

# “Process Improvement and Electrostatic Analysis of Thermoforming Machine”

Level 8 Mechanical Engineering Final Year Project

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## Introduction

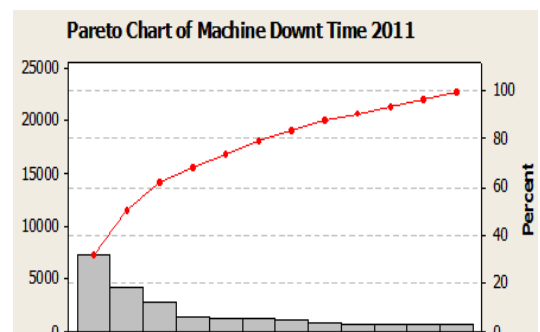
In a pharmaceutical company industrial application, a thermoforming machine places gelatine capsules into a continuous web of blister sheets. The placed capsules often sit incorrectly in the blister pockets. This incorrect placement results in capsule protrusion through the blister sheet surface, causing a level sensor to be triggered resulting in packaging line shut down until the loose capsules are cleared. In some extreme cases, the loose capsules progress into the thermoformer and cause lengthy downtime. Static electricity generation on the capsules was thought to be the reason for this issue.



The author chose to implement Six Sigma methodology throughout the project - namely the DMAIC cycle (Define, Measure, Analyse, Improve, Control). A static analysis of the thermoforming machine determined that the thermoformer was running at an all time low of 89.5% efficiency. Static related downtime was found to be circa 2.2% or 4,700 minutes - equating to a loss of €30,000 per year.

## Investigation

Extensive literature research was carried out to determine the causes of static electricity generation in an industrial setting, means of static elimination and static controls that are commonly available. It was determined that the most likely cause of the static generation concerned materials at opposite ends of the triboelectric series in contact with each other - namely the gelatine capsules and the polymeric capsule feeding tube. In order to confirm this theory, it was decided during the measurement phase of the project to introduce a standardised method for measuring static electricity on the thermoformer at predetermined locations. To achieve this standardised methodology, the movement of the capsules was mapped out using a process map. Static measurement points were taken in each area to determine the level of static electricity present. Temperature and humidity readings were also taken during the measurement time to determine if this had an effect on the static generated. Overall, 56 sets of static data were gathered over a three month period covering different batch sizes, different capsule sizes and product combinations. Varying environmental and storage conditions of the capsules were also taken into consideration.



Analysis of the gathered data was undertaken to verify the advanced theoretical basis. The static measurements taken across the thermoformer were analysed against the size of the capsules used, temperature, humidity and how the material and movement of the capsules in that area could affect the static generated. It was determined that the feeding tube and dispersion box area of the simtap on the thermoformer had the highest static charge present on the entire machine - this charge exceeding 20kV in parts. The capsules travelled extremely fast over the surface of the polymeric tube on this area of the thermoformer, resulting in a large exchange in electrons. The

gelatine capsules and polymeric tube are at extreme opposites of the triboelectric series. The capsules lose electrons to the polymeric tube and generate a positive charge. The polymeric tube leads into the stainless steel dispersion box, which is mounted on plastic components so the charge generated cannot conduct away. Inside the box, a silicone block is placed to disperse the capsules - this is again at the extreme opposite side of the triboelectric series and generates a high static charge, causing capsules to adhere to the block base. This area of the thermoformer is clearly the root cause of the static generation. Implementation therefore of static control devices, such as antistatic bars, will reduce but not eliminate the static present. Thus it was decided to completely redesign the feeding tube and dispersion box area of the thermoformer in order to reduce the static charge generated as much as possible.



## Improvement

After the analysis of the thermoformer was completed, the Improve stage commenced. It was decided to use a systematic design approach to ensure all design criteria were met. A series of designs were developed and Pugh's decision matrix was used to determine which design met all the criteria without compromising product quality. A



3D model of the design was created and fabrication commissioned. The new feeding tube section was manufactured out of grade 316L stainless steel, meeting the quality requirements of regulatory bodies such as the FDA. Once the feeding tube was fabricated and before the developed part could go into commercial use, validation documentation was prepared. The prepared documentation included material and manufacturing certificates, working drawings, functionality report, process FMEA and amended line clearance and cleaning SOP's. Validation testing was carried out to ensure the capsules feed properly through the new feeding tube and did not sustain any damage.

## Results

Once commercial operation commenced, the control stage of the project was implemented. A process FMEA was created to be used as a trouble shooting tool if any problems occurred during operation. The static levels on the new feeding tube were also monitored - the outcome greatly exceeded expectations, the developed system reducing static levels to less than 0.4kV in the feeding tube area from a high of 20kV in the old system. Clearly, this highly positive result indicates elimination of the static generation in this area and therefore the major root cause of static generation on the thermoformer. An efficiency increase of 3% is achieved - bringing the thermoformer to a four year efficiency high of 92.5%. The achieved result exceeded the predicted 2% efficiency increase as the implemented static electricity elimination had further knock-on downtime improvement benefits. This 3% increase in efficiency equates to a saving of €51,000 per annum for the company and increases production by 70,000 packs a year. Secondary savings were also made in the area of cleaning and line clearance due to the simplified design.

