

Abstract

This research project was focused in the First Pass Yield improvement in a cell of a Medical Device Company. In order to improve the first pass yield, the DMAIC methodology was used. This research contributed to improve the yield at the manufacturing cell where the pacemaker header is formed. This was important for the process, because it reduced rework, overtime and the negative impact on product released. It was determined that the top offender was Bubbles and it was identified (using a DOE) that a configuration of seals and Humidity interact with the bubble creation at the Header formation. The goal to improve the First pass yield (FPY) was achieved successfully, based on the results.

Introduction

This research project was focused in the First Pass Yield improvement in a cell of a Medical Device Company using DMAIC methodology. The cell dedicated to the formation of the pacemaker header has had an increase in bubble defects that is causing excess of rework, overtime and negatively impacting the output. Bubbles in the header is the top offender at this cell. With the reduction of this defect a better yield at this cell, named Casting Area, can be achieved.

Research Objective

This project aims to achieve an increase and at maintain the casting manufacturing cell first pass yield at 86%.

This project seeks to achieve a reduction in rework. This improves the process to move faster to the next operation with a positive impact in the cycle time. With less rework the cost associated to over time and the cost of materials can be reduced. This represents approximately \$100,000 yearly.

Methodology

In order to achieve the goal of increasing and maintaining Casting Area first pass yield (FPY) the DMAIC tools project methodology was used.



Figure 1 **DMAIC** Methodology

DMAIC is an acronym for a series of steps used to measure defects in business processes and improve profitability. The DMAIC problem solving method is a roadmap that can be used for any projects or quality improvements that needs to be made. The term DMAIC stands for the five main steps in the process; Define, Measure, Analyze, Improve and Control.

First Pass Yield Improvement on Casting Cell Using DMAIC Methodology

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Results and Discussion

Define Phase:

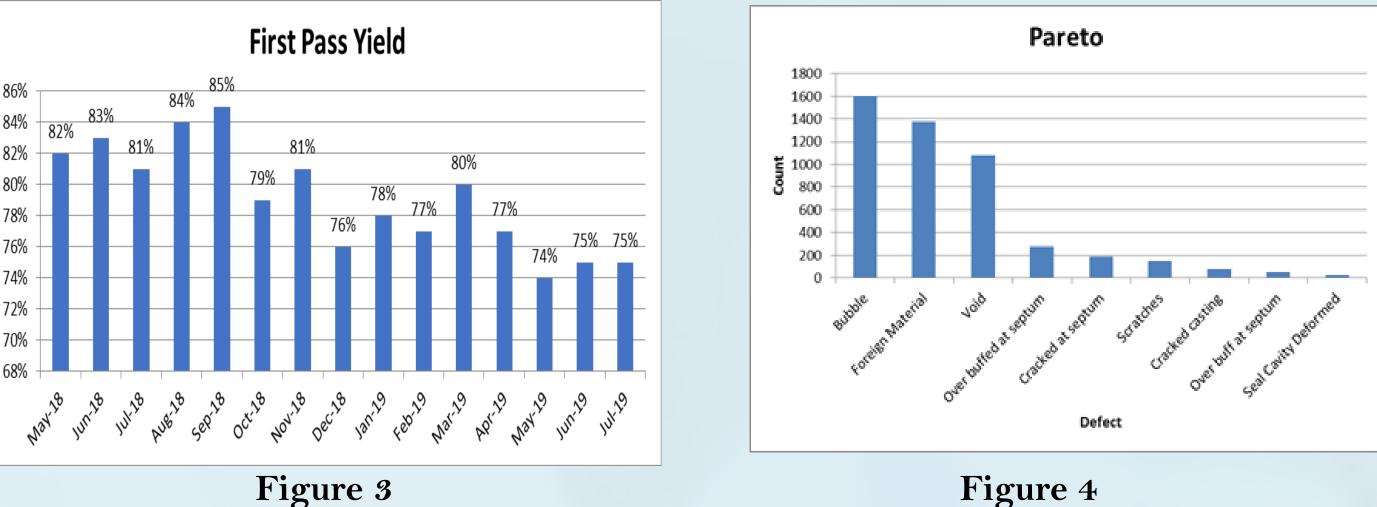
	An increase in bubble defects at th
Statement:	rework, overtime and negatively im
	Increase and maintain Casting FPY
Metric definition:	First Pass Yield

Figure 2 **Project Charter**

As part of this Define phase the VOC tool was performed in order to determine what the customer wants and needs. From the VOC was noted that the greatest concern was to reduce the bubbles at the casting header of the device.

Measure Phase:

The first pass yield was monitored and reported for the Casting header Cell.



First Pass Yield Trend

It is observed that the FPY (First Pass From the Figure 4 (which represents Yield) decrease for the casting header the top offender in a pareto graph) was observed that the top offender in the cell. casting header cell is the bubble in the **Analyze Phase:** casting header.

Analysis of the data collected shows that the Bubbles are the major offender in the data set.

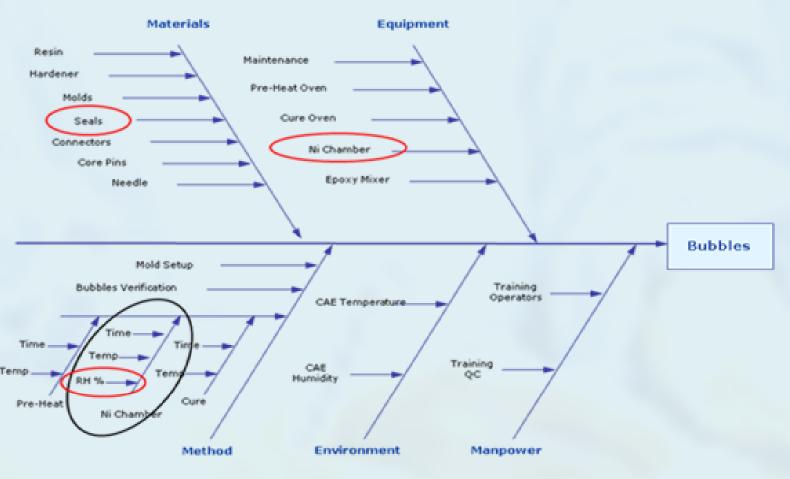


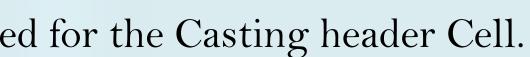
Figure 4 Fish Bone Diagram or Cause and effect Diagram In order to determine which the major contributor for the bubble creation is, a DOE (design of Experiments) tool was used.

Regular	Low Humidity, Regular Configuration Run 1	High Humidity, Regular Configuration Run 2
Optional	Low Humidity, Optional Configuration Run 3	High Humidity, Optional Configuration Run 4
	Low	High
Figure 5		

rigure o DOE

The worst results were seen at Run #2 at High RH and Regular Configuration Seals. That confirms the effect of both factors on bubbles. However, Run #1 and #2 strongly demonstrates the effect of humidity when Regular configuration seals are used. Based on these results optional Configuration Seals and Low RH condition (Run #3) was recommended to be used for manufacture.

e Pacer header causing excess of npacting the UPL. ' at 85% by Quarter 3, 2019.



Pareto Diagram

- From the cause and effect
- diagram it was determine that
- the most potential contributors
- for bubble at casting header type
- 2 are the seals, Nitrogen
- Chamber and Relative humidity percent(RH%).

Results and Discussion

Improvement Phase:

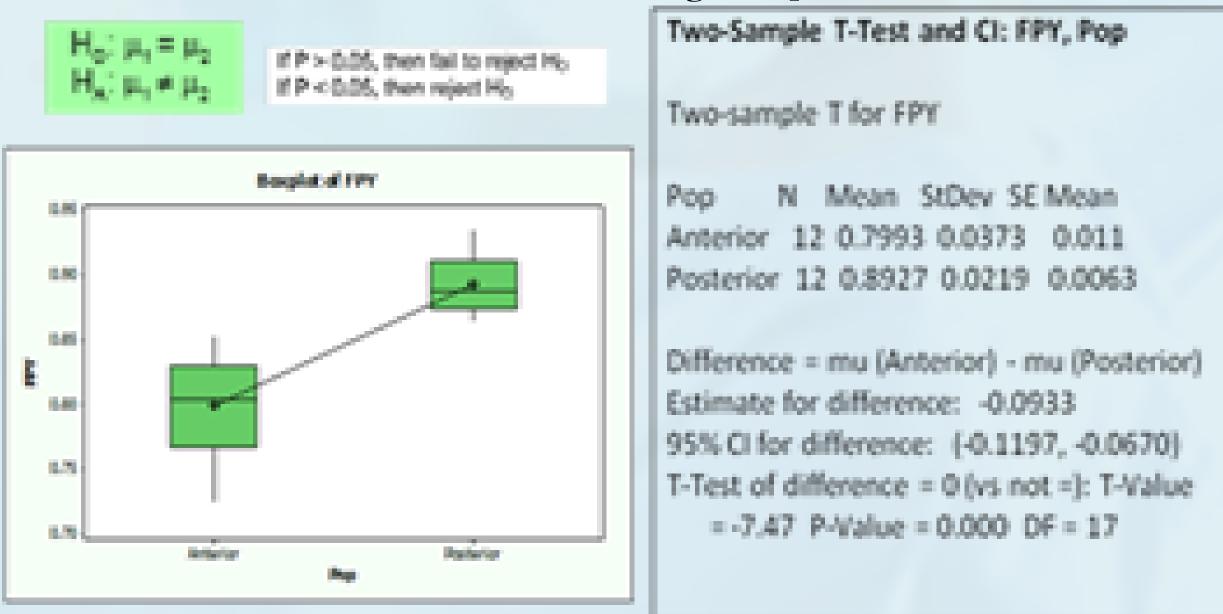
From the results obtained in the analysis phase it was determined to increase Nitrogen flow and change gas distribution in the chamber and stopped using Triangle Rib Seal.

Control Phase:

In this phase of the project it was necessary to establish the following controls to perpetuate the improvements in the process. It was specified a RH% level for the nitrogen chamber in the manufacturing procedure. In addition RH% sensors, with an alarm, were installed in the chamber in order to monitor humidity at all times. RH% sensors were installed in Ni Chamber, connected to the Paperless Chart Recorder to monitor RH% continuously. There is an audible alarm for RH>20% for more than 20 minutes.

Conclusion

This project validated the use of the DMAIC methodology to increase the First Pass Yield (FPY) in a dedicated cell of a medical device industry. The DMAIC methodology brings a structure for the improvement process. The results obtained are show in the following comparison of the FPY.



This Box plot shows populations evaluated before and after implementation. Effects are notable. Since the P-value is less than 0.05 there is a significant difference between populations prior and after this project. (Reject Ho). The goal to improve the First pass yield (FPY) using the DMAIC methodology was achieved successfully, based on the results.

Bibliography

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Figure 13 **Box Plot**