Tracking System for Useful Life of an Insulin Pump Motor

Carla Parrilla Navarro
Master of Engineering in Manufacturing Engineering
Carlos González, Ph.D.
Industrial Engineering Department
Polytechnic University of Puerto Rico

***Abstract* —** *This research project was focused in the implementation of a Tracking System for the useful life of an infusion pump's motor. This component is a sub-assembly of the infusion pump which is used to deliver fluids into a patient's body in a controlled manner. DMAIC is the methodology used in this research as Define, Measure Analyze, Improve and Control. DMAIC is a popularized continuous improvement method. Although there is considerable literature available with the Six Sigma implementations, there is very little research published about the experiences implementing step by step some tools. The goal of this research is to develop a system that will track how many times a motor is reclaimed in the manufacturing line and to make this system determine when is time to scrap the component. This will minimize the amount of returns due to alarms related to motors. In this research were used different techniques to maintain a continuous improvement, demonstrating that the DMAIC methodology is a useful one to have an incremental improvement.*

Key Terms *— DMAIC, Insulin Pump, Six Sigma, Useful Life.*

PROBLEM STATEMENT

Food and Drug Administration (FDA) CFR 21 Part 820.6 established that each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include it. Therefore, it is key to develop a system that is suitable, robust and reliable in order to comply with this requirement.

Research Description

After the completion of two separates audits in a Medical Device Company, there was a similar finding that needed to be attended. There was no established method for tracking an individual infusion pump's motor. Therefore, the number of times (useful life) this component can be used (reclaimed and used again) is not determined. There is also no technical justification for the number of times this component is tested at a specific operation in the manufacturing line.

Research Objectives

Determine the useful life of the infusion pump's motor. Develop a tracking system that will use this information to track each individual motor's life span in order to determine when the motors are not meeting its specifications. The system has to consider the manufacturing process of the infusion pump and the repair process that is used to build up a refurbish unit.

Research Contributions

Comply with regulatory requirements, comply with component specifications, improve component and product functionality and maintain Business Continuity.

LITERATURE REVIEW

An insulin pump is a medical device used by people with diabetes. It is a small device about the size of a beeper or pager, and is worn externally. This device delivers precise doses of rapid-acting insulin to closely match the body's needs. There are

two rates at which the pump functions: basal and bolus. Basal rate generates small amounts of insulin delivered continuously (24/7) for normal functions of the body (not including food). The programmed rate is determined by a healthcare professional. Furthermore, Bolus Rate can deliver additional insulin "on demand" to match the food you are going to eat or to correct a high blood sugar.

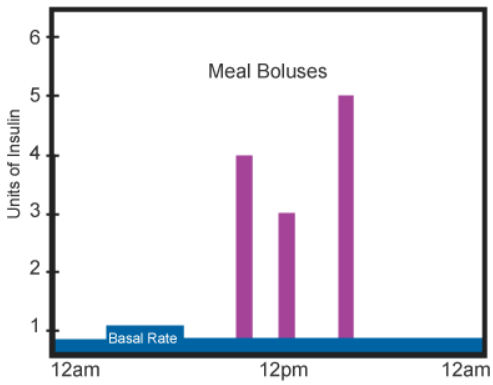

Figure 1
Basal/Bolus Graph

Components of Insulin Pump

Insulin pumps are composed of four (4) main components that work together in order to deliver the medication. These four components are (See Figure 2):

1. Insulin Pump - A small durable medical device that has:
   - Buttons to program your insulin.
   - LCD screen to show what you are programming.
   - Battery compartment to hold 1 AAA alkaline battery.
   - Reservoir compartment that holds insulin.
2. Reservoir – This is a plastic cartridge that holds the insulin inside the insulin pump. It comes with a transfer guard that assists with pulling the insulin from a vial into the reservoir.
3. Infusion Set – This component includes a thin tube that goes from the reservoir to the infusion site on your body. The cannula is inserted with a small needle that is removed after it is in place. It goes into any body area that the human might give insulin injections.
4. Infusion Set Insertion Device - An infusion set is placed into the insertion device and with a push of a button the infusion set is inserted quickly and easily.

Figure 2
Insulin Pump Components

Steps for Insulin Delivery

In order to deliver insulin into the human's body, the insulin located at the pump's reservoir has to travel through flexible tubing; then, it goes through a tiny tube called "cannula" which is inserter under the skin in order to deliver the insulin (See Figure 3).

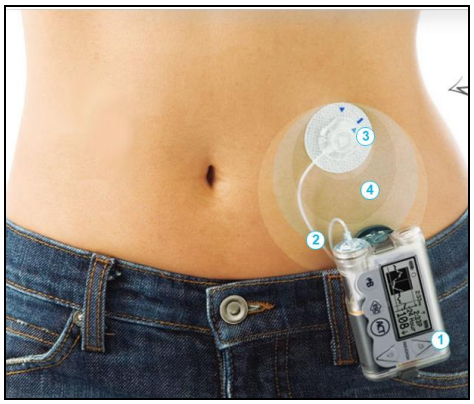

Figure 3
Insulin Delivery Demonstration

Benefits of Insulin Pump Therapy

- More flexibility.
- Fewer injections.
- Tighter control.
- Fewer long-term complications.

- Better predictability.

Insulin Pump's Motor

The Drive Motor Assembly is an external portable gear-motor assembly that, when used in conjunction with controlling electronics and other mechanical systems, will provide the necessary output torque and angular displacement to drive a fluid filled syringe in a safe and reliable manner (See Figure 4).

The Drive Motor Assembly shall consist of a brushed motor with an integral encoder safety circuit, gearhead, drive screw, and home positioning switch.

Figure 4
Example of Insulin Pump Motor

Motor Useful Life

Based on the component's specification, the minimum life expectancy of the motor is approximately equivalent to 10 years of pump usage as directed. This is a sum that takes in consideration the motor's cycles, pulses and other basic functions as rewind, forward and backward drive.

PROJECT METHODOLOGY

This research consists of the design, explanation of the tools to be implemented and the reason for the implementation. It also established the type of analysis and how the data was collected. This research is intended to implement a tracking system that will use this information to track each individual motor's life span in order to determine when the motors are not meeting its specifications. This will be done with the help of different six sigma tools. The methodology of Six Sigma basics in essence creates improvements by managing variation and reducing deficits in the processes of an enterprise. DMAIC these five elements focus on significant process improvements.

You may ask how this process relates to the everyday man or woman. Using data from every conceivable source, the statistical formulas used by the process of the Six Sigma methodology can effectively calculate this data into productive applications. From the time allotments for pizza delivery, to the analytical processes used by insurance companies, statistics play a large part in daily affairs, and this approach enables productivity and profit for businesses without neglecting consumer input. The processes of Six Sigma with its statistical perfections that allow increased profits, less defective products, and millions in the bank, is impressive to those that gain such windfall, but the lingering question to ask may be too little, too late [1]. Six-Sigma is a 21st century concept. It represents a process-focused, resource-based and customer-driven concept. Enterprises implement the Six Sigma business concepts to achieve processes and activities perfection. The essence of Six Sigma concepts is that customers' satisfaction can be provided by increasing the quality of products. The quality of products can be increased by increasing the quality of processes. Finally, the quality of processes depends on resources and capabilities and on their combination. Six-Sigma is more than just a business concept. It is a management philosophy that signifies how expensive defects are. Six-Sigma can be implemented through Six Sigma projects, which involve five phases shown in Figure 5. However, the mentioned phases of improvement in Six Sigma ways include very detailed, concrete measures, instruments and techniques. This makes it possible to call them methodology. Six Sigma methodology (DMAIC) helps to improve any process. It suggests that it is usually possible to improve processes' efficiency, not by changing the combination of resources and capabilities, but by eliminating variation and defects, which appear as a consequence of variation. In summary, the Six Sigma basics of statistical findings for business and

consumer advancement, heralds as the ultimate process for achievement, yet leaves the mind to ponder its effectiveness upon the human race [2].

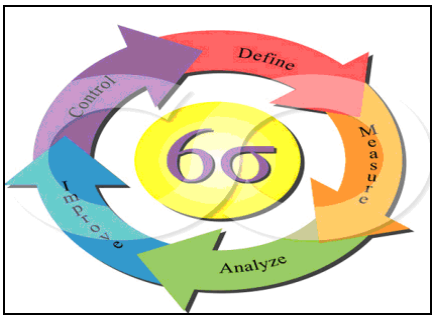

Figure 5
DMAIC Methodology

METHODOLOGY

In this competitive world, each organization needs to fight for a place at the top. To sustain competitiveness, each organization needs to produce and deliver defect free products. In order to do so, organizations follow many different business management strategies witch one of the most popular strategy is six-sigma. Six-Sigma is a business management strategy that involves betterment of the organization's existing products, to make them defect free. The following paragraphs will help you understand this methodology in detail.

DMAIC Methodology Tools

DMAIC is an acronym which stands for Define, Measure, Analyze, Improve and Control. These are tools of DMAIC, and are used in order to find and eliminate defects in the product. A team of experts is formed which uses the DMAIC methodology to find and eliminate the root cause of defects. This team has a leader with a six sigma black belt certification. Other members of the team hold six sigma certifications too. These are experts who look at processes and the products. The outcome of their study helps the organization to raise its position in the market, and cut off competition by producing defect free products. Let us proceed to understand the DMAIC methodology [1].

Define

The team is formed with a specific purpose in mind. This is what the define stage is all about. The team needs to sit together and define the scope, goal, budget, duration and the problem. The leader of the team makes a charter document where they mention all the above aspects in complete detail. Then, work begins. The team defines the problem and then sets about finding the root cause and finding ways to eliminate that cause. The understanding of business process management helps the team at this stage of DMAIC methodology [2].

Measure

Here, the performance of the process is measured. The feedback of people who manufacture products, feedback from customers who use the products and the way the product is processed, are all measured. The team also takes a look at business growth strategies. At this phase, the problem statement and project contract are commonly refined as a result of establishing an accurate baseline for the metrics being targeted. This can be known as the data collection step too. All relevant data, important to the product, and the processes followed to manufacture the product is collected at this stage [2].

Analyze

The next step in DMAIC process, analyze, as the name suggests, is analysis of the data collected in the previous phase. It is important to analyze the feedback given by customers, as they are the end users of the product and the product needs to match their needs. In this stage, the root cause of the problem is identified. A process chart, here, helps the team in understanding where the process of manufacturing the product has gone wrong.

Improve

The process chart helps the team in redesigning the process, after elimination of problems. A complete new process chart is then made, which highlights the changes and improvements to be

incorporated, in order to do away with defects. The concepts of total quality management and lean manufacturing are used in this stage. Documentation accompanies the new process chart, which provides the changes made in the process, in detail. Work at this stage becomes easy, if the team has collected enough data [2].

Control

This is the last stage in DMAIC model. After the new process is designed, the organization replaces the old process with the new one. The team closely monitors the working of the new process and ensures that there are no problems in the new process. They monitor the performance of the new process and ensure that products manufactured are defect free. If there are any further changes to be made, the team makes changes and again measures the performance of the process. Under proper guidance and observance of the team, new process is adopted by the organization [2].

RESULTS AND DISCUSSION

This section discusses all the stages of DMAIC methodology to go to the entire process and capture all the variables using the Six-Sigma Manufacturing Principles.

Define

The Project Team Charter (See Table 1) was filled to understand all the variables of motor's life expectancy tracking. The Project Charter contains all the metrics to be impacted. In addition, all the requirements, scope, resources are identified to facilitate tasks delegation and teamwork. The schedule is important to develop the research organize and in time.

Table 1
Project Team Charter

Project Title	**Implementation of Motor Tracking System**
Project Leader	Carla Parrilla Navarro
Project Start Date	June 2015
Project End Date	June 2016
Element	**Team Charter**
Process : The process in which the opporunity exist	Insulin Pump Assembly Line
Problem Description: Describe the problem that need to be solved, or the opportunity to be addressed	There was no established method for tracking an individual infusion pump's motor; therefore, the number of times (useful life) this component can be used (reclaimed and used again) is not determined. There is also no technical justification for the number of times this component is tested at a specific operation in the manufacturing line.
Objective: What improvement is targeted?	The objective of this research is to track each individual motor's life span in order to determine when the motors are not meeting its specifications.
Metrics: What are the measurements that quantify program process and success?	**Metric** / **Baseline** / **Goal** Life-span of the motor / 1218 cycles of usage / Track the baseline cycles and scrap unit when it reaches maximum cycles of usage
Element	**Team Charter**
Team Members: Names and Roles of Team Members	Jose Medina – Design Engineer Fernando Montano – Mfg. Engineer Hector Toro – QA Engineering
Benefit to External Customers:	Customers will have a motor that will function for the time frame established in the unit's specification.
Schedule: Give the key milestones and dates	**Key Project Dates** Define: June 2015 Measure : August 2015 Analyze: September 2015 Implement: January 2016 Control: June 2016
Budget: What financial resources are required for the team?	Assistance

After filling all the information presented in the Project Charter, many opportunities exist with the actual process.

Measure

In this phase all types of data will be collected in order to understand and identify were the root cause for the lack of a system to control and track how many times a motor can be reclaimed (used again as in a refurbished insulin pump). As part of

the investigation in regards to the motor reclaim process, an assessment was conducted comparing the return rates for "Motor Error Alarm" reason code between new and refurbished pumps during the 2 year period from July 2012 to June 2014. This comparison can be observed in Figure 6.

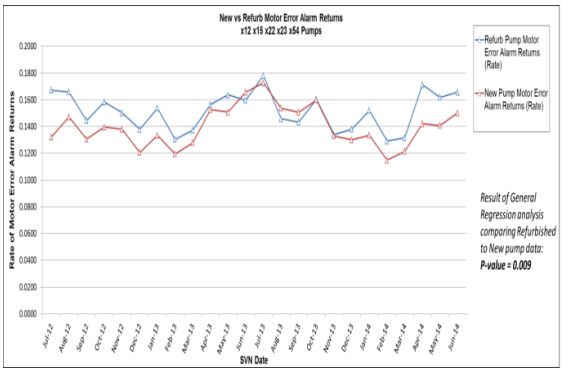

Figure 6
New vs. Refurbish Motor Error Alarm Returns

A regression model was used to evaluate the relationship between return rates between new and refurbished pumps with a significance level of 0.05. The resulting p-value was 0.009 indicating that there is a significant difference in the return rate between the two types of pump.

Based on the significant difference seen, the team investigated further into the data behind the return rate numbers. The top five (5) caused codes from failure analysis for Motor Error Alarm returns over the month of January 2014 are as illustrated in Figure 7:

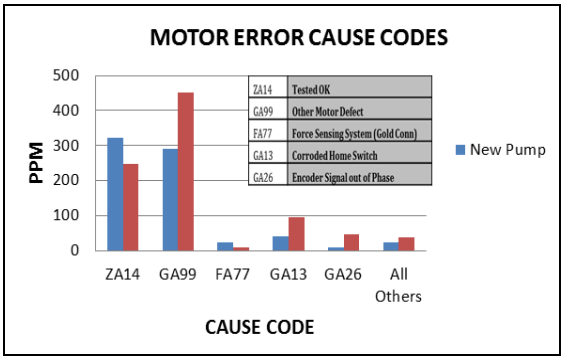

Figure 7
Motor Error Cause Codes

Of the cause codes identified, there is not any further detail behind the Tested OK (ZA14) and Other Motor Defect (GA99) codes to provide further insight into the failure mechanism and its relationship to the harvest process. The FA77 code has the smallest number of returns of the remaining codes and shows a higher rate for New Pumps compared to Refurbished pumps. Furthermore, the All Other category contains various independent failure modes that each provided minimal impact to the overall rate.

The two relevant cause codes, Corroded Home Switch (GA13) and Encoder Signal out of Phase (GA26), had the same regression analysis conducted as was performed on the overall return rate over the same 2 year time period (July 2012 – June 2014). Results are shown below in Figure 8 and 9.

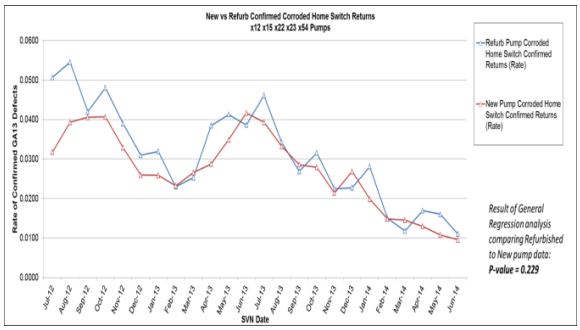

Figure 8
New vs. Refurbish Confirmed Corroded Home Switch Returns

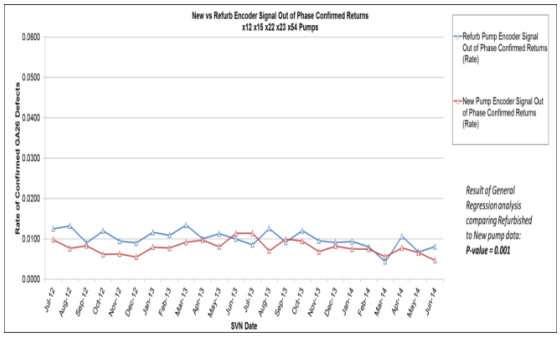

Figure 9
New vs. Refurbish Encoder Signal Out of Phase Confirmed Returns

While an overall statistical difference was not indicated for the Corroded Home Switch Cause Code (GA13) there is a difference for the Encoder Signal out of Phase Cause Code (GA26).

Failure Mode Effects Analysis (FMEA)

FMEA for the reclaim process identifies and documents the critical process failure modes and plans to mitigate and / or eliminate the risk(s) for the harvesting line process based on the assembly procedures. This document makes no distinction between the reclaim of refurbished pumps versus the reclaim of new pumps and does not include the risk(s) of reclaiming refurbished pumps which can ultimately result in the re-use of the same components multiple times.

Analyze

In this phase of analyze, different tools are to be made to identify the root causes for the lack of a system to control and track how many times a motor can be reclaimed (used again as in a refurbished insulin pump). The 5-Whys is a technique used in the Analyze phase of the Six Sigma DMAIC methodology. It is a great Six Sigma tool that does not involve data segmentation, hypothesis testing, regression or other advanced statistical tools, and in many cases can be completed without a data collection plan.

By repeatedly asking the question "Why", you can peel away the layers of symptoms which can lead to the root cause of a problem. Very often the apparent reason for a problem will lead you to another question. Although this technique is called "5 Whys," you may find that you will need to ask the question fewer or more times than five before you find the issue related to a problem.

5-Whys Analysis

A review of all of the configuration documents of the reclaim line was performed in which the following were included: the master validation plan, FMEA and assembly procedures. The conclusion was that the procedures do not contain clear controls for how many times the motor can be reclaimed and re-issued to a refurbished pump. To determine root-cause the 5-Whys problem solving method was used (See Figure 10):

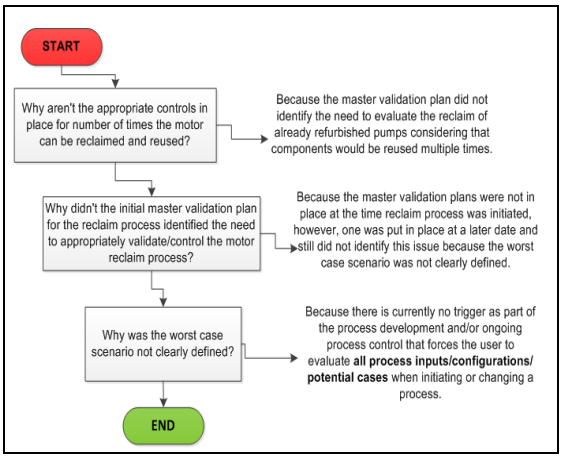

Figure 10
5-Why Analysis Diagram

The 5-Whys problem solving method determined that the lack of a system to control and track how many times a motor can been reclaimed is due to the lack of a triggering mechanism within the process development and/or continuous process control that will alert the process owner(s) to comprehensively assess how different inputs (i.e. a new pump versus a refurbished pump as an input to the harvest line) will impact the potential worst case scenario to be evaluated during process validation.

In addition to the root cause identified above, the team worked with outside experts to determine the product impact associated with the current compliance gap seen in the process. For the motor, while there is a statistically significant difference in the overall return rate for the Motor Error Alarm, this alarm is itself a mitigation to warn the patient of a potential issue. While the return rates are indicating a general increase, there is no immediate safety concern associated with the procedural non-compliance observed.

Motor's Maximum Number of Reclaim

An engineering report was created in order to define the maximum number of burn-in test cycles a new motor can withstand and to define the methodology to limit the number of times a motor and be reclaimed.

The report captures the rationale to limit the number of times a motor, can be reclaimed and

reissued through the harvesting line. Expanding the acceptance criteria within the harvesting process to include a limit to the number of times a motor can be harvested is necessary in order to ensure every motor that is reclaimed, reissued and assembled in a refurbished pump is still under the manufacturer's warranty. In addition this document established the maximum number of times a new motor can go through the Burn-In Test Cycle.

During manufacturing, the motor burn-in process is designed to ensure the drive system and its moving parts all function as intended. If anomalies were to occur in drive system components or during the pump assembly process, these issues could be caught during this test as a failure of the insulin pump to complete the programmed iterations or the pump issuing error codes for health monitoring checks.

To determine the maximum number of burn-in test cycles a new motor can tolerate and still meet the product's requirements, different specifications were used in order to obtain the following data:

1. Motor's Spec.
   - Minimum Life Expectancy = 1218 cycles.
   - 1 cycle = 6000 pulses to deliver 300-Unit vial followed by rewind.
   - Assumes user to consume 1 reservoir vial every 3 days.
2. Standard Operating Procedure for Burn-In Test.
   - Burn-In test = 100 cycles.
   - Burn-In test mimics 300 days of pump usage.
3. Standard Operating Procedure for Second Burn-In Test.
   - Burn-in Stabilization Test= 15 cycles.
   - Burn-in Stabilization Test mimics 45 days of pump usage.

The following acceptance criteria were determined:

1. The motor must pass every burn-in test cycle and burn-in stabilization test conducted.
2. The residual life of the motor after the final burn-in and burn-in stabilization test cycles needs to be equal or greater than four (4) years. The term of four (4) years was selected to ensure the motor's residual warranty by the manufacturer matches with Medical Device Company's warranty for a refurbished pump.

To determine the maximum number of burn-in test cycles a new motor can tolerate, the following equation (1) was created:

$$Residual\ Life \leq 3654\ days - (Number\ of\ Burn\ In\ Cycles) * 345 + 345) \quad (1)$$

Where:

- 3654 days represent the minimum number of cycles, 1218, multiplied by 3, the number of days to deliver 1 reservoir, per the motor's specification.
- Residual Life = 1460days representing four (4) years of usage.
- 300 days representing the first burn-in cycle test administered as part of the pump's assembly process.
- 45 days represent the first burn-in stabilization test administered as part of the pump's assembly process.
- 345 days represent both the burn-in test cycle and the burn-in stabilization test cycle.

Solving for Number_Burn_in_Cycles we have (Refer to (2)):

$$Number\ Burn\ in\ Cycles = (3654 - Residual\_Life - 345) / 345 \quad (2)$$

This equation calculates the maximum number of burn-in cycles for a new motor to be:

Number_Burn_in_Cycle = 5.3594

It can be concluded that for a new motor, the Number_Burn_in_Cycles is 5 (rounded to the nearest integer).

Harvested Motor Analysis

The maximum number of burn-in test cycles a previously reclaimed motor can withstand can't be

determined with the previous equation because the number of days a motor is out in the field is not constant but a variable unique to each pump; therefore, the Residual_Life equation was modified to include the number of days the motor was in used by a consumer. The result is the following equation:

$$Residual\_Life \leq 3654 - (Number\_Burn\_in\_Cycles * 345 + 345) - (Current\_Date - Shipped\_Date) \quad (3)$$

The Residual_Life equation will be part of the motor tracking system database used to identify and only accept motors that have a residual life greater to four (4) years after the motor has gone through pump assembly process. The motor itself has reliability test data that supports up to thirty (30) years of use however the supplier only warrants the motor for ten (10) years based on the specification and therefore only motors with a minimum of four (4) years under warranty will be reclaimed and reissued to refurbished pumps.

Improve

In this phase of improve, different tools were used to make action of the possible root of causes. This phase is important to prove that the possible causes of the problem are the correct one. It is used to identify potential failure modes, determine their effect on the operation of the product, and identify actions to reduce the failures. In resume this phase is going to show the implementation of the different tools to make sure that the real causes that is found in the previous phase is the correct and to show the difference of before and after that tells us the causes of the problem was resolved.

In order to mitigate the lack of a system to control and track how many times a motor can been reclaimed, a vision system with a web-based application that shall be used as the motor tracking system at the manufacturing line.

The system consists of an Optical Character Recognition (OCR) camera with a custom configuration file that reads the motor's batch/serial number for the insulin pumps. The user places a motor drive assembly into a fixture that holds it in position. The user then presses a trigger on a touchscreen display to command the camera to capture the batch-serial number. Once the batch-serial number is captured successfully, it is transferred to a Web-Based Application Report. The report records the batch-serial number if the drive motor assembly is being used for the first time or in case it is been reclaimed, verifies if the motor complies with its expected life and is fit for use (See Figure 11 for a system's high level diagram).

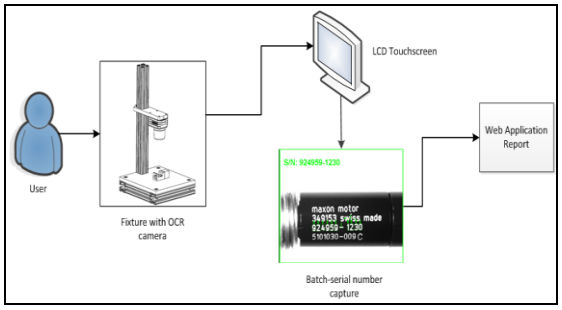

Figure 11
High Level System Diagram

The Web-Based Application Report was created as a table form report. This table-form will make the information easier to understand for the manufacturing operators. The table contains several columns named as follow:

- Motor_Batch_SerialNumber
- 1st_Date_Issued
- Number_of_Reclaim
- Current_Date
- Residual_Life
- Min_Life
- Equation_Result
- Motor_Result

The report will have several scenarios where a new motor's serial number will be entered or a reclaimed (already used by a user) motor's serial number will be the input. The report will be able to update the all the columns depending on the entered serial number and will display a pass/fail result in order to alert the operators to discard the motor since it is not complying with the specification.

Motor_Batch_SerialNumber		1st_Date_Issued		Number_of_Reclaim
1533098-0001		12/31/2008		2
Reclaim_Date	Residual_Life	Min_Life	Equation_Result	Motor_Result
5/13/2015	1460	3654	430	FAIL

Figure 12
Web-Based Application Report – Fail Example

Control

The main goal of this phase is to hand off and delivers to the management the control of the improvement done. For this phase, an effectiveness plan was conducted in order collects evidence to establish whether the actions taken were effective at addressing the identified causes. In the plan, fifty-nine (59) motors that were confirmed to be eligible for use in finished goods were randomly selected between different shifts during one (1) month review period. The review was conducted to confirm the motor samples have correctly been assessed by the operator and met the Motor Tracking System acceptance criteria per the specification and standard operating procedure of the designated manufacturing stations. All fifty-nine (59) motors sampled must meet the following criteria:

- All motors sampled must have gone through the motor tracking system.
- All motors sampled must have remaining residual life greater or equal to 4 years.

After completing the plan, fifty-nine (59) motors were randomly selected between two different shifts over a period of 10 days during the one month review period.

The randomly sampled components were documented on data sheets and initialed by the sampler and verified by a peer reviewer.

The randomly sampled fifty-nine (59) motors were submitted to IT (Information Technologies Department) to run a report to determine that the motor met the acceptance criteria. This report indicated that data gathered by the tracking system reports and displayed remaining life or reclaim time for each component. The report contained a column where it states whether the serial numbers passed the criteria or not (PASS/FAIL). All fifty-nine (59) motors passed acceptance criteria, deeming the effectiveness check 100% effective.

Failure Mode and Effect Analysis (FMEA)

After the implementation of the tracking system, the FMEA for the process that inspect the motor's useful life was updated (See Figure 13). The three criteria, Severity, Occurrence, and Detection, are rated on scale of 1 to 5, with a 1 representing only the minor incidence and 10 represent catastrophic event. The product of these three criteria ratings becomes the risk priority number (RPN). The higher RPN prioritize the need to eliminate the cause, reduce the frequency. RPNs that are between the ranges of zero (0) to thirty-five (35) are considered low-risks and no further actions are required.

Process Step	Potential Failure Mode	Potential Effects of Failure	End User Severity	Mfg. Process Severity	Severity (Max.)	Potential Causes	Occurrence	Current Control	Detection	RPN
Inspection of Motor	Reclaiming a motor that its residual life is deemed as FAIL in Web Tracking System	Loss of pump function causing the user to revert to manual injection of insulin	1	3	3	Operator Error - Scan incorrect number	2	1. SOP and Training 2. Motor Functional Test at Insulin Pump Assembly Line	3	18
Inspection of Motor			1	3	3	Operator Error - Passes already identified in Web Report as Fail unit	2		3	18
Inspection of Motor			1	3	3	Vision System Fail to detect correct serial number	2		3	18
Inspection of Motor			1	3	3	Vision System Cannot Detect Serial Number - Error in manual entry	2		3	18
Inspection of Motor			1	3	3	Motor is not part of the Database	2		3	18

Figure 13
FMEA Analysis

CONCLUSION

During this research the team identified the real causes for lack of a system to control and track how many times a motor can been reclaimed. The main problem was related to an observation that resulted from two separates audits in a Medical Device Company. Using several DMAIC tools, like 5-Why Analysis, the existing gap was measured and analyzed. Then, improvement suggestions were

presented, addressing the causes mentioned above, including the development of an improvement plan, based on the results of the prioritization matrix developed in the improvement phase. The result was the implementation of a tracking system that is able to track an insulin pump's motor useful life, which mitigates the initial problem statement and audit observation. It is important to monitor the effectiveness of this system after these improvements are in place and running.

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