1x16 Post Weld Continuity

Valerie Martínez Adorno
Manufacturing Competitiveness
María García Sandoval, PhD
Quality Management
Polytechnic University of Puerto Rico

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 of 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.*

Key Terms *– Continuity, Laser welding, Medical Devices, Scrap.*

PROBLEM STATEMENT

In the medical device industry, a manual process called laser welding is used as part of the assembly in the manufacturing process of spinal cord stimulation leads (SCS). This is one of the most critical processes and, therefore, it brings with it different offenders as exposed wire, bad welds, broken weld, or broken wire and blown welds that impact the function of the product. For the 1x16 manufacturing line of the Neuromodulation division, the biggest offender is the failed continuity which, when detected, the unit was discarded at its last inspection point at the highest cost of the unit. This brought an impact on quality, productivity, and process, as well as a financial impact on units discarded due to this non-conformance. Continuity failures were found to be the top offender that impact negatively the product with more than 300 units discarded every quarter. This idea is based on the analysis of cost per unit of $73.64 on RWK versus $262.84 per unit discarded at the inspection point. In this case, it is starting with the manual continuity inspection after completing the laser welding process. The manual inspection process took about 2 minutes per unit vs 52 seconds per unit with the semi-automatic, where the impact is notable on process time in production. Is intended to change the optional manual inspection at the workstation for a semi-automatic one that allows to maximize the inspection time with an improvement of 68 seconds cycle time reduction. Is an early detection point where the units that failed continuity are captured and reworked.

It is important because it would contribute positively to the financial area of the company and to the manufacturing process, quality, and productivity of the product since the unit could be reworked to avoid discarding it. It's expected that this research will be possible to achieve each of the established objectives and to continue promoting improvements in manufacturing processes.

Research Description

This research is about the mitigation of the continuity failures defects in the units of the manufacturing line 1x16 at the Neuromodulation division to be able to rework the unit and avoid scrap it. Failures have occurred in this area that have impacted line metrics such as performance or final yield, quality/cost, and production output. It is expected that the improvement in final performance metric to 1% would have a scrap rejection of $88k. Also, is brought to improve and flow of units promoting productivity and maximizing assembly time in manufacturing by switching to automated.

To be able to identify improvements that can result in the research, a problem-solving fishbone diagram was discussed and created. 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 inspection was executed to proof the manual process time before was implemented the semi-automatic. This research is important because it allows a process improvement to be made to keep the units flowing.

Research Objectives

The research objectives are the improvement of scrap due to continuity failures by 1% rejection rate, attack the defect before the unit continues to increase in cost per component and process, rework each unit at $73.64 of cost versus $262.84 per unit discarded and, improve the laser welding process by reducing inspection time by changing the manual method to a semi-automatic one with 68 second of cycle time reduction.

Research Contributions

The current rejection rate is 3.7% of the manufacturing process, however, it is expected to an improvement of 1%. 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. Other contributions are the money saved through the unit rework process "Remove and Replace components" that subtracts from the principal cost of the leads which has an impact cost of $73.64/unit RWK instead of the full cost of scraping the unit which have a cost of $262.84 each one, that equals 3,000 to 4,000 units monthly, approximately 36,000 to 48,000 annually. This is a scrap avoidance of $189.62 per unit. Reduce scrap impact due to continuity failures, recover the unit in time to rework it and contribute positively to the financial state of the company.

LITERATURE REVIEW

"*A complete system solution approach is essential for successful medical device manufacturing"* [1]. Laser welding process is one of the most important steps 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 [1]. For medical device industry, to be able to gain customer satisfaction and loyalty, its crucial to have a real focus in the continuous implementation of process improvement in manufacturing processes. The benefits include repeatable, high-speed, and precise, ideal for high production volumes, minimum part distortion due to small heat affected zones, weld ability near heat-sensitive components and hard-to-reach areas, consistent depth and width control, cost advantage and effective in dissimilar metal joining applications [2].

Laser beam welding is a process by which materials are joined by heating them with a laser. The technique is usually used to join metals, but other materials, including plastics, can also be welded. 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 heat-affected zone, creating a high depth-to-width ratio for the weld nugget. Welds can be made with a high level of precision, allowing for the creation of ever smaller devices. In contrast to resistance welding, which requires electrodes on each side of the weld, laser welds are done from one side. Laser welding can also help facilitate repairs to small devices or components without the necessity of disassembling the device [3]. Is important to know that the laser welding process often uses inert gas to protect the molten pool. For most applications, argon, helium, and other gases are often used to protect the work piece free from oxidation during the process, with those as the most frequently used. Argon gas is cheaper and denser, so the protective effect is better. However, it's susceptible to high-temperature metal plasma ionization, which results in shielding part of the beam towards the work piece, reducing the effective laser power of laser welding, and damaging the welding speed and penetration. This is the most effective shielding gas used in laser welding, but the price is relatively expensive [4]. In this case, the shield gas used to 1x16 product for the laser welding process is the argon, with the nitrogen and the compression air.

For a medical device laser welding process there's many defects as hypotential failure, blow hole, broken weld, bad weld, and the continuity failure. Continuity is the presence of a complete path for current flow. A continuity test is a quick check to see if a circuit is open or closed. Only a closed, complete circuit (one that is switched ON) has continuity [5]. During a continuity test, there's some tools to perform the test. In medical devices, tools used for this test are digital multimeter, and the manual and automatic post weld continuity check. The manual post weld continuity check is established in the laser weld workstation for the PB performance. The digital multimeter and the automatic post weld continuity check is established in the final inspection workstation for the last tests before sterilizing and packing the product. Each defect can impact positively through a reworked unit, or negatively by scrap product, for the industry overall in the productivity, quality, financial area, yield, or efficiency, among others.

In Boston Scientific PR, 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. Other type of testing of welding is the pull test as a process monitoring that each operator must do at the beginning and ending of the shift to ensure that units was perform with the expected force. Medical device welds are tested for strength; common configurations are pull, peel, and shear tests because most engineers are familiar with the issues related to mechanical testing [6]. As it explained, this is an opportunity area that it will be worked in this design project. As it's presented in the article, 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 [7]. The goal of this research 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. The units are separate as a non-conforming product which it's a product or a medical device that does not fulfill its specified requirements like customer or regulatory requirements. The purpose is to separate every medical device from other conforming medical devices thru identify it, separate it, and exclude it or not to deliver it. As it mentions, corrections of nonconforming medical devices may be seen as reworking. This type of reworks includes the repair, reprocessing, or any other adjustments of the medical device for a recuperation of the product and complete all the process [8].

METHODOLOGY

The DMAIC methodology (pronounced "Duh-MAY-ick") is a process improvement strategy that is implemented by the phases of define, measure, analyze, improve, and control. It is a structured problem-solving methodology widely used in business to drive a data quality system by using a set of tools through the phases that are going to be applied depending on which one is implemented [10]. Is important to understand what kind of problem it is tried to be solved and all the process to understood what type of methodology is suitable to improve it. For this project, the problem that would be addressed is related to a product failure in the laser weld workstations at Boston Scientific, PR

The issue is continuity failures and the DMAIC methodology will provide the right tools to improve it.

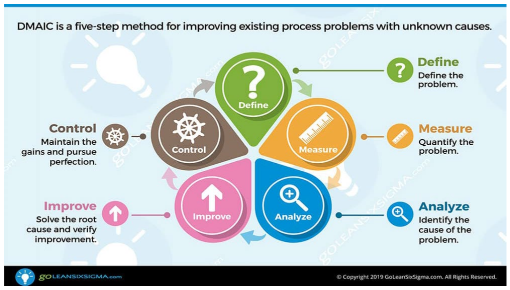

Figure 1

DMAIC Methodology Phases (Go Lean Six Sigma)

As is presented in the Figure 1, the DMAIC methodology is a five-step method for improvement existing process problem with unknown causes [9]. How can these steps or phases be used?

In the define phase, it would define the problem developing a problem statement, define the goal of the project by a goal statement, create a team charter to identify team members of the project and finally, define the objectives of the project.

In the measure phase it would determinate how the process currently performs, create a plan to collect the data, ensure the data is reliable and collect data from many sources to determine types of defects.

In the analyze phase it identifies possible causes of the problem, quantify financial benefits of solving the problem, examine close the process, identify gaps between current and goal performance and prioritize opportunities.

For the improve phase, it develops an implementation plan, solve the problem, brainstorm solutions to mitigate the problem and measure the ensure improvement.

Finally, for the control phase it would sustain the improvement, create a monitoring plan for the success on performance and apply improvement in the areas.

Table 1

DMAIC Matrix

DMAIC MATRIX

Tool Name	D	M	A	I	C
Data Collection		X			
Is/Is not	X				
Fishbone Diagram			X		
Project Charter	X				
Improvement Strategy				X	
Process Flow Map		X			
Pareto Chart		X		X	X

As it presents, the Table 1 shows some of the tools used in DMAIC methodology process and in what phase they could be developed. The DMAIC Matrix is a visual tool that provide an idea of what was developed on each phase to solve the problem and find the root cause. The previous mentioned tools are those that will be used to develop the DMAIC methodology in this design project.

To the define phase, it was used the Is/Is not technique and the Project charter. Is/Is not technique it helps to clearing that is in the scope and what is to be left aside to create the problem statement. However, the Project charter is a document that resume the project with a problem statement established and all their parts. In case of measure phase, it was used the Pareto chart, process flow map and a data collection process. The P chart helped to determine if the process is stable and predictable, as well to monitor effects of process improvement. The process flow map it was to know and illustrate how is the process. Finally, the data collection process is a recompilation of variables to make predictions, calculations, trends or evaluate outcomes in the project. For the analyze phase, it was used the fishbone or cause and effect diagram to determine and evaluate the possible causes and find the root cause. For the improve phase, it was used an improvement strategy to keep focus on improving the ways things are done, as action items, and a pareto chart as a continuous improvement illustration with the implementation. Finally, for the control phase, it was used a pareto chart to illustrate how he process monitoring tools contributes and how stable it goes the process with the implementation.

RESULTS AND DISCUSSION

In the manufacturing process of the 1x16 family, when a unit is confirmed with a continuity test, if unit failed it is discarded with no opportunity to be recovered through the RWK. This process impacts the product with an increase of scrap units. In this chapter, will be presented how the DMAIC tools was used and implemented on each phase, the obtained results through the research and an explanation of how this result contributes to the process of the project. Starting with the define phase with the tools of Is/Is not and Project charter and how these it used. Then, the measure phase with the actual process flow map of the impacted area, the pareto chart of the 1x16 family with the rejections of continuity failures and the data collection obtained through the research. The analyze phase is presented with the fishbone diagram and the possible causes identified in the process. Also, in this phase was identified the two opportunities that will working on in the project. In the improve phase, with the improvement strategies used as action items, to evaluate the root cause identified. Also, this phase presents the expected improvement for the next four months left for this year. Finally, the control phase, that presents the process monitoring tools used to control and sustain the improvement, and a Pareto chart of how the implementation and monitoring tools contributes to the process improve.

Define Phase

In the define phase, the tool used to define the continuity failures problem was obtained in a kaizen with a Is/Is not technique, presented in table 2, to have a clue of the cause. Then, a project charter was created to have a description of the project overall, presented in Figure 2.

Table 2

Is-Is not technique, Boston Scientific Dorado

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 2, as it mentioned, presents the results of the Is/Is not technique that was develop in a kaizen. Is where the problem was defined through ¨what, were, when, who and how¨ questions that provide an idea of is or not a part of the problem. As a result, the major problem occurs only in one product, 1x16 family, in a specific area of the lead, distal area.

1x16 Post Weld Continuity

Project Charter

Boston Scientific

Project Title	1x16 Post Weld Continuity	**Project Leader**	A. Cartagena
Technical Mentor	L. Delgado	**Project Sponsor**	N. Beltran
Start Date	Jan 2020	**Target Completion Date**	Nov 2021
Problem Statement	For the 1x16 manufacturing line of the Neuromodulation division, the biggest offender is the failed continuity which, when detected, the unit was discarded at its last inspection point at the highest cost of the unit. This brought an impact on quality, productivity and process, as well as a financial impact on units discarded due to this non-conformance.	**Process**	DMAIC Methodology
		Project scope	Reduce Failed continuity failures for the 1x16 Infinion Product Family. Failed continuity is the top offender for 1x16 with a high yield fallout of ~4% with high peaks of failures between 5% to 2%.
Project Goals	The goals are the improvement of scrap due to continuity failures by 1.0% rejection rate, attack the defect before the unit continues to increase in cost per component and process, rework each unit at $73.64 of cost versus $262.84 per unit discarded, and improve the laser welding process by reducing inspection time by changing the manual method to a semi-automatic one with 68 second of cycle time reduction.	**Customer Benefit**	Company benefits it would be projected in a scrap avoidance for ~$70K
Team Members	Valerie Martinez Adorno	**Business Results**	Recover units for RWK Less scrap units Positively impact on metrics as yield, quality, scrap or cost, and production output.

Schedule	List the deliverables, supporting activities, resource requirements, and expected completion dates for each phase of the project.						
	Phase	**Deliverables and Activities**	**Resource Requirements**	**Start Date**	**Finish Date**	**Project Sponsor Sign-Off**	**Technical Mentor Sign-Off**
Process Improvement Milestones	Define	Complete problem solving, problem definition and identify scope.	Problem Solving- Is/Is not tool and Project Charter	Jan 2020	Feb 2020	N.B	L.D
	Measure/Analyze	Scrap units, completion task, rejection rate, scrap avoidance, financial expected improvement and root cause analysis	Fishbone diagram, Scrap and Completion reports	Feb 2020	Mar 2020	-	-
	Planning	Define requirement activities to implement post weld fixture	-	Mar 2020	Mar 2020	-	-
	Execution	Tool construction and testing, and installation qualification	-	Mar 2021	Sep 2021	-	-
	Implement. and Control	Semi-automatic post weld and monitoring rejection rate	P Chart, Man and Measurement actions items	Sep 2021	Nov 2021	-	-

Figure 2

1x16 Post Weld Project Charter, Boston Scientific Dorado

In the Figure 2, the results present the definition of the problem and how the project will be developed and structured. The project charter was created by a problem solving that shows the description of the project with the project goal and scope, project team members, manager and sponsor, milestones with the supporting activities, customer benefits, among others.

Measure Phase

In the measure phase, it will be presented the process flow map with the purpose to show it entirety to the improvement plan in the product line of 1x16.

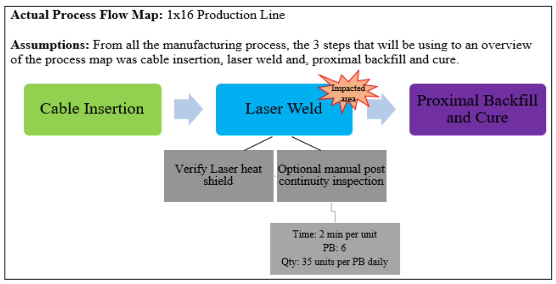

Figure 3

1x16 Actual Process Flow Map, Boston Scientific

Figure 3 shows the results of how the actual process flow map in the 1x16 product without the semi-automatic post weld is. The process flow map is focus on the impacted area on Laser Weld workstation. The post weld continuity check selected to the area is an optional manual continuity check that is performed by the operator and takes 2 minutes per units.

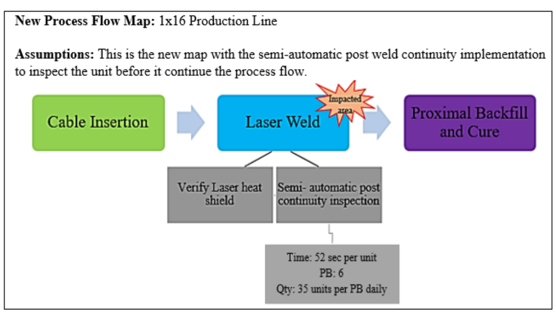

Figure 4

New Process Flow Map, Boston Scientific Dorado

When the semi-automatic post weld continuity check was implemented, this was the new process flow map of 1x16 manufacturing line, presented in the figure 4. The process flow map is an essential tool to know more about the manufacturing process of the product and the impacted area. Figure 4 presents the new process flow map when the semi-automatic inspection is implemented in the laser weld workstation. This new system of inspection provides an improvement on productivity, quality, and time with approximately 68 seconds.

However, P chart it was created using the data from week 2 of 2020 (January) to week 35 of 2021 (August) to presents the current rejection rate for continuity failures of the 1x16 product.

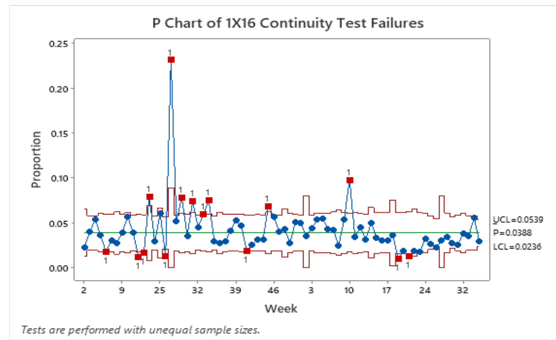

Figure 5

P Chart of 1x16 Continuity Test Failures

Figure 5 shows the tendency of the continuity failures units' data since January 2020 to August 2021. The graph represents the percentage of failures based on the completions per week, calculating the UCL and LCL, and giving the rejection rate of 3.8%. The P chart analyzes the proportion of non-compliant items in a produced batch. The UCL presents the highest percentage of rejection 5.4%, the LCL presents the lowest percentage of rejection 2.4% and the P value presents the actual average percentage of rejection 3.8%.

Through these results for two years, is when the data of task completions and scrap units' reports are collected for a year period to know the impact for the continuity test failures. According with the data collection obtained these reports, and with the cost per unit and per rework, it was calculated the actual percentage (%) of rejection rate, the lost-on scrap continuity units, the scrap avoidance and, the monthly and annually improvement.

Table 3

Reports of rejection from January to August 2021

Reports of January to August 2021				
Total NC scrap units	864			
Total completions	23,536		Scrap units for continuity (Cost Scrap= scrap*total cost per unit)	
Total cost per unit	$ 262.84		$ 227,093.76	
Continuity rejection rate (RR= scrap/completions)	0.0367		Scrap avoidanceper unit (SA= total cost per unit- total cost of rework per unit)	
Total cost of rework per unit	$ 73.64		$ 189.20	
			Improvement (I=completions* % units improvement)	
Units % improvement	1.00%		235.36	
			Improvement in cost of Jan to August (IC= SA*I)	
			$ 44,530.11	

Table 3 presents the results obtained to the task completions and NC Scrap reports from January to August 2021 before the implementation of the semi-automatic post weld continuity. In this part of the project, the product builders must use the manual post weld continuity check that it was established as optional check point. As it presents, the quantity of scrap units was 864 from 23,536 completions in 8 months. The continuity rejection rate obtained was 3.7%. The total cost of scrap units for continuity was $227,093.76. The improvement that could have been obtained if the units was detected on time and reworked, was $44,530.11.

Analyze Phase

In the analyze phase, it was implemented a fishbone problem solving strategy to identify the variables that could trigger the continuity failures.

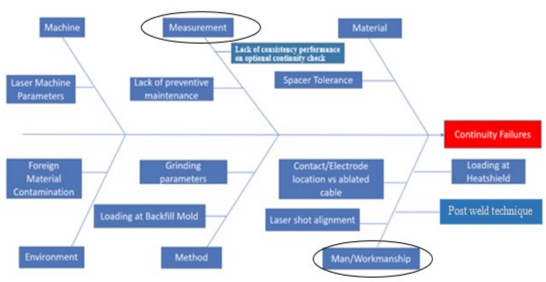

Figure 6
Fishbone diagram, Boston Scientific Dorado

Figure 6 shows the results of the fishbone diagram creation with the possible causes of the continuity failure issue. Some of the variables displayed in this diagram are a representation of some opportunities for standardization improvements that will be worked in other different projects. The continuity failure is the major offender that impact the 1x16 product, which is why, the engineering and quality teamwork in different projects related to environment, machine, among others, to detect the root cause and improve the process. From the opportunities identified as a potential cause, the lack of consistency performance on optional continuity check does not have any project assigned to be improved. Other opportunity identify was the measurement that was evaluate in two projects. As it presents with the black circle, for this research it was analyzing the man-workmanship and measurement.

Man-workmanship is a potential cause related to the operator technique on the contact/electrode location vs cable alignment, loading of the heatshield, tension at cables the post weld continuity and laser shot alignment. It was analyzed all of them to being focus on the post weld continuity technique on the manual and then on the semi-automatic when implementation was done.

Measurement is a potential cause related to the preventive maintenance and the lack of consistency performance on the optional manual continuity check. For this research, it was analyzed specifically the lack of consistency performance by the operators. Also, the implementation of the semi-automatic post weld will not be an option as the manual to prevent the lack of consistency performance from the operators after completed the laser weld task and before send the units to the other task.

Improve Phase

The improve phase is where the semi-automatic post weld it was implemented in the laser weld workstation and manufacturing instructions and, through the fishbone diagram, the variables of measurement and man-workmanship it was evaluated. The implementation of the semi-automatic post weld it was determinate as a solution that would contribute on the two variables selected for the process improvement.

Table 4
Improvement Strategy, test study with action items for Fishbone causes

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 4 presents the results of the action items that was evaluated from man-workmanship and measurement for this phase. The actions were taken to address the root cause related to continuity failures with an execution date assigned to the action item to be able to track them and saw the results.

For the man-workmanship, as an action, it was evaluated the operator technique through the performance with the manual vs the semi-automatic continuity checks. At this point, what was worked is the technique in the unit's position on each post weld check, the specific time by operators on performance and the correct order of inspection starting with the contact and electrode #16 and finishing with the contact and electrode #1 in both continuity checks. As an implementation plan, it was verifying the operator's performance on both post continuity checks and the variation on technique.

In the case of measurement, it was evaluated the consistency performance after welding process. The evaluation was specifically with the semi-automatic tool implementation as a requisite and not an option to detect the continuity failure before continuing the process and recovered through a RWK. As an implementation plan, it was verifying the quantity of units that would be detected and recovered RWK with the semi-automatic post continuity weld.

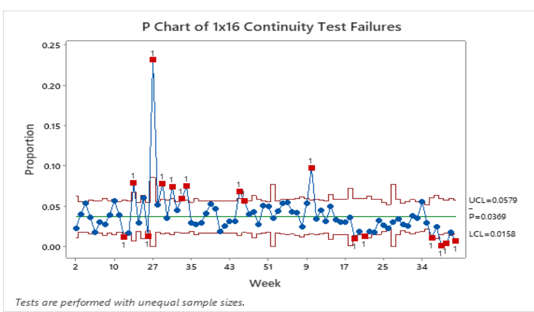

Figure 7
P-Chart 1x16 Continuity Failures, updated

Figure 7 show the results of the continuity failures obtained in September at the week 35 of this year of the 1x16 family. At this point, as it presents, the 1x16 semi-automatic post weld was implemented in conjunction with the compression tool, from other project related to the continuity failures. The P value decrease close to 1.00% from 4% to 3.6% of rejection rate. The compression tool is responsible for the cable alignment, compression, variability on process and operator technique. Otherwise, the semi-automatic post weld continuity check is responsible to work as an early detection point to avoid scrap units and recovered with a RWK of remove and replace components.

Table 5
Future Improvement expected from Sept to Dec 2021

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 5 presents the results expected to obtain from the next month's September to December 2021 after the implementation of the semi-automatic post weld continuity. As it presents, the real completions number is 13,795 units for September to December 2021. The expected annual scrap units are 373, for an annual cost on scrap avoidance of $70,630.25. These results help to have an idea of the improvement that the new post weld can provide after implementation.

Control Phase

In the control phase, the process monitoring tools it was implemented. For this project three process monitoring tools it was used, started with the time-based log where pull test that is entered daily twice a day (before and after the laser weld process is conducted) to analyze the data of each operator. The pull test brings a measure the force required to break the wire from tensile force, and the remnants of the wire bond are used to determine the failure mode. For the Neuromodulation area, the pull test must be higher than 0.50 for all manufacturing lines. For 1x16 product, the engineering and quality team was determined that must be higher than 0.80 to assure the strength of the cable for the high rejection of units at this point.

As an example, if the pull test data if it goes less than 0.80-0.50 on 1x16 product, this indicate a weak weld that is a potential cause of continuity failures, and the unit would be rejected and scrap. The time-based log is a data collection system that monitor the values of each operator, in the laser machine used and, the date and time of the data entry.

The other tool that was used is the compression tool system that will help each operator in the cable alignment, compression, and welding process. For this compression tool fixture, it 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 design of this automatic tool is based on 4 timers, when the operator gives his first shot the compression tool he raises, grabs, and presses the contact or electrode to the second shot, then drop it to start a new “cycle”. This compression tool is a complement of the semi-automatic post weld to the improve of the continuity failures rejection. As an example, when the operators completed the laser process using the compression tool, the units were verified in the automatic post weld to assure the excellence performance. If a unit presented a failure after the inspection on the post weld, the operators was rejected the unit as a non-conformance to recovered as a RWK.

Finally, the third tool was a Pareto Chart that came 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 showed information about what failure are the mayor offenders affecting the yield percentage so when a failure has a spike, it can identify it and address it as soon as possible.

In each process monitoring tool, it was evaluated the operator’s technique as a part of the control phase. The technique evaluation was performing through the semi-automatic post weld performance, the position of the lead in the post weld, the correct order to inspect, and other details of monitoring to control the man/workmanship standard. The others process monitoring tools mentioned previously, were to control the measurement standard identified, selected, and evaluated in the analyze phase. The timed-base log and the pareto chart are tools that can provide a data to ensure how it goes the process improvement and the rejection rate %. The compression tool is a tool that provide a complement of the semi-automatic post weld to avoid the rejection of units and the decrease on scrap. These three processes monitoring tools were selected to assure the quality on the product, but most of all the improvement on process and product.

CONCLUSION

“What get measured, gets managed” (Peter Drucker) This project contributed as a process improvement to the quality of our products and the process development. The objectives stablished as: the improvement of scrap due to continuity failures by 1.0% rejection rate, the detection of the defect before the unit continues process, the rework on each unit and, the improvement in the laser welding process with a reduction on inspection time, were achieved through the DMAIC methodology structure.

There was various important finding related to those objectives with the purpose of evaluate and implement the post weld continuity. One of them was the operator feedback in case of the technique on performing the 1x16 post weld continuity as a strategy of sustain and better handling. In the process of the post weld performance, the operator had to weld all the units and then, work with the inspection on the tool. This feedback was a great finding to optimize and to take advantage of time. In addition, other important finding was related to the rework of the units detected with the continuity failure. The process of rework starts with a non-conformance discrepancy and segregation, inspection by the quality team or dispositioner, put the correct task of rework and then assembly the units from the start. This process can take minutes if it works that way and that can contribute to the cycle time of the unit and the process timing. Finally, the manufacturing instruction was updated with the new data and the steps of the post weld performance.

As a limitation that impact the procedure of the design project, it was several situations with the materials required for the construction of the semi-automatic post weld. The equipment, materials, cable, and the electronic supplies needed some procedures to obtain them. Also, the validation of the semi-automatic post weld required waiting time to complete. The validation was the longest process for this implementation for the documentation, procedures and all the required permits.

Finally, 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%. The expected percentage to an improvement was 1.00%, so the currently is close to the expected. Moreover, the reduction of continuity failure defects decreased from 10 units daily to approximately 3-4 units daily. This contributed to a higher quality product for the patients and bring financial benefits with less units rejected by this failure and more recovered. This improvement was impacting positively our metrics, as a company, like scrap, yield percentage, quality, and production output as expected. Finally, other contributions that stood out with the implementation was the money saved through the unit rework process "Remove and Replace components" 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.

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