Process Improvement for High Precision Components at Medical Devices Company (MDC)

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Abstract

A medical device company had areas opportunities for improvements to production and labor utilization. The objectives were to increase the production by 10% to 20% and an improvement in the labor utilization of 5% to 10%. Some of the challenges identified included the need for standardization, reduce waste (Muda), and redundant operations. After performing a historical data and root cause analysis, several alternatives were recommended. The selected alternatives result in coils electropolishing capacity increase of 8%, coils grinding, and sandbar increase of 12%, with a scrap reduction from 15% to 3%. In the process of passivation, the expected capacity increase is about 3%. These improvements will allow the company to gain a competitive advantage.

Keywords
Lean Manufacturing, Operations Management, Capstone Project, and Six Sigma Applications

1. Introduction
With over twenty years of experience in the medical device industry as a third-party contractor, Medical Device Company (MDC) has produced millions of precision parts for over 100 active clients. By mid-2020, the daily production target in the miscellaneous department could not be reached. When evaluating their operations, it was observed that production processes weren't standardized. Additionally, an analysis of non-value-added activities was required to achieve proposed objectives and gain much-needed production capacity. The findings will be further analyzed with the application of root cause analysis and based on these results, solutions to these problems will be recommended. To complete the project, we will review the benefits and percentage of objectives achieved.

1.1 Objectives
The project team established two objectives: 1) increase the production by 10% to 20%, from 2,800 to 5,600 parts and 2) improvement in the labor utilization of 5% to 10%. Statistical analysis will show if changes made were statistically significant.

2. Literature Review
The literature review will focus on some background on the need of improving medical devices manufacturing industries, defining some medical device terms related to this project, and finally, describing the process analysis tools such as time studies, work-sampling, ergonomics, and standardization. As Niebel (1988) states, a business can only be profitable when productive, this mindset must include all business operations, including sales, finance, and all other non-production activities.

2.1 Medical devices industry and the need for process improvement
Despite a -3.2 percent drop in 2020, the literature suggests that the medical device sector will rise at a 4.4 percent compound annual growth rate in 2021, according to Kluwer (2019). Traditional business drivers, continue to be critical, including product quality, innovative designs, competitive price, and on-time delivery. As manufacturing evolves, new technical challenges become part of the equation, efforts to keep up with these advances, cannot cancel out the need to add value to customers (Abdullah, 2003). Quality is directly correlated to business gains in many companies (Elshennawy,1991). Quality improvements can also be correlated with increases in workflow and productivity. (Feigenbaum, 1991).

From the 1970s to our extensive use of Lean Six Sigma in the 21st century, quality remains one of the most important business drives. Some authors state that for the medical device industry, selecting an adequate process improvement methodology was challenging, with some stating combining several strategies such as TQM, six sigma, and lean thinking resulted in successful implementation reports (Aspinwall and Yusof, 2000; Bhote, 2002; Pande et al., 2000; Stein, 1997).

2.2 Medical devices technical terms

The need for timely delivery of high-quality parts is critical to grow and retain customers. The processes analyzed in this paper are electropolish and passivation. We wanted to define these terms to facilitate understanding. Electropolish is defined by Cutchin (2015) as a process that smooths and streamlines a metal object's surface, and when seen in a microscope, no broken surface is seen, all is smooth. In contrast, passivation is defined by Roll (2020) as a process that "restores stainless steel parts to their original corrosion standards by eliminating ferrous impurities such as free iron from their surface." Passivated stainless steel products are submerged in chemicals at pre-determined temperatures and times.

2.2 IE and Lean Tools

A proportion defective (P) Chart is an attribute control chart used to compute the historic proportion of nonconforming units and monitor its monthly performance (Montgomery 2009). His can be used to measure scrap percentage in our project. Stopwatch time studies and work sampling facilitate the estimation of process baseline. Work sampling is an indirect time measuring tool that requires engineers to tally observations over a reasonable number of occasions at random time intervals. These observations are used to construct interval calculation for a given confidence level about the percentage (or proportion) of time a worker performs each task. The industry standard to review these procedures and formulas is provided by Niebel & Freivalds (2003).
Once the alternatives are implemented, we desired to compare if the changes are statistically significant. The use of a paired T-Test is statistical inference tests, as discussed by Montgomery (2011), facilitate the validation of these results.

3. Methods

Several industrial engineering and lean tools were combined to achieve the maximum impact in the company. For the historical data analysis, it was desired to understand the current process areas of opportunity. By using stopwatch and work sampling studies, standard times were computed, and non-value-added tasks were detected. These were input in the workforce capacity analysis to determine the current production vs. the expected monthly production. An ergonomics study was conducted to determine which tasks need to be improved and reduce the risk of physical fatigue. To discover the root causes of the problems mentioned, tools like fishbone and 5 whys were used. The root cause analysis makes it easier to provide solutions for resolving problems.
After the possibilities were presented, a decision matrix with a scale of 1 to 3 was used to help choose the best one. To validate those objectives were met, the baseline vs the expected monthly production target was compared by adding the expected product after improvement implementation, and standardization was analyzed by using Paired T-Test. The economic aspect was measured in terms of the return of investment and payback period. Finally, a Gantt Chart was utilized to demonstrate the duration of the proposed processes as well as the time savings.

4. Data Collection

For the historical data analysis, a time-study of 34 observations for the electropolish, grinding/sandbar process and 34 observations for the work-sampling was performed. The current standard time for the electropolish is 102.3 seconds and grinding/sandbar 54.6 seconds and for the work sampling electropolish and grinding/sandbar the operator spends in non-value-added activities 2.8hrs daily, passivation 2.2hrs daily. A Waste Walk was conducted to identify non-value-added activities, with results shown in Table 1. From this, the coils' non-value-added activities were 32%, with a daily time spent on non-value-added of 2.8 hours. In passivation, the non-value-added activities are 25% of all working time, for a total of 2.2 hours of unproductive time.

Table 1 Summary of Waste Walk Observations

Waste	Observation
Transportation	Grinding stone is not immediately available around the workstation 3.1 hours yearly
Motion	Measuring the water conductivity in tanks 40.1 hours yearly
	Manually sandbar coils. Operators counting the full package of parts for the job 61.3 hours yearly.

5. Results and Discussion

This section will discuss the steps taken from understanding the process and providing an in-depth evaluation of the root causes. We start with the historical data analysis phase, where the results from several tools such as capacity analysis, time studies, ergonomic evaluation, and process control charts were instrumental in confirming the process baseline. This was followed by the root cause analysis, where the fishbone analysis and 5-whys were used. The section ends with the alternative's presentation and analysis.

5.1 Numerical Results

Capacity Analysis provides an overview of the ability to comply with customers' requirements. Table 2 shows the monthly rate calculated for each process. For the analysis, it utilized from end of January to March 2020, since production was stable. Nevertheless, none of the processes can reach the monthly target of 28,000 parts.

Table 2 Capacity Analysis for the Miscellaneous Department

Process	Standard Time (sec.)	Hourly Rate	Monthly Rate	Monthly Output	Capacity
Electropolish	57.1	63	31487	15530	55%
Grinding/Sandbar	120	30	14994	16208	58%
Passivation Inserter Shaft 1.4mm	18	200	99960	19442	69%
Passivation Inserter Shaft 2.3mm	18	200	99960	8724	31%

A time study was conducted to establish the process's current standard time. The process standard time for electropolish and grinding/sandbar are:

- 102.3 seconds which equal an approximation of 35 parts/hourly for electropolish
- 54.6 seconds which equal an approximation of 65 parts/hourly for grinding and sandbar

5.2 Graphical Results

A proportions chart (P-Chart) is an attribute control chart used to understand the coils defect rate as shown in Figure 1. The historical scrap is about 15% and its sources were determined to be dimension 80% and cut and stain 20%. Parts/Scrap arrive from the manufacturer and value is added to a part that should be discarded from the beginning.

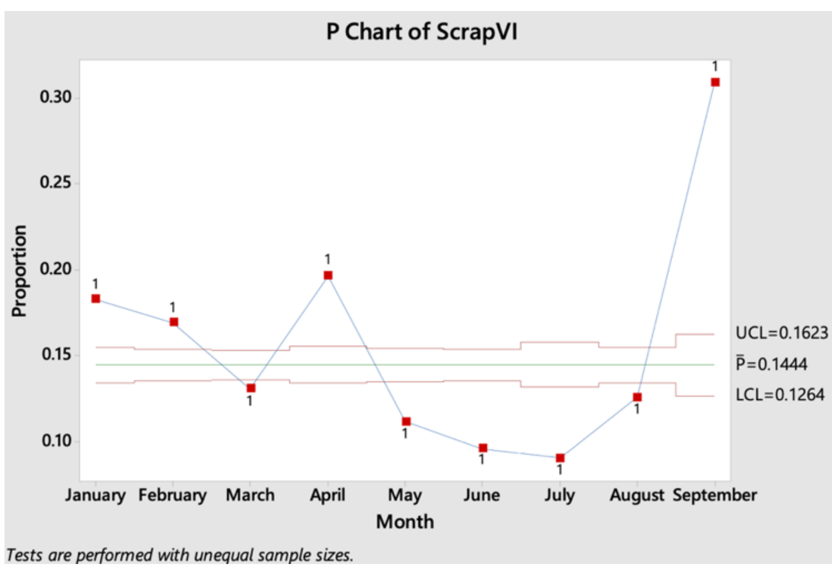

Figure 1 P-Chart for Coils

To measure the sensitivity of individual staff to ergonomic risk factors associated with upper extremity muscular-skeletal disorders, the Rapid Upper Lumbar Assessment (RULA) method (Middlesworth 2020) was evaluated. In the case of electropolish (see figure 2), it was found that the assembly table is low for the operators and the task is constantly repeated. With a RULA Score 5 the conclusion is medium risk, further investigation and change soon. Passivation it was found that the height of the tanks was higher for the operators RULA Score 6: the conclusion is medium risk, further investigation, change soon. We will focus on recommending adequate heights for the work surfaces.

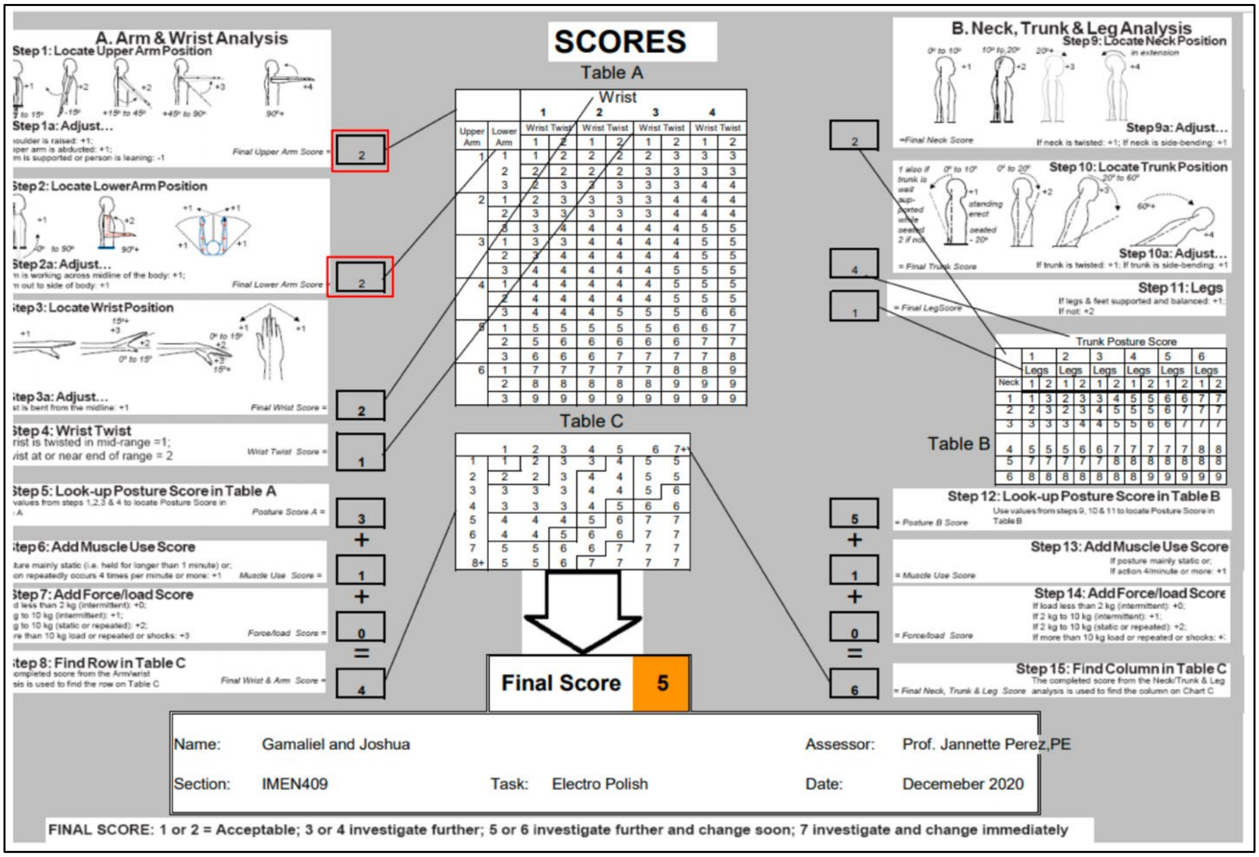

Figure 2 RULA Assessment for Electropolish

A fishbone diagram was developed to facilitate the root cause analysis. During the evaluation of the electropolish, grinding/sandbar, and passivation processes, several opportunities for improvements were observed such as raw material not being inspected, no process standards, and the operator stepping away from the station. The two main significant problems identified (see figure 2) for the miscellaneous department are *"**process does not meet the average monthly production target**"*. The root cause for problem is the lack of standard procedures that ensure best safety practices. For the second problem, "***raw material out of specs"*** the root cause is that raw material dimensions are not inspected at the incoming phase. A significant amount of coil scrap is detected in the final phase of the production. The third problem identified is the ***"improve labor utilization"*** and root causes for this problem were operator searches for grinding components and step away from the stations, the repeated movement such as manually counting parts, and the manual water measuring for conductivity.

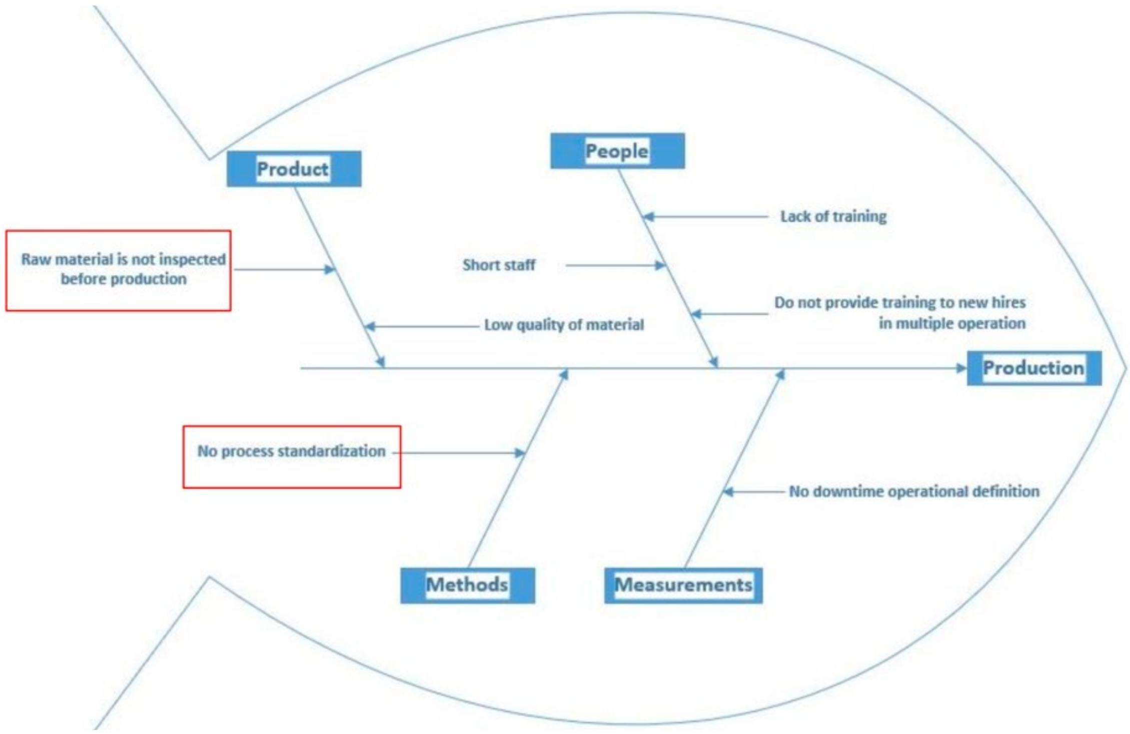

Figure 3 Cause and Effect for Problem #1 – "Process does not meet the average monthly production target"**.**

5.3 Proposed Improvements

The proposed alternatives to resolve these three problems are revealed in parts/yearly. These evaluate the operation and financial information, such as payback period and return of investment (ROI), and support the decision analysis. The alternatives selected using the decision matrix analysis for the electropolish, passivation, and grinding/sandbar problems are summarized in table 6, including the return of investment (ROI) and payback period. Also, the decision-making considers variables such as Benefit, Disadvantages, Time, Ergonomics, Training, and others.

Table 3 Alternatives Design for Electropolish Process

Electropolish Problem #1: Process does not meet the average monthly production target						
Name	Alternative	Implementation Time	Advantages	Disadvantages	% Capacity Improvement	Parts/Year
A1	Reduce Tanks	4 hours	Reduce Tanks	Still requires water change	6%	20,160
A2	Conductivity Sensors	15 days	Eliminates manual measuring	Training	2%	6,720
A3	All	15 days	Reduce tanks and eliminates manually measuring	Still requires a change of water and training	8%	26,880

Table 3 present the three alternatives proposed for the electropolish process. For this process, each alternative seeks to improve the production in parts/year. Implementing both alternatives increases production by a large margin.

Table 4 Alternatives Design for Passivation Process

Passivation Problem #1: Doesn't comply with Monthly Production Target Passivation Problem #2: Labor Utilization							
Name	Alternative	Implementation Time	Advantages	Disadvantages	% Capacity Improvement	%Utilization Improvement	Parts/ Year
A1	Reduce Tanks	4 hours	Reduce Tanks	Requires water change and training	1%	N/A	756
A2	Conductivity Sensors	15 days	Eliminates manually measuring	Training	2%	5%	8,136
A3	All	15 days	Reduce tanks & no manual measuring	Requires water change and training	3%	5%	8,892

Table 4 present the three alternatives proposed for the passivation process. For this process, each alternative seeks to improve the utilization by eliminating non-value-added activities and improve the production in parts/year. Table 5 present the three alternatives proposed for the passivation process. For this process, each alternative seeks to improve the utilization by eliminating non-value-added activities, reduce the scrap percentage and improve the production in parts/year.

Table 5 Alternatives Design for Grinding and Sandbar Process

Grinding and Sandbar Problem #1: Doesn't comply with Monthly Production Target Grinding and Sandbar Problem #2: Labor Utilization							
Name	Alternative	Implementation Time	Advantages	Disadvantages	% Capacity Improvement	%Utilization Improvement	Parts/ Year
A1	One-Piece Flow	10.5 days	Increase Production	Training	12%	3%	37,473
A2	Go or No & Sandbar Machine	25 days	Eliminates manually sandbar	Training and Implementatio n time	7%	3%	25,056
A3	All	25 days	Production increase, no manual sandbar	Training and Implementatio n time	12%	3%	37,473

Table 6 Selected alternatives for each of the main problems

Process	Problem(s)	Alternative selected	Payback Period	Return of Investment (%)
Electropolish	1	A3	2 months	10.7
Passivation	1,3	A3	16 months	6.9
Grinding and Sandbar	1,2,3	A3	1 month	11.5

Implementing alternative 3 for electropolish the capacity is improved 8 percent which equal 2,240 parts monthly. Implementing alternative 3 for grinding and sandbar capability is increased by 12 percent, equivalent to 3,123 monthly parts, and scrap reduction by parts that do not meet with dimensional requirements, a drop from 15 percent to 3 percent. The capability is increased 3 percent by introducing alternative 3 for passivation, which equals 741 parts monthly in both parts and decreases 5 percent of the non-value-added operation.

Figure 4 demonstrates the flowchart comparison for the coils grinding and sandbar. To solve the problem of a scrap of coils for dimension, it is recommended to implement the "Go or No Go" (blue box), to discard from the beginning the coils that don't comply with dimensions. Also, to facilitate and improve the process manually sandbar is replaced with a machine (see figure 5). These result in process improvements of 12% while also discarding non-compliant parts at the beginning of the process. The recommendations reduced the 15% to 3%, by removing parts without specs dimensions.

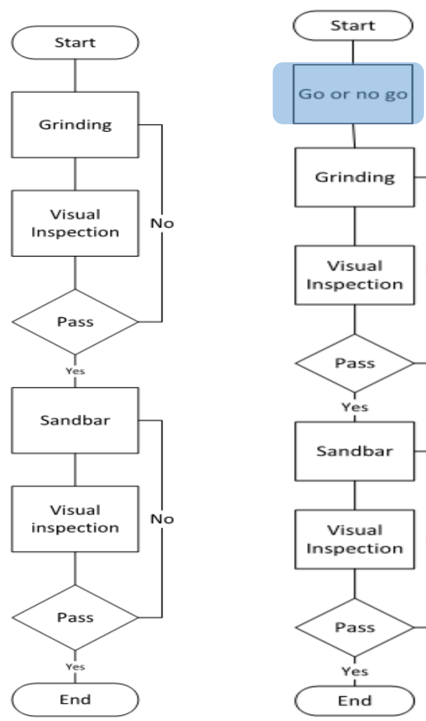

Figure 4 Flowcharts Comparison (left before and right after)

Figure 5 Sandbar Machine

Table 7 presents the new REBA and RULA scores after the alternative's designs are implemented. In this, case there is an improvement of 5 to 3 for electropolish and 6 to 4 for passivation, reducing the ergonomic risk in the operation. Improvements were made by modifying the table heights aligned to anthropometric principles.

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Table 7 Ergonomics Improvements

Task	REBA Score	RULA Score	Dimensions
Electropolish	4	3	Table Height 28”-42"
Passivation	5	4	Table Height 3’

The new layout (figure 6-A) proposed the changes of tank reduction, ergonomic table, and automated conductivity sensor. For this layout, the modification is the reduction from three tanks to two. The task that is eliminated is measuring the water conductivity tank to tank, which takes an average of 45 seconds, worst case 1 minute for the three tanks. Table 7 provides a time comparison. The same principle will be applied to passivation (see figure 6-B). In this case, the task eliminated is the measurement of the water conductivity tank to tank which takes an average of 45 seconds, worst case 1 minute for the three tanks. The task that is eliminated is measuring the water conductivity tank to tank. Numbered arrows (1,2,3) represent the flow in the work area.

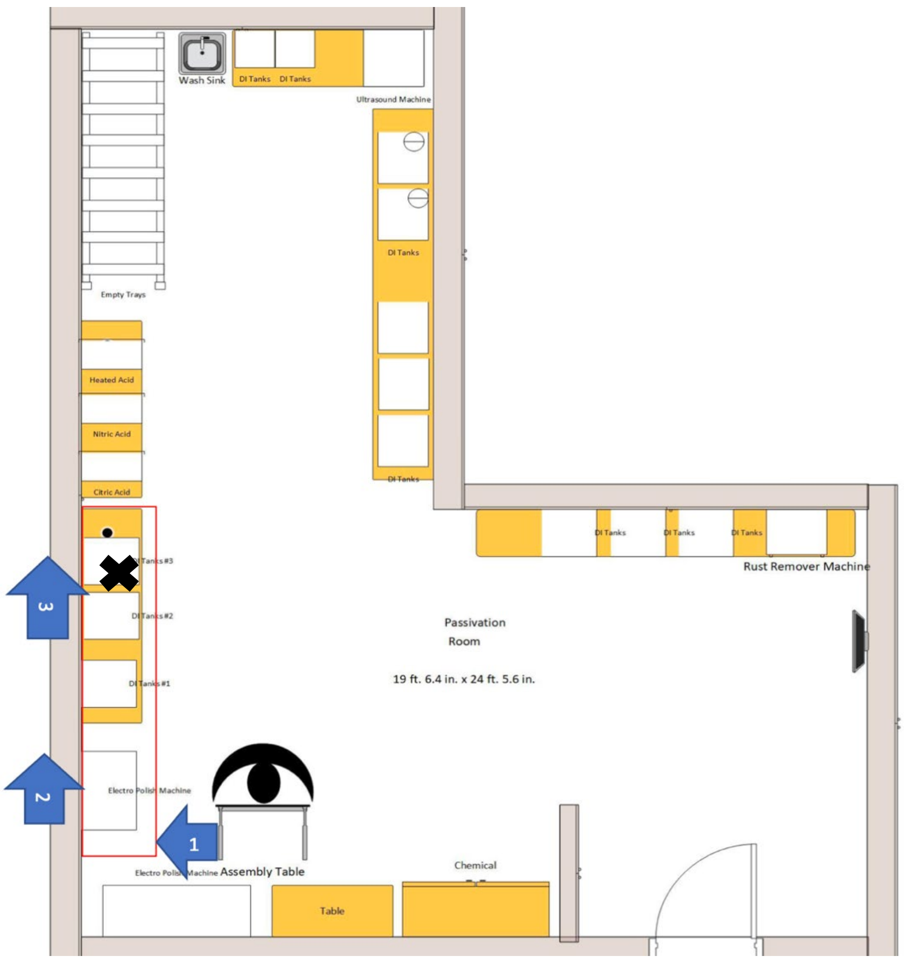

Figure 6 Layout A

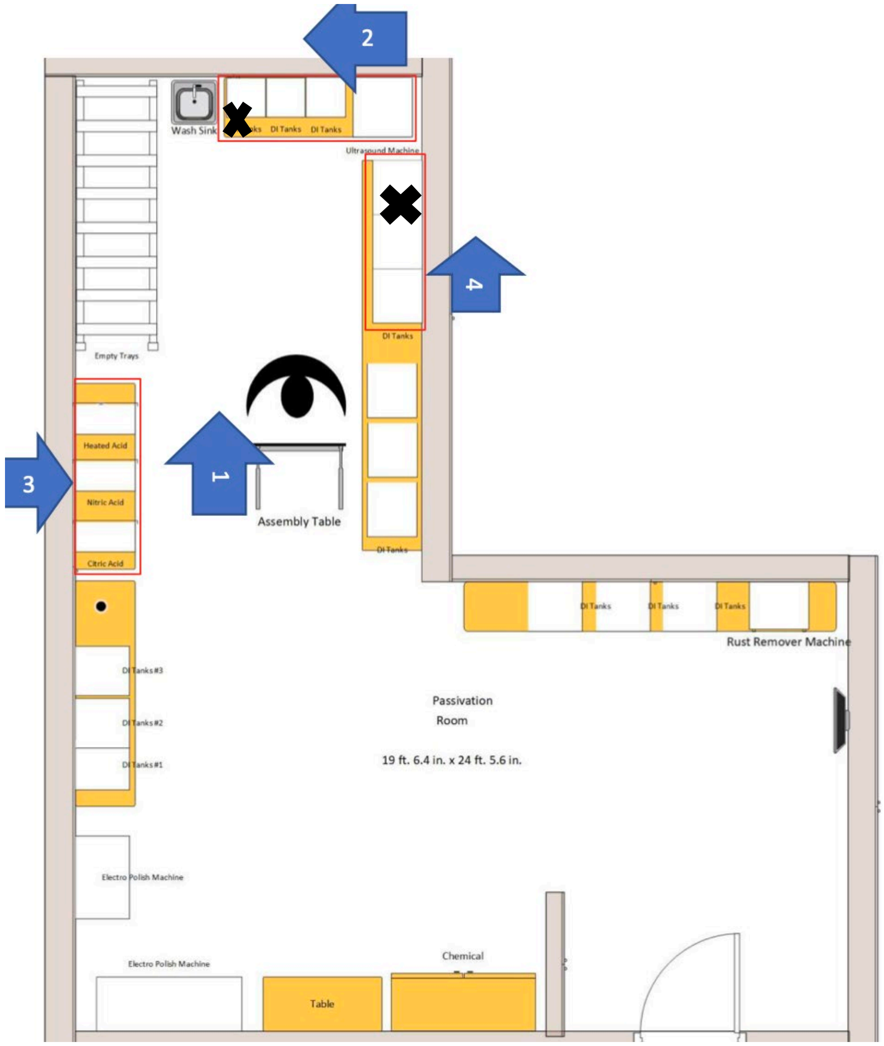

Figure 6 Layout B

5.4 Validation

The baseline standard time calculated for the electropolish process was 111 seconds, which was reduced to 79 seconds for a 28% of improvement as seen in table 9.

Table 8 Electropolish Time Comparison

Element	Duration Before(seconds)	Duration After (seconds)
Take Coil	11	8
Take Tweezers with Coil	20	20
Electropolish (fixed time)	15	15
DI Tank #1	15	8
DI Tank #2	15	8
DI Tank #3	15	0
Dry	20	20
Total	111	79

Similarly, the base standard time calculated for the passivation process was 2,900 seconds, which was improved to 2,842, for a 2% improvement. Lastly, the baseline standard time calculated for the grinding and sandbar process was 55 seconds, which was improved to 35 seconds for a 36% reduction. The paired t-test sample is a statistical test to show no difference between two corresponding sets of observations (Montgomery,2011). The paired test was conducted to validate that there are changes in terms of time in the process. The change, in this case, was to reduce the duration of the task and eliminate non-value-added activities. A statistical test was performed to compare the actual time means and improved meaning. The hypothesis formulated is:

- Ho: There isn't a difference between actual mean and improved mean: $\mu_{i=}\mu_k$
- H1: There is a difference between actual mean and improved mean: $\mu_{i\neq}\mu_k$

Table 9 shows that in each process there is a time improvement, but in this case, the most significant is the passivation process. Since the p-value is>0.05, the null hypothesis is rejected. For the process of electropolishing and grinding/sandbar, there is an improvement, but the difference isn't great, meaning even that the process was improved the alternatives presented didn't achieve a greater difference in times.

Table 9 Paired T-Test Results

A paired t-test (Cutchin Sr., 2015)			
Process	Actual Mean(sec.)	Improved Mean(sec.)	P-Value
Electropolish	15.86	11.29	0.073
Grinding/Sandbar	18.33	14	0.281
Passivation	291	285	0.012

6. Conclusion

This paper demonstrates the process that using industrial engineering and process tools in the medical device industry can result in significant improvements to its operations. After the analysis made for the process of grinding, sandbar, electropolish, and passivation for the Miscellaneous Department and selecting the best alternative for each process, an improvement was made to each process in some like electropolish and passivation the goal of 10% for capacity wasn't achieved and 5% of utilization for coil wasn't possible. Table 10 presents an overview of the achievement of this project. The objectives that weren't accomplished, were due to limitations and availability that presented in the course of this project, but there are opportunities identified that can be improved, such as redesign (updated) the whole process for coils, which involves conducting a study to determine is cost-effective and feasible to bring the entire production to this facility; passivation the is opportunity to reduce the time that parts are in the nitric or citric acid tanks, in this case, more expertise in the chemistry area is required since the materials of the parts and temperatures (higher or lower) can reduce the time of 30 minutes that parts are submerged in the acid.

Table 10 Objective's Review

Objectives	Baseline	Achieved	Differences	Objective Accomplished?
Electropolish Capacity Increase 10%-20%	55%	63%	8%	No
Grinding/Sandbar Capacity Increase 10%-20%	58%	70%	12%	Yes
Passivation Capacity Increase 10%-20%	69%	72%	3%	No
Passivation Capacity Increase 10%-20%	31%	34%	3%	No
Utilization Passivation 5%-10%	32%	29%	3%	No
Utilization Coils 5%-10%	25%	20%	5%	Yes

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