Scrap Reduction Due to Mechanical Failures in Heart Failure Medical Devices

Jamel Elis Galíndez Rosario
Master of Engineering in Mechanical Engineering
Bernardo Restrepo, Ph.D.
Mechanical Engineering Department
Polytechnic University of Puerto Rico

Abstract *— This research addresses the critical issue of reducing scrap in the manufacturing line of medical devices for heart care in Puerto Rico. Currently, manual assembly processes pose risks of mechanical failures, leading to significant financial losses and potential harm to patients. The project aims to identify root causes of mechanical defects, quantify associated costs, and implement measures to reduce scrap by 50% and improve manufacturing line yield by 5%. Employing the DMAIC methodology, the study involves data collection, analysis, and targeted interventions. Key improvements include implementing standardized work procedures, optimizing welding parameters, and enhancing maintenance protocols. Statistical analysis demonstrates significant enhancements in process capability, with notable reductions in rework instances and associated costs. These interventions result in tangible economic benefits and improved product quality, underscoring the effectiveness of continuous improvement initiatives in achieving sustainable manufacturing excellence.*

Key Terms *— Cost, DMAIC, Reduce, Rework, Scrap.*

PROBLEM STATEMENT

During the last years, Puerto Rico has seen progress in the manufacturing of medical devices of different types, but specifically in heart care. Most of these devices are manufactured 100% manually, which means there are risks of different failures at the time of device assembly. These failures cause manufacturing companies to lose millions of dollars a year in component damaged or scrap, which leads to the product leaving the market and the possible closure of these multinational companies. At the same time, due to the assembly and inspection of these devices are 100% manual, there is a risk that one of these devices will escape to the market if existing failure is not detected and could be implanted in a patient, which could cause serious consequences in the patient's health. For this reason, this project will focus at reducing scrap on a manufacturing line due to mechanical problems in heart medical devices.

RESEARCH DESCRIPTION

This research will be based on observing, collecting, and analyzing data from different mechanical failures in a manufacturing line of medical devices for heart problems. Manufacturing processes from subassembly, assembly to packaging will be analyzed with the purpose of capturing the different mechanical failures in these devices. The investigation will also seek to find which are the manufacturing processes where major mechanical defects can be generated in the device and the different costs associated with these defects. This research will help avoid the loss of capital and deliver the best quality products to patients with heart problems.

RESEARCH OBJECTIVES

- Determine root cause of mechanical defects and the cost associated with each mechanical rework in heart failure medical devices.
- Improve rolled throughput yield by 5% in operations that cause mechanical defects.
- Reduce scrap due to mechanical defects by 50% ($ 56,000 per year).

RESEARCH CONTRIBUTIONS

This research satisfies the financial and quality metrics of a manufacturing line of medical devices for heart failure. This will help significantly reduce the risks of product failure, guaranteeing a good quality of life for patients. It also guarantees the

stability and permanence of the industry in which the research will be done. This will help create jobs in Puerto Rico and guarantee the permanence of the medical device industry in Puerto Rico. In addition, it encourages the introduction of new medical devices products made by Puerto Ricans.

LITERATURE REVIEW

It is common knowledge that a vast majority of medical devices are manufactured 100% by hand or with the help of equipment recommended by people. This is why, medical devices for the heart such as defibrillators and pacemakers are not far from this reality and are not exempt from failures that may have an impact on the health of the patient where they will be installed. For this reason, the FDA (Food and Drug Administration) classifies pacemaker defects by severity and manufacturing company [1]. Despite this situation, it is important for pacemaker manufacturing companies to reduce costs in their production lines to guarantee that they are sustainable and that the business is cost-effective. This is why since the 1970s many changes have been made to these devices to improve product quality. In 1974, manufacturing companies began making significant improvements to avoid the risks of scrap and product recalls by replacing zinc batteries in pacemakers and replacing pacemaker casings with metal instead of epoxy [1]. In the manufacture of pacemakers, the most important mechanical process is the welding of the device to create its hermeticity. If this mechanical process is not carried out correctly the devices can experience short circuits due to human body fluids entering on it [2]. It is for this reason that welding inspections are carried out before a product goes on the market and can be implanted inside a patient. When this type of inspection is carried out and a non-conformity is found, the devices go through a series of rework that causes scrap that can cost up to $1,500 dollars per unit. Thanks to improvements in inspection processes and advance equipment, a decrease in premature pacemaker defects that cost money on the production line has been observed over the years [2]. Despite advances in technology, there are certain inspection processes that do not have sufficient technological advances and are carried out by people. As is commonly understood, individuals are not immune to errors. Consequently, manufacturing companies allocate a portion of their generated capital towards advanced training programs led by experts. These initiatives aim to equip personnel with the necessary skills to meticulously identify and address all potential defects in devices prior to their departure from the production line. This proactive approach mitigates the costly repercussions that could arise from unresolved issues post-production. Since the 1970s, when the first commercial pacemaker implants began, regulatory agencies consider a pacemaker with some mechanical failure as a bad practice by the manufacturers of these devices [3]. This is why from 1990 to 2000, pacemaker malfunctions cost approximately 870 million dollars [4]. All these costs create instability in the manufacturing industry, creating the possibility of bankruptcy, line closures, and products going off the market. To solve these problems, different manufacturers have had to invest in new equipment, develop new processes and validate them to avoid capital flight due to damage to pacemakers or defibrillators. Also, process monitoring has been put into practice in the different manufacturing processes where different essential parameters of the devices can be measured that help control the different operations with daily, weekly, and monthly tests, and that helps predict the behavior of the manufacturing line and make projections of the financial metrics of the manufacturing line. In addition, with the development of new technology they create a more efficient product, recover capital wasted on defective devices and create a more robust manufacturing process.

One aspect that also contributes to manufacturing line waste is equipment damage. When manufacturing equipment is not in good condition or maintenance is poor, it encourages defects in the different manufacturing processes

where it generates economic losses and in turn equipment downtime. This also affects manufacturing line yield and productivity metrics, creating economic losses and delays in the product. Effective maintenance extends the useful life of the equipment, improves its availability, and keeps it in proper condition [2].

PROJECT METHODOLOGY

The methodology used for this project was the DMAIC concept (Define, Measure, Analyze, Improve and Control) which will help achieve the objectives of the scrap reduction project due to mechanical failures in a medical device manufacturing line for the heart failures.

The first step was Define in which the problem, the opportunity for improvement, the goals and objectives of the project, and the scope of the project were already defined. In this Define stage, a Critical-to-Quality (CTQ) Tree will be developed, which will seek to analyze what the client's critical needs are and how these needs will be satisfied. Similarly, at this stage a process map will be developed which will help to have a visual representation of the manufacturing processes and the possible scenarios where mechanical failures are created in the device.

The Measure phase will continue with which it will seek to see the scope of the problem with data that supports the problem, thus being able to understand the current performance of the manufacturing line in terms of scrap and subsequently being able to control it. In the measure phase, a data collection plan will be developed to later collect the data and analyze it and data analysis technique will also be defined to establish the different controls that must be done to reach the scrap goal.

In the Analyze phase, the data collected in the Measure phase will be used to find the root cause of the different problems. In this phase, brainstorming, the 5 why method and the fishbone method will be carried out, which will help find the root cause more quickly and efficiently. These methods can also help find problems that were not taken into consideration when starting the project. Once the root cause or causes of the problem are identified, statistical analysis will be carried out, including validations in order to enter the improvement phase with data that supports the entire investigation.

After the analyze phase, the Improve phase will continue, which will seek to identify and execute different solutions proposed from the data analysis to reduce scrap. In this phase, changes to processes, new processes, training, new equipment, or software may be made that help detect possible mechanical failures in the devices and result in scrap. The goal for this phase is to make only the necessary adjustments since it must be taken into consideration that many changes can help reduce scrap but could increase operational costs or impact business productivity. The long-term benefit of the project and the individual benefit of the different changes made in the different manufacturing processes will also be calculated.

For the control phase, the new characteristics of the process will be measured and how this resulted in the improvement of scrap at the manufacturing line level. In parallel, a control plan will be worked on to ensure that the improvements made were implemented. At the end of the control stage, all manufacturing personnel will be retrained in the new procedures and work instructions to guarantee that the control phase is carried out according to the strategy that will be developed in the control plan.

RESULTS AND DISCUSSION

After defining the problem represented by rework on the manufacturing line, the data on the various reworks and the manufacturing processes of the biggest offenders were analyzed. Among the biggest offenders were Can Damaged, Casting Anomaly, nonconforming resistance welding, and damaged components. This initial data analysis leads us to examine each of the manufacturing processes where each of these defects can be generated.

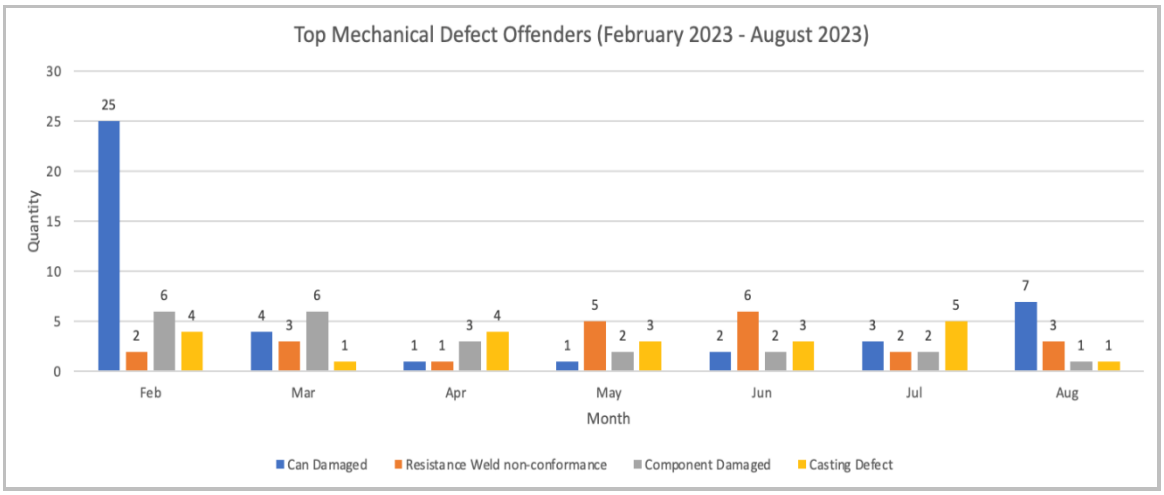

Figure 1
Mechanical defect top offenders since startup of Manufacturing Line in February 2023 until August 2023

Figure 1 show that in the first month of manufacturing, there was a high incidence of mechanical rework, costing $24,050 for the biggest offenders. For the subsequent months from March to August, there were a cumulative 71 defects among the biggest offenders, amounting to $46,150 over a 6-month period. Figure 2 shows the month-over-month cumulative total of mechanical defects leading to rework. It is important to mention that the data shown in Figure 2 includes other mechanical defects that are isolated to the biggest offenders and do not have a particular trend in the observed defects; however, these outliers still contribute to the scrap generated by the line and affect performance metrics. From this initial data obtained until August 2023, the different DMAIC techniques described in the Methodology section began to be implemented. From the initial data, the main cells in the manufacturing line that the project was going to focus on were identified, as they were the most critical operations after the initial data analysis. The focus cells were inspection, welding, and casting.

Following the DMAIC methodology, a Cause-and-Effect diagram shown in Figure 3 (or fishbone diagram) was created to identify the most critical areas of opportunity. It was found that for the manufacture of pacemakers, the headers and cans are the most critical materials. As a result of the Cause-and-Effect diagram, improvements were made to equipment, fixtures, and preventive maintenance processes to avoid rework. These improvements included:

- Implemented weekly and monthly fixture cleaning and inspection by engineer/technician.
- Implemented Lase weld fixture modification.
- Resistance and Hermetic weld parameter improvements.
- Implementation for standard work for Resistance Welding process
- Cleaning workstation daily with compressed air and wipes with 99% alcohol.
- Update Manufacturing Operation procedure to add new inspection point in devices Assembly Operation to evaluate any component damaged.

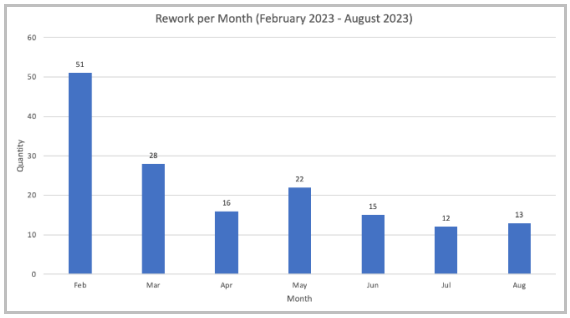

Figure 2
Mechanical Rework per month since startup of Manufacturing Line in February 2023 until August 2023 (each rework cost: $650.00/each)

To improve the hermetic welding process, it was necessary to go through a validation process to ensure that the new parameters were identified to

avoid crack weld, incomplete fusion in weld and hermetic weld non-conformance. To analyze the validations, statistical analysis was carried out with the Minitab Software where a Cpk (Capability Process Index) of 2.40, 1.42 and 1.80 was obtained for runs 1, 2 and 3 respectively for the hermetic welding process. These values obtained exceed the standard established by the industry of a Cpk of 1.33. Figures 4, 5 and 6 show the statistical results obtained with the Minitab Software.

Each of the figures mentioned above shows the data points obtained for each of the runs, this includes the UCL (Upper Control Limit), LCL (Lower control Limit) and the average of the values obtained. The moving range chart shows where the behavior of the data is observed over time when the data is collected.

Also, Figures 4, 5 and 6 shows the distribution of the data, and how it is adjusted in the distribution layer according to the Lower Specification Limit. In turn, the distribution of the data and the Cpk values mentioned above can be observed. According to the distribution obtained in Figures 4, 5 and 6, a normal distribution is observed when compared with the manufacturing industry standard since the 3 validation runs obtained a P-value greater than 0.005. The P-value for hermetic weld runs 1, 2 and 3 was 0.182, 0.426 and 0.064 respectively. This means that there is linearity and a normal distribution between the values obtained in our validation runs.

In the case of resistance welding, 3 validation runs were made to observe the performance of new welding parameters to avoid crack weld, smashed weld and blown weld. Figures 7, 8 and 9 show the statistical results for the validation of the resistance welding process. For the resistance welding process, a value of Cpk 6.56, 7.40 and 6.36 for runs 1, 2 and 3. These values obtained exceed the standard established by the industry of a Cpk of 1.33. These Cpk values indicate the capacity that the process achieves regardless of whether the average is centered between the specification limits.

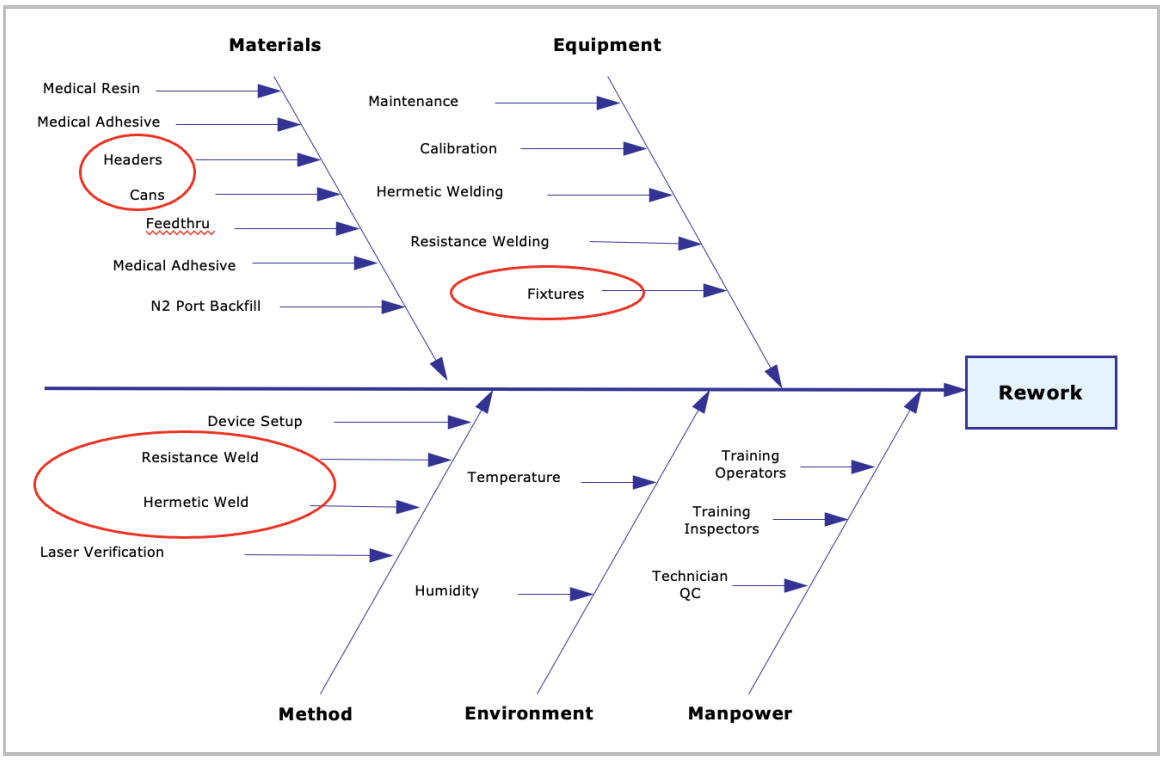

Figure 3
Cause and Effect Diagram

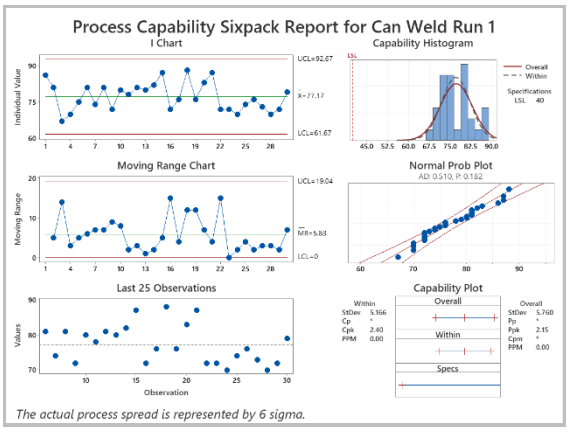

Figure 4
Process Capability for Hermetic Weld Validation Run 1

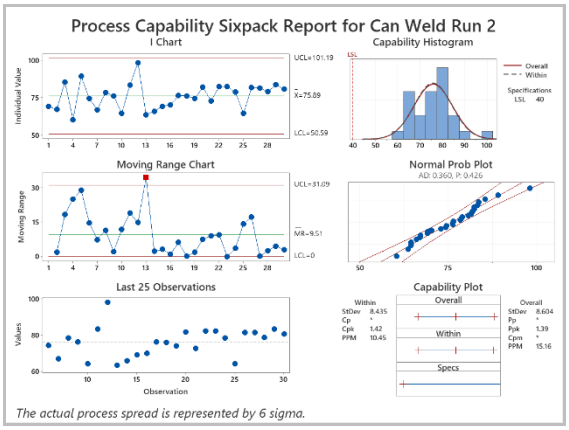

Figure 5
Process Capability for Hermetic Weld Validation Run 2

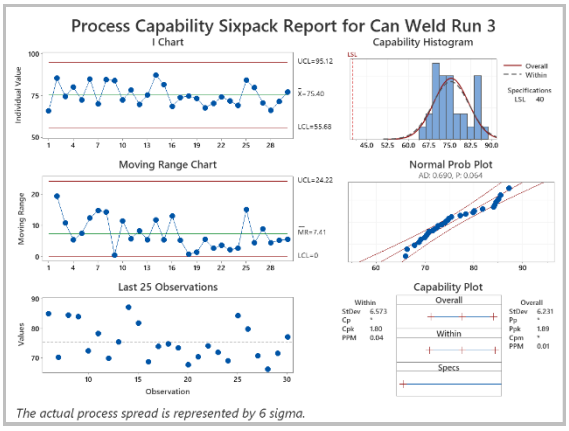

Figure 6
Process Capability for Hermetic Weld Validation Run 3

Similar to the hermetic welding validation, Figures 7, 8 and 9 show the data points obtained for each of the runs, this includes the UCL (Upper Control Limit), LCL (Lower control Limit) and the average of the values. obtained. Figures 7, 8 and 9 show the moving range chart, which shows how the data varies over time. Similarly Figures 7, 8 and 9 show the distribution within the probability campaign. For the 3 validation runs, normal data was observed since P-value values greater than 0.005 were obtained. For runs 1, 2 and 3, a P-value of 0.169, 0.208 and 0.521 was obtained respectively. All these values exceed the industry standard of P-value greater than 0.005 mentioned above. For this type of resistance welding process, the manufacturer's standards require that the data distribution be normal and linear due to the importance of the process and the risk that having dispersed values in this type of process may represent for pacemakers. Figure 13 shows quantity of resistance weld non-conformance behavior after new resistance welding system validation.

For the resistance welding process, a standard work was developed to create a generic process in resistance welding processes to create a work process that was the same for each of the operators who execute that resistance welding process. It also reinforces and improves training processes by certifying personnel in this operation. Table 1 shows the standard work created for the resistance welding operation.

Table 1
Standard Work for Resistance Welding Process

Potential Cause	Action/ Activity
• Smashed Weld • Crack Welds • Incorrect Targeting • Contamination • Blown Weld	• Align header and wire parallel to weld electrodes. • Align weld wire with ribbons in all unit models. • Clean weld electrodes for each unit welded. • Evaluate ribbons and feedthrough wire for visible damage. • Before operator certification, training must perform using scrap components. • Perform go-no go test in electrodes for each unit welded

One of the most impactful improvements was the cleaning of the fixture and workstation periodically. These improvements were created through a preventive maintenance system that

engineering and engineering technicians have access to distribute everything that is preventive maintenance and be able to document it. By periodically cleaning fixtures and workstations, it was possible to significantly reduce Can damaged, which was one of the biggest offenders.

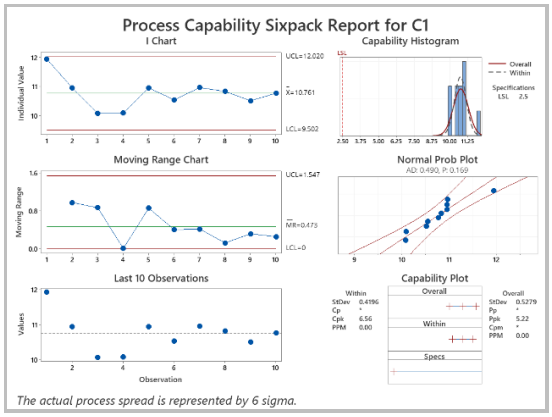

Figure 7
Process Capability for Resistance Weld Validation Run 1

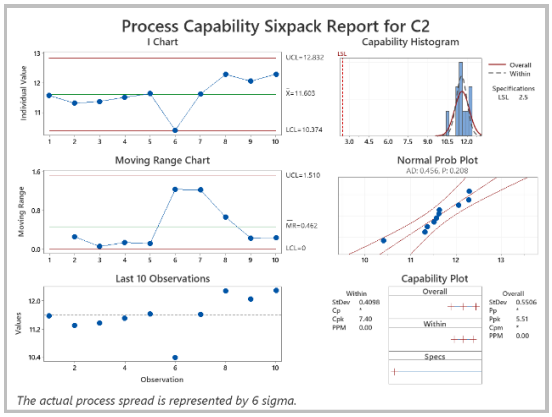

Figure 8
Process Capability for Resistance Weld Validation Run 2

The Can Damaged metric includes Can Dents, Can Scratches and Can Stains. Figure 10 shows the decrease in damaged cans after the implementation of the periodic cleaning system. In a similar way, the cleaning of fixtures significantly improved casting defects since the fixtures where the devices move throughout the manufacturing line are the same fixtures where the casting process is done. Throughout the line, each of these fixtures collects particulate and adhesive used throughout the entire manufacturing line. This particulate penetrates the casting, causing it to have material encapsulated within the material; therefore, it is a unit that must be reworked to correct this defect. Figure 11 shows a decreasing behavior in casting defect since fixture cleaning preventive maintenance was implemented.

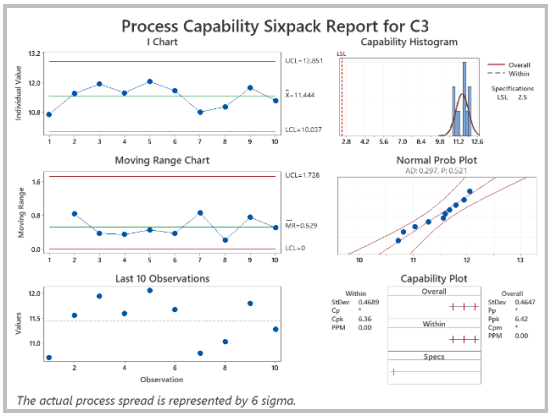

Figure 9
Process Capability for Resistance Weld Validation Run 3

Correcting and updating the manufacturing procedures to include a new inspection point at the device assembly station resulted in only 5 reworks after submitting the change. Figure 12 shows a decreasing behavior in component damaged defect starting in September where the manufacturing procedure was worked on.

Figure 14 shows how using the DMAIC methodology to reduce rework on the manufacturing line took control of the rework that was guided by the different offenders discussed in Figures 10, 11, 12 and 13. Figure 14 shows a significant impact on the scrap and yield metrics since the number of reworks in the manufacturing line decreased from a total of 142 for the months of February to July where the implementation of the different types of control began. After implementation of control variables, a cumulative amount of 42 reworks for the months of August 2023 to January 2024 were observed. This represents an economic impact of $65,000 in a period of 6 months after the implementation of all the changes made using the DMAIC methodology.

In the case of rolled throughput yield, an improvement of 7.2% was seen for mechanical defects based on a production volume of 1500 devices per month.

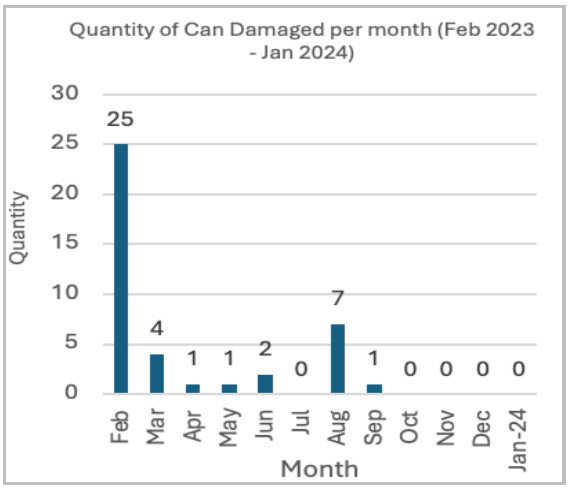

Figure 10
Quantity of Component Damaged Defect per month from February 2023 to January 2024

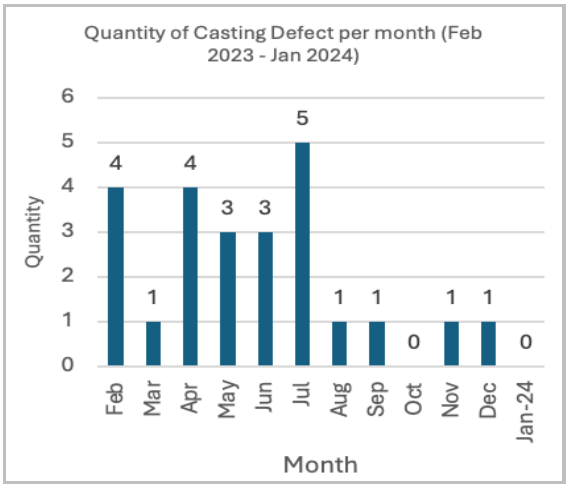

Figure 11
Quantity of Casting Defect per month from February 2023 to January 2024

CONCLUSION

The investigation into manufacturing rework, particularly focusing on the major contributors such as Component Damaged, Can Damaged, Casting Anomaly, and nonconforming resistance welding defects, provided valuable insights into the root causes and potential solutions. Through rigorous data analysis and the application of DMAIC (Define, Measure, Analyze, Improve, Control) methodologies, critical areas of improvement within the manufacturing processes were identified.

Statistical analysis using Minitab software revealed significant improvements in process capability, with Cpk values surpassing industry standards, indicating enhanced process stability and performance. Moreover, the adoption of standardized work procedures facilitated consistency across operators, fostering a culture of quality and efficiency.

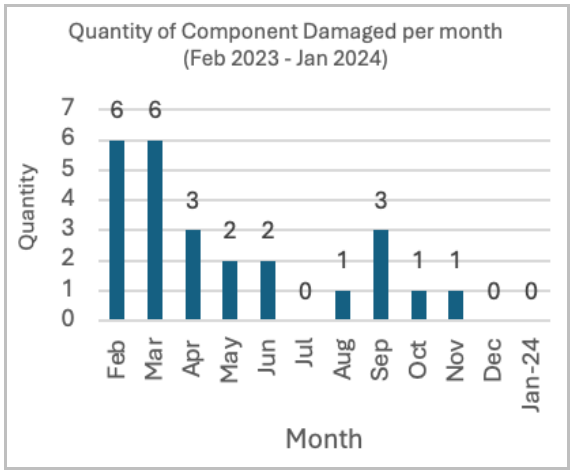

Figure 12
Quantity of Component Damaged Defect per month from February 2023 to January 2024

Notably, the introduction of periodic cleaning systems for fixtures and workstations yielded substantial reductions in defects related to Can Damaged and Casting Anomalies. These preventive maintenance measures contributed to a noticeable decline in rework instances, as depicted in Figures 10 and 11.

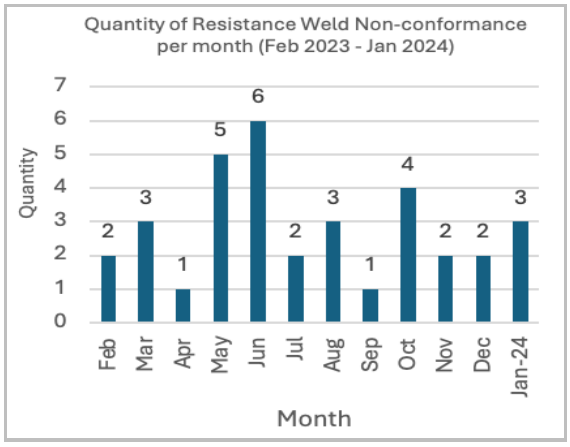

Figure 13
Quantity of Resistance Welding Defect per month from February 2023 to January 2024

The culmination of these efforts resulted in tangible economic benefits, with a reduction of $65,000 in rework costs over a six-month period following the implementation of improvements. Additionally, a notable improvement of 7.2% in rolled throughput yield for mechanical defects was observed, reflecting enhanced overall process efficiency and product quality.

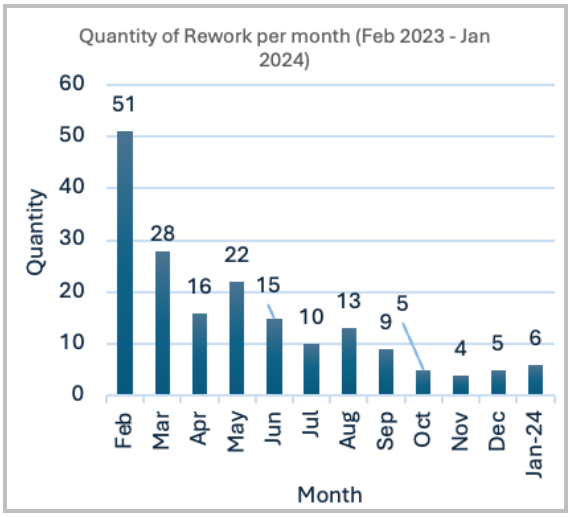

Figure 14
Quantity of Resistance Welding Defect per month from February 2023 to January 2024

FUTURE WORK

To maintain control of scrap in the manufacturing line of heart failure medical devices, several avenues for exploration emerge, each with the potential to enhance the project's impact and contribute to long-term success. One crucial aspect of future work involves the periodic verification and refinement of scrap metrics to ensure ongoing effectiveness in monitoring and managing manufacturing processes. By establishing a structured framework for the regular assessment of scrap metrics, including key performance indicators such as defect rates, and rework costs, manufacturers can proactively identify emerging trends or areas of concern and implement corrective actions in a timely manner. This iterative approach to scrap management fosters a culture of continuous improvement and enables organizations to adapt to evolving production challenges.

REFERENCES

[1] G. F. O. Tyers, “FDA Recalls: How Do Pacemaker Manufacturers Compare?”, *The Annals of Thoracic Surgery*, vol. 48, no. 3, p. 390–396, September 1989.

[2] V. Parsonnet, G. Lawrence, R. Zucker, and M. Maxim, “Complications of the Implanted Pacemaker: A Scheme for Determining the Cause of the Defect and Methods for Correction”, *The Journal of Thoracic and Cardiovascular Surgery*, vol. 45, no. 6, p. 801–802, 1963.

[3] D. L. Hayes, and R. E. Vliestra, “Pacemaker Malfunction”, *Annals of Internal Medicine*, vol. 119, no. 8, p.828, October 1993.

[4] W. H. Maisel, M. O. Sweeney, W. G. Stevenson, K. E. Ellison, and L.M. Epstein, “Recalls and Safety Alerts Involving Pacemakers and Implantable Cardioverter-Defibrillator Generators”, *The Journal of the American Medical Association, vol*. 286, no. 7, p. 793, August 2001.