shape, or size of a first draft mechanism, we used the MakerBot Replicator 5th Generation printers available to us. For most of the prints, we utilized the Biomedical Library's Stratasys uPrint SE Plus. This printer can print in 0.010" layer resolution with higher resolution than the MakerBots. We used ABS, which has good structural properties and worked well for these prototypes (see Fig. 5.29). For extremely high-resolution parts that needed the best possible surface finish but low structural stability, such as the syringe, plunger molds, and demonstration-only cases, we utilized the AddLab's Projet 6000 Stereolithography printer with clear resin.

A handful of parts were machined to increase their structural integrity. For this project, the activation button was machined because it kept breaking during assembly; we later realized this was simply an assembly method error. The quick release mechanism was designed to be made of metal and was therefore machined as well. This was primarily done to support the greater than 89 N spring force acting on the components. The pin is stainless steel, the tube and syringe cap are aluminum, and the plunger block is mild steel. Finally, the revolve sheath key is made from aluminum, and the revolve lock tube is made from brass to reduce friction. An example of the machined revolve lock keys can be seen in Figure 5.30.

The plungers themselves were made by using silicone rubber to fill molds. We used Smooth-on Tin Cure Mold Max 60 two-part rubber for the final design. These allow you to mix part A and part B of the rubber compound in a specific ratio. The user then fills the mold with the mixed rubber, which is a viscous fluid. The mold should be degassed until bubbles stop forming and popping. In our case, this happened at a vacuum gauge pressure of -93 kPa. The mold is left to cure for an amount of time listed on the rubber package, at which point it is fully crosslinked and hardened.

Our manufacturing costs were low because we took advantage of the freely available machines and materials, allowing us to rapidly prototype through all of our designs. Many of the most difficult aspects of this design revolved around the volumetric optimization constraints, which made this rapid prototyping ability essential to our success. We were able to begin designing new subsystems while waiting for components to be printed, allowing the team to work in parallel and significantly increasing our overall work output. We further used this rapid prototyping capability to avoid complex analysis on non-essential elements. Although we analyzed the primary structural elements of our device and thoroughly tested everything to ensure it would not break under standard operating conditions, using rapid prototyping to design the intermediate parts to a "good enough" level instead of an optimized one allowed us to significantly enhance the quality, appearance, and functionality of the final device as a whole. In short, by utilizing the available manufacturing capabilities and rapid prototyping via CAD and 3D printing, we were able to create between 5 and 6 major design iterations with even more tweaks to individual subsystem level components.

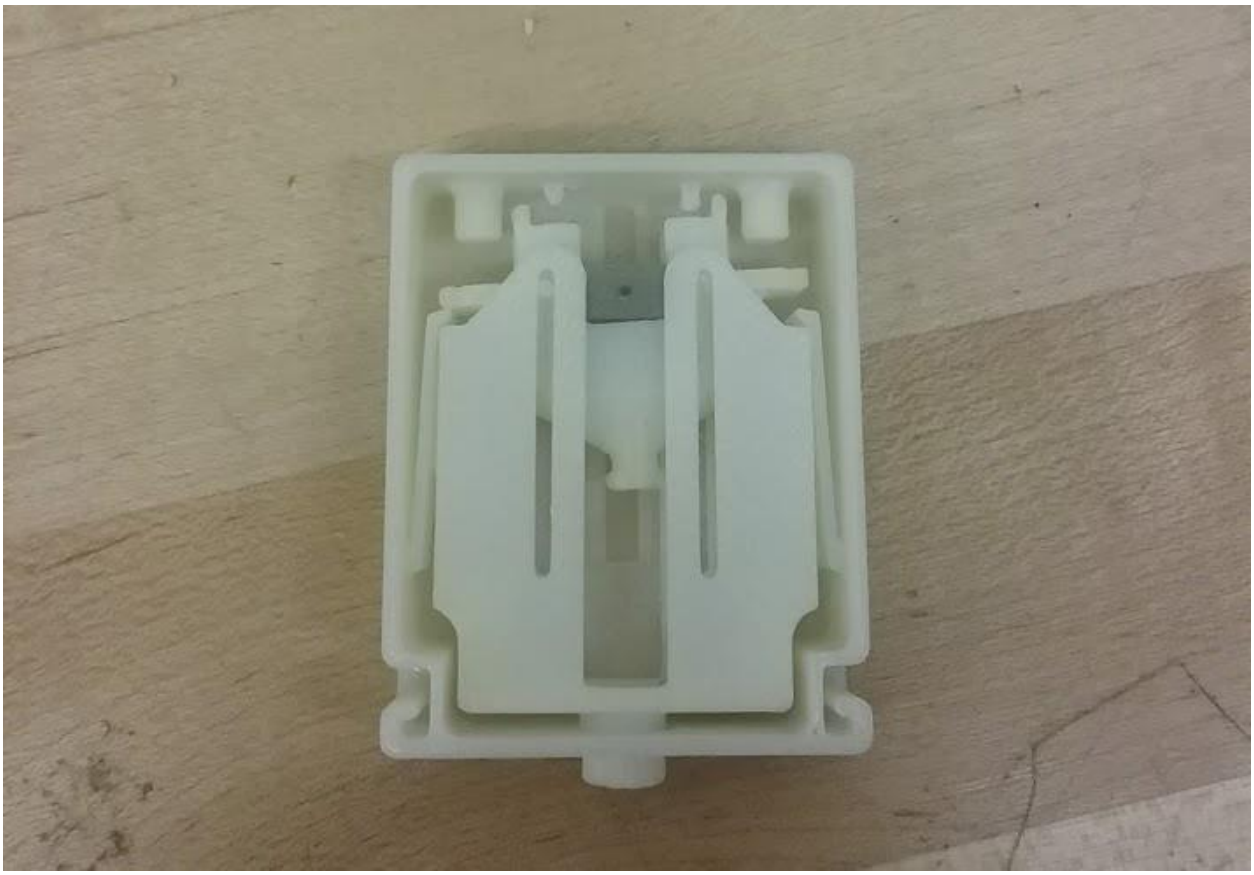

Figure 5.29: Example of uPrint SE Plus printed parts

Figure 5.30: An example of machined parts used in the final design

5.14: Final Embodiment of LifeWatch

In its final embodiment, LifeWatch is an auto-injector that a user wears passively on their wrist. The case that holds the device has two interfaces for a watch band that can be changed by the user. When the device is held inside the case, the full dimensions are 55 x 48 x 14.5 mm. The device should be worn such that the needle points away from the user's hand.

If a user needs to perform an injection, they first pinch the two clasps on the front case. This bends them inwards, allowing them to clear the safety cap holes that they rest in. The user can then pull the safety cap off of the back of the device with the same hand. Next, the user pulls the injection cartridge out of the case using a sliding motion and holds it in their dominant hand.

When the user is ready, they firmly swing the device so that it hits their outer thigh. This is the medically approved location to perform an injection of epinephrine during anaphylaxis [17]. The user must ensure that the activation button makes contact with their leg during activation. When the device is pressed against the thigh, the activation button is pushed into the device. Two deformable flexures attached to the internal walls of the device's main body remain in contact with the activation button at all times. As the button is pushed up, the tangential contact between it and the flexures deforms their tips outward towards the sides of the device. The syringe, which had been resting on the flexure tips, is then unconstrained and springs pushing on it begin driving the needle into the user's thigh.

Just before the syringe reaches the end of its travel, a wire connecting the quick release pin and the top inner wall of the device becomes taut. As the syringe moves further, the tension in the wire pulls the quick release pin from the syringe. This triggers the quick release system and allows the injection springs to push the plunger down. The fluid inside is forced through the syringe tip and needle into the user's body.

After injection is complete, the user pulls the needle out of their thigh. To prevent the needle from accidentally pricking the user, they rotate the needle shield to cover the exposed tip. Once the cover reaches its position over the needle, the keyed lock mechanism engages and prevents the shield from being pushed away. An exploded view of the final iteration of LifeWatch can be seen in Figure 5.31.

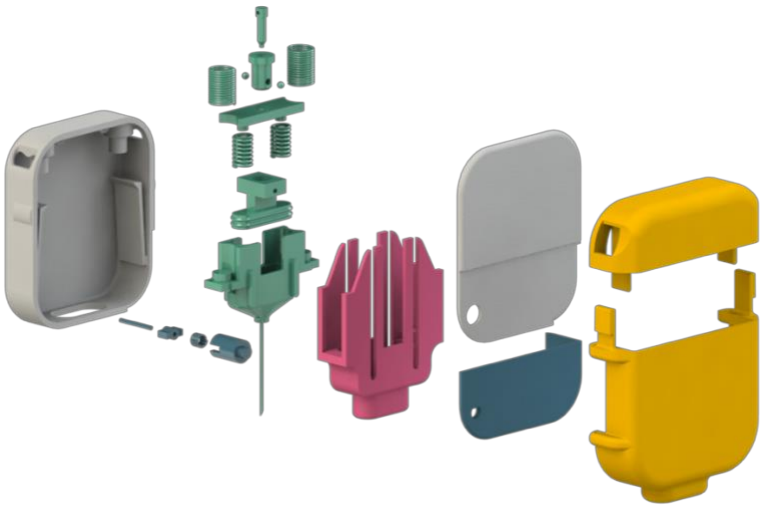

Figure 5.31: Exploded view of the final embodiment of LifeWatch, color blocked by subsystem

6. Validation and Testing

6.1 Final Dimensions

The primary goal of this project was to miniaturize all of the subsystems in an auto-injector such that they fit within a 50 x 50 x 15 mm volume, similar to the profile of a large wristwatch. The final dimensions of the device are 48 x 54.75 x 14.5 mm including the safety case. Although the device is slightly longer than we originally envisioned, its physical volume is smaller than the goal we set.

The additional length is primarily due to the safety caps; the injection cartridge case itself is only 51 mm long, but the length is increased by the activation button and both front and rear safety caps. We allowed the device to extend past the intended length since the safety caps serve numerous functions including preventing accidental injections, protecting the device if dropped, and interfacing with the wristband. Additionally, users must be able to easily remove the safety cap in an emergency, it must be large enough to grip and pull if a user is sweating or shaking. User testing within our group shows that the current device size is optimal such that reducing any dimension would have a significant negative impact on the user experience.

The final physical volume of the device is 33.6 cm^3, which is 47% of the EpiPen's 70.8 cm^3 volume and 58% of the Auvi-Q's 57.4 cm^3 volume as measured by the team. The latter is the smallest available auto-injector on the market today, demonstrating that we have made significant and innovative progress with the device profile. The final mass of the system is well below the initial goal of 150 g, the mass of a large watch, at only 26 g. Note that this mass value does not include the mass of the strap, which the user can change as desired.

6.2: Force Testing

The team first conducted tests to empirically determine the force required for the needle to penetrate the skin and push the fluid into the body. The team started by purchasing several human flesh analogs such as sausages and molded silicone [31]. These systems were placed on a scale and injected with water using a standard syringe and 22 gauge needle. In order to determine the force applied to penetrate the flesh analogs, the team zeroed the scale with the test object on it, read the maximum value as the needle was pushed into the object, and multiplied that value by the acceleration due to gravity (9.81 m/s^2).

The results showed that the force required for penetrating these flesh analogs was no larger than 2 N. Note that, at the time of these tests, the team had yet to acquire a high precision scale; however, these tests functioned as a first-order identification of the range needed for the activation springs. The obtained force value matched a study of needle-tissue interaction, which can be seen in Figure 6.0 below, that used far more accurate measuring tools.

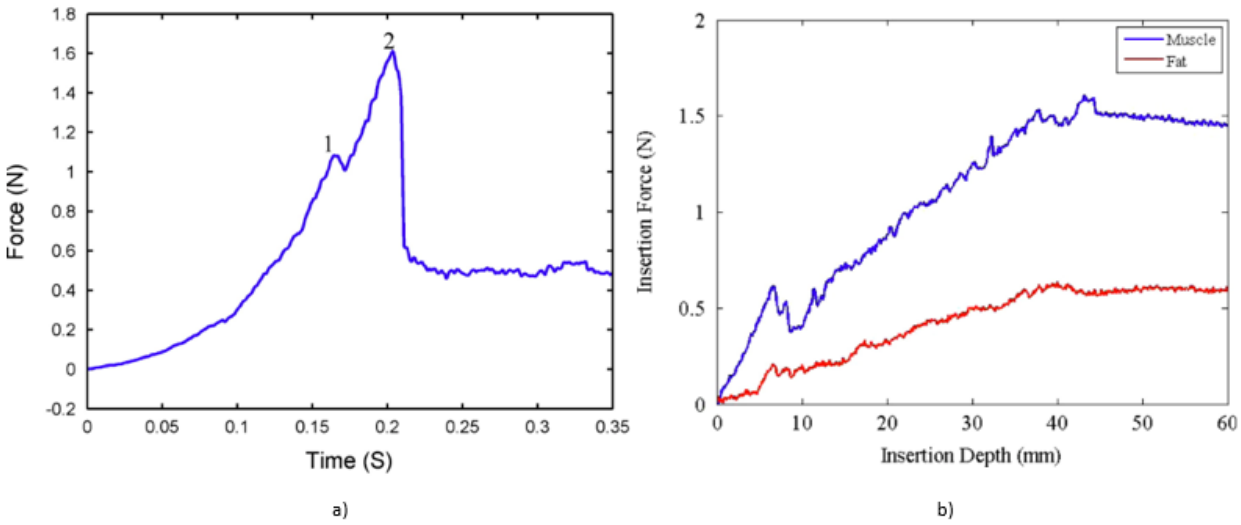

Figure 6.0: a) Injection force to penetrate skin vs. time b) injection force vs. depth for different tissues [32]

In order to force fluid out of a syringe, the plunger must be pushed with a magnitude that is a function of the needle inner diameter, syringe profile, and plunger-syringe interface. We measured the inlet area of the syringe we were using to be 12.62 mm, placed the same flesh analogs on the scale, and zeroed it. We recorded the force required to push fluid through the syringe and needle into the flesh analog as well as the time it took to eject the full volume. These values allowed us to correlate pressure to flow rate (see Fig. 6.1).

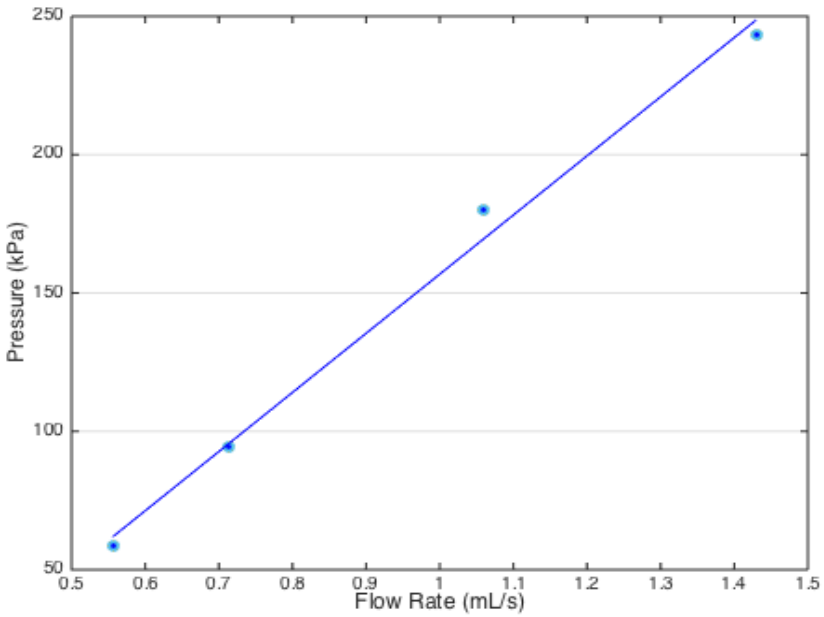

Figure 6.1: Correlating flow rate to pressure

Using this relationship and our flow rate of 1.2 mL/s (calculated below), these tests indicated that under ideal circumstances, we would need at least 200 kPa in order to fully dispense the volume. To add a safety factor and ensure the full fluid was dispensed, the team decided to adopt the higher pressure of 500 kPa that was determined earlier (see Section 5.2: Spring Selection).

$$Flow\ rate\ = \frac{Dosage\ volume}{Time} = \frac{0.3\ mL}{0.25\ s} = 1.2\ mL/s \qquad \text{(Eq. 6.0)}$$

6.3: Injection Testing

The most important medical metric for the validation of LifeWatch is the volume of fluid dispensed when activated and the corresponding standard deviation. The team designed for 0.3 mL, the standard dosage among auto-injectors.

In order to isolate the volume dispensed, the team created a test setup involving the artificial flesh, a cup, a high precision scale, and the LifeWatch syringe subsystem. The flesh was placed in the cup to ensure any leaked fluid would not be lost and subsequently weighed prior to activation; a loaded syringe subsystem was weighed separately. The needle was inserted into the flesh, and the system was activated manually. The cup with the flesh and the syringe were then weighed again after the injection. The difference between fluid dispensed (i.e. - the change in mass of the flesh) and fluid injected (i.e. - the change in mass of the syringe subsystem) was the amount of fluid that leaked past the seal. A total of 50 valid tests were run with the initial plunger design. Many more tests were run but deemed invalid for the following reasons: visible fluid leakage/ricochets from the cup due to high outlet velocity, and visible lack of seal on plunger due to wear from reusing plungers designed for single use. There was also some potential measurement error due to the sensitivity of the scale and presence of air currents in the room we used to test; to minimize these effects, a closed box was placed over the scale and measurements were double checked.

During the first set of tests with what we denote "Plunger A," the average dosage volume was 0.222 mL as seen in Figure 6.2, short of the desired 0.300 mL. However, the standard deviation of these doses was only 0.015 mL, which is less than that of the EpiPen at 0.016 mL [27]. Additionally, the average amount of fluid lost by an incomplete seal, was 0.006 mL, validating our seal's efficacy at

$$\left(1 - \frac{0.006\ mL\ lost}{0.222\ mL\ injected + 0.006\ mL\ lost}\right) \times 100 = \ 97.4\% \qquad \text{(Eq. 6.1)}$$

In response to the dosage falling short of the 0.300 mL target, the team improved the plunger manufacturing process and ran more tests with the improved version (denoted "Plunger B" in Fig. 6.2). Specifically, the plungers were made by filling a 3D printed mold with silicone rubber and letting it cure. With the first set of tests (Plunger A), the molds were all overfilled, causing the design to deviate from CAD. In the next set of tests (Plunger B), the molds were properly filled, allowing a meniscus to form; thus, the plungers more accurately reflected the CAD, and the corresponding average dosage volume became 0.283 mL as reflected in Figure 6.2. Due to project time constraints, we were only able to complete 5 tests with Plunger B.

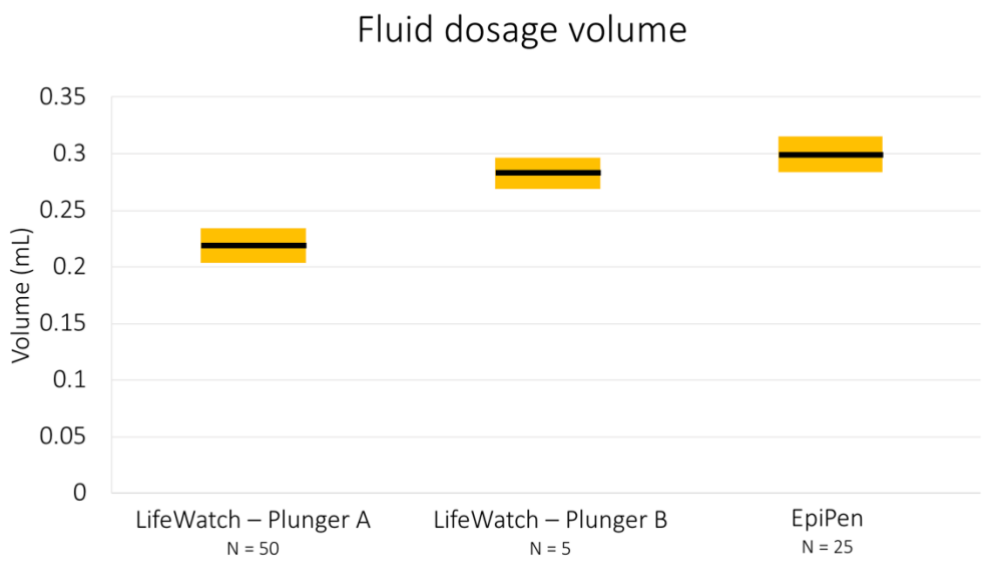

Figure 6.2: Fluid dosage volume with different plungers. The black lines are the mean and the gold boxes are the standard deviation.

Although this is a small sample, Plunger B's tests produced consistent results. Furthermore, the standard deviation was even lower than Plunger A's tests, at 0.014 mL. This result shows high design feasibility for meeting the dosage requirements if we further improve our plunger manufacturing method.

6.4: Fluid Velocity

In order to more thoroughly demonstrate that the device could eject fluid with a sufficient exit velocity, the team recorded video of the device activating using the 240 fps camera on an iPhone. We injected dyed water horizontally into air over a white background for maximum visual clarity. This fluid was aimed at a white paper wall, allowing us to see when fluid contact occurred. The initial video showed only around 5 frames between fluid leaving the syringe and contacting the wall due to the high outlet velocity. We determined that this recording was not precise enough and thus purchased a Sony Cyber-Shot DSC-RX100 IV for further tests, enabling us to record video at 960 fps.

From the higher-speed video, we could see close to 20 frames instead of only 5, effectively increasing the accuracy of our time measurement. The team measured the time between fluid exiting the needle and contacting the paper wall to be 18 m/s and the distance the fluid traveled to be 0.22 m, allowing us to calculate the fluid's exit velocity.

$$\frac{0.22\ m}{0.018\ s} = 12.2\ m/s \qquad \text{(Eq. 6.2)}$$

This result is only slightly above the calculated exit velocity value for the EpiPen, 11.8 m/s, suggesting that there is high design feasibility for the success of this device at medical grade standards.

6.5: Drop Testing

As this device is intended to be worn on the wrist, it must be able to withstand the rigors of everyday life. The team's biggest concern was the potential of the device accidentally activating if it were subjected to an impact. It is crucial that the device be stable and safe for users to wear through everyday activities. Therefore, we needed to ensure that impulses on any face did not lead to accidental injections. To test this, the team performed a series of tests, dropping the system on each of its faces and noting if it activated. Each drop test used an initial height of 1.0 m, the standard for impact testing according to ISO 11608-1 [19] [33]. Further, the device must be able to activate normally after being dropped.

A total of 80 drop tests were conducted, 50 with the safety case on and 30 without. With the safety case removed, a user should be able to activate the mechanism by pressing the activation button. In a similar manner, dropping the device from a height of 1 m and positioning it to land on the activation button should lead to an injection since this is physically equivalent to activation. As such, drop tests were not conducted on this face. Furthermore, the face opposite the activation button should not be tested without the safety case on because the inertial forces involved in dropping the mechanism on this side are mechanically identical to dropping it on the activation button itself. To validate the above claims, we dropped an EpiPen trainer on its equivalent of these two faces and saw a 100% activation rate.

In the 50 trials with the safety caps on, there were 0 cases of accidental activation and 0 cases of failure to activate normally after being dropped. With the safety cap on, 5 of the 6 faces were tested 10 times each. Since the 2 side walls are geometrically identical, we determined that there was no benefit to testing on both of these sides. All of the drop tests completed with the safety cap on were successful due to the design of the safety caps. The front safety cap prevents impulses from acting on the activation button, and the rear safety cap has two extrusions that lock the loaded activation springs in place.

In the 30 trials conducted without the safety caps on, the system remained unactivated on the front and back sides; however, the side walls had a 50% activation rate. Again, no trials resulted in cases of failure to activate normally after an unactivated drop test. 10 trials were conducted dropping the system on its top and bottom faces each, and a further 10 on one side. The 20 on the front and back resulted in 0 accidental activations. The trials dropping the system on its side face resulted in 5 accidental injections out of 10 total trials. As the safety cap was removed during these trials, there is nothing preventing the flexures from deflecting, meaning the compressed activation springs can be released. Stiffening the flexures would improve these results, as the force required to achieve the same deflection could be increased as needed. Figure 6.3 below shows images describing each face of the mechanism.

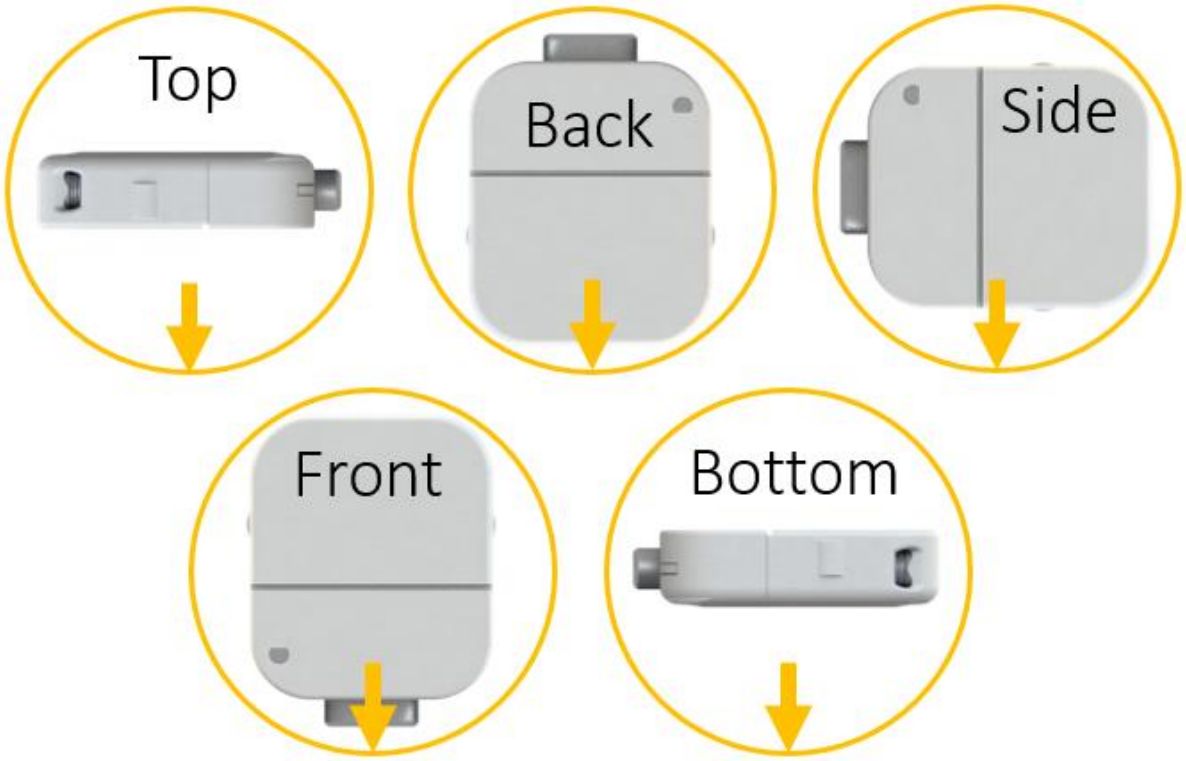

Figure 6.3: Orientation definitions for drop tests

6.6: Needle Depth

The needle in the system must reach a sufficient depth in order to inject intramuscularly (IM). To determine the length of our exposed needle, we measured the length of exposed needle after activating the system. The first set of tests resulted in an average length of 16.10 mm over 7 trials, with a standard deviation of 0.036 mm, after which the needle had to be re-glued. This resulted in a change in the nominal length of the needle due to the imprecision of our assembly methods. An additional 43 trials were conducted after this regluing, resulting in an average length of 16.49 mm, and a standard deviation of 0.0275 mm.

After researching industry standards, we set our nominal needle length at 16 mm. According to the EpiPen UK website, the nominal length of their needle is 16 mm [34]. Interestingly, this is contradicted by a study claiming that the EpiPen needle length is 15.02 mm [27]. Further research showed that the nominal EpiPen length may be inadequate due to biological differences in body composition as well as fat ratios across genders, age, and health statuses [35] [36].

Note that the needle reaches at least the nominal 16 mm length in each of our needle length tests and the standard deviation in length is low. This indicates that the needle will hit its mechanical stop every time and always reach the associated nominal value. Although these tests were conducted without the fluid subsystem set up, our device's standard deviation of 0.0287 mm was lower the EpiPen's 0.25 mm standard deviation.

6.7: Static Tests

In order to further validate the endurance of the flexures, the team set up a fully loaded test system and left it in the loaded state for the duration of the University's 20-day winter recess. After that period, the team successfully activated the system and did not note any evidence of creep or material degradation.

This long duration test, in combination with the FEA analysis, provided sufficient validation of the flexures for the scope of this course. In the future, the team would like to perform similar static tests both over a longer period of time and under extreme temperature conditions. Performing static tests at higher temperatures would effectively accelerate the test. This mock acceleration would enable the team to better explore creep, which could become an issue since the device is meant to be left in a loaded state for months at a time.

6.8 General Tests

Throughout the year, the team extensively tested every component. Although we conducted analysis on the main load-bearing areas (see Section 5.4: Activation System Design), we focused more on experimental validation, as the device is intended to be a consumer product that will be subjected to numerous unpredictable, and thus difficult-to-simulate, loads on a daily basis. No cracks appeared during the drop tests, even when we tried lightly throwing the device at the ground from waist height. Not a single set of activation flexures broke on any iteration of the device. The activation buttons only ever broke during assembly due to user error; occasionally, if we were trying to compress the activation springs during assembly, they would twist out of plane and apply pressure along the weak dimension of the 3D extrusion lines in the activation buttons. By testing rapidly, we gained significant user insight as well on the comfort and feel of the device. Finally, this rapid testing allowed us to decrease our assembly time from about 20 minutes to less than 5 minutes per device, validating that with only a few minor tweaks the device could be mass produced and assembled.

7. Discussion

7.1: Target Versus Accomplished Performance

Overall, we are satisfied with our performance and final result; the goals we outlined for ourselves were almost completely realized. Specifically, in Table 7.0 below, we've outlined the idealized system characteristics that we set forth at the beginning of the fall semester alongside what was achieved. For easier viewing, a column was added with a visual representation of our success; using a colored circle, we show how well we achieved each goal at a glance. Green denotes a goal that was completely achieved, yellow - nearly achieved, and red - not achieved or dropped.

Table 7.0: System Characteristics and Accomplished Performance

Characteristic	Level	Success	Accomplished Performance
Inject 16 mm into thigh	Basic		From the medical requirements on this type of injection. We achieved the required 16 mm needle length in our product.
Dispense 0.3 mL Epinephrine in solution	Basic		From our goal of 0.3 mL of solution dispensed from the device, we achieved 0.28 mL with a standard deviation of 0.015 exceeding our goal of 0.016. This was largely due to the manufacturing techniques available to us in designing the plunger. After testing a variety of materials, we were confident that in mass-production, our device would be able to meet the desired fluid capacity.
0 accidental injections	Basic		During our testing, we found that the device was susceptible to early accidental activation when dropped on its side without the safety case attached. In the next iteration, we plan on increasing the stiffness on the side flexures to mitigate this issue.
0 misfire injections	Basic		In our testing, we never encountered a case where the device could not activate on proper flesh analogs when desired.
Fit in pocket or on wrist (Portable)	Basic		Our device fully fits on the wrist and can be incorporated into any existing watch band on the market today.
Mass produced product < $600	Basic		The material cost of our product on a large manufacturing scale is $1.80. This result is significantly cheaper than both the manufacturing cost of an EpiPen as well as what they go for on the market [37].

Characteristic	Level	Success	Accomplished Performance
Dimensions <= 50 mm x 50 mm x 15 mm	Basic		The final dimensions of our product are 40 x 51.5 x 13 mm. In total, this is a 28.6% reduction in volume from our initial goal.
Mass < 150 g	Basic		The final mass of our product is 26 g. This mass is significantly less due to the use of 3D printing and the lack of machined aluminum parts in the device.
~100 N force at injection	Basic		Through our testing, the device has been able to break the skin on our flesh analogs, insert the needle to the proper depth, and inject the fluid against internal resistance. The injection force was sufficient as was the activation force.
No electronic activation	Basic		Our product fully operates without the use of a battery.
Impact resistant	Basic		With the safety cover on, the device is completely impact resistant during our 1 m drop tests. There were no misfires or accidental activations with the cover on.
At most 30 seconds to remove device and be ready to inject	Basic		As Jake demonstrated on stage during the SEAS Senior Design Day, the device is able to be activated in under ten seconds, much less than half a minute.
Solution temperature between 15˚-35˚ C with allowance for brief deviations	Reach		We decided against designing around this reach goal due to the fact that while this is an industry standard held by EpiPen and Auvi-Q, it does not have medical basis [20].
Waterproof	Reach		Currently, we have CAD and a prototype concept for this concept of waterproofing/sterility. Unfortunately, due to time and manufacturing facility constraints we were unable to incorporate it into the design we showed on design day.
Two injections in one device	Reach		Due to the space constraints, it was infeasible to incorporate two complete injection mechanisms into the small profile of our device. An entire redesign would need to take place in the future for this to occur.
Incorporation of watch functionality	Reach		For this reach goal, similar to the waterproofing, we only have CAD and a prototype for this. Moving forward however, this is an important goal for us to reach, which will require a custom circuit board and reasonable design effort.

Characteristic	Level	Success	Accomplished Performance
Voice instructions	Reach		We decided against moving forward with this reach goal when we realized that the electronics and speaker subsystem would take up too much space in our already small profile.

7.2: Recommendations

To those wishing to pursue a similar project, the greatest piece of advice we can give is to start prototyping as early as possible. Our mentors and advisors were thankfully pushing the team hard in this respect, and we are very grateful that they did so. Having a working product at the end of the fall semester helped to streamline our workflow in the spring, as we knew where improvements had to be made. Through our prototyping process, we found that the more iterations created, the better the solution will be; starting earlier would have potentially allowed us another iteration.

Similarly, starting early work on FEA allowed us to make key design changes without having to wait to receive the 3D printed parts. On average, there was a one-week delay between sending the parts to be printed and receiving them. Without performing FEA on those crucial parts, we could have wasted a full week that could have been used to further design or test.

Additionally, through starting the design process earlier, we could have integrated the watch component fully into our system. As mentioned in Table 7.1 above, the watch was a reach goal for our team. While we have CAD and a prototype for it, the design was ultimately left out of the model that we presented on Senior Design Day.

In terms of testing, we recommend having a clearly delineated testing procedure laid out before beginning. Our team took the time and outlined a specific testing method so that the results would not be skewed by who was conducting the test at a given time. Further, having the testing results explicitly outlined allowed our team to conduct a larger number of injection tests and drop tests than originally anticipated.

Our six-person team seemed like the perfect size to tackle the problem of creating a wearable auto-injector. We were flexible enough to work in parallel as a team and were willing to completely redesign mechanisms instead of trying to modify designs that failed the initial tests. While in the early design phase, there were multiple weekends where our team sat together brainstorming solutions to the problems we only thought of the previous day because of the rapid prototyping. Ideas flowing from multiple concurrent channels of innovation was beneficial in this regard. Counter to this idea of having a parallel workflow, though, there were some drawbacks. Since we were not working in the same location at the same time, there were occasional communication issues. One suggestion that we would like to provide for future groups is to meet more frequently in order to have greater communication between the different subgroups. In our experience, better communication leads to a better product.

8. Budget, Donations, and Resources

Team EpiPenn received the following funds to create LifeWatch, as denoted in Table 8.0 below.

Table 8.0: Funding

Source	Amount of Funding Received
Towne Business Office	$2400.00
The Berkman Innovation Fund	$1000.00
M&T Summit (First Prize)	$2000.00
Couloucoundis Prize[1]	($400.00)
SEAS Design Day (First Prize)[1]	($800.00)
AddLab[2]	($300.00)
TOTAL	**$5400.00**

Further, the team used these funds as described in Table 8.1 over the duration of the project.

Table 8.1: Categorical Spending

Category	Approximate Cost
Manufacturing	$467.50
Testing	$116.38
Off-the-Shelf Parts & Product Accessories	$369.41
Engineering Standards	$248.09
High-Speed Camera Bundle	$983.99
Miscellany	$189.12
AddLab[2]	($155.00)
TOTAL	**$2374.49**

[1] These funding sources are indicated for completeness but were not put towards the project.
[2] Each team was given a 3D printing credit of $300.00 designated for AddLab use only, thus neither contributing to nor detracting from the team's overall budget. It is specified here for posterity.

The projected manufacturing cost at scale of the final product (as of the date of submission) is approximately $9.30. This is broken down in Table 8.2, the final manufacturing cost, below. Note that the parts themselves only cost $1.80 per device.

Table 8.2: Final Manufacturing Cost (at-scale projection)

Part Name	Volume (mm^3)	Material	Density g/cc	Mass g	Material Cost	Quant.	Cost per	Total Cost	Manuf. Method
Bottom Case	4693	ABS	1.04	4.88072	$ 0.003	1	$ 0.042	$ 0.042	Inj. Mold
Top Body	2258	ABS	1.04	2.34832	$ 0.003	1	$ 0.020	$ 0.020	Inj. Mold
Revolve Sheath	660	ABS	1.04	0.6864	$ 0.003	1	$ 0.006	$ 0.006	Inj. Mold
Front Cap	3837	ABS	1.04	3.99048	$ 0.003	1	$ 0.034	$ 0.034	Inj. Mold
Back Cap	2326	ABS	1.04	2.41904	$ 0.003	1	$ 0.021	$ 0.021	Inj. Mold
Needle	N/A					1	$ 0.040	$ 0.040	Buy
Plunger Springs	N/A					2	$ 0.320	$ 0.639	Buy
Plunger Plate	305	Aluminum	2.7	0.8235	$ 0.002	1	$ 0.005	$ 0.005	Machining
Tube	92	Aluminum	2.7	0.2484	$ 0.002	1	$ 0.002	$ 0.002	Machining
Inner	30	Brass	8.73	0.2619	$ 0.006	1	$ 0.018	$ 0.018	Machining
Ball	N/A					2	$ 0.025	$ 0.050	Buy
Syringe	1182	ABS	1.04	1.22928	$ 0.003	1	$ 0.011	$ 0.011	Inj. Mold
Syringe Cap	257	Aluminum	2.7	0.6939	$ 0.002	1	$ 0.004	$ 0.004	Machining
Plunger Rubber	200	TPE	1.05	0.21	$ 0.118	1	$ 0.074	$ 0.074	Inj. Mold
Activation Button	2736	ABS	1.04	2.84544	$ 0.003	1	$ 0.024	$ 0.024	Inj. Mold
Syringe Springs	N/A					2	$ 0.261	$ 0.522	Buy
Revolve Lock 2	130	Brass	8.73	1.1349	$ 0.006	1	$ 0.020	$ 0.020	Machining
Lock Spring	N/A					1	$ 0.207	$ 0.207	Buy
Revolve Lock	26	Aluminum	2.7	0.0702	$ 0.002	1	$ 0.000	$ 0.000	Machining
Revolve Pin	N/A					1	$ 0.064	$ 0.064	Buy
								1.804	

Fixed Cost for 100k	
Tooling Cost	500,000
Part Quantities	100,000
Tooling Cost/part	$ 5.00

Labor	
Labor $/hr	20
Labor time hr	0.125
Labor dollars/part	$ 2.50

Per Part Total	
Direct Materials	$ 1.80
Direct Labor	$ 2.50
Overhead	$ 5.00
Total	**$ 9.30**

The team also took advantage of numerous cost-free resources available from the University to assist in the completion of the project. We used the Biomedical Library to 3D print multiple prototype parts, the Rapid Prototyping Lab to quickly laser cut proof-of-concept prototypes for an easy-to-assemble version of LifeWatch, the Precision Machining Lab to manufacture more robust parts at no cost, and the Penn Center for Innovation to begin pursuing intellectual property protection.

9. Intellectual Property

The auto-injector market has been ingrained into the medical device culture for decades; specifically, the epinephrine auto-injector first entered the market in the 1970s [38]. Historically, the epinephrine auto-injector market has been difficult to tap into due to the heavy barriers to entry, including the high initial cost and intense intellectual property.

There are currently 5 FDA-approved epinephrine auto-injectors in the United States: EpiPen, Twinjet, Adrenaclick, Auvi-Q, and Symjepi [38]. Four of these devices are pen-shaped. The Auvi-Q is the only approved device with a different form factor. However, the internal mechanism that powers the syringe of the Auvi-Q is a small high-pressure gas chamber. As the LifeWatch uses a system of springs to drive the injection, the design of the LifeWatch does not interfere with that of the Auvi-Q.

The pen shaped auto-injectors all have very similar internal compositions. Due to this initial analysis, our team believes we will have freedom to operate (FTO) in this field. Officially, in order to have a comprehensive analysis to grant us FTO, we have hired a practicing patent attorney to confirm our initial views. The costs associated with a true FTO search are very high, so we have paid a patent attorney for a "standard patent novelty search." In this search, the attorney reviews 12 related patent applications in a manner similar to an FTO. This analysis typically takes 3 weeks to confirm and was first started on April 18, 2018.

As the American Inventors Act of 2011 states, the first to file a patent has the rights to the invention [39]. Prior to the American Inventors Act (2011), however, the United States law was first-to-invent [39]. We filed a provisional patent on March 22, 2018 in order to hold the date for first-to-file. The next step in our pursuit of intellectual property involves obtaining a utility patent for the device. Provided that the novelty patent search allows us to continue, we plan to file a utility patent within the next 12 months.

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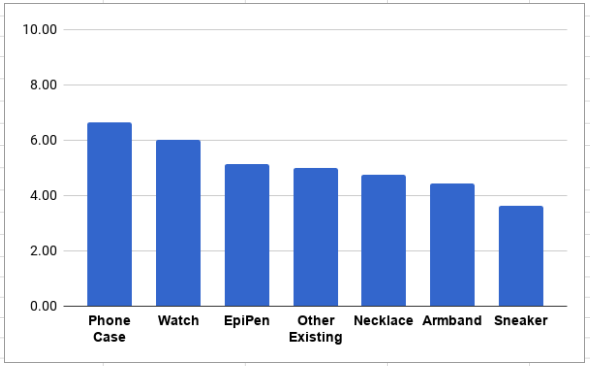
Appendices

Appendix A: Stakeholder Survey Responses

Number of responses		Avg Epipen Satisfaction	Avg Auvi-Q Satisfaction	Avg Other Satisfaction		Avg desire 2 injections		Avg Rating Necklace	Avg Rating Shoe	Avg Rating Watch	Avg Rating Phone	Avg Rating Arm
95		5.189473684	6.909090909	5.303030303		6.10989011		4.610526316	3.526315789	5.842105263	6.473684211	4.336842105
	count >= 8	12	32	7		19		Count >= 8	Count >= 8	Count >= 8	Count >= 8	Count >= 8
	%	12.63157895	48.48484848	21.21212121		19.79166667		19	12	39	47	20
	count >= 8	22	5	8			%	20	12.63157895	41.05263158	49.47368421	21.05263158
	%	23.15789474	7.575757576	24.24242424				Count <= 3	Count <= 3	Count <= 3	Count <= 3	Count <= 3
								40	55	30	19	47
							%	42.10526316	57.89473684	31.57894737	20	49.47368421
								Median	Median	Median	Median	Median
								4.805263158	3	7	7	4

Solution	Average satisf	Extremely Satisfied	Extremely Dissatisfie	Solution	Average satisfaction	Extremely Satisfied	Extremely Dissatisfied
EpiPen	5.19	12.63%	23.16%	Auvi-Q	6.95	48.39%	6.45%
Auvi-Q	6.91	48.48%	7.58%	Phone Case	6.62	50.00%	17.78%
Other Existing	5.30	21.21%	24.24%	Watch	6.02	43.33%	30.00%
Necklace	4.61	20.00%	42.11%	EpiPen	5.14	12.22%	23.33%
Sneaker	3.53	12.63%	57.89%	Other Existing	5.00	16.67%	26.67%
Watch	5.84	41.05%	31.58%	Necklace	4.73	21.11%	40.00%
Phone Case	6.47	49.47%	20.00%	Armband	4.44	22.22%	47.78%
Armband	4.34	21.05%	49.47%	Sneaker	3.63	13.33%	56.67%



Appendix B: Fluid Volume Testing Data Plunger A

Init Flesh mass	Initial Syr mass	Final Flesh mass	Final Syr Mass	Flesh	Syringe	Delta	Notes	Valid?
9.600	6.326	9.648	6.205	0.048	-0.121		No Seal	0
9.634	6.255	9.859	6.022	0.225	-0.233	-0.008		1
9.783	6.275					0.000	No Seal	0
9.661	6.313	9.866	6.085	0.205	-0.228	-0.023	Paper Towel and	0
9.681	6.254	9.873	6.089	0.192	-0.165	0.027	Paper Towel and	0
9.924	6.346	10.105	6.095	0.181	-0.251	-0.070	Paper Towel and	0
9.616	6.277	9.841	6.050	0.225	-0.227	-0.002		1
9.615	6.283	9.828	6.068	0.213	-0.215	-0.002		1
9.633	6.277	9.840	6.060	0.207	-0.217	-0.010		1
9.629	6.273	9.836	6.062	0.207	-0.211	-0.004	Small Airbubble	1
9.614	6.291	9.844	6.048	0.230	-0.243	-0.013		1
9.653	6.380	9.863	6.174	0.210	-0.206	0.004		1
9.583	6.279	9.754	6.054	0.171	-0.225	-0.054	transcription? Po	0
9.598	6.280	9.814	6.058	0.216	-0.222	-0.006		1
12.875	6.280	13.029	6.076	0.154	-0.204	-0.050	Possible leak, po	0
12.866	6.280	13.071	6.068	0.205	-0.212	-0.007	Forgot to mass s	1
12.880	6.273	13.103	6.050	0.223	-0.223	0.000		1
12.896	6.283			-12.896	-6.283	-19.179	Fluid flew out of f	0
15.994	6.283	16.241	6.053	0.247	-0.230	0.017	Taller cup, forgot	0
15.815				-15.815	0.000	-15.815	oops it exploded	0
15.849	6.289	15.945	6.083	0.096	-0.206	-0.110	New needle, no s	0
15.948	6.286	16.172	6.065	0.224	-0.221	0.003		1
15.860	6.292	16.074	6.065	0.214	-0.227	-0.013	Scale was acting	1
15.837	6.276	16.046	6.051	0.209	-0.225	-0.016		1
15.813	6.275	16.049	6.049	0.236	-0.226	0.010		1
15.819	6.269	16.046	6.041	0.227	-0.228	-0.001	Use box cover	1
15.815	6.282	16.052	6.053	0.237	-0.229	0.008		1
15.845	6.281	16.029	6.058	0.184	-0.223	-0.039		1
15.907	6.279	16.117	6.047	0.210	-0.232	-0.022		1
15.846	6.273	16.007	6.040	0.161	-0.233	-0.072	Spray and paper	0
15.833	6.267	16.045	6.047	0.212	-0.220	-0.008		1

15.826	6.284	16.060	6.047	0.234	-0.237	-0.003		1
15.813	6.309	16.041	6.078	0.228	-0.231	-0.003		1
15.809	6.313	16.032	6.087	0.223	-0.226	-0.003		1
15.811	6.334	16.015	6.082	0.204	-0.252	-0.048	Nearly shot danie	0
15.833	6.320	16.068	6.081	0.235	-0.239	-0.004		1
15.813	6.316	16.011	6.094	0.198	-0.222	-0.024	Small amount of	1
15.831	6.315	16.056	6.086	0.225	-0.229	-0.004		1
15.821	6.328	16.059	6.078	0.238	-0.250	-0.012		1
15.818	6.318	16.051	6.085	0.233	-0.233	0.000		1
15.813	6.317	16.047	6.084	0.234	-0.233	0.001		1
15.819	6.321	16.054	6.083	0.235	-0.238	-0.003		1
15.839	6.320	16.050	6.085	0.211	-0.235	-0.024		1
15.815	6.319	16.047	6.084	0.232	-0.235	-0.003		1
15.833	6.309	16.061	6.079	0.228	-0.230	-0.002		1
15.834	6.316	16.049	6.084	0.215	-0.232	-0.017		1
15.824	6.325	16.060	6.077	0.236	-0.248	-0.012		1
15.843	6.264	16.055	6.047	0.212	-0.217	-0.005		1
15.821	6.229	16.018	6.034	0.197	-0.195	0.002	New plunger mol	1
15.829	6.234	16.056	6.006	0.227	-0.228	-0.001		1
15.823	6.231	16.045	6.003	0.222	-0.228	-0.006		1
15.820	6.239	16.062	5.994	0.242	-0.245	-0.003		1
15.820	6.232	16.046	5.994	0.226	-0.238	-0.012		1
15.828	6.234	16.062	5.992	0.234	-0.242	-0.008		1
15.832	6.232	16.069	5.992	0.237	-0.240	-0.003		1
15.839	6.231	16.080	5.985	0.241	-0.246	-0.005		1
15.821	6.227	16.053	5.986	0.232	-0.241	-0.009		1
15.823	6.226	16.060	5.989	0.237	-0.237	0.000		1
15.815	6.227	15.967	5.967	0.152	-0.260	-0.108	HEADSHOT	0
15.821	6.229	16.013	6.028	0.192	-0.201	-0.009		1
15.818	6.246	16.004	6.050	0.186	-0.196	-0.010		1
15.821	6.237	16.063	5.989	0.242	-0.248	-0.006		1

15.818	6.226	16.047	5.989	0.229	-0.237	-0.008		1
15.817	6.225	15.987		0.170	-6.225	-6.055	Seal detached ar	0

Appendix C: Fluid Volume Testing Data Plunger B

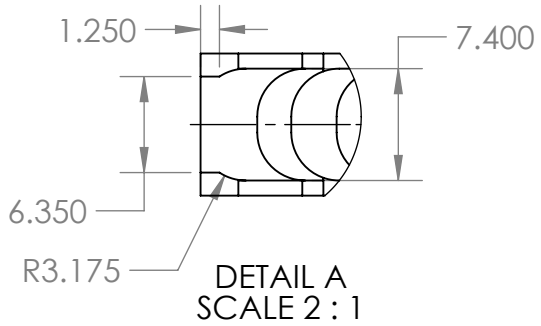
	Initial flesh mass	Initial Syringe ma	Final flesh mass	Final syringe mas	Flesh	Syringe	delta			
	15.758	10.375	16.046	10.087	0.288	-0.288	0.000		STDEV	0.01362717872
	15.775	10.369	16.052	10.091	0.277	-0.278	-0.001		min	0.268
	15.775	10.404	16.054	10.113	0.279	-0.291	-0.012		max	0.304
	15.776	10.471	16.080	10.156	0.304	-0.315	-0.011		Avg	0.283
	15.771	10.413	16.039	10.136	0.268	-0.277	-0.009			0.270
										0.297

Appendix D: Itemized Budget

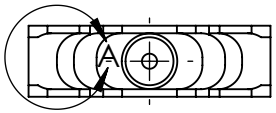
					Total Cost	1364.04			
					Additional Costs	14.74			
					Remaining Budget	1021.22			
Description	Supplier	Part Number	Quantity	Units	Unit Cost ($)	Cost ($)	Notes	Additional Costs	Notes
CarePoint 22 Gauge, 1" Hypodermic Needle	Health Warehouse	822201	100	1	12.25	12.25	Priority shipping (+$10)	10	
Dynarex Sharps Container - 2 Gal	Amazon	B01CH0LKYA	1	1	10.29	10.29			
Momok Syringes x 15	Amazon	Momok20171600	15	1	9.99	9.99			
Compression Spring - 5.4 lb	McMaster	9657K346	12	1	10.35	10.35			Needle extension spring
Compression Spring - 2.3 lb	McMaster	1986K69	6	2	5.01	10.02			Alternative needle extension spring
Compression Spring - 11.9 lb	McMaster	9657K268	12	1	10.35	10.35			Plunger extension spring
Compression Spring - 3.9 lb	McMaster	9435K19	5	1	7.34	7.34			Quick release clasp springs
Dowel pin - 14mm x 1mm	McMaster	91585A909	100	1	12.73	12.73			
Compression Spring - 1.6 lb	McMaster	9002T13	3	1	6.62	6.62			New quick release clasp spring
Fake Skin	Amazon	SMF5001	1	1	7.79	7.79	Shipping = $4.74	4.74	
Steel Balls	McMaster	9291K41	100	1	5	5			
Watch Band 18mm	Amazon	B01N41C57K	1	1	13.9	13.9			
Milligram Scale	Amazon	B0012TDNAM	1	1	22.72	22.72			
compression spring - sheath	Mcmaster	9657K257	6	1	4.97	4.97			
Torsion spring - sheath	Mcmaster	9271K69		1	5.63	5.63			
Rubber 30A	Mcmaster	1370N12 (30 A so	1	1	5.63	5.63			
Rubber 20A	Mcmaster	9109K86 (20 A so	1	1	3.9	3.9			
ABS Bar - 2ft	Mcmaster	8712K151	1	1	8.42	8.42			
Shapeways Parts	Shapeways		5	1	47.46	47.46	Rush manuf and shipping		
Silicone 60A	Smooth on		1	1	39.39	39.39			
Needle-proof gloves	Amazon	B001DZT7KU	1	1	30.66	30.66			
Digital watch	Amazon	847715026167	1	8	6.99	55.92			
Ballistic gel sample	Clear Ballistics	852844007055	1	1	1.98	1.98	Shipping: $6.99		
Steel Compression Spring 1.125" Overall Ler	Mcmaster	9434K71	2	1	$4.98	$4.98			
Polypropylene Rod 1/2" Diameter, 8 Feet Lor	Mcmaster	8658K53	8	1	$1.32	$1.32			
Zinc plated Compression Spring 3/4" Long, 0	Mcmaster	9657K283	1	1	$7.67	$7.67			
High-Strength High-Temperature Thread 0.0	Mcmaster	8800K44	1	1	$28.60	$28.60			
Ballistic gel sample	Clear Ballistics	852844007055	1	1	1.98	1.98	Shipping: $6.99		
Plunger Springs	Mcmaster	9657K268	2	1	$7.67	$7.67			
Activation Springs	Mcmaster	1986K69	4	1	$3.13	$3.13			
Sheath Spring	Mcmaster	9657K257	1	1	$4.97	$4.97			
Sheet Metal	Mcmaster	6544K13	1	1	$8.27	$8.27			
Rubber Round	Mcmaster	1350N13	1	1	$5.71	$5.71			
Finger Cots	Mcmaster	5291T6	1	1	$3.77	$3.77			
Liquid Latex	Amazon	B004WCMKA0	1	1	8.49	8.49			
Magnet Closure Lock Bracelet	Amazon	B01IOJ7EWA	1	1	11.99	11.99			
Magnetic Mesh Watch Band	Amazon	B073ZXS9ZD	1	1	12.48	12.48	$8.49 + $3.99 shipping		
Leather Watch Band	Amazon	B07251TJSY	1	1	12.99	12.99			
Magnetic Mesh Watch Band	Amazon	B073TV4HHL	1	1	11.89	11.89			
Shapeways - Plastic	Shapeways		1	1	198.9	198.9	includes 15.50 Shipping		
Shapeways - Metal	Shapeways		1	1	133.16	133.16	includes 15.50 Shipping		
Berkman						-1000			
High-Strength High-Temperature Thread 0.01	4" Diameter	8800K41	1	1	31.68	31.68			
Steel Balls	McMaster	9291K41	100	2	5.34	10.68			
T-shirts			1	8	23.64	189.12	Includes 10% rush shipping		
Decals	Sticker Mule		20	1	42	42			

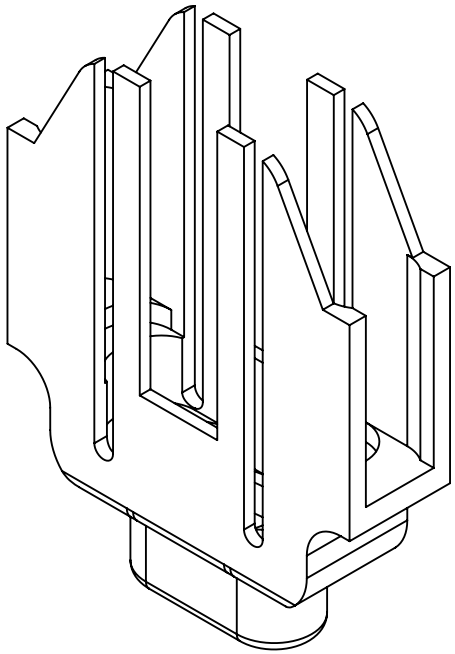
					Total Cost	1364.04			
					Additional Costs	14.74			
					Remaining Budget	1021.22			
Description	Supplier	Part Number	Quantity	Units	Unit Cost ($)	Cost ($)	Notes	Additional Costs	Notes
High Speed Camera Bundle	Amazon	B07864WXVG	1	1	983.99	983.99			
Low-Carbon Steel Balls 1/16" Diameter	McMaster	96455K71	100	1	$4.78	$4.78			
18-8 Stainless Steel Dowel Pin 2mm Diamete	McMaster	91585A221	100	1	$11.78	$11.78			
118 Degree Point Drill Bit Uncoated High-Spe	McMaster	30585A76		7	$1.16	$8.12			
118 Degree Point Drill Bit Uncoated High-Spe	McMaster	30585A71		3	$1.16	$3.48			
High-Speed Steel Slitting Cutter 0.010" Thick	McMaster	3062A37		1	$19.04	$19.04			
ISO 11608-1				1	$159.34	$159.34			
ISO 11608-5				1	$88.75	$88.75			

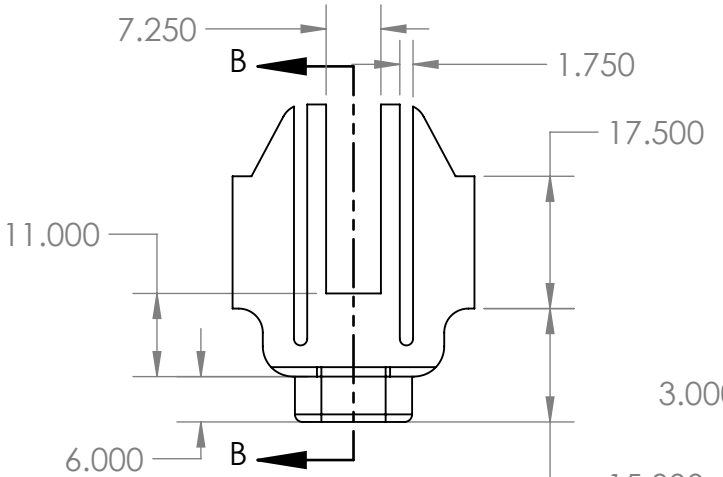
Appendix E: Drawings

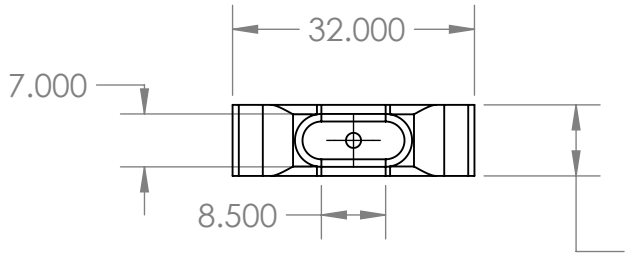


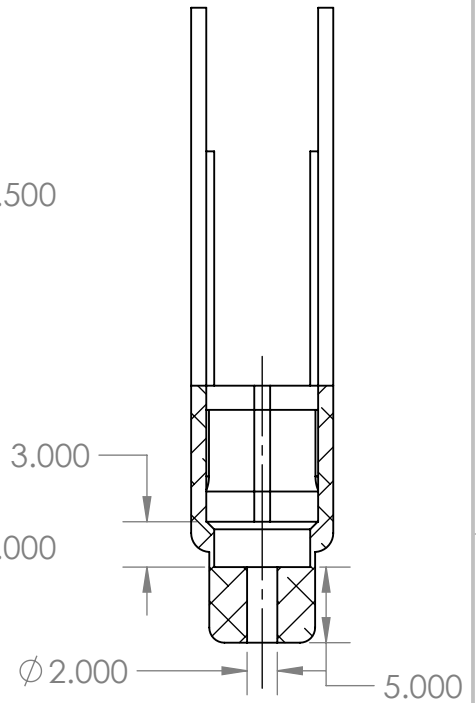
DETAIL A
SCALE 2 : 1











SECTION B-B
SCALE 2 : 1

NOTE: 3D printed.
See digital geometry.

LifeWatch

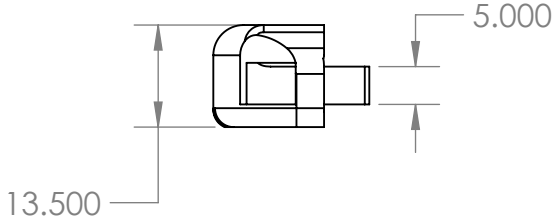
UNLESS OTHERWISE SPECIFIED:		NAME	DATE
DIMENSIONS ARE IN MM TOLERANCES: ANGULAR: MACH ± 1 deg TWO PLACE DECIMAL ± 0.25 THREE PLACE DECIMAL ± 0.127 FOUR PLACE DECIMAL ± 0.0127	DRAWN	BB	3/02/18
	CHECKED	DO	4/30/18
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL: ABS	COMMENTS: Break all edges and sharp corners		
FINISH: N/A			
DO NOT SCALE DRAWING			

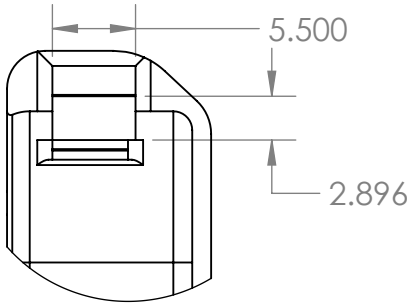
Team EpiPenn

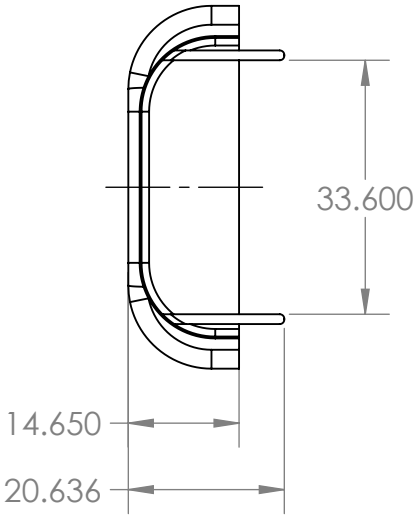
TITLE:
MA - Activation Button

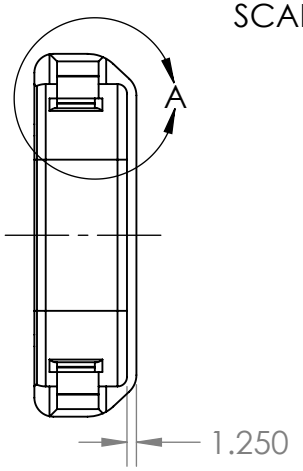
SIZE	DWG. NO.	REV
A	MA - 006	E

SCALE: 1:1 | SHEET 1 OF 1

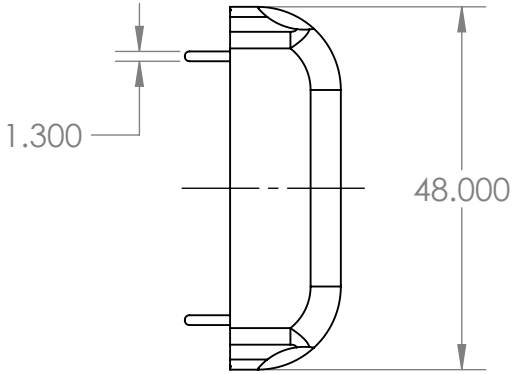




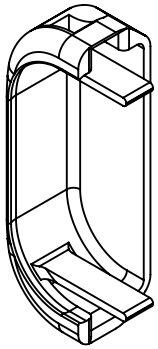




DETAIL A
SCALE 2 : 1



NOTE: 3D printed.
See digital geometry.



LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL: ABS

FINISH: N/A

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	4/04/18
CHECKED	DO	4/30/18
ENG APPR.		
MFG APPR.		
Q.A.		

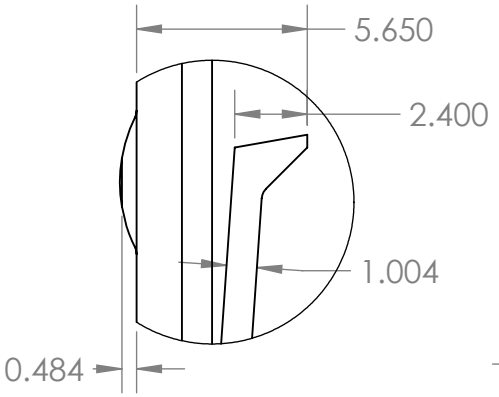
COMMENTS: Break all edges and sharp corners

Team EpiPenn

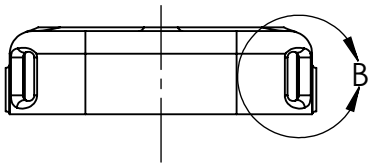
TITLE:
MA - Back Cap

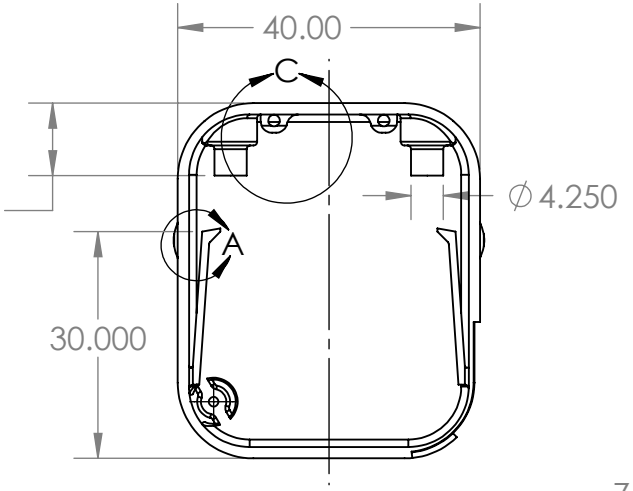
SIZE	DWG. NO.	REV
A	MA - 005	C

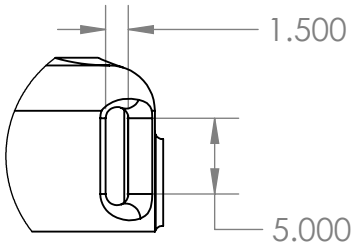
SCALE: 1:1 | SHEET 1 OF 1



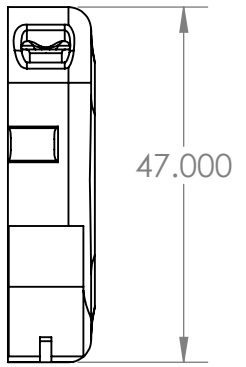
DETAIL A
SCALE 4 : 1

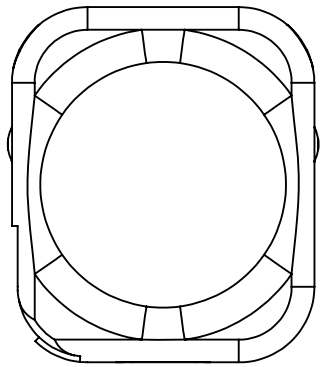




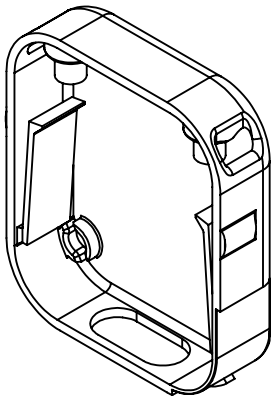


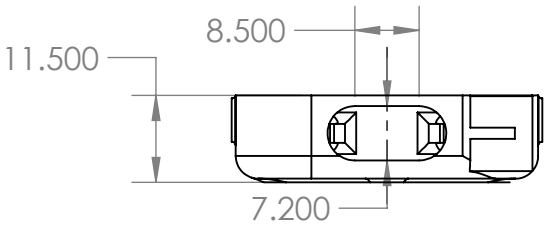
DETAIL B
SCALE 2 : 1

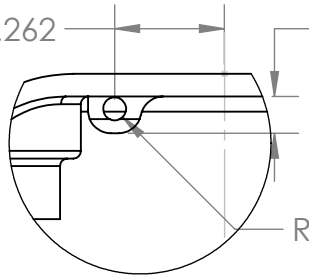




NOTE: 3D printed.
See digital geometry.







DETAIL C
SCALE 2 : 1

LifeWatch

UNLESS OTHERWISE SPECIFIED:		NAME	DATE
DIMENSIONS ARE IN MM TOLERANCES: ANGULAR: MACH ± 1 deg TWO PLACE DECIMAL ± 0.25 THREE PLACE DECIMAL ± 0.127 FOUR PLACE DECIMAL ± 0.0127	DRAWN	BB	4/20/18
	CHECKED	DO	4/30/18
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL ABS	COMMENTS: Break all edges and sharp corners		
FINISH N/A			
DO NOT SCALE DRAWING			

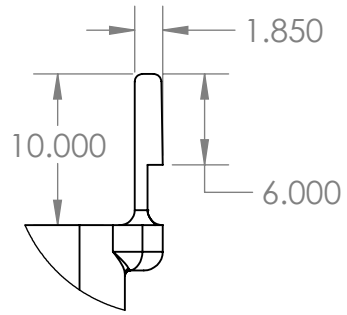
Team EpiPenn

TITLE:

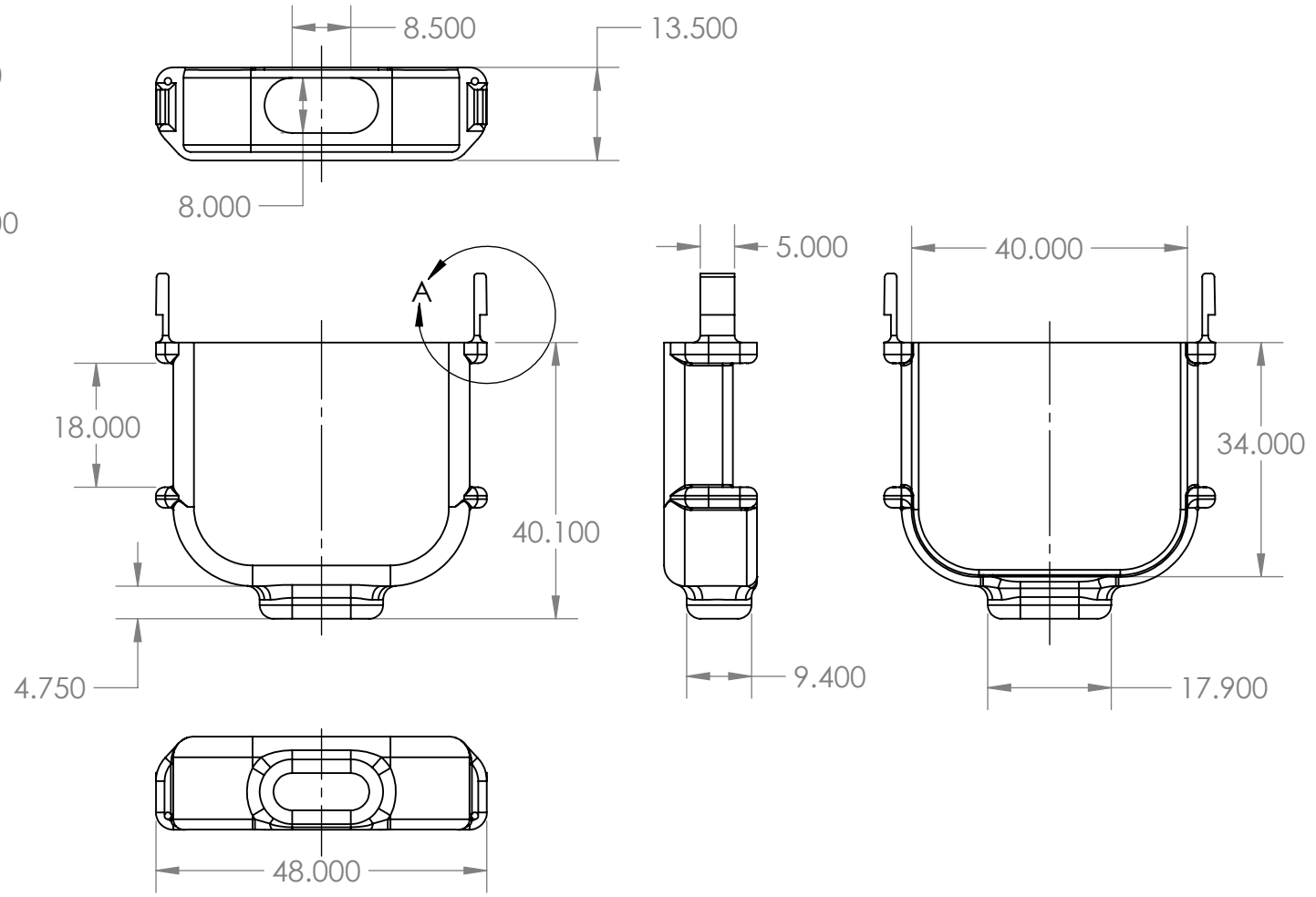
MA - Bottom Body

SIZE	DWG. NO.	REV
A	MA - 001	E

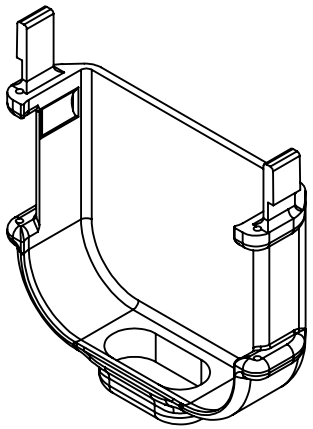
SCALE: 1:1 | SHEET 1 OF 1



DETAIL A
SCALE 2 : 1



NOTE: 3D printed.
See digital geometry.



LifeWatch

UNLESS OTHERWISE SPECIFIED:		NAME	DATE
DIMENSIONS ARE IN MM TOLERANCES: ANGULAR: MACH ± 1 deg TWO PLACE DECIMAL ± 0.25 THREE PLACE DECIMAL ± 0.127 FOUR PLACE DECIMAL ± 0.0127	DRAWN	BB	4/02/18
	CHECKED	DO	4/30/18
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL: ABS	COMMENTS: Break all edges and sharp corners		
FINISH: N/A			
DO NOT SCALE DRAWING			

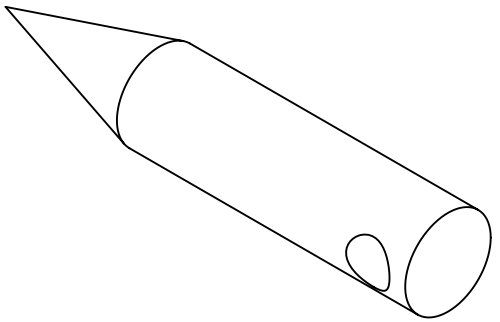
Team EpiPenn

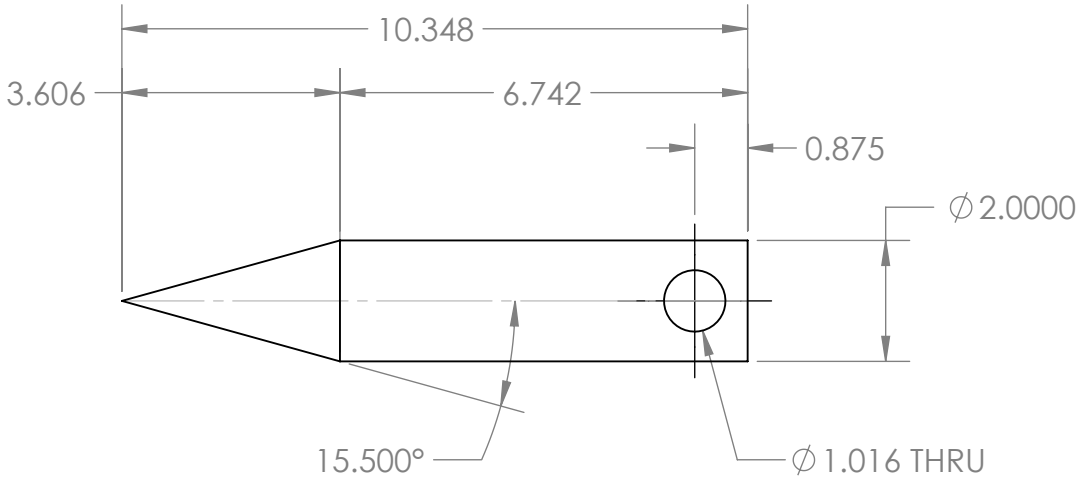
TITLE:

MA - Front Cap

SIZE	DWG. NO.	REV
A	MA - 004	C

SCALE: 1:1 | SHEET 1 OF 1





UNLESS OTHERWISE SPECIFIED:		NAME	DATE
DIMENSIONS ARE IN MM TOLERANCES: ANGULAR: MACH ± 1 deg TWO PLACE DECIMAL ± 0.25 THREE PLACE DECIMAL ± 0.127 FOUR PLACE DECIMAL ± 0.0127	DRAWN	BB	1/13/18
	CHECKED	DO	4/30/18
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL 18-8 Stainless Steel	COMMENTS: Break all edges and sharp corners		
FINISH N/A			
DO NOT SCALE DRAWING			

LifeWatch

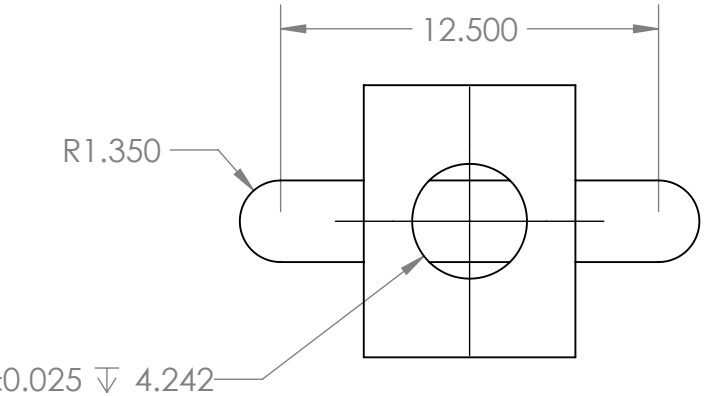
Team EpiPenn

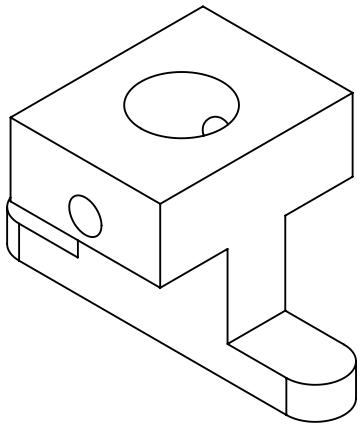
TITLE:

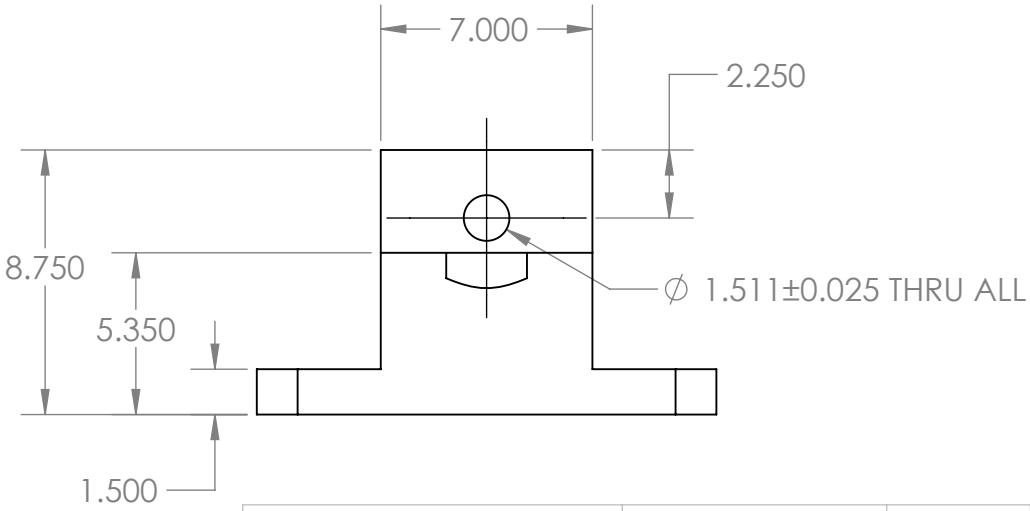
QR - Pin

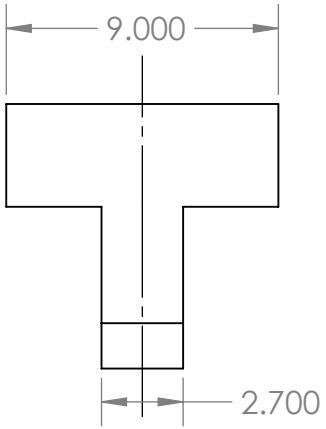
SIZE	DWG. NO.	REV
A	QR - 001	E

SCALE: 8:1 | SHEET 1 OF 1









LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
Mild Steel

FINISH
N/A

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	4/13/18
CHECKED	DO	4/30/18
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS: Break all edges and sharp corners

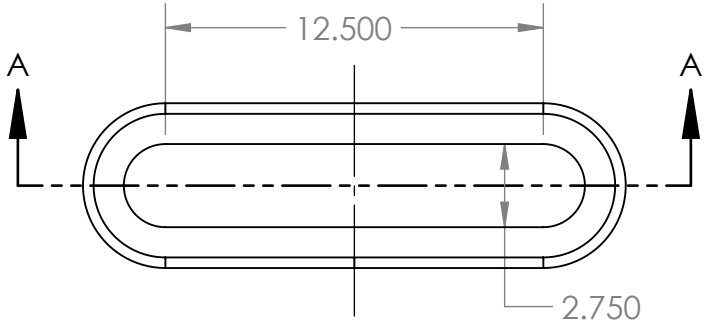
Team EpiPenn

TITLE:

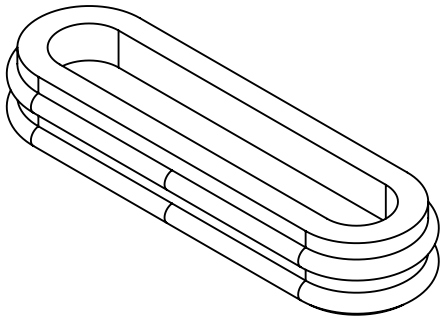
SA - Plunger Block

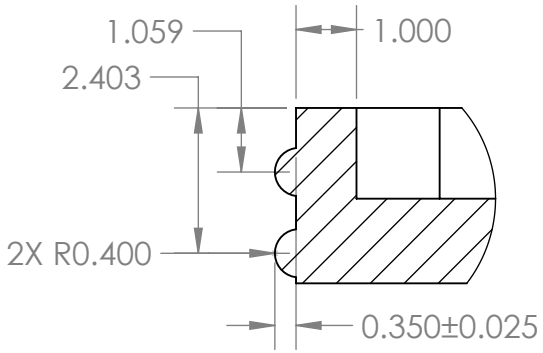
SIZE	DWG. NO.	REV
A	SA - 001	C

SCALE: 4:1 | SHEET 1 OF 1

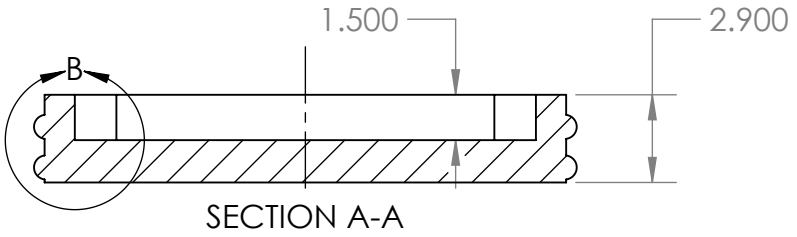


NOTE: Molded component.
See digital geometry.





DETAIL B
SCALE 8 : 1



SECTION A-A

LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
60A Silicone Rubber

FINISH
N/A

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	3/26/18
CHECKED	DO	4/30/18
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS: Break all edges and sharp corners

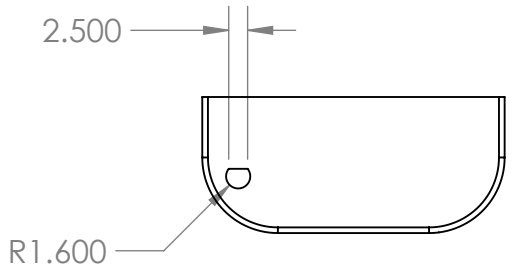
Team EpiPenn

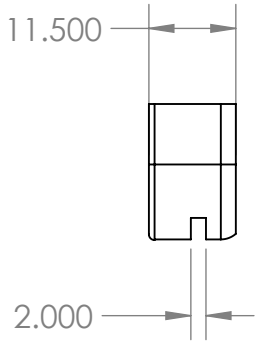
TITLE:

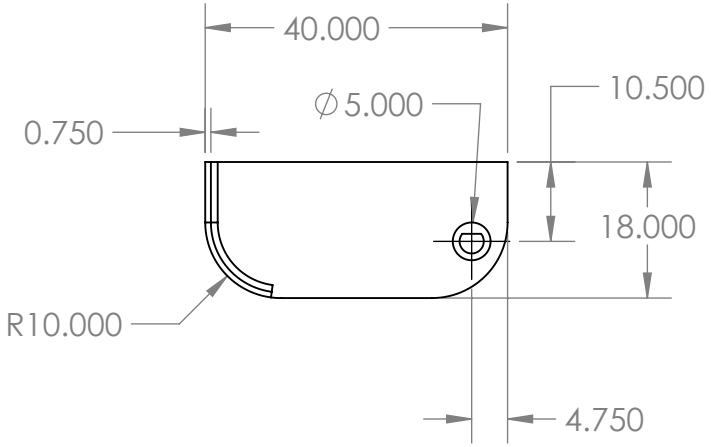
SA - Plunger

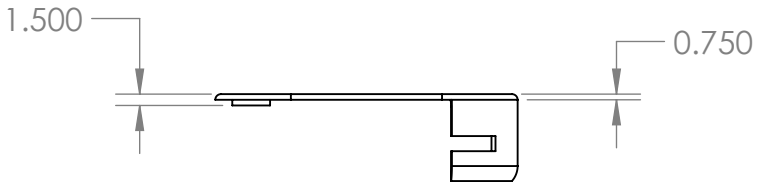
SIZE	DWG. NO.	REV
A	SA - 004	E

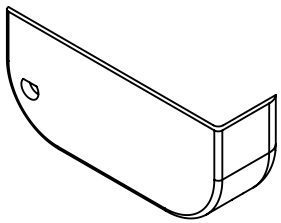
SCALE: 4:1 | SHEET 1 OF 1











NOTE: 3D printed.
See digital geometry.

LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL: ABS

FINISH: N/A

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	4/05/18
CHECKED	DO	4/30/18
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS: Break all edges and sharp corners

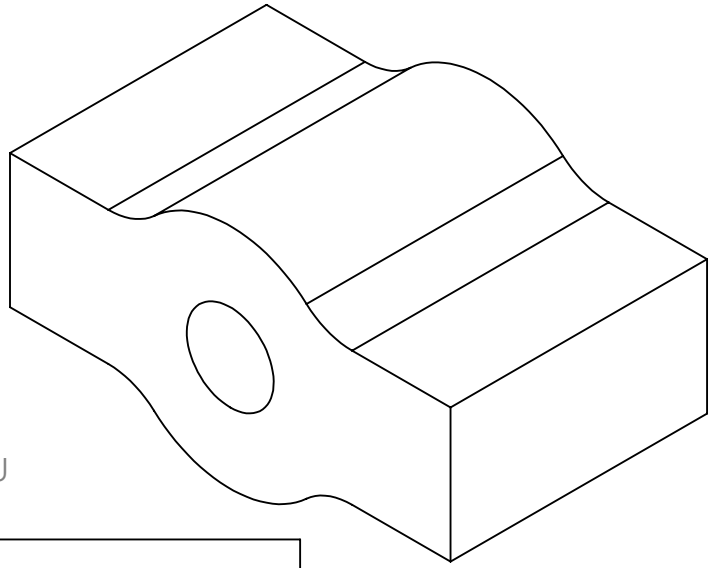
Team EpiPenn

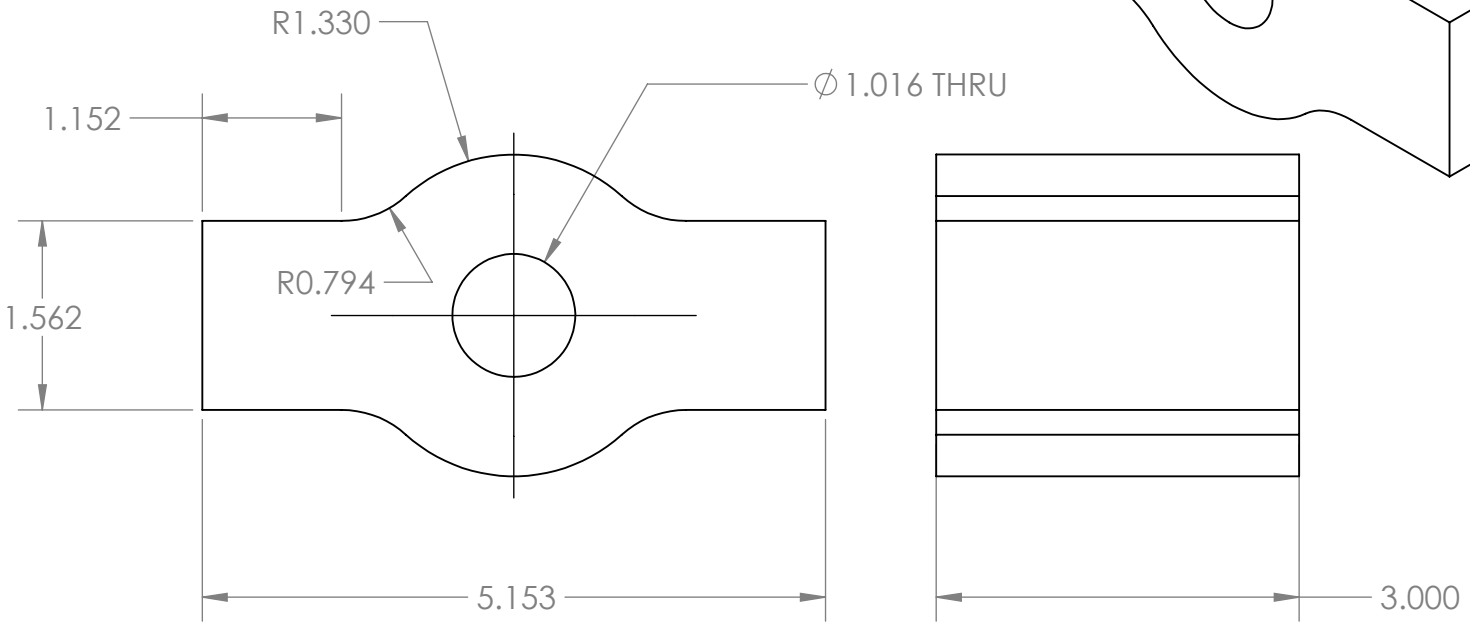
TITLE:

RL - Revolve Sheath

SIZE	DWG. NO.	REV
A	MA - 003	E

SCALE: 1:1 | SHEET 1 OF 1





LifeWatch

UNLESS OTHERWISE SPECIFIED:		NAME	DATE
DIMENSIONS ARE IN MM TOLERANCES: ANGULAR: MACH ± 1 deg TWO PLACE DECIMAL ± 0.25 THREE PLACE DECIMAL ± 0.127 FOUR PLACE DECIMAL ± 0.0127	DRAWN	BB	3/15/18
	CHECKED	DO	4/30/18
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL 6061-T6 Aluminum	COMMENTS: Break all edges and sharp corners		
FINISH N/A			
DO NOT SCALE DRAWING			

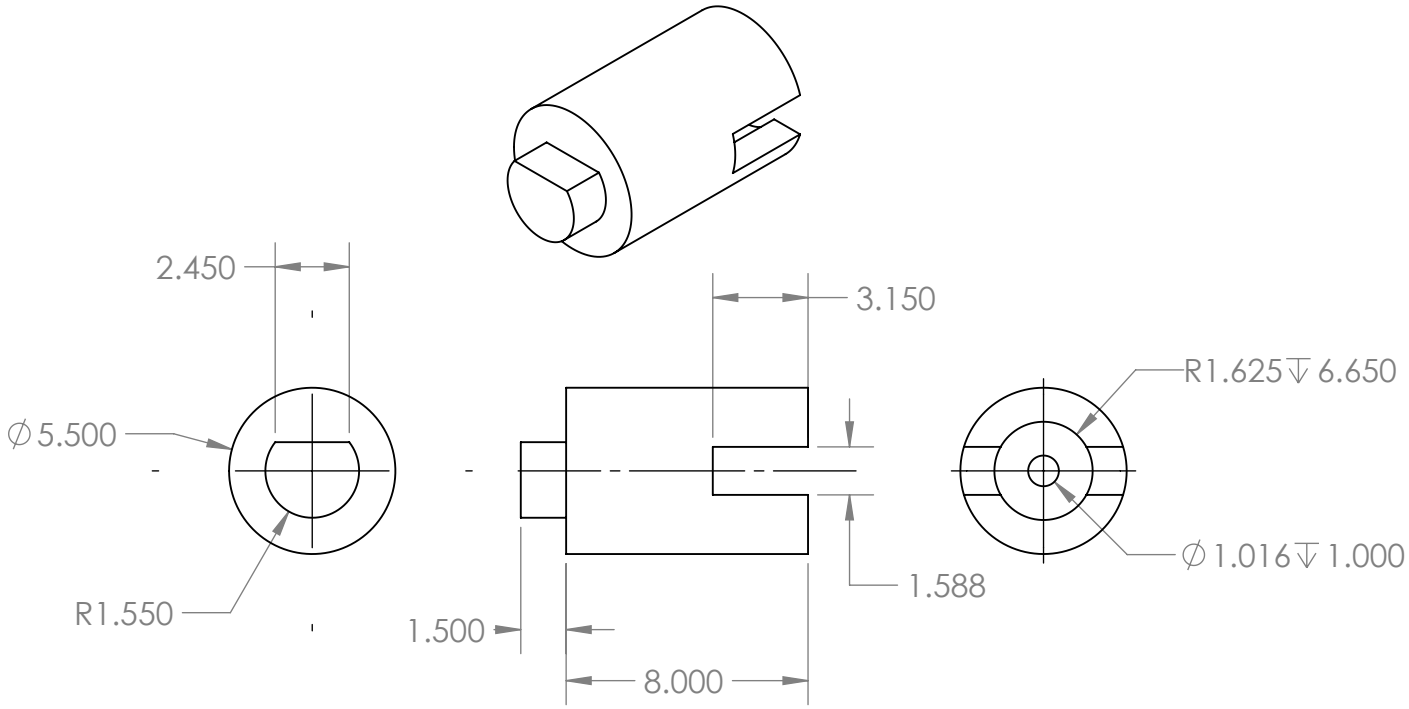
Team EpiPenn

TITLE:

RL - Lock Key

SIZE	DWG. NO.	REV
A	RL - 003	C

SCALE: 16:1 | SHEET 1 OF 1



UNLESS OTHERWISE SPECIFIED:	NAME	DATE
DIMENSIONS ARE IN MM TOLERANCES: ANGULAR: MACH ± 1 deg TWO PLACE DECIMAL ± 0.25 THREE PLACE DECIMAL ± 0.127 FOUR PLACE DECIMAL ± 0.0127	DRAWN	BB	4/03/18
	CHECKED	DO	4/30/18
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL: Brass	COMMENTS: Break all edges and sharp corners		
FINISH: N/A			
DO NOT SCALE DRAWING			

LifeWatch

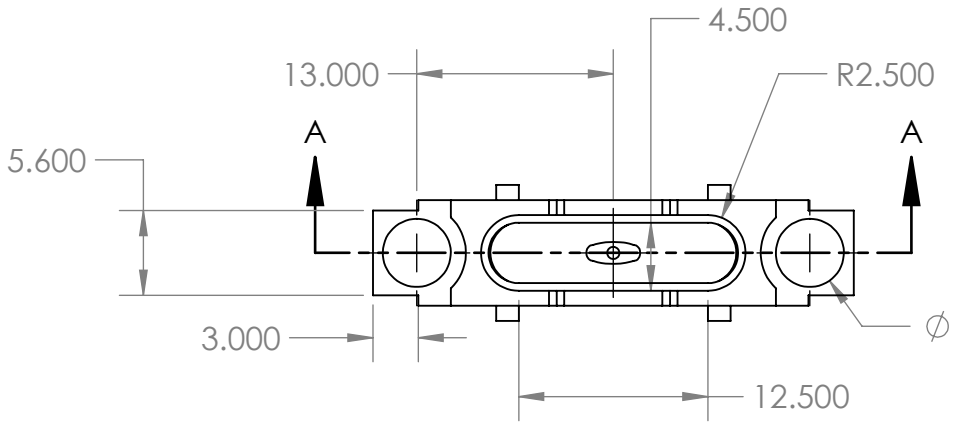
Team EpiPenn

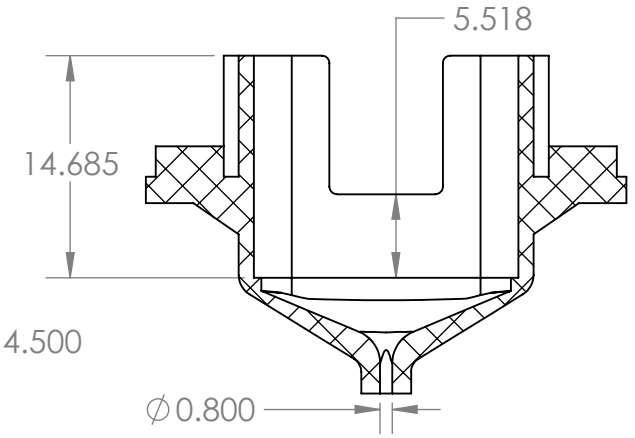
TITLE:

RL - Lock Tube

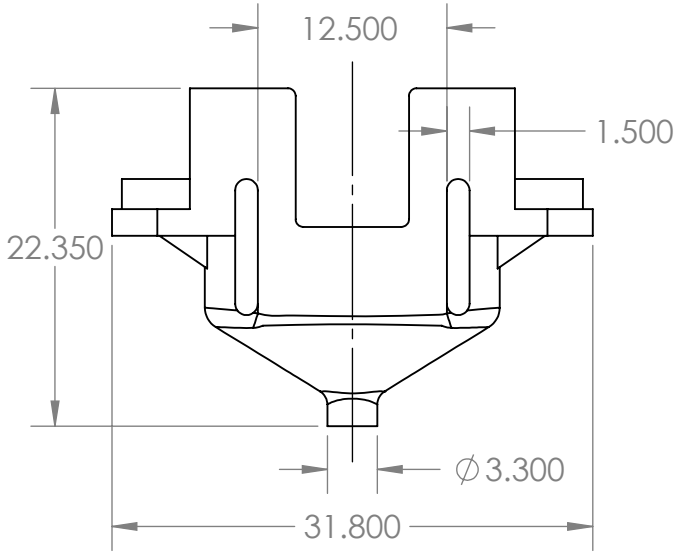
SIZE	DWG. NO.	REV
A	RL - 002	C

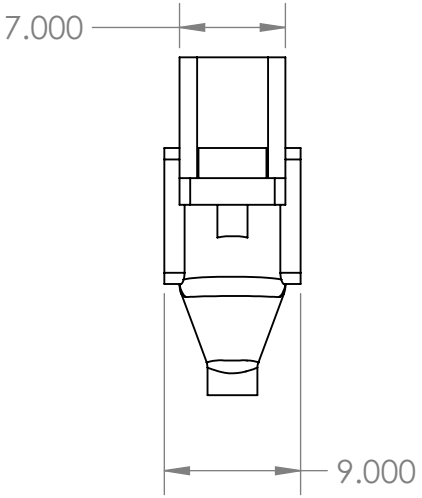
SCALE: 4:1 | SHEET 1 OF 1



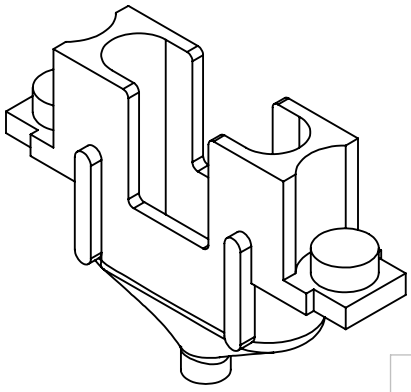


SECTION A-A





NOTE: 3D printed.
See digital geometry.



LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL: ABS

FINISH: N/A

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	4/28/18
CHECKED	DO	4/30/18
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS: Break all edges and sharp corners

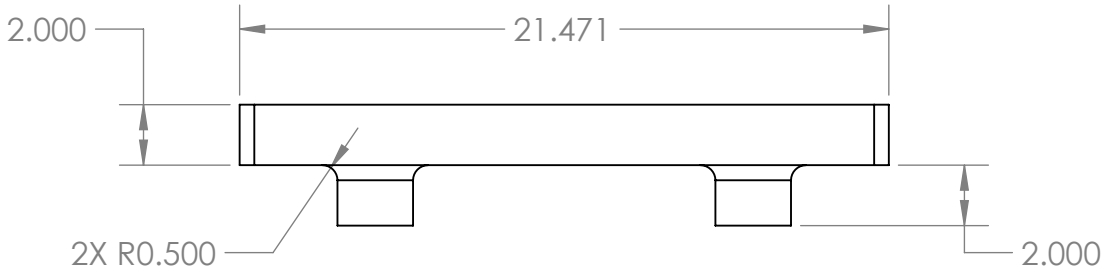
Team EpiPenn

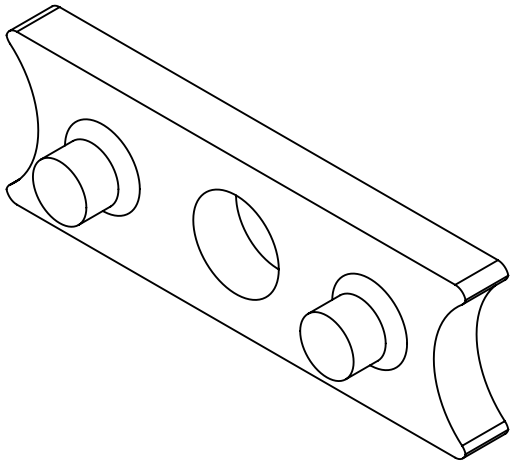
TITLE:

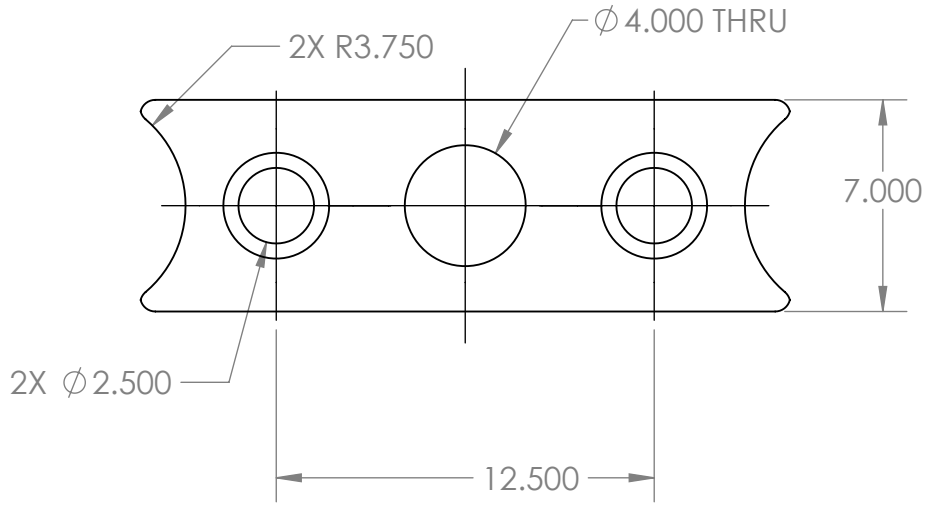
SA - Syringe

SIZE	DWG. NO.	REV
A	SA - 002	C

SCALE: 2:1 | SHEET 1 OF 1







LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
6061-T6 Aluminum

FINISH
N/A

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	3/30/18
CHECKED	DO	4/30/18
ENG APPR.		
MFG APPR.		
Q.A.		

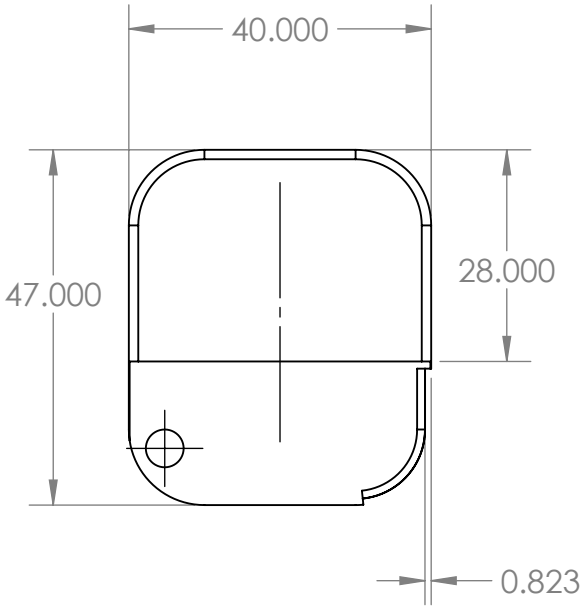
COMMENTS: Break all edges and sharp corners

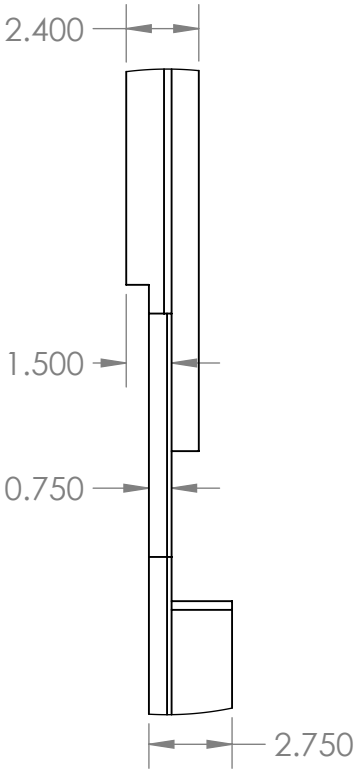
Team EpiPenn

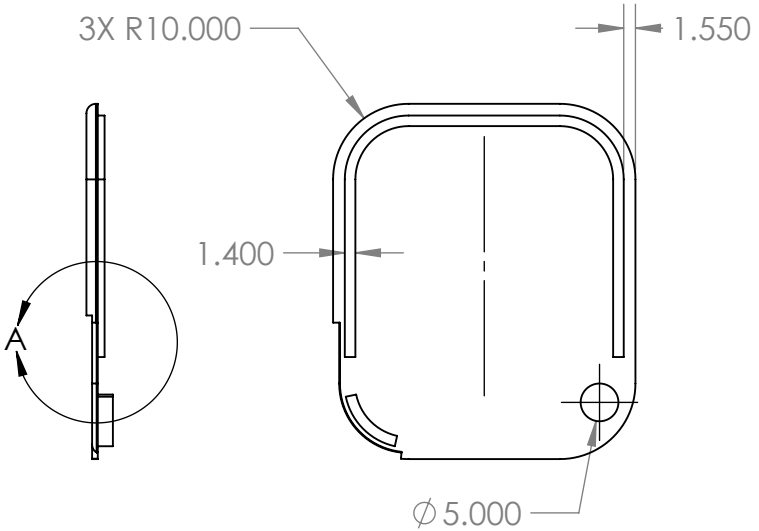
TITLE:
SA - Syringe Cap

SIZE	DWG. NO.	REV
A	SA - 003	B

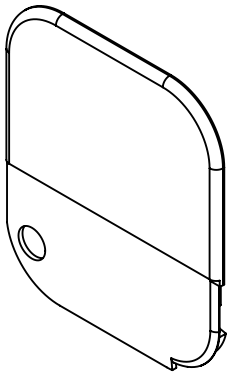
SCALE: 4:1 | SHEET 1 OF 1







DETAIL A
SCALE 4 : 1



NOTE: 3D printed.
See digital geometry.

LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL
ABS

FINISH
N/A

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	4/20/18
CHECKED	DO	4/30/18
ENG APPR.		
MFG APPR.		
Q.A.		

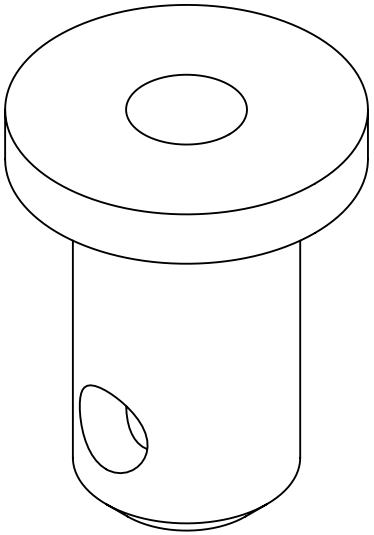
COMMENTS: Break all edges and sharp corners

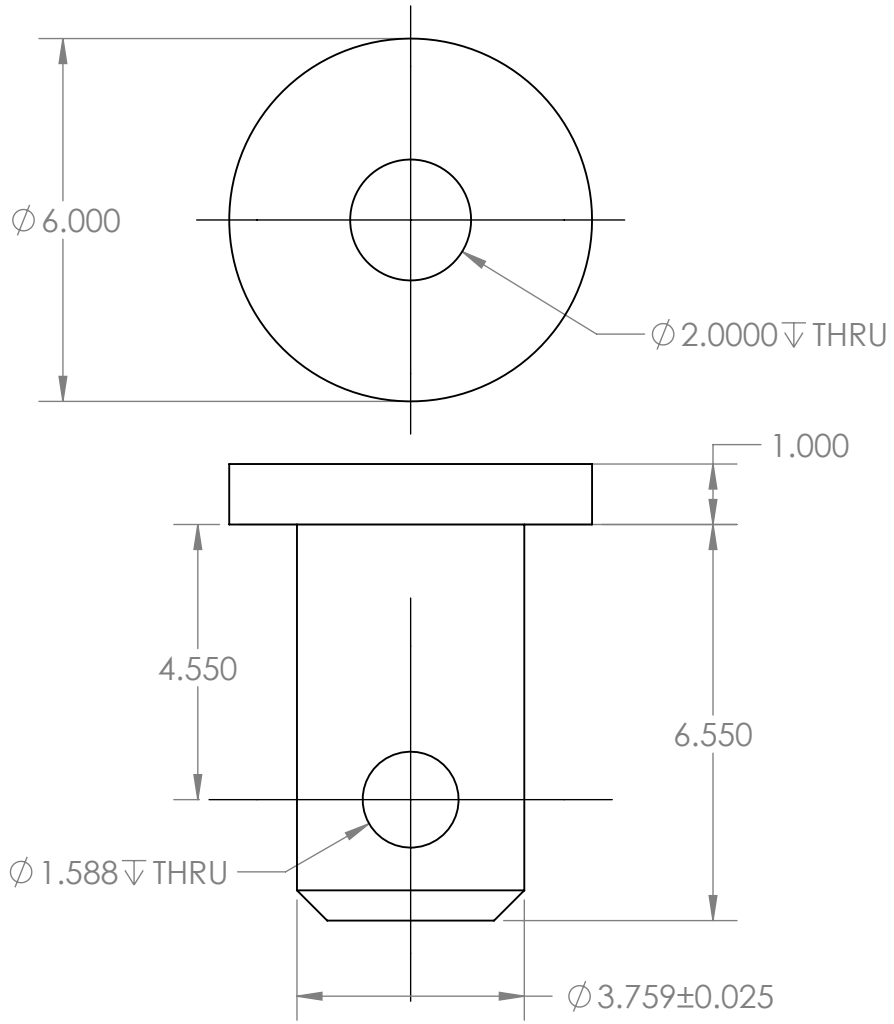
Team EpiPenn

TITLE:
MA - Top Body

SIZE	DWG. NO.	REV
A	MA - 002	D

SCALE: 1:1 | SHEET 1 OF 1





UNLESS OTHERWISE SPECIFIED:	NAME	DATE
DIMENSIONS ARE IN MM TOLERANCES: ANGULAR: MACH ± 1 deg TWO PLACE DECIMAL ± 0.25 THREE PLACE DECIMAL ± 0.127 FOUR PLACE DECIMAL ± 0.0127	DRAWN	BB	1/13/18
	CHECKED	DO	4/30/18
	ENG APPR.		
	MFG APPR.		
INTERPRET GEOMETRIC TOLERANCING PER:	Q.A.		
MATERIAL 6061-T6 Aluminum	COMMENTS: Break all edges and sharp corners		
FINISH N/A			
DO NOT SCALE DRAWING			

LifeWatch

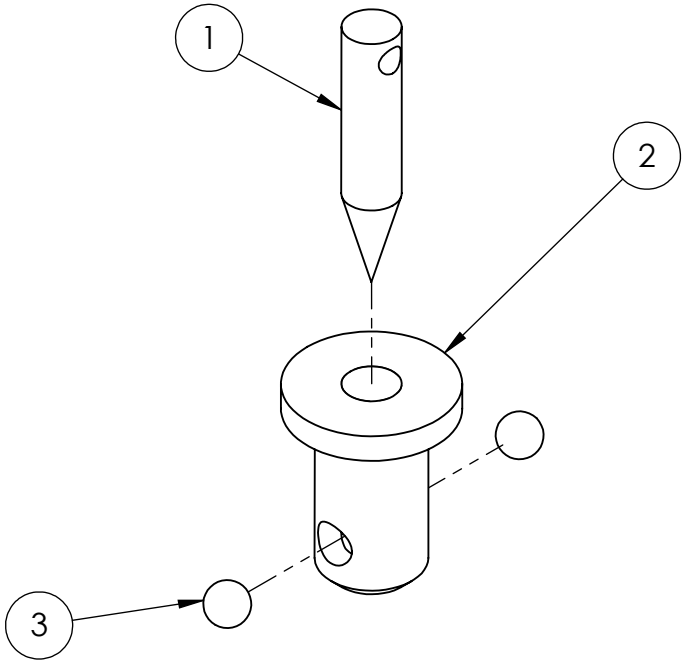
Team EpiPenn

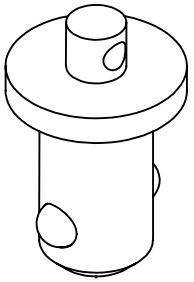
TITLE:

QR - Tube

SIZE	DWG. NO.	REV
A	QR - 002	C
SCALE: 8:1		SHEET 1 OF 1

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	QR - 001	Quick Release Pin	1
2	QR - 002	Quick Release Tube	1
3	McMaster 9291K41	∅ 1/16" Stainless Steel Ball	2





LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	5/6/2018
CHECKED	DO	5/6/2018
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS: Break all edges and sharp corners

Team EpiPenn

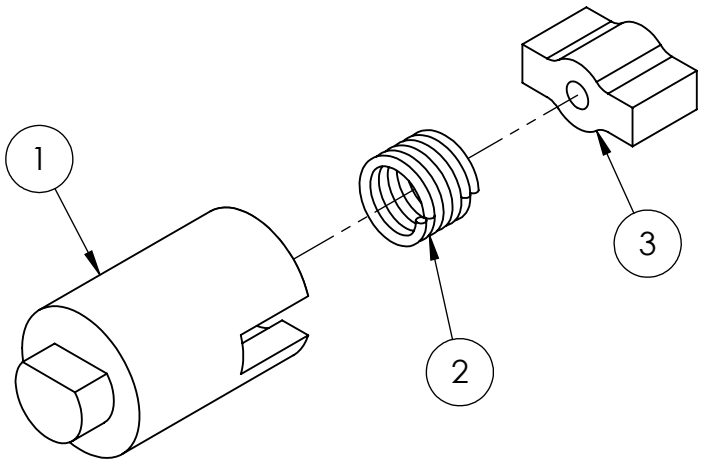
TITLE:

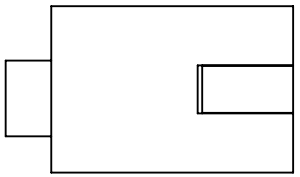
Quick Release Subassembly

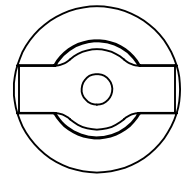
SIZE	DWG. NO.	REV
A	QR - 100	A

SCALE: 4:1 | SHEET 1 OF 1

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	RL - 002	Revolve Lock Tube	1
2	McMaster 9657K257	∅ 1/8" 1/4" Compression Spring	1
3	RL - 003	Revolve Lock Key	1







LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	5/6/2018
CHECKED	DO	5/6/2018
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS: Break all edges and sharp corners

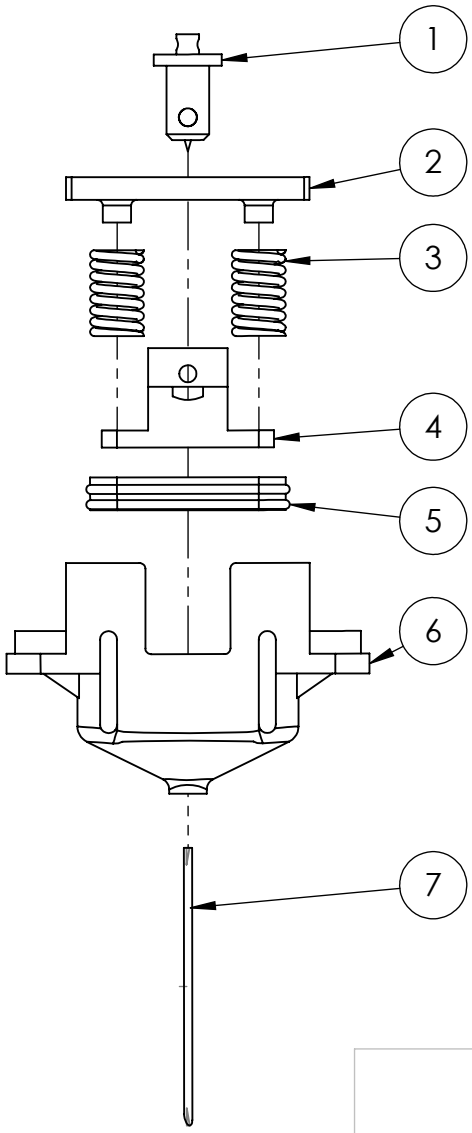
Team EpiPenn

TITLE:

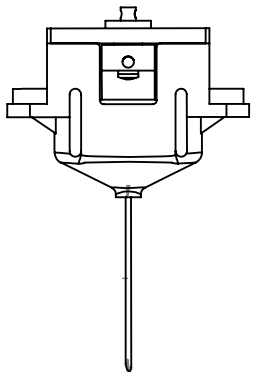
Revolve Lock Subassembly

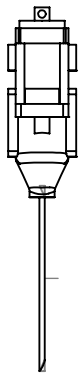
SIZE	DWG. NO.	REV
A	RL - 100	E

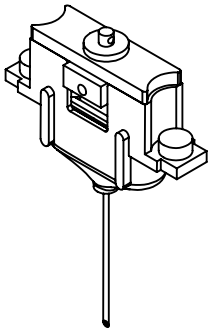
SCALE: 4:1 | SHEET 1 OF 1



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	QR - 100	Quick Release Subassembly	1
2	SA - 003	Syringe Cap	1
3	McMaster 9657K268	∅0.188" 1/2" Compression Spring	2
4	SA - 001	Plunger Block	1
5	SA - 004	Plunger	1
6	SA - 002	Syringe	1
7	Carepoint 822201	22 Gauge 1" Hypodermic Needle	1







LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	5/6/2018
CHECKED	DO	5/6/2018
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS: Break all edges and sharp corners

Team EpiPenn

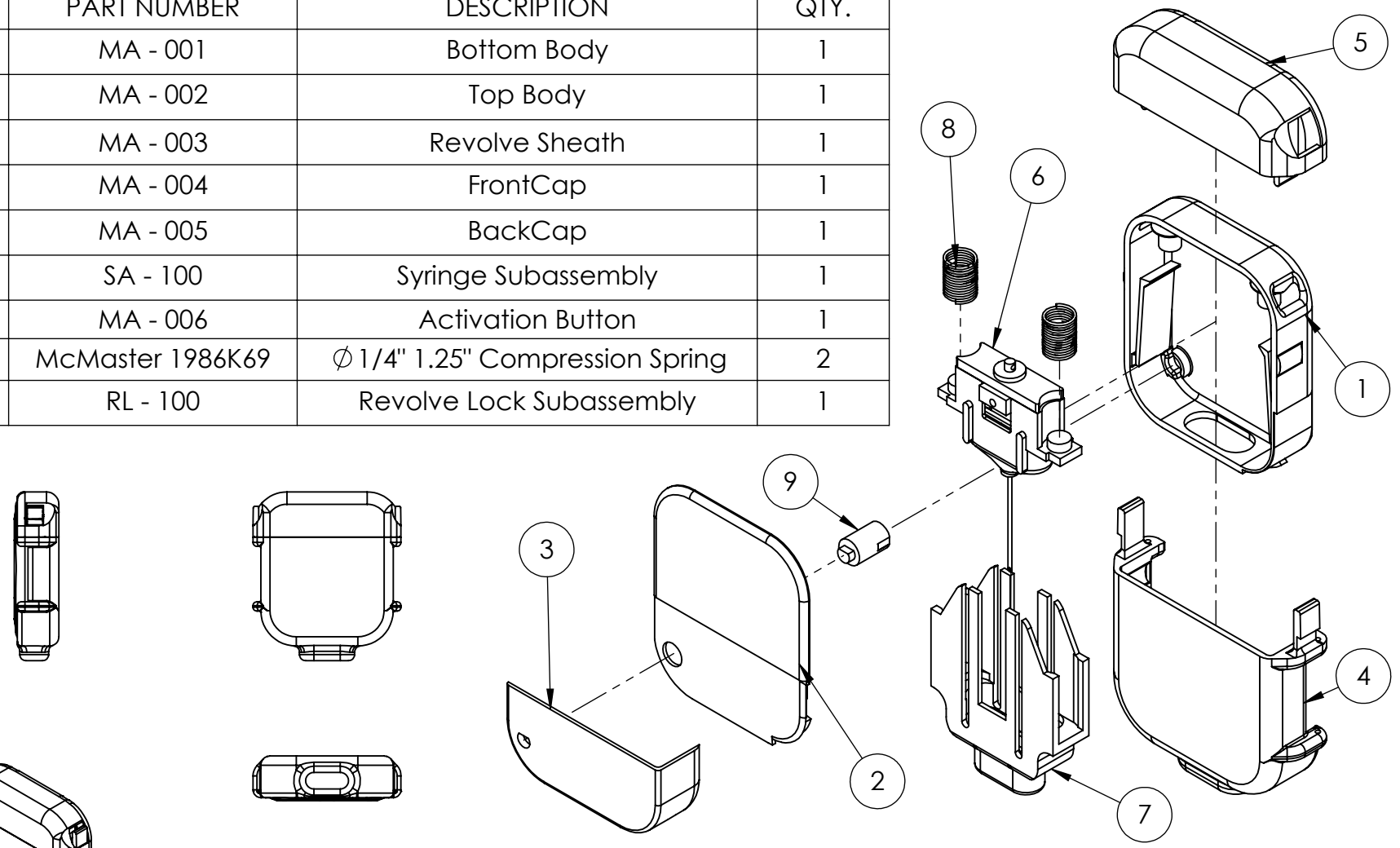
TITLE:

Syringe Subassembly

SIZE	DWG. NO.	REV
A	SA - 100	E

SCALE: 1:1 | SHEET 1 OF 1

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	MA - 001	Bottom Body	1
2	MA - 002	Top Body	1
3	MA - 003	Revolve Sheath	1
4	MA - 004	FrontCap	1
5	MA - 005	BackCap	1
6	SA - 100	Syringe Subassembly	1
7	MA - 006	Activation Button	1
8	McMaster 1986K69	∅1/4" 1.25" Compression Spring	2
9	RL - 100	Revolve Lock Subassembly	1



LifeWatch

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN MM
TOLERANCES:
ANGULAR: MACH ± 1 deg
TWO PLACE DECIMAL ± 0.25
THREE PLACE DECIMAL ± 0.127
FOUR PLACE DECIMAL ± 0.0127

INTERPRET GEOMETRIC TOLERANCING PER:

MATERIAL

FINISH

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	BB	5/6/2018
CHECKED	DO	5/6/2018
ENG APPR.		
MFG APPR.		
Q.A.		

COMMENTS: Break all edges and sharp corners

Team EpiPenn

TITLE:

Main Assembly

SIZE	DWG. NO.	REV
A	MA - 100	A

SCALE: 1:2 | SHEET 1 OF 1