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Lidding Web Alignment

Process Improvement of Blister Packaging at AstraZeneca

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Abstract

Efficiency within the pharmaceutical packaging process is critical for supplying patients and maintaining a profitable business. This report focuses on improving the efficiency of a blister packaging line at the Mt. Vernon, IN site within the AstraZeneca network. This report discusses the narrowing of the problem of sub-optimal line performance to a manageable project aimed at improving a major source of lacking operability and efficiency at the thermoformer on blister line 17. The consistent issues and equipment downtime on line 17 were analyzed, and excessive downtime was discovered relating to the lidding web walking at the thermoformer. This web walking phenomenon was discovered to occur when the lidding material of the blister would become misaligned when navigating the lidding printer, causing defective blisters and a lidding printing process that was difficult to control. This issue is detailed in this report as well as the web alignment system targeted at improving the line with regards to cost, efficiency, and operability.

This web alignment system was designed to be integrated into the lidding printer to provide a meaningful process control with substantial efficiency gains. In this project, a cost savings analysis was conducted based on the alignment system proposal to provide justification for the project. A lidding web alignment system was then designed using a chosen device from a vendor to integrate this automated solution into a limited space with highly specific design requirements. The design decisions made for this system are detailed in this report with engineering reasoning. This system was ultimately tested and qualified to be used during commercial production on line 17. This system was ultimately integrated effectively into the lidding printer and provided an efficiency improvement and cost savings, even exceeding the project goals, for AstraZeneca to better serve its patients and its business.

Acknowledgements

In this section, I would like to acknowledge that this project could not have been completed successfully without the support surrounding me. First, I would like to thank the University of Southern Indiana engineering department led by Dr. Paul Kuban for the many valuable learning experiences during my undergraduate degree. Each of the engineering courses throughout the four years of my manufacturing engineering studies were useful in building a strong foundation to be able to complete this project. From these learning experiences, I have been able to apply my learning of engineering principles to my work at AstraZeneca throughout this web alignment system project and beyond. I would like to thank the USI engineering faculty for their dedication to teaching and guiding students through the development of their career. I would like to especially acknowledge Dr. Susan Ely for her guidance throughout this project. Dr. Ely was very helpful in helping to develop the scope of this senior project, ensuring that I was meeting the project requirements, and applying my coursework to a project completed in industry.

I am also very thankful for the support that I have received from AstraZeneca. There are more people that have helped me than I can list here. I would like to thank Jonathan Laboy, the manager of the packaging engineering department, for giving me opportunities at AstraZeneca to apply my skills and embrace new learning experiences. I would also like to thank all of the members of the packaging engineering department for their mentorship and gradually teaching me about the packaging equipment and how to successfully complete projects at AstraZeneca. This project also would not have been possible without the support of other groups and departments at AstraZeneca. I would like to thank the maintenance team for their support during the installation of the alignment system as well as validation engineering for their support and collaboration with testing and qualifying the new system. The operational excellence team was also very helpful in helping to compile and analyze data. Finally, I would like to thank the line 17 operators for sharing their knowledge of the packaging process and giving their input for design decisions made in this project. Thank you to the AstraZeneca team for working with me and making this successful project possible.

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1.0 Introduction

The pharmaceutical industry is a growing, evolving, and essential industry. From being a significant driver of economic growth to serving the needs of patients worldwide to provide life-altering medications, this industry is very impactful to the surrounding world. Headquartered in the United Kingdom, AstraZeneca is one of the leading pharmaceutical companies in the world featuring continual growth and over 45 billion USD of revenue per year (Kemp). AstraZeneca features research and manufacturing for a wide variety of therapies from oncology to cardiovascular to diabetes spaces. One major operations site within the AstraZeneca network is located in Mt. Vernon, IN and focuses on manufacturing and packaging Type II Diabetes medications. This project is located within packaging operations at the Mt. Vernon, IN site.

The Mt. Vernon site has grown and evolved over the past decades. Within packaging, featured medications have evolved with the market as well as the equipment and processes utilized. Volumes have continued to grow each year, so the process has had to evolve to be able to efficiently package the product for the patient while maintaining high quality standards. Packaging at the Mt. Vermon site continues to seek opportunities for growth and expansion as well as continual improvement in both their bottle packaging and blister packaging processes.

While efficiency has improved as growth has occurred, more improvement is desired to be a world-class manufacturing site and output a large amount of quality product for the customer while increasing profitability. Critical to this manufacturing process for the company is that a lean approach is taken, in which waste within the process is eliminated to improve production efficiency. In this lean approach, it is desired for the packaging equipment to operate as consistently as possible without breakdowns and downtime in which product is failing to be produced. This project will focus on improving the efficiency of the packaging equipment and process on a specific packaging line, line 17, to eliminate waste within the blister packaging process and improve packaging efficiency.

In this report, an opportunity for significant improvement will be explored within line 17, a blister packaging line, and a specific problem defined to increase the efficiency of the manufacturing operation. This problem specifically identifies misalignment of the lidding web, discussed in Section 2.3, as a key issue impacting the efficiency of the line 17 blister packaging process. An automated lidding web alignment system will be designed and integrated into the current manufacturing system in this project. The requirements for a successful project within this pharmaceutical industry are discussed in this report as well as criteria for success. Ultimately, the major design decisions for the web alignment system are discussed in this report as well as an analysis of the major subsystems and their functionality. More detailed information is further provided in the appendices of this report relating to the project schedule, bill of materials, and a detailed failure modes and effects analysis.

2.0 Background

With a focus on improving the blister packaging process, this process must first be understood. A blister card, displayed in Figure 1, consists of an aluminum forming material with pockets to be filled with tablets, and an aluminum lidding material to cover the tablets. The lidding material is typically printed with product and market specific artwork for identification.

Figure 1: Blister Card

(“Buy Xigduo XR 10mg/1000mg Tablet 7’s Online: Check Price & Substitutes.”)

The forming material is mechanically “formed” to create pockets, and then the pockets are filled with tablets. After the pockets are filled, the lidding material can then be heat sealed to the forming material to close the blister before the blisters are perforated and then punched out using a cutter. At the blister sealing station, the lidding material meets the forming material after it has undergone its own introduction process. The lidding material is fed into a digital printer where it is transported to a printing station, the print is cured using UV light, and the material is stretched all before it comes into the sealing station. This entire process, which is automated, is considered the larger “thermoforming” process. After thermoforming, the filled blisters are transported down the line into the cartoner and ultimately through a checkweigher, tamper evident sticker machine, casepacker, and palletizer to be fully packaged for the customer. This process can be visualized in Figure 2 below. The line 17 thermoformer is pictured in Figure 3, and the lidding printer is seen circled in the top right corner of the figure.

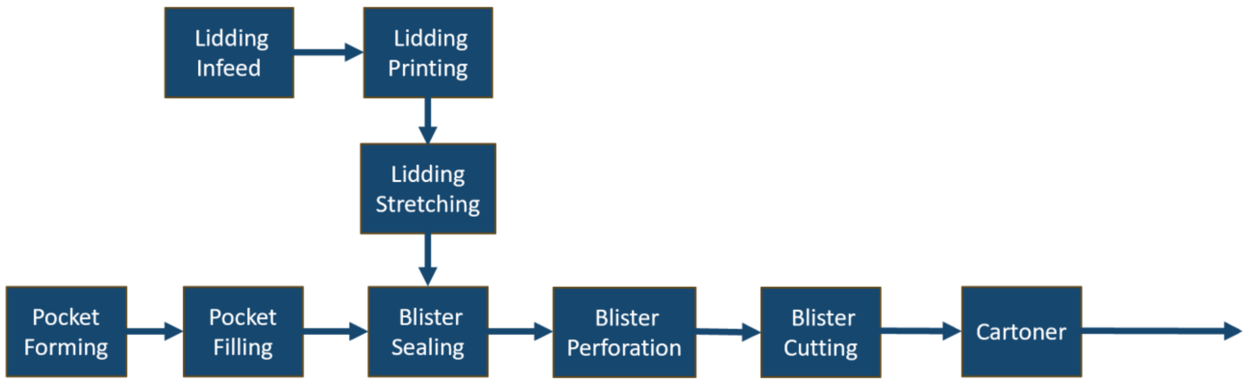

Figure 2: Thermoforming Process Map

Figure 3: Line 17 Thermoformer

2.1 System Hierarchy

Given that the lidding web alignment problem and system considered in this project are a small part of a large pharmaceutical business, it can be difficult to identify where this fits as a part of AstraZeneca operations and goals. AstraZeneca's Mt. Vernon, IN site is a leading manufacturing site in the network as it is the main location of the Type II Diabetes medicine franchise within the company. AstraZeneca has developed bold goals for its future including a goal to increase revenue from about $46 billion in 2023 to $80 billion in 2030 (Kemp). AstraZeneca also aims to launch 20 new medicines by 2030 to deliver life-saving solutions to their patients (Kemp). With the commercialization of major Type II Diabetes medicines including Farxiga and Xigduo, the Type II Diabetes franchise is very important within the AstraZeneca network as the company presses forward toward bold goals. The centrality of the

Mt. Vernon site in the manufacturing of Type II Diabetes medicines is displayed in the system hierarchy below in Figure 4.

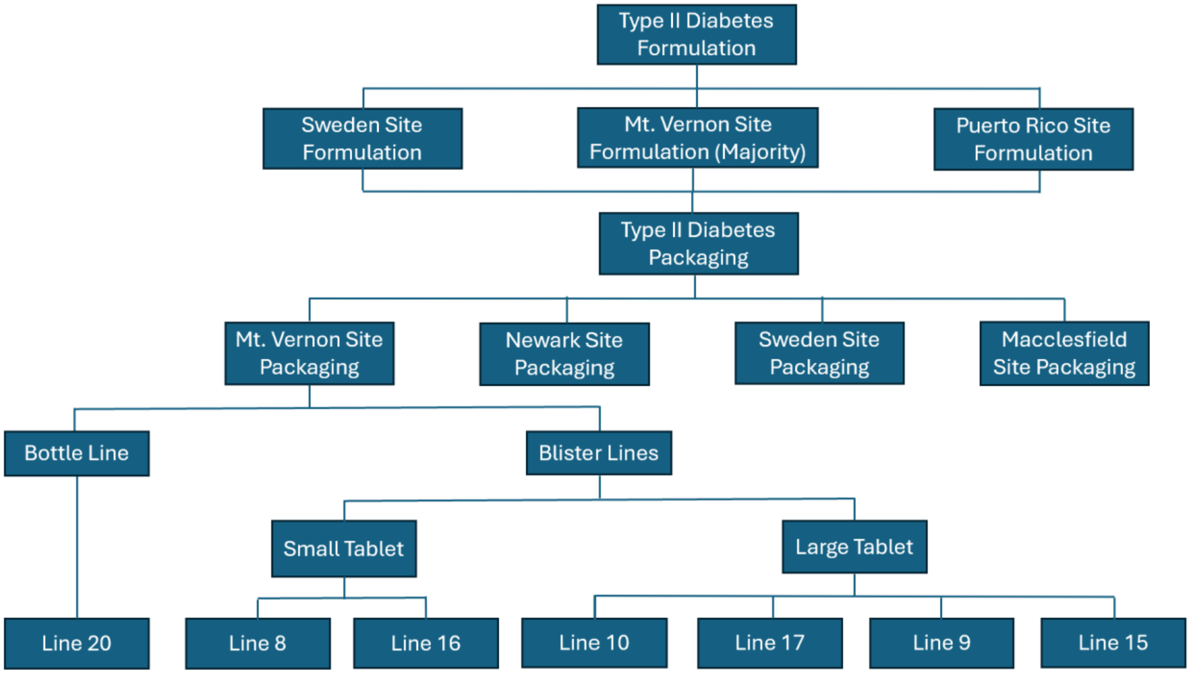

Figure 4: AstraZeneca Type II Diabetes Packaging System Hierarchy

The placement of the packaging line 17 system, which this project is focused on, within the overarching system of the Type II Diabetes medicine manufacturing at AstraZeneca can be seen in Figure 4. Line 17 is one of seven packaging lines at the Mt. Vernon site, and one of six blister packaging lines. Line 17 is also a line designated for large tablets, while lines 8 and 16 package small tablets, which currently carry lower volumes.

Tablets are formed in an overarching process called "formulation." The Mt. Vernon site produces the majority of the Type II Diabetes tablets within the network, while sites in Sweden and Puerto Rico also contribute. These tablets are then packaged between multiple sites, including Mt. Vernon which carries the largest volumes. With line 17 at the Mt. Vernon site carrying some of the highest volumes of blister packaging for Type II Diabetes tablets, it is of strategic importance within the Type II Diabetes packaging system. So, an efficient process for packaging on line 17 is of heightened importance for AstraZeneca as a part of its strategic goals. Process improvements along this line not only assist in the critical significance of delivering quality medicines to the patient but also making the best use of capital within a growing industry of ambitious business goals.

2.2 Packaging Department Performance Initiative

Given the state of the pharmaceutical market and its growing demand, it has become critical for the packaging department to continue to improve in efficiency to increase profitability and meet demand. To capture the efficiency of the packaging process, Overall Equipment

Effectiveness (OEE) is regularly calculated and reported at AstraZeneca for each packaging production line. OEE is the fraction of the time the equipment is producing products that meet specifications in the time that production can be run. OEE consists of three components which are equipment availability (A), performance (P), and quality (Q). This is calculated using equation 1 (Santos 14).

$$OEE = A * P * Q$$

(eqn. 1)

Availability is the calendar time that the line is available for work, and its percentage is most impacted by changeovers. Quality is the percentage of acceptable units of product out of those produced and is impacted by defects. Performance captures the amount of product that is run through the line when it is available to be running. Performance percentage is dropped by unplanned downtime due to breakdowns or short line stops, as well as a slowdown of cycle time. In the current state of operations at the Mount Vernon plant, quality and availability values are very good, so the most is to gain for OEE by improving performance. Management has noticed that performance is consistently keeping OEE values below its potential across the department, so they have made improving performance a point of focus. Furthermore, lines with more demand have more effect on the success of the department, so improvements on these lines are most critical. Line 17 is one of the most heavily loaded packaging lines given the demand for the products run on this line, so it is of heightened focus amongst the packaging department.

2.3 Narrowing the Problem – Data Analysis

When analyzing the performance of line 17 through data collection and analysis, the thermoforming process became a major area of focus as it was found to have the most room for improvement. Carrying heavy demand and operator workload, it became clear that solutions would be needed to increase the line's performance. The target performance level is 65%, but the actual performance was 8% below this target monthly on average in 2024. This performance gap has been identified to be caused by a combination between short line stops and downtime events, defined as a line stoppage lasting at least 15 minutes. Through compilation and analysis of downtime data on line 17, issues at the thermoformer account for over 40% of the line's downtime. Further, the Mean Time Between Stops (MTBS) on line 17 is analyzed for trending. While the MTBS has gradually increased on the line, the MTBS at the thermoformer has remained the lowest of any of the processes recorded along the line thus indicating that it has the most frequent stops. The MTBS at the thermoformer is only 7.8 minutes while the MTBS is 7 minutes on the entire line and significantly higher at the other machines. So, the thermoformer accounts for the most frequent stops. Therefore, since the thermoformer causes the most frequent stops as well as the most downtime on the line, it should be a place of focus for meaningful improvement of line 17 performance to maximize its uptime.

The major sources of downtime at the thermoformer are further broken down to the main causes shown in Figure 5. It can be seen that lidding tears, web walking, print alignment or registration issues, and vision system issues are some of the most impactful causes of downtime at the thermoformer, and actually on line 17 as a whole. This downtime data was compiled over 6 months making up the first half of 2024 by the operational excellence team at AstraZeneca to be analyzed by engineering. The pareto diagram in the figure below shows these major causes of downtime at the thermoformer with those related to a common web walking issue, which will be discussed throughout this report, highlighted in yellow.

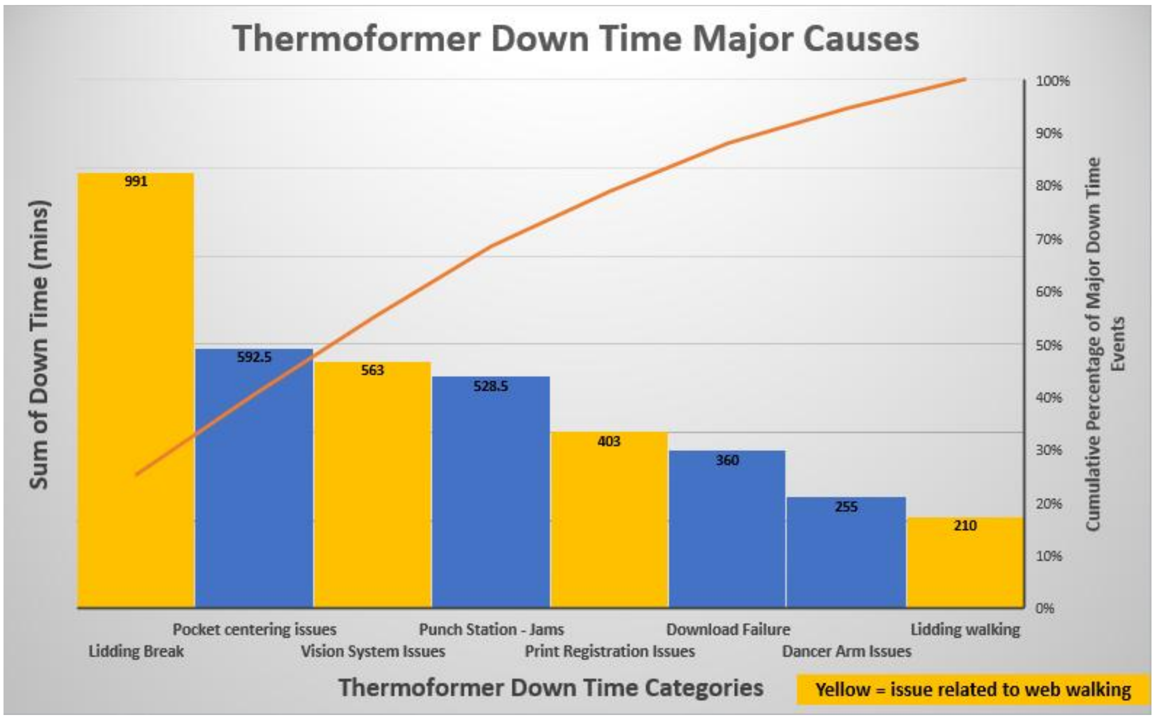

Figure 5: Line 17 Thermoformer Leading Downtime Causes

A common issue that has been observed is the web walking throughout the printer, a phenomenon in which the web moves laterally as it passes over rollers and fails to line up with the forming material when the blister is sealed. A web is strip of material that is "very long in relation to its width, and very long in relation to its thickness" (Shelton). In this case, the web is the thin aluminum lidding material that traverses through the lidding printer and is ultimately sealed to the top of the blister. Issues with web walking have resulted in long downtime events, classified as a duration of over an hour, with lidding and forming material failing to align properly. Web walking also has led to much of the downtime associated with print alignment issues due to printing in the wrong spot on a poorly aligned web as well as incorrect alignment into the vision system for checking this print alignment. The incorrectly aligned web has also been the cause of some of the downtime associated with lidding tears as the misalignment can cause tears as the web is being stretched at the stretching station. Also, some of the downtime due to vision system issues can be attributed to web walking due to its misalignment. Given that the root cause of many stops and downtime events on line 17 is the walking of the lidding web, a solution for this issue must be investigated. With the notable consequences and impact of this web walking phenomenon, this will be the focus of the problem for this project to make an impact on the performance of line 17.

2.4 Statement of Problem Focus

This project will focus on combatting this issue with the web walking in the line 17 digital lidding printer and the consequences of this issue. While this issue was not observed when the machine was new, it became prevalent over years of machine wear. The rollers in which the web traverses in the lidding printer have begun to sag over time after undergoing regular forces, and this, in combination with imperfections in the lidding material, causes the machine to lose alignment and the web to "walk" as it passes over the rollers which are now not perfectly square. Nip rollers, noted in Figure 6, that pull the web along to move it through the printer have undergone wear and further exacerbate the issue with the web failing to retain its lateral position throughout each touchpoint with a roller throughout the machine. Overall, through slight machine wear, issues with web walking have gradually become more prevalent. This wear is inherent to the machine and must be controlled to prevent the issues that have been identified.

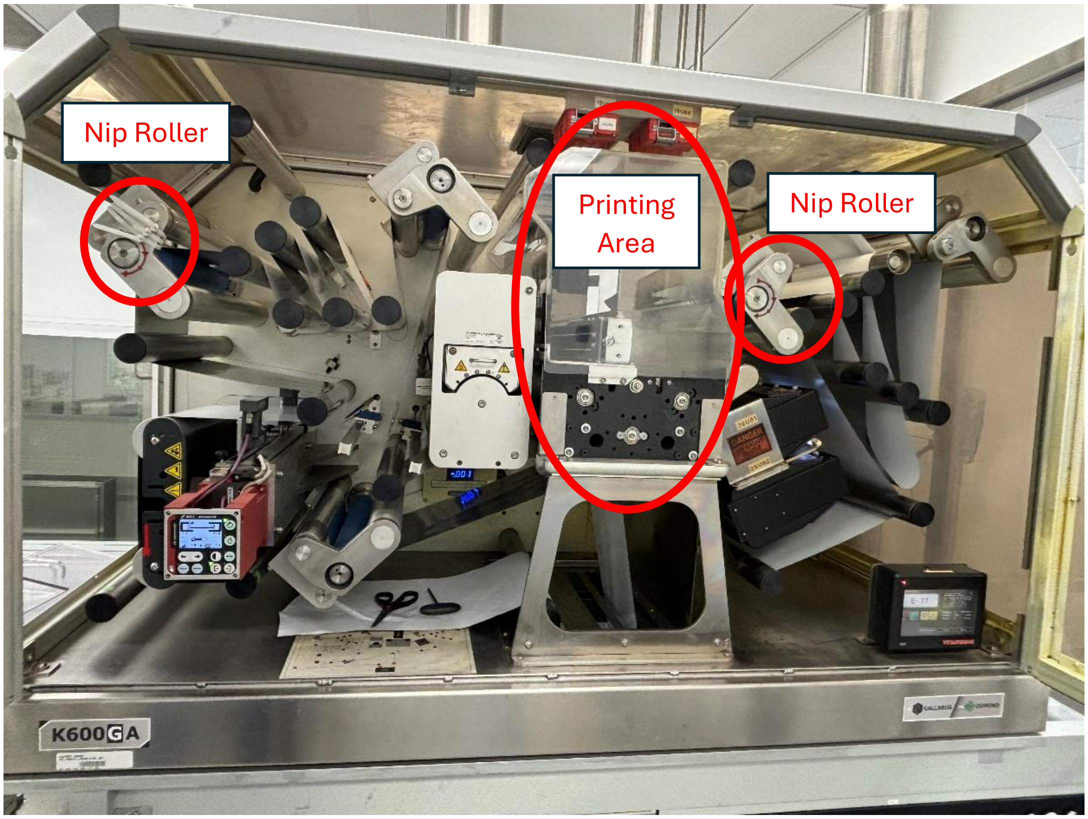

Figure 6: Inside of Lidding Printer

In this project, a solution must be developed to integrate a way to control this web walking in the digital lidding printer. A method of aligning the web must be used to overcome the imperfections in the lidding printer to gain control over the position of the web before the sealing station. While the web is already aligned using an alignment device before it enters the printing station, another method of alignment must be integrated into the system to align the web as it traverses a long distance after printing and before being sealed to the forming material. Thus, this new alignment method must be integrated into the lidding printer which has a limited space, so the challenges of integrating a new system into a pre-existing machine must be considered. This web alignment solution needs to be capable of controlling the web for the future life of the lidding printing machine on line 17. This project ultimately needs to minimize issues from web walking and the associated problems to reduce downtime on line 17 at the thermoformer and increase the performance of the entire line.

Ultimately, offering a solution to this web walking issue through a web alignment system would be expected to offer cost savings for the company. Based on the data analyzed in Section 2.3 as well as understanding of the issue and proposed solution that will be detailed in this report, it was estimated that 30 hours of downtime on line 17 would be eliminated per year by completing this project. This is based on realistic assumptions for how much of this downtime would be expected to be eliminated for each of the downtime categories related to web walking. For example, it was estimated that 20% of the lidding breaking downtime would be eliminated due to reducing the frequency of tearing at the sealing station due to better alignment, while possible tears would likely not be prevented in other areas of the lidding printer before the application of the alignment device. Additionally, some savings would be estimated to occur in material savings by eliminating the waste observed during the troubleshooting of these issues from web walking. Overall, based on the cost of the materials saved and the AstraZeneca provided cost of downtime on line 17, $70,849 of yearly savings were estimated from completing this project. This estimation was presented to management in order to justify the costs of this project. With a cost of $19,000.45 for the project, the payback period estimated was approximately 3.25 months. The final cost implications of the project are further discussed in Section 6.3.

2.5 Existing Solutions for Web Alignment

Multiple companies have created products to assist with the alignment of a web. Across the packaging department at the Mount Vernon site, web alignment devices have been used from two different vendors: Maxcess-Fife and BST. While AstraZeneca has some experience with web alignment devices, these have come as a part of a larger machine sourced from another vendor, so they have never purchased a new web alignment device as a standalone product and integrated it into an existing process.

Devices for web alignment and guiding have been around for decades and advanced over time, with the first web guide being invented by Irwin Fife in 1939 to keep paper in a newspaper press aligned (Fife: Web Guiding Equipment). This invention leads us to the Maxcess-Fife company that exists today for selling web alignment, or guiding, solutions. Another company, BST, manufactures custom web guiding solutions for precise alignment for a variety of production applications from web infeeds to unwinding and from rubber manufacturing to paper products (Ellerbrock). Yet another company that has developed solutions for web alignment is Roll-2-Roll Technologies. In general, all of these web guiding devices tend to use the normal entry principle for correcting web movements which involves deliberately changing the axis of rotation of the guide roller to steer the web to its desired position ("Web Guiding System: Why, What, Where and How?"). This works because a web "tends to align itself perpendicular to the axis of rollers" ("Web Guiding System: Why, What, Where and How?"). From a top-level view, these web guiding devices typically use sensors to detect the position of the web in conjunction with a controller that sends signals to an actuator to control the device and ultimately the position of the web. These devices have proven effective for automatically correcting web position, so a web alignment device tailored to the problem statement with the line 17 lidding web will be considered in this project.

3.0 Conceptual Design

The design of this web alignment system is primarily concerned with the overall improvement of AstraZeneca processes and its goals. This project fits within the constraints of what can be accomplished at the AstraZeneca Mount Vernon site and must attain its approvals. Each component of the new web alignment system needs to be designed to be reliable for full-speed production on line 17. Therefore, the desired outcome of this project is not a prototype, but a fully functional, streamlined, and improved system. While it would be possible to design a web alignment device from scratch, this would be a different design process that has already been accomplished in the past and would not be geared toward this specific problem statement. This project includes the decision process for the desired specifications and needs for an alignment device that would best integrate into the line 17 thermoforming process but relies on a chosen vendor to construct the device.

From a conceptual perspective, the web alignment system will be designed to modify the web handling already imbedded into the digital lidding printer to control the web on the exit side. A chosen web alignment device will be used that corrects the position of the web in real time and can be integrated into the lidding printer system. With very limited space, the design process will be needed to discover the best solution for including this new system. The web alignment device will also be mounted into a pre-existing space, and it must allow for the proper angles and distances for the device to allow for correction. Also, a digital interface to control the device will be mounted, and considerations must be made in the design process given that the alignment device will be stationed over 7 feet above ground level. Powering and controlling the unit is another consideration for the design of the system for the web alignment device to function in conjunction with the existing process. The web alignment system will operate continuously as the line runs on a 24-hour, 5 day per week schedule.

3.1 Requirement Specifications

To meet the objective of this project to improve the line 17 thermoforming process by controlling the alignment of the lidding web, key requirements have been established. To accomplish this overarching purpose, the following specifications must be met. The evaluation metrics for these specifications are listed in Section 3.2.

- ✓ Improve line 17 performance
- ✓ Reduce downtime associated with web walking
- ✓ Reliable for 3 shift, 5 day per week production
- ✓ Maintainable by AstraZeneca

Additionally, to properly integrate a web alignment device into the lidding printer system and thermoformer system, the following specifications must be met.

- ✓ Automatic, accurate correction for web movement
- ✓ Configurable for aluminum lidding material
- ✓ Retain proper web tension for web handling over rollers and into sealing
- ✓ Retain proper web speed for qualified production at 260 blisters per minute
- ✓ Lidding printer system remains enclosed
- ✓ Device rigidly mounted with sound engineering design
- ✓ Device setup follows manufacturer recommendations
- ✓ Device has proper infeed and outfeed for correction

Finally, the needs of the line 17 operators are also critical to consider as they will interact with the system regularly. To meet the requirements of the operators and the business, which must comply with pharmaceutical industry regulations, the following considerations must also be met.

- ✓ Device digital interface easy & ergonomic to access
- ✓ Device can be shut on or off in no more than 2 interactive steps
- ✓ No additional manual process steps
- ✓ No exposed rollers in commonly accessed areas
- ✓ No exposed sharp edges
- ✓ Complies with industry GxP regulations
- ✓ Installation and qualification of new system fits within the line 17 production schedule

3.2 Evaluation Criteria

To meet these specifications, evaluation criteria were developed to analyze the success of the web alignment system. In the workplace, the change control and validation process will be used to test and document the changes made to the system to ensure functionality. This ensures that there are no quality concerns for the customer, and that the change accomplishes the goal of the project. Outside of the specific criteria set in the workplace, the following criteria will be used to evaluate the success of the project.

- ✓ Line 17 performance increases by 1%
- ✓ Downtime from web walking reduces by 75%
- ✓ Web tension is maintained - not causing bunched lidding, tears, or slack at the sealing station
- ✓ Web speed remains within a range from 40.5 to 42.5 feet per minute
- ✓ Lidding printer system remails enclosed
- ✓ Alignment device structure does not sag or deform
- ✓ Alignment device automatically corrects web as the sensors detect movement
- ✓ Operators are comfortable with the new system design
- ✓ Sign-off on change control from Validation & Compliance
- ✓ Installation and qualification completed in the allotted planned downtime

3.3 Design Framework

The framework for this design project was largely determined to fit into the needs of the industry scenario and is pictured in Figure 7 below. Given the nature of the larger problem, which is the effort to improve line performance, much consideration was made to narrowing the problem to a reasonable scope. This discovery process led to identifying a common issue with the results of the lidding web walking, and thus a need for this specific project. From there, ideas for solving the problem could be created and designs developed to fit within the AstraZeneca budget, approvals, and timeline. This timeline was especially critical due to the high demand on line 17 which leaves little time for project implementation work. Due to time constraints set by production scheduling, it was critical for the new web alignment system to be able to be installed and validated within 24 hours, so the design was evaluated to be possible for a robust and efficient installation.

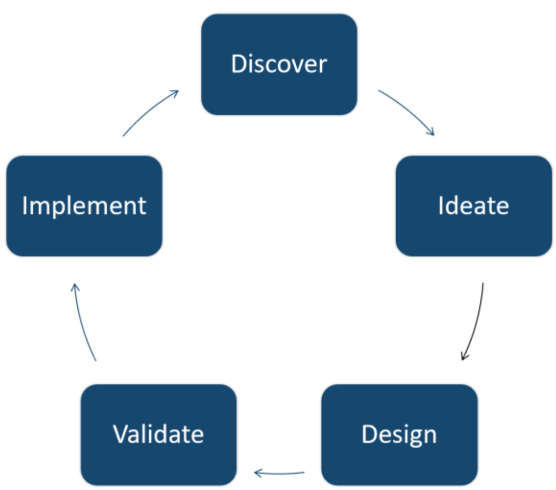

Figure 7: Design Process

4.0 System Design

Following the requirements and the general concept of the design, the overall design of the system could be broken down and progressed. The major subsystems for integrating a web alignment system into the existing system will be detailed in the coming sections. The decision to use a web alignment device, which is important to the division into subsystems, is detailed in Section 5.1. These subsystems are useful for dividing the system up into manageable chunks for decision making and design at the component level. Additionally, the general functionality of the system will be described for this design to develop a main goal for how this system interacts with the lidding material, and ultimately the blister packaging.

4.1 Subsystem Hierarchy

At its core, this project is a system integration of a new web alignment system into an already existing system. The system hierarchy is displayed visually in Figure 8 below.

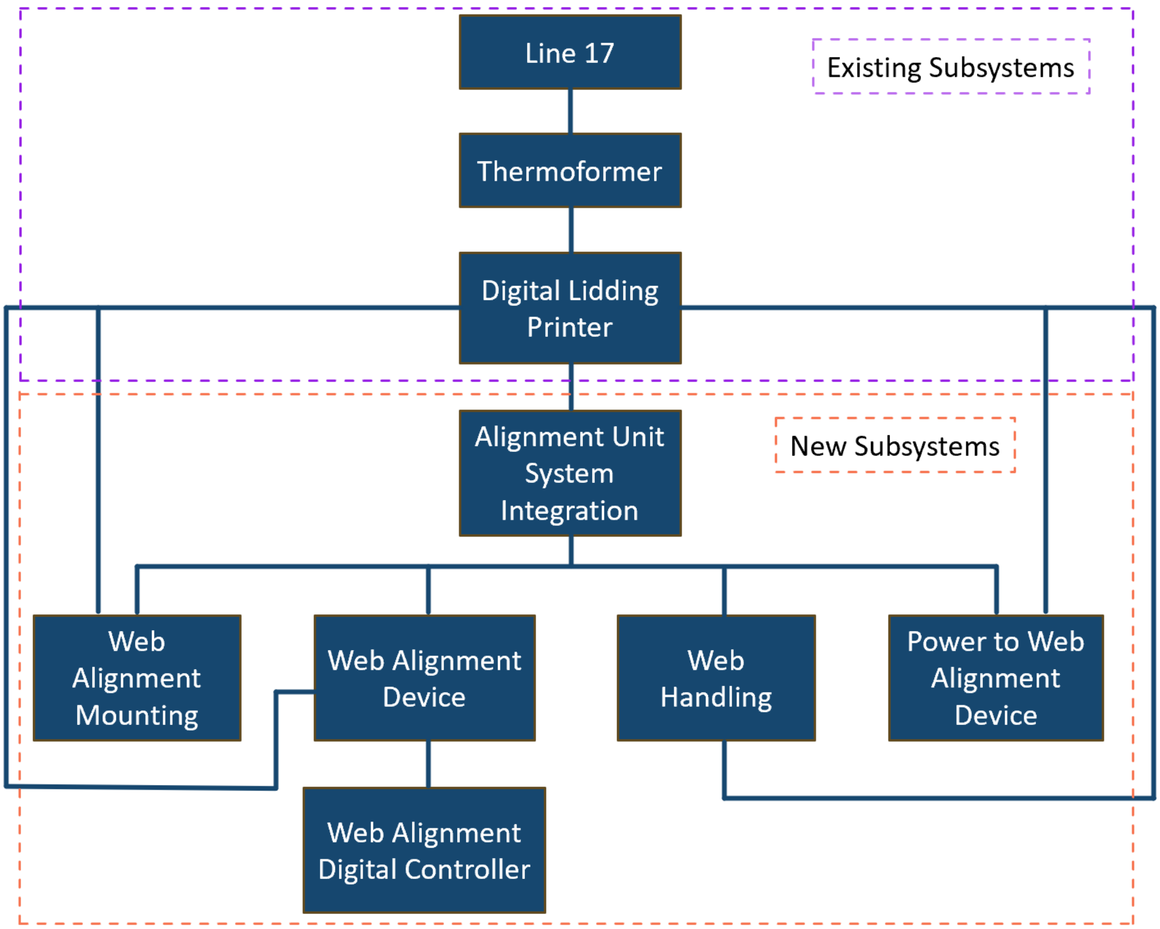

Figure 8: Subsystem Hierarchy

The greater system primarily affected by this project is the line 17 blister packaging process. The focus of the project is on the thermoforming process, and ultimately on the digital lidding printer. However, this process is tied to the entire operation of the line. The alignment unit system integration, which is a new system designed in this project, is tied primarily to the digital lidding printer. The alignment unit system can be broken down further into the web alignment device, web handling, power to the web alignment device, and web alignment mounting. Each of these sub-systems are integrated directly into the digital lidding printer. The web alignment digital controller is directly tied to the web alignment device, but it is not integrated into the digital lidding printer. These systems and how they interact will be explored in further detail in the next sections.

Given that the web alignment unit system is not a standalone system, each design decision must be made with consideration of the entire line 17 system. The web alignment unit system can affect the entire line 17 process downstream of it and ultimately the product delivered to the customer. The interconnected nature of this project brings its unique set of challenges for successful integration.

4.2 Functional Block Diagram

The system design for this web alignment device integration can be further subdivided into components and their functionality within the impacted system. The functional block diagram in Figure 9 below displays the interactions between the major components of the lidding system. With web transport and contact central to the system design of this project, these associated components are located in the center of the diagram in blue. Blue blocks indicate the major components that interact with the lidding web, and blue arrows indicate the flow of the web. Red blocks indicate signals and components of the web alignment device which is central to the system modifications, and red arrows indicate the flow of signals throughout the process. The green block displays the power source, and arrows display the interaction of major components with the power source. Furthermore, components within the guarding of the lidding printer are within the green dotted line while components located within the thermoformer. These enclosures within the functional block diagram indicate the presence of the alignment device and its components outside the guarding of the lidding printer.

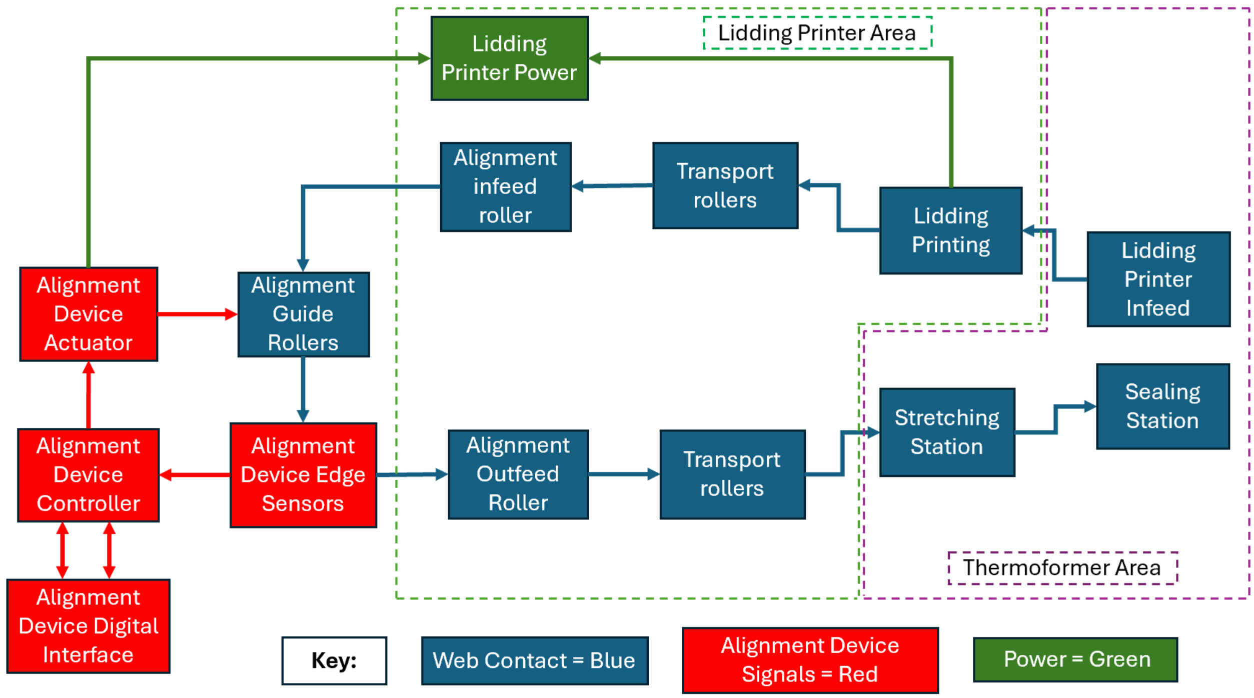

Figure 9: Functional Block Diagram

This functional block diagram depicts the location of the system modifications for web alignment within the operations of the lidding printing and thermoforming process. After the lidding is printed and transported throughout the printer using rollers, the web passes outside the lidding printer on the exit side of the printer. The infeed roller to the alignment device brings the web outside of the lidding printer before the web passes over the alignment guiding rollers, through edge sensors, and back into the printer for manipulation by the alignment outfeed roller as the web undergoes the rest of the process. These edge sensors at the alignment device are critical to the operation as these signals are sent to the alignment device controller. The controller then sends signals to the digital interface, which can be interacted with to make or change adjustments to the device and to the web. When these adjustments are made, the alignment device actuator is triggered which adjusts the position of the associated guide rollers, which sets the positioning of the lidding web. Continuous signals from the edge sensors ensure that the alignment guide rollers are positioned properly for the desired web alignment to meet the goals of the system.

5.0 Design of Subsystems

In this section, the design of each of the subsystems will be described in detail. The major design decisions will be discussed, including the major alternatives that were considered. In the design process for the web alignment system, the alignment method was first considered due to its centrality to the system regarding functionality as well as footprint. After the method for alignment and its design details were decided upon, the design of the other subsystems was completed to successfully integrate the alignment device into the overall system. This section is laid out using the framework of the subsystem breakdown in Section 4.1 following logical progression of the design of each subsystem. Finally, design considerations are discussed in Section 5.7 regarding the long-term operability of the workstation and the operation of the new system through the lifespan of line 17.

5.1 Web Alignment Device Design

First, in considering automated solutions to web alignment that could be integrated into web handling within the lidding printer system, two options were discovered. One option is a web alignment, or web steering, device with guide rollers. These devices allow the guide rollers to move to change the position of the web to a desired state set by the user. The guide rollers are moved by an actuator which receives signals for the necessary web position correction from a controller. This controller receives signals from sensors, which detect the lateral position of the web to identify the necessary position of the guide rollers for the proper correction of the web. This allows for the automatic adjustment of the web position as a part of the process and effectively controlling the web without interaction. An example of a web alignment device is displayed in Figure 10 below.

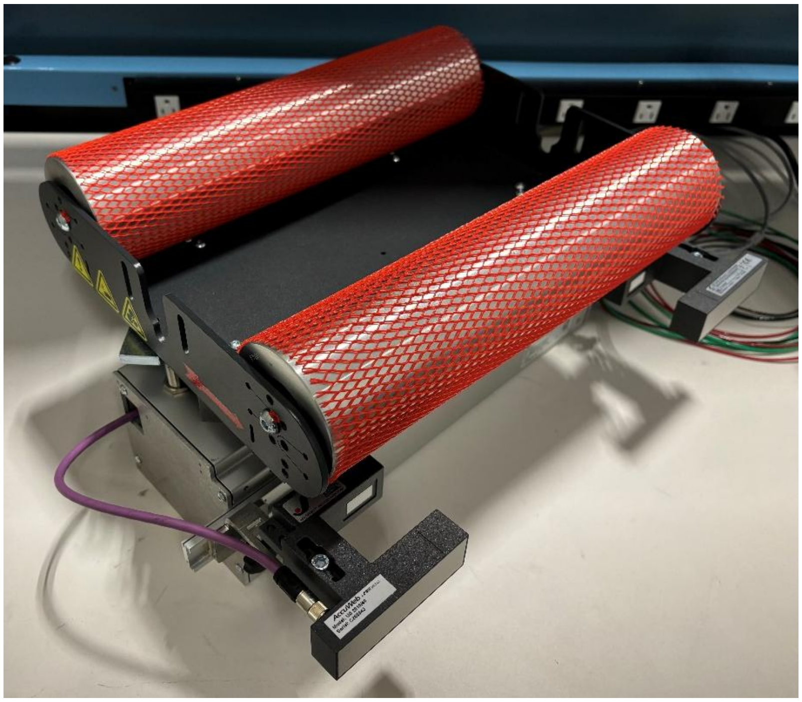

Figure 10: Alignment Device

Another option for aligning the web is a specialized positioning roller, which is pictured in Figure 11 below. Such a roller would be porous and allow for air to enter through the hollow roller and escape slightly through the pores. This air would cause the web to rise slightly above the surface of the roller, thus allowing for movement. This positioning roller would have collars placed on both sides of the roller for a set position in which the web must align itself to be properly aligned. As the web enters this roller, and essentially hovers over the roller surface, it must enter the proper area between the collars to have the correct alignment. The web then passes beyond this roller with the correct positioning. The smaller footprint of this alignment solution with only a single roller does provide an advantage for the limited space available in the lidding printer. However, it provides more uncertainty and is not as customizable in comparison to the alignment device. It also has more potential to lead to tearing the lidding material. These alternatives will be compared in the following decision matrix.

Figure 11: Positioning Roller

Critical to the design scenario is the problem statement for the project and ensuring consistent functionality and a long-term, reliable solution to web walking. The weights for the decision are used as such in the following decision matrix. While the footprint of the alignment method is a factor in decision making, the risk of lidding tears of the webbing as well as the reliability are much more important for solving the problem. Also, operator familiarity and customizability are factors to consider for implementing this as a long-term solution.

Table 1: Alignment Method Decision Matrix

	Footprint (0.1 weight)	Operator Familiarity (0.1 weight)	Low Risk of Lidding Tears (0.2 weight)	Customizable (0.1 weight)	Reliability of Preventing Web Walking (0.5 weight)	Total Weight of Alternative
Alignment Device	3	9	8	9	10	8.7 ✓
Positioning Roller	9	1	2	2	4	3.6

Due to the alignment device being more reliable, customizable, and less of a risk for lidding tears, as well as being a familiar solution at the Mt. Vernon site, the alignment device was selected. From the weighted scores for the two design alternatives in Table 1, the alignment device was shown to be a much better alternative.

After choosing the alignment device as the general method of web correction, a specific device must be chosen. Multiple vendors including BST, Maxcess-Fife, and Roll-2-Roll Technologies offer solutions that are applicable to this scenario. While solutions from each of these vendors may be workable for the design of the web alignment system for the line 17 application, the best option must be chosen. Most critical to this decision is the familiarity of the operators with the device chosen. An alignment device that has already been used at the Mt. Vernon site will require a smaller learning curve for implementation and operation. This will require less new training for operators and maintenance technicians as well as fewer spare parts needed as it is a standardized solution. Given that a similar BST device is already used on line 17, it is given the best score for familiarity for decision making while Maxcess-Fife is given a medium score because it is used in the packaging department at the Mt. Vernon site. Roll-2-Roll Technologies has never been used before at this site, so it is given a low score for familiarity. Cost and lead time are also important factors that are considered in the decision matrix below.

Table 2: Alignment Device Vendor Decision Matrix

	Site Familiarity (0.6 weight)	**Cost (0.3 weight)**	**Lead Time (0.1 weight)**	**Total Weight of Alternative**
BST Device	10	7	8	8.9 ✓
Maxcess-Fife Device	6	4	5	5.3
Roll-2-Roll Technologies Device	0	7	5	2.6

Largely due to the high familiarity with the BST device, this alternative received the highest weighted score in the decision matrix in Table 2. It also had a good cost and lead time in comparison to its alternatives. Thus, the BST alignment device is the best alternative and will be utilized in this web alignment system design.

After choosing BST as the vendor to supply the alignment device, the proper details for the device needed to be chosen. Despite the fact that the device was purchased from an original equipment manufacturer (OEM), as is standard for most AstraZeneca projects, design considerations were made as alignment devices are heavily customized for specific scenarios. It is not possible to go directly to a listing on a website and order a web alignment device. Discussions were held with the vendor from their sales department to their engineering department to make decisions regarding the device and to ensure that it would function best as a part of the line 17 lidding printer system.

One of the first considerations when selecting the device is the environment in which it would operate in. This scenario within pharmaceutical packaging is unique in that it is a clean production room held at a regulated room temperature and pressure. Therefore, any environmental compensation, which has been achieved using dual beam edge detectors to compensate for environmental changes to the web position, built into the device for less regulated environments would not be necessary (BST GmbH Product Sheet US 2010). However, it would be useful to be able to reposition the web edge detectors with changes in the setup of the web and the equipment. It was ultimately determined that ultrasonic edge sensors would be best for this application to detect the position of the web edges and ultimately use these measurements to make adjustments to keep the web aligned. The flutter of the edges of the lidding material from drafts and lack of tension at the web edges could be concerning, but these edge sensors would not be influenced by this possible issue. These ultrasonic edge sensors were found to be ideal for this application.

Additionally, the setup of the lidding printer and the web itself was considered in obtaining the desired alignment device. After learning the general footprint of the device, a location was chosen where it could fit within the lidding printer system. Referencing Figure 12 below and after many careful measurements, the circled area on the left side of lidding printer was found to be the only viable location to add an alignment device. On the right side of the machine, there is not enough space to fit the alignment device within the guarding of the machine, and there is not enough space beyond the guarding due to the window enclosing the room only a few inches outside the machine. While there is enough physical space above the machine, it is not a viable option because it is approximately 11 feet above the ground, so it would be extremely difficult to service the system. Any space under the lidding printer would require cutting into the support structure of the lidding printer and would also interfere with the stretching station below. The area on the left side of the printer was carefully discovered to be the only viable space for the alignment device. It is also ideal that the web is nearest to being transported into the stretching station and then sealing from this area where web alignment correction will occur. With this knowledge, the general web path and direction through the alignment device was determined so that the device could be properly configured.

Figure 12: Lidding Printer Available Space Option for Alignment Device

Furthermore, information on the web was supplied to the vendor in order to properly size the device. The lidding web is 20-micron aluminum foil with a width of 300 mm. From this, the alignment device rollers were sized to a length of 350 mm to allow the full width of the web plus additional space for correction and/or adjustments. Additionally, based on the issues previously detected on the line and the need for adjustments away from a nominal value, correction of +/- 6 mm was determined to be enough for correcting alignment error. 12 mm of total adjustment is more than enough to make adjustments to get the lidding of 300 mm width to properly line up with the forming material. Typically, the web was found to "walk" or become misaligned by about 2 mm.

Following the design requirements of this project, the web tension and speed of the lidding printing system needed to be maintained. These parameters were supplied to the vendor to ensure that they would have no concerns with the device altering these parameters. From a lidding printer machine parameter, the maximum web speed was found to be 42.5 feet per minute. The web tension was more difficult to determine. From completing testing on lidding material in a makeshift tensile test using hanging weights, it was estimated that around 9 pounds per linear inch is the maximum tensile force that the 20-micron aluminum lidding material can withstand before failure. While this displayed that the web tension must be less than 9 pounds per linear inch, it is inconclusive on a typical range for web tension throughout the printer. Discussion was held with a technical expert from the manufacturer of the lidding printer, in which he explained that the printer is designed to have a web tension within a range from 1.0-5.0 pounds per linear inch throughout the printer. Given that the web near the alignment device would not be manipulated with large direction changes with rollers very close together, it seems reasonable that the web tension would not be affected to be higher in this area. These needs for web tension were consistent with web tension across the chosen alignment device, suggesting that it was designed to be acceptable for the design requirements. This would be further tested after the installation of the new system to verify proper web tension throughout the printer and into the sealing station.

5.2 Web Handling Design

In order to transport the lidding web into and out of the alignment device, the web handling design needed to be adapted by adding rollers for modifying the direction of the web. Considerations were taken to ensure that the alignment device would properly correct the web as it travels through the new web alignment system. For example, if the alignment device was applied for the web to flow directly over the alignment device rollers with no re-direction, the web would fail to pass through the edge sensors and properly utilize the device. Additionally, there needs to be enough material leading out from the device for the web to fully pass through the edge sensors. Furthermore, if the web is wrapped around nearly the entire diameter of the roller immediately following the alignment device, it may produce too much tension in this area and make it difficult for the alignment device to fully make corrections to the alignment of the web by pivoting its frame to move the web as it contacts the two rollers attached to the frame of the alignment device. To ensure that the web is properly manipulated through the area to maximize efficacy of the alignment device, the diagram obtained for the vendor for web handling geometry recommendations was followed. This diagram is shown in Figure 13 below with the “correction span” being the distance for web travel between the contacting rollers on the alignment device.

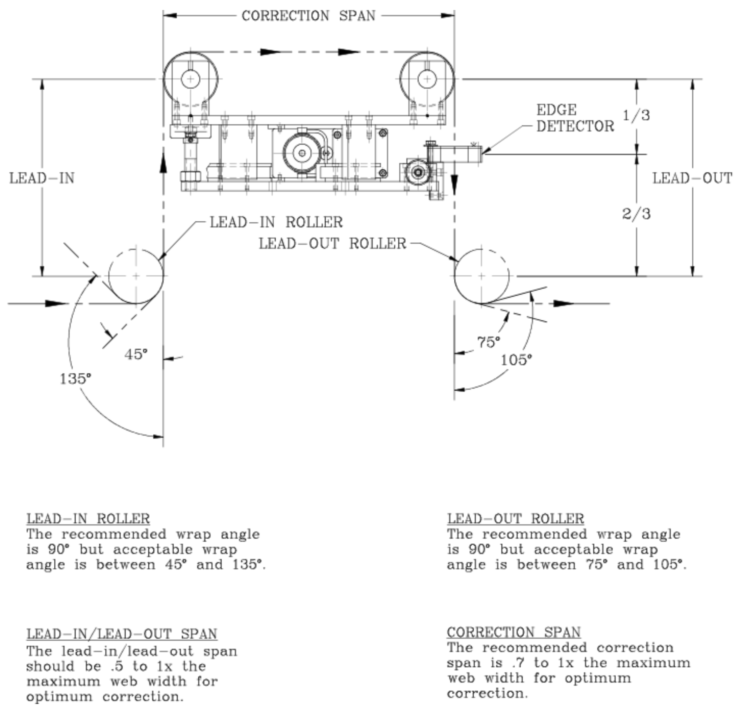

Figure 13: Web Handling Geometry Requirements (BST GmbH Installation and Commissioning Manual)

Following these vendor recommendations for web handling geometry, the design geometry to be integrated into the new system can be seen in Figure 14 below. Lead-in and lead-out rollers would need to be added to manipulate the web into and out of the device with proper wrap angles according to the recommendations. With the constraints of many other rollers in the area, and it being undesirable to make changes to the web path in other areas of the printer, there were few options for locations to allow the web to travel without incidentally contacting any other rollers. Ultimately after careful measurements and 3D modeling the available space in the area, space was found to add rollers with wrap angles of 94.1 degrees for the lead-in roller and 95.1 degrees for the lead-out roller. The ideal correction span was determined by the vendor, and the lead-in and lead-out spans were determined while being designed in tandem with the mounting design in Section 5.3 below. The lead-in and lead-out spans were considered with regards to how far the alignment device would be outside of the lidding printer based on the chosen mounting design. With a 300 mm wide web, these spans could be between 150 mm and 300 mm, or 5.906 inches and 11.811 inches. Ultimately, the distances that were chosen allowed for the sensors and wiring of the alignment device to be outside of the guarding of the lidding printer so that they would be easy to access.

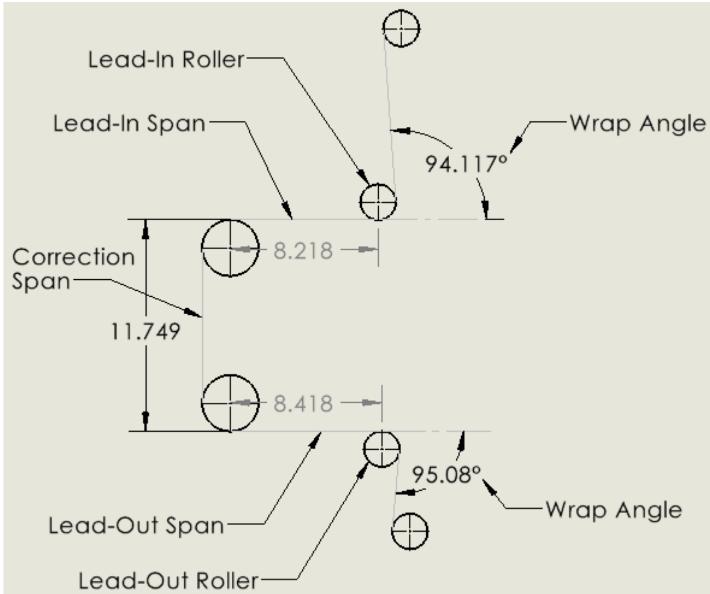

Figure 14: Web Handling Design Drawing

With this completed web handling geometry in Figure 14 above, only two new roller assemblies would need to be added. Given that the functionality of these rollers would need to have the same functionality for simply changing the direction of the lidding web as all of the other idler roller assemblies, these same rollers can be used. These rollers were found in the vendor supplied drawings of the lidding printer. Upon contacting the vendor, they were able to supply detailed part drawings and assemblies to confirm that AstraZeneca was able to order all of the correct parts. Each roller consists of a shaft with bearings supporting a rotating roller sleeve on top of these parts to physically contact the web and transport it. The dynamic portion of the roller assembly can be seen in Figure 15 below.

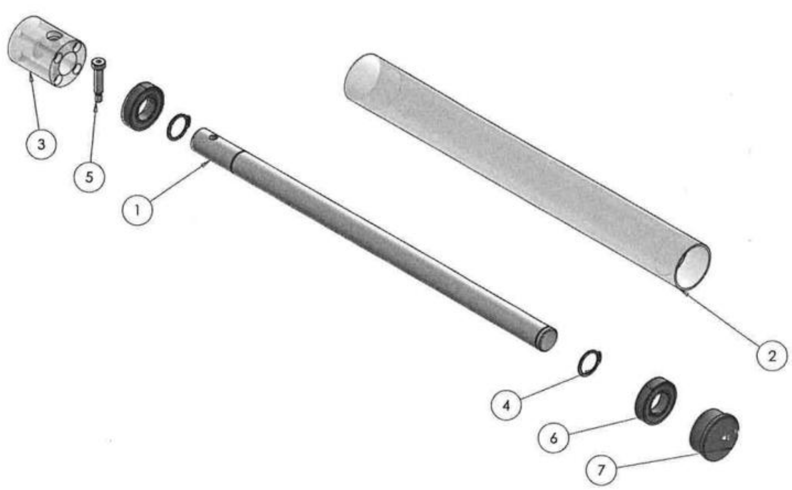

Figure 15: Roller Assembly Exploded View – Dynamic Portion (Gallarus Industry Solutions A01 Roller Mount)

Additionally, the roller assemblies needed to be mounted in place using bolts. It was verified that these rollers would properly mount as discussed in Section 5.3. The static, mounting portion of the roller assembly can be seen below in Figure 16 in which the mount fastens part 1 shown in place.

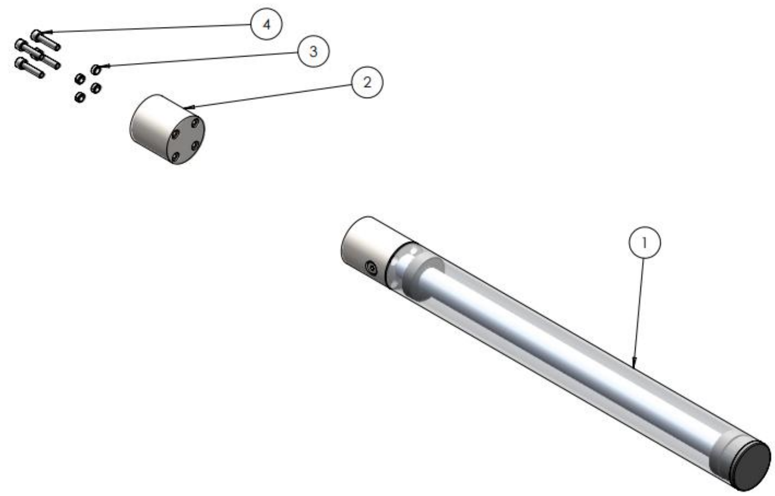

Figure 16: Roller Assembly Exploded View - Mounting Portion (Gallarus Industry Solutions A09 Roller Assembly)

Finally, it was verified that the parts of the roller contacting the web were an appropriate material for the pharmaceutical manufacturing situation in which the lidding material, which is on the inside of the blister cavities, contacts the tablets. The supplier was able to provide certifications of the material of the outer roller sleeve as requested, proving that it was 316 stainless steel as desired. 316 stainless steel is commonly used by AstraZeneca for parts that can directly or indirectly contact tablets due to its advantageous material properties (AstraZeneca Product Contact Material Certifications). It provides excellent corrosion resistance preventing rust from entering the product stream, and it is also very easy to clean which is helpful for parts that are regularly washed or wiped down. While it would be possible to fabricate these roller assemblies, it would be challenging to precisely replicate the work of the vendor. It is also preferred by AstraZeneca to purchase parts from the original equipment manufacturer (OEM) when possible, so two roller assemblies were purchased which match the other roller assemblies within the lidding printer. These would complete the necessary modifications to the web handling design.

5.3 Mounting Design

The design for the mounting of the alignment device was completed in tandem with the web handling design to ensure that all rollers are correctly positioned. The purpose of the mount is to rigidly fasten the device in the proper position. Following from the location for the device discussed in the previous section, the mount would need to be fastened to the lidding printer structure in some way integrating it into the system while positioning the device in the desired position outside of the lidding printer guarding.

One option for the integration of the alignment system into the lidding printer system is displayed below in Figure 17. This alternative uses the back panel of the lidding printer as a mounting point for the device. However, due to the lack of space to fit the device within the printer guarding, slots would have to be cut out of the guarding to fit this mounting as well as the web pass-throughs into the alignment device guide rollers. Since the lidding printer must remain an enclosed system, the guarding cannot simply be fully removed. Additionally, rollers leading into and out of the lidding printer guarding would need to be mounted to the back panel of the lidding printer, in a limited amount of space. Careful attention must be made in every area of the design to allow for proper spacing of the web and fit all mounting and rollers within the workable area.

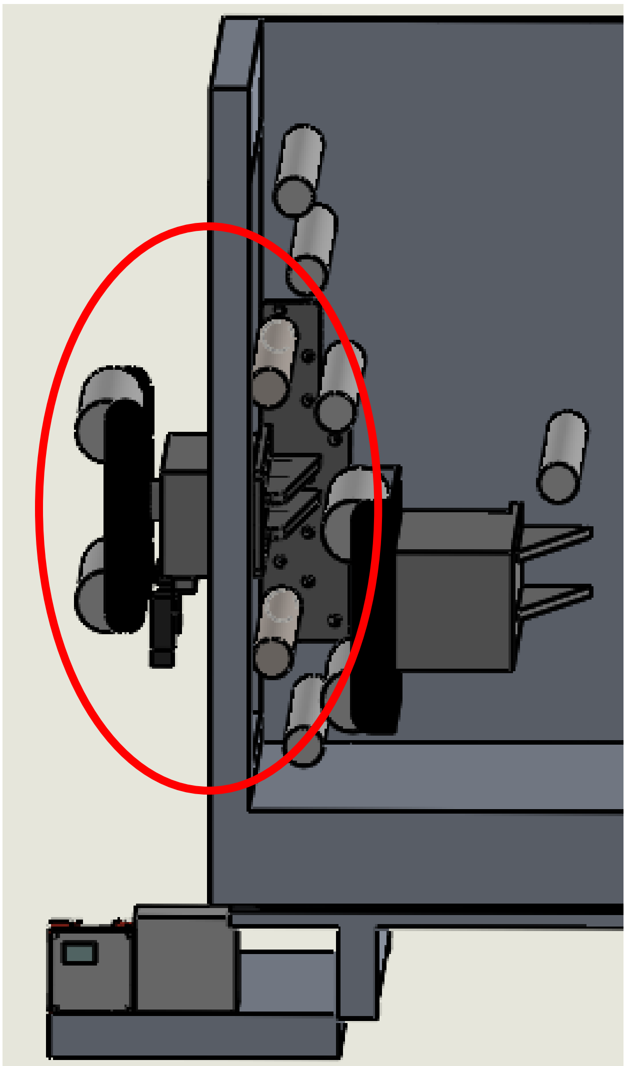

Figure 17: Device Mounted to Lidding Printer Back Panel Alternative

Another option for mounting the device in the outfeed space of the lidding printer is to fabricate a completely new guarding to be custom to the mounting of the device. This would involve fabricating a new guard for the lidding printer out of metal in which the alignment device could be directly mounted to. Rollers could then be custom designed and machined to be fastened directly to the metal guarding to ensure proper lead-in and lead-out distances and angles. Instead of modifying the current guarding for a mounting system, an entire new guarding would be designed to mount the alignment device and rollers directly. While this allows for more workable space, the custom design would require a large amount of material and the custom manufacture of multiple complex parts, including roller assemblies.

In order to decide the mounting design approach for the integration of the alignment device system into the lidding printer system, the decision matrix in Table 3 below was used. Given that the custom adapted lidding printer guarding design would raise the price significantly and the capital budget is limited, cost was given a significant weight. Also, the ease of designing precise custom components and manufacturing them for a successful install was considered. Finally, the space in the system to easily install the new alignment system was considered as limited space is a limiting factor of the design.

Table 3: Mounting Design Decision Matrix

	Cost (0.4 weight)	Designability & Manufacturability (0.3 weight)	Workable Space for Ease of Install (0.3 weight)	Total Weight of Alternative
Mounted to lidding printer back panel	8	8	3	6.5 ✓
Mounted to adapted lidding printer guarding	2	3	9	4.4

Largely due to the lower cost of the design alternative of mounting the alignment device to the lidding printer back panel, this alternative had the higher total weight. Therefore, this design alternative was selected.

When designing this mount, the available area was carefully measured and 3D modeled to fit the mount precisely into a very limited area. It was decided to create this mount out of 7075 aluminum. This material was chosen due to its high strength to weight ratio as well as good rigidity and high modulus of elasticity (Callister). This would prevent the mount from deflecting significantly as this needed to be a rigid structure that maintains the alignment and perpendicularity of the alignment device to the back panel of the lidding printer. It also has good corrosion resistance properties and is utilized in applications near product contact surfaces in pharmaceuticals due to this property.

The most critical part of this mounting design is that it would remain rigid and not allow for any sagging, or deflection, of the alignment device which would impact its ability to properly correct the web without exacerbating any of the issues in the lidding printer with the deflection of rollers over time. In addition to the material choice, the mount was designed to remain flush with the back panel of the lidding printer as well as resting directly against the support structure of the lidding printer to assist with getting the mount square during the installation. The mount was designed with a section to be fastened to the back panel of the lidding printer as well as a 0.5 inch thick piece of material to allow the alignment device to rest against. The alignment device would be fastened from this by the suggested bolts which are thread directly into locations on the device designed for mounting, specifically with M6 bolts. These mounting holes were on slides, and an extended area created in the mount for inserting bolts, in order to make adjustments to the lateral location of the alignment device during installation. Additionally, two gussets were added to support this plate for the alignment device to rest with the back section of the mount. These gussets would ensure that a twisting moment would be offset that could be created by the weight of the alignment device which extends outward from the mount itself. These gussets would strengthen the structural integrity of the mount.

Furthermore, some simple strengths analysis was completed on the mount to check that it would remain rigid while supporting the alignment device. The deflection of this structure supporting the alignment device itself was analyzed for how it would be expected to behave under the load of the nearly 35-pound alignment device. This could be estimated in a worst-case scenario with the loading of 35 pounds being applied to the end of the mount in a cantilevered beam style scenario. While the load is truly distributed across a portion of the mount, this would be an extreme scenario that simplifies the loading. The true loading would have less of an impact that would be able to cause deflection of the mount. This analysis expressed the purpose of giving a general idea to verify that the mount would function rigidly as intended. This loading was simulated using Finite Element Analysis (FEA). A plot of the estimated deflection over the mount is displayed in Figure 18 below.

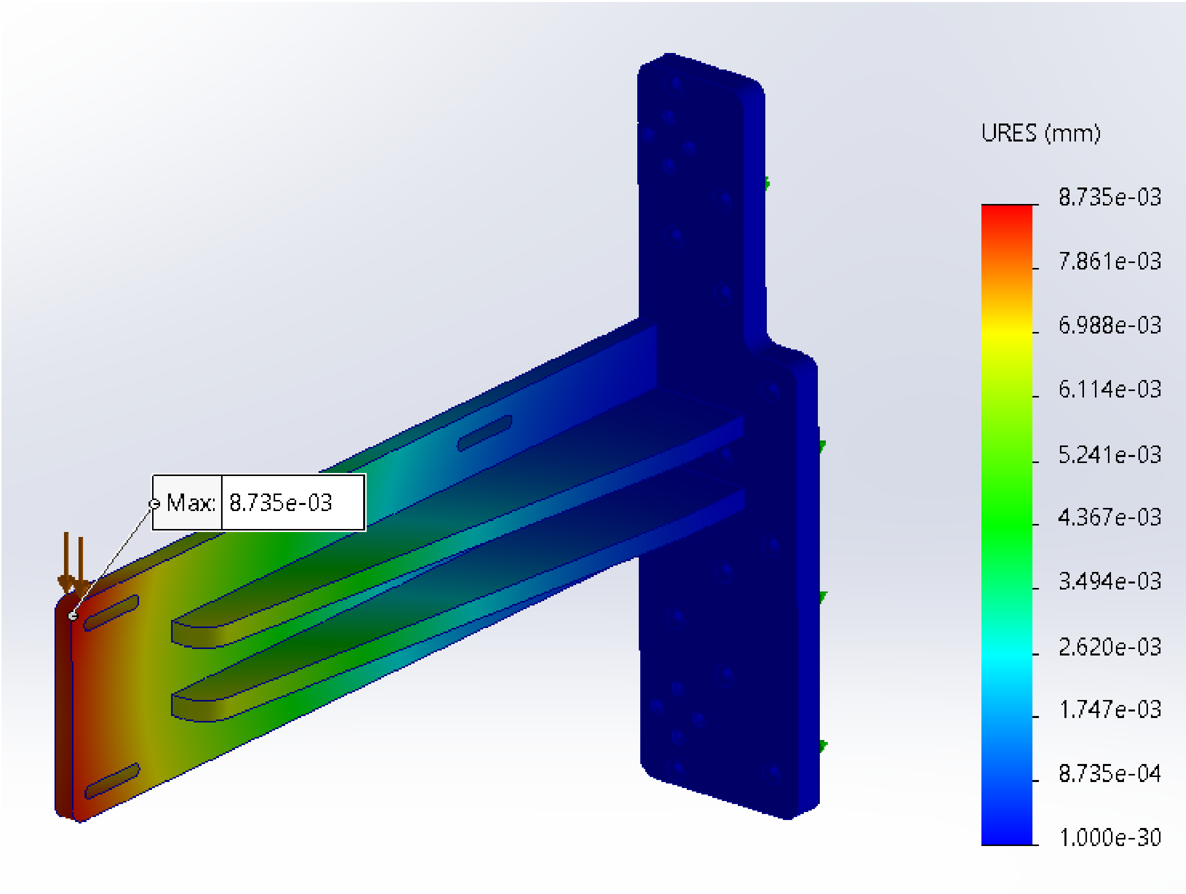

Figure 18: Displacement Plot Using Extreme Case of Cantilever Beam

It was estimated in this study that the maximum deflection of the mount would be about 0.009 mm. This result was also compared to that of utilizing the equation for the deflection of a cantilever beam as in equation 2. A modulus of elasticity of 10400 ksi was utilized for the 7075-T6 aluminum (*ASM Aerospace Specification Metals Inc)*. This value was created and obtained in accordance with ISO standard 77.120 (International Organization for Standardization).

$$\delta = PL^3 / (3EI)$$

Eqn. 2 (*FE reference handbook 10.0.1)*

Utilizing this equation, an estimate close to the result of the FEA study was obtained. Since this deflection near only 1/100th of a millimeter was estimated, it was decided that this effect was negligible with this design, so no further strengths analysis was needed for this mount.

The ease of installation of the new system was also considered with this mounting design. Working behind the back panel of the lidding printer was found to be very challenging with minimal space to insert tools without loosening and moving the lidding printer electrical cabinet. If at all possible, it would be ideal to fasten all items from the front of the lidding printer back panel to limit installation time. For this reason, the mount was designed to be able to fasten the bolts from the front of the mount by drilling and tapping threads into the 1 inch thick support panel. A robust bolt pattern was created in the mount to ensure that perpendicularity with the support panel would be achieved as well as rigidity. This robust bolt pattern of 12 bolts would also ensure that the mount would easily be held in place without shearing the bolts. Regarding these bolts, vibrations of the lidding printer were discussed for any potential impact causing the bolts to be worked loose over time or sheared. However, the vibrations within the lidding printer were observed to be negligible, and especially in the area of the printer where this mount would be installed.

Additionally, the new roller assemblies that would be added as a part of the web handling subsystem were considered. Fastening these roller assemblies to the back panel of the lidding printer would be challenging due to the lack of usable space. For this reason, the mount was designed to have the roller assemblies directly attached to the mount, and then the mount would be inserted in one piece. This would make the installation even easier to complete. The precise positioning of these rollers was designed into the mount. Bushings were utilized to locate the fastening bolts of the roller assemblies to the mount, and indentions were precisely placed on the mount to insert these bushings. This finalized mount design, including the roller assemblies, can be seen in Figure 19 below. This mount would be fabricated by the contractor that AstraZeneca uses in order to create custom parts as a part of its suggested standard practices and then lack of equipment (especially a waterjet) on site to fabricate this part.

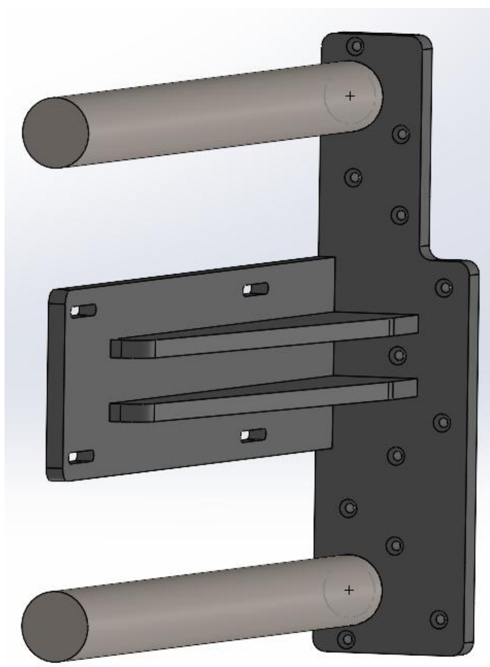

Figure 19: Final Mounting Design

Finally, as a result of the mounting strategy, the lidding printer polycarbonate guarding would need to be modified to allow for the lidding web to pass into and out of the enclosed lidding printer system. This cutting pattern was 3D modeled and designed in tandem with the rest of the mounting and web handling subsystems. The rectangular cutouts were designed to allow for 2 inches of width for the web to pass through in and out of the lidding printer. This ample space was created in order to allow the operators to easily pull the web through the gap with their hands. A third cutout was created for the alignment device itself to fit onto the mount and be located primarily outside of the lidding printer enclosure. The design for this adapted guarding can be seen in Figure 20 below. Given that this polycarbonate material was nearly 1 inch thick, it was cut out on a waterjet off site by the contractor who fabricated the mount due to the lack of tools to effectively and neatly cut out this material on the AstraZeneca site.

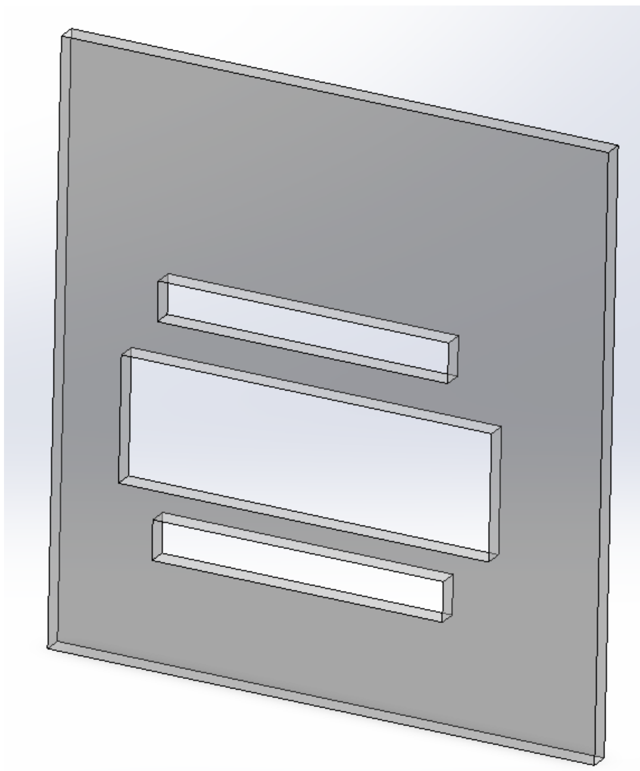

Figure 20: Modified Lidding Printer Guarding Design

5.4 Electrical Design & Integration

In order to power the new web alignment device for functionality within the system, a voltage or 24 Volts DC and an amperage of 4 A were needed. However, this supply of power could be obtained with a multitude of strategies. Incoming power could be used from sources on the line that supply 120 Volts or 480 Volts for the machinery on the line. From this, an outlet could be dropped in many different locations. On the other hand, power could be sourced directly from circuits on the nearby machines on the line as long as there is found to be enough power remaining in the machine. These could include sources from the thermoformer or the lidding printer.

Ultimately, it was decided that if possible, it would be an advantage to utilize a circuit from the existing machines, preferably the lidding printer. Dropping an outlet would require cutting into the ceiling which could be done, but it would add time to the installation as well as the cleaning requirements. Additionally and perhaps more importantly, the alignment device would power on and off in conjunction with the machine that its electrical system is connected with. Otherwise, the alignment device would have to be powered off separately which would add an additional, unnecessary step to regular operator work. Given that the web alignment device system would be a part of the lidding printer system, it would be most desirable to pull power off of the lidding printer control system. The alignment device would then be powered on and off in conjunction with the lidding printer. From here, options were considered to find a viable power source in the lidding printer.

When analyzing the electrical system design of the lidding printer, two 24 Volt DC circuits were discovered. However, the electrical headroom, or spare power that can be utilized in addition to what is already utilized, would need to be known to ensure that there was enough power remaining to power the additional 24 V, 4 A alignment device. After analyzing the amperage that the devices on each of these 24 Volt circuits would be consuming, it seemed that there was not enough headroom on either circuit to add the alignment device. However, upon closely analyzing the lidding printer electrical diagrams, it was found that there was a spare source of power coming off of a 10 A fuse. After discussion with the supplier of the lidding printer machine, it is common for an additional power source to be provided in their machines for future changes or expansion. After finding this spare source in the machine, it was confirmed to be viable for usage for the alignment device. This spare 10 A power source can be seen circled in purple from one of the pages of the lidding printer electrical diagram displayed below in Figure 21.

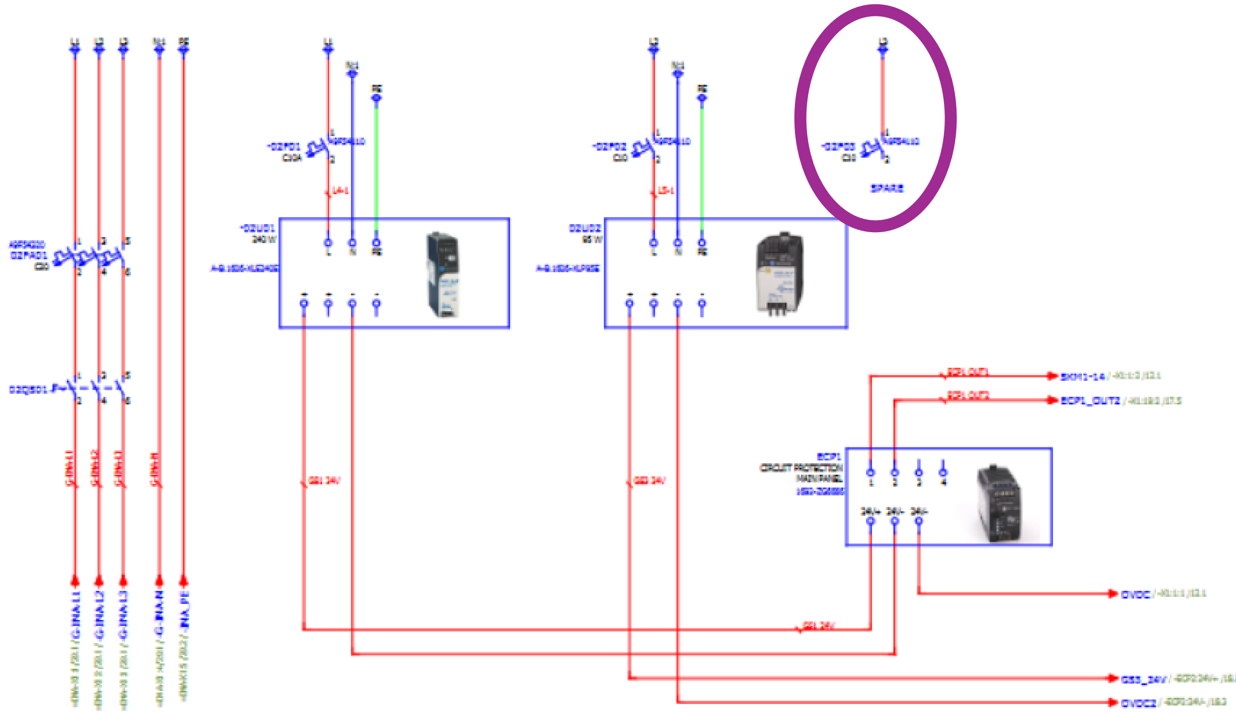

Figure 21: Lidding Printer Electrical Diagram - Spare Power Source (Gallarus Industry Solutions K600iGA)

After discovering this power source, a circuit needed to be designed to properly bring 24 VDC to the alignment device. First, an Allen Bradley power supply, similar to the other power supplies in the lidding printer electrical system, was chosen to provide 24 VDC to the circuit. Given that the spare supply was 240 VAC, an input rating of 100-240 VAC was acceptable. The output amperage was chosen to be 10 A since this amperage is present from the spare power source, and having 6 A of extra current in the circuit would allow for future expansion if it were ever needed. From this, an Allen Bradley 1606-XLE240E power supply was chosen due to its input compatibility and a 24V DC 10A output. After this, an electronic circuit protection module was added. Power blips have been a frequent issue with harming electronics within AstraZeneca in the past year due to wide fluctuations in amperage. Thus, electronic circuit protection would help protect the alignment device control system from negative effects from power surges. This circuit protection module was chosen from Allen Bradley rated with a 24VDC input and 10 A being within its 40 A maximum. Then, the circuit would be protected at 6A output from the protection module, shutting down the circuit by “tripping” it if excessively high amperage is experienced. Two 6A outputs were added to allow for another output in the case of future expansion to the lidding printer electrical system. The output would then be able to supply the necessary 24VDC and 4A to the alignment device to its 3 prong plug input. Figures 22 and 23 below show the drawing of the new electrical system modified for the alignment device. Figure 22 shows the elimination of the power source as a spare.

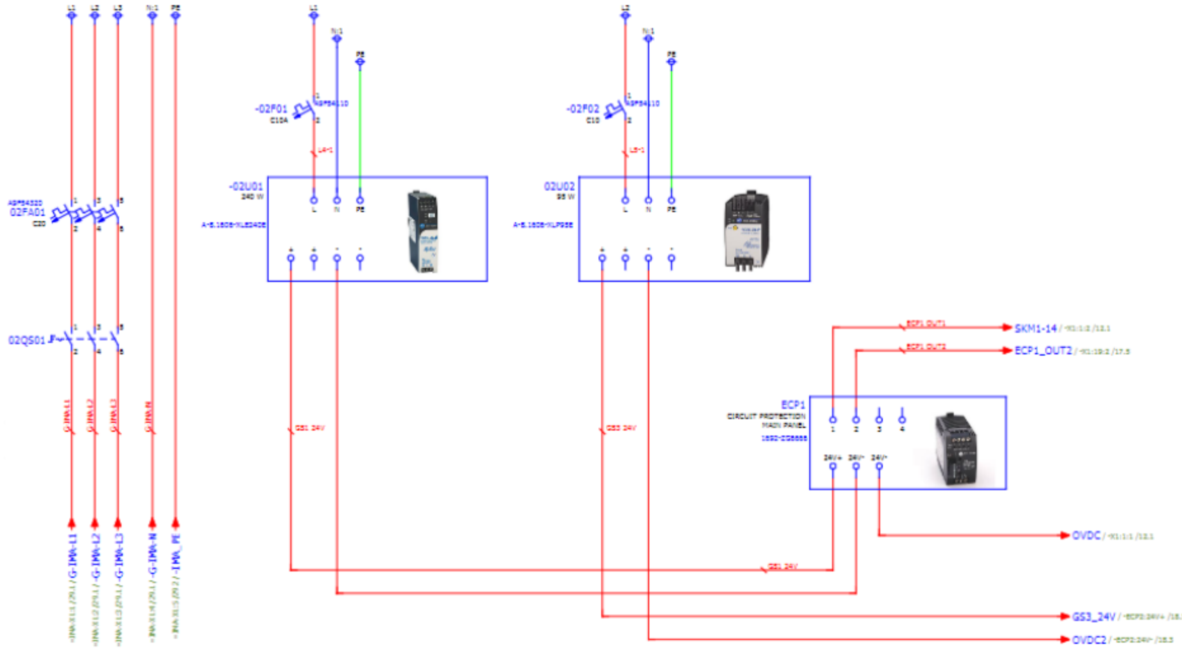

Figure 22: Updated Electrical Drawing - Spare Source Now Utilized for the Figure 23 Circuit

Figure 23 below shows the new 24V DC circuit to be used for the web alignment device supplying 240 W, as called out next to the power supply on the electrical diagram below. This power was calculated using equation 3.

$$P = V * I$$

(eqn. 3)

This is with V being the voltage and I being the current. A negative source was found in the lidding printer electrical system, and ground was taken from metal electrical cabinet door. The wiring diagram shown below in Figure 23 shows red as positive, black as negative, and green as protective earth and would be followed during the installation.

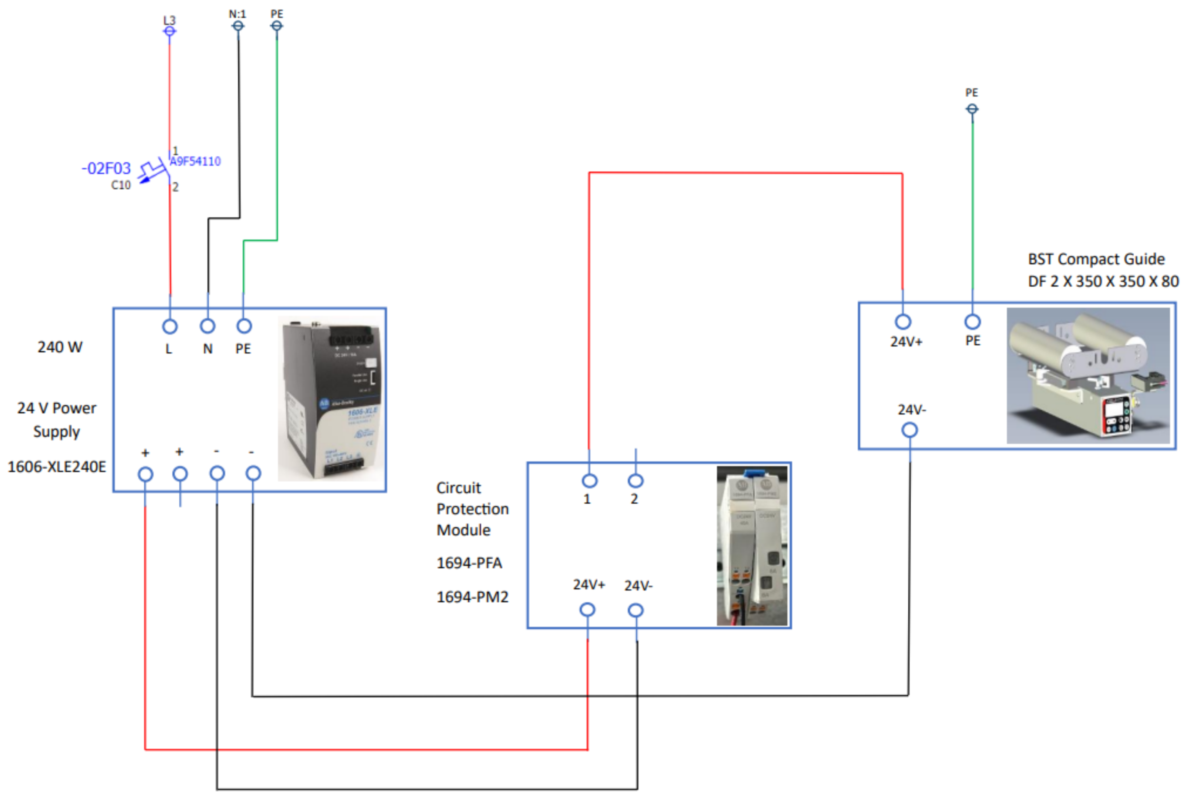

Figure 23: Updated Electrical Drawing - Additions From Spare Power Source

Before the day of installation and qualification of the web alignment system, space was found in the electrical cabinet to mount the power supply and electronic circuit protection module. In fact, these items were mounted prior to the day of the installation to save much needed and limited time. These items including the fuse from which spare power was pulled can be seen in Figure 24 below, after being fully wired. The 12-gauge wiring from the alignment device itself would be tied back and then inserted through a hole in the back panel of the lidding printer and finally into the electrical cabinet. The inside of this electrical cabinet is what is shown in Figure 24 below.

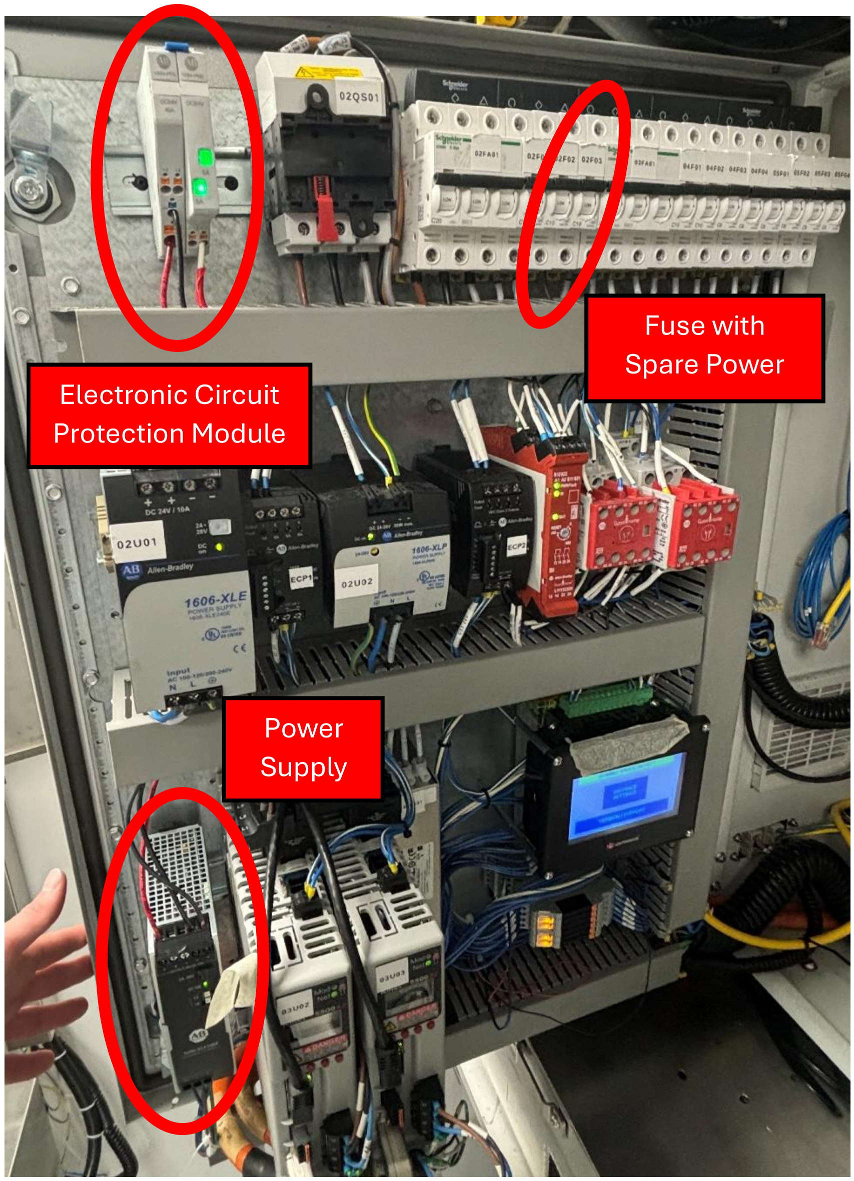

Figure 24: Electrical Control Cabinet

One more factor to be considered for the design of the system is the capability of the web alignment device to integrate with an external programmable logic controller (PLC). The alignment device could have an additional CAN bus cable, a communication system which allows the exchange of information between control systems, to provide a connection with the PLC of the lidding printer. However, after studying the capabilities that could be provided as an output from the control system of the alignment device to an external device, it was decided to not use this capability. The only output that would be sent to the lidding printer control system and displayed its human machine interface (HMI) would be the presence of a fault and the alignment device. This would not be very useful for the operators as the fault and the details of the fault would be displayed on the alignment device controller and would be in clear vision of the operators making it obvious that the alignment device was in a faulty state. It was also confirmed that all operations could be carried out locally on the alignment device controller. Therefore, it was deemed unnecessary to add complexity to the system by integrating with the lidding printer PLC in this scenario.

5.5 Digital Controller / Housing Design

In order to control the alignment device with ease, the digital controller needed to be considered as a subsystem. While the controller is supplied by BST as a part of the alignment device, it is only supplied as a panel which can be custom implemented by the customer. These controllers are often mounted directly off of the support frame of the alignment device, but this would not be ideal for this application given that it is above a reachable height. Instead, it would be preferred to place the controller at a location that operators can easily reach to make adjustments as well as to easily see the information displayed on its screen.

The location of this was chosen with ergonomics in mind. Ultimately, the most viable location to mount the digital controller was directly above the thermoformer enclosure. The reach and line of sight necessary for the operator regularly check and make adjustments to the device was within a reasonable reach of 72 inches. This maximum reaching height was very near the preferred maximum reach published and suggested by the United States Department of Energy in their standard for human factors and ergonomics (United States Office of Environment, Health, Safety & Security). It was also decided to mount the digital controller as near as possible to directly under the alignment device itself to have a convenient line of sight between the controller itself and the physical location of the alignment device.

In order to fasten the controller in this location, a custom housing would need to be created. Given that no significant loads would be experienced by the housing and it would need to be custom designed and fabricated, it was decided to 3D print the housing. PLA was used to 3D print using the Bambu Lab X1E 3D printer at AstraZeneca so that the part would be cheap to fabricate.

This housing was designed using 3D modeling software to precisely fit the control panel with dimensions supplied by BST of 91 x 105 mm (BST GmbH Operating Manual). Additionally, a circular cutout was created in the back of the housing to fit the CAN bus communication cable to the controller. This cable was purchased in a custom length from BST to reach the desired location for the controller from the output connection on the support frame of the alignment device (BST GmbH CANopen User Gateway). The size of the housing was created to fit within the stainless steel support structure above the thermoformer. Holes were also created in the housing in locations that could be threaded with machine screws into the support structure. Finally, holes were created to fasten the controller with machine screws to the housing. The hex size and shape of the nut was made inner to the housing to easily tighten the screws. Additionally, enough space was included in a cutout to be able to insert a finger to hold the nuts in place while tightening the screws from the front. Each of the design decisions for this housing was carefully made to ensure that the housing and controller can easily be constructed and deconstructed in the case that modifications or troubleshooting would be needed to access the back of the controller, remove the cable, or remove the entire housing. The housing design can be seen in Figure 25 below.

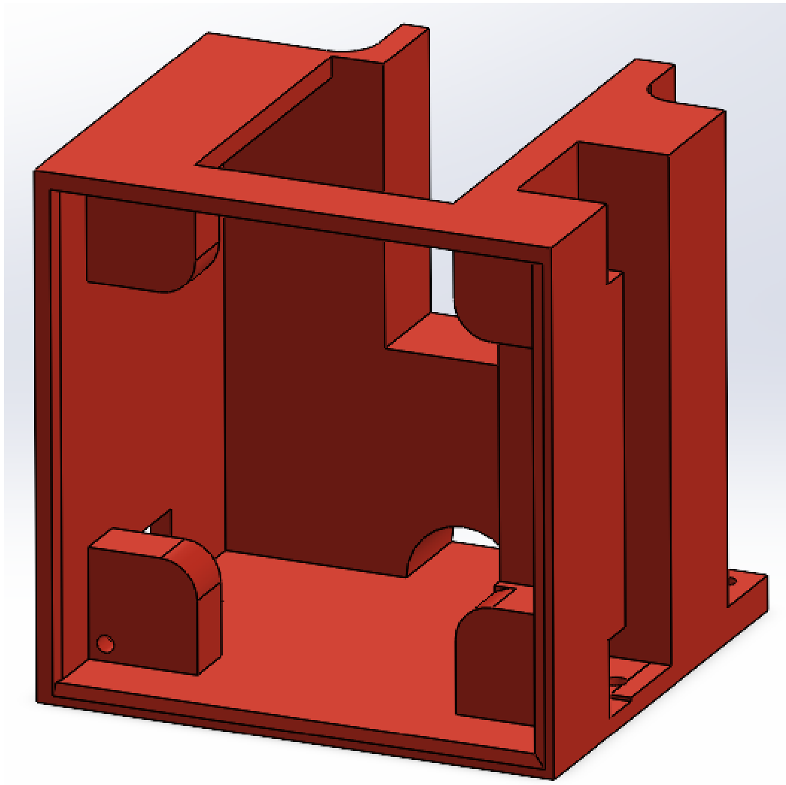

Figure 25: Controller Housing 3D Model

One iteration of the design was initially printed as a prototype to ensure correct fitting due to the low cost of 3D printing with PLA. The prototype was found to work fairly well with only minor adjustments of dimensions. The main design change that was made was adding a chamfer to give some room to help the controller fit easier into the housing when inserting it. A final housing was then 3D printed to use for production and the controller put into place as seen in Figure 26 below.

Figure 26: Controller Mounted Inside Housing

Given that the digital interface itself was not designed in this project, and was based simply on what the vendor could provide, it will not be discussed in detail in this report. However, it was critical to understand this part of the system to set it up properly for production as well as to train the operators for how to interact with it. The operation display on the digital interface is shown and detailed below in Figure 27. This display includes an image of the edge sensors with a bar representing the position of the web and described by the positional readings of the ultrasonic edge sensors. This display will be utilized by the operators to help understand the adjustments being made using the left and right arrows as well as the guiding modes that can be seen in Figure 27 below. The display for the gain setting would also be useful for optimizing the gain. More detailed information can be found on the display using the setup command to make detailed adjustments.

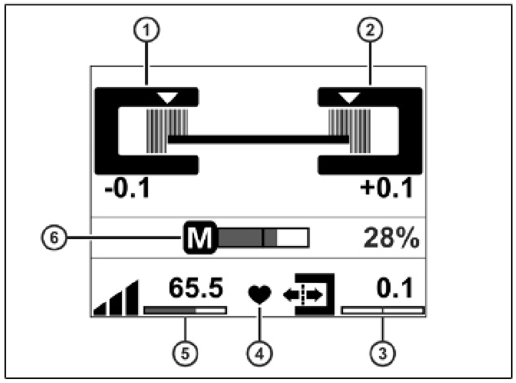

Fig. 15: Operation display for application with edge sensors

Pos.	Symbol	Display function
①	-0.1	Operation display edge sensor (Sensor 1)
②	+0.1	Operation display edge sensor (Sensor 2)
③	0.1	Displays the setpoint of the web edge
④		Status display *System OK* (heart beats)
⑤	65.5	Displays the controller gain
⑥	M 28%	Actuator operation display

Figure 27: Digital Interface Display & Functions (BST GmbH COMPACTGuide net Operating Manual)

On this digital display, there are also a series of faults that can be detected by the controller and will be displayed for the operators, maintenance technicians, or engineers to analyze. These faults include special symbols, and the description for these faults can be found in the setup functions of the digital display and in the manual. Some of the most useful fault displays for this application include the following (BST GmbH COMPACTGuide net Operating Manual):

- Supply voltage outside of the permissible range (displayed with a U in a yellow triangle)
- Motor control timeout for the actuator running in the same direction for too long (displayed with a stopwatch in a yellow triangle)
- Setup lock active signifying that the setup command is blocked (displayed with a key in a yellow square)
- Bus connection fault (displayed by a broken connection in a yellow triangle)
- Edge sensor malfunction (displayed by a red exclamation point on the sensor that is failing to communicate)

5.6 Overall System Design

While completing the mechanical and electrical design for each of these subsystems, the design and integration between the subsystems and with the overall system was considered. When designing the system and analyzing the available space, a 3D model was created, based on reverse engineering, of the lidding printer in the area in which the web alignment system would be added. Each of the major components from the web alignment system was modeled and added into a SolidWorks assembly to help verify proper integration. The work completed in the electrical system cabinet was not included in the 3D modeling process. Figures 28 and 29 below show the completed 3D assembly of the web alignment system design from different views to show the main components that would need to be added to the larger lidding printer system.

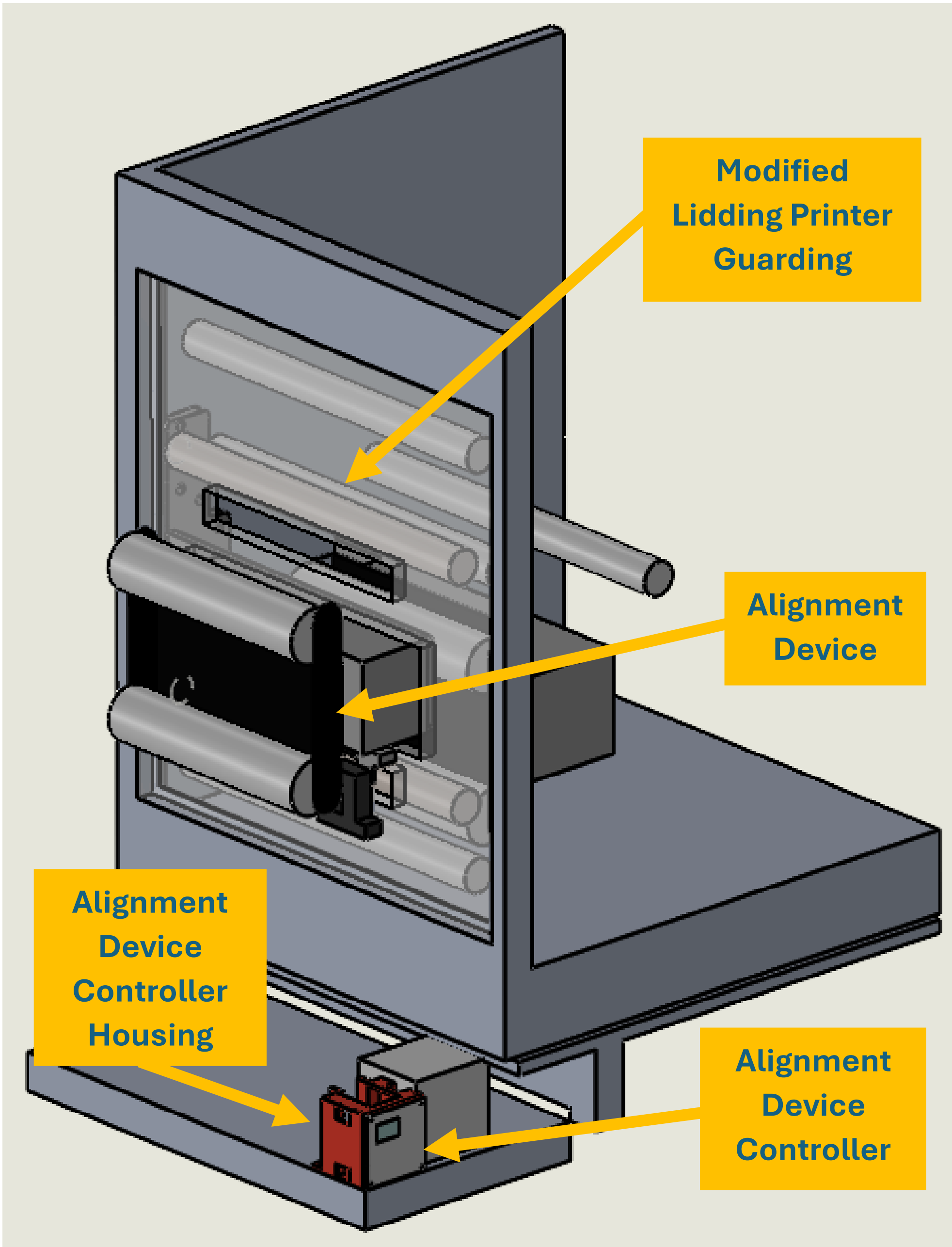

Figure 28: Overall System 3D Model - Isometric View

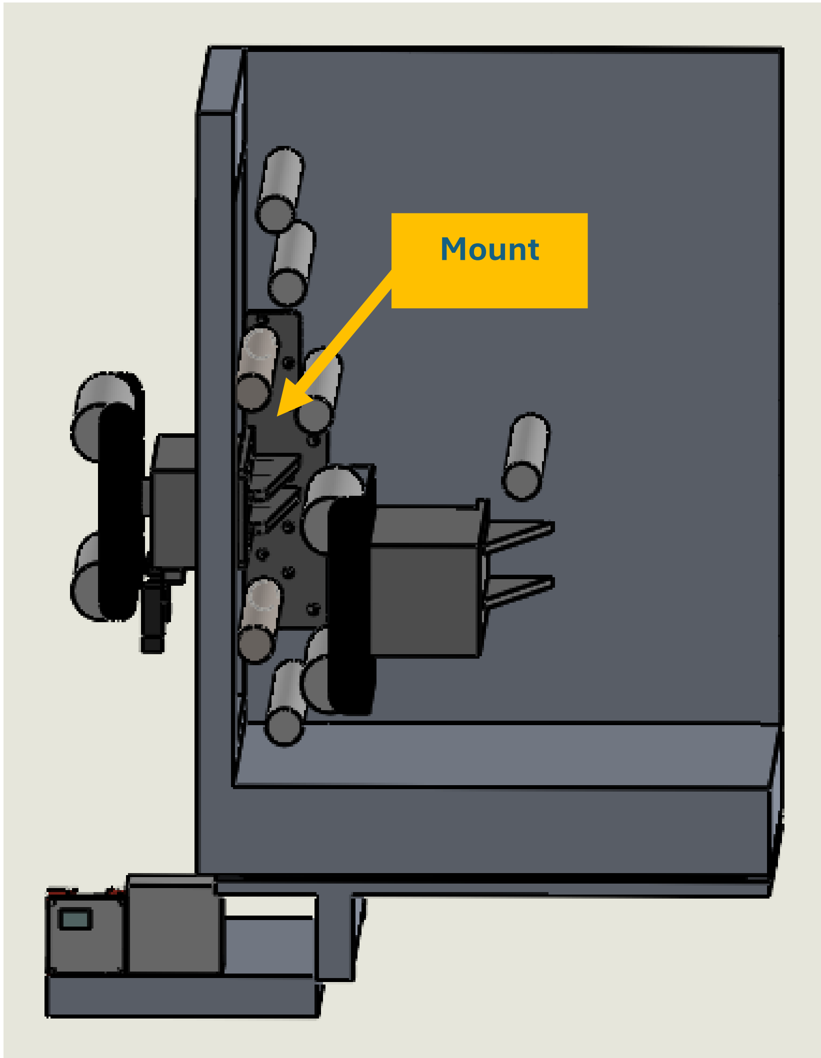

Figure 29: Overall System 3D Model – View From Front

Finally, a motion study simulation was created to display how the alignment device would pivot to move the web laterally through the web handling system. This simulation helped to visualize the functionality of the system and verify that the design was reasonable, as well as clearly display how the system would operate for people viewing the senior design presentation on this project.

5.7 Design For Ongoing Operation

Outside of the design of the web alignment system itself, it must be considered that this design is a part of a larger work cell and operation. Either one or ideally two operators are always stationed at the thermoformer during production to facilitate the process. The operators as well as the other teams within packaging such as maintenance will regularly interact with the system. Based on the roles of these packaging teams, operators would make common adjustments to the positioning of the web with the alignment device, maintenance would assist with any breakdowns or preventative maintenance, and engineering would facilitate optimizing the system and making any design adjustments. With the familiarity on site with the BST alignment devices, less learning was required for these groups to be prepared to use the new system. However, many discussions were conducted to explain how to best use and troubleshoot the new system with line 17 operators and maintenance. Beyond this, additional actions were taken to integrate the new system into the overall operation of Mt. Vernon packaging as well as the line 17 workstation.

First of all, the alignment device and its controller were set up to best serve the line during production. Many parameters were checked within the device from the setup from the vendor before choosing the guiding mode. The device was set on its automatic guiding mode for production usage to automatically make adjustments to achieve the positioning set into the machine using setup commands on the controller. The desired setpoint could then be adjusted by the operator simply by pressing right and left arrows, and the controller would then make automatic adjustments to this new value. Only one of the edge sensors was needed for controlling these adjustments, so the rear sensor was arbitrarily selected. One other setup item that was adjusted was the gain to ensure that the proper feedback was provided by the controller to the actuator. This gain had to be increased to provide faster feedback and adjustments.

The system also needed to be properly set up for maintainability. The maintenance engineer for the department was included in project discussions to ensure that the maintenance team would be as prepared as possible to fix an issue with the device. Thus, “wear parts” were identified and spare parts were purchased to be prepared for a possible failure. Wear parts are components that are susceptible to failure due to regular usage, or wear and tear. The rollers of the alignment device, the edge sensors, and a proximity sensor measuring the position of the frame controlled by the actuator were all identified as wear parts. Spares were purchased by the maintenance team and stored in order to be prepared to quickly fix a breakdown of these parts instead of having to order them from the vendor which could cause a risk of the line being down for an extended period of time. Additionally, with the implementation of total productive maintenance (TPM) on line 17, TPM tasks were also considered. TPM strives to make maintenance proactive instead of reactive, and it also strengthens the ownership of maintenance by operators through “autonomous maintenance.” Autonomous maintenance tasks are minor, quick activities that can be completed by operators while working on the line to help keep the equipment well maintained and monitored. These are often called CILT tasks standing for cleaning, inspection, lubrication, and tightening. The only CILT task identified to be added for the web alignment system was a cleaning task for the edge sensors. Sensors often have a buildup of different types of dust that can cause them to stop working properly. This cleaning task ensures that the sensors are regularly cleaned to function optimally over the life of the parts.

Additionally, a backup for the controller was discussed from an automation perspective for maintenance as it is important to be able to save any critical data and parameters in production computer systems for restoration in the case of electronic failures. However, there are not any parameters or batch information saved within the controller that would be costly to lose in the event of losing such data. The purpose of the alignment device is mainly for operators to be able to make adjustments as needed in real time, and all setpoints and settings changed by the

AstraZeneca users could be quickly reverted. There is no data that would cause significant downtime or functionality issues from losing, and there is no good way to create a backup from the controller. So, no backup was taken from the device for maintainability purposes.

Another factor in the operability of the system is the occasional need by operators to thread the lidding web through all the proper rollers in the lidding printer. Given that this is not a common task and is typically only completed after an unplanned lidding tear, the operators are not very familiar with this task. Thus, a diagram is provided to clearly show the operators the complex path between the rollers that must be followed. This diagram has been placed at the bottom of the lidding printer for several years to help the operators with this task. However, with modifications to the web handling system, this needed to be updated to show the modified system. A new, clean diagram was created and placed in the printer to clearly display the threading path. Additionally, after discussion with the operators, new laminated copies of the threading diagram were created that can be moved by hand to be easier to see while working through the expanse of the printer. This copy should make it possible for the operators to thread the printer slightly quicker and decrease frustration. The updated web threading diagram is displayed in Figure 30 below.

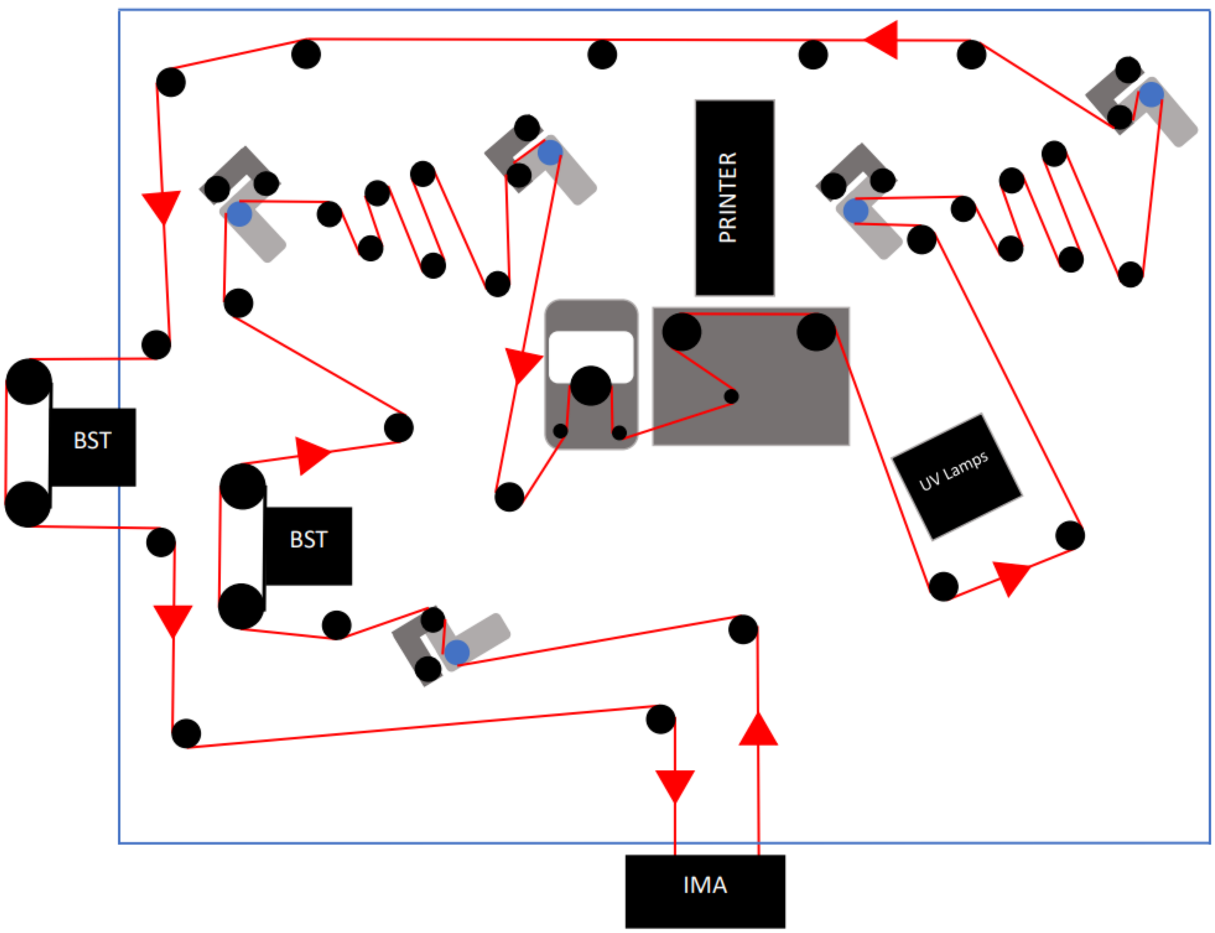

Figure 30: Lidding Printer Threading Diagram (AstraZeneca Threading of the Lidding Material)

Finally, given that this system is one of many within the packaging department, any information to help analyze the system in the future needed to be stored in an accessible location. Troubleshooting or modifications are often carried out by different people months and years down the line, and the information needs to be accessible for their learning. Therefore, the documentation from the system was organized and stored in the common shared drive folder with equipment drawings and manuals for line 17. These items included operating and installation manuals from the alignment device, sensor and actuator information sheets, roller drawings, updated electrical drawings, and the updated threading diagram. Design documentation and models were retained within the packaging engineering shared folder. This ensures that information is easily shared and retained to utilize the web alignment system and its design for the lifespan of line 17's operation.

6.0 System Evaluation

After the design of the system was completed by breaking the project down into interacting subsystems and components, the system was ready to be implemented in production and tested. With all of the components designed, fabricated, and obtained as discussed in Section 5, the evaluation of the completed system will be discussed in this section. First, the physical installation of the new web alignment system will be discussed as well as the initial testing. Then, the final cost of the system will be discussed after design decisions were previously made with cost considerations. The system itself in production usage is shown and discussed, as well as the larger impact of the web alignment system on the line 17 system over a period of three months. Finally, the completed system will be evaluated based on the design requirements created in Section 3 to analyze the success of the project in relation to its stated goals.

6.1 Testing / Line Trial

Beyond designing the new system, integrating it into full speed production as a robust solution was the ultimate goal of the project. In order to do this, the line needed to be reserved to be taken out of production and utilized for installation and qualification of the web alignment system. Time was reserved on the line and a line trial was created to complete this work. A line trial is created at AstraZeneca for any construction, testing, or qualification activities in which packaging materials, such as lidding material or cartons, are needed. Given that line 17 is a very heavily loaded line, discussions with the supply chain team were held in order to secure precious line time. While more time would have been desired for this line trial, one 24-hour period was obtained for October 21st, 2024. After significant issues on the line unrelated to this project occurred near this date, the line trial was rescheduled for November 27th, 2024.

In the pharmaceutical industry, a change control must be completed in many circumstances including when design changes to machinery are made such as in this project. Within this change control which documents the change and any necessary actions needed, a qualification was required to be completed by validation to test the functionality and compliance of the new system. A qualification document and report was prepared and approved ahead of the line trial for an installation qualification operational qualification (IQOQ). Close collaboration was taken with the validation team to draft appropriate testing measures for functionality. The installation qualification included inspections of the new system for regulatory compliance and safety as well as identifying information such as name plates on the alignment device. It would also be verified that all documentation was compiled in the correct locations.

The operational qualification included measures to verify that the alignment device functioned properly according to the goals of the project in conjunction with the lidding printer. This included items such as that the alignment device properly powered on and off with the lidding printer, and that the controller would move the web in the correct directions in the manual and automatic modes and properly display these adjustments on the digital interface. Additionally, acceptable web tension would be verified by showing that the lidding did not tear or leave slack when passing through the modified web handling system including a lidding splice passing through in which the web is most likely to be broken. A 15 minute run of the thermoformer, creating 15 minutes worth of blister packs, was also included within this operational qualification to ensure that the new system would not negatively impact the quality of the blisters. Samples of 63 blister packs would be pulled at 5 evenly spaced intervals within the 15 minutes of running to check for different features of the blister pack that could potentially be impacted by modifying the lidding printer. These checks would include that the print on the lidding was not smeared and that there was no foreign material on the lidding, and the classification of an acceptable amount of defects in the samples to pass the testing was set using the AstraZeneca Acceptable Quality Limit (AQL) levels. Additionally, leak testing would be carried out on each of these samples to ensure that the additional rollers are not defective giving the potential to cause seal integrity issues with the blister packs. The testing protocol including all of these items and requirements was approved before the line trial. Since this protocol and report is a part of the company audit trail, the document and precise language included in its items are not included in this report (AstraZeneca Installation and Operational Qualification). Due to the low risk of this new system for AstraZeneca and its low impact on product quality, a performance qualification was not required to verify proper functionality and quality during a commercial batch.

While the project management side of the work for this project is not discussed in detail in this design report, properly managing this line trial time window was critical enough that it will be discussed here. All of the installation work needed to be completed during this 24-hour time window as well as all testing and signoffs into a qualified state to be able to run the line in resumed production. To communicate with all team members the plan for best managing this timeline with little buffer, a schedule was created and discussed. This install timeline can be seen in Table 4 below. The people who were involved with supporting the installation have only their initials listed to keep this confidential. The detailed project schedule can be viewed in Appendix A.

Table 4: Line Trial Installation Timeline

Install Timeline		
What?	**When?**	**Who?**
Mount Power Supply/Breaker	Week of 11/12	DJ
Modify Lidding Printer Guarding	Week of 11/12	JK, SC
Fabricate Mount	Week of 11/19 delivery	SC
Attach Rollers to Mount	Week of 11/19	JF
Prepare Power to Device	11/27 – 2:30am	RV, JF
Attach Controller & Housing	11/27 – 3:30am	JF
Attach Mount, Device, Guarding	11/27 – 5:00am	SC, RV, SD, JF
Setup Machine for Testing	11/27 – 10:30am	Operators, JF
Run Machine for Testing	11/27 – 11:30am	CZ, JF
Signed Documentation & Go-Live	11/27 – 4:00pm	CZ, CH, JF
Turn Line Over to Production for Startup After Thanksgiving Shutdown	11/27 – 10:30pm	All

After arrival at 1:30am on November 27th, the installation work began. As scheduled, the maintenance technician began helping to route wiring, and the controller housing was mounted to the top of the thermoformer. Then, the holes were drilled and tapped for the mount. The mount was then aligned and installed, and the modified lidding printer guarding was reinstalled. The alignment device was then carefully fastened in the correct place within the sliders on the mount. Wiring was then fed through the control cabinet of the printer to power the alignment device. While each of these steps was carried out as planned, the installation fell behind pace by about 2 hours. This was due to the time consuming and difficulty of aligning the mount and fastening the alignment device. Most of the difficulty with the installation work was due to the lack of space to maneuver within the installation area that was also located above a comfortable working height. After a stressful and demanding night and morning installing the new system, it was ready for testing at approximately 12:30 pm. It is important to recognize the great support from multiple maintenance technicians in helping complete this installation.

The work area then needed to be cleaned of any metal shavings and tools used during the installation. Much of the afternoon was then spent in unplanned time troubleshooting issues with the equipment that were not directly caused by the project. The lidding printer had many difficulties starting back up, and the thermoformer had issues properly centering the blister cavities largely due to not being fully set up as it would be during a normal production run. These unplanned hours of struggling to get the machines properly working led to a time of about

5:30pm before it was about ready to be utilized for the qualification testing. By this time, the group involved became frustrated and exhausted in need of a break. With hours of testing ahead, it also would have become difficult to obtain the necessary signatures needed to finalize the qualification documentation. After careful discussion with the process facilitator for line 17, it was decided to adjust the line's schedule to complete the testing on Monday morning when business resumed after the Thanksgiving shutdown. Despite unplanned changes to the schedule, this was deemed to be acceptable to absorb to eliminate extreme difficulty late at night the day before Thanksgiving in which production would not resume until after the Thanksgiving weekend. Since it was not possible to complete the validation work on 3rd shift after Thanksgiving weekend, this shift of work was re-located to the end of the week for the next Friday night and into Saturday morning. Finally, the additional day shift needed to complete the qualification would be rescheduled as one shift of overtime during the following weekend. This overtime requirement was fairly routine for the line and while not ideal, it was acceptable.

After regrouping from an unexpected change of plans due to unexpected delays, line 17 was set up to complete testing and complete the extended line trial on December 2, 2024. The qualification protocol was then followed and verified as expected. The alignment device performed as it was expected while running the thermoformer, and it passed all items with no exceptions. After inspection of each of the samples collected while creating 15 minutes worth of blisters at 260 blisters per minute, there were no failures to meet the quality requirements. The lidding print met specifications and there were no other defects. After testing each of the 315 total samples on the non-destructive leak tester to check for proper seal integrity, each sample passed with zero defects. This was very positive for the new alignment system as it was verified that it did not negatively impact the lidding material as each blister continued to be sealed properly with no cracks, holes, or tears within it that would impact the safe shelf-life of the product. The non-destructive leak tester with all green, or passing, results for each cavity for 4 of the 315 blister samples can be seen in Figure 31 below. With this, the installation qualification operational qualification was completed with no exceptions required from the desired outcomes described in the testing protocol. The qualification protocol was then signed and documentation completed and the change control was moved into a "go-live" state with approval from quality compliance signifying that the new system had become viable for production usage in a qualified state.

Figure 31: Non-Destructive Leak Testing of Blister Samples

6.2 Completed System in Operation

After the qualification of the web alignment system was completed, it was then utilized in production on December 2nd starting in the afternoon. The web alignment system continued to function as expected after its robust setup during the line trial. The completed system integrated into the larger line 17 system can be seen in Figures 32, 33, and 34 below. Figure 32 shows the lidding web running through the alignment device and the modified lidding printer guarding. Figure 33 additionally shows the alignment device controller in automatic correction mode ready for regular adjustment from the operators. Finally, Figure 34 shows the successful and precise mounting of the alignment device within the lidding printer. Note that the wiring was tied down along the mount directly after this image was taken during the installation to ensure that it would not incidentally contact moving rollers or lidding.

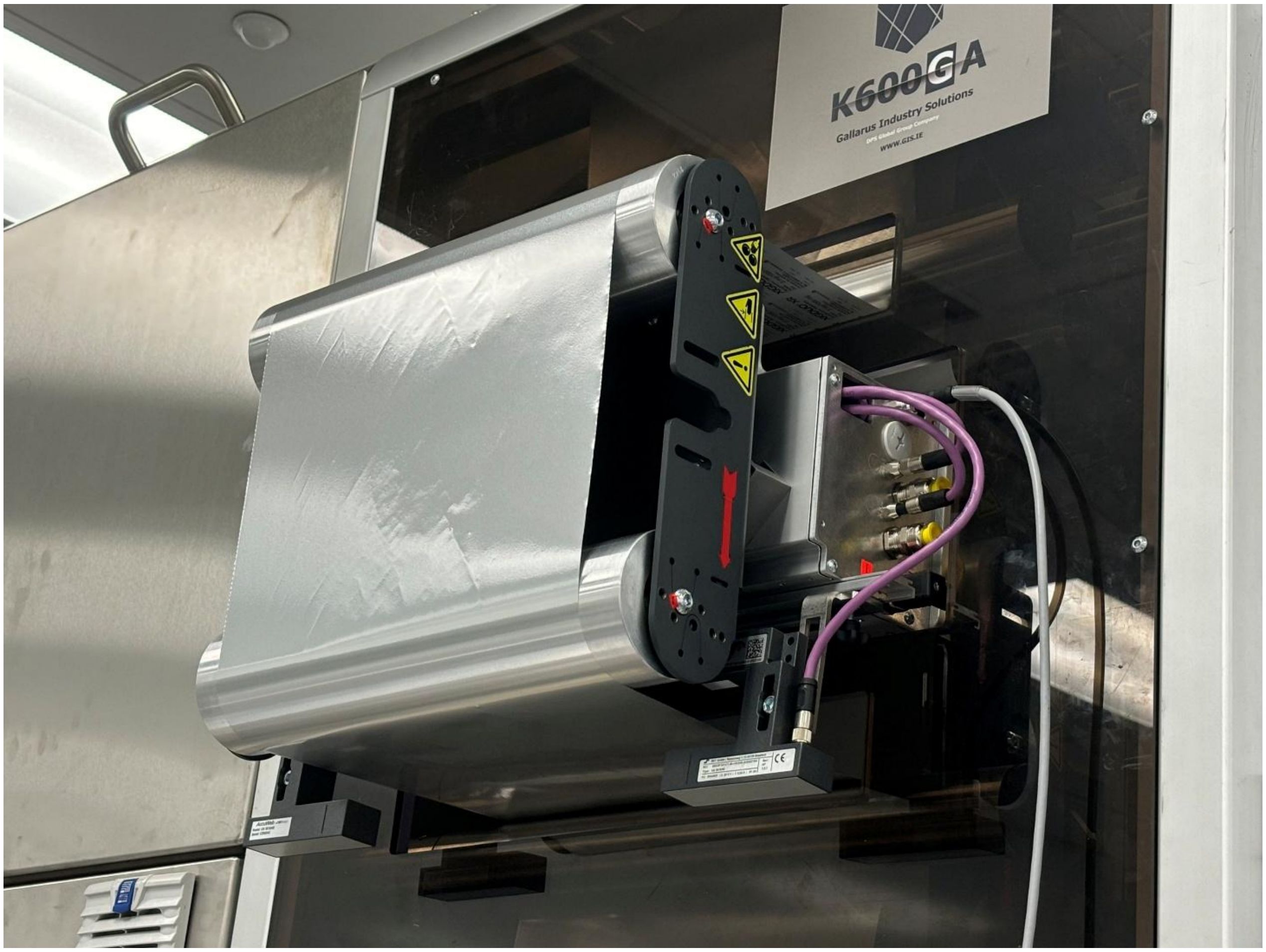

Figure 32: Alignment Device Used During Production

Figure 33: Alignment Device Adjustable Using Controller

Figure 34: Alignment Device Mounting Within Lidding Printer

6.3 Final Cost Breakdown

While not explicitly discussed frequently in this design report, the cost implications of a project are very important to any company, including AstraZeneca. A cost goal was not explicitly stated in this report because there was not a required budget for the project. However, an estimate for the cost of the project was approved after much of the design work was completed and part costs estimated. This approval came from the packaging department leadership team after presenting the goals of this project as well as the estimated cost and timeline. While capital was available enough to ensure that all parts of the project were selected and made at a high quality to function as best as possible, the budget also needed to be used carefully. Each part was considered with cost in mind to drive down the cost as much as possible. A lower cost would lead to a lower payback period for the project, which is the metric that is analyzed by AstraZeneca to determine the attractiveness of a project. With this final cost and the estimated downtime and material savings of $70,849 per year discussed in Section 2.4, this project remained very positive with its financial outlook. This project was finalized with an estimated payback period of only 3.25 months which is very strong for projects at AstraZeneca. The major expenses include the custom fabricated mount, the web guide system, or alignment device, itself, and the two idler roller assemblies that were added for web handling. A summary of the project material costs with a total of $19,000.45 can be seen in Table 5 below, and the detailed bill of materials can be found in Appendix B.

Table 5: Overall Cost Breakdown Table

Material Costs	
Part Name	**Total Cost**
BST Web Guide System	$4025.00
Idler Roller Assemblies (2)	$4923.24
Custom Mount	$8676.80
240W XLE Power Supply	$316.93
Circuit Protection Power Feed Module	$32.50
Electronic Circuit Protection Modules (2)	$134.98
Custom Guard Window Adaptations	$891.00
Total Cost	$19000.45

6.4 Data Analysis Post-Implementation

After the implementation of the web alignment system, it began usage in commercial production and was carefully monitored for any necessary adjustments. Additionally, the downtime experienced on line 17 was analyzed to monitor if the alignment device was having the expected effect and meeting its conceptual design requirements for making these improvements to the line 17 process. The data compiled by the operational excellence team during the first half of 2024 and analyzed by the engineering team consisted of 6 months' worth of data, so 3 months of data was collected afterwards to easily be able to compare values to the previous 6 months. Comparison was completed between the pre-implementation and post-implementation data by simply dividing the pre-implementation data by 2 to be able to easily compare across 3 months. The data for the downtime events on the line was compiled for 3 months after implementation of the web alignment system, thus extending into the beginning of the month of March 2025. Many of the major downtime categories across the line were similar to previous months with the addition of a significant amount of downtime associated with the lidding printer overheating. This issue was resolved in February and will be discussed as an issue to monitor on the line in Section 7.1.

Regarding the downtime observed related to web walking, a decrease in the impact of these issues was observed after implementation. No downtime was recorded directly due to web walking after implementation. Lidding vision system issues also experienced a 100% decrease after implementation, and the impact of lidding breaks or tears was greatly diminished by 86.88%. Print registration issues did climb slightly from an adjusted 201.5 minutes before implementation to 280 minutes after implementation. This increase was further investigated as it was desired that it would decrease after implementation of the alignment system and is discussed in Section 7.1. Overall, the total downtime related to web walking decreased significantly by 68.16%. Each of these categories are displayed on the chart in Figure 35 below with the adjusted downtime before implementation displayed in blue bars and the downtime after implementation displayed in adjacent orange bars. The percentage decrease in each category is also displayed.

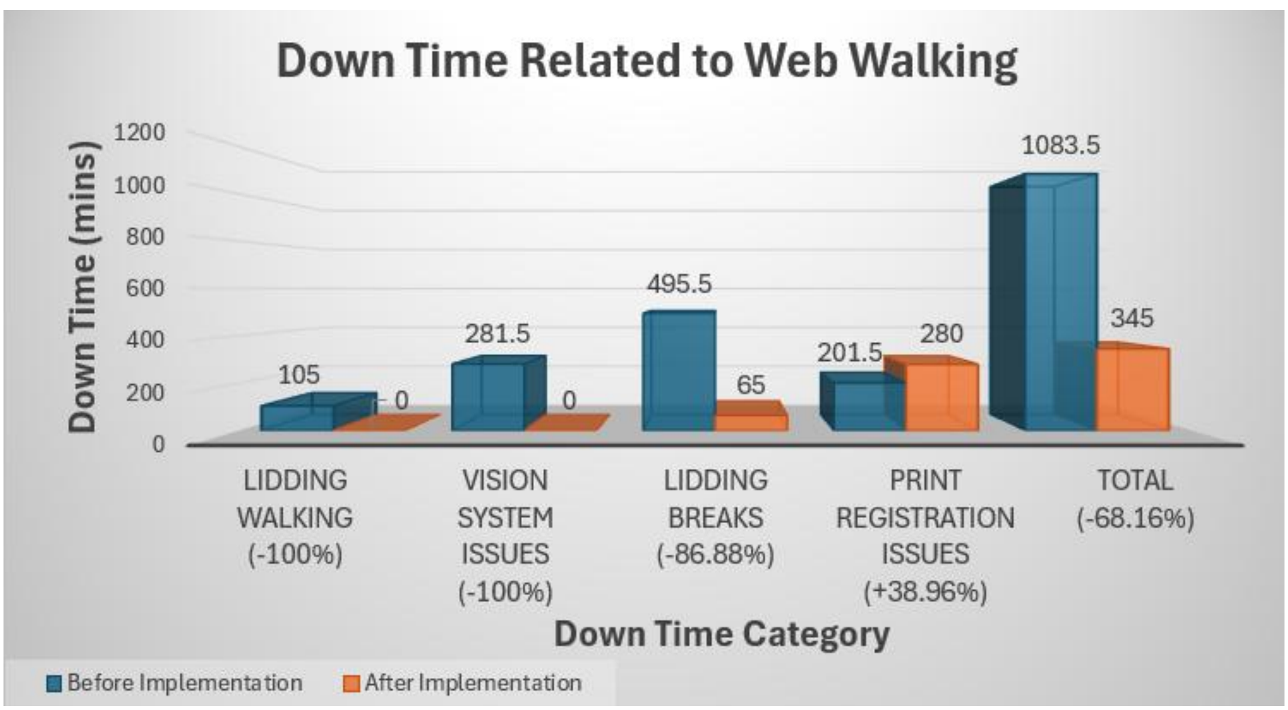

Figure 35: Downtime Related to Web Walking After Implementation

Given that the impact of these events related to web walking was found to be decreased, it would be expected to offer a boost to the performance of the entire line as one of the major issues had been diminished. After analyzing the weekly performance of line 17 over time, this did help to show a performance increase. It was calculated that on average, the average weekly performance of line 17 in 2024 before alignment system integration was 57.3%. After implementation, the average weekly performance of line 17 increased to 61.7%. This was an increase in 4.40% average weekly performance. Furthermore, after data collection for this project was stopped, the line performance has increased even further. The line has even begun to show consistency in the past month of reaching its 65% performance target. This has had a significant impact on the success of this critical blister packaging line and has translated to an improvement in the achievement of overall packaging department goals. While there are many activities and factors that can influence the performance on line 17 and it is impossible to fully attribute the increase to the addition of the web alignment system, it is clear that it was a catalyst for improvement and reduction of issues on the line at the thermoformer.

In addition to the overall analysis of collected downtime and line performance, data was collected while being directly on the line to analyze the impact and cause of short stops. Seven hours' worth of detailed data was collected for the status of the line during production simply to observe how the line was running, especially at the thermoformer. Qualitatively, it could be seen that after months of operation, the web alignment system was still functioning as desired. On a more quantitative level, the most frequent and impactful short downtime events were analyzed. Table 6 below shows the downtime categories sorted with those that caused the most total downtime at the top.

Table 6: Line 17 Detailed Short Stop Data (Sorted with Most Impactful Categories at Top)

Downtime Categories	**Number of Instances**	**Total Downtime (min)**	**Average Downtime per stop (min)**
Print Registration	19	24.92	1.31
False Leak Test Failure - Glue Tac	1	24.00	24.00
2900 Cartons Jammed On Line Machine - Casepacker Issue	6	15.42	2.57
New Forming Roll	4	10.00	2.50
Pocket Filling Errors	7	7.67	1.10
Blister Not Rejected (Outer Row)	2	7.50	3.75
Place Booklet Tray On Suction Cups	6	6.50	1.08
New Lidding Roll	3	6.42	2.14
Pocket Centering	1	5.83	5.83
Machine Running - Blister Recovery at Cartoner	3	4.00	1.33

Cartons Jammed On Line Machine - TE Machine Issue	2	3.00	1.50
Cartons Jammed On Line Machine	2	1.75	0.88
Stack Not Inserted Correctly Into Carton	3	1.75	0.58
Overload at Stacking and/or Leaflet Introduction in Carton	2	1.42	0.71
Forming Film Splicing - Factory Splice	1	0.50	0.50
Empty Blister Collection Box Full	1	0.25	0.25
Booklet Trays Finished	1	0.25	0.25
Carton Not Closed Properly	1	0.25	0.25

Overall, many of the common issues causing short downtime events were observed. Many of these issues were discussed internally with the goal of eliminating as much downtime as possible. Some of the issues that happened downstream at the casepacker are ongoing issues due to poor components supplied to AstraZeneca and are being worked on by a variety of people. Other line stoppages such as replacing forming rolls have future projects to eliminate the need for stopping the line to complete a regular process task. Additionally, pocket centering training is being developed by the engineering department, and false leak test failures are being studied. Each of these efforts offer credence to the high ceiling that is possible for line 17 over the next year. Perhaps the most interesting result of collecting data on these short stops was the high frequency of print registration errors. These were observed in many cases after other line stoppages and could be seen to occur due to poor traction at the nip rollers in the lidding printer. Solutions for this issue are discussed in Section 7.1. Reduction of short stops for print registration errors would offer even more performance increase on the line and further improve the thermoforming process.

6.5 Evaluation of Project Requirements

After completing initial testing of the web alignment system as well as analyzing its effects on the line 17 process after 3 months of production usage, the project requirements were reviewed. The evaluation of these conceptual design requirements follows from the evaluation criteria listed in Section 3.2. These evaluation criteria ultimately show that the system design met its requirements for integration into the system as well as the goals for improving the efficiency of line 17 by reducing the prevalence of the web walking issue and its negative effects. The success for meeting the project requirements follow with a green checkmark indicating that the requirement was met and an amber circle indicating that the requirement was partially met:

- ☑ Line 17 performance increases by 1%
- ☑ * Downtime from web walking reduces by 75%

- ☑ Web tension is maintained - not causing bunched lidding, tears, or slack at the sealing station
- ☑ Web speed remains within a range from 40.5 to 42.5 feet per minute
- ☑ Lidding printer system remains enclosed
- ☑ Alignment device structure does not sag or deform
- ☑ Alignment device automatically corrects web as the sensors detect movement
- ☑ Operators are comfortable with the new system design
- ☑ Sign-off on change control from Validation & Compliance
- ◎ Installation and qualification completed in the allotted planned downtime

The major, overarching goal of this project to increase the performance of line 17 was successfully achieved. While a reachable target of a 1% increase in performance was set at the beginning of the project, it was significantly exceeded as a 4.40% increase in weekly performance was observed. While there are many factors impacting performance on the line, this is a very positive indicator that the web alignment system was a catalyst for significant improvement on line 17. This success was also observed by the reduction of downtime related to web walking. In Section 6.4, it was discussed that downtime over the examined period directly from web walking reduced by 100%. This exceeded the requirement that downtime directly caused by web walking would be reduced by 75%. Downtime from vision system issues also decreased by 100%, and downtime from lidding breaks, which can be very costly, was decreased by 86.88%. The asterisk is shown for this project requirement due to the increase in downtime caused by print registration. Print registration is a by-product of the web walking, so reducing this issue was expected by implementing the alignment device. However, there are many factors influencing print registration issues in the lidding printer. In the cases observed over this time period, it was found that the issues resulted mostly due to worn nip rollers throughout the printer before the print is applied to the lidding. Therefore, the alignment device itself would not be expected to correct this issue as it was functioning properly, so these other contributing factors must be addressed and are discussed in Section 7.1. Overall, the downtime from categories that can be associated with the lidding web walking were reduced by 68.16% after the implementation of the alignment device, which exceeded expectations.

Additionally, the other requirements associated closely with the design of the system and its integration into the lidding printer and thermoformer systems were met. The web tension and web speed was maintained, and these items were verified in the operational qualification of the system. The lidding printer also remained an enclosed system as careful attention to this was taken in the mounting design so that only small passthroughs were cut in the guarding thus keeping the lidding printer system contained. The alignment device structure and mounting was also observed to remain square and not deflect over time, staying successfully rigid to keep the device in its place. Additionally, using edge sensors, the web position was detected in an automated fashion and automatically corrected as desired with the automatic correction mode on the controller. After discussing with operators and explaining the design of the new system and how they needed to interact with it, there were no lingering complaints and the operators have expressed increasing comfort with utilizing the system. Finally, the change control was completed as planned with validation signing off for successful testing and compliance signing off for adherence to quality standards.

However, the only requirement that was not fully met was that the installation and qualification of the web alignment system was not completed within the planned line downtime. Due to unexpected challenges and a narrow 24-hour window, the qualification had to be paused and resumed during the next business day. This caused nearly two shifts of production time to be lost on the line. This includes one day shift as well as the night shift prior because testing could not be completed by other groups on site during the night shift. However, the schedule was adjusted with minimal difficulty after the qualification was completed. Due to buffer time in the line's schedule, this additional project downtime did not have too much negative impact on the line. Despite requiring additional time, all components were ready to be installed on the date scheduled by the supply chain team with no delays. Therefore, this requirement was marked as amber since it was partially, but not fully, met.

7.0 Conclusions and Recommendations

After nearly one year of work on this project designing a web alignment system, managing a complex project, and analyzing the details of the line 17 blister packaging process, this particular project is coming to a close. However, packaging line 17 will continue running for multiple years with new issues, solutions, and projects. In this section, the learnings from this project and future improvements for the line will be discussed. Additionally, the collaborations within the AstraZeneca to complete this project will be discussed as well as the many lessons learned from this project for a professional engineering career in manufacturing.

7.1 Future Line Improvements

Despite the considerable improvements over the past year, especially including the web alignment system, that have moved line 17's performance near its target, there are many more improvements ahead. It is critical in continuous improvement to analyze the issues that appear over time and address them without ever becoming complacent. In a competitive industry, the line will need to continue to improve and strive towards more stringent goals towards 70% performance and beyond.

First of all, the lingering print registration issues detected in the data analysis after the implementation of the web alignment system in Section 6.4 needs to be fully addressed. When monitoring the issue, it was found that the print registration issues were caused by the web moving before the printing is applied to the material causing the location of the print to be slightly off when analyzed by the vision system. This movement of the web was found to occur directly after the nip rollers which are intended to pull the web forward through the printer, and mostly at the nip roller directly before the lidding is printed. Over time it was found that the rollers had become slightly loosened and were not clamping down fully on the lidding web. This would cause the lidding to become slightly misaligned after the nip roller. The rollers had also become worn over time making it more difficult for the rollers to properly grip the lidding, especially in the final month of data collection when the downtime caused by print registration issues had increased.

In order to improve the nip rollers, the grip of the rollers on the lidding material as well as the maintenance on the rollers will need to be improved. After studying the various rollers at the AstraZeneca Mt. Vernon site, it is believed that using a lower durometer roller will help the nip roller to have a better grip on the lidding material as it moves forward to help prevent sliding. In layman's terms, the new roller will be more "squishy." This is currently being attempted by recoating the old spare set of rollers that were replaced after the rollers were found to be worn and causing much of this downtime. Additionally, it has been observed that these nip rollers tend to start failing after 8-9 months and need to be replaced, but no preventative maintenance (PM) has been created for them yet due to a lack of understanding of how they behave. So, a new 6-month PM has been put in place to replace the rollers. Additionally, a 2-month PM will be put in place to tighten the nip rollers so that they remain clamped down properly on the lidding web. A jig may need to be designed and built to help properly tighten the nip rollers and in a quick manner. With these new action items, much of the print registration downtime remaining that was observed should be eliminated in future months.

Another issue that has been observed causing downtime in recent months on line 17 has been the lidding printer control cabinet overheating. This is not a new phenomenon with the machine, but it began meeting a threshold that would cause the printer to fault out and stop running. While there are a variety of factors that seem to have been creating this overheating and are unrelated to the new alignment system, the root cause of the issue is not fully understood. However, it is clear that the airflow design through the cabinet was never very robust and the sensor was placed, intentionally, in the area of least airflow through the cabinet. After coming to an understanding of the issue, a vent was added to move hot air from the electrical cabinet fan directly out of the machine. A larger fan was also added to the control cabinet to move cool air in as well as an additional small fan replacing an existing filter. These airflow design modifications have provided better airflow within the lidding printer than it has ever experienced during its production usage. This issue just needs to be continuously monitored for any lingering issues or future modifications.

Pocket centering issues have been another issue that has been one of the leading downtime categories on line 17. In fact, this was the 2nd most impactful downtime category at the thermoformer observed in Figure 5. Most of this downtime could be prevented by increasing the understanding of the operators of how to fix the issue when it arises. One of the other members of the packaging engineering team is currently working on creating training for the operators for how to properly make adjustments for pocket centering. As operators become more skilled with the thermoformer, this issue should create a lower impact on performance.

Another project that is in progress for line 17 is an auto-splicer for the forming material infeed. This machine is expected to be implemented later in the year and will eliminate the need to stop the thermoformer when a roll of forming material is finished and needs to be replaced. While changing and splicing rolls of forming material does not cause major downtime, it was observed as a short stop causing about 2 minutes of downtime about every 2 hours. This new piece of machinery will reduce downtime that is inherent to the process and further help to increase performance.

Total productive maintenance (TPM) is another future improvement opportunity for line 17. TPM, which is discussed in Section 5.7, aims to reduce and ultimately prevent breakdowns on the line by utilizing a proactive maintenance strategy. Improved preventative maintenance measures have been implemented already on many of the machines on the line as well as autonomous maintenance. As maintenance and operators continue to create a better relationship and more ownership over the equipment, it will be better maintained which should help reduce downtime. More CILT's are being identified on the line implementing a more proactive strategy and changing the culture. As a member of the line 17 TPM team, I see the benefits of taking this strategy to help move toward better line performance and involvement with the equipment.

Another project on the line as a part of the continuous improvements to the line is the consolidation of the thermoformer guide rails. I completed this project in the past year, and this was primarily targeted toward reducing changeover times. The guide rails are all very similar between the different products produced on the line, so three different formats were reduced to one set of guide rails to be used across all products. This project eliminated the need to change the guide rails when changing between products, thus saving 10-15 minutes on many of the line's changeovers.

One more project as a part of this improvement effort is a casepacker glue auto-feed system. I also have completed this project in the past year. This auto-feed system implements a hopper that automatically fills the glue melt system for the casepacker. This glue is applied to a box, or case, to seal it closed. The auto-feed system eliminates the operators from needing to manually fill the glue melt system multiple times per shift making it easier to operate the line with fewer workers. With the new auto-feed system, glue feeding only needs to be attended to about once per week. Despite the considerable improvements to line 17 discussed in this report, it is critical that this culture of continuous improvement for the line is maintained as a part of an ongoing process to maintain and improve OEE. New issues as well as areas for improvement will continue to arise, and it is important that the department remains vigilant, as exemplified by this section of the report, to continue to take action for the ongoing excellence of the line 17 system.

7.2 Work Collaborations within AstraZeneca

Despite this senior project being completed as an individual, it could not have been successful without the collaboration and insights of a large group of co-workers at AstraZeneca.

The collaborations discussed in this section barely scratch the surface of those within this project, let alone my full time so far at AstraZeneca. Throughout my time in packaging engineering, I have been fortunate to gain many insights from the engineers around me as well as valuable support from other departments. In leading this project, I had the opportunity to gain insights from senior packaging engineers Robert Schleter and Dalton Burk. Their expertise with the equipment proved valuable with questions I had for defining the scope of the project and verifying my design work.

Beginning this project, I held discussions with the multi-disciplinary team that focuses on line 17 including Robert Schleter, the process facilitator for the line, and operational excellence specialists. Working with the operational excellence team, we were able to utilize data collected by that team to understand the scope of some of the issues on the line and develop a case for the addition of the web alignment system. I also worked closely with multiple representatives from BST to develop the best alignment device offered to fit the application on line 17. I also worked with technical experts from Domino, the manufacturer of the lidding printer, to ensure the compatibility of the new web alignment system with the existing lidding printer system in the early stages of the project. I also had the opportunity to work with the supply chain team to integrate planned downtime into the schedule for the line trial, and with purchasing to obtain all of the parts needed for the new system. I am also very grateful for the great work completed by the validation engineer assigned to my project as we collaborated closely to ensure that the correct testing was completed to ensure functionality and compliance with industry standards. Discussions with safety and quality representatives also helped shape the design requirements of this project.

Regarding the installation of the new alignment system, I could not have completed this by myself. I was able to schedule assistance from multiple members of the packaging maintenance team to help install wiring and the mount. I needed to hold discussions, and overall planning meetings with everyone involved in the installation, with these maintenance team members so that they understood the project and the specific tasks that needed to be done. Their assistance was very valuable during the unexpected challenges during the installation. Finally, I had some great discussions with the operators on line 17. Their expertise was critical in understanding the issues encountered with the machinery and giving suggestions that would make the alignment system easiest and most effective for them to use in production. The help of the operators setting up and running the thermoformer during the qualification was also very appreciated, and they did an excellent job.

7.3 Lessons Learned

Through the journey of this project over nearly an entire year, I learned many lessons about working with a team and managing projects. I learned the ways of working at AstraZeneca and the dedication required by a team to meet bold goals for advancing an industry and providing quality medications to patients around the world. By bringing my best every day, I have very real opportunities for the company and patients and to bring a joy and strong work ethic to a driven team. I have learned firsthand how willing to help many of my co-workers at AstraZeneca are, as well as their genuine care for the success of the company and the people around them. I learned that it is encouraged to ask questions of other engineers and of other groups, and to think through problems and verify design ideas with others.

Additionally, I have learned to include maintenance technicians and operators in my projects. While they may not have some of the technical expertise of an engineer, they are experts with the packaging process and the equipment. They work hands-on with the equipment every day and have seen many of the changes and details of the equipment over time. They often have very valuable insights, design ideas to spur new and thoughtful changes, and are great at selecting alternatives that would be best to use for operability. I quickly learned to go to Rick, an operator who has worked in blister packaging for multiple decades, for his opinion on design choices for the web alignment system as he would have thoughtful ideas and reasoning based on his experience. Operators such as Rick have seen firsthand the changes and issues on the line and are valuable for putting issues into perspective, troubleshooting, and ensuring that any changes that are made to best support the line. They also are the people directly interacting with any engineering design changes, so it is very important to talk with them and get them on board with any new ideas. One of the experienced maintenance technicians also helped begin the idea to mount the new roller assemblies directly to the mount, which was a design decision that shortened the installation time likely by over an hour. The experience of these technicians and operators is incredibly useful in supporting projects, so their voices should be included.

Another critical major lesson that I learn is the importance of communication while managing a project. When a team is involved from many different departments, it can be difficult to express the need for the project as well as the steps that need to be completed. As a project manager, the project may be one of your most important tasks and a focus of your time. However, other co-workers may be only involved in smaller parts of the project, and it is not their focus. I found that it is important to reach out and overcommunicate the status of the project and what is needed. According to Gido, it is the responsibility of the project manager to facilitate a cooperative team in an ongoing effort to build commitment toward a common goal (376). I have found that these people are always willing to help and are not purposefully neglecting the project, but that they just need to be included in communication. I also found that it is important to gain buy-in on the project from all team members by clearly expressing the need for the project and how it will benefit the company and its work environment. For example, I came to work briefly during the night on multiple nights to talk with a third shift maintenance technician who was helping me with the project. I had not previously worked with him before and he did not know about the project at first, but I was able to build a strong working relationship with him and he became invested in the success of the project after I explained to him the purpose of the project. Working with a diverse team in a manufacturing environment can be challenging and additional communication is necessary, but this ultimately pays off due to the wide range of expertise that a team can offer.

7.4 Project Conclusion

Overall, this project narrowed a large issue of sub-optimal efficiency of a key blister packaging line within the AstraZeneca network to a manageable project aimed at improving this efficiency. This focus was around a web walking issue found to be a major factor holding line 17 back from reaching its performance target. While some of the project management aspects of this web alignment system project were discussed in this report, it was mostly centered upon the design of the new system. Stemming from overall design requirements, components were selected for the new system through a series of design decisions. Ultimately, the new lidding web alignment system was able to be installed for production usage integrated into the larger system on line 17. Over time, this project was found to have a meaningful impact on the line, even seeing an increase in line 17's performance of 4.40%. The design requirements for the project were met, along with the learning experience designed by this senior design course. This lidding web alignment project utilized multiple principles of design into a process improvement objective tying many of the foundational concepts of manufacturing engineering together into a project. This project, even according to the data, provided a meaningful improvement to the AstraZeneca Mt. Vernon site and sits within an ongoing continuous improvement effort. This effort and improvement mindset will prove to serve the AstraZeneca brand and its patients into the future.

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Appendix

Appendix A: Project Schedule – Network Diagram

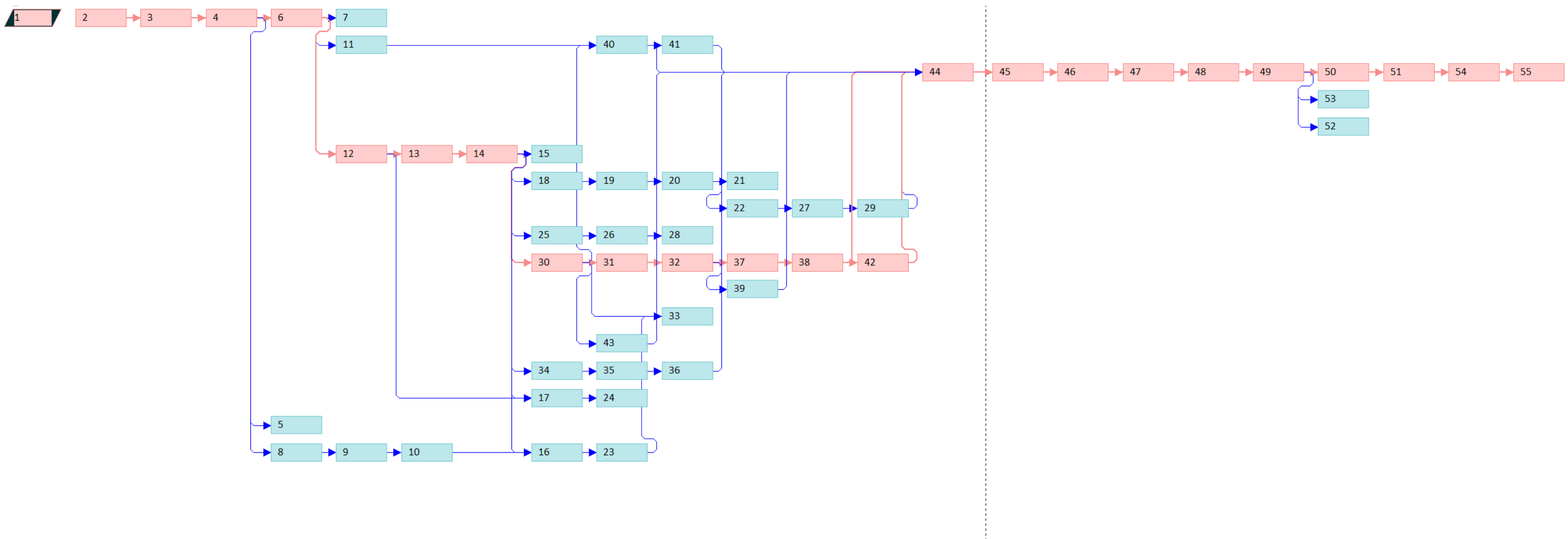
Appendix B: Bill of Materials

Appendix C: Failure Modes and Effects Analysis

Appendix D: Design Factor Considerations

Appendix A: Project Schedule – Network Diagram

Note: the critical path is displayed in red.



Event description, dates, and resources in this network diagram are detailed in the charts below for the sake of space and readability. The event numbers from this network diagram are displayed in the left-most column below.

	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names
1		Web Alignment Project	152.76 days	Mon 5/20/24	Wed 12/18/2		
2		Collect Downtime Data	4 days	Mon 5/20/24	Thu 5/23/24		Josh Feil,OpEx Team
3		Define Problem	2 days	Fri 5/24/24	Mon 5/27/24	2	Josh Feil,TriForce Team
4		General Conceptual Design Ideation	2 days	Tue 5/28/24	Wed 5/29/24	3	Josh Feil
5		Determine lidding system parameters	2 days	Thu 5/30/24	Fri 5/31/24	4	Josh Feil,BS
6		Determine main web alignment component	2 days	Thu 5/30/24	Fri 5/31/24	4	Josh Feil,BS
7		Determine Vendor	4 days	Tue 6/11/24	Fri 6/14/24	6	Josh Feil
8		Determine Web Tension	12 days	Thu 5/30/24	Fri 6/14/24	4	Josh Feil
9		Complete Quote Sheet	1 day	Mon 6/17/24	Mon 6/17/24	8	Josh Feil
10		Obtain quote for alignment device	4 days	Tue 6/18/24	Fri 6/21/24	9	Josh Feil
11		Obtain quote for mount	17 days	Mon 6/3/24	Tue 6/25/24	6	Josh Feil,SC
12		Obtain quote for roller assemblies	19 days	Mon 6/3/24	Thu 6/27/24	6	Josh Feil,SK
13		Develop Estimated Cost Savings from project	1 day	Fri 6/28/24	Fri 6/28/24	12	Josh Feil
14		Obtain approval for capital	1 day	Mon 7/1/24	Mon 7/1/24	13	Josh Feil
15		Obtain line time for install	1 day	Tue 7/2/24	Tue 7/2/24	14	Josh Feil
16		Complete order for alignment device	1 day	Tue 7/2/24	Tue 7/2/24	14,10	Josh Feil,JC
17		Complete order for roller assemblies	10 days	Tue 7/2/24	Mon 7/15/24	14,12	Josh Feil,JC
18		Open change control	1 day	Wed 7/3/24	Wed 7/3/24	14	Josh Feil
19		Create project team	3 days	Thu 7/4/24	Mon 7/8/24	18	Josh Feil
20		Complete impact assessments	11 days	Tue 7/9/24	Tue 7/23/24	19	Josh Feil,Change Control Team
21		Determine change actions	3 days	Wed 7/24/24	Fri 7/26/24	20	Josh Feil,Change Control Team
22		Complete risk assessments	3 days	Wed 7/24/24	Fri 7/26/24	20	Josh Feil
23		Obtain alignment device	31 days	Wed 7/3/24	Wed 8/14/24	16	Josh Feil
24		Obtain roller assemblies	22 days	Tue 7/16/24	Wed 8/14/24	17	Josh Feil
25		Complete design for electrical modifications	22 days	Tue 7/2/24	Wed 7/31/24	14	Josh Feil
26		Order electrical components	4 days	Thu 8/1/24	Tue 8/6/24	25	Josh Feil,JC
27		Move change control to "In Change Execution"	5 days	Mon 7/29/24	Fri 8/2/24	22	Josh Feil
28		Obtain electrical components	9 days	Wed 8/7/24	Mon 8/19/24	26	Josh Feil
29		Create line trial memo	8 days	Mon 8/5/24	Wed 8/14/24	27	Josh Feil
30		Complete Mount Design	62 days	Tue 7/2/24	Wed 9/25/24	14	Josh Feil
31		Submit WO's for maintenance assistance	4 days	Thu 9/26/24	Tue 10/1/24	30	Josh Feil
32		Schedule WO's	5 days	Wed 10/2/24	Tue 10/8/24	31	Josh Feil,JC
33		Complete IOQ documentation approval	11 days	Thu 9/26/24	Thu 10/10/24	30,23	Josh Feil,CZ
34		Design 3D printed housing	83 days	Tue 7/2/24	Thu 10/24/24	14	Josh Feil
35		Build housing prototype	3 days	Fri 10/25/24	Tue 10/29/24	34	Josh Feil
36		Build optimized 3D printed housing	2 days	Wed 10/30/2	Thu 10/31/24	35	Josh Feil
37		Prepare electrical modifications in lidding printer	26 days	Wed 10/9/24	Wed 11/13/24	32	Josh Feil,DJ
38		Test modified electrical system	2 days	Thu 11/14/24	Fri 11/15/24	37	Josh Feil,DJ
39		Cut modifications to lidding printer gaurding	28 days	Wed 10/9/24	Fri 11/15/24	32	Josh Feil,JK,SC
40		Obtain Fabricated Mount	38 days	Thu 9/26/24	Mon 11/18/2	30,11	Josh Feil,SC
41		Attach roller assemblies to mount	4 days	Tue 11/19/24	Fri 11/22/24	40	Josh Feil,JK
42		Update electrical diagrams	7 days	Mon 11/18/2	Tue 11/26/24	38	Josh Feil
43		Update threading diagram	43 days	Thu 9/26/24	Mon 11/25/2	30	Josh Feil
44		Attach power to alignment device	0.07 days	Wed 11/27/2	Wed 11/27/2	41,38,39,40,43,29	Josh Feil,RV
45		Attach digital interface and housing	0.05 days	Wed 11/27/2	Wed 11/27/2	44	Josh Feil,RV
46		Mount alignment device	0.1 days	Wed 11/27/2	Wed 11/27/2	45	Josh Feil,SC,RV
47		Setup alignment device for production	0.07 days	Wed 11/27/2	Wed 11/27/2	46	Josh Feil
48		Complete validation IOQ	0.17 days	Wed 11/27/2	Wed 11/27/2	47	Josh Feil,CZ
49		Signed documentation & Go-Live	0.2 days	Wed 11/27/2	Wed 11/27/2	48	Josh Feil,CZ,CH
50		Turn line over to production in changed state	0.1 days	Wed 11/27/24	Wed 11/27/24	49	Josh Feil
51		Close change control	3 days	Wed 11/27/2	Mon 12/2/24	50	Josh Feil
52		Check that all payments are complete	4 days	Wed 11/27/2	Tue 12/3/24	49	Josh Feil,JC
53		Recognize project team	4 days	Wed 11/27/2	Tue 12/3/24	49	Josh Feil
54		Complete Effectiveness Check	9 days	Mon 12/2/24	Fri 12/13/24	51	Josh Feil
55		Analyze evaluation criteria post-project	3 days	Fri 12/13/24	Wed 12/18/2	54	Josh Feil

Appendix B: Bill of Materials

Part Name	Supplier	Part Number	Description	Unit Cost	Qty	Total Cost	Lead Time
Web Guide System	BST	BSTe Compact Guide DF 2 X 350 X 350 X 80	(1) Commander EKR CON 600 Controller (2) 350mm diameter x 80mm aluminum idler roller (1) EMS actuator (2) Sensor cable with mating plug (2) US 2010/40 Sensor (1) 2m BUS cable for COMMANDER (1) Manual, Instruction, Current Revision, USB	$4025	1	$4025	4-6 weeks
Idler Roller Assembly	Gallarus Industry Solutions	GIS01-A09-GA	**GIS01-A09-GA – A09 Roller Assembly** GIS01-A04-GA Roller Assembly • GIS00002 Roller Shaft Sus 304 2 EA • GIS00001 Roller Sleve Sus 304 2 EA • GIS00004 Nip Arm Sus 304 2 EA 98541A440 C-Clip 4 EA Socket Head Shoulder Screw 2 EA 6005ZZ Groove Ball Bearing 4 EA T-01011-0500A-005-005 Threaded Tube 50MM 2 EA	$2461.62	2	$4923.24	4 weeks

			• GIS00009 Upstand Sus 304 2 EA 150927 ZBH-9 Locating Ring 8 EA M6X25 SS SHCS 8 EA 6005ZZ Groove Ball Bearing 4 EA • Entire Roller Assembled Before Shipping • Shipping Cost Included				
Custom Mount	Precision Services	N/A	Custom designed mount (designed by J. Feil) for alignment device to be precision machined, installation support included	$8676.80	1	$8676.80	3-4 weeks
240W XLE Power Supply	CED – Evansville Supply	AB 1606-XLE240E	Allen-Bradley XLE Power Supply 240W 24VDC 10A	$316.93	1	$316.93	In Stock
Circuit Protection Power Feed Module	CED – Evansville Supply	AB 1694-PFA1244	Allen-Bradley 40A Maximum Power Feed Module for Protection Module	$32.50	1	$32.50	1 week
Electronic Circuit Protection Module	CED – Evansville Supply	AB 1694-PM266	Allen-Bradley 6A Protection Module (2 x 6A)	$67.49	2	$134.98	1 week
Custom Guard Window Adaptations	Precision Services	N/A	Adapted lidding printer guard window with cuts for system modification using waterjet, design by J. Feil	$891	1	$891	1 week
					Total Price	$19000.45	

Appendix C: Failure Modes and Effects Analysis

Quality Tools

Failure Mode and Effects Analysis

ASQ

Description

This template illustrates a Failure Mode and Effects Analysis (FMEA), also referred to as a Potential Failure Mode and Effects Analysis (PFMEA) or Failure Modes, Effects and Criticality Analysis (FMECA). A detailed discussion can be found at www.ASQ.org

Please follow the link for detailed instructions for data entry

Initiate action to reduce the RPN

Re-evaluate the RPN value after completion of the recommended actions

Learn More

To learn more about other quality tools, visit the ASQ Learn About Quality website.

Learn About FMEA

Learn About Quality

FAILURE MODE AND EFFECTS ANALYSIS

Item: Lidding Web Alignment	Responsibility: AZ Pack Engineering & Maintenanc	FMEA number:	
Model: Line 17 Web Alignment System Design	Prepared by: Joshua Feil	Page: 1 of 1	
Core Team: Joshua Feil, AstraZeneca Mt. Vernon Packaging Engineering, Maintenance, and Operations		FMEA Date (Orig):	Rev: 1

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Potential Cause(s)/ Mechanism(s) of Failure	Occur	Current Process Controls	Detec	RPN	Recommended Action(s)	Responsibility and Target Completion Date	Action Results: Actions Taken	Sev	Occ	Det	RPN
Power to alignment device	No charge to allow alignment device to operate	Device cannot make adjustments to alignment, lidding web only passes directly over the stationary rollers that may be misaligned. The line can remain running during this failure, but performance will likely be impacted negatively.	4	Internal wiring/connections failed	1	Breakers protect the alignment device from a potential power surge	7	28	N/A, the worst potential effects are prevented by cuircuit breakers	N/A	N/A	4	1	7	28
			4	Lidding printer powered off, so failing to supply aligment device with power	3	Lidding printer HMI will clearly be off in case of no power to the system	1	12	Make operators aware of how to react to this case of the lidding printer being powered off	Josh Feil 11/27/24	Operators aware of lidding printer power functionality	4	2	1	8
			4	Lidding printer fails to have enough extra power to run additional alignment device	2	Supply Voltage Outside the Permissible Range alarm appears on digital interface in a yellow triangle	7	56	Perform testing/measurements to ensure the lidding printer has sufficient power headroom at max capacity	Josh Feil 8/1/2024	Measurements and testing confirm that there is sufficient power	3	1	2	6
			4	No power to the lidding printer, power outage	3	Generator quickly turns on to return power to the machine	1	12	N/A, the generator is sufficient	N/A	N/A	4	3	1	12
Digital Interface controls alignment device	Controller fails to make the proper adjustments to the device when operator interacts with digital interface	Setpoints or manual position cannot be adjusted, alarms cleared, or guiding modes or settings changed. The device may not be able to make changes to alignment. The line can remain running during this failure, but performance will likely be impacted negatively. Down time will be required to fix the issue.	5	Bad/pinched/disconnected cabling between digital interface and controller	2	Bus Connection Fault is displayed in a yellow triangle on digital interface	2	20	Tie cabling to machine during install to prevent poor routing	Josh Feil 11/27/24	Cabling is tied tightly to machine with comfortable routing	5	1	2	10
			5	Switch board has a wrong position	3	N/A	6	90	Check switch board positions with manual before installation	Josh Feil 11/20/24	Switch board positions are verified to be correct	5	1	6	30
			5	Fried control board	1	N/A	6	30	N/A, this potential cause is highly unlikely and not worth the cost of keeping a spare control board	N/A	N/A	5	1	6	30
			5	Operator makes incorrect adjustment on digital interface	5	Digital interface displays the adjustments that were made	2	50	Train operators for making basic manual and automatic adjustments	Josh Feil 11/27/24	Operators are aware of how to make adjustments properly	5	2	2	20
			5	Controller gain has been set too low	2	Gain is displayed on the digital interface	3	30	Use manual for knowledge of optimizing controller gain on the device and carry out procedure upon installation	Josh Feil 11/27/24	Gain is optimized and knowledge is attained to adjust as necessary upon production startup	5	1	3	15
Rollers handle the web into and out of the alignment device	Roller fails to turn as web is transported over the roller	Improper web tension occurs or the lidding breaks. Shuts the line down, possibly for multiple hours for maintenance and re-threading	6	Bearing fails on roller and roller assembly loses functionality	1	N/A	4	24	Order spare roller assembly for quick replacement in case of failure	AstraZeneca Maintenance Team, 10/1/24	Spare part stored on site	6	1	3	18
			6	Web moves backwards (in improper direction) or fails to move due to extraneous forces on web	2	N/A	5	60	Complete force analysis of web to identify any problem areas and identify troubleshooting scenarios	Josh Feil 11/20/24	Knowledge of troubleshooting scenarios are gained in case of failure	6	2	3	36

Rollers handle the web into and out of the alignment device	Rollers are misaligned and fail to transport the web with proper direction and angles	Improper web tension occurs, lidding bunches, or lidding tears. Shuts the line down, possibly for multiple hours as position adjustments are made	6	Roller loses perpendicularity with the back panel of the lidding printer	2	N/A	4	48	Bushings are placed in a precision machined countersink to maintain alignment	Josh Feil & Fabricator 10/1/24	Mount is designed for roller attachment to best maintain precise alignment	6	1	4	24
			6	Rollers deflect over time due to continual applied forces	2	Alignment device mitigates much of this deflection by making corrections in real time	3	36	N/A	N/A	N/A	6	2	3	36
			6	Alignment device mount sags, so the alignment device loses perpendicularity with the back panel of the lidding printer and the alignment device rollers become mis-positioned	2	N/A	4	48	Mount is designed to be rigidly mounted to back panel of printer with high strength fasteners	Josh Feil & Fabricator 10/1/24	Mount is designed for rigid fastening that will last over time	6	1	4	24
Web Correction by alignment device	Web alignment device detects web outside of the correction range of the sensors	Web and/or device controller has to be manually adjusted to bring the device back into an acceptable range. This will likely lead to a line stoppage until resolved	3	Alignment device has moved to its limits of correction after being adjusted rapidly in its operation, most likely in startup or after re-threading the web	4	Actuator blocked alarm displays on digital interface with a yellow triangle	2	24	Ensure that operators know how to make simple manual adjustments	Josh Feil 11/27/24	Operators aware of manual mode on digital interface	3	2	2	12
			3	Prox Sensor fails to correct the proper position relative to its sensing block	1	Actuator blocked alarm displays on digital interface with a yellow triangle. In this case, this is a false alarm.	5	15	Order spare sensor for quick replacement in the case of failure	AstraZeneca Maintenance Team, 10/1/24	Spare sensor retained in the site storeroom in case it is needed in the case of a breakdown	3	1	3	9
			3	Web walking has occurred that is excessively severe and has caused the web to move beyond the sensing range in automatic mode	1	Actuator blocked alarm displays on digital interface with a yellow triangle	2	6	Ensure that operators know how to make simple manual adjustments	Josh Feil 11/27/24	Operators aware of manual mode on digital interface	3	1	2	6
Web Handling to downstream processes	Web handling causes a pinhole or tear	Completed blister fails leak test, showing that product is not fully sealed by lidding material. This will likely lead to over an hour of downtime and rework.	7	Rollers on alignment device contain material imperfections or collect particulate	3	Lidding vision system detects and rejects any blisters with a pinhole or tear. Additionally, leak tests are performed each hour to detect any issues causing bad seals from lidding material.	1	21	Approved product contact materials are used and verified (stainless steel)	Josh Feil and Validation, 10/1/24	Approved stainless steel material is verified	7	2	1	14
			7	Rollers for web transport contain material imperfections or collect particulate	3	Lidding vision system detects and rejects any blisters with a pinhole or tear. Additionally, leak tests are performed each hour to detect any issues causing bad seals from lidding material.	1	21	Approved product contact materials are used and verified (stainless steel)	Josh Feil and Validation, 10/1/24	Approved stainless steel material is verified	7	2	1	14
			7	Lidding material makes incidental physical contact with any item that is not a roller	2	Lidding vision system detects and rejects any blisters with a pinhole or tear. Additionally, leak tests are performed each hour to detect any issues causing bad seals from lidding material.	1	14	Provide extra space for web pass-throughs including cuts in printer gaurding and sensing area	Josh Feil 10/10/24	Extra space for web pass throughs is confirmed within design	7	1	1	7
Web alignment device sensing and controller	Sensors fail to detect misalignment of web for correction	Controller does not receive signal to move to correct the web, so the alignment device fails to correct web walking. This may cause downtime associated with uncorrected print alignment errors or web walking.	5	Sensor becomes dirty, so fails to detect web position	4	Edge Sensor Malfunction alarm displays on digital interface with a red exclamation mark	2	40	Create CILT task for operator to clean sensors at an assigned interval	AstraZeneca Maintenance Team, 11/1/24	Cleaning task created for sensors to be cleaned regularly	5	1	2	10
			5	Sensor becomes bent, or suffers an internal failure	2	Edge Sensor Malfunction alarm displays on digital interface with a red exclamation mark	2	20	Order spare sensor for quick replacement in the case of failure	AstraZeneca Maintenance Team, 10/1/24	Spare sensor retained in the site storeroom in case it is needed in the case of a breakdown	5	2	1	10
Lidding Printer Web Handling to Downstream Processes	Lidding material is threaded improperly through printer modifications during production	Lidding tears and line is down for about 45 minutes to re-thread printer	2	Operator makes mistake during lidding threading due to lacking knowledge of system modifications	5	A threading diagram exists in the printer, but not with the updates to the system	3	30	Update threading diagram to clearly display the new requirements and share with the operators	Josh Feil 11/27/24	Threading diagram is updated and shared with operators	2	2	1	4

Appendix D: Design Factor Considerations

ABET Outcome 2 states "*An ability to apply engineering design to produce solutions that meet specified needs with consideration of public health safety, and welfare, as well as global, cultural, social, environmental, and economic factors.*"

ABET also requires that design projects reference appropriate professional standards, such as IEEE, ATSM, etc.

For each of the factors in Table N.1, indicate the page number(s) of your report where the item is addressed, or provide a statement regarding why the factor is not applicable for this project.

Table N.1, Design Factors Considered

Design Factor	Page number, or reason not applicable
Public health safety, and welfare	See pages 3-4 as well as page 62 for how this project connects with AstraZeneca's purpose to deliver innovative, life saving medications to patients
Global	See page 1 and pages 3-4 for how this design is a part of a global effort and fits within a global hierarchy in AstraZeneca producing Type II diabetes medications for patients around the world
Cultural	Not applicable because this project is confined completely within AstraZeneca operations
Social	Not applicable because this project is confined completely within AstraZeneca operations
Environmental	Not applicable because this project is located within a controlled environment in pharmaceutical packaging and has negligible impact outside of this confined room
Economic	See page 1 for the wide economic reach of the AstraZeneca network and how this project fits into that reach
Ethical & Professional	See page 52 for how the capital for the project was professionally obtained from AstraZeneca budget through their approval process
Reference for Standards	See page 27 referencing ISO, and see page 35 for referencing the human factors and ergonomics standards from the United States Department of Energy