Improving the Overall Equipment Effectiveness of a Hemostatic Products Production Line in a Medical Devices Company

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Abstract *— Overall Equipment Effectiveness (OEE) is a performance indicator highly used in the Medical Devices industry. By analyzing the results of this indicator, the organization can reduce losses in the manufacturing process and increase productivity. Due to a demand increase of hemostatic products in a medical device company, a productivity and efficiency increase of 5% in Line C is needed. The Multivac Packager was identified as the bottleneck step in the manufacturing process of the hemostatic products. This project aims to determine the baseline OEE value for this equipment and identify the root cause of the most influential losses. The calculated OEE for the Multivac Packager of 27% is under the standard world-class of 85-90%. Results show that the components of Availability and Performance should be improved to increase the productivity and efficiency of Line C. There were three very influential losses that were identified: operator lunchbreak, changeover, and setup processes.*

Key Terms *— Overall Equipment Effectiveness, OEE, losses, productivity.*

INTRODUCTION

Overall, higher productivity and efficiency translate to a more productive organization. Every year the manufacturing organizations receive the forecasted demand for the next year. Based on the received forecast, adjustments in production are made to ensure the fulfillment of demand without increasing costs.

This project arises as an initiative in a medical device company that manufactures hemostatic products that is facing a demand increase from 1.2 million units in 2021 to 1.3 million units for 2022. The OEE it is a performance indicator highly used in the industry to understand current performance and identify opportunities to increase efficiency and productivity. By identifying the Line C bottleneck and calculating the OEE, is intended to identify actions to achieve a 5% of OEE improvement.

OEE

Different metrics are used to measure manufacturing performance in the industry. Some of them include downtime, capacity utilization, production volume, costs, among others. Although several performance indicators can be used, the Overall Equipment Effectiveness (OEE) is recognized as one of the most important being used in the industry [1]. OEE is a key performance indicator introduced by Nakajima in 1988 [2]. This metric has its roots in the total productive maintenance (TPM) methodology, which was developed to measure the equipment productivity in a manufacturing system [3]. The main objective of measuring OEE is to identify the manufacturing process constraint or "bottleneck" equipment to improve it and make it run efficiently.

OEE can be defined as a productivity ratio between real manufacturing and what could be ideally manufactured [4]. World-Class OEE is considered to be greater than 85-90% [5]. OEE identifies six big losses covering aspects of availability, performance, and quality that reduce the equipment effectiveness. These three aspects can be considered by answering the following simple questions: for availability – "Is the equipment up and running or not?"; performance –

"At what speed is the equipment running?"; and quality – "How many products are within specification?" [6]. Availability measures downtime losses due to breakdowns or setup/adjustments; performance measures speed losses due to idling, minor stoppages, and reduced speed; and quality measures defect losses due to process defects or rework [5].

OEE is a great tool that helps the organization management to understand hidden productivity, reduce overtime, and defer major capital investments to meet customer demands. Usually, management prioritizes equipment improvement based on the lowest OEE. However, the lowest OEE does not necessarily represent the highest losses since the equal in the performance rate, availability, and the quality rate does not mean the same loss [7]. On the other hand, a clear understanding of the needed OEE is fundamental since a high OEE without the customer demand could result in overproduction and creating inventory.

Before the implementation of the OEE, the organization's management should understand the methodology, have a clear operators' role definition, knowledge of equipment losses, and basic equipment maintenance handling in place [8]. Management support and involvement in the initiative are key to have a successful OEE program implementation. Management involvement makes clear task prioritization and fosters a collaborative work environment [8].

METHODOLOGY

The first step of this project consisted of evaluating Line C manufacturing operations to identify the bottleneck. Figure 1 shows the Line C manufacturing operations. Pouching and Packaging operations were identified as the bottleneck process observation, capacity, and output analysis. Therefore, the focus of this project is on the Multivac Packager, equipment used in the packaging, and pouching operations. Subsequently, OEE training was provided to the manufacturing personnel and with staff feedback, the data collection tool was developed.

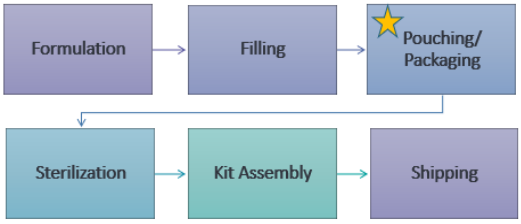

Figure 1
Line C Manufacturing Operations

In the second phase, the data collection tool was implemented to support the generation of the results regarding the OEE of the Multivac Packager, through the collection of events of unavailability records, production output, and results of quality inspections. The collected data was analyzed with a cross-functional team to validate data correctness. Once data was validated, the Multivac Packager OEE baseline, the availability ratio (AR), performance efficiency (PE), and the quality rate (QR) were calculated. Equation 1 shows the OEE calculation formula.

$$OEE\ (\%) = AR\ (\%) * PE\ (\%) * QR\ (\%) \qquad (1)$$

The third phase consisted of the proposition of improvement actions and their application. The priorities were defined by the criteria of simplicity, required resources, and expected results.

DISCUSSIONS

Although the company has a TPM Program in place, Line C was not part of it. Without calculating the OEE, it cannot be improved. The overall equipment effectiveness is 27%, where the availability of the equipment was 51% of the production time and the performance was 55% while the quality factor is 94%. Table 1 shows the comparison of the equipment indicator and the world-class standards [5]. It can be observed that the lowest values were in the availability rate and performance efficiency components.

Table 1
Comparison between Multivac Packager Machine and World-Class Standards

	Multivac OEE	World-Class OEE
Availability	51%	90%
Performance	55%	95%
Quality	94%	99%

Figure 2 shows the data from the identified losses during the manufacturing process. It can be observed that the biggest losses are on the changeover process by 32%, operator lunch/break by 23%, and setup process by 14%. Evaluation from these losses disclosed the following:

- The changeover and setup losses occur because the time allocated to complete is less than the required to complete it.
- In addition to the lack of training, operator skill level, materials, and tools availability, the lost time due to operator lunch/break mainly occurs due to poor surveillance or supervision which causes the operator to exceed the allocated time for lunch/break, increasing the idle time of the equipment.

From Figure 2 it can be observed that the next losses are due to broken machine/engineering by 11%, gowning by 9%, waiting for signatures for release by 6%, and rework by 5%. Maintenance evaluation of the broken machine/engineering contributor disclosed multiple replacements of the cutter blade.

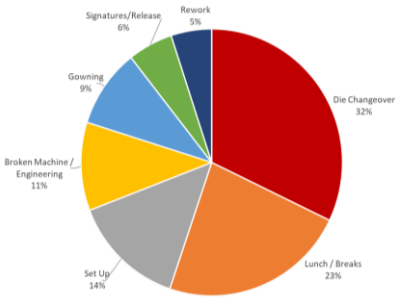

Figure 2
OEE Results of Multivac Packager August- September 2021

As part of the root cause assessment conducted to reduce the big losses, the following actions were implemented:

- Update training material for changeover and setup processes to ensure robustness and completeness.
- Training sessions for changeover and setup processes scheduling a highly skilled operator with a less skilled operator to ensure knowledge and experience are used during training sessions.
- Checklist for the setup process to provide the operator a readiness document before starting a new configuration.
- Update preventive maintenance job plans to ensure it contemplates cutter blade replacement frequency.

After the implementation of the identified actions, the overall equipment effectiveness is 45%, where the availability of the equipment was 78% of the production time and the performance was 61% while the quality factor is 94%. From Figure 3 it can be observed that the major improvement was in the availability component depicted in blue color.

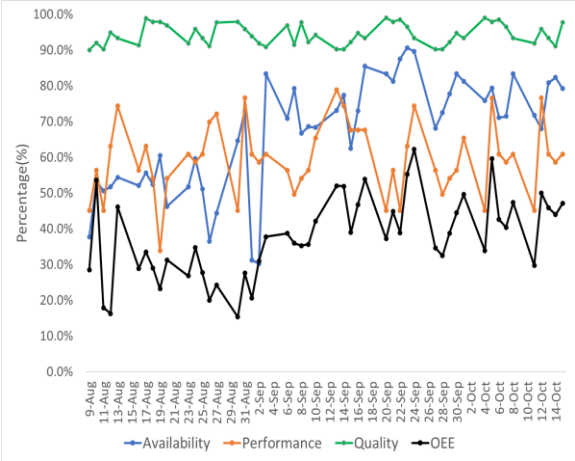

Figure 3
OEE Results of Multivac Packager August- October 2021

Table 2 shows the comparison of the OEE baseline and after actions implementation. An improvement of 18% can be observed which is higher than the goal established in this project of 5%.

Table 2
Comparison between Multivac Packager OEE baseline and after implementing actions

	Baseline	Improvements
Availability	51%	78%
Performance	55%	61%
Quality	94%	94%
General OEE	27%	45%

CONCLUSIONS

The OEE is an indicator that allows the organization to know where they are and helps them to identify where the opportunities are and how to improve them. By calculating the OEE and analyzing each of its components, losses were identified throughout the pouching and packaging manufacturing process of Line C. The Multivac Packager was identified as the bottleneck of the manufacturing process. Most of the losses were related to the time exceeded of lunch/breaks, changeover, and setup. An improvement of 5% was observed by implementing the actions identified in this project.

This project is a step of integrating the Multivac Packager from Line C to the company's TPM Program and a new work culture. Having the OEE indicator visible and discussing it in the Line C daily meeting represents a new way to work where the operator's accountability for downtime increases, operator training level is discussed, and where the equipment breakdown ownership is shared between Maintenance, Engineering, and Manufacturing.

As part of this project, it is recommended to integrate the Multivac Packager machine in the TPM program and enhance the Maintenance program and Maximo system utilization to track equipment malfunctions, breakdowns, and the downtime associated with them. This project exemplifies the importance of management involvement to ensure a satisfactory OEE initiative implementation and how teamwork plays a key role in solving problems.

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