Neuromodulator Device Scrap Reduction Using DMAIC Methodology

Author: Ismael S. Fuentes Cruz
Advisor: Carlos González, Ph D.
Department: Manufacturing Engineering Management

Abstract

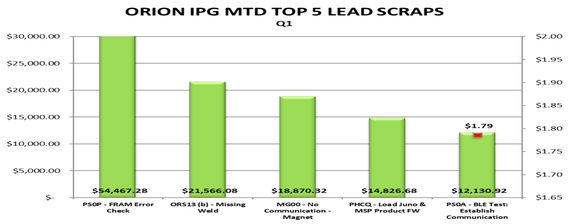
Abstract — This research project was focused in the Scrap reduction in a final electrical test area of a medical device company. In order to reduce the Scrap, the DMAIC methodology was used. The term DMAIC stands for the five main steps in the process: Define, Measure, Analyze, Improve and Control. This research seeks to reduce the Scrap on this manufacturing area where the neuromodulator device is finally verified electrically. This is important for the process because it will reduce unnecessary Scrap related to this false failure. DMAIC methodology brings a structure and the tool to identify and solve the problem. In this case, reduce the Scrap in a medical device company.

Introduction

The cell dedicated to testing and verified of the neuromodulator has had an increase in FRAM failures at Post Sterile test area. This electrical failure is the top offender at this cell since the beginning of this product line in February 2018. With the reduction of this defect, a significant Scrap reduction can be achieved [2]. The goal is to reduce and maintain Post Sterile false failures per FRAM test code. In order of achieve this goal the purpose is to use the DMAIC project methodology.

Background

A SCS (Spinal Cord Stimulation) neuromodulator device failed due to FRAM Error code at Post Sterile Automated Test level at final pack area. It was no represented by significant FPY decrease (less than 1%) but a high cost (material, labor & overhead) was already injected to this manufacturing process. This area was close to 99.2% for 2018 an less than 1% (.876% of RR) was related to this failure condition on 2018. For Q1 2019 the process presented approximately $55,000 of Scrap related to this condition.



FRAM (Ferroelectric Random Access Memory) is a non-volatile memory embedded in the hybrid (board) that can hold data even is power off. This memory is not affected by a magnetic fields as there is not ferrous material (iron) in the chip and offer the same functionality as a flash memory. This failure condition was the 1st top offender for Scrap metric during Q1 2019 as same of total 2018. Communication with R&D global started on 2018 but the project was not taken under priorities as a low risk due to process capability capture. Data was obtained and transform in dollars per unit in order to prioritize project as a cost saving project for 2019.

Problem

This research is about reducing the Scrap at the manufacturing area where the neuromodulator is finally tested. Is important to the process to reduce Scrap and the negative impact on product released. This project aims to achieve a reduce Scrap at maintain the Post Sterile manufacturing area by 15% of Scrap reduction at this cell. This will reduce the Post Sterile false failures, cycle time, scrap and maintain a properly flow rate without impacting monthly demand commitment.

Methodology

In order to achieve the goal of reduce Scrap at Post Sterile test area related to FRAM failures, the DMAIC tools project methodology was used.

At the **Define** steps, the following tools used are:

Project Charter: is a statement of the scope, objectives and participants in a project. It provides a preliminary delineation of roles and responsibilities, outlines the project objectives, identifies the main stakeholders, and defines the authority of the project manager. It serves as a reference of authority for the future of the project.

Table 1
Project Charter

Problem Statement:	An increase in FRAM failures at Post Sterile test area affected significantly scrap goal and negatively impacting the UPL.
Goal:	Reduce FRAM failures with a final Scrap reduction of 15% by 31 Dec 2019.
Metric definition:	Scrap Reduction

Voice of the Customer (VOC): is a market research technique that produces a detailed set of customer wants and needs, organized into a hierarchical structure, and then prioritized in terms of relative importance and satisfaction with current alternatives.

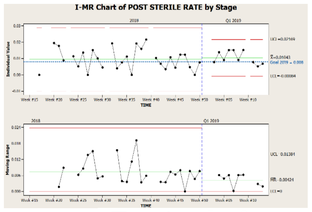
Table 2
Voice of Customer (VOC)

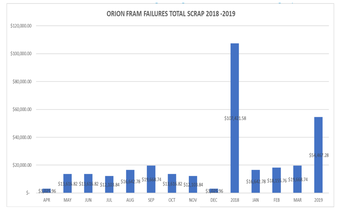
Key Customer	• Operation Manager • Supervisor
Approach	• Research possible root causes per PFMECA. • Observed similar failures with approved reworks on Post Sterilization areas on other devices product lines. • Speak to process owners and developers' experts to obtain their recommendation on areas to focus. • Based on the PFMECA, other similar failures on different devices areas, their recommendations devices were analyzed and documented. • Revise the defects data daily. • Involve operators, technicians, and supervisors. • Share data with the team. • Gather feedback for evaluation. • Evaluate if improvements have impact on metrics.
Customer Concerns	• Finances • False Failure Scrap • Daily Output
Boundaries (in scope vs out of scope):	• Project will be focused in Scrap reduction.

At the **Measure** steps, the following tools used are:

Control Charts: also known as P-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. Other tools could be used during the measure step.

The following P-Chart shows the first pass yield reported for the Post Sterile Test Area since 2018 and the bar second chart show the monthly scrap per this failure mode since 2018.





For Analysis:

- 32 devices that failed due to FRAM ERROR were verified.
- Image were performed using Image Analyzer tool.
- Image provide exact date and time when the error occurred.
- After firmware was downloaded the error appears.
- Firmware was downloaded at Post Header electrical test level.
- Suspected operations that were analyzed as part of PR analysis in order to find a high failure rate trend are:
- Immediately after Post Header Test
- Sterile Tray Seal
- Sterilization Process

For the following steps (**Analysis, Improvement, and Control**) tools to be used were determined during the project process according the previous steps results.

Results and Discussion

At the **Analyze** steps, was noted that the greatest concern was to confirm that a high percentage of FRAM failures were false failures. The areas to be focus will not be the previous provided areas, process induced was not confirmed. Device memory errors or software soft errors will be verified. The following steps were performed to determine if the units can reload the firmware and then pass Post Sterile Test successfully and continuously.

ATE PR Analysis – 32 Samples Experiment

Next Steps
- 32 scraped units were segregated for evaluation
- DWLD TCC was performed to each unit
  - 2 units were unable to DWLD TCC (Err -8003)
- Post Header Test was performed on November 2018 to each unit
  - 29 units pass firmware reload successfully
  - 1 failed Load Product FW
- Post Sterile Test was performed on November 2018 to each unit
  - 28 units pass successfully
  - 1 unit failed per FRAM Err

Next Steps:
- Device Image was performed on December 2018 to each unit
  - 28 units pass successfully
- Device Image was performed on January 2019 to each unit
  - 28 units pass successfully

ATE PR Analysis – 32 Samples Experiment

Final Summary
- In summary the obtained results are:
  - *87.5 % confirmed good devices (False Failure)*
  - 6.3 % failed unable to DWLD TCC not open Physical Chanel
  - 3.1 % failed Post Header Test unable to Load Product FW
  - 3.1 % failed Post Sterile Test after firmware was re-downloaded (FRAM Err)

Final Summary
- A total of 71 devices failed per this condition during 2018
- A total of $107,421.58 was launched in Arecibo during 2018 per FRAM failure mode
- Rejection Rate of .876 % was obtained during 2018 per this condition (71 Device Failed/8105 Manufacturing Units)
- Experiment can't confirmed a process induced error

In addition:
- A total of 200 devices failed per this condition during 2018 at Plano, Texas
- A total of $302,596.00 was launched in Plano during 2018 per FRAM failure mode.

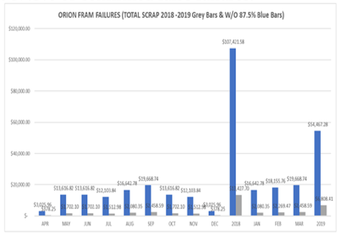
ATE PR Analysis – 32 Samples Experiment

What we need to do?
- Concentrate efforts on the 87.5% of false failures.
- Dedicate a team to confirm a soft error on test software and corrected.
- Validate a test retest for this particular failures if necessary.

What can we get?
- 87.5% of savings on this particular failure mode
  - In comparison with 2018
    - $93,993.88 (Arecibo, PR)
    - $264,771.5 (Plano, TX)
  - In comparison with Q1 2019
    - $47,658.87

$235,646.63
in savings for Arecibo for the last 1.5 years

Next figure show the expected Scrap costs improvement due to FRAM failures without 87.5% of confirmed false failures.

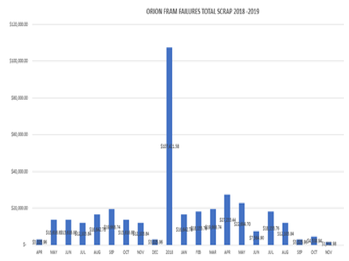


Expected Scrap Costs Improvement

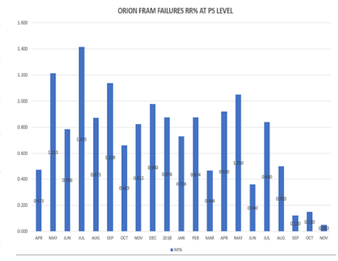
At the **Improve** steps, from the results obtained in the analysis phase, it was determined to update the Post Header test software, which is the one that load the firmware per device model previous the device was tested at Post Sterile Test area. Most of the FRAM errors detected at Orion Post-Sterile test system are one SED (Single Error Detection) or DED (Double Error Detection) FRAM error. The FRAM error appears to occur within 24 hours after initial installation of production firmware at Post-Header. Analysis of test data for all the failed devices didn't show any correlation to the JUNO IC manufacturer lot, manufacturing location or manufacturing period. Analyzing test data and test logs resulted in finding that at least 2 Clear FRAM functions at Orion Post-Header test system resulted in a FRAM error failure rate decreasing from 0.809% to 0.0146%. This Juno IC issue is documented in Unity00095328 SWR that FRAM errors are avoided by writing data twice to FRAM. In summary, now at this test level, the test station should be able to load firmware, verify memory errors, and correct, if it's necessary, previous sterilization and Post Sterile Test. This second Clear FRAM verification was implemented under software code resulting in satisfactory yield improvement; therefore, a significant Scrap reduction. All steps performed for the validation of this software change were documented under Engineering Test Report 90511139.

Conclusions

The DMAIC methodology brings a structure for the improvement process. The results obtained are show in the following comparison of the Scrap reduction and FPY behavior.



Improvement was implemented on 02 Sep 2019



Rejection Rate favorability after September 2019

These graphs show populations evaluated before and after implementation. Effects are notable. Since the savings for the past three months, in comparison with the beginning of the year, are close to $40,000 per month; so, there is a significant difference between populations prior and after this project.

Prior Improvement
Jan 2019 – Aug 2019 = $357,063.08
Average per month = $44,632.89

After Improvement
Sep 2019 – Nov 2019 = $9,077.88
Average per month = $3,025.96

Based on the results, the goal to reduce Scrap by a 15% using the DMAIC methodology was achieved and exceed successfully the expected output.

Future Work

At the **Control** steps, it was necessary to establish the following controls to perpetuate the improvements in the process. It was specified a new software change (90362743 Rev B), was updated at 5 Post Header Test Stations and documented under an Unscheduled Work Order. In addition, process monitoring in a weekly basis is still in place to monitor Post Sterile Test area behavior.

Acknowledgements

The main group of persons that represent a critical support during this project are:

- R&D Team – Direct support and qualifiers
- Carlos González, Ph D. – Advisor
- Dra. Denise M. Cobián - Reviewer

References

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[2] J. M. Juran and J. Defeo, *Juran's Quality Handbook: The Complete Guide to Performance Excellence*, 6th ed., McGraw-Hill, New York, NY, 2010, Section 8, 9 & 13.

[3] J. P. Womack and D. T. Jones, *Lean Thinking Banish Waste and Create Wealth in Your Corporation*, Free Press, City, New York, NY, 2003, Chapters 1-2.