College of Engineering

Department of Mechanical Engineering

Final Report

Engineering Senior Design Project, ME-490B

Dexcom Overlay Patch Characterization

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Table of Contents

Table of Figures

Table of Tables

1. Project Overview

- **Problem Statement:** Dexcom provides an overlay patch that is placed onto a glucose monitor wearable to enhance the adhesion over time. Some patients have difficulty retaining the wearable onto their bodies. This project is intended to determine a test method for comparing patch performance of the overlay on an Instron with LDPE plates, creating the fixture of the Instron and developing an on body working model to compare, correlate the results of the patch and creating the final design of the patch.
- **Need:** Determine the overlay patch material adhesive performance of a peel test using an Instron bench test as a guide to develop a proposal of an on body test for creating the final design of the patch. Doing conduct adhesive material characterization tests to evaluate the impact of sterilization, temperature and humidity. The new adhesive life should be around 14-15 days.
- **Course Instructor:**

  Scott Shaffar, Ph.D.

  Department of Mechanical Engineering

  San Diego State University

2.Project Management

- **Schedule**

I have to follow the following deliverables during the whole year: project definition document, project management plan, system requirement document, preliminary design review, critical design review, manufacturing review, test review, final presentation and final report.

In this document I recollect a summary of all of them.

• Final Project Budget

The initial budget for this project was 25,000$ which was appointed by my sponsor Mr. Barbod from Dexcom. This amount had to cover all materials, tests and any services required for the development of the project. As of the end of this project, I have spent $893.46 from the budget. This number consists of $709.00 spent in the Fall, and $184.46 spent in the Spring. This leaves the unused budget at $24,106.54.

Table 1: Fall and Spring Budget

Component	**Amount**
Initial Budget	$25,000
Fall	
Spent	$709
Unused Budget	$24,291
Spring	

Spent	$184.46
Fall + Spring	
Total Spent	$893.46
Unused Budget	$24,106.54

Final Labor Budget

It was estimated that I have to spend a total of 12-15 hours each week before the COVID-19 outbreak. This included sponsor and lab meetings, and individual work time. After the shutdown of facilities in mid March, fabrication and testing were no longer an option which decreased the labor hours.

Table 2: Work Breakdown Structure Descriptions

WBS Title	Description
Overlay Patch Performance	This is the Overlay Patch Performance characterization project sponsored by Dexcom.
Project Management	This work package covers the scope goals, cost goals and schedule goals. It is the baseline of the entirety of work. That includes Organization, Risks, Research up until Final Reports etc.

Systems Requirement	Covers the user specification and requirements, constraints and verification methods.

Final Report	Compilation of all the work done during the year
Design	Mainly includes design and engineering analysis and how it was achieved and why
Research	Find answers to questions that came from conceptualizing.
Trade Studies	Determine which approach would be best based on a numerical evaluation of options.
SolidWorks	Model the final product that was the result of previous design tasks. Review for any geometric errors.

Preconditioning	Desired overlay patch preconditioning with EtO sterilization, humidity and temperature to understand the effect of these conditions on the peel and shear tests.

Peel	Required. Our main testing system involving a 90 degree peel on a bench test also a 90 degree peel on body test.
Shear	Strongly desired test that will help Dexcom understand patch performance.

- **Risk and Issue Management**

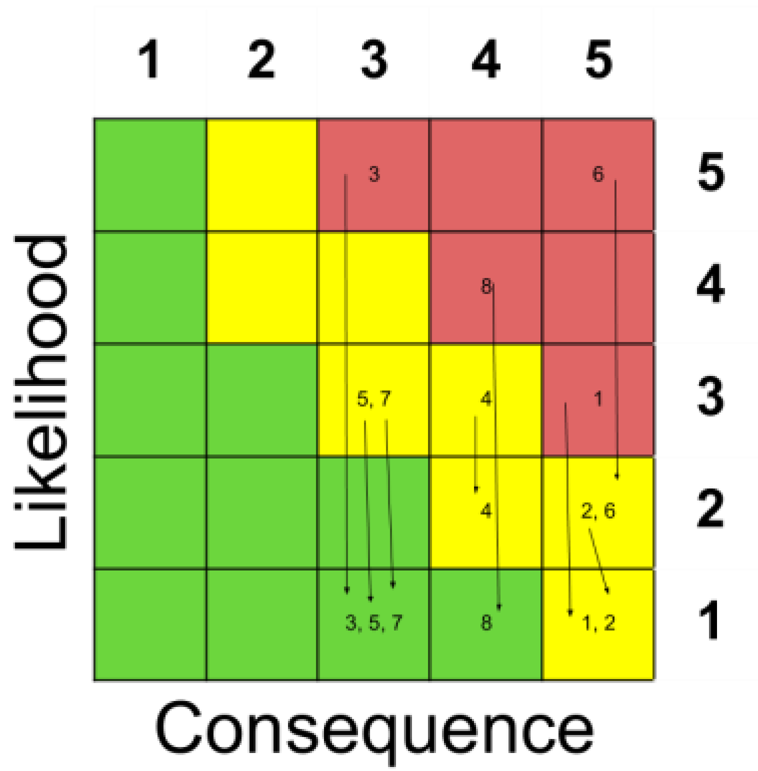


Figure 1: Risk Cube

Table 3: Risk Management

#	Subject	Risk and Mitigation
1	Timeline	Risk: If the timeline is not followed could fall behind schedule Issues: Schedule delays occurred because of on-body design mechanism iterations Risk: If the timeline is unrealistic in setting progress may actually be behind schedule

		Mitigation: Although schedule delays occurred, finally completed the final design on time for deliverables.
2	Material Failure	Risk: If Spun lace overlay material stretches during test resulting in a nonuniform peel line. Mitigation: Throughout testing the patches, many torn or stretched. I applied a reinforcement (PET tape) which significantly reduced stretching and I was able to test the materials resulting in a uniform peel line.
3	Safety	Risk: If On-body peel test causes skin damage to test subjects Mitigation: This step is considered traveled work. A test emergency button must be handy throughout testing so the subject is able to stop the peeling immediately in case of skin damage
4	Schedule	Risk: If I don’t meet enough each week ,project management could fall apart and I could fall very behind Mitigation: I met regularly to discuss project management and design progress.
5	Budget	Risk: If design is very complex and requires a lot of equipment Mitigation: For both the on-body design and Instron fixture: Through trial and error, research and trade studies, the design chosen was best fit to avoid complications in equipment access and costs

6	Apparatus Accuracy	Risk: If data recorded is not accurate Mitigation: I was trained by technicians at Dexcom to ensure testing accuracy and consistency.I was trained to conduct tests with the correct apparatus set up and consistent test method every lab session which ensured accuracy.
7	Manufacturability of Parts	Risk: If manufactured part models aren't reviewed, critical components could be impossible or too expensive to manufacture Mitigation: After multiple meetings with the sponsor, adapters were easy to manufacture and assemble to purchased components.
8	Failure to Receive Materials	Risk: If component "ship-by" date is too far away Mitigation: I made sure all purchased components had a fast delivery window. There was no delay in ordered materials. This is because materials were chosen with respect to timeline
*	COVID-19	Risk: If the COVID-19 outbreak gets extreme then the facilities used for labs and manufacturing, testing will not be available. Mitigation: I can complete capstone project virtually. I also completed an on-body design proposal, data and analysis on many tests completed unsterilized patches.

3. Final Design

- **Instron Fixture**

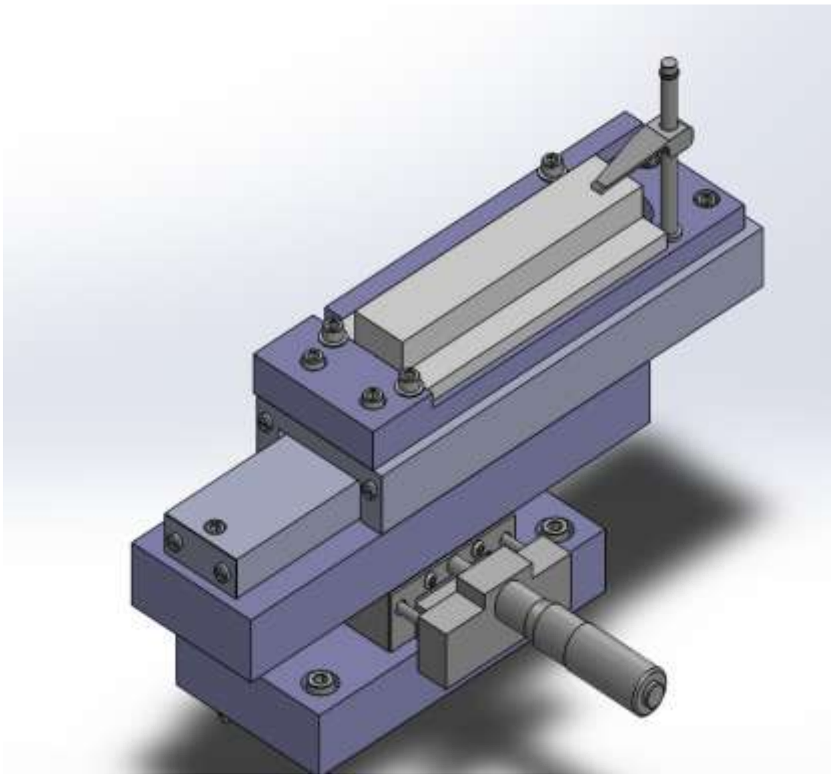


Figure 2: Instron Fixture

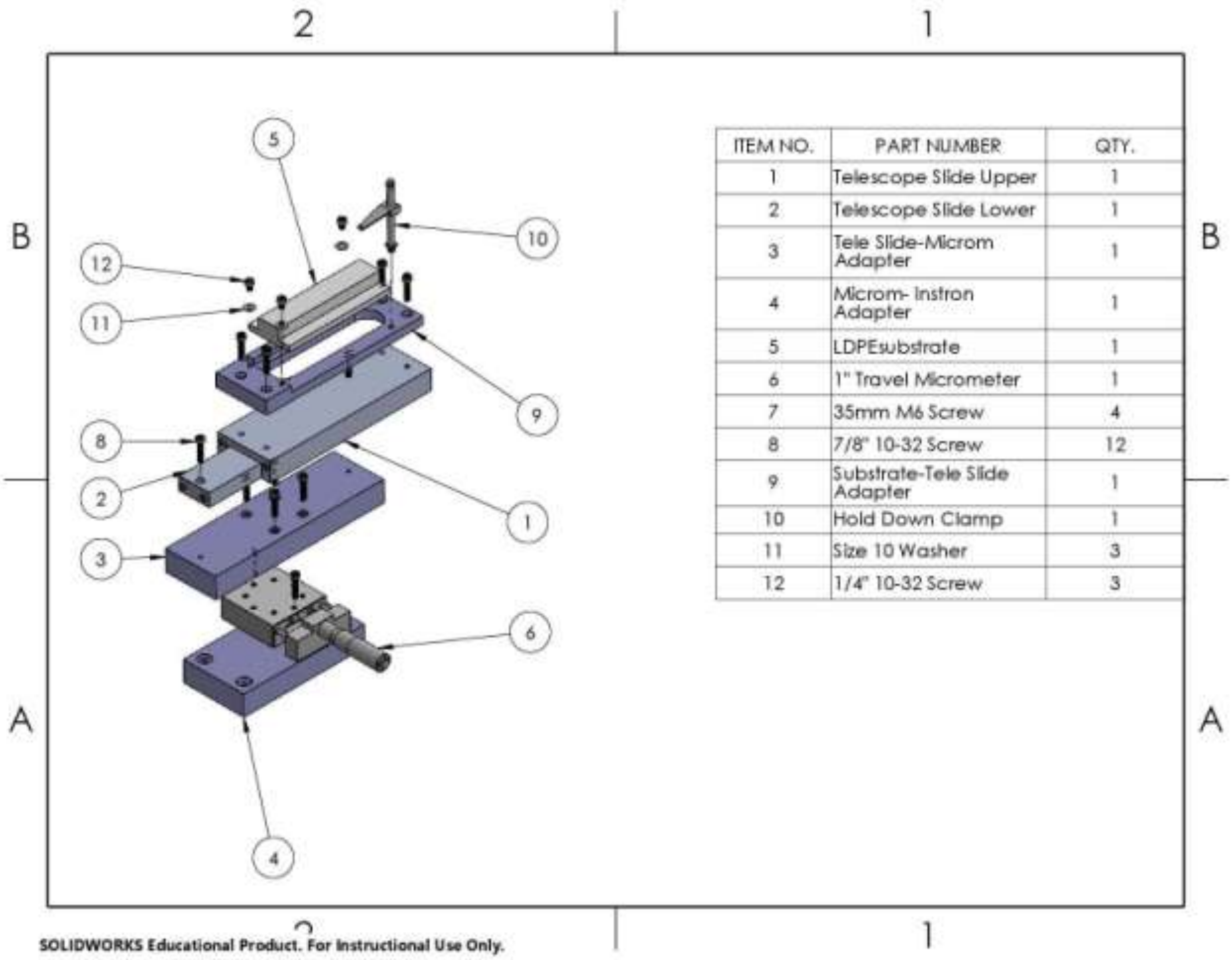


Figure 3: Instron Fixture Exploded View

The Instron fixture consists of 7 components. There are 3 adapters, 2 translating components and 2 types of hold-down mechanisms. The functionality of the telescoping slide was to provide frictionless movement for the dynamic part of the Instron fixture. Determining factors for the choice of this slide were: availability, travel length and friction. The micrometer is also for translation but this is for removing any offset from the center of the Instron grippers with the center of the overlay material. Design considerations for the micrometer were: ability to lock position, 1” travel length and availability. The necessity of the adapters was because there are no other available solutions for interfacing the Instron to the micrometer, micrometer to the telescoping slide and telescoping slide to panel. Design considerations for the adapter slides were manufacturability, strength and ability to interface to desired components. The top adapter also was designed to be lightweight because I wanted to reduce the inertia of the dynamic portion of the Instron fixture.

- **The Arm fixture**

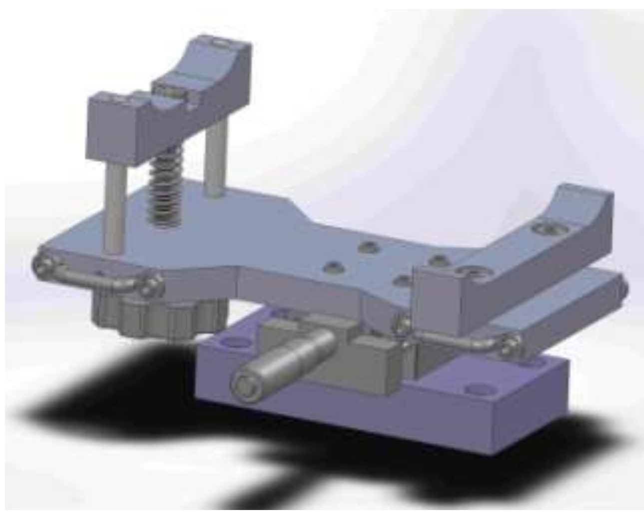


Figure 4: Arm Fixture

The arm-instron fixture’s purpose is to statically hold a test patient’s arm. The fixture should be comfortable and be able to accommodate the different shapes and sizes of people forearms. The arm-instron fixture was designed to mount onto the micrometer of the instron fixture. The knob on the arm-instron fixture is used to level the test patient’s forearm. When the knob is turned clockwise, it pulls down the threaded bolt. The spring around the bolt pushes up the wrist cup and is strong enough to keep a patient’s wrist in place. The spring-bolt-knob system satisfies the specification of leveling the arm. The webbing guides attached to the fixture next to the arm cups are for the straps to secure the test patient's arm. The extra wide size of the arm cups accommodate for all sizes of forearms. The reason why the baseplate for the arm fixture attaches to the bottom components of the previous instron fixture is because I wanted to run tests with this fixture attached to the instron before I finished the on body design. With arm-instron tests I could have some expected force responses for overlay material on actual human skin. The issue with an arm-instron test is that there would be a variable peel angle throughout the test rather than a constant 90° peel angle.

- <u>On-Body Design</u>

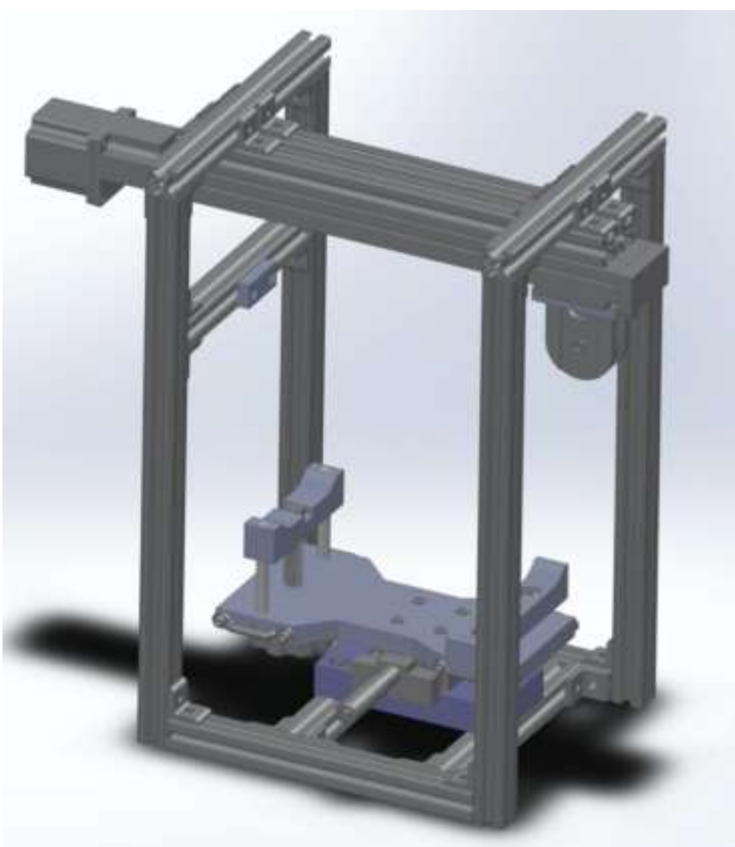
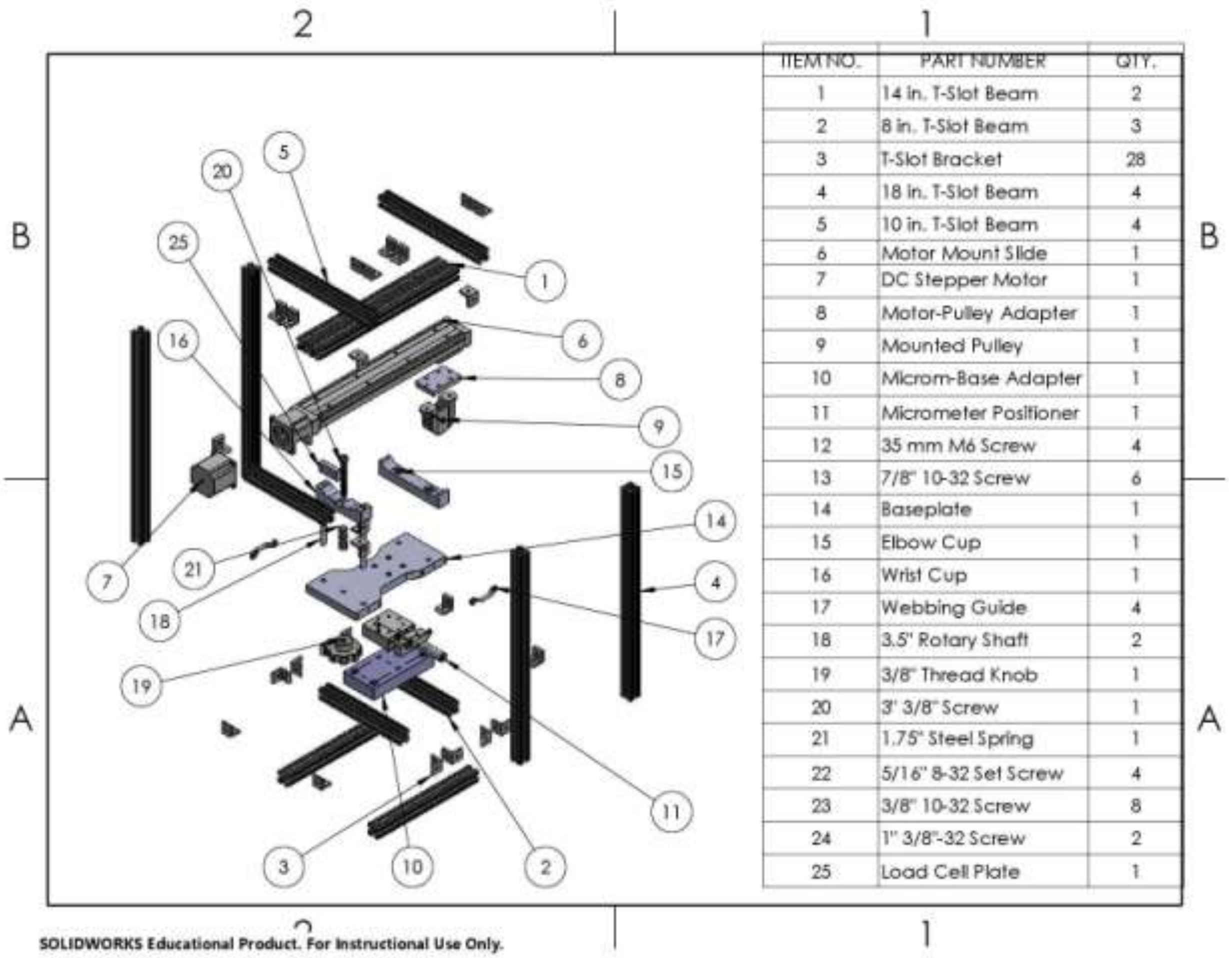


Figure 5: On-body Design.



ITEM NO.	PART NUMBER	QTY.
1	14 in. T-Slot Beam	2
2	8 in. T-Slot Beam	3
3	T-Slot Bracket	28
4	18 in. T-Slot Beam	4
5	10 in. T-Slot Beam	4
6	Motor Mount Slide	1
7	DC Stepper Motor	1
8	Motor-Pulley Adapter	1
9	Mounted Pulley	1
10	Microm-Base Adapter	1
11	Micrometer Positioner	1
12	35 mm M6 Screw	4
13	7/8" 10-32 Screw	6
14	Baseplate	1
15	Elbow Cup	1
16	Wrist Cup	1
17	Webbing Guide	4
18	3.5" Rotary Shaft	2
19	3/8" Thread Knob	1
20	3" 3/8" Screw	1
21	1.75" Steel Spring	1
22	5/16" 8-32 Set Screw	4
23	3/8" 10-32 Screw	8
24	1" 3/8"-32 Screw	2
25	Load Cell Plate	1

Figure 6: On-body Design Exploded view

Mechanism

T-slot frames are connected to the base and each other with brackets. A motor-mount positioning slide is fixed to the top T-slot frame. A pulley is screwed to the carriage with an adaptor designed. There is an assembly of components under the pulley not shown on the view. This includes a Pulley cable that would be connected to an S-Shape load cell through an eye bolt. The load cell would connect clamps at the bottom which grips to the overlay material. The Pulley and all the components below the pulley move to the side along with it, thus, the cable pulls the assembly of components below the pulley in a vertically upward direction. This force is the peeling force. The pulley converts the horizontal movement of the slider in vertical upward movement. Ultimately, as the overlay patch is peeled, the assembly of components under the pulley including the S-Shape load cell, clamps and eye bolt moves upward. For manufacturing, within the design are adapters that have to be printed to assemble the components together.

Selection of Major Components

- Lead-screw positioning slides

Required speed of a 90° peel test is 300 mm/min (12 in/min) as per ASTM standards D3330 I followed. This cannot be compromised. So the chosen mechanisms should satisfy this requirement. Self-locking of the mechanism is important so that the system does not have backward drive. Accuracy required is very high. Linear motion should have accuracy of 5 ± 0.2 mm/s as per ASTM standards D3330.Third most important requirement of this mechanism is that it should be able to apply a thrust force of 10 lbs plus move hanging components in the direction of peeling. Based on research I conducted, two different mechanisms were selected for comparison as shown in Figure 7.

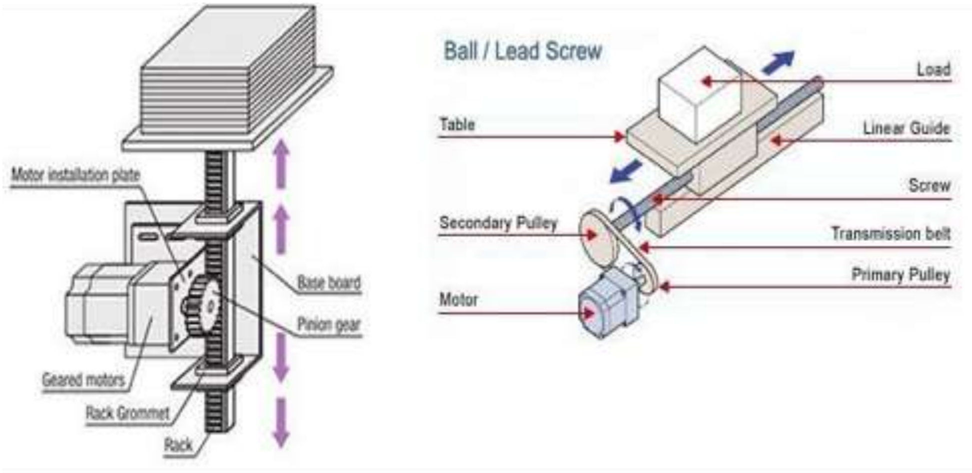


Figure 7: Mechanisms selected for trade studies (Why Rack & Pinion Systems Should Be Considered for High Load, 2019)

Table 4: Trade study of rack-pinion vs. positioning slides (Linear motion tips, 2015)

#	Features	Rack and pinion mechanism	Lead screw position slides
1	Backlash and pitch errors	3	5
2	Operation Speed requirement of 12in/s	5	5
3	Thrust force requirement	5	4
4	Ease of Manufacturing and assembly	5	4
5	Cost	3	5
6	Noise and vibration	4	5
7	Mounting alignment	4	5
8	Efficiency	5	4

9	**frictional losses**	3	3
10	**Lubrication**	3	4
	Total	40	44

Based on the above analysis, it can be observed that rack and pinion mechanism, and lead screw position slides have a very close match. Lead screw position slide was available easily to purchase online with complete assembly and was a perfect fit for the project while the rack and gear mechanism required machining, custom components and purchasing standard components from different websites. While lead screw motion control components were easily available with less shipping time and had better trade studies results, thus, it was concluded to use lead screw positioning slides with the component chosen included in the Bill of Materials.

- Load cell - Force Measurement

Force requires to be continuously measured during the peel test and hence it's more reliable to have an automatic system to read force data with displacement and time instead of manual force reading. There are various different types of options available in the market for force measurements. Most commonly used are digital force gauges and load cells.

Table 5: Trade study of digital force gauge vs. load cell

#	**Features**	**Digital force gauge** (IMADA CO.LTD, 2019) **(tension)**	**S type load cell** (Force Sensor, 2020)**(tension)**
1	**Accuracy**	**3**	**4**
2	**Software to record reading**	**3**	**5**

3	**Repeatability**	**5**	**5**
4	**Cost**	**3**	**5**
5	**Load range**	**5**	**4**
6	**Size**	**3**	**4**
7	**Availability**	**3**	**5**
	Total	**25**	**32**

Based on the above trade study, it was found that digital force gauge had a lower accuracy, and software for force recording had a higher cost. Also, it was available only in abundance through the company's website. On other hand, S type load cell is very easily available on Mcmaster.com and has very good accuracy, is small in size, comes with integrated PC connections and can be read by any compatible software for load cells, it's highly accurate and is very compact in size. It can be purchased in a single quantity through McMasterr-Carr. Therefore, an S-type load cell (tension) was selected for this project. Ultimately, for this peel testing, tensile force acts on the overlay patch. Most suitable option for this design was to select a load cell which can be easily fitted for tensile application. Most commonly used load cell for tensile force measurement is an S-Shape load cell. S-shape load cells can be fixed between the tension cable and the clamp to measure peel force. The load cell in the Bill of Materials was selected with which complete accessories are provided to use with a computer for data acquisition from a force sensor.

- Clamps

Maximum load that has to be handled by the gripper is 10lbf and the width of gripper needed to hold the overlay patch strip end is 24mm, thus. This selected clamp in the Bill of Materials can handle up to 100lbs.

- Eye bolt

The main function of the selected eye bolt in the Bill of Materials is to connect a rope to the top of the load cell. The screw part of the eye bolt is manufactured to a size of M3 x 0.5mm and would then be fitted on top of the load cell. The eye of the eyebolt is connected to the rope. There is negligible force acting on the eyebolt to deform because the load is considered too low.

System Level Diagram of the Instron

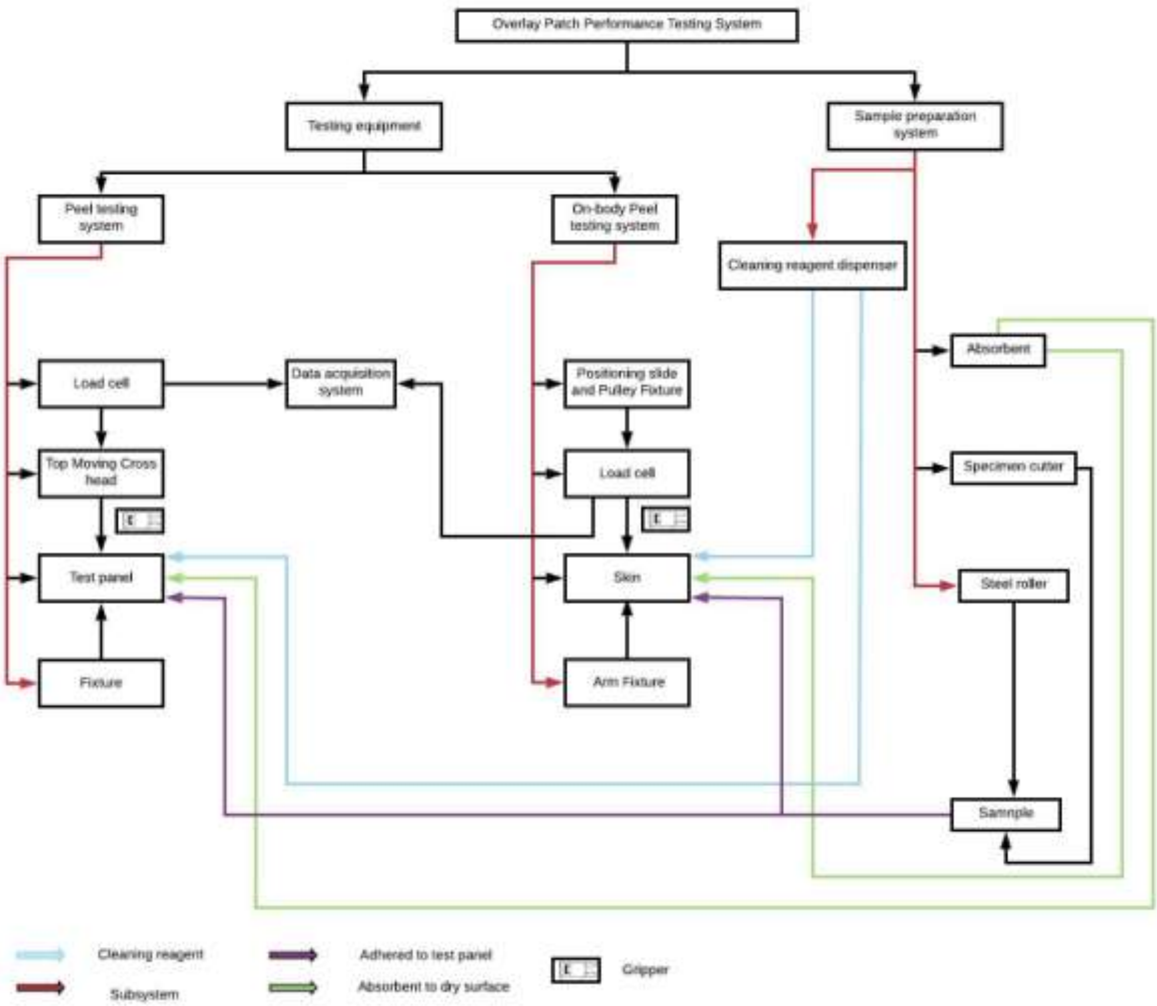


Figure 8: System Level Diagram

The main components of the system are the Instron Peel test and On-Body peel test. Red lines represent the subsystems, Blue lines indicate what's cleaned before testing, Green lines indicate what's dried with an absorbent and anything connected to Purple represents the sample adhered to the test panel/ skin. The system level diagram above entails all possible processes this project will undergo. Initially, samples of overlay patches are prepared as indicated in the Sample Preparation system. Test panel samples are connected to a cleaning reagent dispenser where they are cleaned with a reagent solution and dried with an absorbent so that the overlay patch sample can be adhered to a dry surface using a steel roller. All overlay patches and test panels of every testing system is prepared in a similar way except for the on body subsystem in the peel testing system where skin is simulating the test panel. The skin must be cleaned and dried before applying the test strips. Next, test panels with the adhered patch are fixed between crosshead members in Instron or clamps of on-body design. Gripper symbol indicates the fixtures held with grips. All load cells connect to a data acquisition system where stress and strain data is generated.

4. Bill of Materials

Table 6: Bill of Materials

Product	Quantity	Delivery	Cost $	Supplier
Positioning Table with Micrometer, 60 lbs. Slc, 1" Travel Length	1	12/06/2019	316.42	McMaster-Carr
Low-Friction Telescoping Slide, 1-1/2" Wide x 8" Long Rail	1	12/17/2019	211.93	McMaster-Carr
Compact Hold-Down Toggle Clamp, Steel, 150 lbs. Hc	4	12/06/2019	47.44	McMaster-Carr
Black-Oxide Alloy Steel Socket Head Screw, 10-32 Thread Size, 7/8" Long	50	12/09/2019	6.68	McMaster-Carr
Black-Oxide Alloy Steel Socket Head Screw, 8-36 Thread Size, 3/4" Long	50	12/09/2019	15.03	McMaster-Carr
Fine-Thread Alloy Steel Socket Head Screw, M6 x 0.75 mm Thread, 35 mm Long	4	12/09/2019	23.32	McMaster-Carr

White Delrin® Acetal Resin Sheet, 1" Thick, 12" x 12	1	12/09/2019	88.18	McMaster-Carr
18-8 Stainless Steel Male Hex Thread Adapter, 1/4" OD, 1/8" Long, 10-32 Thread Size	2	03/10/2020	7.70	McMaster-Carr
Male Threaded Standoff, 7/16" OD, 1/2" Long	1	03/10/2020	3.32	McMaster-Carr
Super-Thin Splicing Tape, 3M 850, Red, 1" Wide, 216 Feet Long	1	03/10/2020	63.91	McMaster-Carr
Screw-Head Mount Knob, Single Arm Grip, Acetal, for Number 10 Screw Size, Black, packs of 50	1	03/10/2020	9.00	McMaster-Carr
Screw-Head Mount Knob, Single Arm Grip, Acetal, for 1/4" Screw Size, Gray, packs of 50	1	03/10/2020	9.72	McMaster-Carr
Screw-Head Mount Knob, Two Arm Grip, Acetal, for Number 10 Screw Size, Black, packs of 50	1	03/10/2020	9.00	McMaster-Carr
Screw-Head Mount Knob, Two Arm Grip, Acetal, for 1/4" Screw Size, Gray, packs of 50	1	03/10/2020	9.75	McMaster-Carr
Hook and Loop Cable Tie with Buckle, 18" Overall Length, 1" Wide, Blue	4	03/10/2020	8.80	McMaster-Carr
Webbing Guide for 1" Maximum Webbing Width, Steel, packs of 10	1	03/10/2020	8.83	McMaster-Carr
Super-Cushioning Polyurethane Foam Sheet, Adhesive-Back, 1" Wide, 1/4" Thick, 17 Feet Long	1	03/10/2020	5.27	McMaster-Carr
Ribbed Plastic Comfort-Grip Knob with 3/8"-16 Threaded Through Hole	1	03/10/2020	3.25	McMaster-Carr
Zinc Yellow-Chromate Plated Hex Head Screw, Grade 8 Steel, 3/8"-16 Thread Size, 3" Long, Fully Threaded, packs of 5	1	03/10/2020	5.92	McMaster-Carr

Music-Wire Steel Compression Springs, 1.75" Long, 0.6" OD, 0.466" ID, packs of 5	1	03/10/2020	5.71	McMaster-Carr
Rotary Shaft, 1566 Carbon Steel, 3/8" Diameter, 12" Long	1	03/10/2020	7.83	McMaster-Carr
18-8 Stainless Steel Cup-Point Set Screw, 8-32 Thread, 5/16" Long, packs of 100	1	03/10/2020	4.81	McMaster-Carr
18-8 Stainless Steel Low-Profile Socket Head Screw with Hex Drive, 3/8"-16 Thread Size, 1" Long, packs of 5	1	03/10/2020	8.02	McMaster-Carr
18-8 Stainless Steel Socket Head Screw, 10-32 Thread Size, 3/8" Long, packs of 100	1	03/10/2020	7.37	McMaster-Carr
Motor-Mount Positioning Slide for NEMA 23 Frame, 300 mm Travel Length	1	3-4 Weeks	1216.05	McMaster-Carr
Position-Control DC Motor NEMA 23, 600 Maximum 600 rpm, 17 in.-oz. Torque	1	1 Day	81.09	McMaster-Carr
Mounted Pulley for Wire Rope-for Horizontal Pull /single-Groove, for 1/4" Diameter Rope, 2" OD, 1" Wide	1	1 Day	17.63	McMaster-Carr
Force Sensor S-Shape, for Compression and Tension, 10 lb. Capacity, with Kit	1	1-3 Weeks	1257.14	McMaster-Carr
T-Slotted Framing End-Feed Single Nut with Button Head 1/4"-20 Thread Size	4	1 Day	7.4	McMaster-Carr
Silver Corner Bracket, 1" Long for 1" High Rail High Rail T-Slotted Framing	2	1 Day	10.42	McMaster-Carr
Force Gauge Gripping Attachment For Sheets	1	1 Day	203.45	McMaster-Carr
Unthreaded Steel Routing Eye Bolt Without Shoulder- Not For Lifting, 1/4"	1	1 Day	2.95	McMaster-Carr

Diameter x 1" Long Shank				
T-Slotted Framing Single 4-Slot Rail, Silver 1" High x 1" Wide, Solid, 2’ Long	3	1 Day	23.37	McMaster-Carr
Total			$3706.71	

Above is the Bill of Materials including purchased parts of the Instron fixture, and chosen components for the on-body design. The Major suppliers for this project are McMaster-Carr. Dexcom’s lab provided me with some overlay materials, double sided tapes, and PET strips. About half of the materials were not able to be purchased due to testing delays and the COVID-19 pandemic which is why the Total in the table does not reflect the actual budget spent.

5. Manufacturing and Assembly

Instron Fixture

Figure 9: Instron Fixture

All components fit together with fasteners. Components include toggles holding down clamps for even pressure of substrate connected to telescoping slide for a 90 degree peel. A micrometer to center the peel strip and Delrin adapters to interface all the pieces.The micrometer and telescoping slide were bought components. The 3 adapter plates were machined at Proto-Labs starting from a block of Delrin then milled down to the specified geometry in the Solidworks drawings. Some of the holes were threaded with taps at Proto-Labs while counterbored holes were left untouched.

Figure 10: Clamps swapped 3 button head screws

Swapped clamps for 3 button head screws with washers and a tension clamp. Without clamps, unnecessary geometry could be removed.

Arm-Instron Fixture

Figure 11: Arm Fixture

The arm fixture is made of only a few manufactured parts. The elbow cup, wrist cup, and baseplate were all 3d printed at Dexcom. All of the holes were filled with support material that was carefully removed with pliers. The holes were threaded with hand taps. The foam pads were cut using a razor blade and adhered to the cups with an already applied adhesive. The guide rails were cut down to 1.5 inches using a hacksaw and a metal file was used to smooth sharp edges. Assembly of the arm fixture is relatively simple. Almost all the parts are held in place with screws. The assembly of the arm fixture was as followed:

1. Guide pole holes on the baseplate were sanded until the guide poles could fit in them after a few gentle taps from a hammer.
2. Once in place, set screws were screwed in locking the guide poles in place
3. The wrist cup guide holes were sanded to the point were the guide poles could move through them with little to no resistance
4. Springs were placed around both guide poles
5. The wrist cup had the ⅜” bolt placed in the center hole
6. Then the guide poles on the basepate were fed through the respected guide holes on the wrist cup
7. The knob was then screwed onto the exposed bolt thread underneath the baseplate
8. The elbow cup was fastened to the baseplate using two ⅜” bolts
9. The four webbing guides were fastened to the baseplate using two 10-32 bolts each
10. The foam padding was adhered to both cups using the pre-applied adhesive on the back of the pads

11. Finally, the blue straps were looped around the webbing guides

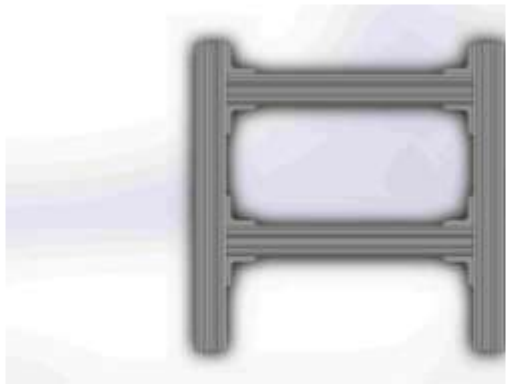
The only defects with the arm fixture was in the manufacturing. There is a part of the baseplate that looked like it was peeling off of the print bed. The only component this defect may affect would be the webbing guide. Since pulling on the webbing guides was not a part of the way I designed the peel tests this shouldn't be an issue. If it does become an issue, Dexcom could just print another baseplate and follow the manufacturing steps.

On-Body Peel Tester

Only 2 adapter plates need to be 3d printed for the on-body peel tester. Of those plates only 3 holes need to be tapped. I would tap those holes with the same hand taps that were used for the arm fixture. The t-slots also need to be cut down to size using a band saw.

Table 7: Number of beams needed at specified lengths (left) and number and lengths of beams to be ordered (right)

# of Beams	Lengths needed	Beams to cut	
3	8"	#	Length
4	10"	5	1'
2	14"	6	2'
4	18"		



1. Connect the two 10” T-slots with perpendicular 8” T-slots with 8 corner brackets and 16 ¼”-10 screws ½” in length and nuts

2. Connect the four 18” T-slots using 4 corner brackets and 8 ¼”-10 screws ½” in length and nuts

3. Place the two 14” T-slots next to each other and center them on a 10” T-slot on each end. Use 8 corner brackets and 16 ¼”-10 screws ½” in length and nuts

4. Attach the Motor-mount positioning slide to the 14” T slots with 4 ¼”-10 screws ½” in length and nuts

5. Attach the pulley adapter to the motor mount with 4 M5 screws 15mm in length

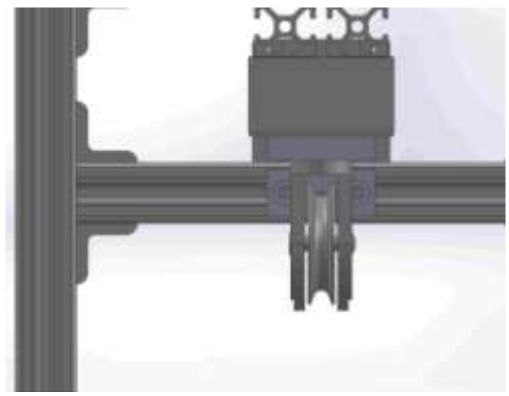
6. Attach the pulley to the pulley adapter with 2 M6 screws 12mm in length

7. Attach 4 corner brackets about 1” away from the ends of the 10” t-slots with 4 ¼”-10 screws ½” in length and nuts

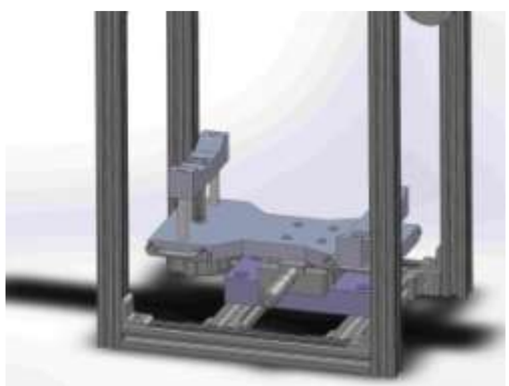
8. Attach the top half of the housing to the bottom half with 4 ¼”-10 screws ½” in length and nuts

9. Attach crossbar to motor side of housing with 4 corner brackets and 8 ¼”-10 screws ½” in length and nuts

10. Attach load cell adapter to crossbar with 2 ¼”-10 screws ½” in length and nuts



11. Adjust crossbar to line up the centerhole of the load cell adapter with the top of the pulley



12. Attach arm fixture to on-body housing using 4 M5 screws 25mm in length

6. Requirements Verification and Final System Demonstration

Research

Sources of information for the Peel Test fixture were ASTM D 1876-08 and ASTM D3330 which is the one for the 90º. Standard Test Method for Peel Adhesion of Pressure-Sensitive Tapes, Instron's fixture website, Dexcom lab staff and Dexcom engineers... the test plan I created followed the standars of the ASTM that I have mentioned, which is shown below. Dexcom engineers determined that LDPE panels provided the most consistent data. There are circular steel fixtures on instron's website but that wouldn't work for my experiments because the substrate needs to be LDPE and planar LDPE panels are easier to obtain. Since it is cost effective to use flat planar LDPE panels, the shape of the panels will influence how the fixture operates. Therefore, it was determined that the fixture would need to linearly travel the length of the substrate. This is why there is a telescoping slide in the fixture. During review of model, a Dexcom engineer pointed out that it is necessary to adjust fixture perpendicularly to the axis of the telescoping slide. This is what led to the addition of a micrometer to the fixture. It was known that a part would need to be manufactured in order to hold the LDPE panel but Dexcom engineers pointed out that interface adapters would need to be made in order to connect the instron base to the micrometer then the micrometer to the telescoping slide on account of the different bolt patterns and sizing. All tapped holes in adapter panels go all the way through the panel because as explained by Lenny that it would greatly reduce manufacturing time if the machinist didn't have to worry about how deep into the panel to go. The adapter component material that Dexcom wished we would use was Delrin an easily manufacturable material that is widely used in industry. The clamps were necessary for holding down the LDPE panel. The channel in the top Delrin panel was requested by my sponsor Lenny Barbod since it would be easier and cheaper to get manufactured at Proto Labs. All in all a major source of design parameters have been defined using Dexcom's industry experience and specialized expert personnel. Given the low expected forces and simplicity of design, it would be a misuse of time to explore other options. The design of the on-body test was based off of Instron test results and recreating instron-like data on a body. Preferably living.

The shear test would have been done following the ASTM F2255-05. I decided to do this test based on the following trade study that I show below, a few tests were done but not all completed because of the COVID-19 outbreak.

Here is all the research and information of how this was done:

Table 8: Trade studies for the shear test.

Design - Trade Studies

ASTM	F2255-05	D6463/D6463M-06	D3983 – 98	D905 – 08
Name	Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading	Standard Test Method for Time to Failure of Pressure Sensitive Articles Under Sustained Shear Loading	Standard Test Method for Measuring Strength and Shear Modulus of Nonrigid Adhesives by the Thick-Adherend Tensile-Lap Specimen	Standard Test Method for Strength Properties of Adhesive Bonds in Shear by Compression Loading
Scope	Comparing adhesives or bonding processes for susceptibility to fatigue and environ-mental changes	It measures time to failure and determines cohesive strength of the adhesive specifically for pressure sensitive articles. It considers effect of temperature and humidity on specimen being tested.	It is specifically to measure shear modulus and rupture stress of adhesive bonded joints. It neglects compressive and tensile forces in the joint.	Measures shear strength of adhesive bonds used for bonding woods, metals, etc.
Suitable for this study	Suitable option because it considers effect of change in environmental condition. It measures the load at failure. Thus, maximum load it can handle can be measured.	Suitable option because it considers effect of temperature and humidity. Samples in this study has to be evaluated at higher temperature of 37 degree Celsius and 90% humidity. Humidity and temperature effect can be clearly observed in this test.	Not suitable as it measures strength of joint formed using adhesive between two hard surfaces while our product is a pressure sensitive article which can stretch and it might influence the result significantly. Thus, this test can't be used for this study and hence rejected.	Not suitable as it is more applicable for adhesives for woods. Thus rejected.

Design - Trade Studies (Decision Matrix)

Decided that the Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading ASTM F2255 was the best option.

Criteria		Designed for flexible adherends	Designed to test environmental conditions	min adherend thickness	relevance of material properties	best simulates point load	Totals
Weight		35	20	30	10	5	100
ASTM Test	D0905	no	No	19.0 mm	shear strength	5 mm/min	
Score		35	20	30	50	25	160
ASTM Test	D3166	no	no	1.63 mm	fatigue	cyclic	
Score		35	20	120	40	15	230
ASTM Test	D3983	no	no	16.0 mm	shear strength	1.0 mm/mm min	
Score		35	20	30	50	5	140
ASTM Test	D6463	yes	no	0.025 mm	quality control	hanging weight	
Score		175	20	150	20	10	375
ASTM Test	F2255	Yes	Yes	0.025 mm	fatigue	5 mm/min	
Score		175	100	150	40	25	490
	5	yes	yes	<= 1 mm	shear strength	constant v pull	
	4			<= 2 mm	fatigue		
	3			<= 3 mm		cyclic	
	2			<= 10 mm	quality control	hanging weight	
	1	no	no	> 10 mm		strain rate	

Table 9: Decision Matrix for the trade studies of the shear test.

While at Dexcom, I performed a shear test and from that data I got a general idea of the type of force the fixture should expect. The maximum force applied was about 0.8 lbf. When dealing with such low forces the factor of safety for deflection for each component is expected to be in excess of 30.

One issue that arose because I didn't include fasteners in the design before sending it to Proto Labs is that all the imperial counterbored holes are 5/16" instead of 10-32. Now the socket screws won't interface with panels so washers, and if need be stacked washers in increasing size, will be put to spread the load over the oversized holes. FEA analysis was done on the screw-washer-panel interface to estimate stress and deformation on washers. One thing to note about this analysis is that it does not account for the preload of the fastener. Since it wasn't a part of the design I am just going to continue with testing and if it becomes a problem I will replace the panels when necessary. Luckily there are four counterbored holes for each interface so the fasteners only need to be snug enough to not move or come undone during testing.

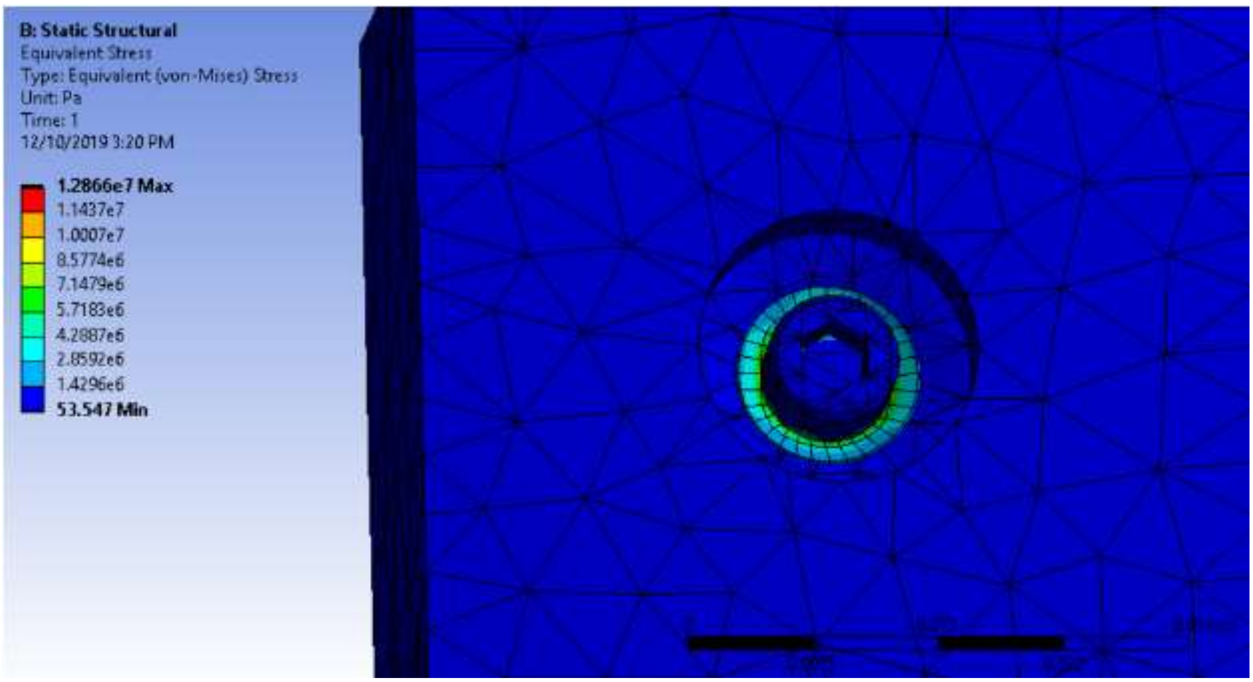


Figure 12 Equivalent Stress FEA analysis. As expected the most stress is in the washer the highest being about 7.14 Mpa well below the 228 Mpa shear strength.

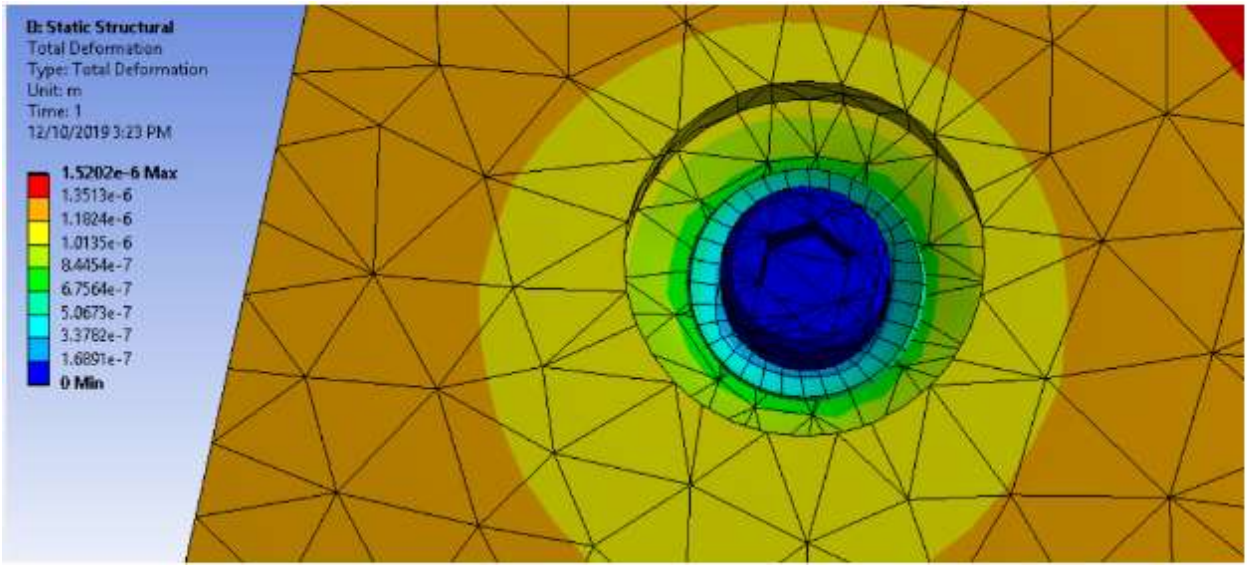


Figure 13 Deformation FEA analysis. Focusing on the effects of the washer, the washer will deflect a very small amount that's negligible.

For the temperature tests:

- Body temperature would be varied while maintaining constant humidity in temperature chamber to estimate the effect of variation of temperature on patches.
- Initial temperature would be 35 degrees Celsius. Change in temperature would be in range of 35 to 43 degrees Celsius. Temperature will be increased by 0.5 each day.
- Graph would be plotted for variation of the adhesive performance over duration of 15days for each test against temperature.

The humidity tests:

- Variation of humidity while maintaining constant temperature.
- Humidity will be varied from initially 20% to 95% for constant temperature of 37 degree Celsius. The samples will be tested using same procedure for peel and shear test as mentioned.

- Data will be collected on daily basis for each test from day 0 to day 15 and will be used for producing graph against time duration and change in humidity to evaluate performance of adhesive.

The test would have been done in Test Equity 123H Temperature/Humidity Chamber. The whole name of the Instron that I have used is Single Column Instron 5943.

Test plan

- 90° Instron Peel Test

The main aim of this test was to evaluate adherence of overlay patches when peeled at 90 degree angle to a LDPE test panel. For this test plan, specimens of overlay patches were restricted to only one type, unsterilized overlay material. A test plan with detailed outline of preparation methodology is prepared for testing to be adopted for overlay patches. Test plan was designed to be such that it will produce consistent results for about 30 tests. The equipment to be used for this test is specified such as a test fixture that needs to be customized and designed specifically for this test. It is proposed to use the ASTM D3330 and ASTM D1876-08 Standard test method for peel adhesion of pressure sensitive tape to be used as a guideline for this test plan. Specimens to be used for this test needed to be standardized to an exact size and shape so that it can be compared with another identical overlay patch. It was necessary to maintain consistency in the preparation of specimens to be tested. If there is any inconsistency in specimens shape and size, it might deflect results which are not desired. Test panel size, shape and cleaning methods need to be specified.

1. LDPE Panel Preparation

a. Conduct LDPE panel prep. In a clean environment using gloved hands and cleaned surfaces. Recognize that adhesive testing is dependent upon a consistent and clean test area, controls, sample preparation, and testing fixtures and equipment. Further, the time between test sample adhesion and testing can influence variations in test results.
b. Control contamination of test panels and materials by limited contact of adhesion surfaces to contaminants through the use of controls.
c. Wash the smooth side of the LDPE panel with a 70% of Isopropyl Alcohol and 30% of ultra pure water. Some of the tests were done with this sterilization and other without them.
d. Use an antistatic disposable wipe to clean the smooth side of the LDPE panel and then leave the panel to air dry.
e. Place the panel in the panel holder by pushing it into the marked corner.
f. Peel about half an inch of the backing off a test strip and place it on the center mark on the panel holder.
g. Line up strip with the centerline on the opposite side of the panel holder and peel the backing off and gently lay the strip on the panel
    i. Assume that removing the backing starts exposure time
    ii. Recommend that you keep track of this as a start time/test sample
h. Cut off the extra strip of the LDPE panel from the first side.
i. Take the LDPE panel out of the panel holder carefully removing the strip from the panel holder as well.

   j. Place the LDPE panel in the roller, hold the panel in place until the roller is on top.

2. 90° Peel Test Materials and Supplies
   a. Nitrile gloves
   b. Anti Static Wipes
   c. Panel Holder (custom printed part)
   d. LDPE panels
   e. Unsterilized adhesive test strip cut to 1” x 10”
   f. IPA/ Ultra pure water wash (70%Al / 30% Water)
   g. Roller (ChemInstruments Roll Down)
   h. Instron Tensile Tester
      i. Load Cell 50 kN
      ii. Pneumatic Gripper 250 kN

Outcomes

Test results represent a continuous plot of force variation with respect to displacement. The linear part of the plot will be used for evaluation of peel strength of adhesive. At least 30 tests needed to be completed, which were. Force variation with displacement plot showed any variations in peel of the specimen during the test or problems in the testing plan, and that generated wrinkles in the plot. This can be helpful in terms of feedback from the plot itself to take corrective action in test plan design and improve the testing process. The peel strength of different conditioned specimens will show different results. If there are significant differences in results of identical test specimens subjected to identical conditioning, it becomes necessary to measure humidity of ambient to check if it might influence the results. Dwell time for the test, humidity, testing temperature and testing speed needs to be specified in outcome along with plots of force vs displacement if needed. With the tests conducted, there were no indications of different results with the samples, so no specific preconditioning was needed as all samples were identical. Results were consistent with expectations, and results were the desired outcome that I and Dexcom were looking for.

Figure 14: Instron configuration with designed Fixture.

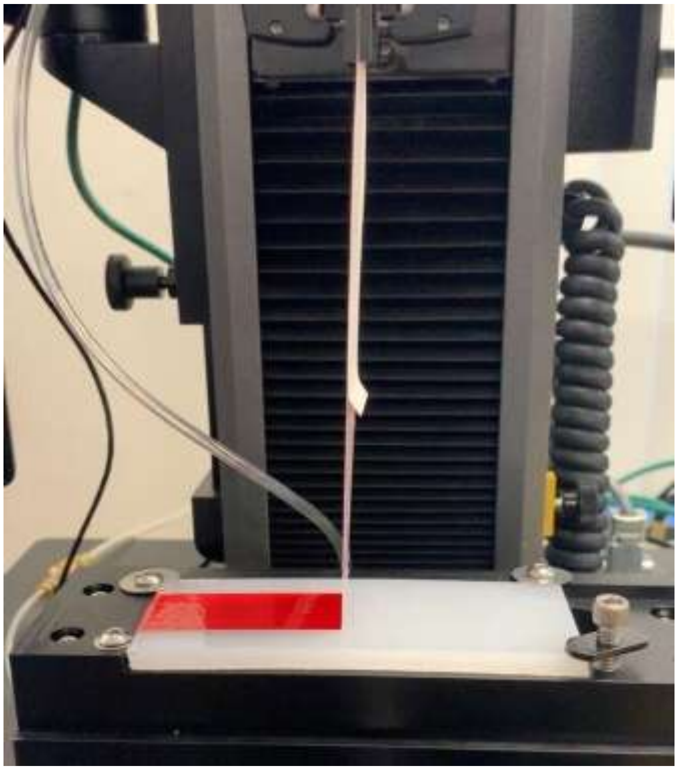


Figure 15: 90º peel with red tape adhered to patch for reinforcement.

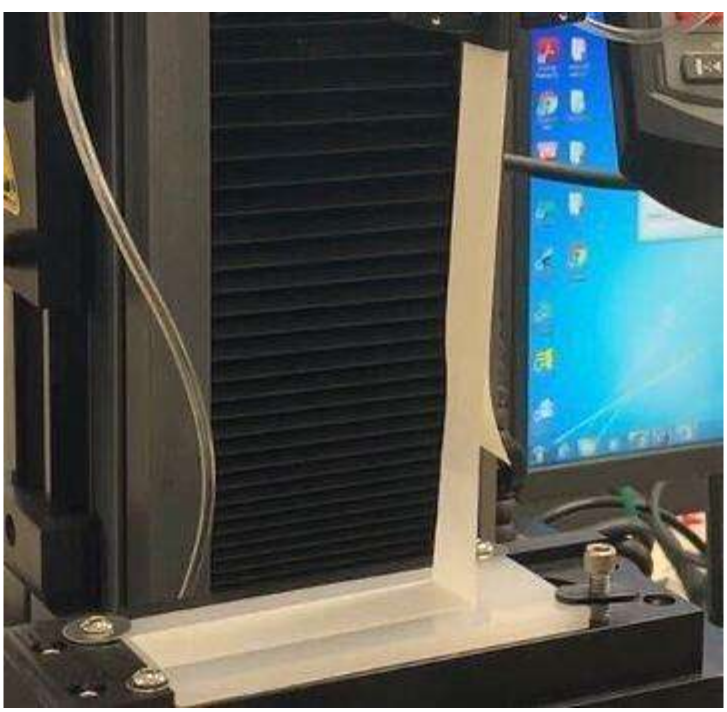


Figure 16: 90º peel test of overlay material without reinforcements

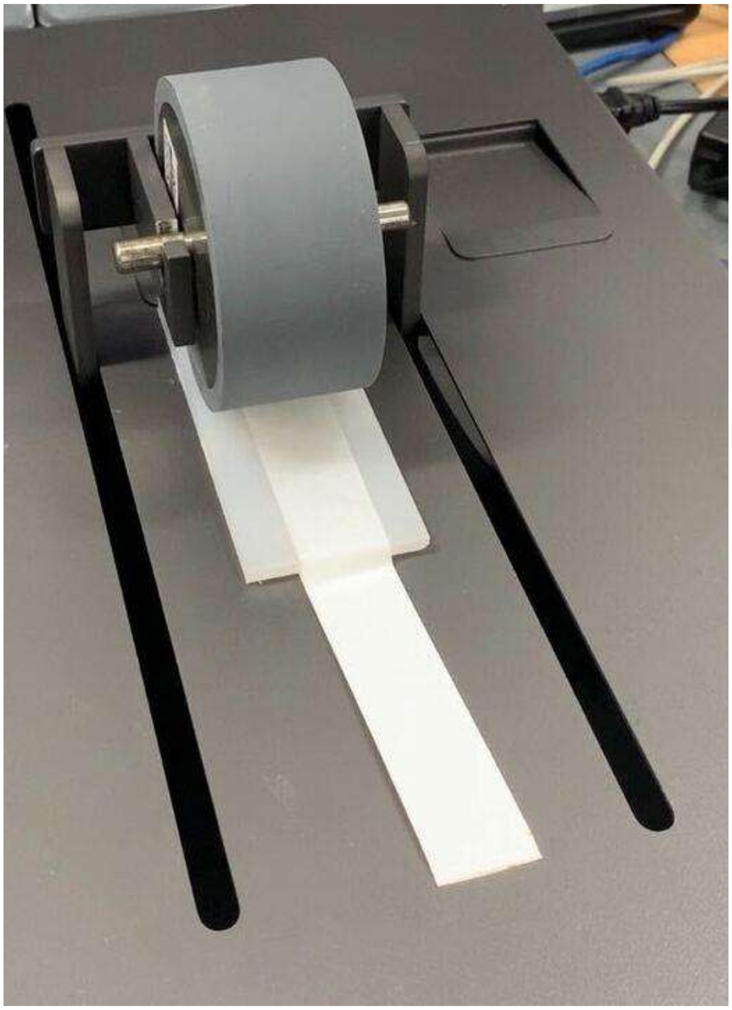


Figure 17: Sample Preparation of overlay material in the cheminstruments roll-down machine

Requirements Verification

Table 10: Requirement Verification

Req. #	Engineering Specification	Verification Method	Verified?
1.1	Adjustable perpendicularly to sample axis ±0.5”	Positioned micrometer to min and max	Yes, measured inner channel relative to instron head
1.2	Able to withstand 2 lbf of pull force	Simulated a peel test	Yes, some pre-tests went up to 6 lbs
1.3	Pull axis must be perpendicular to substrate at peel edge	Simulated a peel test	No, greatly reduced lag. Accepted error
1.4	Interface with a Single Column Instron 5943	Bolted fixture to Instron	Yes
1.5	Able to statically hold a 2”x5”x0.25” LDPE panel	Simulated a peel test	Yes, visual inspection

Req. #	Engineering Specification	Verification Method	Verified?

2.1	Pull axis must be perpendicular to skin at peel edge	A start would make sure that the forearm could be levelled	Yes, a bubble level was used to verify
2.2	Can withstand stresses up to 2 lbf and strain data	A 2+ lbf book was used to test strength of string and clamp design	Yes, a force gauge was used to measure applied weight

Figure 18: The arm fixture demonstrating that it can level a forearm

The way I calculated the range of movement for the wrist cup was by resting the arm on a flat surface and then placing a stack of cards under the wrist until the top of the forearm was level. Then I took that difference, added 0.5” to it and made that value the new difference in height between the wrist cup and elbow cup when the spring is not compressed for the arm fixture. During verification of leveling the forearm, the placement of one’s elbow on the elbow cup also played a factor in leveling the forearm. This gives me another option to level a test patient’s forearm.

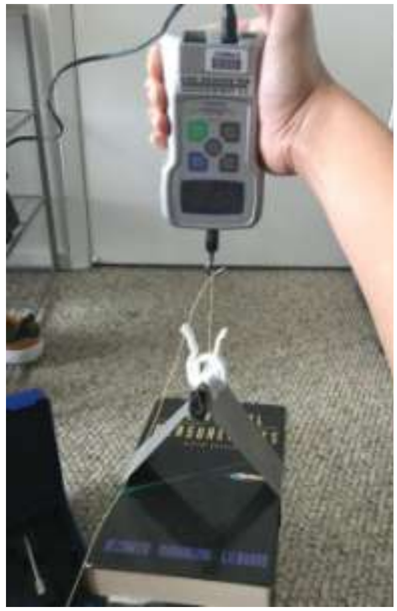


Figure 19: Prototype clamp demonstrating that it can grip 2.74 lbs

Since I wanted to make sure that samples would not slip out during testing, the jaws of the clamp are jagged. It was easier to print a prototype to test than it would have been to model considering the friction factors of the overlay protective material and reinforcing backing around the jagged teeth of the clamp. So I tested the jaws by lifting a book with them and they were able to hold 2.74 lbs. The kevlar string was overengineered and could withstand up to 50 lbs. Needless to say the kevlar string survived the 2.74 lbs test.

Test Results

Initial testing had one main issue:

There was a lag in the peel axis due to stretching of peel material.

Steps I took to mitigate lag:

- Reinforced backing with a less flexible material

- Reduced weight of dynamic portion of fixture

Separation of test backing and overlay material defeated the purpose of an inflexible backing because the overlay stretched anyway.

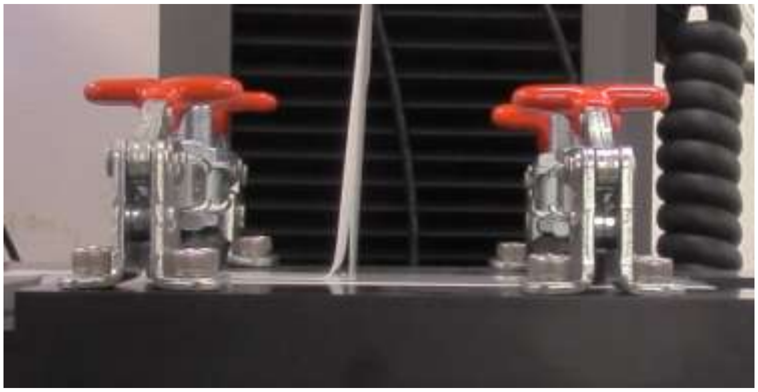


Figure 20: Separation of backing from patch

After testing an array of backings, a suitable reinforcing tape that eliminated stretch and remained in contact with overlay throughout the entire test was found. This was the red tape shown in Figure 13.

I reduced the weight in the dynamic portion of the instron fixture by swapping out the 4 toggle clamps for 3 screws with washers and a tension hold down clamp. Not only were the new hold down devices much lighter but that allowed us to remove material from the dynamic part of the fixture.

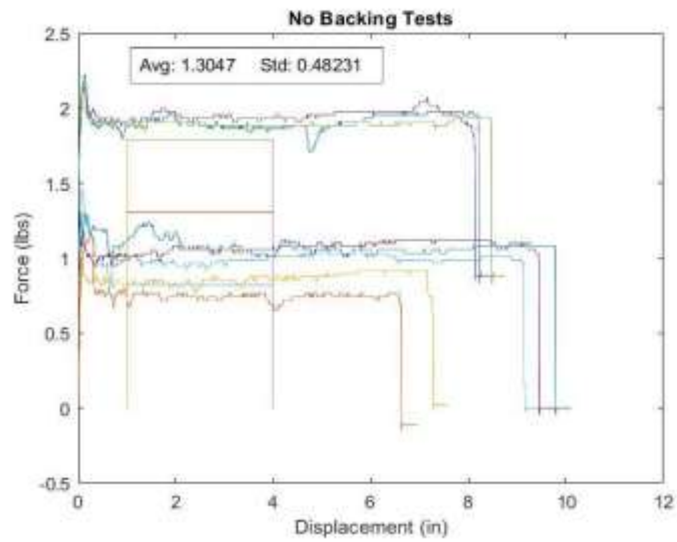


Figure 21: No Backing Tests

I had issues in the beginning with unreinforced tests. There was less adhesion shown by the smooth response and stretching in the material created lag.

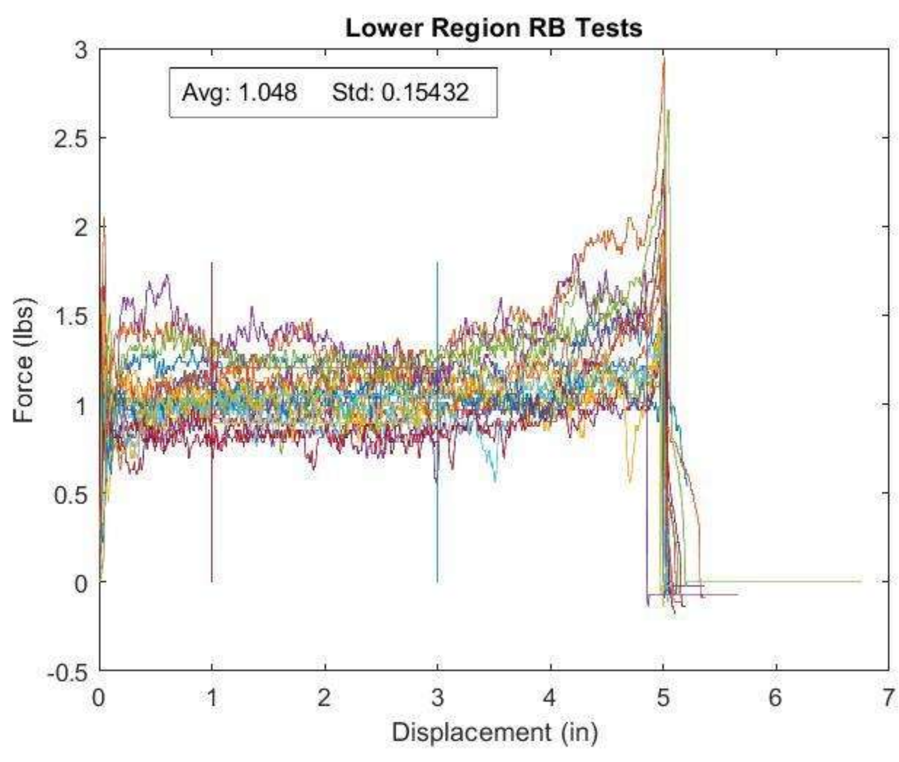


Figure 22: Lower Region Reinforced Backing Tests

After troubleshooting I learned that there were 3 types of responses. Tests that averaged in the 1 lbs range, tests that averaged in the 2 lbs range and tests that started in the 1 lbs range and transition to a 2 lb range. Since most tests were in the 1 in. range I chose to analyze those tests. Of these tests, the range from 1-3 inches showed a linear region that I used to get an average and a standard deviation. The method of analysis was consistent with ASTM methods. From this graph, I get a bench test standard to compare to the on body tests. These pictures collect the set of all the peel tests I have done with different conditions (sterilized and unsterilized).

Traveled Testing

Table 11: Traveled Work Requirements

#	Requirement	
2.1	Design a device to gather stress and strain data from an on-body peel test.	Pull axis must be perpendicular to the skin at the peel edge.
2.2	Gather stresses up to 2 lbf and strain data.	
2.3	Pull travel must be at least 10"	
2.4	Need to stop instantly in case skin pain.	
3.1	Compare data from instron peel test to on-body peel test.	Data used must be reliable and contain a region with standard deviation of 0.15 lbf.

Table 12: Traveled Work Verification Plans

#	Verification
2.1	Take a video facing pull test and observe with video analysis.
2.2	Intended to hang a 2 lb weight along the pull axis of gripping component, calibrate and position gripping component along length of travel.
2.3	Fix a tape measure to the same rigid body peel tester along the pull axis. Put grippers at lowest setting, attach tape measure tape, take the measurement, set grippers to highest setting, take measurement and get the difference.
2.4	Test emergency button with a test attached to a subject.
3.1	Create or find software to take data and finds regions with $\pm$0.5”

Table 11 and Table 12 show the traveled requirements and verification plans of the on-body design that I was not able to complete due to COVID-19. Although requirement 2.1 and 2.2 were simulated and verified with the arm placement fixture and a force gauge, further testing and verification is necessary when the on-body design components are fabricated and assembled. Traveled work that is to be conducted serves the purpose of comparing the peel bench test (Instron fixture testing) with an actual skin peel test (on-body fixture). This data comparison provides Dexcom with actual real life complications and variables of overlay adhesive strength that patients face on a daily basis. Stress/strain data that would be generated from an on-body peel testing system provides a strong background for Dexcom for further research and effort in characterization of overlay patch material performance.

These are the characteristics that the patch and their tests(as a summary) must have:

●Overlay patch size should not exceed 4.5” x 3.5” .

● It should allow skin to breathe and should be suitable for all skin tones and types.

● It should be gentle on skin and should cause least trauma during removal process.

● Should be flexible, comfortable and elastic so that it can move with skin surface easily.

● It should be water resistant so that user does not have to remove it while swimming or using showers.

● It would be latex free and hypoallergenic.

● It should be easy to cut so that it can be cut to size and fit on different versions of CGMs easily.

● Overlay patch should cover least area around the device as possible so that it does not cause too much irritation or trauma when removing. If patch occupies more surface area then it would cause more trouble when removing it.

● Overlay patch should be able to withstand extreme humid conditions up to 90% and body temperature up to 42ºC (considering hot season). When in hot weather, perspiration rate is high for human body, thus, skin humidity is higher.

● Some of the tests requires preliminary sterilization process to be done for which ethylene oxide gas exposure (EtO) is necessary. EtO process would be used for sterilization because it is done at lower temperature and would not damage the overlay patch material and adhesive. Which has been shown before when I was talking about the 90º peel test, when the cleaning was done, it hasn’t been exactly EtO but they have been sterilized.

● Material used for peel test bed should be corrosion resistant, high strength, chemically stable, clean, and smooth surface. Thus, substrate material considered is stainless steel.

● Test setup should be easy to produce, assemble, reliable in readings, and could be used for multiple types of tests such as tensile, peel, tack and shear strength test with least modifications.

Here is a drawing of the overlay patch with the measures and materials:

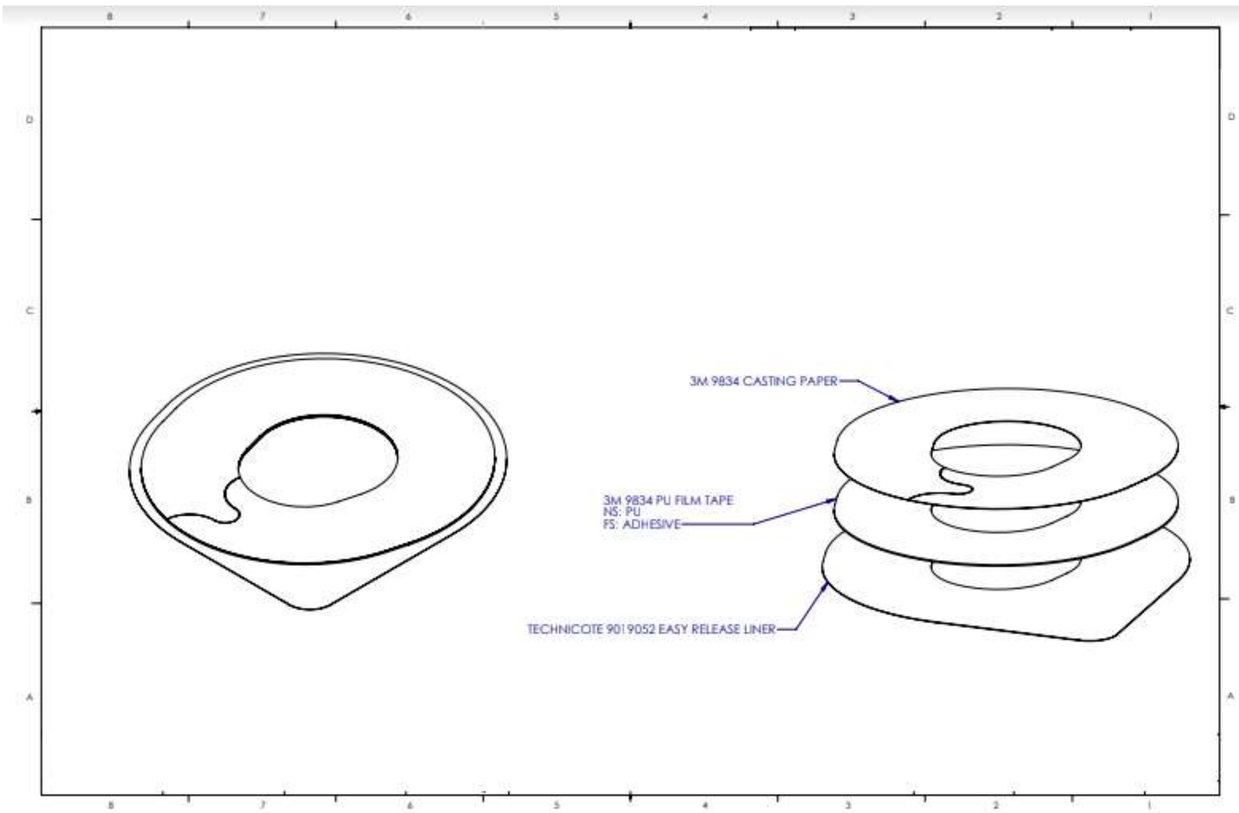


Fig 23: Overlay Patch drawing.

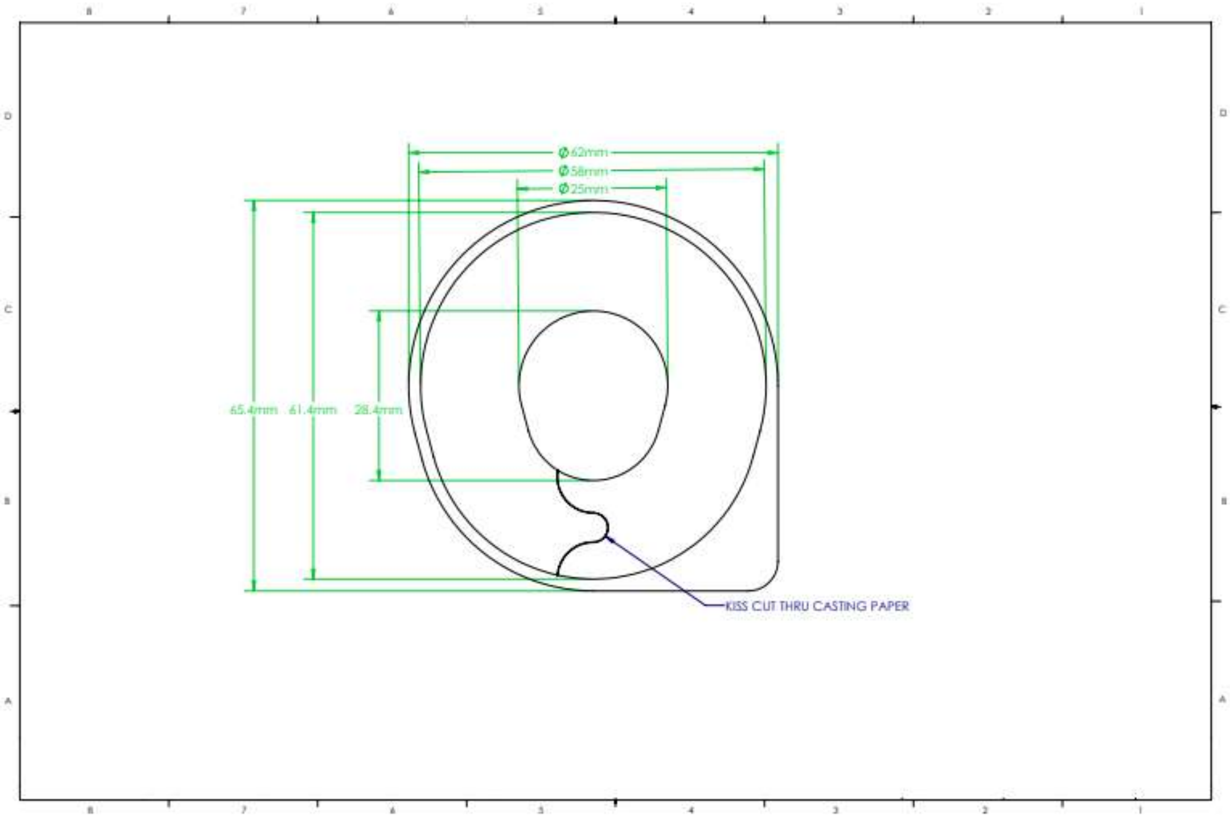


Fig 24: Overlay Patch drawing.

7. Project Summary

To conclude, my project Overly Patch Characterization, is sponsored by Dexcom. My collaboration was focused on testing an overly patch that is placed into a glucose monitor wearable to enhance the adhesion over time. The project is based on creating an Instron fixture, and the development of an on-body working model in order to compare and correlate the results between the two, and creating the final design of the patch. Also, to improve the quality and adhesion to be capable of 14-15 days adhesion if conditions are understood. This project will help those patients who suffer from retaining their wearable patches on their bodies. I had to conduct adhesive material characterization tests to evaluate the impacts of sterilization, temperature and humidity on the adhesive performance. I started focusing on the research for design aspects and testing methods and analysis. I followed a test plan to evaluate adherence and peel forces of overly patches when peeled at 90-degree angle from an LDPE test panel using the fixture that I designed tested on an Instron tensile tester. I have completed around 30 peel testing with the designed fixture. And the results I got were analyzed using ASTM standards. 19 out of the 30 peel testes that were collected, had the desired response. So, that was the range I decided to analyze. From the 19 tests that were analyzed, the system performance data I gathered showed an average peeling force of 1.048 lb. So, I decided to analyze those tests farther. In the second design phase, I worked on designing an on-body fixture, to be more realistic of how the patch is placed into the body. Which consisted of: an Arm Instron fixture with a purpose of statistically holding a subject's arm ,I intended for it to be comfortable and be accommodated with different shapes and sizes of people's forearms, that was done to be more similar to when the patch is placed onto the body, to help me with the final design of the patch. It was also designed to mount into the micrometer of the Instron fixture. I have completed manufacturing the arm fixture, but due to the COVID-19 outbreak I was forced to stop manufacturing the rest of the design. Therefore, testing on skin was not possible. Overall, I have compiled valuable test result data and fixtures that provides Dexcom with a strong background for continued research on overlay patch performance characterization.

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9.0 Appendix

Acronyms and Drawings.

ASTM	American Society for Testing and Materials
LDPE	Low-Density Polyethylene
EtO	Ethylene Oxide
COVID-19	2019 novel coronavirus

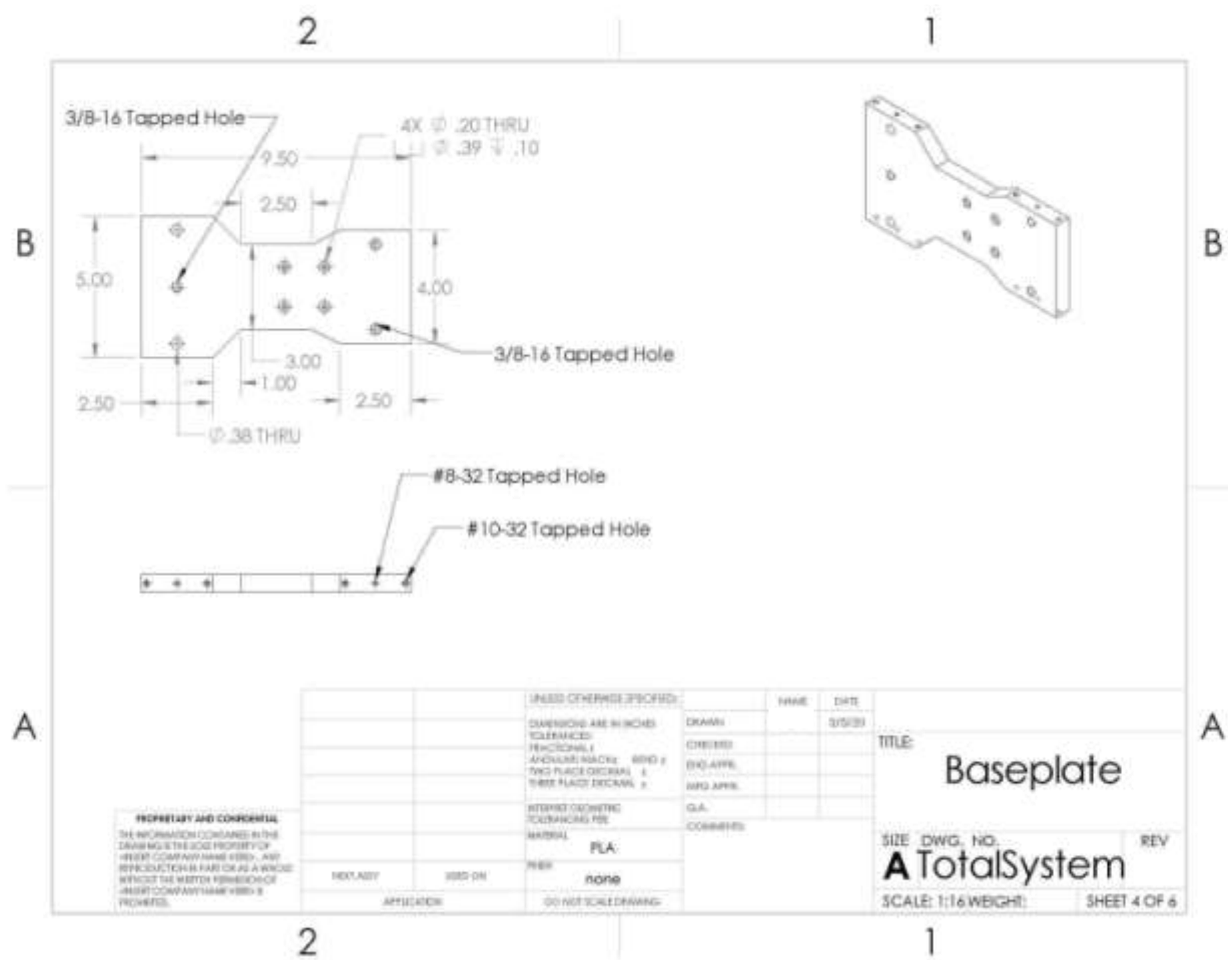

Figure 25: Baseplate adapter drawing

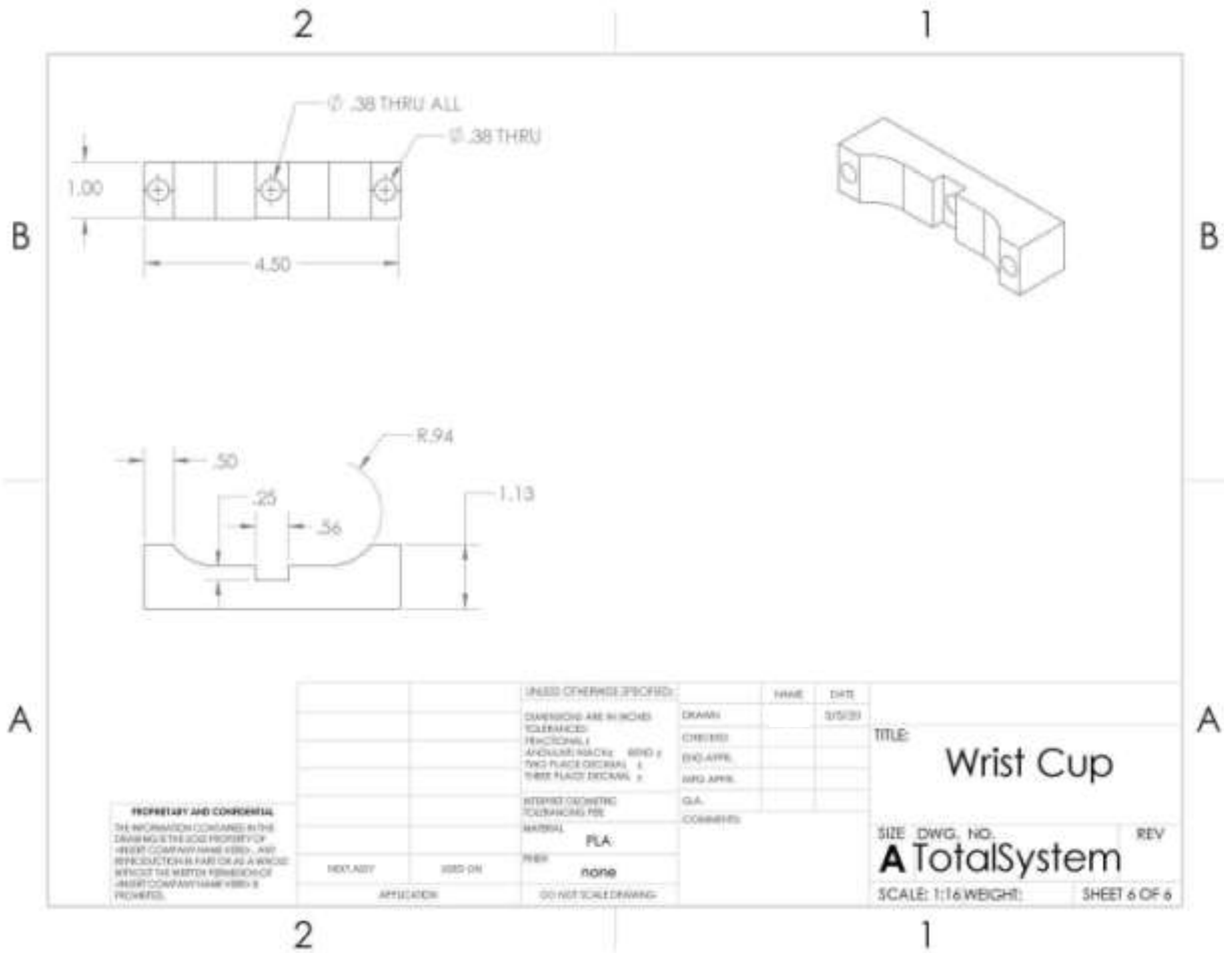

Figure 26: Wrist Cup Drawing

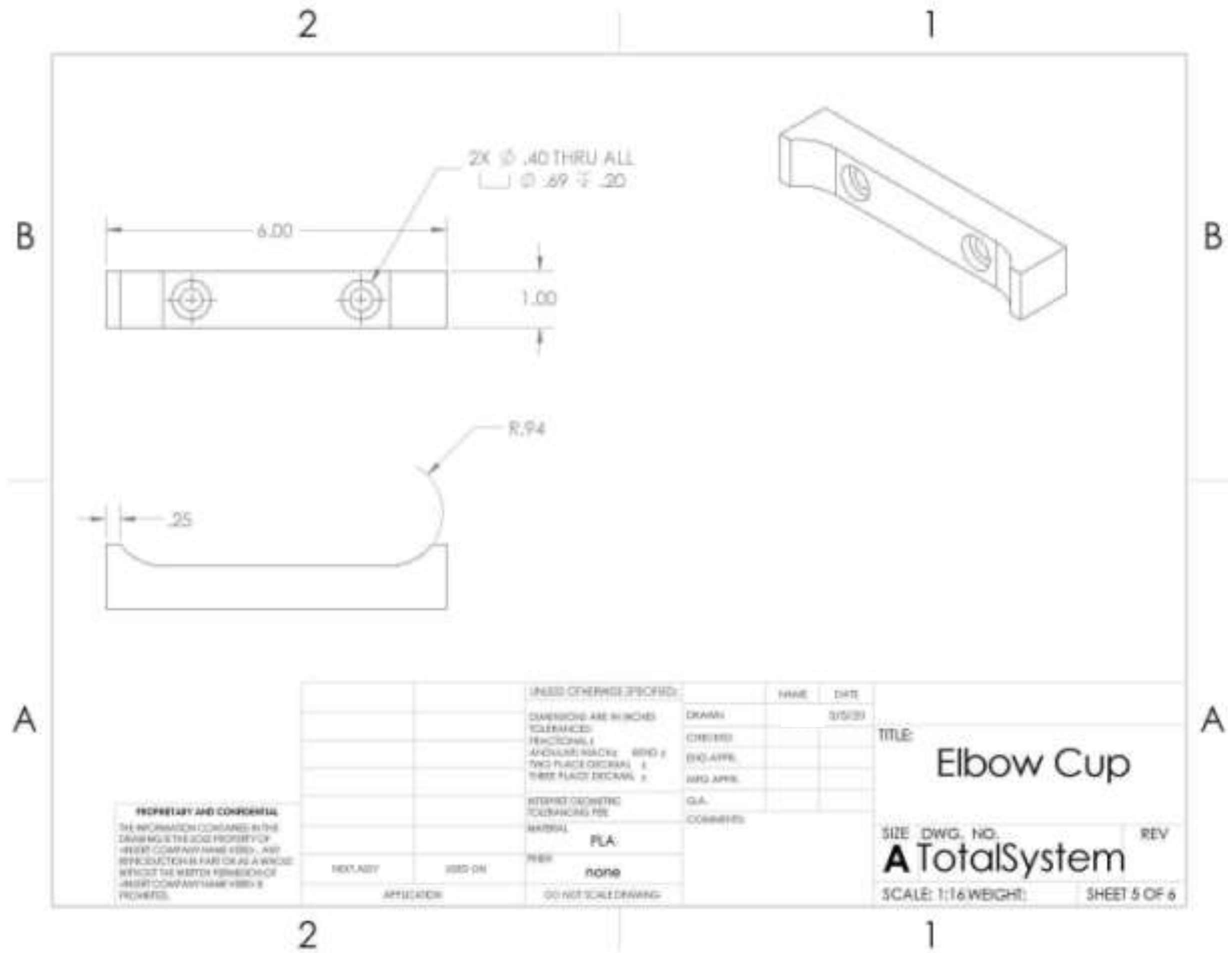

Figure 27: Elbow Cup drawing

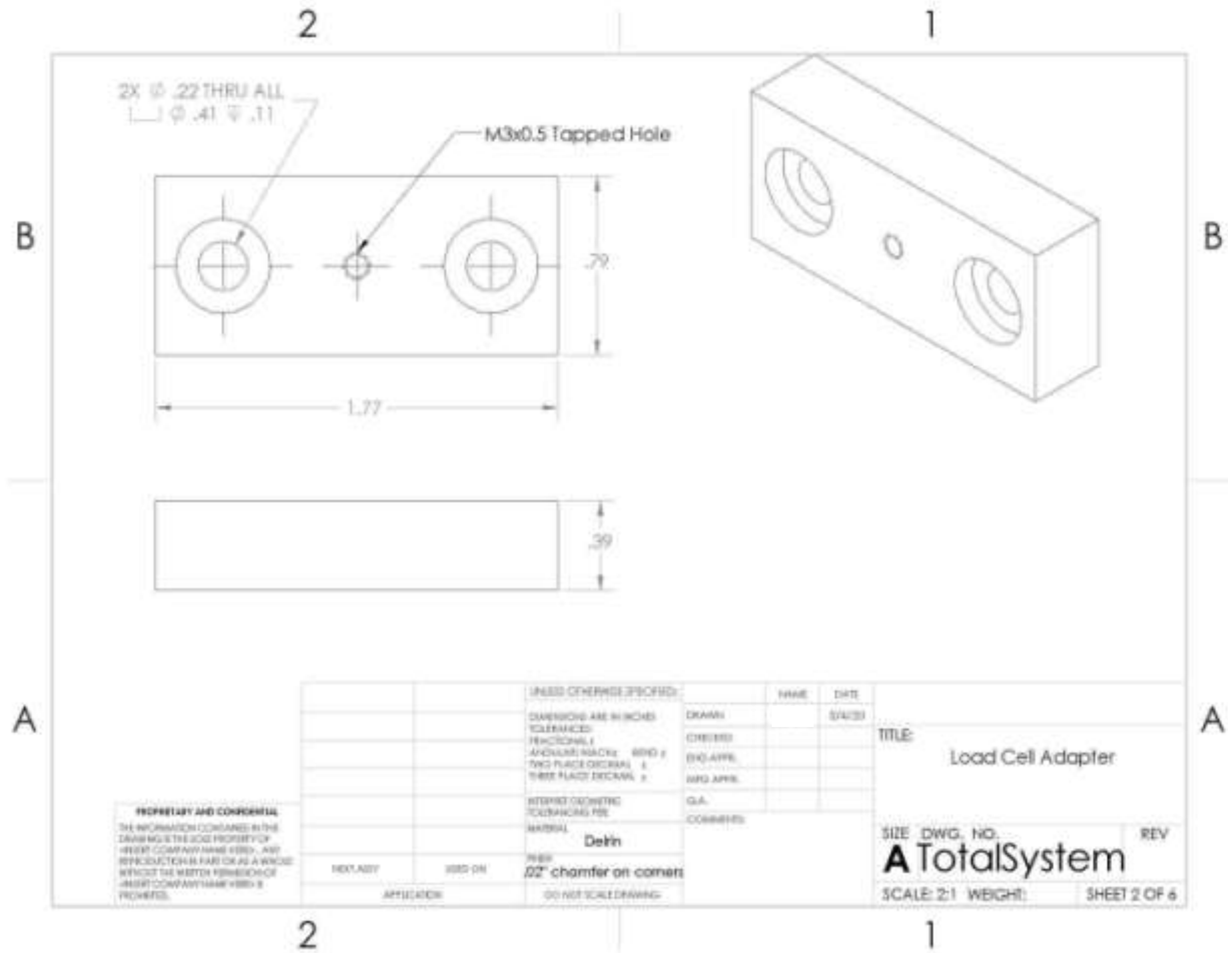

Figure 28: Load Cell Adapter drawing

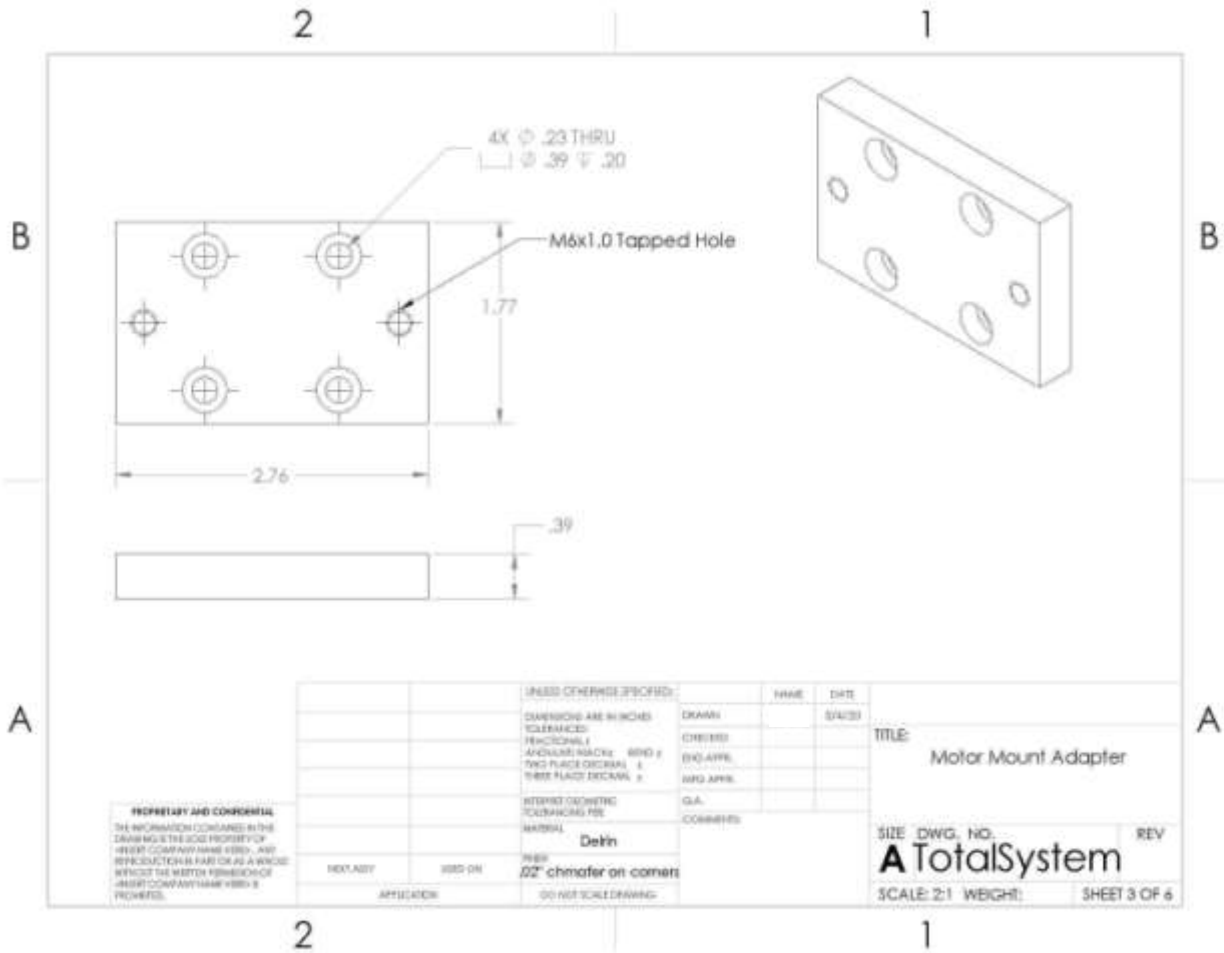

Figure 29: Motor Mount Adapter drawing