1x16 Post Weld Continuity

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Abstract

Laser welding is a critical process of medical device used for the manufacturing process of spinal cord stimulation leads that brings different offenders. The highest for 1x16 family is continuity failure with 4% of rejection rate. It intended to improve the process with a new post weld continuity as an early detection point to avoid scrap and recover the unit as RWK. Improvement consists to change the manual inspection for an automatic that allows to maximize the inspection time with an improvement of 68 seconds. Benefits from improvements include product output, yield, less scrap, process performance and financial area. Process performance is evaluated by the technique of the operator with the automatic check through unit position, time and correct inspection order. A P-chart results demonstrate the improve and control in continuity with a rejection rate of 3.6%. The welding process will continue to be evaluated to reducing the % rejection.

Introduction

This project will evaluated the improvement of the implementation of a new automatic post weld continuity for the laser weld process to mitigate continuity failures issue in 1x16 product. The current process use a manual post weld continuity which influences more inspection time with 2 minutes per unit. The new automatic post weld allows to maximize the inspection time with an improvement of 68 seconds per unit.

Laser Weld Current Process	Laser Weld Improvement
Optional manual post weld continuity inspection (2 minutes per unit)	Semi-automatic post weld continuity inspection (52 seconds per unit)

Background

Laser welding process is one of the most important and critical task for a medical device product. Successful manufacturing of medical devices requires an in-depth understanding of the weld process, a highly stable laser source, and, most importantly, an integrated solution that incorporates the laser, software, motion, vision, and tooling with a proven weld process. In the company, it is using a continuity test at the last inspection point to detect any failure on the units before they pass through the sterilization and packing area. At the beginning of the assembly process, in the laser weld workstation, the product builder has an optional manual continuity check to an early inspection. The automation is one of the three ways that provide an improvement in the process, product, quality and time of production, but also gives for medical devices a simple testing. The goal is to change the optional manual check to a semi-automatic post weld check to simplify the testing and to maximize the time of inspection. Otherwise, it would act like an early point of inspection to decrease or avoid the scrap and reworked the units. The rework of "Remove and Replace Components" is one of the dispositions that allows a recovery of the product to continue its assembly process.

Problem

The research evaluation and the implementation contributed in an improve 1.0% rejection rate on the scrap due to continuity failures. Attack the defect before the unit continues to increase in cost per component and process, it was achieved successfully. The units detected and reworked on the post weld check contributed an scrap avoidance of $44k. The improvement was obtain through $73.64 per unit reworked versus $262.84 per unit discarded. In addition, the improvement on laser welding process contribute in a reduction on inspection time by changing the manual method to a semi-automatic with 68 second of cycle time reduction.

Methodology

The DMAIC methodology tools and was used and implemented on each phase, to define the problem, measure the data, analyze the possible causes, identify the root cause and possible solution to obtained results through the research. To define phase, it was implemented an Is/Is not tool. As show table 1, is the results of a kaizen where the problem of continuity failures was defined only in 1x16 product.

Define Phase:	Continuity Failures Units	
Is-Is not	Is (Observation)	Is not (Comparison)
What is the product?	Infinition 1x16 both 50cm and 70 cm	Not seen on any other product lines or sites to date.
What is the defect?	Increase on scrap units with continuity failures	Same defect on all rejected units
Who is affected?	Laser weld operation and product overall	Not a manufacturability issue with previous operation
Where on the product?	Predominantly on distal side	Not seen on proximal side
Where in the process?	Not precise	An specify manufacturing process
When? (the first seen?)	The highest increase in defects was in 2019-2020	Avicenna laser ablated tubing used
What is the pattern over time?	On average, 10 NC's daily for continuity failure.	Not seen on other product
How much?	From 01/21 to 08/21, a total of 861 units on scrap.	Not all containers have defective issue

Table 1: Is/Is not technique, Boston Scientific Dorado PR

To measure the data, a P-chart was created to analyzes the proportion of non-compliant items in a produced batch and presents the current rejection rate for continuity failures of the 1x16 product. As show figure 1, there is the tendency of the continuity failures units' data since January 2020 to August 2021 with a rejection rate of 3.8%.

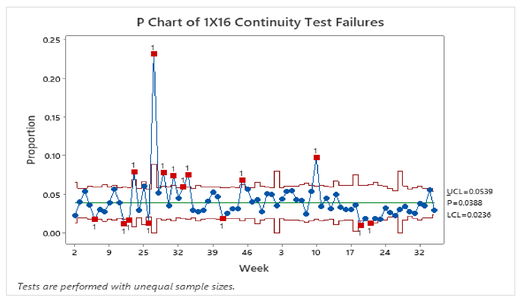

Figure 1: P Chart of 1x16 Continuity Test Failures of January 2020 to August 2021

Analyzing the possible causes, it was evaluated the man-workmanship and measurement sections of a fishbone diagram created. As shows the table 2, in man-workmanship would be evaluated the operators techniques with the manual and semi-automatic post continuity check. In measurement, would be evaluated the consistency on performance after welding with the semi-automated tooling implemented. All of this to obtain an improvement in scrap avoidance, rejection rate and financial area as show the table 3.

Fishbone Section	Action	How
Man-Workmanship	Evaluate operator techniques	Manual vs Semi-automatic continuity check
Measurement	Consistency performance after welding	Semi-automated tooling implementation

Table 2: Improvement Strategy, test study with action items for Fishbone causes

Future Improvement of September to December 2021		
Real number of completions	13,795	
Improvement (I=completions* % units improvement)	137.95	
Expected scrap units annual (ES= Sum of units of annual improvement	373.31	
Annual cost on scrap avoidance (AC= ES*total cost of rework)	$ 70,630.25	
Expected improvement in cost of Sep to Dec (EI= I*total cost of rework)	$ 26,100.14	

Table 3: Table 6: Future Improvement expected from September to December 2021

Results and Discussion

- Implementing the semi-automatic 1x16 Post Weld Continuity brings excelents results.
- The operator technique using the post weld after completed the laser weld impact positively in the process improvement.
- As figure 2 presents, the rejection rate for the month of September decrease for 3.7% as rejection rate. For the unit detected in the post weld.

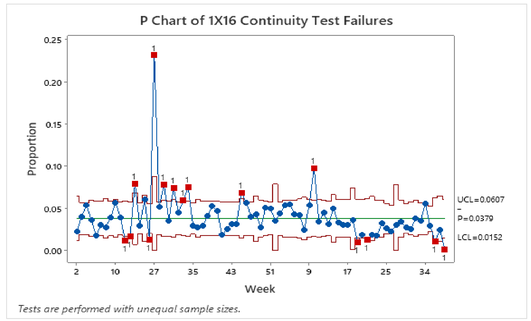

Figure 2: P- Chart 1x16 Continuity Test Failures of September 2021

- As the figure 3 presents, the rejection rate for the first 2 weeks of October month, the P-value decrease 3.6% as rejection rate. For the units detected in the post weld.

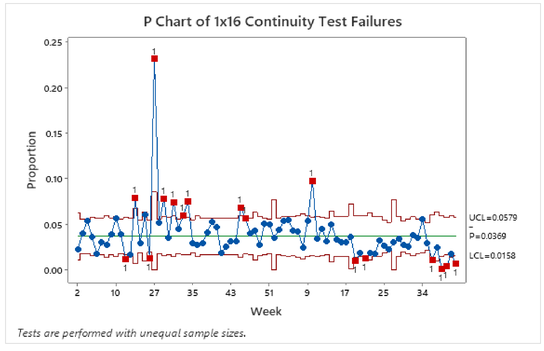

Figure 3: P Chart of 1x16 Continuity Test Failures of October 2021

- As a process monitoring, the implementation of the semi-automatic post weld in figure 4, will continue evaluating by different "tools" of control.

Figure 4: Semi-automatic 1x16 Post Weld Continuity

- The time-based log, where pull test that analyze that data of each operator is on target 0.50-0.80. As a result, the operators pull test was high than 1.00, this represent a strong weld.
- The compression tool system, a complement of the semi-automatic post weld, to the improve of the continuity failures rejection and help each operator in the cable alignment, compression, and welding process. As a result,

Conclusions

- The automatic 1x16 Post Weld Continuity proved that is capable of successfully early detection point for continuity failure.
- This project contributes as a process improvement to the quality of our products and the process development and the objectives was achieved through the DMAIC methodology.
- The findings in the process was the operator feedback in the technique on performing the post weld to optimize time, the rework process of the units detected to control cycle time of unit and process, and an updated in the manufacturing instruction with the post weld performance.
- The contributions of this project to an improvement on product and process was achieved successfully. The last rejection rate was 4% of the manufacturing process but, currently the rejection rate is 3.6%, close to the expected %. The reduction of continuity failure defects decreased from 10 units daily to approximately 3-4 units daily, less failure and more recovered. Finally, the money saved through the rework process and less scrap units. The actual improvement is more than $30k with the new implementation that is expected that it will be more with the passing of time.

Future Work

The failed continuity defect is one of the most evaluated in the Neuromodulation, specifically with 1x16 family. Two systematic studies that was identify as a possible project for the continuous improvement.

- The standardization on the pull test as a process monitoring is the first research. Currently, there is a pull tester machine to perform this step before and after the process of laser welding. A new standardization that provides a new machine or a new process in the manufacturing instruction brings a better opportunity of improve and avoid the variation on each operator performance.
- Finally, a new laser welds technology as the other research. Currently the laser weld is a manual process perform through a lamp laser machine. A new brand technology, it would be the most favorable for a complete improvement in the process. This laser weld technology can be changed from manual to automatic with a structure and stablished parameters for a secure implementation.

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