REDUCE SCRAP LOSS OF A PACEMAKER LEAD APPLYING LEAN-SIX SIGMA

Orlando Babilonia Ayala
Manufacturing Engineering

Carlos A. Pons Fontana, Ph.D.
Industrial Engineering Department
Polytechnic University of Puerto Rico

ABSTRACT

A pacemaker is an electronic device that is placed under the skin to help control abnormal heart rhythms. It consists of a battery, a computerized generator, and lead (wires) with electrodes on one end. In a pacemaker leads manufacturing plant, the loss related to scraps from May 2008 to December 2008 was $81,223.92. Sleeve Head Assembly was identified as the loss higher generator related to scraps with a total loss of $49,765 representing a 61% of the total scrap loss. Appling DMAIC methodology from Lean Six-Sigma, the possible causes and action were evaluated. The major cause for the Sleeve Head Assembly scraps is related to leakage at the sleeve head joint. DOE (Design of Experiments) was use to optimize distal & proximal Sleeve Head Bonding. A factorial experiment 2^k (for $k \geq 3$ Factors) was run to determine the significant factors. The experiment results appoint to prime with adhesive tab 5, use adhesive Tab 5 for the 360° and one (1) grove layer. A change on manufacturing process was implemented on April 07, 2009 to reduce leakage defect at the sleeve head joint.

PROBLEM STATEMENT

A pacemaker is an electronic device that is placed under the skin of the chest or abdomen to help control abnormal heart rhythms. It consists of a battery, a computerized generator, and lead (wire) with electrodes on one end. The battery powers the generator, and a thin metal box surrounds it and the generator. A computerized generator figures out what types of electrical pulses to send to the heart and when those pulses are needed. The lead connects the generator to the heart.

In a pacemaker leads manufacturing plant, the loss related to scraps from May 2008 to December 2008 was $81,223.92. Sleeve Head Assembly was identified as the loss higher generator related to scraps with a total loss of $49,765 representing a 61% of the total scrap loss. The major cause for the Sleeve Head Assembly scraps is related to leakage at the sleeve head joint.

The objective of this research was to improve the pacemaker lead manufacturing process to avoid leakage at the Sleeve Head Sub-assembly and reduce loss related with scrap. With an efficient manufacturing process, variability was reduced and more leads comply with the acceptance criteria. Less worked material were loss as scrap. Cycle time of product was reduced. Manufacturing process will be leaned. The total manufacturing cost will decreased.

DMAIC methodology from Lean Six-Sigma was use to study an existing pacemaker lead manufacturing process that was not performing adequately. The possible causes and action were evaluated to improve the manufacturing process to reduce leakage defect at the sleeve head joint.

The research demonstrated the benefit of Lean Six-Sigma to improve the manufacturing process. The process is leaned. Defect waste and the financial loss was decrease. Cardiologists are supplied with the pacemaker leads on time to avoid delay in the implantation surgery. The patient (final customer) will be provided with a quality pacemaker. Lead will remain being manufacturing in the site.

The pacemaker is the only opportunity for life for some people with heart disease. The pacemaker leads has to be deliver to the patients when they need it without any defect.

LITERATURE REVIEW

A pacemaker is use to help control abnormal heart rhythms. The intention of the research was to reduce loss related with scraps in a pacemaker leads manufacturing plant applying Lean Six-Sigma. A literature review was performed to provide to the research the required background.

PACEMAKER

A normal heartbeat is created by an electrical impulse that is generated within a specialized area of the heart and travel down specific pathways to stimulate the cardiac muscle to contract. If any part of the conduction system is dysfunctional for some reason, the normal heartbeat may become too slow (Bradycardia) or fast (Tachycardia). These are abnormal heart rhythms or arrhythmias and in some cases, physicians will recommend implantation of a pacemaker to correct it [4].

Pacemakers are electronic devices that are placed under the skin of the chest or abdomen to help control abnormal heart rhythms. The pacemaker's generator sends electrical pulses that may stimulate the upper chambers of the heart (atria), lower chambers (ventricles) or both. These signals make the heart contract in a more regular rhythm than the chamber would otherwise to prompt the heart rhythm to beat at a normal rate [5].

A pacemaker consists of a battery, a computerized generator, and lead (wires) with electrodes on one end. The battery powers the generator, and a thin metal box surrounds it and the generator. A computer chip figures out what types of electrical pulses to send to the heart and when those pulses are needed. The lead connects the generator to the heart. The computer chip uses the information it receives from the leads connected to the heart. It also may use information from sensors in the wires that detect the movement, blood temperature, breathing, or other factors that indicate the level of physical activity. The leads in the pacemaker send electrical pulses to and from the heart and the generator. Pacemakers have one (1) to three (3) leads that are placed in different chambers of the heart. [6]

LEAN SIX-SIGMA

The goal of any business is to produce the highest quality product or service in the shorter lead time possible with the least amount of resource investment delivered to the customer at the lowest possible cost. Lean Manufacturing seeks to improve flow in the value stream and eliminate waste. Lean methods typically target seven types of waste; defects, wait time, over-production, transportation, motion, inventory and processing. By eliminating waste, manufacturers can do more with less; capital equipment, floor space, operator effort, direct and indirect labor, and inventory. Lean Manufacturing systems are designed to be clearer, safer, better organized, produce better quality and be more productive [2].

Six Sigma is a business management strategy that emphasizes the improvement of process for the purpose of reduction variability and making general improvement. It seeks to identify and remove the causes of defects and errors in a process using a set of quality management methods including statistic [1].

Six Sigma uses a powerful framework knowing as DMAIC, a system that brings measurable and significant improvement to existing processes that are falling below specifications. DMAIC is an acronym for five interconnected phases: Define, Measure, Analyze, Improve and Control.

In the Define phase, the project team identifies a project for improvement based on business objectives and the needs and requirements of the customers. In the Measure phase, the team begins with the proper metrics to evaluate the success of the project. The initial capability and stability of the project is determined in order to establish a measurement baseline. Valid and reliable metrics to monitor the progress of the project are established during the Measure phase; input, process and output indicators are identified. Through the Analyze phase, the team can determine the causes of the problem that needs improvement and how to eliminate the gap between existing performance and the desired level of performance. This involves identify identifying the key variables that are most likely to create process variation and defects. The Improve phase is where the process transitions into solutions. Critical inputs have been verified and optimized toward nailing down the problem causes. Once problem causes are determined in the Analyze phase, the team finds, evaluates through testing, and selects creative new improvement solutions. Success in the Control phase depends upon how well the team did in the previous four phases. Solutions are now implemented and tools are put in place to ensure that the key variables remain within the acceptable ranges over time so that process improvement gains are maintained. The team develops a project hand off process, reaction plans, and training materials to guarantee performance and long-term project savings. Documenting the project is very important so that the new procedures and lessons learned are maintained and provide concrete examples for the organization [3].

DOE (Design of Experiments) is a systematic approach to investigation of a system or process. It is a structured, organized method that is used to determine the relationship between the different factors (Xs) affecting a process and the output of that process (Y). A series of structured tests are designed in which planned changes are made to the input variables of a process or system. The effects of these changes on a pre-defined output are then assessed. Refers to experimental methods used to quantify indeterminate measurements of factors and interactions between factors statistically through observance of forced changes made methodically as directed by mathematically systematic tables [1].

A combination Lean Manufacturing and Six Sigma (Lean Six Sigma) provides a structured improvement approach and effective tools to solve problems. This creates rapid transformational improvement at lower cost.

METHODOLOGY

DMAIC methodology was used to determine the causes of defect to improve the process and comply with specifications. It consisted in determining the current manufacturing process conditions and provides improvements to reduce scraps loss.

DEFINE

The loss related to scraps from May 2008 to December 2008 in a pacemaker leads (wire) manufacturing plant was $81,223.92. Table 1 shows the pace maker lead scrap per component (item) identified by letters from A to K. Item B was identified with the higher amount of scrap with a 61% of total scrap following by Item F with a 22% of total scrap. However, monetary loss was higher for item F with a total loss of $49,765 representing a 61% of the total scrap loss.

Table 1: *Pace Maker Lead Scrap per Component*

Item	Total Piece Scrap	Percentage of Total Scrap	Scrap Cost	Percentage of Total Scrap Cost
A	3	0.15%	$ 2.75	0.00%
B	1,257	60.84%	$ 3,396.79	4.18%
C	110	5.32%	$ 2,093.66	2.58%
D	5	0.24%	$ 54.71	0.07%
E	32	1.55%	$ 1,222.43	1.51%
F	450	21.78%	$ 49,764.96	61.27%
G	3	0.15%	$ 336.74	0.41%
H	2	0.10%	$ 238.97	0.29%
I	106	5.13%	$12,388.56	15.25%
J	83	4.02%	$ 9,837.92	12.11%
K	15	0.73%	$1,886.43	2.32%
Total	2,066.00 units		$ 81,223.92	

The item F (Sleeve Head Assembly) had been selected for the research to reduce the scrap loss. Figure 1 illustrates a Sleeve Head Assembly Diagram. The defects found in the Sleeve Head Assembly were evaluated and the major of scraps is related to leakage. Refer to Table 2. Sleeve Head leakage occurred at the joint where the two (2) Sleeve Head Subassemblies (Proximal and Distal) are connected. The leakage causes non-compliance in the pace/sense inter-circuit 100V dielectric test and in the pace/sense inter-circuit impedance test. The pace/sense inter-circuit on the lead does not meet dielectric test requirements for finished leads tested.

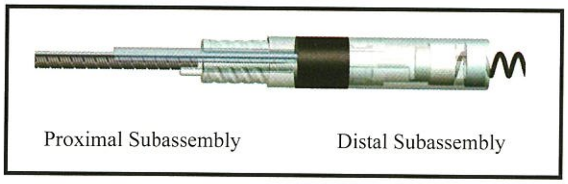

Figure 1: *Sleeve Head Assembly*

Table 2: *Sleeve Head Assembly Defects*

Month	QTY Defect	Leak Defect	% With Leak Defect from Total Defect
Aug-08	86	67	78%
Sep-08	358	111	31%
Oct-08	175	122	70%
Nov-08	76	49	64%
Dec-08	148	32	22%
Jan-09	52	38	73%
Total	895	419	47%

The lead Manufacturing Process was reviewed. The Sleeve Head Assembly is built into the lead at the beginning of the manufacturing process. The causes for the leakage were during the seal process of the gap between the distal and proximal Sleeve Head subassemblies on the Sleeve Head sub-assembly operations. A significant area of concern was the groove on the proximal Sleeve Head and the gap that existed when the part was made to the distal Sleeve Head. Refer to Figure 2.

During the Proximal Sleeve Head Assembly operation, the electrode ring is assembled into to the proximal sleeve head assembly. The tubing band is positioned over electrode ring and threaded portion of sleeve head. Urethane adhesive (Tab 6) is applied in the distal slot of the sleeve head and let dry for 5 minute in a dry box. Refer to Figure 3. On the Distal Sleeve Head Assembly operation, the distal sleeve head assembly is threaded onto the helix, rotate until distal sleeve head assembly and proximal sleeve head are close to each other. The sleeve head is filled with urethane adhesive (Tab 6) and the sleeve heads are slide together maintaining their orientation. The joint are place in a dry box for 15 minutes. Refer to Figure 4.

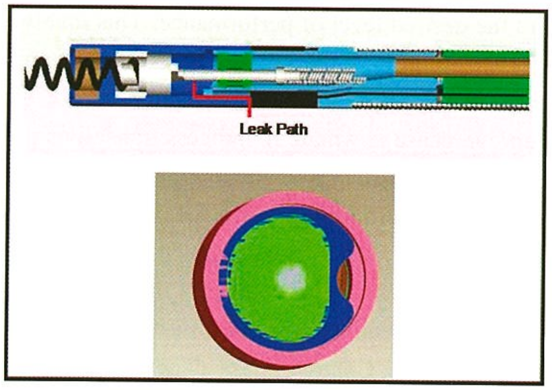

Figure 2: *Gap in the Distal Sleeve Head*

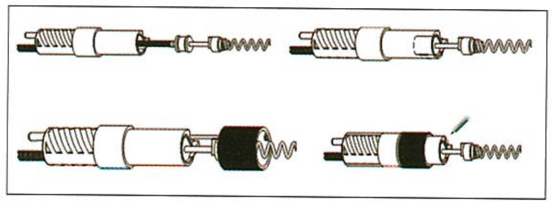

Figure 3: *Proximal Sleeve Head Assembly Operation*

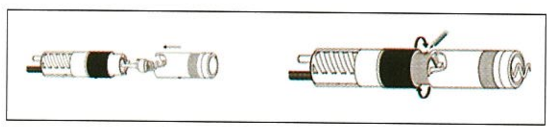

Figure 4: *Distal Sleeve Head Assembly Operation*

MEASURE

Three (3) functional tests are performed to the leads: Leak Test, Impedance Test and Dielectric Test. All leads (100%) are tested as part of the manufacturing process. The leakage at the Sleeve Head creates an ionic bridge decreasing the resistance. It causes non-compliance in the pace/sense inter-circuit impedance test and dielectric test.

For the qualification process, 32 lead will be submitted to the three (3) tests. Refer to equation (1) for test 2 and 3.

- **Test 1:** Leak Test (4.0 psi)
- **Test 2:** Impedance Test ($R > 50k\Omega$)
- **Test 3:** Dielectric Test ($I < 2mA$)

V = I x R (Example: 100V = 2mA x 50k ohms) (1)

ANALYZE

An impedance distribution was calculated to evaluate the impedance variability. The results on the impedance test do not follow a uniform distribution, obtaining values out of specifications. Refer to Figure 5.

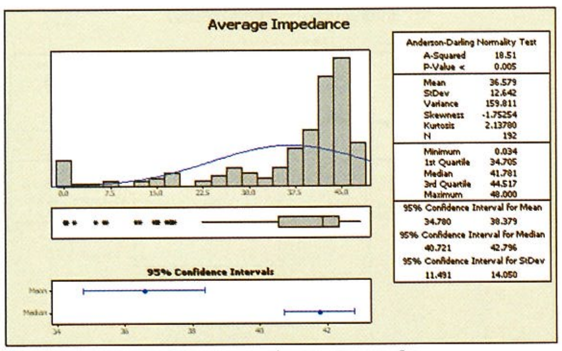

Figure 5: *Impedance Distribution*

The cause of non-conformities in the lead leakage test was the lack of process steps to seal the gap between the distal and proximal Sleeve Head assemblies. Likely suspect were prime on part, 360° adhesive type (Tab 5 or 6), dry time, number of groove layers and piece alignment and handling. The immediate decisions were cleaning parts with Heptane, add a thick coat of adhesive and use adhesive Tab 6 in grove. The factors to optimize were to prime parts with adhesive tab 5, the 360° adhesive type (Tab 5 or Tab 6) and number of groove layers.

IMPROVE

DOE (Design of Experiments) was use to optimize distal & proximal Sleeve Head Bonding. A factorial experiment 2^k (for $k \geq 3$ Factors) was run to determine the significant factors. This study included 3 factors, therefore, design was a 2^3 factorial design and it had eight (8) runs or treatment combinations. Geometrically, the design is a cube with the eight runs forming the corners of the cube. Refer to Figure 6 for the 2^3 Design and Table 3 for the 2^3 design matrix.

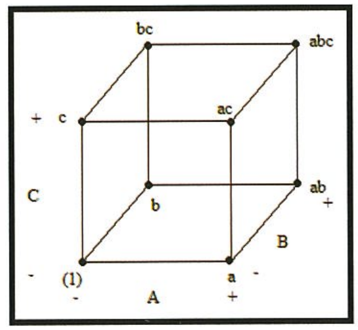

Figure 6: *The 2^3 Design*

Table 3: *The 2^3 Design Matrix*

Run	A	B	C
1	-	-	-
2	+	-	-
3	-	+	-
4	+	+	-
5	-	-	+
6	+	-	+
7	-	+	+
8	+	+	+

The factors in the experiment were:

- A-Primer (Tab 5)
- B-360° Adhesive
- C-Layers in Grove

The experiment results appoint to prime with adhesive tab 5, use adhesive Tab 5 for the 360° and one (1) grove layer. Refer to Figure 7. In addition, the experiment showed that the combination of the three (3) factors have significant effect in the response. Refer to Figure 8, Figure 9 and Figure 10.

A new procedure was developed with the information obtained in the DOE. During the new Proximal Sleeve Head Assembly operation, the electrode ring is assembled to onto the proximal sleeve head assembly. The tubing band is positioned over electrode ring and threaded portion of sleeve head. Refer to Figure11. During the new operation, Heptane Cleaning and Priming, proximal sleeve head distal to ring outside is cleaned with heptane, using a swab. Adhesive-Polyurethane Tab 5 is applied on proximal sleeve head 360° (including the groove) entire surface distal to ring. Refer to Figure 12. In addition, the Fill Proximal Sleeve Head Groove operation was added. In this operation, urethane adhesive Tab 6 is applied in the distal groove of the proximal sleeve head and filled 360° around distal face of the electrode ring. Refer to Figure 13. On the new Distal Sleeve Head Assembly operation, the distal sleeve head assembly is threaded onto the helix, rotate until distal sleeve head assembly and proximal sleeve head are close to each other. A small bead of adhesive Tab 5 is applied to the inside of distal sleeve head. The sleeve heads are slide together maintaining their orientation. The joint are place in a dry box for 15 minutes. Refer to Figure 14.

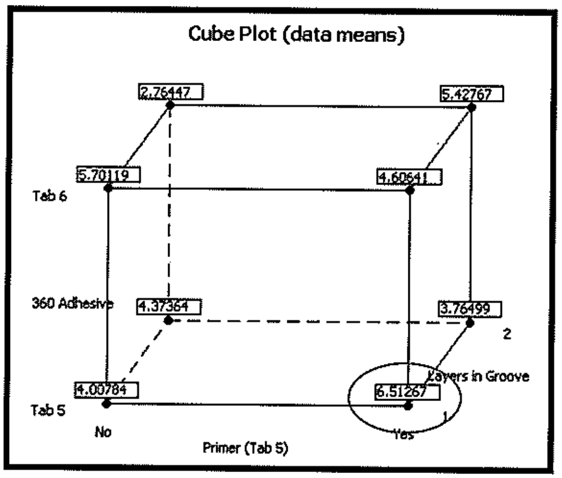

Figure 7: *Factors with Significant Effect in the Response (A)*

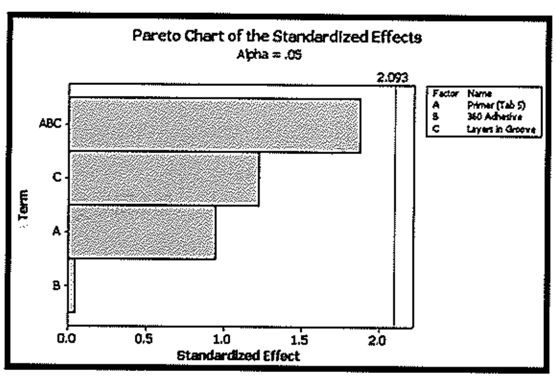

Figure 8: *Factors with Significant Effect in the Response (B)*

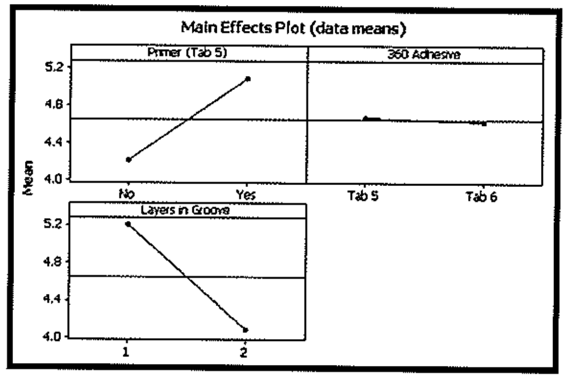

Figure 9: *Factors with Significant Effect in the Response (C)*

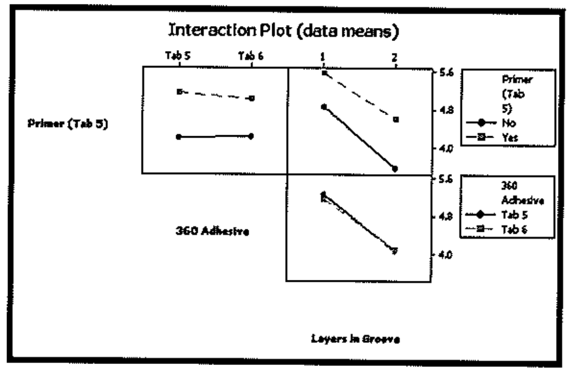

Figure 10: *Factors with Significant Effect in the Response (D)*

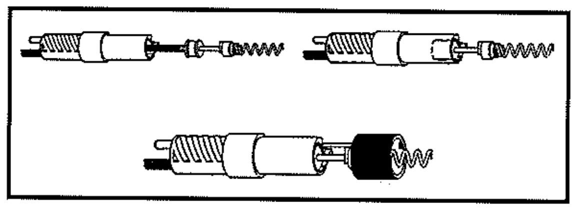

Figure 11: *New Proximal Sleeve Head Assembly Operation*

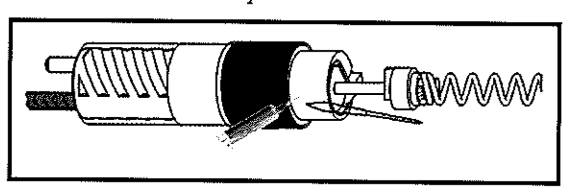

Figure 12: *Heptane Cleaning and Priming Operation*

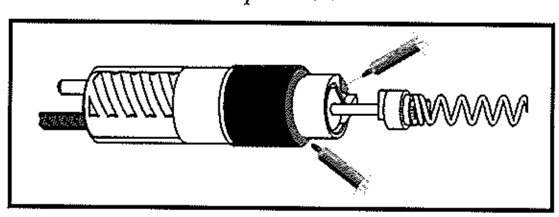

Figure 13: *Fill Proximal Sleeve Head Groove Operation*

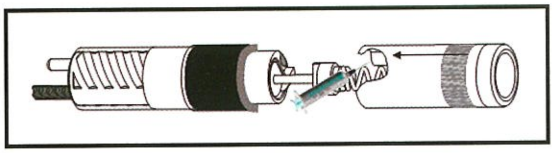

Figure 14: *New Distal Sleeve Head Assembly Operation*

CONTROL

Standard Operating Procedures (SOPs) were updated. Three (3) additional operations were added to the Sleeve Head Sub Assembly process. Personnel were trained in the procedures changes and were certified in the operations.

CONCLUSION

Appling DMAIC methodology from Lean Six-Sigma, the causes of scrap and action were evaluated. The assembly that generated more scrap was the sleeve head due to leakage at the joint. DOE (Design of Experiments) was use to optimize distal & proximal Sleeve Head Bonding. A factorial experiment 2^3 was run to determine the significant factors. Factor evaluated were Primer (Tab 5), 360° adhesive (Tab 5 or Tab 6) and layers in Grove. The experiment results appoint to prime with adhesive tab 5, use adhesive Tab 5 for the 360° and one (1) grove layer. In addition, the experiment showed that the combination of the three (3) factors have significant effect in the response. A new procedure was development with the information obtained in the DOE. Personnel were trained in the procedures changes and were certified in the operations.

The research improves the manufacturing process of a pacemaker lead. Variability was reduced and more leads comply with the acceptance criteria. Less worked material is loss as scrap.

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Orlando Babilonia se graduó del programa de Maestría en Ingeniería de Manufactura, en la colación de grados de 2009. El señor Babilonia posee un grado de bachillerato en Ingeniería Mecánica y sus intereses en investigación van alineados al área de Gerencia de Calidad.