Optimized Design for Electrochemical Test Product Preparation

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Abstract *— This project focuses on improving the processing time for the Electrochemical Performance Test Preparation Process using the DMAIC methodology integrated with Design for Reliability and Manufacturability tools. Time studies and Design for Reliability and Assembly tools provided a baseline measurement of the current processing time and complexity of the process steps. Concept Engineering was implemented to create innovative designs to improve the process while using Analytic Hierarchy Process to objectively evaluate the proposed concepts. A total process time reduction of 22.31% was obtained with the implemented improvements, reducing the penalty score of complexity from 263 to 100. As a medical devices industry, with a high demand for products, process improvements that contribute to decreasing product time to the patient or increase capacity makes a significant difference for the company, increasing market growth.*

Keywords *— AID, AHP, CGM, DfMA.*

INTRODUCTION

Continuous Glucose Monitoring (CGM) sensors are medical devices intended to measure the glucose level on diabetic patients and communicate the value to external devices such as Automatic Insulin Delivery (AID) systems or phone applications to record the value. The CGM oversees measuring the current value because of a chemical reaction caused by the glucose molecules when in contact with the sensor, converting the level of glucose in blood to a tangible value that can be transmitted. Like many other products, CGM sensors are submitted to Electrochemical Performance Testing (EPT) assuring proper functionality of the device before being released to the market. During the process, the product is subjected to controlled environmental conditions, very similar to the conditions in a diabetic patient, where its performance is challenged.

There are several manual preparation steps that need to be completed before submitting the product to the actual test: Disassembly, Adhesive Cover, Ejection, Cutting, and Inspection. As a medical device manufacturing facility, there are three main topics: Quality, Safety, and Costs. Manual steps generally are time consuming, taking into consideration the high volume of products manufactured, these two factors become greatly important.

Problem Statement

Highly manual processes are very time-consuming and bring several potential risks of damaging the product during the process. During an evaluation of processes across the manufacturing site, the EPT preparation process of the new introduced product is half an hour longer than the legacy product (~10% additional time). As a manufacturing site, it is expected to have better processes that can be done more efficiently decreasing manufacturing costs for new products instead of the opposite. The goal is to reduce the EPT preparation processing time by applying the DMAIC methodology combined with Design for Reliability and Manufacturability (DRM) tools.

Description

The research project focuses on decreasing the processing time for EPT product preparation process to reduce manufacturing costs for the newly introduced product. As a medical device manufacturing plant, it is highly important to continue improving processes and reduce costs to increase competitiveness in the market and company revenues.

Objectives

The main objective of the project is to decrease the EPT product preparation time for the new introduced product by at least 15% (approximately 7.5% lower than the legacy product).

Contributions

Market Competitiveness and revenue is a frequent topic not only in the medical devices industry, but for all entire manufacturing environment. Keeping low manufacturing costs or Labor Burden Material (LBM) allows the company to keep product prices low in the market, increasing competitiveness and enlarging revenues. Additionally, decreasing the processing time for the EPT product preparation as a release condition for product to the market results in an increase of release capacity for the manufacturing site.

LITERATURE REVIEW

Continuous improvement is certainly a priority for those manufacturers that want to stay competitive in a world that is changing every day, with new technologies and innovations arising, a standardized and systematic approach to solving problems is often desired.

Most manufacturers are regulated by different agencies, which establish Quality Management Systems, for example, current good manufacturing practices (cGMP) are for manufacturers regulated by the FDA [1]. There are multiple ways of applying problem solving, however, one of the most worldwide used methodologies is DMAIC, which stands for Define-Measure-Analyze-Improve-Control. Despite the DMAIC improvement methodology from Six Sigma is a standard process, the individual application may be quite different [2].

The method is highly based on facts, figures and data, therefore, one of the critical aspects of applying this method is how the data is collected. A well understanding and identification of several factors is required for incorporating this methodology into a problem solving: Process Inputs, Controlled Process Variables, Uncontrolled Process Variables or Noises, and Process Output Variables [2].

METHODOLOGY

DMAIC is considered a systematic improvement cycle used in Six Sigma for the optimization and stabilization of processes, highly structured and driven by data. This methodology is divided into five main points of phases: Define, Measure, Analyze, Improve and Control. Several tools can be used on each phase to build the project and assure the best possible results. DMAIC is broadly used in the manufacturing industry in Six Sigma projects, focusing on reducing waste and improving processes by reducing waste, equipment downtime and idle time, increasing efficiency and productivity. The phases of DMAIC methodology are described as follows [3]:

- Define: During this phase the problem is identified typically as a problem statement. Problem statements must be very clear and avoid any potential ambiguity. Project goals shall also be established aligned to the defined problem statement. Also, the customer, which may be internal or external, must be identified and their requirements well understood. The key deliverable of the Define phase should be the Project Charter and a clear definition of success.
- Measure: A strategy to collect data must be developed to obtain proper information about the existing process. The main intent of this phase is to establish current performance and identify baseline data or metrics. The key delivery of the Measure phase should be the quantified process under its current conditions based on process data.
- Analyze: This phase is intended for investigation of the problem statement based on the measured data. During this phase, problem root causes, conditions that affect the process or situations that promote the existence of the problem shall be identified. The key

deliverable of the Analyze phase should be a root cause analysis.

- Improve: This phase consists of developing and testing problem solutions to be implemented. The main objective of this phase is to eliminate the problem and improve the process. The key deliverable of the Improve phase should be to improve performance by implementing solutions that eliminate the identified root causes assuring appropriate cost to benefit ratio.
- Control: This final phase is where the implemented solutions to the process are monitored to ensure sustainability and ensure process performance. The key points for the Control phase are the Control Plan and standardization of the process.

The visual representation of the DMAIC phases and the corresponding order is included in Figure 1 [4].

Figure 1
DMAIC Methodology [4]

RESULTS AND DISCUSSION

The EPT preparation process optimization was developed using DMAIC methodology and the project results are included below.

Define Phase

One of the most used tools for the Define phase is the Project Charter. A Project Charter was developed to present the process optimization to the manufacturing site senior management which includes the problem statement, project goals, identified customers or stakeholders and the impacted metrics as shown in Table 1.

Table 1
EPT Preparation Process Optimization Project Charter

Project Charter
Problem Statement – EPT preparation process of the new introduced product is half an hour longer than the legacy product (~10% additional time).
Project Goals – The goal of the project is to decrease the EPT product preparation time for the new introduced product by at least 15% (approximately 7.5% lower than the legacy product).
Customers – As the project is intended to optimize a destructive process (the product is used for destructive test as a process monitor) and not for human use, the customers are identified as Operations Division of the Manufacturing Site. As a regulated company, Quality and Engineering teams must be also included as project stakeholders.
Impacted Metrics – Process Time.

In addition, a process flow map was developed to clearly define the EPT preparation process and its corresponding steps in the scope of the project as shown in Figure 2.

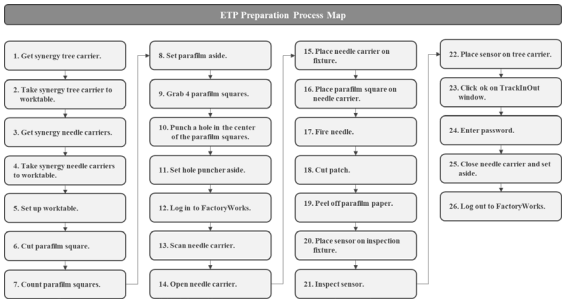

Figure 2
EPT Preparation Process Map

A common error during projects development is to dedicate time and effort to designing and testing improvements that do not mitigate the actual problem. Having said that, the most important part of a project is the Define phase. A well-defined problem statement helps to maintain the focus on the actual conditions, designing potential solutions that directly impact the stated problem and can be easily measured after implementation. Also, a good process flow map, detailed step-by-step, provides a deep view of the potential opportunities along the

process and brings perspective to the problem solver to attack develop solutions.

Measure Phase

The main objective of the measure phase is to develop a data collection strategy to define the current process performance based on the metrics that are impacted by the project. As the goal is to decrease the process time, a time study was performed to obtain baseline data of the existing process, results are shown in Figure 3.

No.	Element	AVG per Observation (sec)	AVG per Observation (min)	AVG per Lot (min)
1	Get synergy tree carrier	15.00	0.25	4.00
2	Take synergy tree carrier to work table	10.00	0.17	2.67
3	Get synergy needle carriers	8.00	0.13	0.00
4	Take synergy needle carriers to work table	5.50	0.09	0.00
5	Set up work table	21.00	0.35	0.35
6	Cut parafilm square	6.00	0.10	0.00
7	Count parafilm squares	6.00	0.10	0.00
8	Set parafilm aside	6.00	0.10	0.00
9	Grab 4 parafilm squares	5.00	0.08	0.00
10	Punch a hole in the center of the parafilm square	13.50	0.23	0.00
11	Set hole puncher aside	2.00	0.03	0.00
12	Log in to FactoryWorks	10.50	0.18	0.18
13	Scan needle carrier	5.22	0.09	27.40
14	Open needle carrier	3.77	0.06	19.77
15	Place needle carrier on fixture	1.25	0.02	6.58
16	Place parafilm square on needle carrier	5.75	0.10	30.17
17	Fire needle	4.20	0.07	22.05
18	Cut patch	15.25	0.25	80.06
19	Peel off parafilm paper	5.50	0.09	28.88
20	Place sensor on inspection fixture	2.73	0.05	14.36
21	Inspect sensor	4.42	0.07	23.21
22	Place sensor on tree carrier	5.61	0.09	29.45
23	Click ok on TrackInOut window	2.11	0.04	11.09
24	Enter password	4.94	0.08	25.92
25	Close needle carrier and set aside	4.86	0.08	25.49
26	Log out of FactoryWorks	8.00	0.13	0.13
			Total Time (min)	*351.75*
			Total Time (hr)	*5.86*

Figure 3
Current Process Time Study

During the study, a total process time of 5.86 hours was obtained, where some activities were observed that are completed ahead of the starting of the actual without affecting the process time and are shown in Figure 3 highlighted in grey. Time measurements were taken for process steps that do not affect the process time; however, they were considered as a value of zero in the average time per lot.

While reviewing the time study, an assessment of process steps was performed to identify and differentiate those steps that can be modified, which are marked with a red squared in Figure 3, from those that cannot be due to quality system policies or FactoryWorks (MES) structure. The assessment provided a great benefit to focus the project on the process opportunities in terms of steps. In addition, it was identified that a great amount of time is spent on the actual transformation of the product during its preparation process, bringing a high opportunity for improvement.

In addition to the time study, another tool used during the Measure phase was the Voice of Customer (VoC). This tool assures the project contains and is focused on what the customer needs, in this case, the Operations team, Quality team and Engineering team. A different strategy was used for the VoC, after gathering all voices, a prioritization exercise was performed where a total of 100 points were assigned to each group. The exercise consisted in spreading the points into the voices each group is most interested in, the average value was calculated for each voice and the top values were selected to be prioritized. VoC tool is shown in Figure 4 and prioritized voices are highlighted in green.

Voices	Quality Team	Operations Team	Operations Team	Average
Sensor Flex is damaged (ej. nicked or cut) inadvertently during the sensor preparation (use of scissors)	10	10	10	10.00
Operators gets pinch or cut during the sensor preparation (incorrect use of tool or scissors)	10	10	10	10.00
Sensor Flex is damaged (ej. nicked or cut) inadvertently during the sensor preparation (use of tweezers)	10	10	6	8.67
Cut compatible with current design of BTS Rack Carrier	6	10	10	8.67
Lower shell barcode must be readable	2	10	10	7.33
Unit is ejected without the fixture lid	6	6	6	6.00
Reduce actual processing time	2	10	6	6.00
Sensor Flex is damaged (ej. nicked or cut) inadvertently during the sensor preparation (use of hand)	6	6	2	4.67
Fixture is incorrectly used by operator (unit is incorrectly placed into the fixture)	6	6	2	4.67
Semi Automated process	2	6	6	4.67
Sensor ejection downwards	10	0	2	4.00
Parafilm is misaligned in the tool. Operator ejects the sensor into the parafilm.	2	2	6	3.33
Units falls/dropped during sensor ejection. Fixture in not fixed to the table.	6	2	2	3.33
Allow to expand to process multiple units at the same time	2	2	6	3.33
Mechanical process	2	2	6	3.33
No programmable logic	2	6	2	3.33
Fixture is incorrectly used by operator (fixture is incorrectly assembled)	6	2	0	2.67
Operators forget to punch hole into the parafilm prior to placing it into the tool. Operator ejects the sensor into the parafilm.	2	0	6	2.67
Operators forget to place the parafilm in the ejection tool. Device adhere to the fixture.	2	0	0	0.67
Unit is incorrectly placed into the Synergy Rack	2	0	0	0.67
Unit falls from the rack (unit dropped) during transport. Unit is not correctly placed into the Rack	2	0	0	0.67
Operator places more than 8 units into a Rack	2	0	0	0.67
Improve punching process on Parafilm	0	0	2	0.67
Operator prepares a unit that does not belong to the Sterilization Monitor	0	0	0	0.00
Total Points per Team	100	100	100	100

Figure 4
Prioritized Voice of Customer

Having the current process performance properly measured obtaining the baseline values of the metric to be impacted, and voices from customers and stakeholders gathered and prioritized, it is possible to move forward with the next phase of the DMAIC methodology: Analyze.

Analyze Phase

The Analyze phase of the project has the as objective to investigate the potential root causes of the problem, in this case affecting the EPT preparation process time, using the current

performance data obtained during the measure phase.

A deeper evaluation of the identified process steps was performed introducing a Design for Reliability and Manufacturability (DRM) tool named Design for Reliability and Assembly (DfMA). The DfMA tool helps on measuring the complexity of a step in a quantitative way providing objective values to evaluate the process. To make the evaluation easier, identified process steps per Figure 3 were presented and evaluated accordingly in Figure 5.

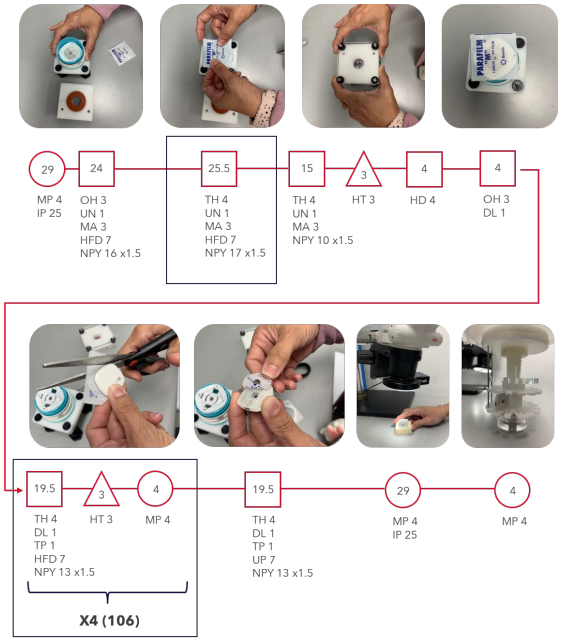

Figure 5
DfMA Tool Applied to Current Process

On the DfMA, steps are evaluated according to the following criteria: 1) Pick up, Contact, Mating, 2) Tools and 3) Operations. Inside each criterion, there are multiple items with a complexity punctuation to be assigned to the step (Refer to Figure 6). For example, whenever two hands are required to perform an action, a TH (Two hands) value of 4 is added. On the other hand, when only one hand is required to perform an action, a lower complexity value is added: ON (One Hand) equal to 3. The more complexity is observed on the process step or group of steps, the higher the value will be. The main objective of this tool is to identify steps with more complexity to be addressed first. Typically, when a step has high complexity, the higher the processing time; Therefore, the process step complexity can be associated with the required processing time. Legend of DfMA is included in Figure 6.

Figure 6
DfMA Tool Legend

After evaluating each step from Figure 5, two steps were identified to have a very high complexity value: Place parafilm square on needle carrier and Cut patch. These two steps also match the time study, being the higher two process time values. Besides two major offenders have been identified, more steps can be included as problem root causes to be improved. A total penalty score for the current or baseline process based on the DfMA is 263.

Once the top offender process steps, a 5 Whys tool is used to determine specifically the cause of complexity for the step. A 5 Whys is a problem-solving tool or method broadly used in Six Sigma projects that helps to identify deeper root causes by repeatedly asking "Why?" every time the question is answer. Number five is not a fixed structure but rather a guide to know how to stop asking based on experience. A 5 Whys could take less than five Whys to find the root cause while for highly complex problems it could take more.

For the first highly complex step identified from DfMA, Place the parafilm square on needle carrier, 5 Whys was performed as shown in Table 2.

Table 2
5 Whys for Placing Parafilm Square on Needle Carrier

Questions	Answer
Why is the step complex?	Manual alignment of the parafilm to the center of product.
Why is aligning to the center difficult?	No control features are in place.

Why are not control features in place?	Designed fixture does not have the capability.

For the second highly complex step identified from DfMA, cut patch, 5 Whys was performed as shown in Table 3.

Table 3
5 Whys for Cutting Patch

Questions	Answer
Why is the step complex?	Product handling is difficult.
Why is product handling difficult?	The operator's hands are too big in comparison to product size.
Why are hands used to handle product?	Product needs to be moved to cut around.
Why does the product need to be moved?	The current cutting process does not provide another way.

Based on the results of the 5 Whys tools used, two major actions resulted from this exercise: 1) Improve the fixture used in the process and 2) Improve the patch cutting process step. These two actions will be managed during the Improve phase of the DMAIC methodology.

Improve Phase

On the improve phase innovative ideas are developed and transformed into implementations to improve process performance. The implemented improvements must address what was established in the problem statement and shall be able to be measured. During this phase, several tools are used to design, test and implement creative solutions to achieve project goals.

One of the methods used in DRM when designing a new solution is Concept Engineering. Concept Engineering is a way for developing ideas converting them into real and viable solutions to be subjected to test. The scope of this project has been focused on the placement of parafilm on needle carrier and patch cutting steps based on the measure and Analyze phases, driving the opportunities for improvement on the fixture used and the cutting process, which are going to be addressed in this phase. The design must consider customer voices gathered and ensure to meet project goals. Two concepts were developed integrating improvements for both identified process steps. The first concept presents a cam style concept (Figure 7) and the second concept presents an air cylinder actuator concept (Figure 8).

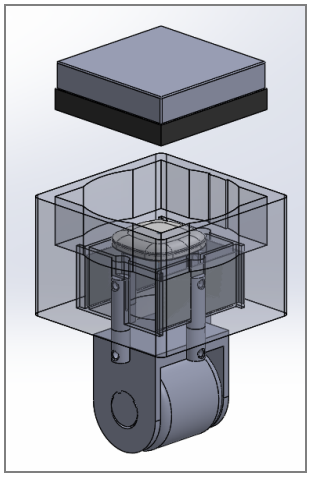

Figure 7
Concept 1 – Cam Type Model

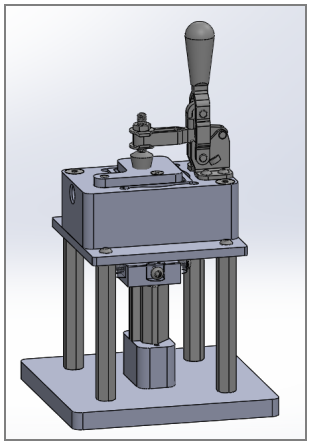

Figure 8
Concept 2 – Pneumatic Cylinder Model.

The concepts were developed to improve the fixture in a way that provides several poka-yoke features for aligning the parafilm square and automatically perform the patch cutting process step without needing operator intervention. These designs mainly consist of an internal square shape that serves as a poka-yoke feature for the parafilm square piece, in addition, it contains a blades subassembly that performed the patch cut automatically using cam profile concept or a pneumatic cylinder as actuator.

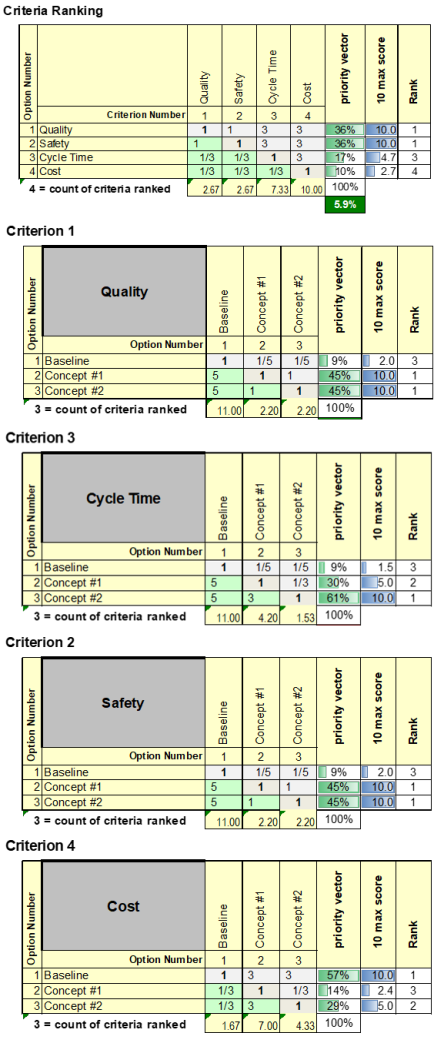

Figure 9
Analytic Hierarchy Process (AHP)

As part of the Improve phase, both created concepts were evaluated using another tool used in DRM named Analytic Hierarchy Process (AHP). This tool helps to objectively compare multiple concepts using the same criteria, in this case, quality, safety, cycle time and cost as shown in Figure 9. In addition, the baseline concept of the fixture was also included in the evaluation.

The AHP consists of assigning priority or weight to one criterion over the others until all criteria have been evaluated between them. The tool reads as follows: Criterion in row one is (more, equal or less) significant than the criterion in column 1. Each comparison is being filled until the comparison matrix is completed. Once the evaluation of the criteria has been performed, the same evaluation is performed for the concepts but now on each criterion. Concepts are evaluated within them for quality, then for safety, cycle time and finally cost as shown in Figure 9. At the end of the exercise, the tool provides an objective value based on the evaluation performed on each concept per criteria and establishes the best concept as shown in Figure 10.

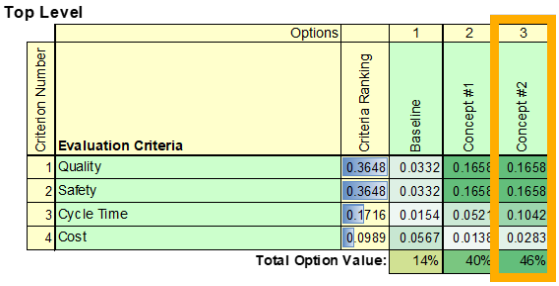

Figure 10
Analytic Hierarchy Process (AHP) – Best Concept Option

According to the AHP results, the total option value for Concept 1 is 40% while the total option value for Concept 2 is 46%, contrasting with 14% of the baseline concept. Once the concept is selected, presented and agreed with the customer and stakeholders it is possible to proceed with the implementation and measurement of the actual performance of the new design.

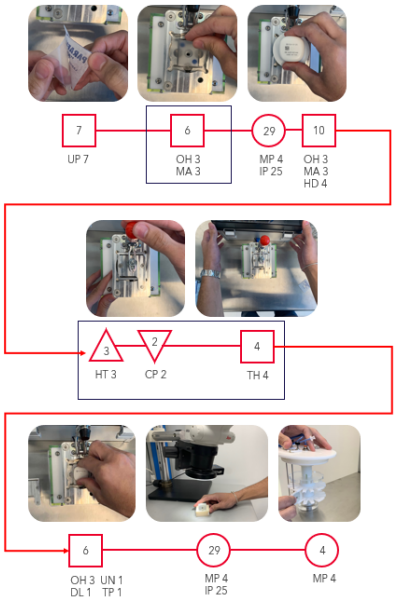

Figure 11
DfMA Tool Applied to Improved Process

To verify and confirm that the new process using the improved fixture design meets the project goals and customer needs, the DfMA was applied again to calculate the penalty score as shown in Figure 11.

From the DfMA tool applied to the improved process, a total penalty score of 100 in comparison to the baseline process with a penalty score of 263. This result indicates that the improved process contains a significant amount less complexity.

On the other hand, an evaluation of the impacted metric, process time, shall be performed as well for the improved process. Time study results for the improved process are shown in Figure 12.

No.	Element	AVG per Observation (sec)	AVG per Observation (min)	AVG per Lot (min)
1	Get synergy tree carrier	15	0.25	4.00
2	Take synergy tree carrier to work table	10	0.17	2.67
3	Get synergy needle carriers	8.00	0.13	0.00
4	Take synergy needle carriers to work table	5.50	0.09	0.00
5	Set up work table	21.00	0.35	0.35
6	Cut parafilm square	6.00	0.10	0.00
7	Count parafilm squares	6.00	0.10	0.00
8	Set parafilm aside	6.00	0.10	0.00
9	Grab 4 parafilm squares	5.00	0.08	0.00
10	Punch a hole in the center of the parafilm squares	13.50	0.23	0.00
11	Set hole puncher aside	2.00	0.03	0.00
12	Log in to FactoryWorks	10.50	0.18	0.18
13	Scan needle carrier	5.22	0.09	27.40
14	Open needle carrier	20.82	0.35	109.30
15	Place needle carrier on fixture			
16	Place parafilm square on needle carrier			
17	Fire needle			
18	Cut patch			
19	Peel off parafilm paper			
20	Place sensor on inspection fixture	2.73	0.05	14.36
21	Inspect sensor	4.42	0.07	23.21
22	Place sensor on tree carrier	5.61	0.09	29.45
23	Click ok on TrackInOut window	2.11	0.04	11.09
24	Enter password	4.94	0.08	25.92
25	Close needle carrier and set aside	4.92	0.08	25.83
26	Log out of FactoryWorks	8	0.13	0.13
			Total Time (min)	*273.88*
			Total Time (hr)	*4.56*

Figure 12
Improved Process Time Study

From the time study, a total process of 4.56 hours was obtained for the improved process in comparison to the 5.87 hours of the baseline process. This resulted in a process time reduction of approximately 22%. A summary of the project results obtained is included in Table 4.

Table 4
Summary of Project Results

Criteria	Baseline	Improved
Process Time	5.87 hr/lot	4.56 hr/lot
Total Process Time Reduction	22.32%	
Complexity Penalty Score	263	100

Control Phase

The main objective of the Control phase is to assure the process is sustainable and standardize the implemented improvements. As part of the implementation the Process Operation Description (POD), which is the procedure that drives the EPT preparation process, was revised and updated introducing new instructions for the use of the implemented fixture. In addition, a new workstation was prepared for the use of the new fixture providing commodities and all materials required to perform the operation accordingly.

After the implementation was released to the operations team, a period of hyper care was given to the new introduced process assuring consistency and efficiency during the initial phase and operators learning curve.

CONCLUSION

As a manufacturing facility, continuous improvement of existing processes is a focal point to decrease operational costs and waste. One of the most common problems is to reduce processing time in operations for many reasons including increasing capability and reducing operational costs or LBM. The preparation process for the Electrochemical Performance Test is not an exception. Opportunities for improvements were found on the process through time studies and Design for Reliability and Assembly tools, being able to drive an innovative solution designed by using the DMAIC methodology integrated with DRM tools. A total of 22.32% of process time reduction was achieved exceeding the project goal of 15% assuring customer voices were incorporated in the implemented design. Standardization of the process was performed by updating the Process Operation Description and sustainability was monitored during the hyper care period. As a medical devices industry with a high demand of products, every improvement to the existing processes that impact product led time to the patient or increased capacity generates a significant

difference for the company, increasing market growth. The successful implementation of the new process not only enhances the existing process efficiency but also serves as a demonstration of commitment to the patients, passionately working to alleviate pain, restore health and extend life.

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