# *First Pass Yield Improvement on Casting Cell Using DMAIC Methodology*

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***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.*

***Key Terms*** *— Define, Measure, Analyze, Improve, Control (DMAIC), Design of Experiment (DOE), First Pass Yield (FPY).*

## 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 OBJECTIVES

This project aims to achieve an increase and at maintain the casting manufacturing cell first pass yield at 86% by 3rd Quarter 2019. This will reduce the reworks and maintain a properly flow rate.

## RESEARCH CONTRIBUTIONS

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. The process flow will be continuous and linear. With less rework the cost associated to over time and the cost of materials can be reduced. This represents approximately $100,000 yearly.

## LITERATURE REVIEW

An implantable pacemaker monitors the heart's rhythm and provides electrical stimulation when the heart does not bet or beats too slowly. The pacemaker is designed for patients who have an abnormal heart rate [1].

Current device consists of a titanium body and epoxy head, as shown in Figure 1. Internally the titanium case encloses the chip containing the program also contains the battery. The header is an epoxy casting which encloses the electrode connectors. The casting header process consists in dispensing the epoxy inside a mold with the connector attached to the pacemaker.


**Figure 1**
**Typical pacemaker**

### General Concepts of 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 [2]. The term DMAIC stands for the five main steps in the process: Define, Measure, Analyze, Improve and Control.

- Define: Define the problem, the process, and the project goals. In Six Sigma it is imperative that the problem is specifically defined. The problem should be clearly established in quantitative terms.
- Measure: Measure and collect data that will determine the factors that have influence over the outcome of the process or procedure.
- Analyze: The data is analyzed using statistical tools to assess whether the problem is real (and solvable) or random, which makes it unsolvable within the Six Sigma framework.
- Improve: If the problem is real, the Six Sigma team identifies solutions to improve the process based on the data analysis.
- Control: Control planning, including data collection and control mechanisms, is required to ensure that the solutions are sustainable and deliver peak performance. It also ensures that early deviations from the target do not materialize into process defects.

## PROJECT METHODOLOGY

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

At the Define steps the following tools were used:

- Project Charter, which is a statement of the scope, objectives and participants in a project. It provides a preliminary delineation of roles and responsibilities.
- Gantt Chart, which is a type of bar chart that illustrates a project schedule. Gantt charts illustrate the start and finish dates of the terminal elements and summary elements of a project.
- Voice of the Customer (VOC), which is a market research technique that produces a detailed set of customer wants and needs [3].
- SIPOC, which is a tool that summarizes the inputs and outputs of one or more processes. The acronym SIPOC stands for Suppliers, Inputs, Process, Outputs, and Customers [4].

At the Measure steps the following tools were used:

- Pareto, also known as the 80–20 rule, the law of the vital few, and the principle of factor sparsity. It states that, for many events, roughly 80% of the effects come from 20% of the causes.
- Control Charts, also known as Shewhart charts or process-behavior charts, in statistical process control are tools used to determine if a manufacturing or business process is in a state of statistical control.

## RESULTS AND DISCUSSION

The results obtained through the five phases of the DMAIC methodology.

### Define

As part of this Define phase the VOC tool was performed in order to determine what the customer wants and needs. From the VOC it was noted that the greatest concern was to reduce the bubbles at the casting header of the device. Using a SIPOC diagram it was determined that the areas to be focus will be the Inputs (Material, Labor, Equipment and environment) the process to be studied will be Epoxy Dispenser, bubble removal and epoxy cure and mold breakdown.

### Measure

Every part rejected is documented at the disposition area of the traveler and then entered into the database. All data was validated by the project leader to assure accuracy of the data entry process.

Figure 2 shows the first pass yield reported for the Casting header Cell. It is observed that the FPY (First Pass Yield) decrease for the casting header cell.

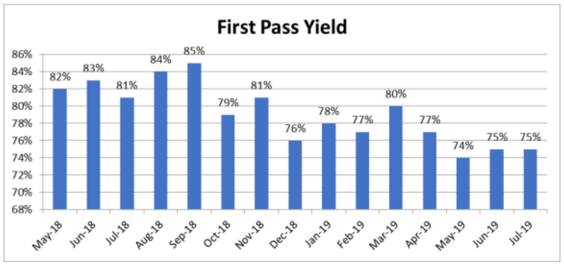


**Figure 2**
**First Pass Yield Trend**

From the Figure 3, which represents the top offender in a pareto graph, it was observed that the top offender in the casting header cell is the bubble in the casting header.

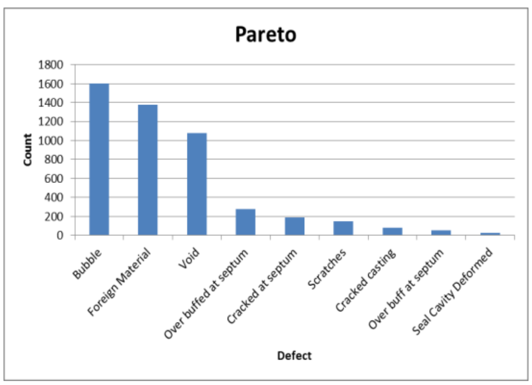


**Figure 3**
**Pareto Diagram**

## Analysis

The Analysis of the data collected shows that the Bubbles are the major offender in the data set. The major effects occur within the bubbles removal and curing cycle. Temperature and humidity greatly affect the curing cycle of the epoxy resin mix in terms of bubbles, as shown in Figure 4.

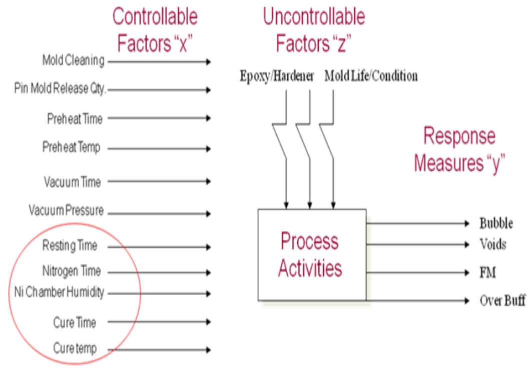


**Figure 4**
**Factors and Response**

Bubbles are seen after the Nitrogen Cure stage, where they cannot be extracted. Therefore, casting bubbles will be defined as follows:

- Type 1: The bubbles that come from the Mixer when epoxy is poured into the molds, which are removed at Bubbles Verification.
- Type 2: The bubbles that come out at the beginning of the Casting curing process; specifically, at the Nitrogen cure stage. These bubbles are always seen at Zones 03 and 10 (refer to Figure 5 for zone locations).


**Figure 5**
**Pacer Zones**

Since the major offenders are there on Manufacturing Travelers data ***Type 2 bubbles***, (at Zones 03 & 10). The major offenders based the project target will be focused in reducing the ***Type 2 bubbles.*** In order to reduce the incidence of the type 2 bubbles, Figure 6 was generated to determine the potential contributors. It was determined that the most potential contributors for bubble at casting header type 2 are the seals, Nitrogen Chamber and Relative humidity percent (RH%).

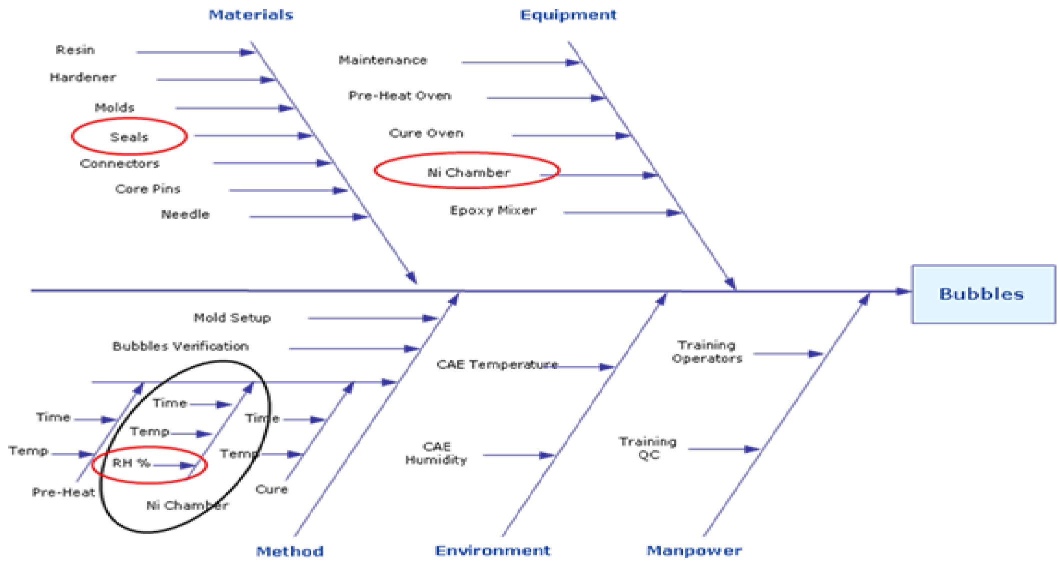


**Figure 6**
**Fish Bone Diagram or Cause and effect Diagram**

In the seals, the air is concentrated in certain areas and can create bubbles during the curing process as shown in see Figure 7.

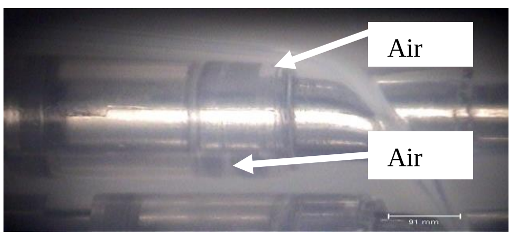


**Figure 7**
**Air Location**

The following seals were analyzed: Seal with triangle rib and rounded rib (see Figure 8). Air can be seen between triangle ribs when they are installed at Molds Setup. Rounded (optional) configurations does a better seal than the Triangle (Regular) configuration.

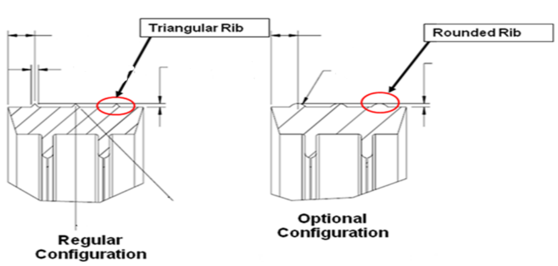


**Figure 8**
**Seal Configurations**

In order to determine which is the major contributor for the bubble creation, a Design of Experiments (DOE) tool was used. An experiment was performed with a total of 96 Pacers (Qty 24 per Run), which were processed through the entire Casting Process. The experiment tested both the seal configuration and the Relative Humidity (RH) effect for bubbles, as shown in Figure 9.

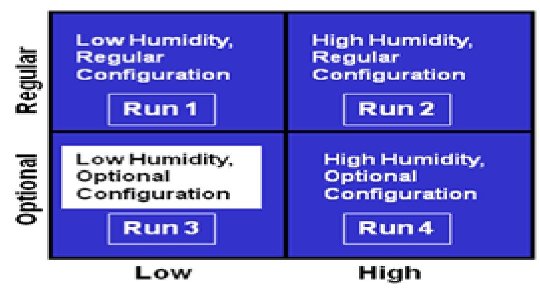


**Figure 9**
**Experiment Diagram**

Run 1 shows that at Low RH and Regular Configuration Seals only a 5% of the units had bubbles. That confirms the effect of RH on bubbles. The worst results were seen at Run 2 at High RH and Regular Configuration Seals. That confirms the effect of both factors on bubbles. Run 4 shows 100% Yield at high humidity. However, Run 1 and 2 strongly demonstrates the effect of humidity when Regular configuration seals are used. For this reason, this combination is not recommended. Based on these results optional Configuration Seals and Low RH condition (Run #3) was recommended to be used for manufacture.

The 5 Why's tool is used as additional tool to determine the root cause for the bubble in the casting header.

- Why so many bubbles in the epoxy? Because it exposed to humidity for too long.
- Why it is exposed to humidity? Because RH in Nitrogen Chamber was high.
- Why RH was high? Because RH is not measured/monitored inside chamber.
- Why RH is not Measured/Monitored? Because is not required in the process.
- Why is not required in the process? Because it was validated that way.

### Improvement

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.

A Nitrogen box was built for the Bubbles verification ramp, on which the pacers rest for approximately 20 minutes, exposed to room conditions (55% to 67% RH), when they are being worked at bubbles verification.

One flow meter was installed per Cavity and was installed in the Nitrogen Chamber and set at 50+/-10 SCFH.

### Control

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 shown in comparison of the FPY presented in Figure 10. 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).

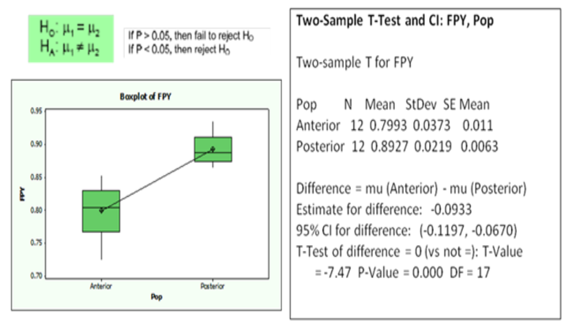


**Figure 20**
**Box Plot**

The goal to improve the First pass yield (FPY) using the DMAIC methodology was achieved successfully, based on the results.

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