



SAN DIEGO STATE UNIVERSITY

# Dexcom Labeling And Adhesive Post Sterilization Testing

**Dexcom**  
One Step Ahead

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## Project Objective

Dexcom is a medical device company who manufactures wearable diabetes monitoring systems. In order to continuously improve their product line, new material combinations for their product labels, as well as research on how they interact while being sterilized is continuously being performed. The team was tasked with testing two unique label and substrate combinations to determine their viability for use as sterilized medical equipment labels. In order to properly test these new combinations, a custom fixture was developed which constantly varies the peeling angle, starting at 90° and moving towards 180°.

## Fabrication

The final product was assembled using a mix of pre-built parts, as well as aluminum stock that was cut to size. All machining operations were performed at SDSU's machine shop using a water jet cutter, and Prototrak Mill. The team would like to thank Mike Lester for guidance during fabrication, and SDSU for use of the machine shop.



## Requirements

Dexcom gave the following requirements in order to determine their packaging.

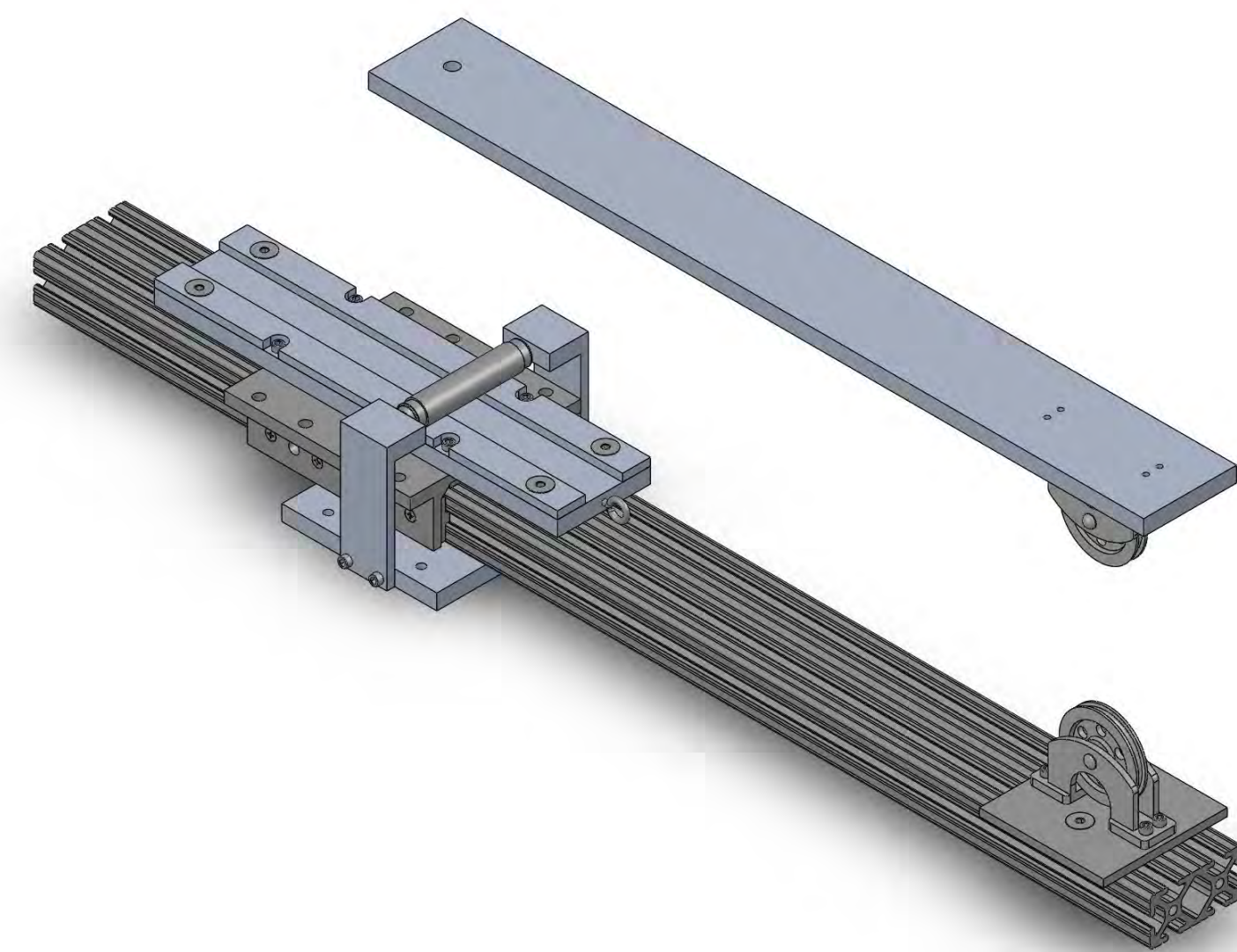
- Develop a test method to reliably and accurately test the sample combinations for their viability after Ethylene Oxide and electron beam sterilization.
- Develop a custom fixture to peel samples at a varying angle.
  - Simulates how a sticker is actually peeled
    - 90° - ~180° peel angle
- All testing must follow ASTM standards.

## Additional Research

Along with creating a fixture and test method, the team also researched two topics related to our project:

- EtO vs E-beam sterilization comparisons.
  - How materials are affected.
  - The effect it has on production.
- FDA recall
  - Types of packaging failure leading to recalls.
  - GS1-labeling organization standards.

## Final Design



## Fixture Design Characteristics

- Uses a pulley and cart system.
- Fixture is mounted onto the Instron tester using base plate.
  - Top pulley is bolted onto the Instron tester column.
- Top pulley moves as Instron column moves up to peel label.
  - Pulley pulls cart 2x faster than pulley moves up, pulling it across the roller to reach peel angle required.

## Samples Being Tested

Two different materials, Solid Bleached Sulfate (SBS) folding cartons, and corrugated brown shipping containers were chosen as label substrates for testing. Custom labels with barcodes and all relevant medical symbols were printed out so that both barcode scanning and visual inspection methods could be used.

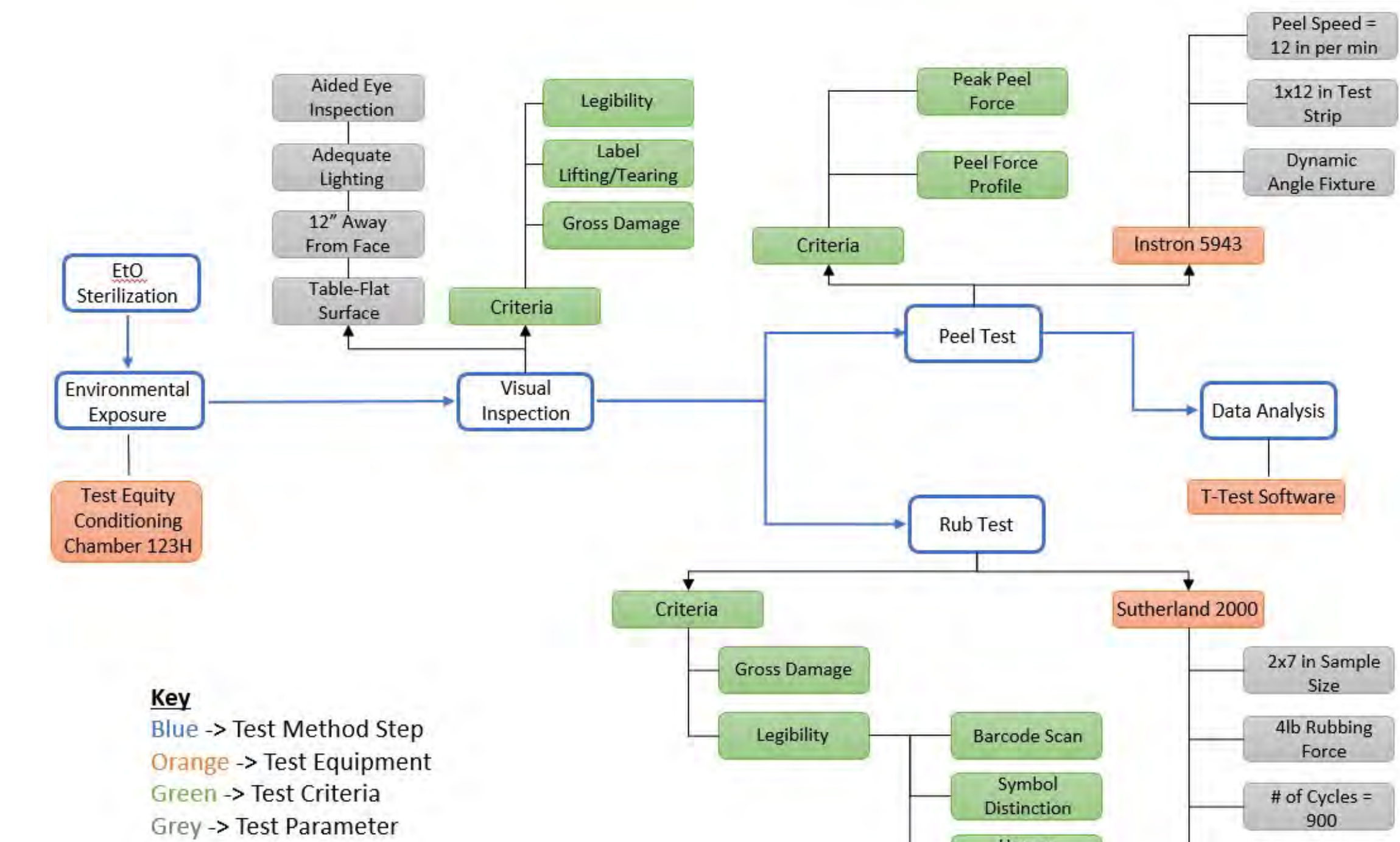


## Testing

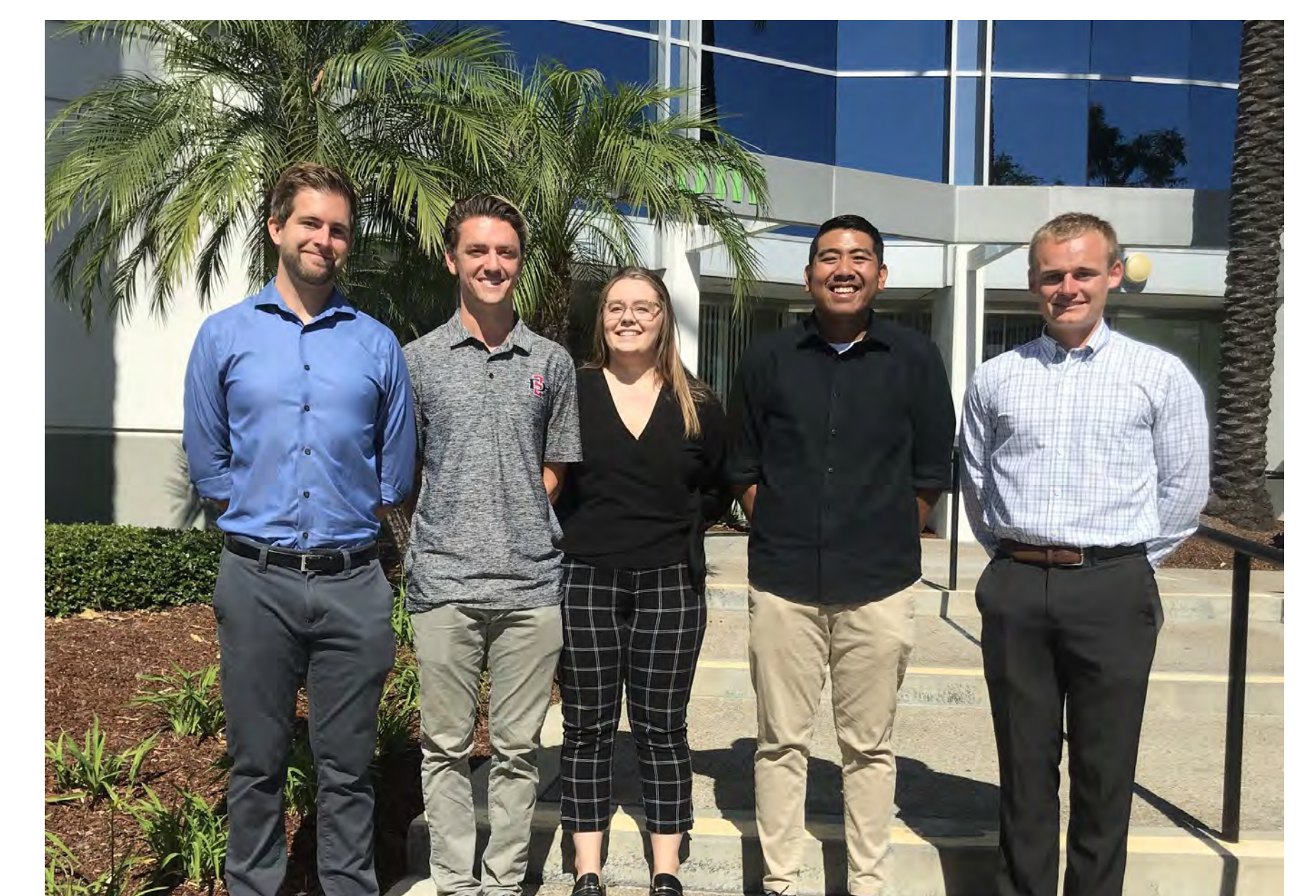
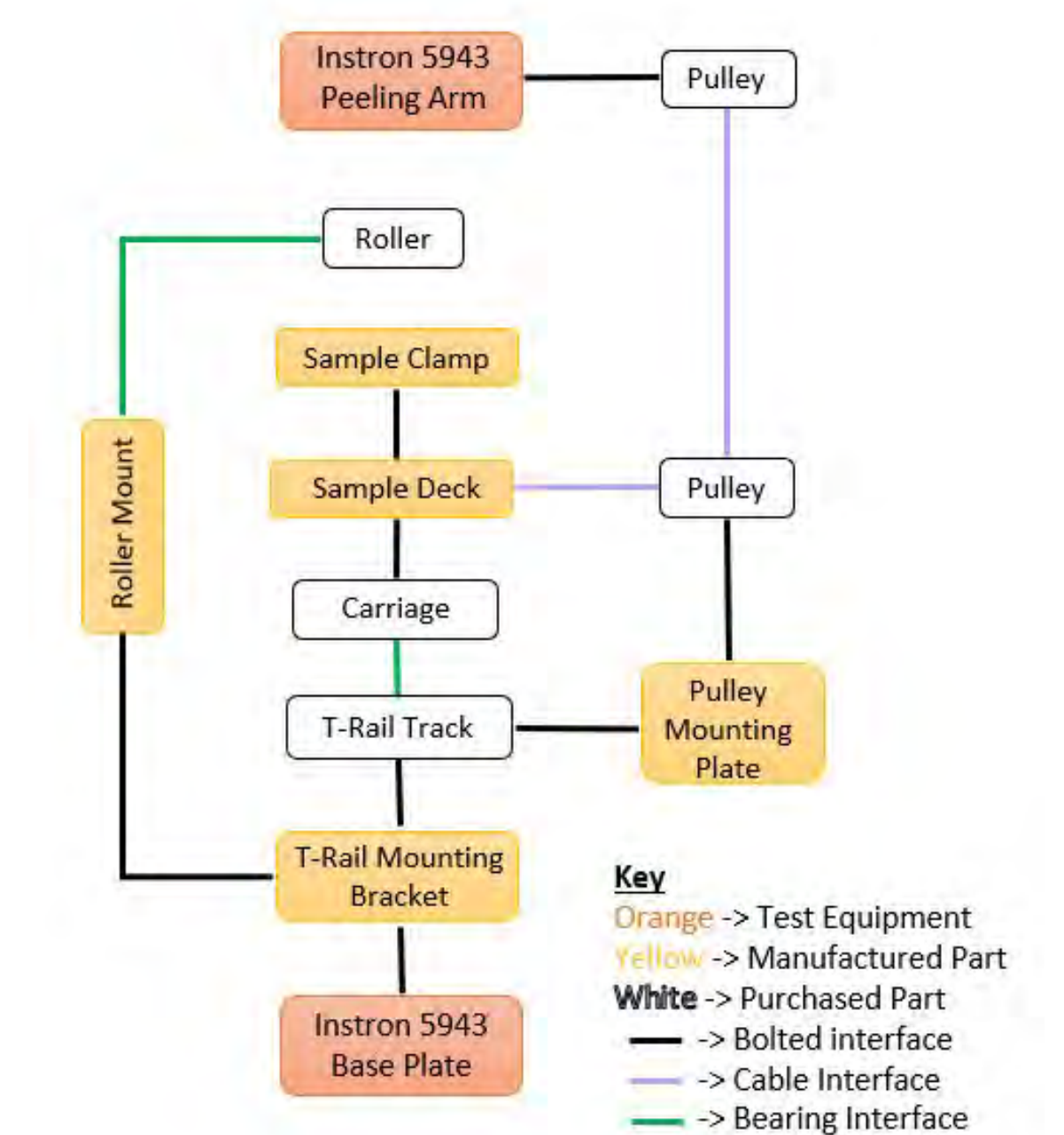
In order to test how well the label materials and substrates, an Instron 5943 Universal Peel Tester, and Sutherland 2000 Rub Tester are to be used. However, due to the COVID-19 outbreak, Dexcom and SDSU were forced to close and therefore this portion of the project remains as travelled work to be completed at a later date. Upon receiving the prepared and sterilized samples, they were to be divided into peel and rub test categories.

- Sutherland Rub Tester
  - Using a known weight, two samples are pressed together and rubbed back and forth 900 times at a specified speed to replicate packages interacting during shipping.
- Instron Peel Tester
  - Using the custom fixture developed, samples are attached to the testing bed, and a small corner of the label is peeled up and placed in the jaws of the Instron.
  - The Instron head then pulls up at a constant rate, as the custom fixture varies the peeling angle of the label.
  - Instron proprietary software then records the force required to remove the label at points throughout the test.
  - All data is recorded and analyzed according to ASTM standards and known label and substrate samples. From there, viability of label and substrate combination is determined.

## System Level Diagram - Test Method



## System Level Diagram - Fixture System



From left to right: Nicholas Greene, Sean Estabrooks, Sheridan Irvine, Mark Reyes, Devon Anable

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