Improvement to a Medical Device Packaging Output Using Lean Six Sigma Tools

Idiana Matos Rolon
Manufacturing Engineering
Rafael Nieves, Pharm.D
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— Packaging is the science, art, and technology of enclosing or protecting products for distribution, storage, sale, and use. Mainly, the packaging of a product assures the quality of the product to the end user after its transportation. Daily, Companies around the world are developing better devices for the treatment or cure of a disease. Moreover, improve their process in order to obtain cost efficient process and maintain quality standard for their customer. As part of a business goal for a medical device company, the cost per unit requires to decrease by a 0.28%. In alignment with this main goal of the Company the packaging lines require to increase its output. The objective of this design project is to meet business goals by the increasing of the packaging Line 1 output following lean and six sigma tools. After the application of the lean six sigma tools, the output was increased to 27,000 units per shift after the implementation and the original target was 25,000 units per shift. Furthermore total downtime was reduced by a 23%.*

Key Terms *— Downtime, Lean Six Sigma, Output, Packaging.*

INTRODUCTION

The packaging of a product is an important part of any manufacturing process. Is the way Manufacturers assure the integrity of a product before, during and after shipping to the customer. But what it is also important for a Company, apart to assure a quality product to their customer, expert says that they need to find ways to trim the fat and increase overall profit margins [1]. Is extremely important to know where every cent is being spent and find ways to incorporate new technologies and improve process in order to obtain the required economics benefits.

Methodologies like lean six sigma are used for improve, reduce variability and optimize process. Six Sigma is a business management strategy, originally developed by Motorola in 1986. Six Sigma became well known after Jack Welch made it a central focus of his business strategy at General Electric in 1995, and today it is widely used in many sectors of industry. Six Sigma projects follow two project methodologies inspired by Deming's Plan-Do-Check-Act Cycle; DMAIC and DMADV. PDCA (plan–do–check–act or plan–do–check–adjust) is an iterative four-step management method used in business for the control and continuous improvement of processes and products. Figure 1 show the PDCA cycle.

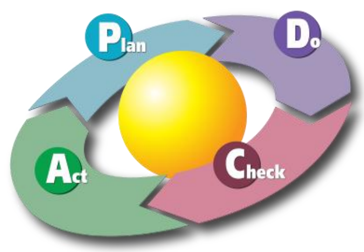


Figure 1
PDCA Cycle

DMAIC is used for projects aimed at improving an existing business process and consists of five basic phases: Define, Measure, Analyze, Improve, and Control. Based on the level of this project which consists of increase the output of a packaging process and given the fact that it is categorized as business management strategy, DMAIC methodology will be used for the successful completion of the project.

Packaging can be described as a coordinated system of preparing goods for transport, warehousing, logistics, sale, and end use. Custom packaging is done as per the requirements of the customer, as well as kind and design of product. Basic kinds of packaging are plastic boxes, thermocol packaging, textile packaging, foam packaging and film packaging. Most used packaging technology is the film. Blister film packaging is used in pharmaceutical, medical as well as for consumer good as primary packaging of the end product.

Blister pack is a term for several types of pre-formed plastic packaging used for small consumer goods, foods, and for pharmaceuticals. The primary component of a blister pack is a cavity or pocket made from a "formable" web, usually a thermoformed plastic. Thermoforming is a manufacturing process where a plastic sheet is heated to a pliable forming temperature, formed to a specific shape in a mold, and trimmed to create a usable product. The sheet, or "film" when referring to thinner gauges and certain material types, is heated in an oven to a high-enough temperature that it can be stretched into or onto a mold and cooled to a finished shape. In the most common method of high-volume manufacturing lines, continuous thermoforming of thin-gauge products, plastic sheet is fed from a roll or from an extruder into a set of indexing chains that incorporate pins, or spikes, that pierce the sheet and transport it through an oven for heating to forming temperature. Then, in most of this kind of machines, formed plastic sheet is sealed with a paper lid and finally cut in packages.

The majority of these automated production lines have several quantities of verification points. Most of them automated inspection performed per automated cameras, barcode scanners and sensors which are integrated by a programmable logic controller which provide the benefit of decrease labor cost and cycle time and increase product quality and consistency.

Inspection cameras such Cognex and Keyence are commonly used to perform in-line inspection. Commonly this kind of system is calling Vision Systems. Specifically the Cognex Vision System consists of a series of configurable tools that are set to inspect the desired object. Inspection criteria are individual per tools, but positions' can depend from other tools.

In the case of industrial sensors, they provide a means for gathering information on manufacturing operations and processes being performed. In many cases, sensors are used to transform a physical stimulus into an electrical signal that may be analyzed by the manufacturing system and used for making decisions about the operations being conducted. The purpose of sensors is to inspect work in progress, to monitor the work-in-progress interface with the manufacturing equipment, and to allow self-monitoring of manufacturing.

Mainly, all automated elements are synchronized by a programmable logic controller (PLC). The PLC has input lines where industrial sensors or cameras inspections results are connected to notify upon events (e.g. presence of the blister, placement of literature, inspection performed etc.), and output lines to signal any reaction to the incoming events (e.g. stop the machine, continues the machine cycle, etc.).

The good functionality of those systems is critical for manufacturing line performance and efficiency. A malfunction or bad performance of these automated elements have a huge impact in the line, causing increase of scrap, downtime and reduction of the line output, converted in money lost and sometime in customer dissatisfaction.

METHOD

Research objective will be achieved using DMAIC (Define, Measure, Analyze, Improve and Control) methodology.

- Define: The first phase of this methodology is Define. In this phase key element like project charter, voice of customer (VOC) and SIPOC diagrams should be use to define the problem. A project charter is an agreement between management and the team about project goals, deliverables and expectations. The advantages of project charter is that provides clear expectations, keep focus in the project goals, and keep the team working toward organizational priorities. Other element that could be use is VOC. It identifies key business drivers of customer satisfaction. Understanding the VOC will be necessary in order to focus the improvement project properly and to develop the right measures. The data obtained from a VOC helps an organization to decide what product and services offer, identify critical features and specification for those products and services, decide where to focus improvement efforts, get baseline measure of customer satisfaction and identify key drivers of customer satisfaction.

In the case of a SIPOC diagram, it is a high level map of your process that includes: process steps, inputs that feed the process, the suppliers (sources) of those inputs, outputs that result from the process and the Customers (recipients of those outputs. The SIPOC is useful to keep a clear scope of the project, highlight areas for improvement and ensure focus on the customer.

- Measure: The second phase of this methodology is measure. In this stage of the project base data is collected of defects and/or possible causal factors. The data that will be collected is required to be sufficient, relevant, representative and contextual. It should be enough to understand or pinpoint the problem and a full range of actual process conditions. The data can be collected by sampling, identification of variation using control charts, frequency plots and Pareto charts.
- Analyze: Once the data is obtained the third stage is analyzed. The purpose of this phase is to identify deep causes and confirm it with the collected data. The main goal of this step is that the theory is tested and confirmed. For the analysis of the data the use of cause and effect diagrams, brainstorming and five (5)'s Whys tools are commonly used.
- Improve: The goal of the improve phase is to develop, pilot, and implement solutions that address root causes. Some key deliverables of the improve phase is to identify candidate solutions to process root causes, evaluation and selection of best solution; including cost-benefit studies and risk assessment, pilot test of solutions and finally the full scale implementation.
- Control: The control phase is the last stage of the DMAIC methodology. The goal of this phase is use data to evaluate both the solutions and the plans, validate that all changes adhere to all operating company change control, GMP, and compliance requirements, maintain the gains by standardizing processes and outline next steps for on-going improvement. Some outputs that should be obtained of this phase are a monitoring system, a complete analysis that compare the before and after to demonstrate improvement and finally document results, learning experience and recommendations.

Results and Discussion

In this section the results obtained using the DMAIC methodology will be presented and discussed [2]. The project was driven from April 2012 thru January 2013.

Define

The define phase of this project was performed using a project charter. This project is a corporate initiative to reduce the unit cost of the manufactured product. Table 1 shows the project charter presented to management. It's describes the mainly details of the projects, goals and desired outcomes.

Measure

Factors which affect the output were identified during this phase. The output could be affected by any factor that causes the equipment goes down. Based on this, data collected was downtime in Line 1.

The output data was also observed to determine a baseline. Figure 2 describes the obtained output during the last six (6) months of the FY12. Output decreased to around 8,000 units average per shift on April (Figure 2).

Table 1
Project Charter for the Improvement to a Medical Device Packaging Output using Lean Six Sigma Tools

Project Charter	
Project Description	Improvement to a Medical Device Packaging Output Using Lean Six Sigma Tools
Scope	This design project applies to the packaging Line 1.
Goal and Measures	Increase Line 1 output to al least 30,000 units per shift.
Team Members	Line supervisor, Quality Engineer, Manufacturing Technicians, Line Operators, Area Manager
Support Required	Team: Weekly Meetings Line Operators, supervisor and manufacturing technicians: Data collection, Support projects implementation Quality Engineer and Area Manager: Documents approval
Business Background	As part of the business goal the cost per unit require to decrease by a 0.28%. In alignment with this main goal of the Company the packaging lines require to increase its output.
Expected Business Benefits	Decrease the cost per unit increasing the output of packaged units and the efficiency of the equipment.
Project Plan	Define: 2 weeks; Measure: 4 weeks; Analyze: 6weeks; Improve: 4 weeks; Control: 4 weeks. Expected Completion Date: December 2012.

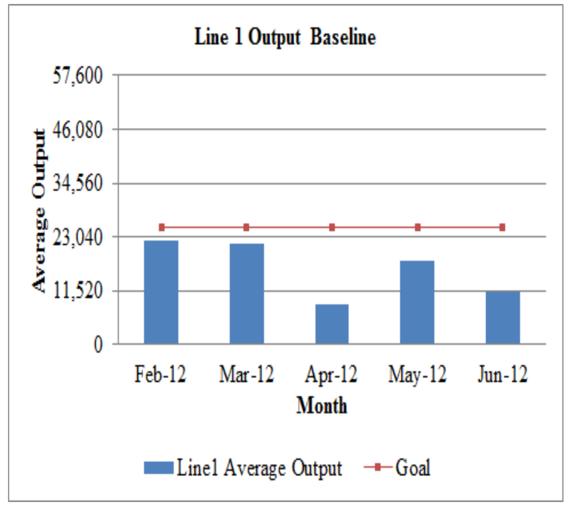


Figure 2
Line 1 Output per Shift Baseline

Downtime data collection was performed using a designed sheet in excel where the operator document during its shift all the period where the equipment went down due to equipment, method, resources, material, quality and/or environmental issue. Data was collected since the end of April thru May 2012 during the three shifts (First, Second and Third Shifts). A Pareto Chart was constructed with the collected downtime data. Figure 3 shows the Pareto with the major offender which affect the output of the Line 1.

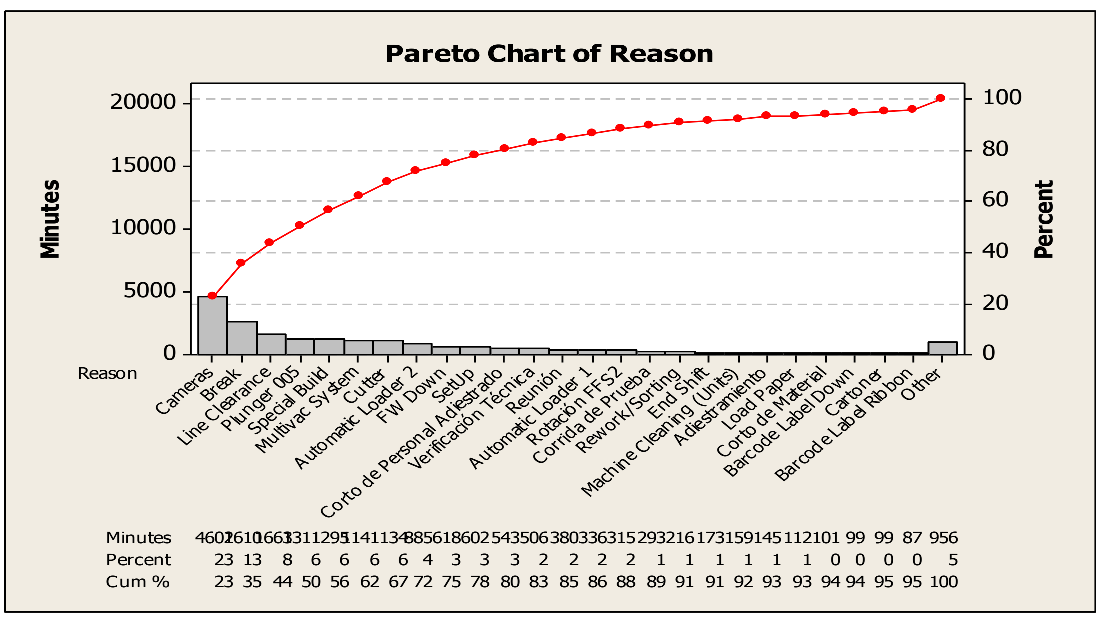


Figure 3
Pareto Chart for Downtime Data

Based on the Pareto Chart the five major offenders for the downtime events were the following: cameras system, breaks taken by the operators during the shift, the line clearance performed between lots, the manufacture of the product using a components plunger 005, and engineering study runs (special builds). Specifically operators reported a total of 4,600 minutes during the period of April, May and June (approximately 2200 minutes per month) of downtime in the cameras system during the measure phase. It represents a 23% of the total downtime reported during the measure period

Analyze

The first five top offenders were analyzed in order to prioritized and identified which one provide the bigger impact to the output increment [3]. The current cycle time of Line 1 is 0.133 shippers per minutes (720 units per shipper case). Current shift are of 450 minutes uptime. Based on that it was estimated the additional units per shift that could be manufactured correcting the majors offenders. Table 2 summarized the estimates of additional units per shift.

Table 2
Estimate of Additional Units per Shift per Downtime Reason

Top Offender Downtime Reason	Estimate of Additional Unit per Shift
Cameras System (2200min/month)	15,120
Breaks[1]	N/A
Line Clearance (953min/month)	3,802
Plunger 005 Component[2]	N/A
Special Builds[3]	N/A

It is estimated that with the improvement of the camera system the expected output goal per shift is achieved. Since the improvement in the cameras system is enough to reach the required goal, it was decided to only perform the cameras system improvement, at this time.

The purpose of this system is to avoid non-conforming product and customer complaints regarding missing components or incorrect reservoir inside blister packs. The Cameras Inspection System is installed in the Line 1 to inspect assembled units during their packaging into blisters. The inspection includes the presence verification of main components that are part of the unit assembly for two different models. When a fail condition is detected, the system stops the machine and alerts the operator so he/she can manually replace the failing unit with a good one and eventually it will acknowledge the vision system to perform another inspection prior in allowing the machine to cycle. Figure 4 shows a general overview of the system hardware.

A brainstorming was performed with a group of operators to figure out the main reasons why the system stopped. During the exercise it was determined that the most cause of downtime is because the machine stopped due to false rejects.

During the Lean Six Sigma process, the collected data was analyzed to build a cause–effect diagram to determine the causes of false rejects in the Cameras Vision System. Figure 5 illustrates a fishbone diagram. The diagram acts as a key map of the brainstorming process to determine the factors that are affecting the performance of the cameras system. The diagram was developed by operators, quality engineer, supervisors, technicians and the manufacturing engineer to determine the root causes for the camera system downtime.

Each identified causes were evaluated. After the evaluation of the inspection image it was found that the reflection that created the system's illumination against the plastic film was interpreted by a software tool in the camera as edge of the plunger component.

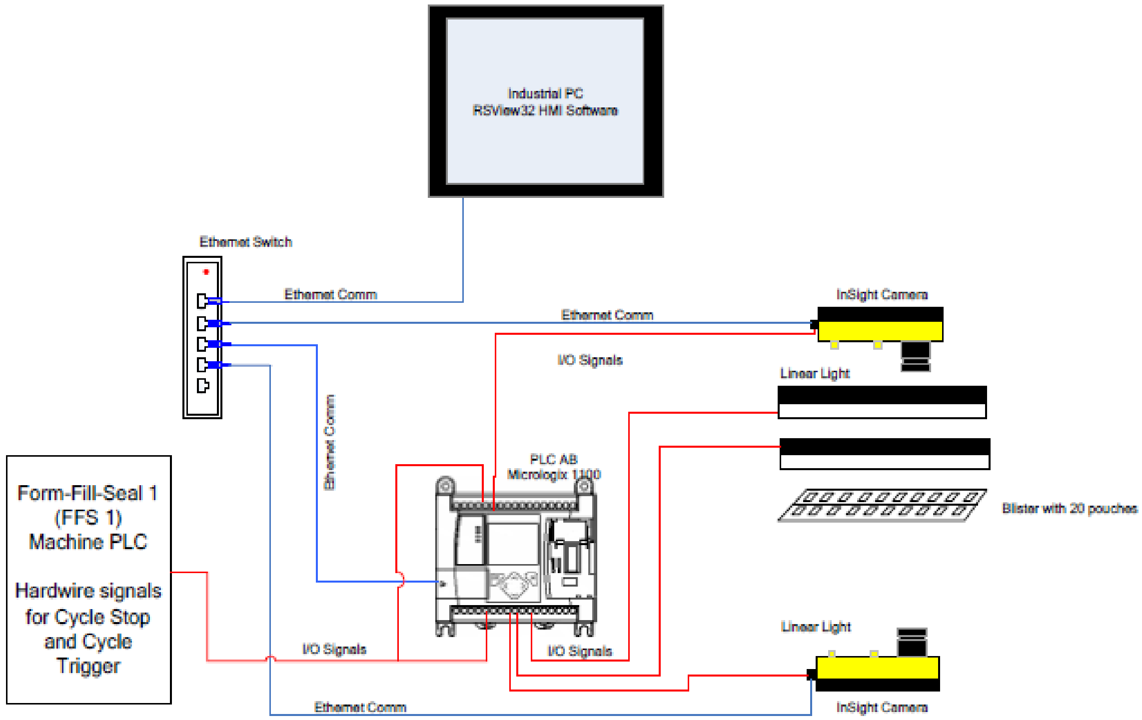


Figure 4
Cameras System Overview

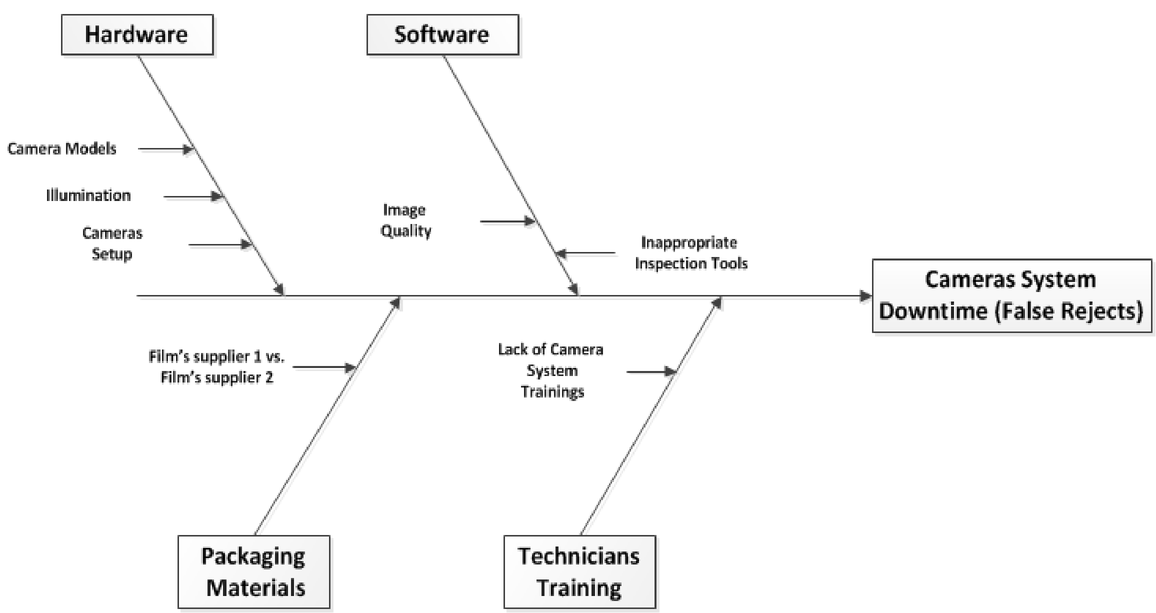


Figure 5
Fishbone diagram for Line Cameras System Downtime Analysis

Software is configured that other tools are positioned based on the position of the Plunger component (Figure 6). Since the main component tools were positioned wrongly, the other tools are positioned incorrectly as well, generating the false reject.

After the evaluation of false rejections in an hour, it was obtained that the equipment stopped 23 times due to false rejects. Based on the analysis performed, it is required to improve the acquired image and at the same time use an inspection tool more reliable for plunger inspection.

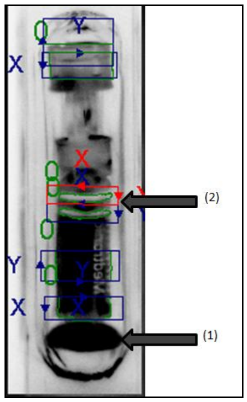


Figure 6
Once the Plunger (1) is Located; O-rings Tools (2) are Positioned

Improve

During the improve phase the camera system was modified. Software tools for Plunger and O-Ring components were changed. Also, the inspection will not be performed using a filtered image; the normal image captured by the camera will be used to the inspection to avoid reflection. Table 3 summarizes the performed changes to the system. The new software version was developed with In-sight Explorer 4.7.2, different than previous developer (In-sight Explorer 4.5.2). New tools offered by Cognex (cameras manufacturer) were incorporated to this new version in order to reduce downtime maintaining inspection requirements.

Figure 7 shows a print screen of the camera software in In-Sight Explorer 4.7.2. Tools are listed with its respective tools. Fourth and seventh columns show both, obtained score and the acceptance criteria value respectively.

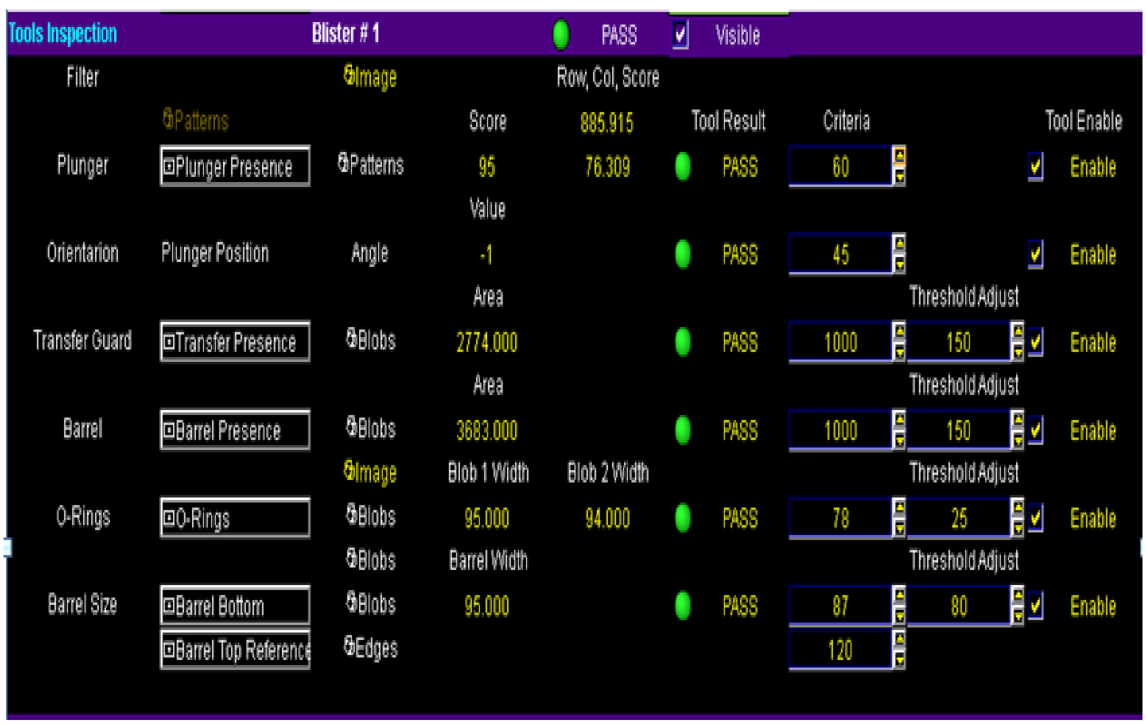
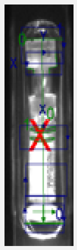
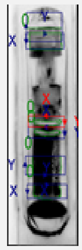
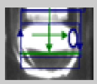
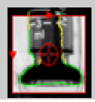
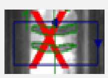
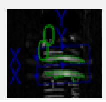


Figure 7
Camera System Software Spreadsheet (In-Sight Explorer)

Table 3
Camera System Change Details

Component	Before	Tool After
Image	Filter 	No Filter 
Plunger Presence (PP)	Edge 	Pattern 
Transfer Guard Edge (TGE)	Edge	Edge
Transfer Guar Presence (TGP)	Blob	Blob
O-Rings (OR)	One Blob 	Two separated blobs 
Barrel Presence (BP)	Blob	Blob
Barrel Size (BS)	Blob	Blob

.

The criterion was obtained characterizing the inspection. Good and bad units were inspected by the system. Obtained score values were collected and box plots were developed to obtain a save region to establish the acceptable criteria. Figures 8 and 9 illustrate the box plots for Plunger and O-Ring components as an example of the developed plots.

From Figure 8 it was determined that under current conditions a Pattern score acceptance value between 65 and 75 will consistently discriminate between Good and Bad parts. From Figure 9 it was determined that under current conditions a Blob width acceptance value between 75 and 84 will consistently discriminate between Good and Bad parts.

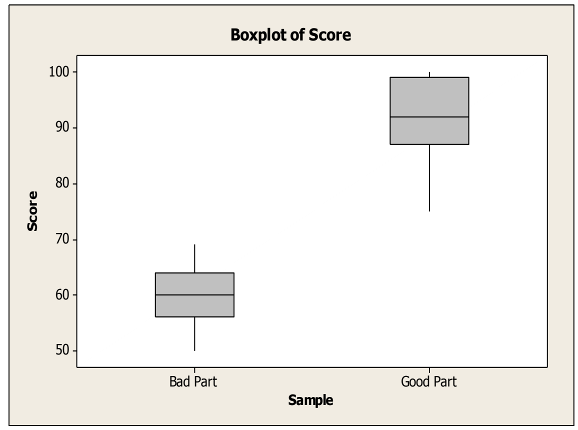


Figure 8
Plunger Patterns tool Score Boxplot

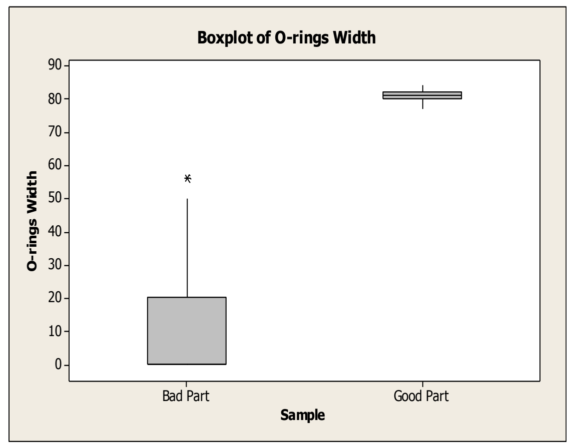


Figure 9
O-ring Width Tool Boxplot Score Values

Table 4 summarized the obtained acceptable criteria for each device component.

Table 4
Acceptable Pass and Fail Criteria for Product Components

Attribute	Inspection Tool	Pass/Fail Criteria		
		Min	Target	Max
Plunger Presence	Patterns	65%	70%	75%
Transfer Guard presence	Blob	1300 pixels^2	1500 pixels^2	1800 pixels^2
Barrel Presence	Blob	1500 pixels^2	2500 pixels^2	2800 pixels^2
O-rings presence	Blob	75 pixels	80 pixels	84 pixels
Barrel Size	Blob	86 pixels	N/A	130 pixels

The new camera system was released for manufacture on October 22, 2012 after the completion of all quality requirements.

Control

During this phase the output and downtime data were monitored. During the months of November and December the output increased by a 25% and 8% respectively (Figure 10).

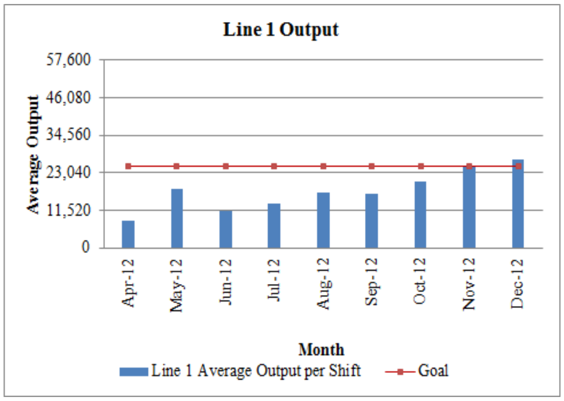


Figure 10
Obtained output after Camera System Improvement

The total downtime reported on November was 8,308 minutes. It is 3285 minutes minus than reported on May, so is a reduction of 28%. Specifically for the camera system the downtime was reduced by a 79.5%. Figure 11 illustrated obtained results for downtime.

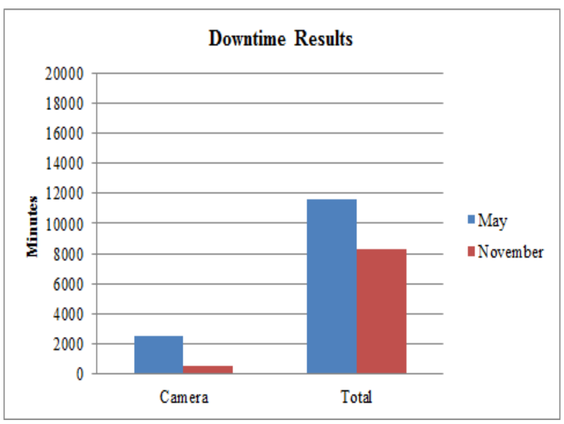


Figure 11
Downtime Results for Line 1 after Implementation

Control measures were implemented in the camera system to assure the good functionality and maintenance of the system. Procedure of the setup, troubleshooting and maintenance of the system were developed to provide the required knowledge to technicians and improve quickly respond during an intervention.

CONCLUSION

After the application of the lean six sigma tools for the increment of the Line 1 output, it was identified that the camera system installed in the equipment was the major cause of downtime, affecting the line output. Based on the evaluation performed in the camera system the required upgraded were performed in the camera software obtaining reliability and good functioning of the system.

The total downtime reported on November was 8,308 minutes. Total downtime was reduced by a 23%. Furthermore the downtime for the major offender; camera system, was reduced by a 73%. The main objective of this design project was to meet business goals by the increasing of the packaging Line 1 output. The output was increased to 27,000 units per shift after the implementation and the original target was 25,000 units per shift.

After the implementation of the cameras system and during the control phase several opportunities of improvement were identified to obtain more output in the Line 1. Downtime data was used to generate a Pareto Chart (Figure 16). Projects such as improvement in the Line Clearance process and resources management are fundamental to decrease the downtime and at the same time increase the output. In that way the business goal will be met and will be providing to the Company the required reliability to invest in Puerto Rico.

REFERENCES

[1] Kraus, A. ".2 Important Factors You Must Consider to Save on Packaging Costs", Procure, September 6, 2012, Retrieved from http://procurex.co/blog/

[2] Kang, J.O., Kim, M.H., Hong, S.E., Jung, J.H., Song, M.J. "The Application of the Six Sigma Program for the Quality Management of the PACS", *AJR*, 185, November 2005, 1361 - 1365

[3] Nave, D. "How to Compare Six Sigma, Lean and the Theory of Constraints." *Quality Progress*, March 2002, 73-78