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.*

Key Terms — *Continuity Failures, Laser Beam Welding, Medical Devices, Process Capability.*

PROBLEM STATEMENT

In the medical device industry manufacturing processes such as the laser weld process for spinal cord stimulation leads it is critical to understand it's capability and the different type of variables that can have a negative effect in yield percentage by triggering spikes of different types of failure modes which can be related to process, materials, or workmanship. In the case of this research, two issues will be addressed, and both are related to process. With the implementation of a new fiber laser weld technology in combination with the implementation of a compression tool fixture based on baseline data analysis that came out from a time-based log report after the buildup of special work orders units (SWO) it is expected to improve process capability and reduce continuity failure defects. The neuromodulation division at Boston Scientific, Dorado, is currently facing a challenge with the laser welding process where one of the major issues is related to a high variation in pull test data results which does not allow for the data to fit in any distribution of a capability sixpack analysis. The other issue is related to continuity failures in the spinal cord stimulation units. At the beginning of the problem solving, it was thought that this defect was only related to operator's technique but after a continuous analysis of the data through time it was found out that this not the only factor, there are also opportunities in the design of the laser welding machines that can be improved to make the process less dependent on operator's technique.

Research Description

This research 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 as shown in Figure 1. 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.

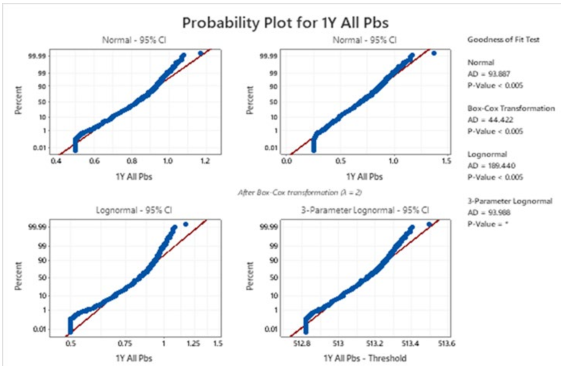

Figure 1

Data Distribution Fit 1

Research Objectives

The research that will be developed in this project will 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.

Research Contributions

The current yield of the manufacturing process is 91%; however, it is expected to increase it up to 95%. Moreover, reducing the continuity failure defects will also result in a higher quality product for the patients and could bring some financial benefits since less units are expected to be rejected due to this failure mode. It will also positively impact metrics like scrap, yield percentage, quality, and production output. As an added benefit, it will increase the process understanding and will allow to have a more robust and improved laser welding process and a better understanding of the capability of the laser weld machine. One of the possible benefits in metrics impacted that were previously mentioned could be an increased and stabilized yield percentage and process capability (Ppk) by the implementation of a new fiber laser weld technology in combination with the installation of a compression tool to mitigate continuity failure defects by reducing operator error and increase process understanding.

Literature Review

For organizations in the medical device industry to be able to gain customer loyalty it is vital to have a real focus in the implementation of process improvement in manufacturing processes especially the most critical. Laser welding is one of the manufacturing processes that is most important and critical due to its complexity and wide range of variables that can affect this process. 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. It is recommended to obtain all these resources from a single vendor [1]. Laser beam welding is a fusion process that can melt to metal parts by heating them with a laser. It can produce both spot and seam welds. The technique is usually used to join metals, but other materials, including plastic. In a laser weld, a beam is directed at the target material. Because the beam is amplified and focused, heat penetration is deep within a small heath affected zone, creating a high depth to width ratio for weld nugget. The depth of the weld can be controlled by varying the power output of the laser and adjusting the focal point of the beam. Laser welding offers several benefits in the manufacture of medical devices. Welds can be made with a high-level precision, allowing for the creation of even smaller devices. In contrast to resistance welding, which requires electrodes on each side of the weld, laser welds are done from one side. The ability to create the weld from a greater distance means a beam can perform a weld in a cramped space that other instruments would have difficulty reaching. Laser welding can also help facilitate repairs to small devices or components without the necessity of disassembling the device. Laser welding can be highly automated using robotic controllers, allowing many precision welds to be created quickly.

Laser welding uses a focused beam of laser light to melt and weld the two parts. Laser welding is a noncontact process and does not require any electrical connection to the part. A laser light source is monochromatic (single wavelength) and coherent (all rays are parallel). These properties allow the laser to be focused on a very small spot with sufficiently high energy density to melt metals. Laser energy is delivered in either pulsed or continuous mode. Continuous-mode welding is not common for medical devices [2]. During pulsed welding, the laser energy is delivered in a short, high-energy burst. Time scales are in milliseconds, and peak power is typically on the order of 3–5 kW. Pulses can be overlapped 80–95% to form a hermetic seal. Pulse welding is commonly used to seal titanium cans for implantable devices.

The laser source most used for pulsed welding is an Nd: YAG laser, which emits a near-infrared wavelength of 1.064 µm. Internal configurations of the lasers include flash lamp pumped rod lasers, disk lasers, and fiber lasers. Most metals that are not highly electrically conductive or reflective, such as titanium and stainless steels, absorb laser light reasonably well and therefore welding is not a problem. Welding alloys of copper, gold, silver, and platinum can be difficult for several reasons [3].

The alloys are reflective, so it is difficult to couple the laser energy into the material to initiate the weld. Even if the light is absorbed, the high thermal conductivity diffuses the heat pulse away from the weld zone. The laser pulse must be programmed carefully to produce coupling and avoid excessive melting. The typical welding sequence for laser spot welding is very similar to the resistance welding sequence. The parts must be brought together and held in place to ensure proper presentation to the laser energy, which is like the combination of force and squeeze time for resistance welding. The weld pulse can have an upslope, weld time, and a downslope for reasons like those for resistance welding. An upslope prevents excessive heating and expulsion; the downslope can be used to control the cooling rate of the weld metal. Lasers are usually programmed by sectors in a single pulse. Newer units can have up to 20 sectors and can effectively produce any pattern needed, including upslope and downslope. Pulsed lasers also offer the flexibility to reduce energy in a series of pulses toward the end of a seam weld to provide a gradual transition. Even after the laser energy is turned off, the parts must be held together during a hold time to avoid disturbing the weld as the fused metal cools and then solidifies.

Laser welding offers many choices for weld configurations but for the purpose of this literature review we are only going to compare lasers that uses flash lamps and lasers that uses fiber laser. Flash lamps are gas discharge lamps which are used for generating intense light pulses. This contrasts with arc lamps, which are designed to be operated continuously. The outer appearance of a flash lamp is often quite similar, but there can be differences, particularly concerning the metal electrodes. While arc lamps may have pointed cathodes, it is usually better to use rounded electrode shapes, using larger surface area for flash lamps which are operated with high peak currents. One tries to obtain a smooth distribution of the current, avoiding hot spots which might lead to blown welds. Also, it is necessary to use electrode seals which have a low enough electrical resistance to apply the high peak currents; that largely excludes the use of ribbon seals, for example. Rod seals are most common [3]. The glass envelope is often somewhat thicker for increased mechanical robustness. Most flash lamps are based on noble gases like xenon, krypton, or argon. Particularly xenon lamps are quite common as broadband emitters of white light. It is generally not feasible to use metals or other materials which would first have to be evaporated, since the drive pulses are too short for such processes; the pulse durations are usually well below one millisecond. Many flash lamps produce a substantial amount of ultraviolet light. That can be best utilized with a well UV-transmitting glass envelope, for example made of quartz. In other cases, UV generation is unwanted; that can be suppressed by using envelopes of doped glass, exhibiting increased UV absorption. There are some other types of flash lamps, not based on a gas discharge, but on some chemical reaction.

Fiber Laser Welding Systems are designed with the needs of the precision micro-welding and micro-cutting industry in mind, providing a level of accuracy and consistency previously unavailable. This is made possible due to the unique capabilities of the fiber laser engine, including sub 0.5% pulse-to-pulse energy variation, /-0.5% CW power stability over time, single-mode beam quality and focused spot sizes down to 10μm. These features, coupled with close-loop power feedback, pulse profiling, high energy efficiency and no optical parts to align or calibrate, make the Fiber Star laser welding system an attractive laser engine for practical shop floor environments. Fiber laser welding systems do not exhibit the shortcomings in output power, spot size and focal point variations caused by thermal effects on the glass rods of traditional Nd: YAG laser welders.

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. The focused beam of energy consistently affects a very small area of metal, providing the benefit of very little heat generated around the weld point. High quality, precision laser welding can be performed extremely close (0.1mm) to the most complicated and intricate component parts. Fiber laser welding system applications are not limited to just welding. Cutting of medical grade steels and wire end preparation for medical components are both effectively produced with the fiber welding systems. From an economics standpoint, the consistent and improved laser welding performance reduces scrap and generates faster production throughput, resulting in a lower cost of ownership and improved laser up-times. These financial and performance advantages mean that fiber laser technology is now frequently chosen as an upgrade over conventional flash-lamp pumped solid state lasers, or even DPSS laser technology in many other laser-based manufacturing segments. In addition, a small footprint and fast ROI open markets that were previously out of reach for some laser welding applications.

METHODOLOGY

DMAIC methodology is a process improvement strategy that is implemented by going through phases. This is a data driven quality system that in each of its phases uses a set of tools that are going to be applied depending on which phase is being implemented. To be able to make improvements in manufacturing processes especially in the medical device industry it is important to first understand what kind of problem it is tried to be solved so then it can be understood what type of methodology applies best to minimized it or to fix it. For this project the type of problem that it is going to be addressed is related to a process failure mode in the laser weld workstations at Boston Scientific Dorado. This issue in the laser weld process is continuity failures and the DMAIC methodology provide the right tools to mitigate it. To better understand the tools available in the DMAIC methodology and in what phase they could be used a tool matrix that display some of the tools that can be used in this type of methodology has been developed. The tools that are marked in blue shown on Figure 2 are the ones that will be used in the process of collecting the data required to find and mitigate the root cause related to continuity failures.

	DMAIC Phase				
Tool name	D	M	A	I	C
Voice of the customer	x				
Data Collection		x			
Brainstorming				x	
Afinity Diagram	x				
Process Map		x			
Design of experiment			x	x	
Fishbone Diagram			x		
Benchmarking				x	
Control Plan					x
Measurement System Analysis		x			
Hypotesis Testing			x		
Audit Plan					x
Prioritization Matrix				x	
Pareto Chart		x			
Plan-Do-Check-Act					x
Cause and efect matrix			x		
Improvement Strategy		x			
5 Why Analysis			x		
Is/Is Not	x				
Develop SOP					x

Figure 2

DMAIC Matrix

Define is the first phase of the DMAIC methodology where the problem is going to be define. The data collection tool that will be used for this phase is the Is/Is Not table as shown in table 1. Due to the fact of process capability issues that reflects low Ppk results and continuity failures it is important to use this practical tool that uses a table to document the conditions that do not exist when the problem occurs. The Is/Is Not tool ensures that the problem definition objectively describes what, who, where and when. This tool helps identify key differences between each Is and Is Not element.

Table 1

Is/Is Not Table

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

In the measure phase is where pull test data results are collected using a time-based log report to then export this data to a Minitab software to run a process capability sixpack to measure the performance of the laser weld machines in terms of Ppk results to be able to have a better understanding of the actual process capability performance. Right now, this data can only make a fit on a normal distribution if is analyzed by each operator performance. Also, in this phase a post weld continuity test is going to be conducted with a continuity test fixture as shown in figure 3 to understand if this failure mode is occurring during the laser weld process or in another workstation after laser welding.

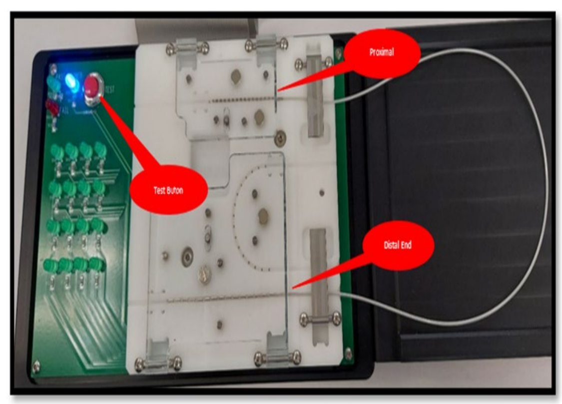

Figure 3

Continuity test fixture [4]

In the analyze phase a fishbone problem solving strategy has been implemented to be able to identify all the variables that can possibly be triggering the continuity failures. As shown in figure 4, some of the variables displayed in this diagram, specifically the ones that are related to workmanship are a representation of some opportunities for standardization improvements.

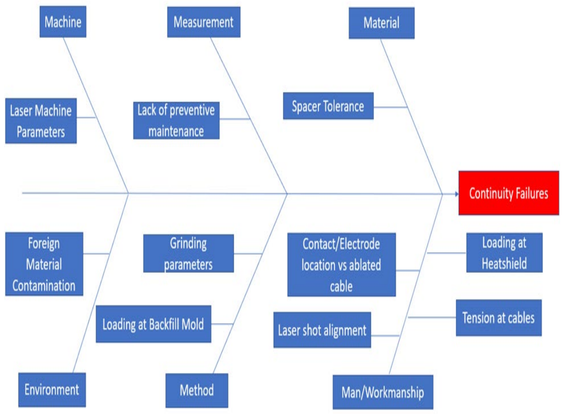

Figure 4
Fishbone Diagram

In the improve phase actions are going to be taken to address the root causes related to continuity failures with an execution date assigned to each action item to be able to track them overtime as shown in Table 2. In this phase is where the new fiber laser weld machine in combination with the compression tool fixture are going to be implemented.

Table 2
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

In the control phase process monitoring tools will be implemented. For this project three process monitoring tools will be used: as shown in figure 5, it can be seen a time- based log where pull test data is entered daily

twice a day (before and after the laser weld process is conducted) to then analyze this data on SPC charts.

Recorded Date & Time	Time Based Log Name	Time Based Log Revision	Time Based Log Description	Resource	Resource Description	Submitter ID	Submitter Full Name	Data Point Name
1/7/2020 4:19:58 PM	25069025 OPEN OPTEST (SCS)	A	OPEN - SCS Close/Open Outer Peel Test	25069025		grandev	Victor Javier Grandel	Parameters are out of Spec?
1/7/2020 4:19:58 PM	25069025 OPEN OPTEST (SCS)	A	OPEN - SCS Close/Open Outer Peel Test	25069025		grandev	Victor Javier Grandel	Peel Test Data is out of Spec?
1/7/2020 4:19:58 PM	25069025 OPEN OPTEST (SCS)	A	OPEN - SCS Close/Open Outer Peel Test	25069025		grandev	Victor Javier Grandel	SID Number
1/7/2020 4:20:40 PM	25069026 OPEN OPTEST (SCS)	A	OPEN - SCS Close/Open Outer Peel Test	25069026		grandev	Victor Javier Grandel	Parameters are out of Spec?
1/7/2020 4:20:40 PM	25069026 OPEN OPTEST (SCS)	A	OPEN - SCS Close/Open Outer Peel Test	25069026		grandev	Victor Javier Grandel	Peel Test Data is out of Spec?
1/7/2020 4:20:40 PM	25069026 OPEN OPTEST (SCS)	A	OPEN - SCS Close/Open Outer Peel Test	25069026		grandev	Victor Javier Grandel	SID Number
1/7/2020 4:33:43 PM	25069027 OPEN IPTEST (90603702)	A	OPEN - SCS Close/Open Inner Peel Test (90603702)	25069027		rosark2	Kelvis Joel Rosario	Parameters are out of Spec?
1/7/2020 4:33:43 PM	25069027 OPEN IPTEST (90603702)	A	OPEN - SCS Close/Open Inner Peel Test (90603702)	25069027		rosark2	Kelvis Joel Rosario	Peel Test Data is out of Spec?
1/7/2020 4:33:43 PM	25069027 OPEN IPTEST (90603702)	A	OPEN - SCS Close/Open Inner Peel Test (90603702)	25069027		rosark2	Kelvis Joel Rosario	SID Number
1/7/2020 5:04:06 PM	25069030 OPEN IPTEST (5063172)	A	OPEN - SCS Close/Open Inner Peel Test (5063172)	25069030		rosark2	Kelvis Joel Rosario	Parameters are out of Spec?
1/7/2020 5:04:06 PM	25069030 OPEN IPTEST (5063172)	A	OPEN - SCS Close/Open Inner Peel Test (5063172)	25069030		rosark2	Kelvis Joel Rosario	Peel Test Data is out of Spec?
1/7/2020 5:04:06 PM	25069030 OPEN IPTEST (5063172)	A	OPEN - SCS Close/Open Inner Peel Test (5063172)	25069030		rosark2	Kelvis Joel Rosario	SID Number
1/7/2020 7:54:46 PM	25069031 OPEN IPTEST (DBS)	A	OPEN - DBS Close/Open Inner Peel Test	25069031		rosark2	Kelvis Joel Rosario	Parameters are out of Spec?
1/7/2020 7:54:46 PM	25069031 OPEN IPTEST (DBS)	A	OPEN - DBS Close/Open Inner Peel Test	25069031		rosark2	Kelvis Joel Rosario	Peel Test Data is out of Spec?
1/7/2020 7:54:46 PM	25069031 OPEN IPTEST (DBS)	A	OPEN - DBS Close/Open Inner Peel Test	25069031		rosark2	Kelvis Joel Rosario	SID Number

Figure 5
Time Based Log

Another tool that will be used as shown in figure 3 is an in-process continuity test that will be performed by the product builder right after the laser weld process has ended. For this post weld continuity test a fixture was designed and constructed by the manufacturing engineering team and instructions were added to the manufacturing instruction explaining how to use this fixture to perform the post weld continuity test. As shown in figure 6, the third tool that will be used would be a pareto chart that comes from an NC and task list completion report displaying the information on how the manufacturing lines are performing in terms of units completed and yield percentage. This report also displays information about what failure modes are the mayor offenders affecting the yield percentage so when a failure mode has a spike, it can identify it and address it as soon as possible. A final tool that will be implemented is a process capability sixpack to monitor pull strength data results on a weekly basis to understand if the implementation of the compression tool has been able to reduce the variation of the process so the data can fit a normal distribution of the process overall.

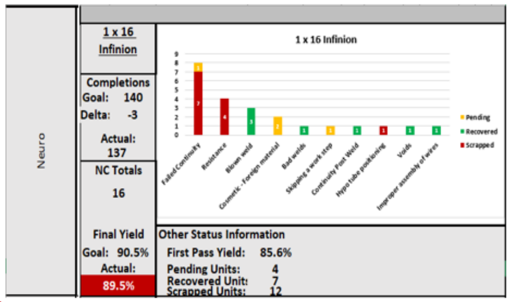

Figure 6
Pareto Chart

Results and Discussion

Figure 7 below represents the results taken from the special work order units (SWO) that were built with the new fiber laser weld machine and the compression tool installed. This time the data of the process overall can make a fit on a normal distribution without the need of analyzed by operator. Also, the process has a low standard deviation of 0.047 which is an indication of a centralized data distribution within specifications, and this can be appreciated in the next image of the capability sixpack analysis.

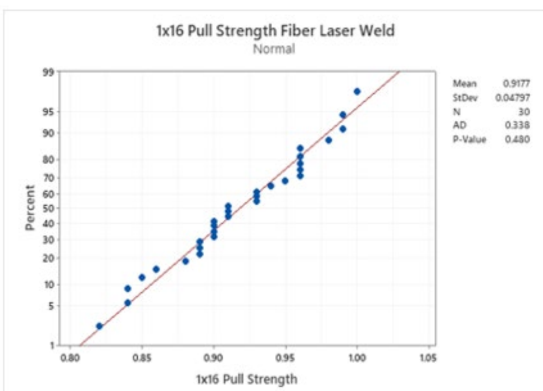

Figure 7
New Laser Process SWO Results Distribution

Figures 7 thru 8 show 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 9 shows a boxplot analysis where it can be seen an improvement in the process as pull strength data results are higher after the implementation of the compression tool meaning that a stronger and a higher quality weld joint is formed.

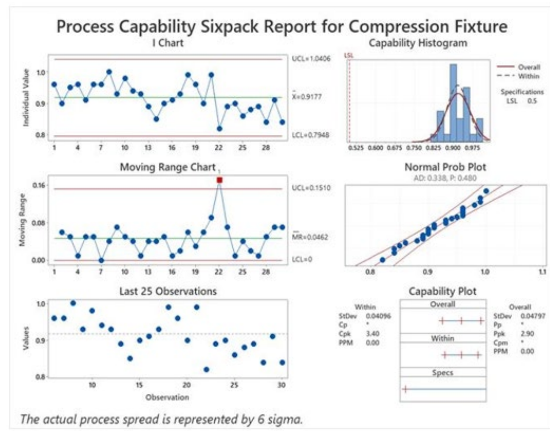

Figure 8
Process Capability Sixpack Report for Compression Fixture

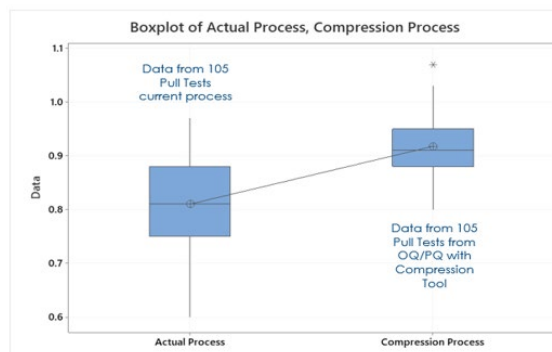

Figure 9
Boxplot of Actual Process, Compression Process

Conclusion

Based on 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.

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