Hot Stamp Sealing of Medical Diagnostic Cartridges

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Abstract
Our team was asked to optimize the heat sealing of medical diagnostic cartridges for Siemens Healthcare. We have built and tested a number of sealing head configurations for small scale experimentation. Our team has found that the most important criteria for a good seal are efficient heat transfer, accurate temperature control, and conformity to the shape of the sealed object via an adaptable sealing surface. The most promising subsystem configuration has been tested on a full scale production line with excellent results. We have made recommendations to Siemens for the next generation of sealing stations based on our experimentation.

Introduction

Motivation
Siemens Healthcare is the world’s leader in clinical diagnostics. The company provides products that are used to diagnose medical conditions in hospitals across the globe. Our team is focusing on Siemens’s polyethylene Flex cartridges. These cartridges have depressed wells filled with different diagnostic reagents. There are two series of cartridges currently in production. The cartridges are hot stamp sealed and then packaged and sent to medical centers. The quality of the seal is crucial to accurate diagnoses for the end users. The goal of this project is to optimize the sealing process within the time constraints of the semester.

Goals and Metrics
The fundamental goal of our project was to completely seal the cartridges as consistently as possible. The rejection rates of the Dimension and Vista lines were already quite low; 0.10% and 0.23% respectively. Any improvement or additional explanation of these sealing failures would be useful for Siemens.

In order to quantify the objectives set by the team and the sponsor, a list of metrics was derived. The most critical metric was the sealing success rate which should be as close to 100% as possible. The turnover rate, the time it takes to change sealing pads, should be less than ten minutes. The cost of the sealing system should be comparable to that of the current hardware. Throughout this project, the goals and metrics evolved as we prioritized our design decisions.
**Design Methodology**

**Concept Generation**
Siemens currently employs a very unique heat sealing method that is, tailored to the specifics of the cartridge geometry. This made benchmarking more difficult due to lack of competition. The team focused its attention on optimization of the current Siemens seal head. Multiple concepts were generated, and when compared against the wants and metrics in UDesign, the “layered” design was quantifiably superior.

**Selected Concept and Subsystems**

The “Layered” design, seen in Figure 1, is composed of five main components or subsystems. The first component is the sealing pad. Currently a compliant pad is used by Siemens which allows for a complete seal on a surface that is not perfectly flat. We tested a Graphfoil pad, a Silicon/rubber compliant pad and a flat aluminum plate for the sealing surface. Another subsystem crucial to effective sealing is accurate temperature sensing of the pad. Both a thermocouple and an infrared (IR) sensor were tested. IR sensors give a way to measure temperature without physical contact, and as a result don’t interfere with the sealing surface. The next subsystem is the heating block which rests between the heater and sealing pad and functions to transfer and store heat. Above the heating block lies the strip heater. The current Siemens design uses a cylindrical heater, which directs heat in all directions. The flat strip heater directs only in the desired direction, towards the pad. Insulation will be used to minimize the heat to the sealing tower and the atmosphere. Lastly, an attachment block was designed to mount to the Dimension production line.

![Sealing Tower](image1)

*Figure 1 – Sealing Tower*

**Experimental Engineering Approach**

In order to find the optimal sealing head design, the team used an experimental approach. Several experiments were undertaken to find the most efficient combination of subsystems. The prototype was designed so it could be easily disassembled and a new combination of parts could be tested. Each subsystem was tested and focus was given to individual subsystem performance as well as performance of the prototype as a whole.

**Experimentation**

**Prototype Testing**

Siemens provided us with a sealing station to aid us in testing our design. The tower was adjustable to allow us to set the proper height of the pad. The tower control had a pre-
programmed time-pressure profile of the heating cycle currently employed by the Siemens production line. Our prototype was bolted to the base of the tower and carefully adjusted for proper sealing height. The heater and thermocouple were connected to the thermal controller supplied. The standard thermocouple was screwed to the bottom face of the sealing pad in a non-critical location. The thermocouple was initially used for controlling the heater due to the assurance of proper functioning. It could be potentially dangerous to control the heater with an untested sensor such as the infrared because of the threat of inaccurate measurements causing the heater to run continuously. We found there to be a substantial discrepancy between the thermocouple reading and the actual surface pad temperature measured by a contact thermocouple. This we attributed to heat flowing through the conductive steel screws holding it in place. To remedy this, we insulated the thermocouple from the screw which proved to be effective. Two types of ceramic fiber based insulations were sandwiched together in the block. For seal testing we employed both visual inspection and bell jar testing. The bell jar consisted of a tank partially filled with water, with a hose going to a vacuum pump. Vacuum was pulled on the tank and if a seal failed, water would find its way into the cartridges. For sealing, strips of polyethylene were held over the cartridge surface and the tower control was instructed to seal.

**Infrared Temperature Control**

For comparison purposes, both the IR sensor and a standard J-type thermocouple were used for measuring temperature as seen in Figure 2. The IR sensor was mounted in a way such that its line of sight was on the sealing surface at all positions of the sealing process. The angle of inclination was about 60°, well above the 45° limit where the IR would become inaccurate. It was calibrated using a surface contact thermocouple by adjusting the emissivity of the sensor until it read an accurate temperature. With this sensor in place, it was possible to detect an average temperature over the critical sealing surface. A standard would interfere with the sealing surface at the critical location, and it only measures temperatures at a point. In addition, it is still vulnerable to heat conduction from the heat block through the screw, leading to a higher-than-actual temperature reading.

**Sealing Surface Testing**

According to the testing plan, we initially tested 3 different types of sealing pads with ten cartridges from both the Vista and Dimension lines. The first of the tests was the flat aluminum pad which succeeded every time for the Dimension cartridges, but failed immediately for the Vista. After close investigation, it appeared that the Vista cartridges were slightly curved at each end which caused the seals at both ends to be insufficient. This observation motivated another sealing pad design described below. Next, the Graphfoil pad was tested and after
sealing several cartridges, visual inspection of the sealing pad surface revealed signs of degradation. This concept was subsequently rejected. The compliant silicon pad was tested and passed all ten tests on both types of cartridges. However, when comparing the seal on the Dimension cartridges, we saw that the compliant pad seals had a visually more consistent seal than that of the flat metal plate. We decided to proceed with the experiments using the compliant pad.

As mentioned previously, the failure of the flat aluminum pad prompted an additional design. The flat aluminum block was modified to ramp down on each end of the cartridge. The profile of the Vista cartridge was carefully measured and these determined the angles of the ramps. This new pad was tested with the sealing station, and all 10 results passed the vacuum test. As a proof of concept for a ramped design, we continued testing this pad. However, it must be noted that this design is only applicable to the Vista line, as the Dimension cartridges don’t have this curvature.

The next step in our experiment was to test deformed cartridges to see how well the remaining pads help up to deformities. To compare directly, we tested Dimension cartridges alone because the ramped design was incompatible with the Vista line. In the first iteration of these tests, we scratched high grit sandpaper on the sealing surface of the cartridges and tested both pads. For both the ramped and compliant pads, the seal data seemed very inconsistent. When looking at the process carefully, we hypothesized that the aberrations due to sandpaper were not an accurate way to represent deformities on the cartridges because it created sharp points that cut the seal plastic, regardless of the pad type.

To further compare these two designs, we filed the edges of the cartridges down to represent a more realistic injection molding defect. We sealed these again with both designs and found at first most of them didn’t seal. We raised the temperature continuously until all 10 cartridges were sealed properly. After analyzing the data, we found both designs to be both statistically equivalent in effectiveness. In addition, we found a good temperature range to ensure quality sealing.

**Production Line Testing**

We hoped to test both of these designs on the Siemens production line, but due to restrictions with both time and feasibility, we could only test on the Dimension line. A full installation photo can be seen in Figure 3. As a result, we could only test the compliant pad. Attaching our prototype to the line's sealing station was simple due to the similitude of the testing station. The regular thermocouple and heater were attached to the controller. The IR sensor was
attached as in Figure 2. Our set temperature was 460°F due to its previous success in testing. We tested 400 cartridges and recorded our results.

Results

Prototype Testing Results

After our experimental iterations we narrowed down to two promising choices for pads. Unfortunately we weren't able to test the ramped design. Our results from running our design on the production line were very promising. There were no failures out of the 400 cartridges we vacuum tested. This doesn't necessary mean much statistically, assuming a simple binomial distribution. Should we suppose the same failure rate of .1% that is currently recorded for the Dimension process, there would be a 67% chance that we would achieve these results. Siemens couldn't allow us to test any further cartridges because of process scheduling and the difficulty of shutting down a production line for our testing, but they will be able to test these designs on the line in the future. Our design conformed to our metrics reasonably well as seen in table 1 below, but unfortunately our constraints didn't allow for the amount of testing needed to statistically prove our design was superior.

<table>
<thead>
<tr>
<th>Metric</th>
<th>Goal</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Parts</td>
<td>Less than 10</td>
<td>8</td>
</tr>
<tr>
<td>Sealing Time</td>
<td>1 second</td>
<td>1 second</td>
</tr>
<tr>
<td>Turnover Time of the Seal Head</td>
<td>Less than 10 min.</td>
<td>8 min.</td>
</tr>
<tr>
<td>Success Rate</td>
<td>Vista – 99.77%</td>
<td>Cannot be determined.</td>
</tr>
<tr>
<td></td>
<td>Dimension – 99.90%</td>
<td>Further testing necessary</td>
</tr>
<tr>
<td>Life Span</td>
<td>10000 cartridges</td>
<td>Cannot be determined.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further testing necessary</td>
</tr>
<tr>
<td>Implementation Cost</td>
<td>Less $15,000</td>
<td>$12,800</td>
</tr>
</tbody>
</table>

Table 1 – Metric Comparison Data.

Our sealing success wasn't just in terms of 100% vacuum seal passing. The temperature during the sealing process stayed very constant, and our sponsor Matt said from looking at the process control variables, he could tell immediately that our design was more robust. The sealing surface temperature maintained about 30 degrees lower than the set temperature at steady state, and several of the line workers and engineers who looked at the sealed cartridges complemented on a better looking, more consistent seal. This gave us positive confirmation
that our prototype has a very good chance at working better than the current design. It seemed that our strip heater, in combination with our insulation scheme, better directed the heat. Also, our strip heater proved to be powerful enough to keep up with the old design's dual cylindrical heaters, which have much higher power capabilities.

**IR Sensor Results**

The IR sensor tests seemed to be very promising as well. The sensor seemed to track the surface temperature of the pad much more accurately than did the thermocouple. However, the offset between the measured thermocouple and IR sensor stayed relatively constant throughout the process, which hints that the IR sensor might not be necessary for an improved sealing rate. Though this may be the case, the sensor still can provide a very useful function of monitoring the actual surface temperature. The temperature difference between the metal in contact with the thermocouple and the rubber/silicon surface could be critical in predicting failures.

An additional result of our experiment was that our design was easily adaptable to the production lines currently implemented at Siemens. This implies a low cost of changing to our new design.

**Path Forward**

Our team is assembling the necessary tools for Siemens to continue the research that we began this semester. We will provide our sponsor with drawing packages of our working prototype and an optimized design based on our experimental results. We will recommend operating conditions that can improve the sealing rates without drastically changing the existing hardware for immediate application. Siemens will also be provided with detailed testing plans so that they can continue researching promising subsystem possibilities.

**From Prototype to Production Line**

The working prototype that our team developed was very successful when it was installed in the full scale Siemens production line. We have optimized the sealing head design based on our results and input from our sponsor and production line employees. The final iteration is designed to supply heat directed from the strip heater to the compliant pad through effective use of insulation. The temperature will be accurately monitored with a thermocouple imbedded into the silicon pad and regulated. Optionally, an IR sensor can be incorporated to give additional sealing surface temperature data.
The compliant surfaces will be the same silicon pads that Siemens currently uses, but the pads for the Vista line will be slightly ramped to accommodate the contours of the Vista cartridges.

**General Operational Recommendations**

In addition to optimizing the design of the sealing head, our team also varied the operating conditions of the sealing station. We found that the placement and orientation of the thermocouple significantly impacted the accuracy of the temperature control and therefore the sealing quality. When the thermocouple was bolted to the compliant pad, the display was around 30 °F higher than the true temperature of the surface of the pad due to conduction through the bolt. Our team was able to reduce this temperature gradient considerably by insulating the thermocouple from the bolt.

When we began benchmarking to Siemens current design our group was surprised to learn that the actual surface temperature of the sealing head is not monitored in testing. Instead, the temperature control is based on a thermocouple imbedded within the heating block. This control loop relies on approximations of temperature gradients and lacks robustness.

Based on our experiences trying to accurately measure the temperature of the sealing surface, we recommend that Siemens use IR sensors to acquire data on their current production lines. The employees at Siemens already understand that the thermocouple readings used for control are not accurate. Implementing IR sensors would allow the line workers to instantly quantify the temperature differential from the thermocouple to the sealing surface. This information could prove very useful to regulate proper operating conditions and explain sealing failures.

**Future Testing Recommendations**

Resource management was a critical component of our senior design project. Our team’s scarcest resource was time and there were a few concept tests that we could not fit into our schedule. We have developed testing procedures as part of our deliverables so that Siemens can continue to research important sealing ideas.

Our team successfully used the IR sensor for closed-loop controlling of surface temperature on the small scale sealing station. We did not have time to evaluate the performance of the IR sensor on the production line. We believe that this sensor could function very well, so we have developed procedures for Siemens to test the IR sensor in the full scale application. The testing plan involves running the production line with the IR outputting data to the controller, but also using a surface thermocouple. The thermocouple could be used to find the temperature differential and to prevent dangerous over-heating due to IR failure.

We experienced successful sealing of the Vista line of cartridges using both the silicon compliant pad and the ramped aluminum pad. Our team believes that a hybrid of these pad designs will yield the most consistent seals. We have developed two sets of technical sketches...
of this hybrid. One version will fit with the existing hardware so that Siemens can use the design immediately. The second version is designed for use in our final concept optimization.

Conclusion

Our team has successfully developed working sealing heads using multiple subsystem configurations. Siemens will be implementing concepts from our design in the next generation of sealing stations and may begin to use some of our ideas immediately. We have created an engineering package so that Siemens can continue to research designs that our team did not have time to employ and test. The documentation of our work will augment our sponsor’s understanding of heat sealing dynamics. Siemens will save time and money by having to track less failed seals. The company’s reputation and consumer trust will progress because of improved product consistency.
Appendix

Gantt Charts

Phase 1

Phase 2
Phase 3

Phase 4
## Data Tables

### Sealing success rates (%)

<table>
<thead>
<tr>
<th>Type of Pad</th>
<th>Temperatures</th>
<th>380</th>
<th>400</th>
<th>420</th>
<th>440</th>
<th>450</th>
<th>460</th>
<th>470</th>
<th>480</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant</td>
<td></td>
<td>20%</td>
<td>50%</td>
<td>60%</td>
<td>60%</td>
<td>70%</td>
<td>80%</td>
<td>90%</td>
<td>100%</td>
</tr>
<tr>
<td>Ramped</td>
<td></td>
<td>30%</td>
<td>50%</td>
<td>60%</td>
<td>70%</td>
<td>70%</td>
<td>80%</td>
<td>80%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### IR Sensor Temperature Offset

<table>
<thead>
<tr>
<th>Type of sensor</th>
<th>Seal number</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>IR Sensor</td>
<td></td>
<td>460</td>
<td>446</td>
<td>450</td>
<td>450</td>
<td>445</td>
<td>448</td>
<td>450</td>
<td>454</td>
<td>454</td>
<td>454</td>
</tr>
<tr>
<td>Wire Thermocouple</td>
<td></td>
<td>475</td>
<td>476</td>
<td>475</td>
<td>474</td>
<td>473</td>
<td>473</td>
<td>474</td>
<td>475</td>
<td>475</td>
<td>476</td>
</tr>
</tbody>
</table>
## Cost Estimate

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant Pad</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Silicon</td>
<td>1</td>
<td>$16</td>
</tr>
<tr>
<td>- Grafoil</td>
<td>1</td>
<td>$0</td>
</tr>
<tr>
<td>- Aluminum</td>
<td>1</td>
<td>$3</td>
</tr>
<tr>
<td>Heating Block</td>
<td>1</td>
<td>$12</td>
</tr>
<tr>
<td>Heater</td>
<td>1</td>
<td>$45</td>
</tr>
<tr>
<td>Insulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Ceramic Fiber</td>
<td>1</td>
<td>$75</td>
</tr>
<tr>
<td>- Alumina Silica</td>
<td>1</td>
<td>$88</td>
</tr>
<tr>
<td>Mounting Block</td>
<td>1</td>
<td>$12</td>
</tr>
<tr>
<td>Key Inserts</td>
<td>10</td>
<td>$20</td>
</tr>
<tr>
<td>Nuts and Bolts</td>
<td>13</td>
<td>$20</td>
</tr>
<tr>
<td>IR Sensor</td>
<td>1</td>
<td>$700</td>
</tr>
<tr>
<td>Controller</td>
<td>1</td>
<td>$300</td>
</tr>
<tr>
<td>Testing Station</td>
<td>1</td>
<td>$1300</td>
</tr>
<tr>
<td>Bell Jar</td>
<td>1</td>
<td>$500</td>
</tr>
<tr>
<td>Flexes</td>
<td>550</td>
<td>$5</td>
</tr>
<tr>
<td>Polyethylene Strips</td>
<td>550</td>
<td>$1.50</td>
</tr>
<tr>
<td>Transportation Cost</td>
<td>60 mi.</td>
<td>$69.6</td>
</tr>
<tr>
<td>Man Hours</td>
<td>960</td>
<td>$9,600</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>12,800</strong></td>
</tr>
</tbody>
</table>
Path Forward Compliant Pad

Imbed a thermocouple into the middle of the silicon during the molding process.