Laser Weld Technology and Compression Tool improvement to increase capability and prevent continuity failures

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Abstract

Laser beam welding is a non-contact, high power density welding process which uses the energy emanating from a laser beam to join materials together. Benefits of continuous laser beam welding include a deep weld penetration that can be closely controlled by engineers. Additionally, laser beam welding has a high feed rate making it more cost efficient. Conducting this weld process correctly is key for the appropriate performance of medical devices to prevent malfunctions such as continuity failures. This project is focused on reducing data variation by standardizing compression technique when performing the weld process with a compression tool fixture so the data can fit on a normal distribution and a process capability can be runed to understand the actual process capability. Benefits from this improvement can be the mitigation of continuity failures, blown welds and ergonomic issues. A DMAIC methodology was applied in this project to implement actions for improvement.

Introduction

This project is about understanding the capability of the laser weld process of the manufacturing line 1x16 at the Neuromodulation division and understanding root cause for continuity failures defects. To understand process capability a capability sixpack analysis was performed but it was found that the data does not fit in any distribution of the capability sixpack analysis. To be able to identify improvements that can result in a reduction of process variation and to identify root cause related to continuity failures a problem-solving fishbone diagram was created. From the variables identify in the fishbone diagram, this research will focus on two of them, man/workmanship and machine. This is a manual process where the correct manipulation of the leads is critical for the process to run effectively. For this reason, an assessment of operator's technique vs work instruction was executed to verify if the operation was performed correctly and understand how much variation between operator's technique could be found.

Background

Successful manufacturing of medical devices requires an in-depth understanding of the laser 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. Studies show that fiber laser welders offer true welding consistency at all power levels, across all pulse sequences and during the entire lifetime of the laser. The laser parameters remain predictable and consistent. The reason for this is that the generation and transport of the laser beam to the workpiece takes place entirely within the confines of a single mode fiber. The beam shaping provided by this fiber neither degrades over time nor changes with laser power - this also makes the laser physically robust and stable, thus suitable for the most challenging of industrial environments. Additional advantages of fiber laser welders are the small spot size and high beam quality that translate to high irradiance at the focal plane. Workstations equipped with fiber laser welders can produce better results at lower power levels. High quality, precision laser welding can be performed extremely close (0.1mm) to the most complicated and intricate component parts.

Problem

The research that will be developed in this project is going to be related on analyzing the data results that will come out after the implementation of the fiber laser weld technology in combination with the installation of the compression tool to assess data results to confirm if there is a reduction in the number of rejected units for continuity failure defects and confirm if there is an increase in process capability and a reduction in process variation. The importance of this research is that it will provide information on how to find root causes for major offenders, action plan for mitigation, understand process capability to identify areas of improvements and standardization of key process steps to be in compliance with customer requirements by having a more reliable and stable laser weld process.

Methodology

This project was developed by implementing a DMAIC methodology to understand actual process capability, identify future process improvements and reduce or mitigate continuity failures through standardization of compression technique during the laser weld process.

DEFINE

Table 1: Is/Is Not

Initial Problem Statement		Continuity Failures
Team Members:	J. Boscana, J.Barrios, M. Ortega, H. Hernandez, E. Torres, W. Dominguez, E. Ocasio, H. Ramos	
Is/Is Not	Is (Observation)	Is Not (Comparison)
What is the product?	Infinion 1x16 Both 50cm and 70cm affected	Not seen on other product lines or sites to date
What is the defect?	Continuity Failures	Same defect on all rejected units.
Who is affected?	Laser Weld Operation	Is not a component issue
Where on the product?	Proximal and Distal side	No defects seen in any other side of the units
Where in the process?	Defect occurs during the laser weld process	Not caused down stream in the process
When was first seen?	Trend increase in defects started March 22, 2018	When more new operators started in this workstation
What is the pattern overtime?	On average, a minimun of 10 NC's daily for continuity failures	No history of continuity failures prior March 2018
How much?	03/17 up to 03/27, a total of 110 units amongst 75 containers	Not all containers have defective units

MEASURE

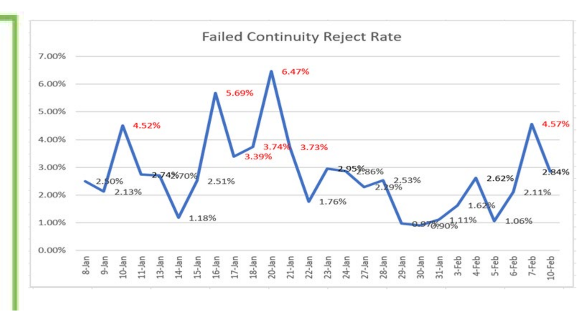

Figure 1: Failed Continuity Reject Rate

Table:2 Operator Capability Analysis Summary

Operator	Distribution Fit	P-Value	Ppk
Robert	Weibull	0.136	3.67
Melvin	Normal	0.43	1.76
Kevin	Weibull	0.374	0.72
Joshua	Normal	0.416	1.45
Jonathan	Normal	0.316	1.40
Heidy	Normal	0.067	1.38

ANALYZE

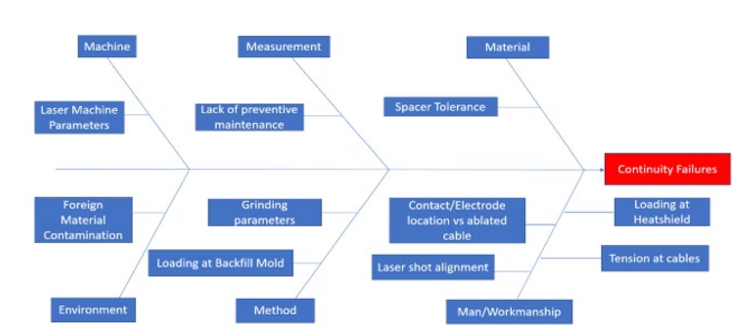

Figure 2: Fishbone Diagram

IMPROVE

Table 3: Test Study Action Items for Fishbone Causes

Fishbone Section	Action	How
Man	Evaluate operator techniques	Technique vs Work Instruction Assessment Re-Training
Method	Compression Technique Standardization	Semi-automated tooling implementation
Machine	Improve equipment technology	Upgrade to Fiber Laser technology

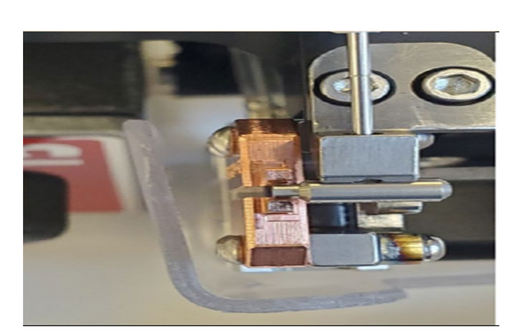

Figure 3: New Compression Tool

CONTROL

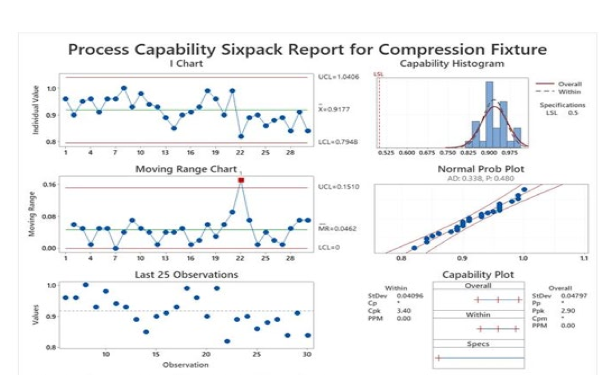

Figure 4: Capability Sixpack for Fiber Laser and Compression Tool

Results and Discussion

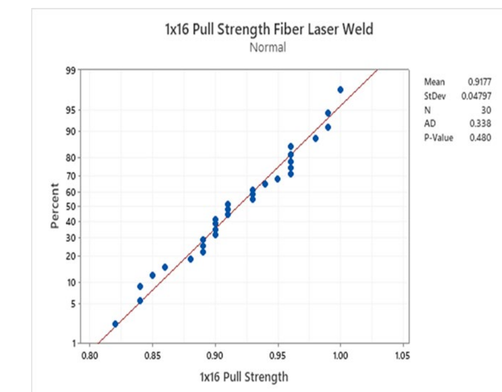

Figure 5: New Laser Process SWO Results Distribution

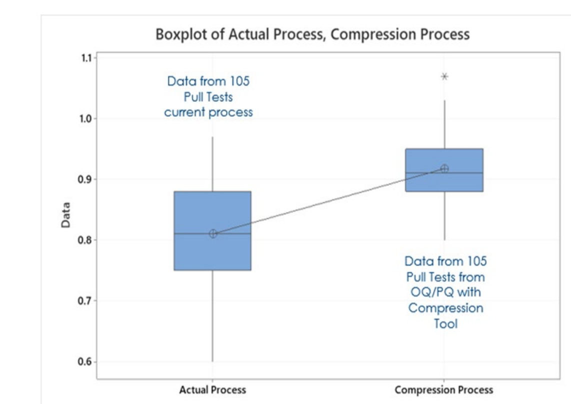

Figure 6: Boxplot of Actual Process, Compression Process

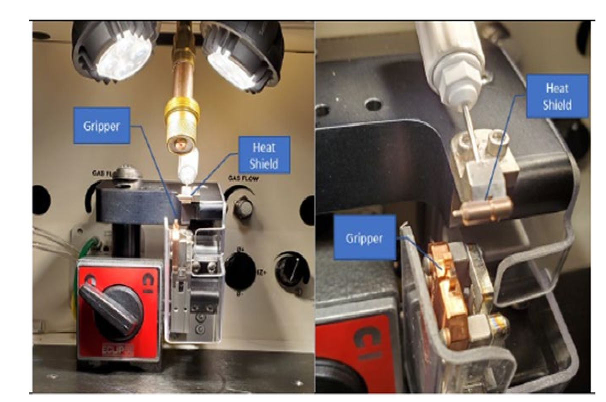

Figure 7: Compression Tool Assembly Parts

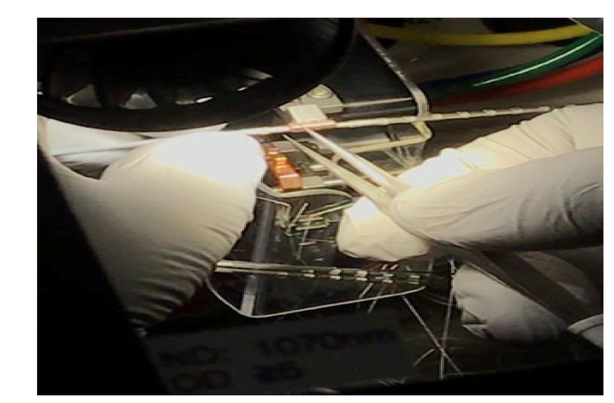

Figure 8: New Compression Tool being used by an operator

Figure 5 shows a capability sixpack analysis after the implementation of the fiber laser weld machine with the compression tool. This time the data was able to fit a normal distribution of the process overall without the need to filter the data by operator. This shows that the process capability has improved with a P-value of 0.480 and process variability has been reduced. This means that by eliminating the variation of how much compression is applied to the contacts and electrodes during the laser weld process and in combination with the implementation of the new fiber laser technology the overall process capability can be analyzed. This is confirmed with this process Ppk of 2.90 and with a standard deviation of 0.048. Figure 6 shows a boxplot analysis where it can be seen an improvement in the process as the range of pull strength data results is higher after the implementation of the compression tool meaning there is a stronger and better weld joint.

Conclusions

Based on the data collected from the new fiber laser weld machine with the compression tool and analyzing the data on a capability sixpack it can be concluded that the laser weld process has potential to have a higher and stabilized capability which allow the data to fit on a normal distribution with a P-value of 0.480 making this process more standardized and optimized. These two improvements have the potential to also help reduce continuity failures under the 2.5% reject rate target by allowing the process to produce stronger and high-quality weld joints which is critical to mitigate this defect. These two improvements also have the potential to reduce the variation of the process which will allow the data to fit on a normal distribution making possible to conduct a capability sixpack analysis of the process overall. The most important aspect of process capability studies is that this type of analysis allows to benchmark processes and measure how successful improvements have been over time and provide valuable information on how processes run within specifications.

Future Work

During this project, the pull test was one variable identified that is impacting the results of tensile strength. This opportunity was identified by the fact that operators don't have a standardized method to execute this test and for this reason each one of them perform the assembly of the components in the pull test fixture using different techniques which can be having an impact on the results. This can be one of the main drivers for the variation of the results on this test. For this reason, a standardized method will be implemented. Another variable that will be addressed in the future to increase weld quality and process capability is a change in laser technology from lamp to fiber laser.

Acknowledgements

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References

[1]C. Marley and G. Shannon, "Welding Medical Devices," Industrial Laser Solutions, 2004 [Online]. Available: https://ezproxy.pupr.edu:2408/ehost/pdfviewer/pdfviewer?vid=20&sid=ce25ca0c-7a04-4f76-997a-582f95aab494%40redis. [Accessed Jan 22, 2020].

[2] G. P. Kelkar, "Resistance and Laser Welding for Medical Devices," Medical Device and Diagnostic Industry, June 1, 2006 [Online]. Available: https://www.mddionline.com/news/resistance-and-laser-welding-medical-devices. [Accessed Jan 22, 2020].

[3] M. Rodighiero, "Advances in Laser Welding Systems," Medical Design Technology, vol. 10, no. 2, pp17-20, Feb 2006 [Online]. Available: https://ezproxy.pupr.edu:2408/ehost/pdfviewer/pdfviewer?vid=8&sid=ce25ca0c-7a04-4f76-997a-582f95aab494%40redis. [Accessed Jan 22, 2020].

[4] Boston Scientific, EP70717. Rev A.2 p. BSC Process Library, 2021.