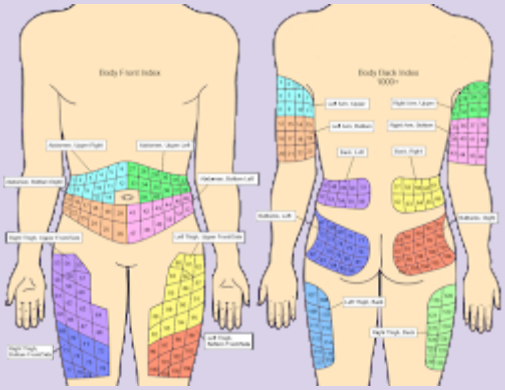
PROBLEM:

Diabetes is one of the world's most common long term health conditions, affecting one in every eleven adults[1]. 350,000 Diabetics in the United States alone use a pump to manually inject themselves with insulin, because their pancreas can no longer produce insulin for them[2]. In addition to the physical inconveniences, there is also mental and psychological pain and suffering that diabetic patients must go through, that often gets overlooked. According to a study done by Virtahealth, 76% of people with type 2 diabetes feel shame around their diagnosis[3], and perceptions of stigma are significantly higher among patients with type 1 diabetes than among those with type 2 diabetes[4]. In fact, as stated by openaccessgovernment.org, People with diabetes suffer disproportionately high rates of mental health problems[5]. This is amplified when coming into contact with water, because the diabetic will need to remove their pump as the vast majority of pumps, for example, the Medtronic Minimed 530G, the Accu-chek combo, and the T:slim:, are not waterproof [6]. This is a psychological burden, as every time a diabetic is forced to take their pump off they are reminded of how different and embarrassing their condition is. A lot of diabetics are fearful of other people taking notice, which causes anxiety in a lot of cases.



Above is a picture of common pump sites.

I have had conversations with my endocrinologist, and I contacted diabetes.co.uk, which is an online global diabetes community. We are all in agreement that this is a real problem that all diabetics face. This is why I would like to solve the problem of making the Medtronic Minimed 530G pump waterproof, which will allow me to swim or shower without having to take my pump off. The Medtronic Minimed 530G insulin pump was chosen because, according to integrated diabetes services, they are a large, secure, long-established company, and they are the industry leaders in research and development of insulin pumps[7].

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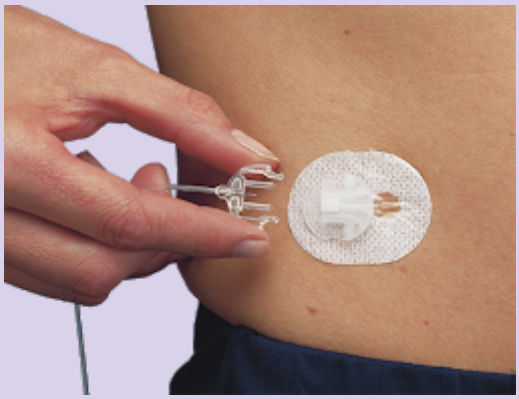
[1] https://www.diabetes.co.uk/diabetes-prevalence.html
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4730130/
[3] https://blog.virtahealth.com/type-2-diabetes-shame/
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5241772/
[5] https://www.openaccessgovernment.org/diabetes-mental-health/52327/
[6] https://dlife.com/the-best-insulin-pumps-on-the-market/
[7] https://integrateddiabetes.com/updated-insulin-pump-comparisons-and-reviews/

DESIGN BRIEF:



The expected outcome is to design a product that will make the insulin pump waterproof. This will allow diabetics to have the exact same experience as nondiabetics when it comes to being exposed to water. This will in turn diminish the psychological stress caused by the perception of diabetics that they are not 'normal'. The product must be portable, so that a user can easily take it with them when swimming. It must be easy to use, as people as young as 5 years old or younger may use the pump, meaning it must be very user friendly. The product also must not limit the pump's functionality, meaning one should still be able to utilize the pump's features while the product is in use. This is necessary because it is critically important to sustain healthy blood sugar levels. The product needs to be lightweight and minimalistic too, because the larger and heavier the product is, the less practical it will be to carry around when swimming or showering for example.

DESIGN SPECIFICATION:

The target audience for this product is people suffering from diabetes who use the Medtronic: Minimed 530G insulin pump. Creating a custom product for the Medtronic: Minimed 530G system will produce better results. This would decrease the potential for sales, however, Medtronic dominates the market share and is the preferred in-network DME provider of insulin pumps [8], and having a product that works well with one product will be much more successful than creating a product that somewhat works with everything.

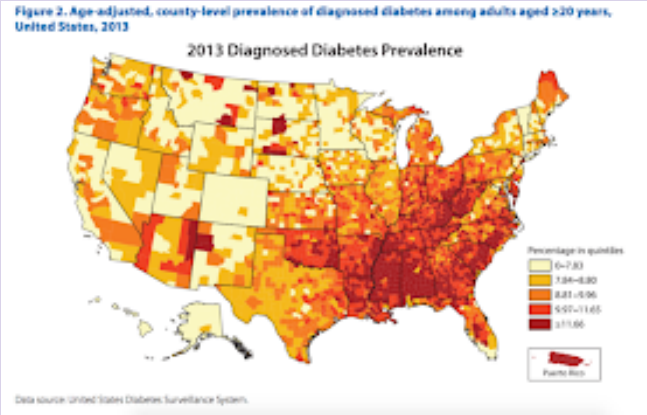
Diabetes affects all people, regardless of age, gender, and demographic, and this has an effect on the aesthetic design of the product. Because the product must be inclusive to all groups of people, and because the product must not draw attention, the product will be designed in a color that keeps it looking as neutral and unnoticeable as possible, such as black or white. Continuing with the idea of an

[8] https://www.mddionline.com/how-medtronic-dominating-insulin-pump-market

unnoticeable design, the product must be very simplistic and the design must not grab attention. A good example of a simple, unnoticeable product that people wear is prescription glasses, as they are typically not meant to be attention grabbing or flashy.

The product's main function is that it eliminates the issue of water damage to the pump. The product also allows users to interact with the pump even when in use. The product must be portable and minimal in size, making it easy to take with you anywhere. Another function would be the ease of use of the product. It should be easy to understand how to properly secure the pump in the product. A final function would be impact protection. The pump must be safe and well supported within the product.

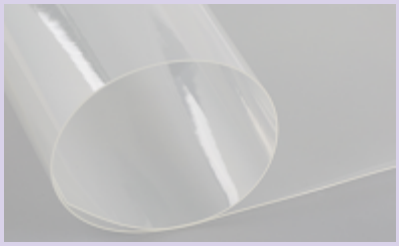
Some production constraints however, include that the product will only be usable by diabetics with the same pump model. This limits the groups of people that will be able to purchase and utilize the product. Furthermore, there may be limited access to an adequate supply of parts and materials, because the shape of the product has to fit the pump snugly and securely. The medtronic: minimed 530G system is around $7,500[9], so protecting it with a waterproof product is a very large priority. Because it is so expensive, people may not be willing to pay even more for an accessory for their pump, so ensuring a reasonable price is also a priority. Because I am protecting such a valuable product, I must use very high quality materials, which may result in a higher price for production. This means that funding is another constraint. On the other hand, economies of scale can be achieved because of how common diabetes is and how this product can reach a market of at least 100,000 individuals. This number comes from the fact that 350,00 people are estimated to be using insulin pumps worldwide, and the majority of them use the Medtronic Minimed 530G system[10]. Another constraint is the limited accessibility to manufacturing techniques, such as blow molding, and materials, such as particular rubber compounds and polycarbonate.



[9] https://www.diabetesnet.com/diabetes-technology/insulin-pumps/current-pumps/medtronic-530g
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4730130/

The size will be minimized as much as possible, so that the user does not feel constantly reminded of the product. Furthermore, the smaller the size, the lighter the product is, making it easier and more practical for the user to carry around. The product will also be adjustable, so that different sized users can benefit from the product.

Waterproof products are predominantly made of polycarbonate[11] or hydrophobic materials such as waterproof polyester, and thermosetting polyurethane, and this product will be no different, as these are the top waterproof materials on the market[12]. The incorporation of a clear, soft, screen will allow the user to interact with the pump. An example of this screen integration would be in motorbike GPS covers. The adjustable belt used in the product will be a standard nylon and will incorporate an adjustable plastic slide and a set of delrin clips. The material for the adjustable piece will need to be able to survive tough circumstances, such as swimming with strong waves. Furthermore, it will be relied upon to keep the pump safe, meaning that the adjustable piece must be very hard to rip or break. This makes nylon a good choice, because it is very powerful and can withstand a large amount of tension[13].



In regards to quantity, the product will be manufactured in a mass production method. This is because diabetes is one of the most common global long-term diseases, and the product is designed for the most common insulin pump in the market. This means that the product is at a high demand, since it can be utilized by a very large demographic.

Word Count: 1269

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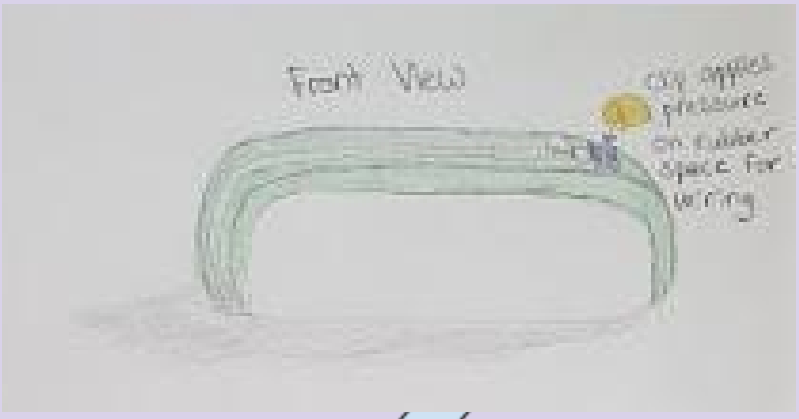
[11] https://www.nytimes.com/2012/08/30/technology/personaltech/a-review-of-protective-and-waterproof-cases-for-smartphones.html

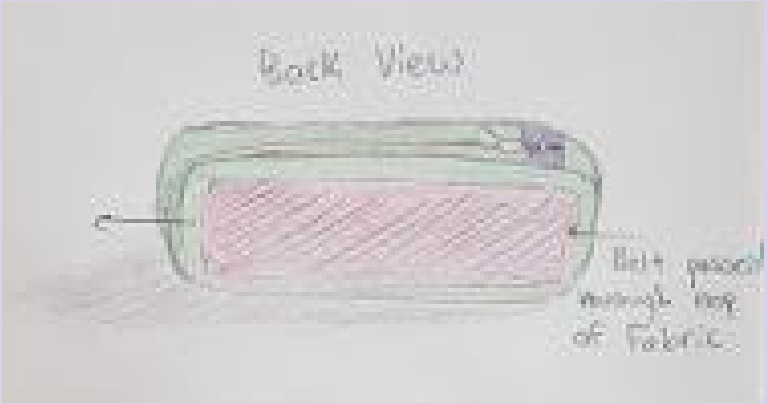
[12] https://sewguide.com/waterproof-water-resistant-fabric/

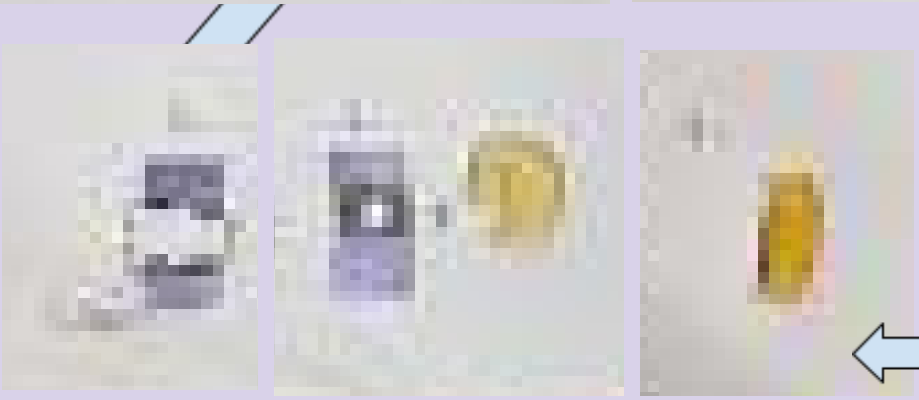
[13] https://www.creativemechanisms.com/blog/3d-printing-injection-molding-cnc-nylon-plastic-pa

Sketches:

Idea 1:





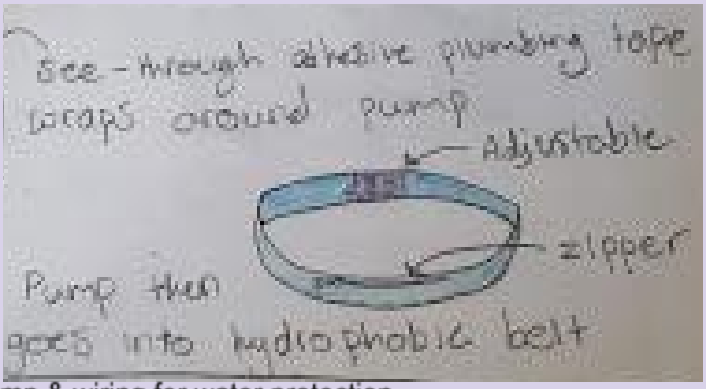


Locking Mechanism Steps

Yellow clip presses two plastic pieces together

This idea was immediately disregarded because zipper design would not be effective at keeping water out for extended periods.

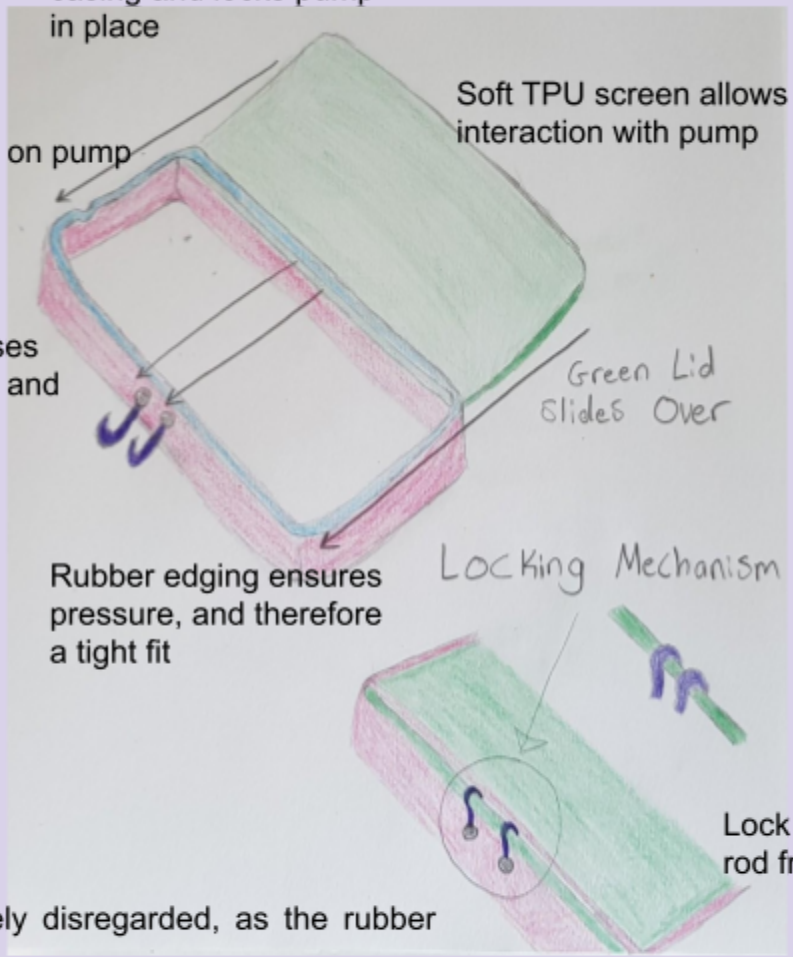
Idea 2:



Adhesive tape wraps around pump & wiring for water protection

Idea was immediately disregarded because tape will leave sticky residue on pump. Tape may also lose its adhesion in water, resulting in a potential water leak.

Idea 3:



Top piece slides over casing and locks pump in place

Soft TPU screen allows for interaction with pump

Small divot for wiring on pump

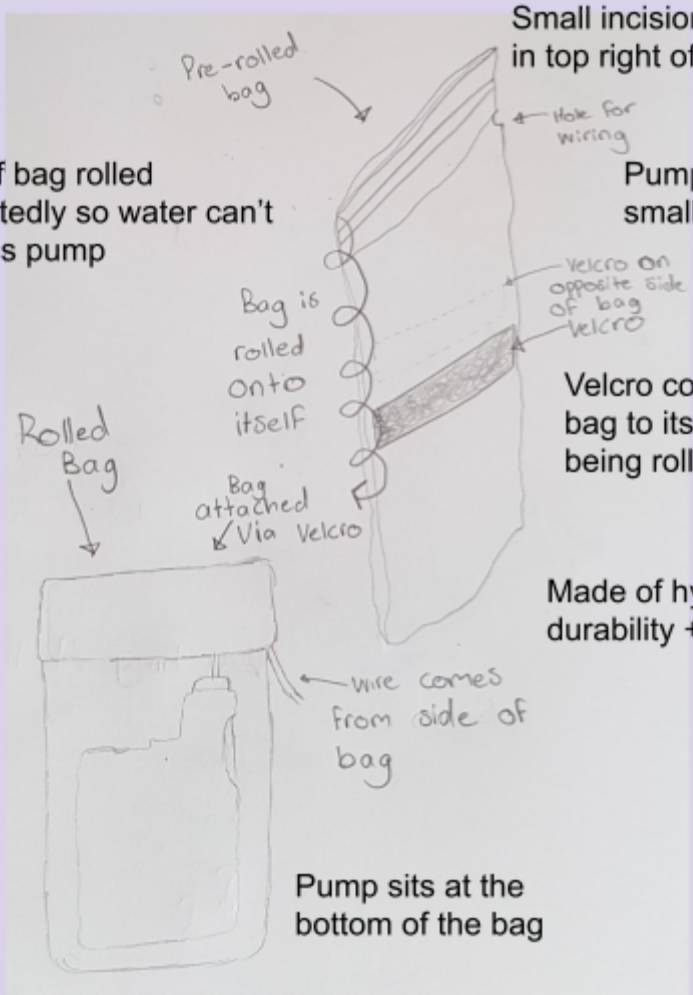
Hard plastic case increases durability but also weight and heftiness

Rubber edging ensures pressure, and therefore a tight fit

Lock mechanism connects rod from lid to two hooks

This idea was immediately disregarded, as the rubber padding around the case would make it very difficult to close the pump with the sliding lid mechanism.

Idea 4:



Small incision is made in top right of bag

Top of bag rolled repeatedly so water can't access pump

Pump wiring goes through this small incision

Velcro connects the bag to itself after being rolled

Made of hydrophobic nylon/TPU for durability + water resistance

Pump sits at the bottom of the bag

Testing

Product was tested 20 minutes under water

Results

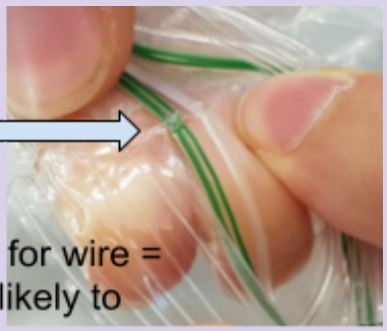
Pump can interact with user within case

Lightweight

Technique is too unpredictable to risk on an insulin pump

Wiring hole isn't airtight, relying on rolling technique is unsafe

Solution: Small divot made at top of bag's lock



Smaller divot for wire = water is less likely to pass

Wire placed directly in divot made by incision

Structure after redesign

The pump is safest the more the bag is rolled up

More rolls = more bag needed

Does not supply a lot of impact protection

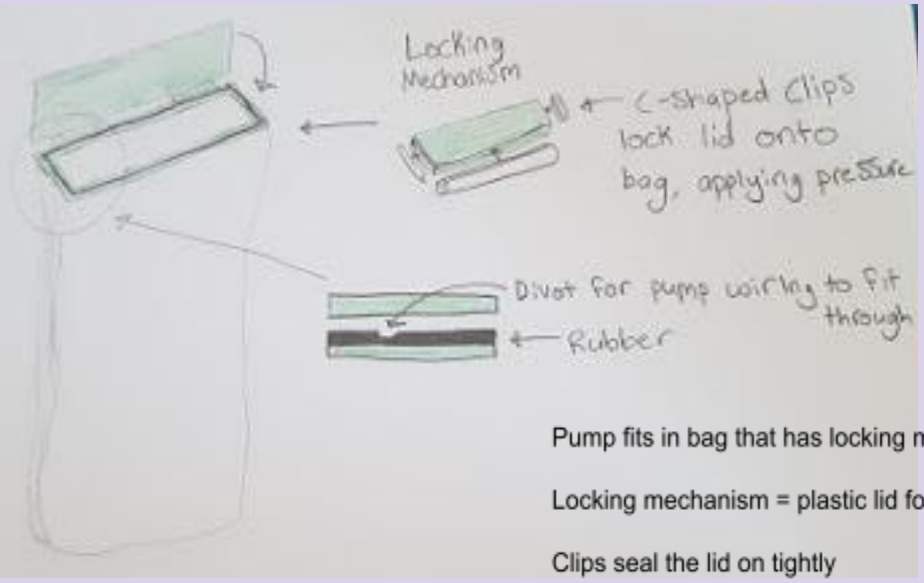
Minimalistic design; not flashy

More bag needed = more wire needed within bag

More wire required within bag = less wire available for user

Wire is rolled repeatedly, potentially getting damaged and causing kinks

Idea 5:



Pump fits in bag that has locking mechanism at the top.

Locking mechanism = plastic lid folding over top of bag

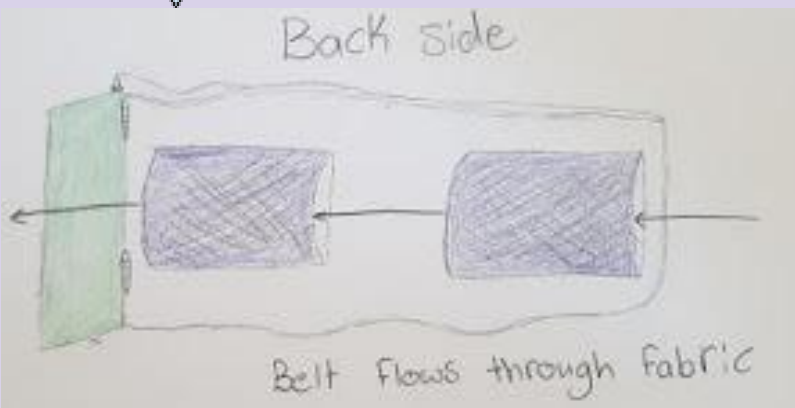
Clips seal the lid on tightly

Rubber surrounds top of bag, supplying air tight fit

Pressure applied by clips when closed, forcing air tight connection

Lid is connected via hinges

Fabric strap on opposite side allows belt to loop through



Very lightweight case

Very portable

Air tight lock

Allows interaction with pump

Not flashy at all

No impact protection

Improvement: Line bag with soft foam for greater pump security

Includes benefits of idea 4, without risk of wire damage

Improvements

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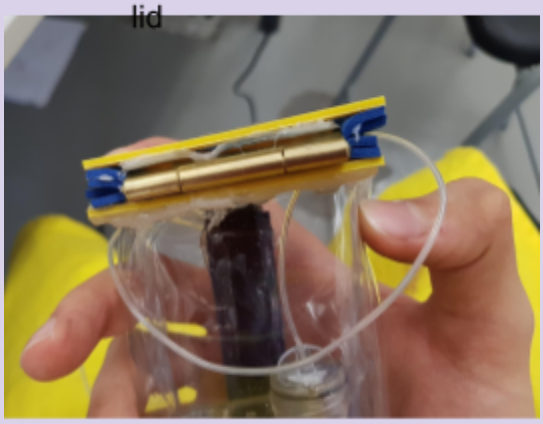
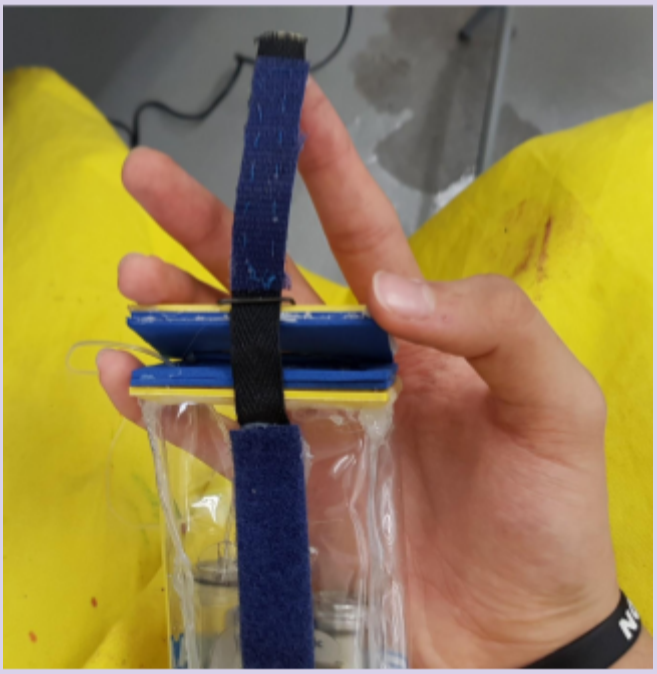
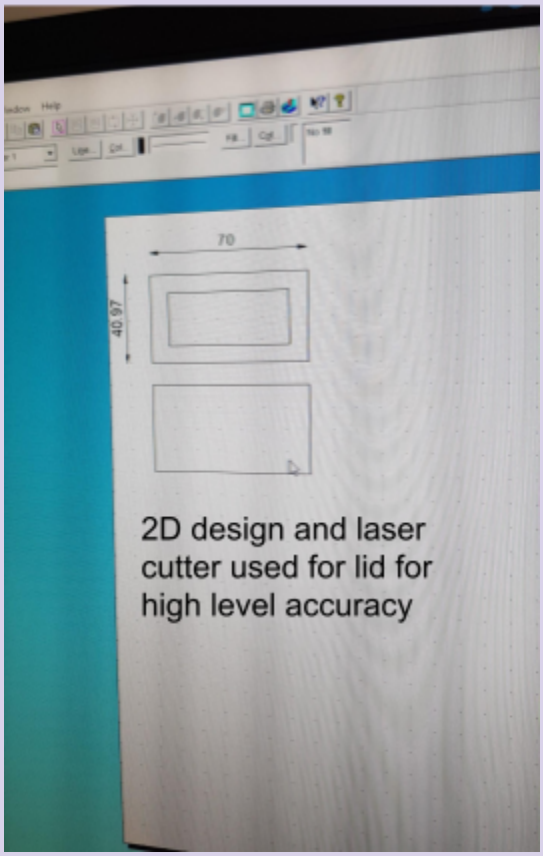
More secure fit, as baggage is tighter

Hinges placed for lid

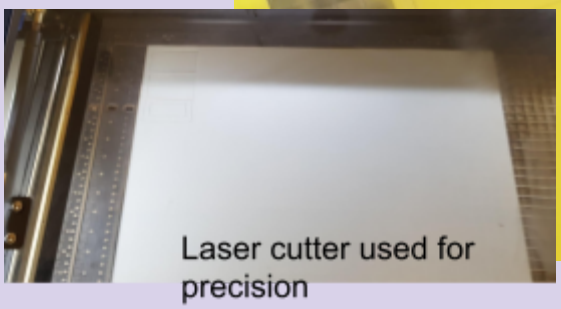




Velcro locking system allows for pressure to create watertight fit



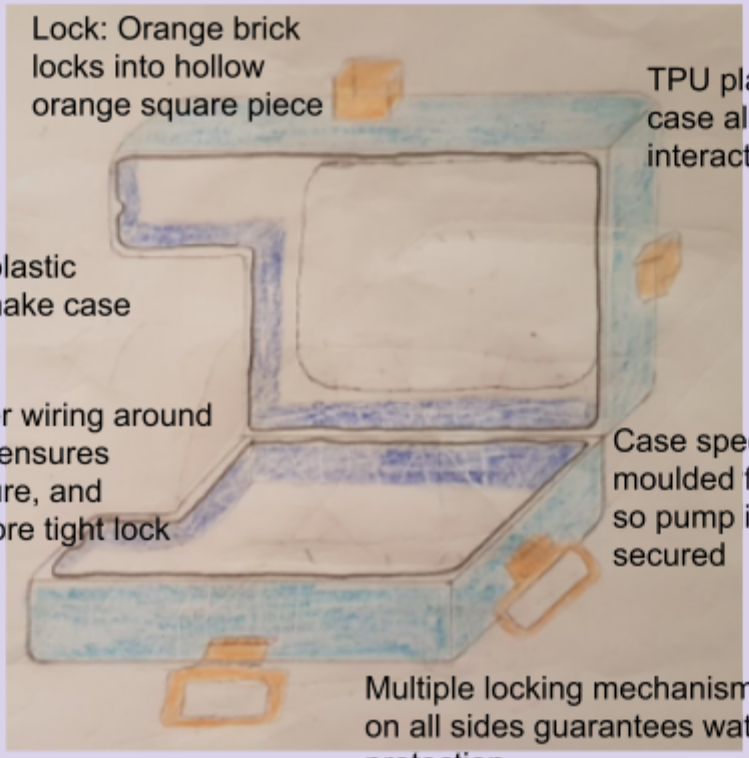
2D design and laser cutter used for lid for high level accuracy



Laser cutter used for precision

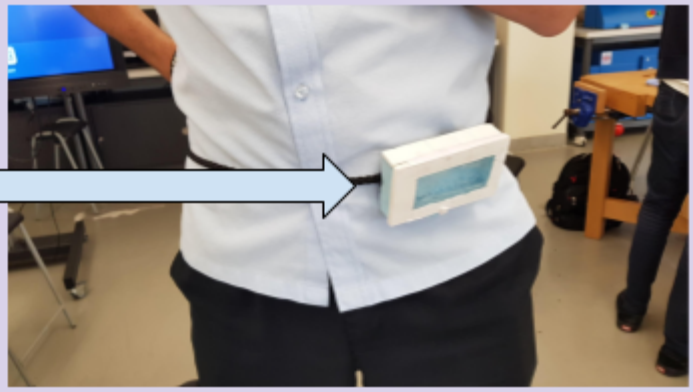
Foam used to surround edging. Rubber was inaccessible

Idea 6:

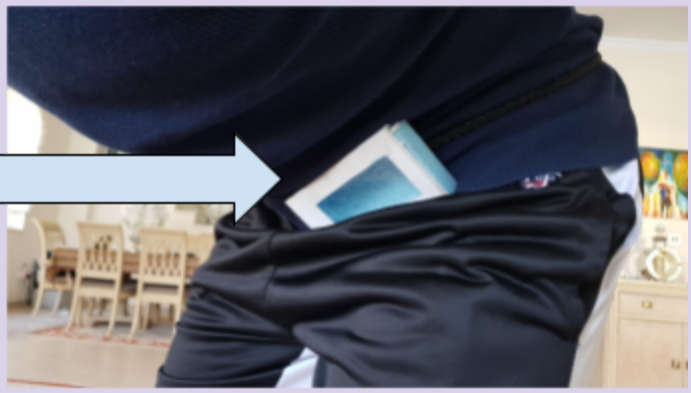

Lock: Orange brick locks into hollow orange square piece
TPU plastic screen on case allows for interaction with pump
Hard plastic may make case heavy
Rubber wiring around pump ensures pressure, and therefore tight lock
Case specifically moulded for pump so pump is secured
Multiple locking mechanisms on all sides guarantees water protection

Testing

Using real materials, case will sag/pull down on user



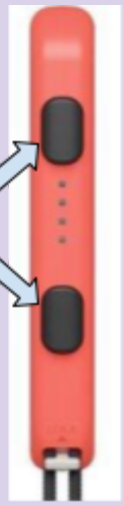
Case's rigidity will annoy user when bending over and turnin



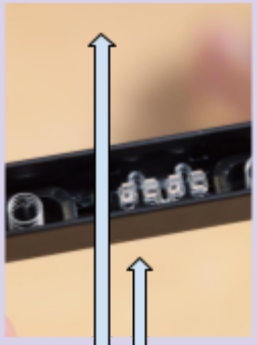
Case's size and stiffness will interfere with arm movements

Idea 7:

Inspiration for interaction w/ pump via hard buttons came from Nintendo Switch Joy-Con straps.

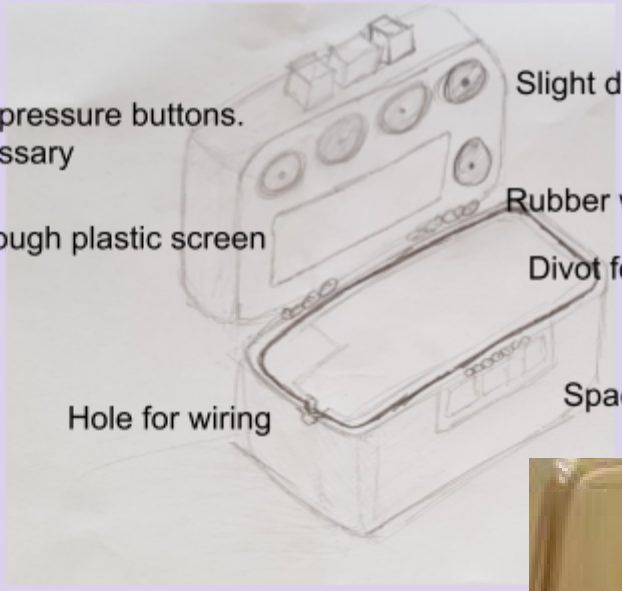


Buttons



Plastic piece gets pushed when button is pressed

Buttons on joy-con are subsequently pushed



Hard plastic pressure buttons.
TPU unnecessary

Hard see-through plastic screen

Slight divot on locking blocks for tight fit

Rubber wiring surrounds casing for pressure

Divot for pump to fit

Spaces for blocks

Hole for wiring

Very unique and tight fit designed specifically for pump

Vacuum plastic mould technique ensures pump is tightly fit

Main focus = making a hard case while still remaining small

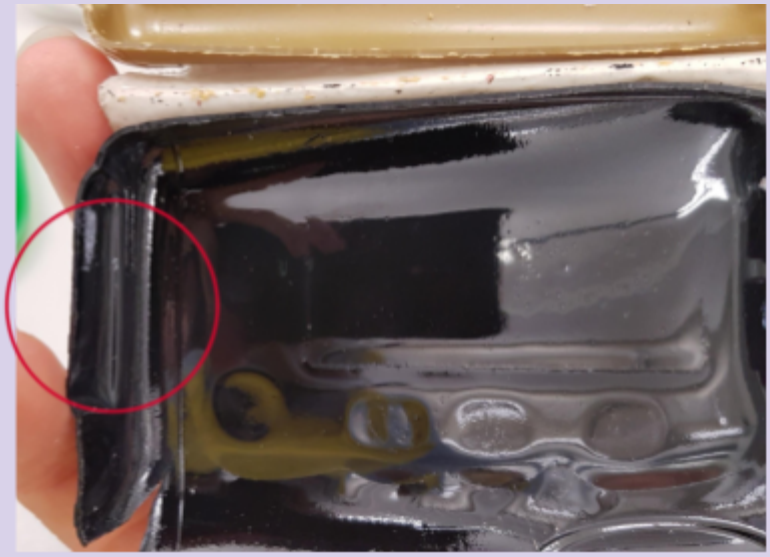
Impossible to surround thin case with rubber for airtight design.

Different method for airtight fit needed

Single wall: Gets sandwiched by double wall on lid

Double wall: Envelops walls of container on both sides

Double Wall

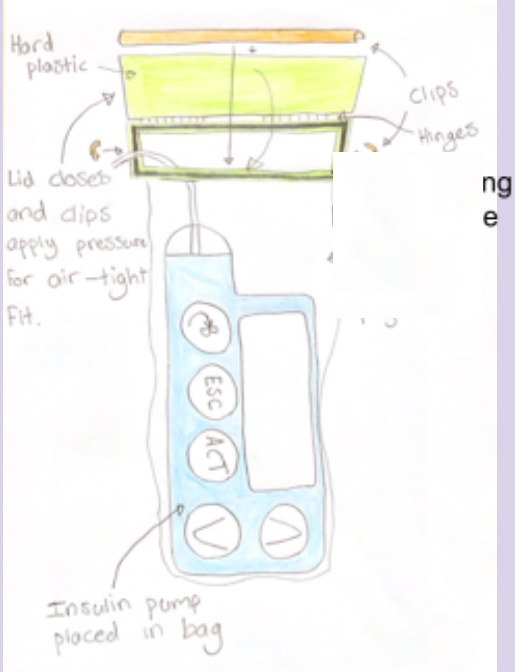


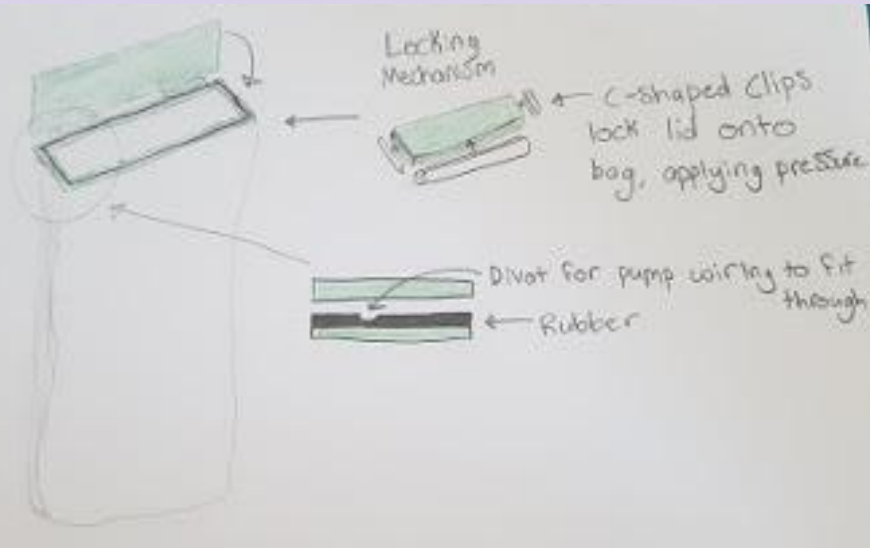
Single Wall

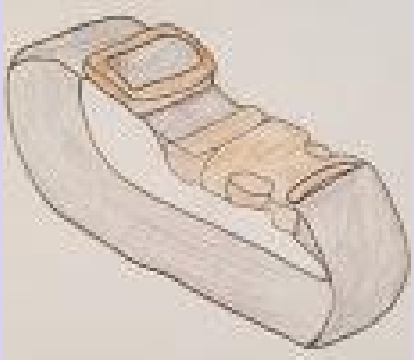
Testing the tupperware's seal, it was clearly splashproof
Pressing down on tupperware revealed air can leak in/out
Locking mechanism not safe to keep underwater for extended periods

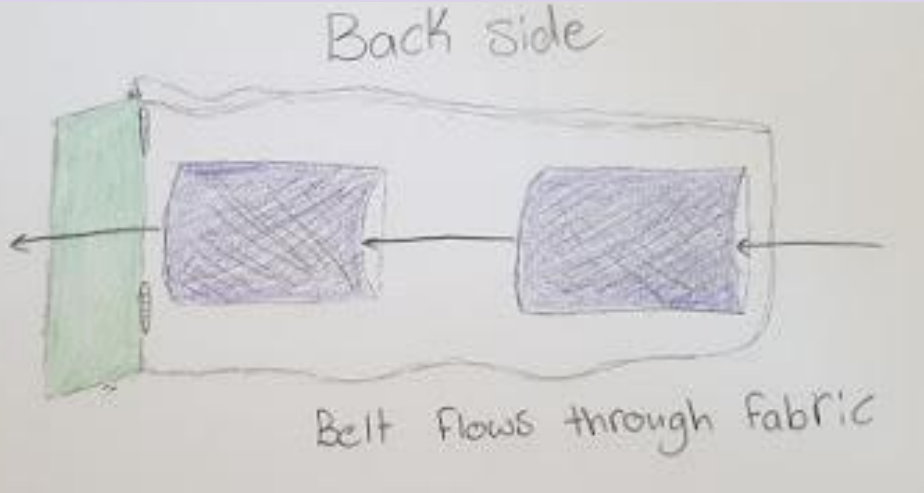
Justification of Appropriate Idea:

Idea 5 was the ideal design because it perfectly fit the design specification. The product's dimensions are made to fit the medtronic minimed 530G snugly. This design is also very unnoticeable and not flashy. The bag itself that holds the pump is transparent, and the hard plastic locking system is not large and can utilize neutral colors such as black or white. The product will also allow the pump to be submerged in water for an extended amount of time, which is its primary function and main priority. The bag design allows for the user to interact with the pump while it is in use, as the bag is malleable enough for buttons to be pressable through the product. This design also allows the integration of high quality materials such as waterproof nylon, or thermoplastic polyurethane, which are both very durable and good for minimizing the size/weight of the product, making it portable and easily accessible. This is because thermoplastic polyurethane is not a thick material and there can be a very thin layer of the material surrounding the insulin pump. The incorporation of a belt loop at the back of the product allows for a belt to be used for increased adjustability, as well as allowing the product to be attached to the user's body easily and securely.









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Justification of Materials, Components, and Manufacturing Techniques:

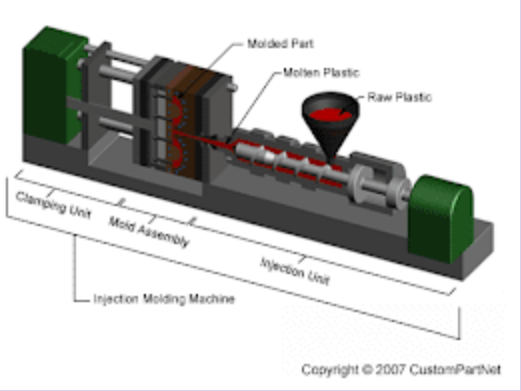
Materials/Components	Justification Based on Prototype Requirement
Thermoplastic Polyurethane (TPU)	The thermoplastic polyurethane will be the bag, used for holding the pump. High elasticity and flexibility over a wide temperature range is very important for the ability to interact with the pump. Its robust weather resistance allows the bag to maintain its water-tight seal, by ensuring it will not rip or be punctured easily. It is also very easily processed via blow molding, which means that a tight fit, unique to the shape of the pump is attainable. This will help keep the pump more secure and increase comfort, as there will be less size and mass to the product[14].
Polypropylene	Polypropylene is widely used to make tupperware containers. This material is very tough, meaning it won't fracture or rupture under pressure. This is important when creating a water-tight seal, as pressure needs to be placed on the locking system and the lid in order to keep the pump safe from water damage. It also has great fatigue strength, which means that it can handle repeated stress, which is important, as the lid and the locking mechanism will be under stress consistently while in use[15].

[14] https://omnexus.specialchem.com/selection-guide/thermoplastic-polyurethanes-tpu
[15] http://order.tupperware.com/coe-pdf/tupp_2010_materials.pdf

Materials/Components	Justification Based on Prototype Requirement
Nitrile Rubber 	Nitrile rubber is used for making seals for all kinds of plumbing and appliance applications, which means that it is very good at creating water-tight seals. This is important, as it will be used to insulate the case, and keep the pump safe from water damage. It has inferior strength in comparison to other rubbers, meaning when pressure is applied, it will squeeze down an exceptional amount ensuring no water can pass through. It is also wear resistant, so there will be minimal damage caused by overuse. This is necessary for ensuring a durable product that lasts long and can remain waterproof indefinitely[16].

Manufacturing Techniques	Justification Based on Prototype Requirement
CNC Machining 	CNC machining has high production and scalability, meaning it can execute huge quantities of the product. This is valuable, as there is a very large market for my product. These machines can also produce any size, shape, or texture needed when utilized in tandem with advanced design software. This is also very important, as it can create both a custom and a uniform locking mechanism for my product that can ensure a watertight fit[17].

[16] http://www.industrialrubbergoods.com/nitrile-rubber.html
[17] https://www.fairlawntool.com/blog/advantages-cnc-machines/

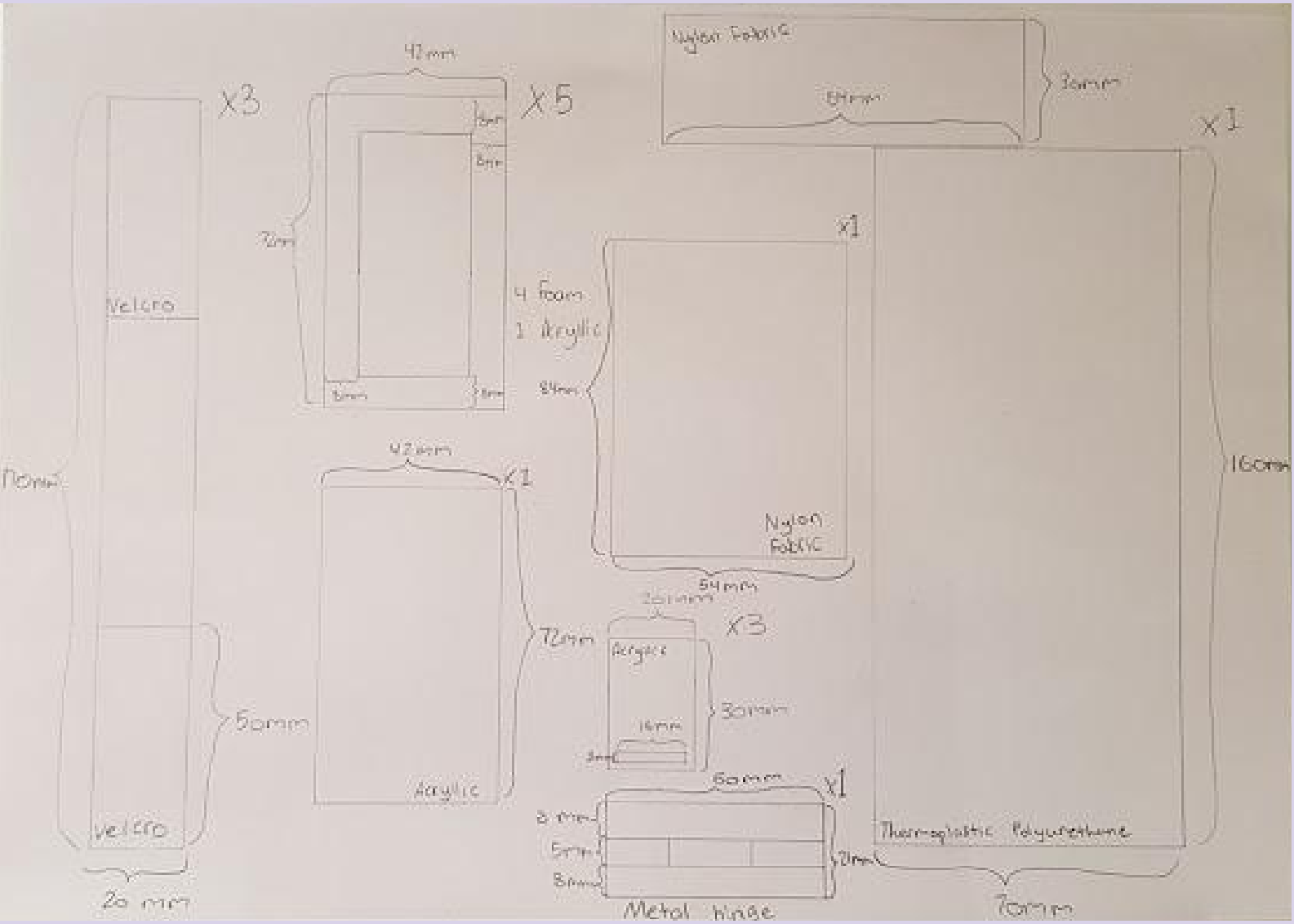
Manufacturing Techniques	Justification Based on Prototype Requirement
Blow Molding 	Blow molding is very scalable, very cheap, and is very commonly used for plastic containers[18]. Fillers can also be added during the molding process, increasing the strength and reducing the density of the plastic, which will create a more durable lid and locking mechanism. This is significant as these parts will undergo a lot of stress during utilization by the user[19]. Ziploc uses this technique to make their bags too[20].

[18] https://connectusfund.org/11-advantages-and-disadvantages-of-blow-moulding
[19] https://nanomoldcoating.com/5-major-advantages-to-using-plastic-injection-molding-for-the-manufacturing-of-parts/
[20] http://www.designlife-cycle.com/ziploc-bags

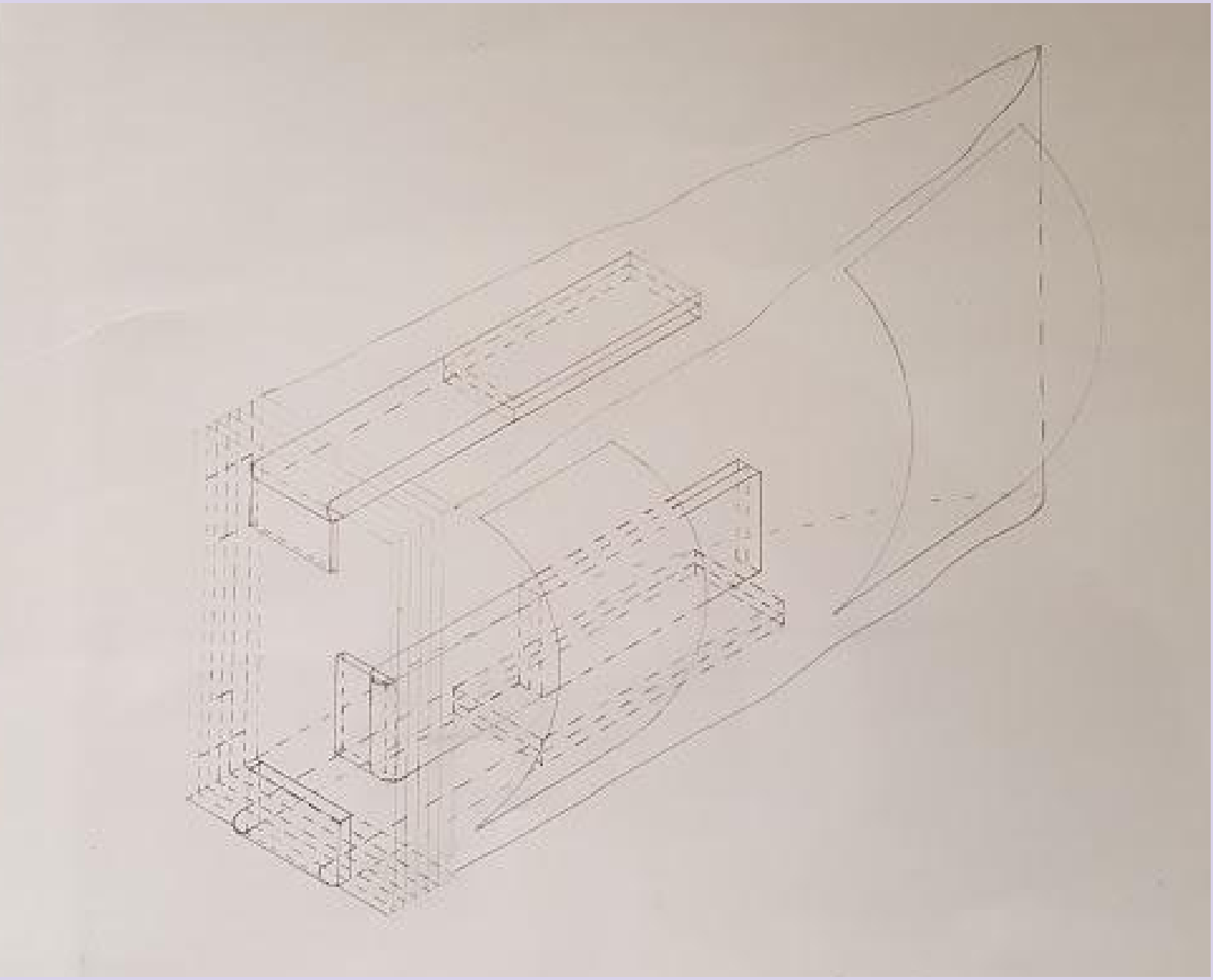
Development of Accurate Design Proposal:

Technical Drawings:

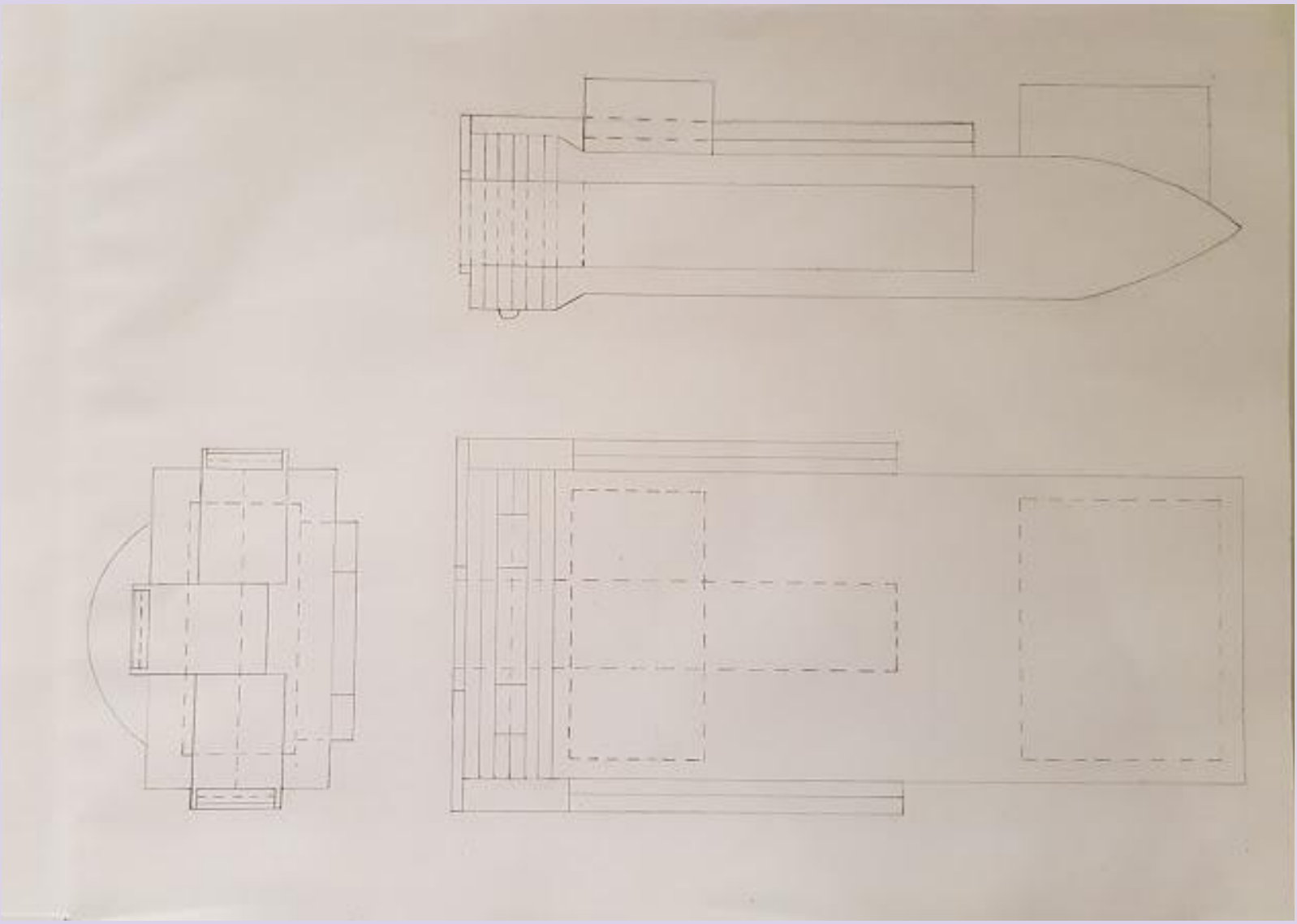
Individual Component Parts With Dimensions



Isometric Drawing:

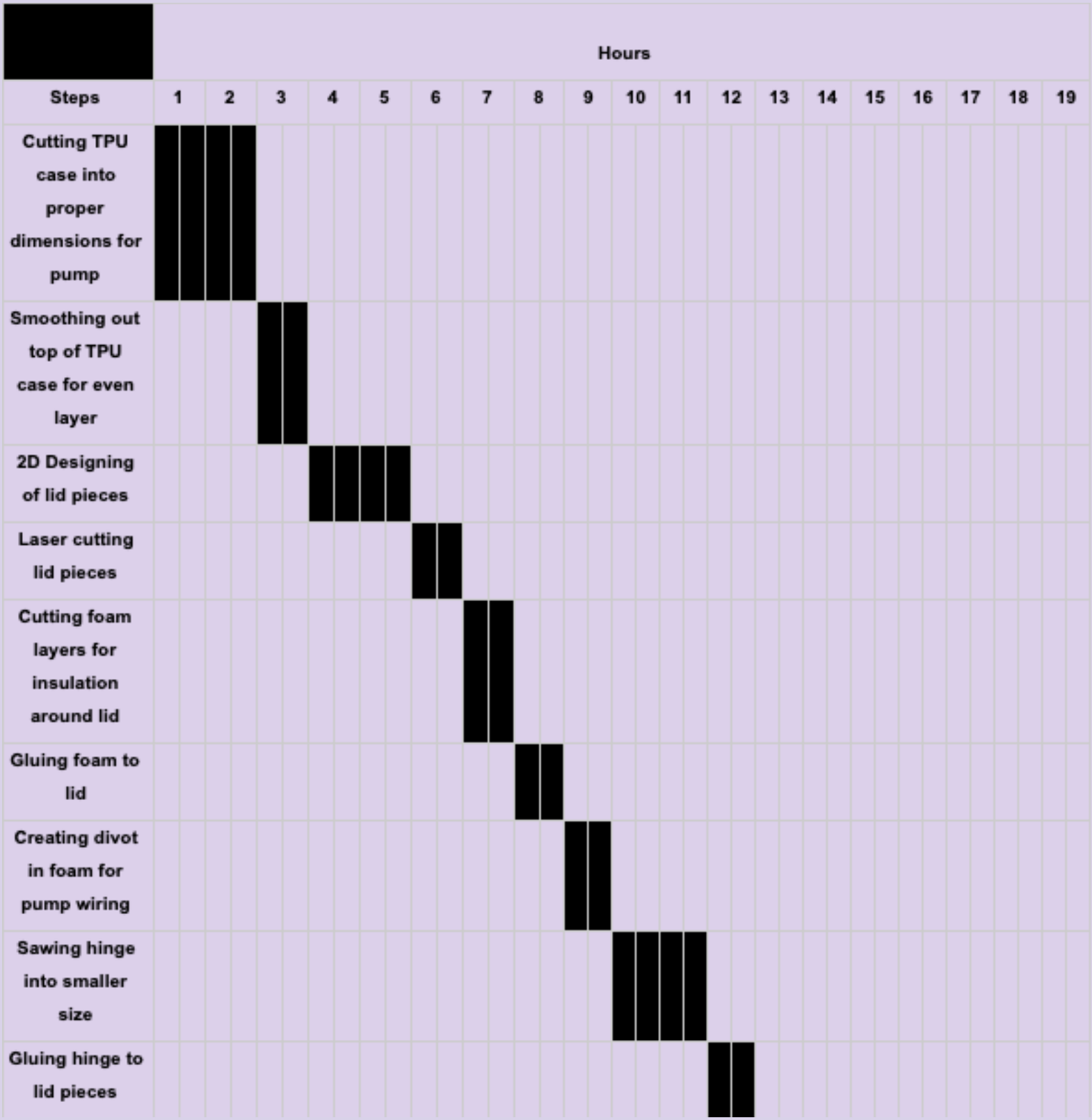


Orthogonal Drawing:



Prototype Manufacturing Plan:

Construction Plan:



[redacted]	Hours																		
Steps	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Gluing lid piece to top of TPU bag																			
Cutting three metal wire pieces for locking mechanism and shaping them as hooks																			
Gluing 3 metal wire hooks to top of lid																			
Cutting and stitching velcro to long strips of cloth																			
Gluing long strips of cloth to bag																			
Cutting/gluing cloth strip to back of case for belt																			

Word Count: 2064

Testing Strategy:

I gave my product to a group of 8 type 1 diabetic people, ranging from 5 years old to over 50. They wore the product with a plastic block inside roughly the same mass and size of an actual insulin pump, and there was a wire protruding from the case that was the same as the wire on an insulin pump. The participants swam with the product for around 2 hours each. This is a realistic and practical testing strategy because it brings different users of different sizes and ages to test the product how it would naturally be used. Because the users will be using the product in a pool, many of their physical actions with the product will mimic the actual actions that users would make while using the product. This includes kicking with their legs, diving, twisting, bending over, jumping, etc. Different success criteria of the product such as comfort, ease of use, portability, and size/weight can be tested.

Data From Tests and Conclusion Reached:

- **Comfort**

7/8 users claimed that the lid's rough, sharp edges were uncomfortable and painful. There was also discomfort with the velcro rubbing on skin. One user claimed to have developed a rash due to the velcro irritating his skin as he swam. Users, however, did praise the bag's thermoplastic polyurethane bag, claiming that it was light, soft, and did not seem to interfere at all when swimming. One user said that because the bag is so elastic and malleable, "it was barely noticeable," while swimming.

- **Water Leakage**

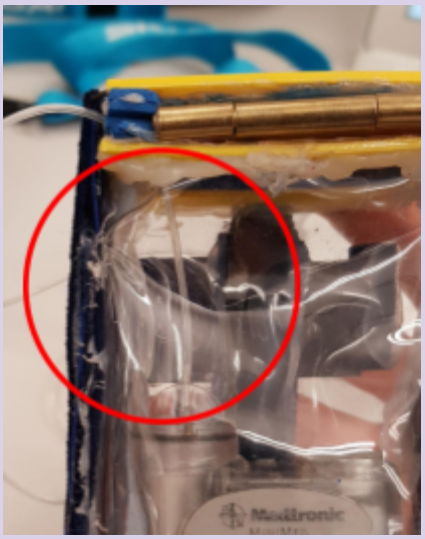
Because I was unable to use the ideal insulating material, nitrile rubber, as it was inaccessible, instead I used polyurethane foam. The issue with this is that polyurethane foam is porous, which means it is very easy for water to pass through it. This is a major

issue, as many of the participants noticed. All users experienced water leakage. However, the water leakage was very minimal, even after hours of use. When the velcro was tightly sealed, it made it hard, but not impossible for water to seep through. I am confident that if the proper ideal materials were used, the product would be 100% waterproof.

- **Interaction with Pump**

Users found it very easy to interact with the pump while it was in the product. Users all had the same opportunity to use the pump in the product. All buttons were clickable, the screen was easily visible, and it was not challenging to click any of the buttons. 2/8 users were concerned that later on in the product's life, scratches to the bag may make it harder to view the pump screen and buttons, making it harder to interact with the pump.

- **Portability**



One major issue was portability. All of the users, especially the kids, felt the bag was too big and hard to carry around while swimming. 8/8 users claimed it was too big to carry in their pockets, and was noticeably large and uncomfortable to carry on a belt on their stomach. The bag is too long, and as a result eats up a lot of excess wire, as can be shown in the image on the right. Furthermore, the insulator used to keep water out was polyurethane foam. Because it is such a weak insulator a sizable amount of foam was used.

- **Ease of Use**

2 children, ages 5 and 9, were used to test the product. The 5 year old struggled significantly to secure the pump in the product, and the 9 year old also required guidance and help. This is because the locking mechanism requires an exceptional amount of strength to properly keep the pump safe from water. Pulling the velcro strap through the loop and back down onto itself requires the user to use force to ensure tightness. Furthermore, one of the straps is placed behind a piece of fabric used as a loop for a belt.

This made it even harder for the children to secure the pump in the product properly. All in all, the locking mechanism is not as straightforward as it should be, which makes it harder for children to use.

- **Weight**

Out of all of the participants that tested the product, there were no complaints with weight. The design is minimalistic, and the materials used are all very light. The weight can still be decreased for increased user comfort.

Improvements:

- **Comfort**

- **Water Leakage**

Utilizing nitrile rubber will make the product waterproof, as it is a very common insulator in plumbing, and is very good at keeping water out.

- **Interaction with Pump**

Coating the TPU bag with a scratch resistant plastic coating will decrease the amount of visible scratches, making it easier to see the screen of the pump, and therefore interact with it.

- **Portability**

Decreasing the length of the bag will make it more portable, as it will be a smaller size. The bag can be decreased by 55 millimeters.

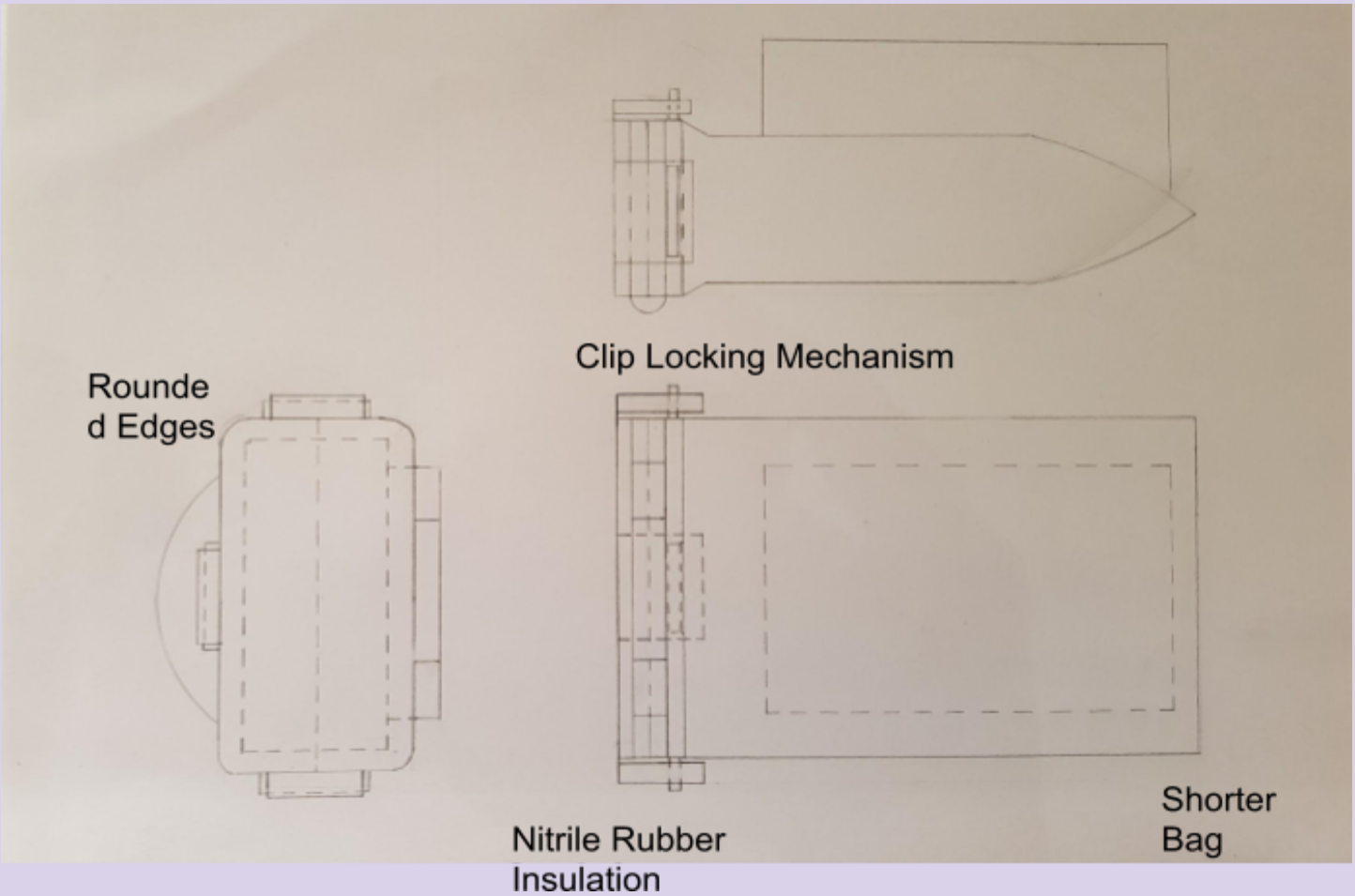
- **Ease of Use**

Using a typical tupperware locking mechanism that uses clips will be a lot easier for all users to use, as it will require less strength and will be a lot easier to understand.

- **Weight**

Decreasing the length of the bag, utilizing a typical tupperware locking mechanism instead of the heftier velcro system, and using nitrile rubber instead of foam as an insulator are all ways to decrease the weight of the bag.

Updated Orthogonal:



Word Count: 2963