Battery Assembly Re-design in a Medical Device Company

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Abstract *— Today, customer complaints is a strategic business metric for the organizations to measure the customer satisfaction and product's performance. During YR2011, an adverse trend on complaints per million (CPMs) was observed in a medical device due to loss of power issues. This represents a decrease in customer satisfaction and product's performance. The intention of this Design Project was to reduce the CPMs by 50%. DMAIC (Define, Measure, Analyze, Improve and Control) methodology was used as a problem solving tool to identify the root causes and improve the product performance. Brainstorming, Failure Analysis, Cause & Effect diagram and Pareto chart were some of the tools used to understand the relationship between the potential causes and determine which contributes significantly to the top offender. Finally, a solution was implemented to address the root cause of the top offender achieving a reduction of CPMs by 81%.*

Key Terms *— Complaint per Million (CPMs), DMAIC, Error 0010, Medical Device.*

PROBLEM STATEMENT

The medical device industries are regulated and monitored by the United State (U.S.) Food Drug and Administration (FDA) to ensure that organization operates in a known state of control. FDA requires that the companies manufacture and deliver safe and effective products. Complaints per million (CPMs) are one of the quality indicators measured by the medical device industry to evaluate the customer satisfaction and cost of poor quality. During YR2011, an adverse trend on CPMs were observed in a medical device (Product X) causing a decrease in customer satisfaction.

Research Description

In comparison with the last year (YR2010), the CPMs for this medical device were 956. For year 2011, the CPMs were 5000. The complaints received for this medical device are associated to loss of power or unit did not turn on. Products with a high quality level are requested by the customers in a timely manner.

Research Objectives

The objective of this design project is to reduce the CPMs of this medical device by 50%.

Research Contributions

The reduction of the CPMs for this medical device leads to increase the safety and effectiveness of the device, reduce potential liability and regulatory exposure, increase customer satisfaction and lower failure costs due to sales revenues lost. Also, it will help to increase the competitiveness of the Medical Device Industry and reduce the potential risk of a product action.

LITERATURE REVIEW

This literature review provides relevant information in essential topics to enrich readers' knowledge of the problem statement and the business area of this design project.

Medical Device

A medical device is defined within the Food Drug & Cosmetic Act as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or

prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." [1]

The medical device under this design project is a diagnostic tool that helps to identify discogenic pain or degeneration, condition in which the physical and chemical properties of the disc slowly deteriorate. This device does not sustain or support life.

Quality Indicators

Quality indicators are objective and quantitative measures of key system elements performance. They indicate the extent up to which a certain system meets the needs and expectations of the customers. Quality indicators should have clear and unambiguous definition and interpretation, whereas the ability to measure the indicator is a pre-requisite for its successful implementation, reproducible application, monitoring and evaluation. Some medical device industries establish as quality indicators the following metrics: yield, rework, and scrap rate, defects per million or complaints per million. Besides for self-evaluation, quality indicators can also be used for benchmarking and to recognize or implement program that helps to achieve organizational breakthroughs in performance.

Complaints

Customer complaints is any written, electronic, or oral communication that alleges deficiencies related to a device after it has been released for distribution, including the device's identity, quality, durability, reliability, safety, effectiveness or performance [2].

Today, customer complaints represent an opportunity to increase customer loyalty and a risk of losing customers. As part of an effective complaint handling system, manufacturers should understand that any complaint received shall be evaluated and, if necessary, thoroughly investigated and analyzed to take the appropriate corrective actions. Also, complaints are an excellent indicator of problems with the use, design, and/or manufacture of a product.

Six Sigma

Six Sigma is a set of practices originally developed by Motorola in the mid-1980s to improve customer satisfaction by eliminating defects [3]. This methodology pursues continuous improvement in customer satisfaction and profit that goes beyond improvement methodology to reduce variation of key elements. It is commonly used in organizations in order to help large and small companies to reduce defects, improve process, delight customer satisfaction and increase profits. The success of Six Sigma is linked to a set of cross functional metrics that lead to significant improvements in customer satisfaction and bottom line benefits [4].

The Six Sigma Methodology consists of five steps that help to identify the direction of the project: Define Measure, Analyze, Improve and Control. Define phase determines the customer's requirements or what's importance for the customer, the objectives that need to be evaluated, the team charter, project plan, process maps, and it evaluates the just do-it opportunities. Measure phase collects the data on the type of defects or key characteristics, reviews customer requirements and determines key processes, product standards, and settings the process performance. Process Map and Cause & Effect Diagram are developed to identify the critical inputs that need to be evaluated. Analyze phase is the critical part of the DMAIC methodology in which data collected in the Measure is analyzed using Pareto charts, histograms, and statistical hypothesis testing to narrow down the cause of defects. The purpose of this phase is to reduce the number of variables that need to be investigated or improved by the team. During the improve phase, designs and experiments are executed in order to confirm the root cause of

the defects and the relationship to the process. Also, the team should have identified suspect variables and developed a plan for improvements. Finally, the Control Plan step implements and monitors the improvements to sustain the outcome.

PROJECT METHODOLOGY

DMAIC Methodology was used as problem solving tool in order to reduce the adverse trend on CPMs. The methodology consists of five phases: Define, Measure, Analyze, Improve and Control. Each phase will be described in details to show the methodology used on each stage of this Design Project.

Define

During this phase, a project charter was created to define the problem statement, the business impact, goals, scope, timeline and defined team. A high level process map "SIPOC" (Supplier, Input, Process, Output & Customer) was generated to capture the information critical of the project and to verify that process inputs match outputs of the process. Critical to Quality (CTQ) are described to present the project objectives, identify the internal and external customers and the metric to improve.

Measure

As part of the measure phase, baseline and target performance of the process were defined with the collection of reliable data on quality. Trend analysis was used to evaluate the tendency of CPMs by manufacturing date. Pareto Chart was created to identify the top offender on complaints received for this Medical Device during the affected time frame.

Analyze

The analyze phase consists on root cause analysis to determine the critical X's or critical inputs that affects the process outputs (complaints per million). Some of the tools used for the root cause analysis were the following:

- Brainstorming – to determine potential source for the defect
- Failure Model Effect and Criticality Analysis (FMECA) – step-by-step approach that identify all possible failures in a design, manufacturing or assembly process, or product helping to remove causes of failures and to develop systems that can mitigate the effect of the failure. This approach is executed during the design phase of a product.
- Failure analysis – to investigate and evaluate the received complaints to determine possible root causes.
- Cause and effect diagram – to trigger potential sources (causes) of a problem (defect). Each of the potential causes identified during the brainstorming, FMECA review, failure analysis were investigated to rule out and determine the most likely source of the defect.

Improve

The objective of the improve phase is to generate robust solutions in order to improve the causes that affect the critical outputs (CPMs). Decision matrix was developed in order to evaluate the different alternatives to address the problem and to select the best alternative for implementation. The deliverable of this phase is to achieve an improved process that is stable, predictable and meets customer requirements.

Control

The control phase consists of generate a control monitoring plan to verify that the implemented actions address the root cause and to evaluate the CPM metric after the improvement. To sustain the implementation, drawing and manufacturing procedure were updated and training was provided to the manufacturing associates to certify them on the new revision of the procedures.

RESEARCH RESULTS AND DISCUSSION

The results and deliverables obtained in this design project will be presented and discussed following the DMAIC methodology.

Define

The adverse trend of CPMs for this medical device from 2010 to 2011 represents an increase of 523% (5000 YR2011 vs. 956 YR2010). The scope of this design project is to reduce the adverse trend of CPMs due to loss of power issues on this medical device. Figure 1 shows the project charter created to define the problem statement, objective, project scope and team for this project.

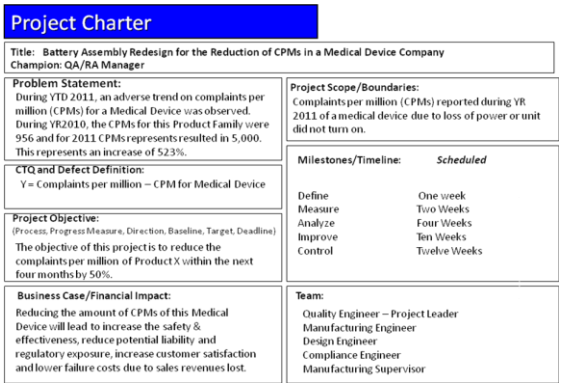

Figure 1
Project Charter

To determine the customer needs, a Critical to Quality (CTQ) Diagram was created. Figure 2 defines the customer need as receive a medical device with 0 defects due to out of box failures or failures during usage of the device. The drivers to have a product with 0 failures at the customer level are associated to no defects on components, capable manufacturing process with Standard Operating Procedures (SOPs), and well trained manufacturing associates and users of the device. SIPOC diagram on Figure 3 was developed to provide a snapshot of the process. For this medical device, the suppliers of the components on this medical device as the main printed circuit board (PCB), batteries, housing, syringe and liquid crystal display (LCD) screen were identified. The inputs of the assembly process until delivery are the components (PCB, batteries, LCD, etc), operators, inspectors, manufacturing instructions, equipment, etc. The output of the process will be finished product and batch record. The customers are the patient, doctor, Quality Assurance Department and Regulatory Agencies.

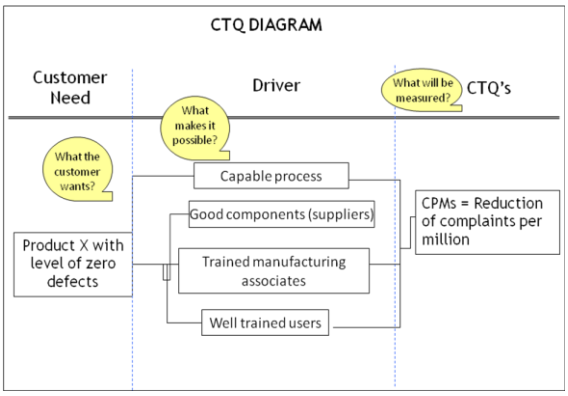

Figure 2
CTQ Diagram

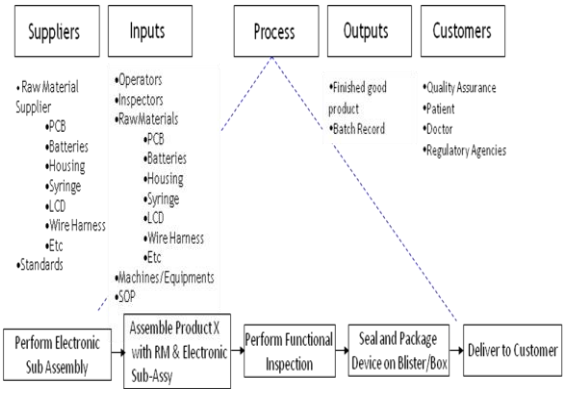

Figure 3
SIPOC Diagram

Measure

During the measure phase, trend analyses were performed to evaluate the complaints received by entry date and manufacturing date for this medical device. On Figure 4, it was observed a peak of complaints received of Product X during August 2011. The reported CPMs for August 2011 were 60,606 vs. 956 CPMs for YR2010. In terms of complaints, a total of 58 complaints were reported during YR2011 vs. 12 complaints on YR2010. After August 2011, a reduction of complaints was observed due to the containment actions taken on September 2011. On Figure 5, trend analysis for manufacturing date was performed and it was observed that the spike of complaints for the Product X belongs to devices manufactured on April 2011 (20 complaints). As containment, product hold action was taken for lots manufactured on April 2011. Lot information for 18 reported

complaints was not provided by the account; therefore, manufacturing date cannot be determined.

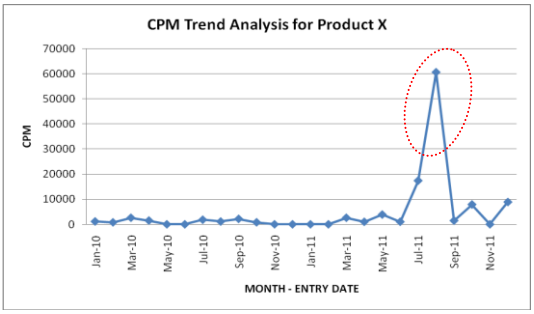

Figure 4
CPMs Trend Analysis for Prodcut X by Entry Date

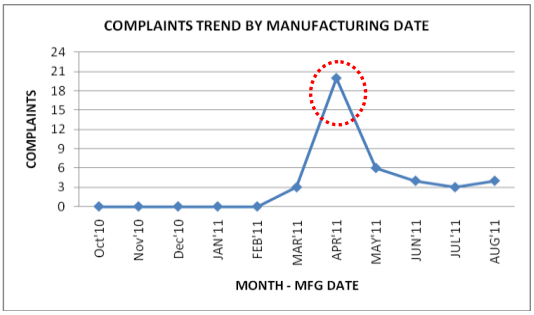

Figure 5
Complaints Trend Analysis per Manufacturing Date

Figure 6 shows the Pareto Chart created to determine the top failure mode or complaints for Product X for YR2011. According to Pareto Chart, the main defect (complaint) is low battery (Error 0010) which represents 80% (46 out of 58 complaints reported) for Product X during YR2011.

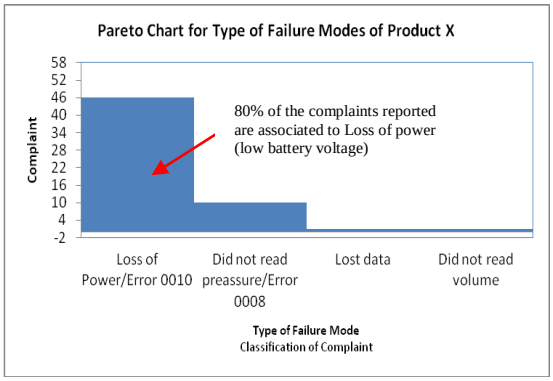

Figure 6
Pareto Chart for Type of Defects

The actual configuration of the electronic sub-assembly (Figure 7) consists of this medical device consists of a PCB board with a battery holder which carries two shim washer on the bottom and two lithium batteries of 3 volts (V) on top of the shim washer. The shim washers are used on this electronic sub-assembly to create more compression between the batteries and holder to avoid separation from the holder. Also, a foam pad is used to keep the assembly in place.

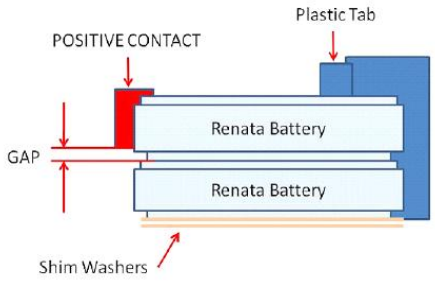

Figure 7
Electronic Sub-Assembly (Actual Configuration)

A low voltage failure represents a dead on arrival or an Error 0010 on the LCD screen. According to the FMECA (Failure Mode, Effect & Criticality Analysis) for this medical device, this failure mode results in a primary function loss (device will be inoperable). According to the data obtained on this phase, it is assumed that some input of the manufacturing process changed on April 2011 (raw material, inspection process, SOPs, etc) affecting the device's performance in terms of loss of power issues at the customer level.

Analyze

As part of the problem solving process, cause and effect diagram was used to trigger potential sources (causes) of a problem (defect). Potential sources for low battery voltage were provided by the FMECA (Failure Mode, Effect and Criticality Analysis) that was documented in the Design Phase of Product X. According to Figure 8, the sources that can contribute to low battery voltage on Product X are:

- Materials
  - Corrosion on lithium batteries
  - Lack of adhesive on the foam pad
- Method

- Design of the battery holder with the assembly of two shim washers causing a short circuit

- Man
  - Missing two or one of the shim washer
  - Missing one or both lithium batteries
  - Missing foam pad
  - Shim washer placed at the incorrect location (between batteries) creating a short circuit
  - Foam pad not placed correctly causing that batteries get loose
- Measurement
  - Shim washer thickness out of specification
  - Battery thickness out of specification
  - Battery holder height to positive contact out of specification

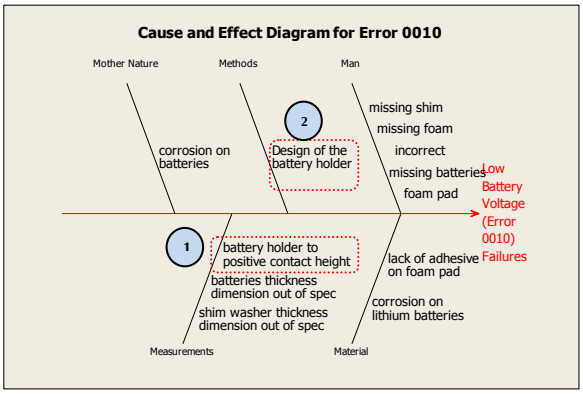

Figure 8
Cause & Effect Diagram of Error 0010/Low Battery Voltage

Failure analysis was performed to investigate received samples and to rule out the potential causes. The results of the investigations were the following:

- no corrosion on batteries and foam pad was in place
- presence of adhesive of foam pad was observed
- electronic sub-assembly were assembled as per manufacturing procedures (no missing components, or inadequate location of the components)
- shim washer and batteries thickness are within specification

As part of the failure analysis of the complaints received by the account vs. retained samples of the Product X, it was observed differences in the battery holder component of the PCB board. Defective units with low battery voltage did not have a "Swiss Made" engraving on the battery holder that the good units have. See Figure 9 for Non Swiss Made Engraving (China Battery Holder) and Figure 10 for Swiss Battery Holder.

Figure 9
Non-Swiss Battery Holders (Bad)

Figure 10
Swiss Batter Holder (Good)

The battery holder is supplied by a distributor to a second party supplier for the manufacturing process of the PCB board. Then, this PCB board is supplied to this medical device company for the manufacturing process of the Product X. As part of the failure analysis, it was found that the supplier of the battery holder changed the manufacturing location from Switzerland to China and the change was not informed to the distributor and supplier of the electronic PCB board.

A dimensional analysis for three different battery holder groups was performed to evaluate if there is a difference in the battery holder housing to positive contact height that could affects the stack up of the parts creating a short circuit. The groups to measure the battery holder height were the following: five (5) good units with battery holders "Swiss Made", five (5) good units with battery

holders “China Made” and five (5) bad units with battery holder “China Made”. According to Table 1, it was found that the average height of the “Swiss Made” parts was 0.072”. The average height of the “Good- China Made” holders is 0.069” which is already 0.003” less than the average height of the Swiss made parts. The failed “China Made” holders are even worse with an average height of 0.068” which is a total of 0.004” less than the good “Swiss Made” parts.

Table 1
Summary of Battery Holder Dimension

Type of Battery Holder	Min – Max	Average	Standard Deviation
Bad China Battery Holder	0.066”-0.069”	0.068”	0.001291”
Good China Battery Holder	0.068”-0.070”	0.069”	0.000816”
Good Swiss Battery Holder	0.071”-0.073”	0.072”	0.000957”

A two sample t test was performed to analyze the difference between the two means (China Battery Holder Heights vs. Swiss Battery Holder Height) to determine whether the difference is statistically significant. The hypotheses of a two-tailed test were defined as:

- H_0: $\mu_1 - \mu_2 = 0$ (means from both battery holder height are equal)
- H_1: $\mu_1 - \mu_2 \neq 0$ (means from both battery holder height are different)

According to the results obtained on the two sample t-test, the p-value is less than .05. Based on this statistical analysis, it was determined that the difference between both means are statistically significant different. The box plot shows the difference between the averages of the two samples (Good_Swiss vs. Bad_China). According to the Figure 11, it was confirmed a reduction on the battery holder height for the samples classified as Bad_China.

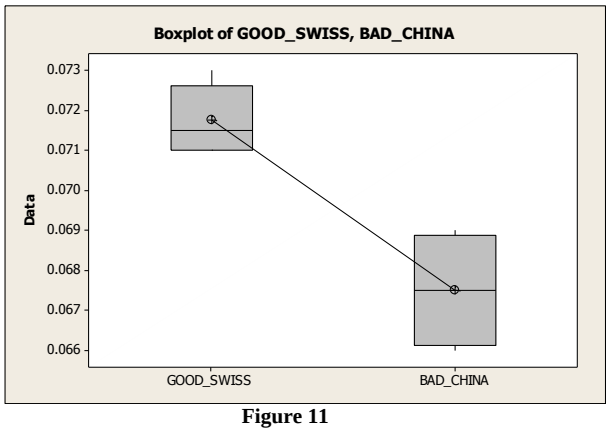

Figure 11
Boxplot of Swiss vs. China Battery Holder

To confirm the root cause, functional testing was performed with thirty (30) units with battery holders from China and thirty (30) units with battery holder from Switzerland. The testing consisted on verify the functionality of the samples at different process inspection points with Swiss Made and Non Swiss Made (China) Battery Holders. According to results on Table 2, the root cause for this failure mode was confirmed. Loss of power or did not turn on Product X is caused by a discharged or drained top battery due to a short circuit of the positive contact of battery holder with the bottom battery due to a reduction on height dimension of the battery holder from housing to positive contact. This dimension was affected by a change of the manufacturing location of the battery holder’s supplier from Switzerland to China.

Table 2
Testing for Root Cause Confirmation

Process Inspection Points	Switzerland (Swiss Made)	China (Non Swiss Made)
During the assembly of the PCB Board at the manufacturing line (in-process inspection)	No failures	2 failed Error 0010
During the test in functional tester (final inspection)	No failures	No Failures
Functional testing after shake and drop	No failures	5 Units failed: - 2 Error 0010 - 3 Dead on Arrival (Didn’t turn on)

Improve

Based on the analyze phase results, improvements were required to re-design the electronic sub-assembly or battery holder helping to remove the cause of the defects. Since the specification for this dimension could not be controlled at the supplier, it was decided to re-design the electronic sub-assembly of the main PCB Board.

Actual configuration for the electronic sub-assembly consists of two metal shim washers and two lithium batteries of 3 volts in the battery holder with a foam pad placed to hold the batteries in position (Figure 7). The thickness for the bottom metal shim washer is 0.135 ± .015mm. The two short terms solutions consist of:

- Top shim washer design (Figure 12) - metal shim washer on top of the batteries instead of two bottom metal shim washer.
  - Thickness specification: 0.18 ± .02mm
  - Material: Metal (Steel)
  - Unit Cost:
    - $ 0.187 per medical device (1 metal washer)
    - $ 1.87 per box (10 devices per box)
  - Human Error Possibility: Wrong placement of washer
  - Detection/Verifiable: 100% Verifiable (Visual)
- Middle shim washer design (Figure 13) – plastic and metal shim washers to be located in the middle of the two batteries instead of two bottom metal shim washers.
  - Thickness specification for metal washer: 0.135 ± 0.015mm
  - Thickness specifications for plastic washer: 0.045 ± 0.005 mm
  - Material: Plastic and metal (Steel)
  - Unit Cost:
    - $1.483 per device
    - $14.83 per box (10 devices per box)
  - Human error possibility: Missing one of the washer
  - Detection/Verifiable: Unable to verify after placement of foam pad

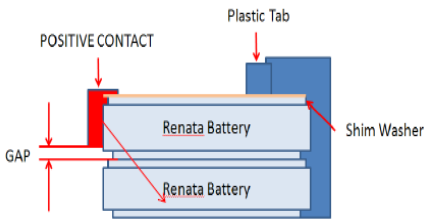

Figure 12
Top Washer Battery Assembly Redesign

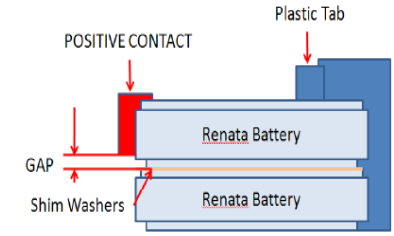

Figure 13
Middle Shim Washer Assembly Redesign

Testing was conducted to evaluate both alternatives in terms of robustness design. According to the testing results, zero failures of short circuit and batteries coming loose after environmental and packaging simulation testing (vibration and drop) for the middle and top washer were identified. An additional extreme test was conducted to evaluate the potential failure mode without packaging and it was found that failure rate for the top washer was 26.7% (4 out of 15) and 53.3% (8 out of 15) for the middle washer. The observed defect was batteries coming loose, no short circuit was observed.

Decision matrix was generated to evaluate the alternatives in terms of time to market, robustness, verification requirements (validation activities), ease of installation (manufacturability) and unit cost. According to the results on Table 3, it was found that the top shim washer design was selected with a score of 60. The top washer design will prevent short circuit of the bottom battery with the positive contact. The middle washer idea will be a backup plan since both alternatives y both demonstrated to be effective after testing.

Based on the selected alternative, the proposed configuration consists of two lithium batteries

placed on the bottom of the battery holder, then the top shim washer and the foam pad to hold the parts in position. The relocation of the shim washer to the top of the assembly will help to have the bottom battery away from positive contact.

Table 3
Battery Holder Short Term Decision Matrix

Solutions	Factor	Time	Robustness	Verification of requirements	Ease of installation	Unit Cost	Score
	Weight	5	4	3	3	1	
Top Washer		5	3	4	2	5	**60**
Middle Washer		5	2	4	3	4	58

As part of the implementation of the corrective action, functionality test was conducted after environmental conditioning, drop and vibration simulations of the packaged units with top washer design. After simulation, units were removed from the package to verify that medical device turn on after press the ON button. According to the test results, all samples units (37) turned on. No failures of Error 0010, loss of power issues or did not turn on (Dead on arrival) were observed.

Drawings and manufacturing tasks instructions were updated to reflect the new redesign of the electronic sub-assembly. Training was provided to the manufacturing associates to certify on the new manufacturing process for the electronic subassembly of this medical device.

Control

Control plan was implemented to monitor the CPMs trend for the Loss of Power Issues on this product. As part of the effectiveness evaluation, three months of monitoring were established to verify that the implemented action addressed the root cause. Currently, the improvement is under monitoring to complete the period of three months of evaluation. A trend analysis of the CPMs to evaluate the following stages was executed:

1. Before corrective action – a total of 48 complaints were reported from January 2011 to September 2011
2. During containment action, product hold of potential lots manufactured with China battery holders was performed and Product X was manufactured with the depletion of the Swiss Battery Holder. A total of 12 complaints were reported from October 2011 to January 2012
3. After corrective action – two complaints have been reported for units from February 2012 to March 2012 after the top washer implementation. The two complaints reported are not associated to the Loss of Power or Didn't Work Failures.

After the implementation of the top washer battery redesign, it can be observe on Figure 14 that the CPMs improvement represents 81% of reduction from the baseline 5000 CPMs during YR2011 vs. 962 CPMs after corrective action. Complaints are reported in a weekly basis and discussed with the staff in order to monitor the goal of this design project.

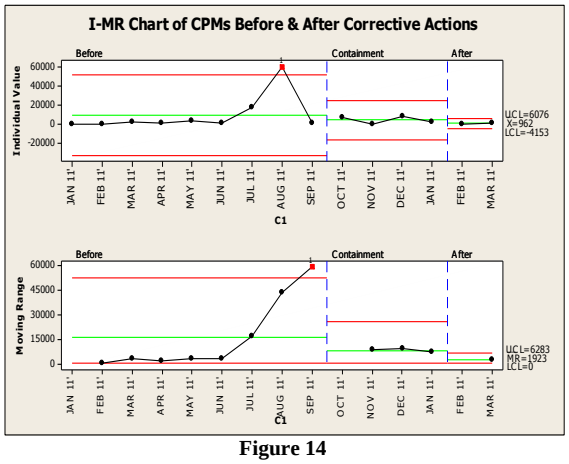

Figure 14
CPMs Trend Before and After

CONCLUSION

The continuous monitoring of quality metrics as CPMs and applications of problems solving tools (DMAIC) are fundamental to evaluate the customer satisfaction and performance of a medical device

and to address the root cause of the failures. According to the investigation, the root cause for the adverse trend of CPMs due to loss of power issues on this medical devices was identified as a short circuit of the bottom battery with the positive contact due to a change on height dimension on the battery holders provided by a new manufacturing location (China instead of Switzerland). A new re-design of the battery sub-assembly was implemented as corrective action to avoid this short circuit.

As part of the improvements, a reduction of CPMs by 81% for this medical device was obtained in comparison with the baseline CPMs for YR2011. After the implementation of the top washer configuration, no complaints have been reported for Loss of Power during February 2012 & March 2012. Therefore, the goal of reduce 50% of the CPMs after improve phase completion was achieved.

The results of this design project represent an increase on the performance of this medical device associated to low battery voltage and reduction of a potential regulatory exposure. Since the complaints measure the customer dissatisfaction, the reduction of the CPMs after the corrective action by 81% represents an increase of the customer satisfaction on this medical device.

As part of a future research, custom battery holder can be evaluated to remove the foam pad and top washer of the electronic sub-assembly reducing material costs and avoiding potential failures of low battery voltage due to loose batteries during shipping or handling by missing foam pad.

To sustain the continuous improvement, quality metrics as CPMs and process needs to be monitored to identify potential quality defects on the medical devices and prevent out of control trend.

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