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ABSTRACT

Poor fill rates at manufacturing line for models 5038 and 4968 are problems that affected the cost metrics due to overtime and dissatisfaction of our patients around the world. The main cause of this problem is high lead time and waste during the operation process. The processes in the two-manufacturing models 5038 and 4968 were studied in an effort to reduce the operational waste during manufacturing process, reduce or eliminate the overtime, reduce the lead time for both models and create pull system. Applying the DMAIC methodology, the fill rate was improved from 64.3% to 93 % by reducing operational wastes, reducing lead time, and creating pull system that will allow cost saving around \$15,000 and improve patient satisfaction.

INTRODUCTION

Medtronic was founded in 1949 by Earl Bakken and his brother-in-law Hermundslie Palmer. Medtronic is a leading manufacturer and supplier of heart pacemakers, and, at Puerto Rico, it has plants in Juncos, Humacao, Ponce and Villalba.

This project was carried out at the Medtronic Villalba Campus (MVC), where its main manufacturing process are the cables for multiple models of pacemakers. MVC is currently experiencing problems with pacemaker leads at Legacy Business Units on Multi Line areas 202 and 208. The main problem is the poor fill rate causing cost issue and not meeting fill rate demands on time.



Figure 1: Medtronic Company Logo



Figure 2: The Six Sigma DMAIC methodology

BACKGROUND

The objective of this project is to decrease the time of the operations for models 5038 and 4968, complying with a weekly fill rate between 93% to 95% of the internal client. The Six Sigma DMAIC methodology was followed to perform the project. This methodology has five phases (Define, Measure, Analyze, Improve and Control) which try to optimize processes and provide solutions.

The Fill Rate is the percentage of what is delivered to the client weekly according to demand. Weekly is defined from Monday to Friday. The problems were identified on 5038 and 4968 models. These models are not reaching the client on time due to the high demand and the large number of other models that run through these lines. This issue is impacting cost metrics at around \$15,000 per month since they are working overtime on Saturdays to meet the weekly demand.

The current state for these models is a 64.3 % of fill rate, working overtime increasing cost metrics, high operational waste, and poor customer services. The future state is increasing the fill rate percentage between 93% to 95%, reduce overtime, eliminated waste, and reduce operational lead time.

ANALYSIS

The Define phase was the first activity completed for the project. The scope of this phase was to generate project kickoff meeting to formally notify the sponsors and stakeholders that the project begun, interview the manufacturing operators, engineers, manager, amount other key personal to request information and completed Gemba walks to understand current process.

The Measure phase is used to explain and understand the current state of the manufacturing area, operational processes and products that represent the current problem. During this phase, various Industrial Engineering tools that will support to understand processes of models 5038 and 4968 were developed. The focus is to collect all significate data as time studies to apply statistical methods as Initial Capability, Takt time and spaghetti diagram to provide visual aid to understand current processes.

Time studies for 5038 model has 17 operations and 4968 model has 13 operations where each operation is divided into elements and time recording were performed for all element and identified each as Value Added or Non-Value Added. Figures 3 and 4 present the time studies data for models 5038 and 4968.



Figure 3: Time studies data for Model 5038

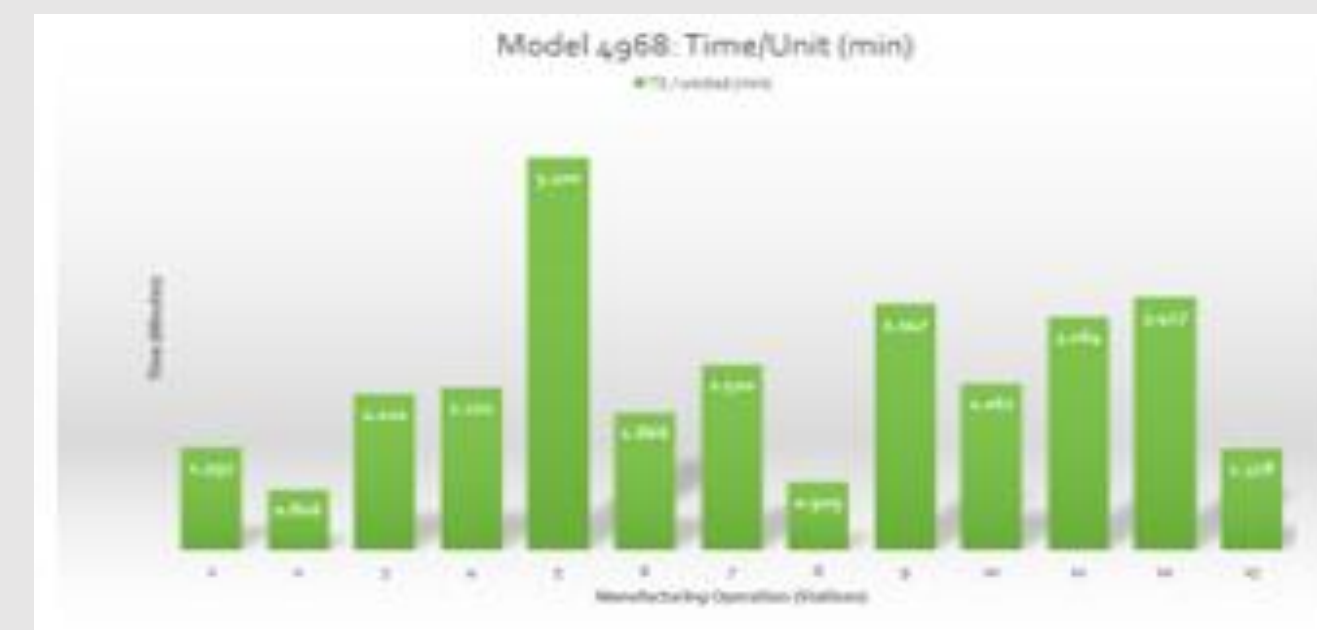


Figure 4: Time studies data for Model 4968

MVC provides a report to understand the fill rate for the last 22 weeks to generate the Initial Capability. The Initial Capability is used to determine whether the process is capable of meeting the desired specifications. After obtaining the data, the computer program Minitab was used to develop the control charts for the Individual Value & Moving Range Chart. Process Data table shows the Low Specification limit (LSL) which is 93% and the Upper Specification Limit (USL) which is 95%. The mean is 64.28% with an N of 22 weeks.

The Analyze phase had numerous tools that support any team to spot the problems and effectively determine the main reason of the issue. One of the tools used to analyze all the data gathered during Measure phase is the Cause-and-Effect Diagram with the Fishbone Diagram. This graphical tool helps the team identify the cause of the problem, not just the symptoms.

This diagram enables a team to focus on the content of the problem rather than its history or the individual interests of team members. The problem is stated at the right side of the diagram. The project team works to the left by filling in and examining potential causes of problems such as materials, people, and methods. The Spaghetti Diagram tool, useful industrial aid that provide visual for the current flow that the products go through on each operation. Figure 5 and 6 present visual aid for current flow for each model.

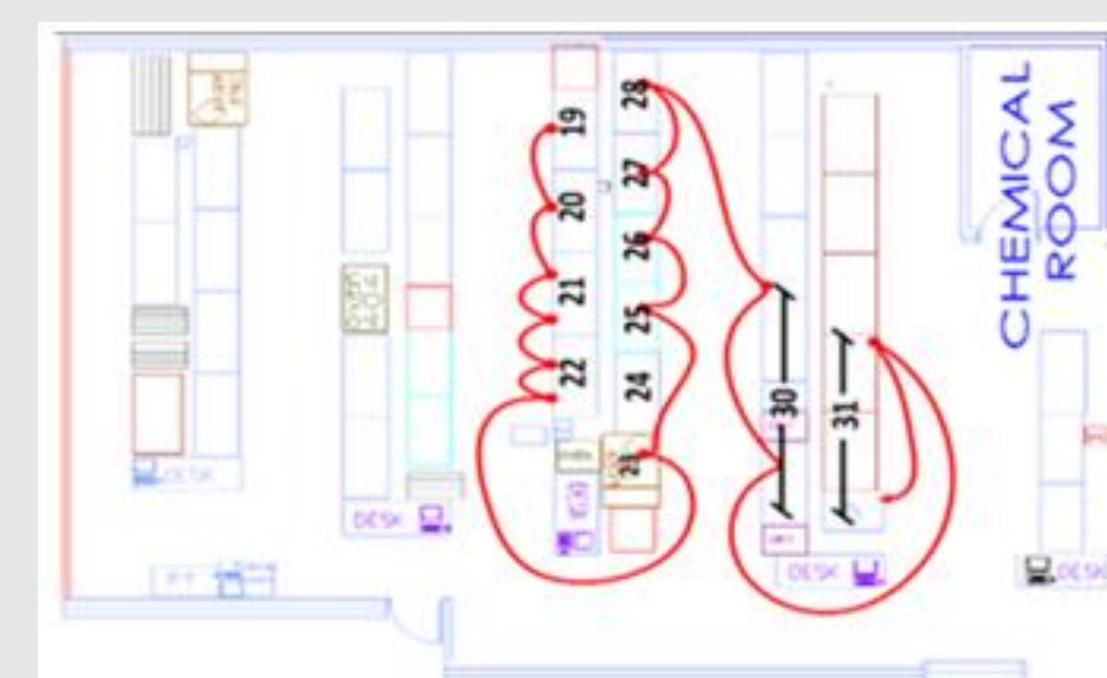


Figure 5: Spaghetti Diagram Model 5038

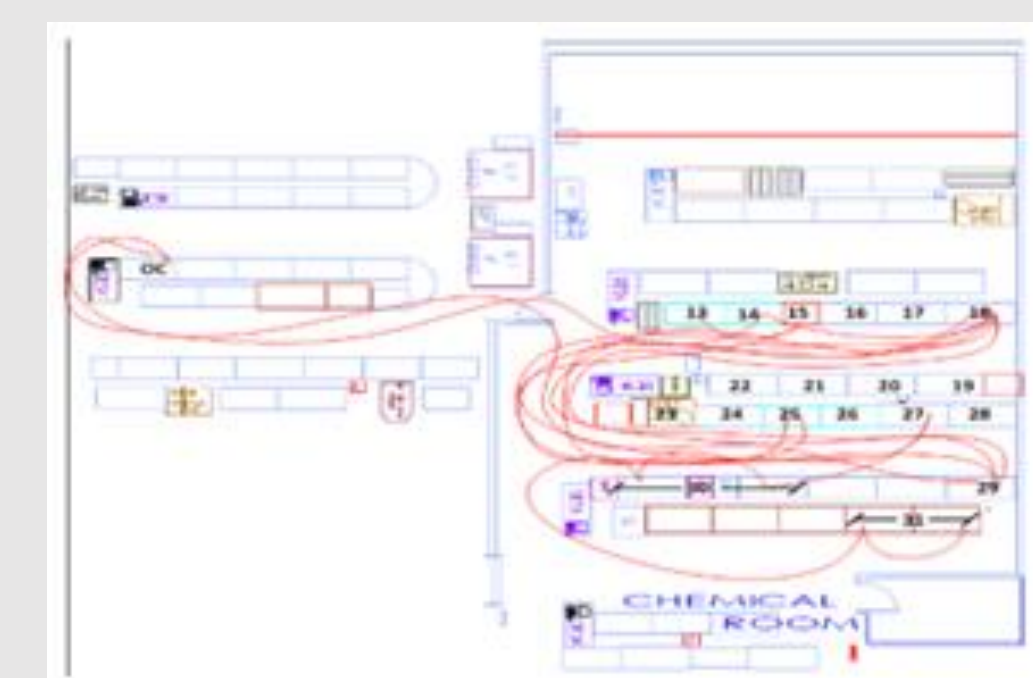


Figure 6: Spaghetti Diagram Model 4968

The fish bone diagram used on this project, as shown on Figure 7, is divided into six objectives known as the 6M's: personnel, equipment, methods, materials, environment, and measures. It was identified that material availability and tools were a potential contributor of the problem. On personnel, the absenteeism and lack of certified operators also were identified. On the methods section, drying times, set-up times, transportation, unbalanced lines, and planning. At the equipment section, issue related to calibrations and the follow up to complete calibration assessment. In measures, for model 4968 the layout is not effectively constructed and does not have a continuous flow, while for model 5038 the layout was identified as proper and does have continuous flow using the U-shape line configuration.

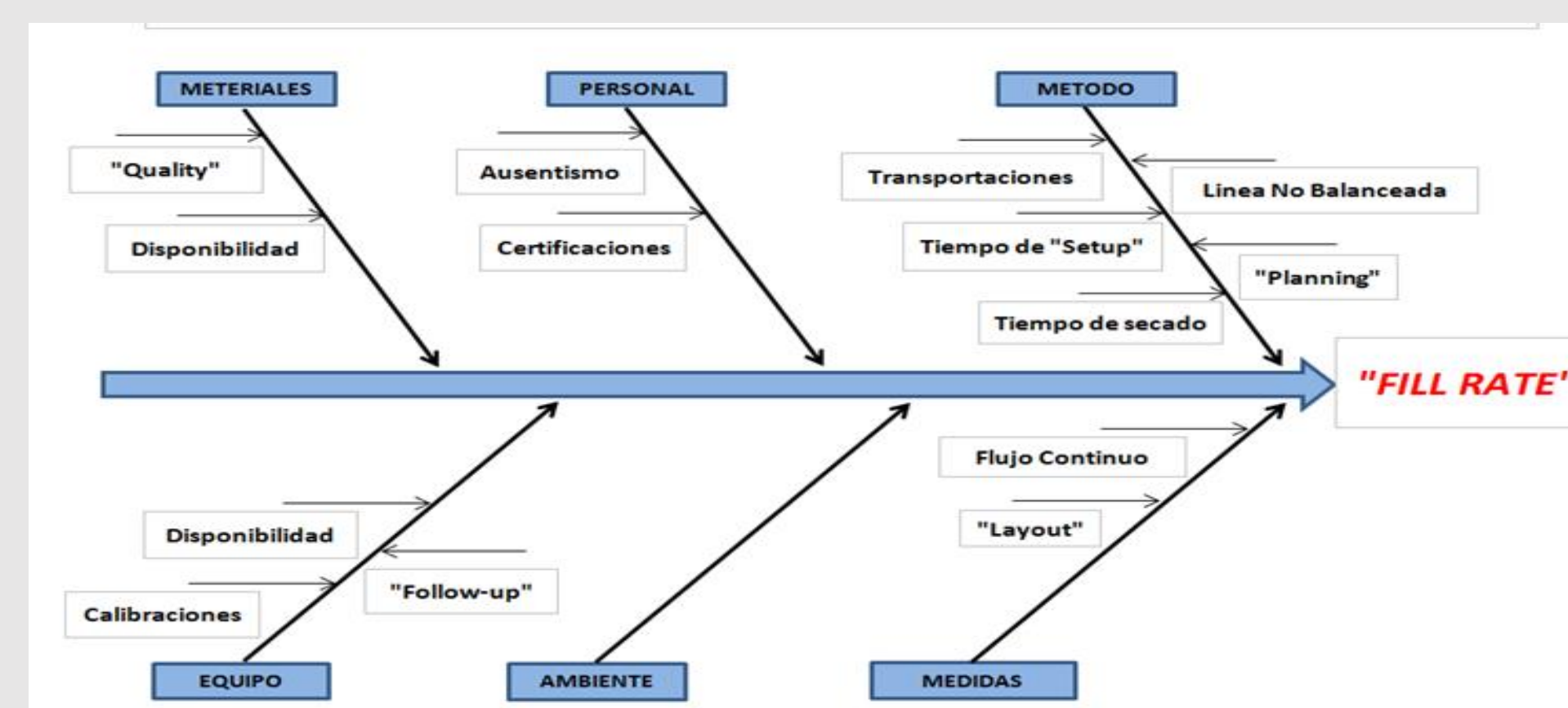


Figure 7: Cause and Effect Diagram

After having analyzed the possible causes, the four most critical causes were identified. Some observation was related to the drying times of the model 4968, Set-Up times, continuous flow and the improve the effectiveness of the unit's transportation. By understanding these problems, it can be concluded that they are waste that can be eliminated or reduced the lead time.

RESULTS AND RECOMMENDATIONS

In order to reduce the drying times of the model 4968, which was identified as the critical cause, the recommend changing or design new drying chamber to be able to effectively dry the cable areas that are needed and about to dry other area on the cable that are not part of the operational procedures and be able to comply with Quality control. The drying chambers are required to be used in nine operations. Each drying chamber has a cost of \$1,316.50, the total cost of the nine drying chambers is \$11,848.50. Figure 8 present a drying chamber for the manufacturing process.



Figure 8: Drying Chamber

To improve the flow and transportation of the 4968 units, the recommendation is to proceed with a new layout of the area. It is not based on moving machines, tables, or ovens. The purpose is to have a continuous flow or U-Shape configuration to be more effective. Figure 9 presents the new spaghetti diagram with the recommendation to improve the flow of model 4968.

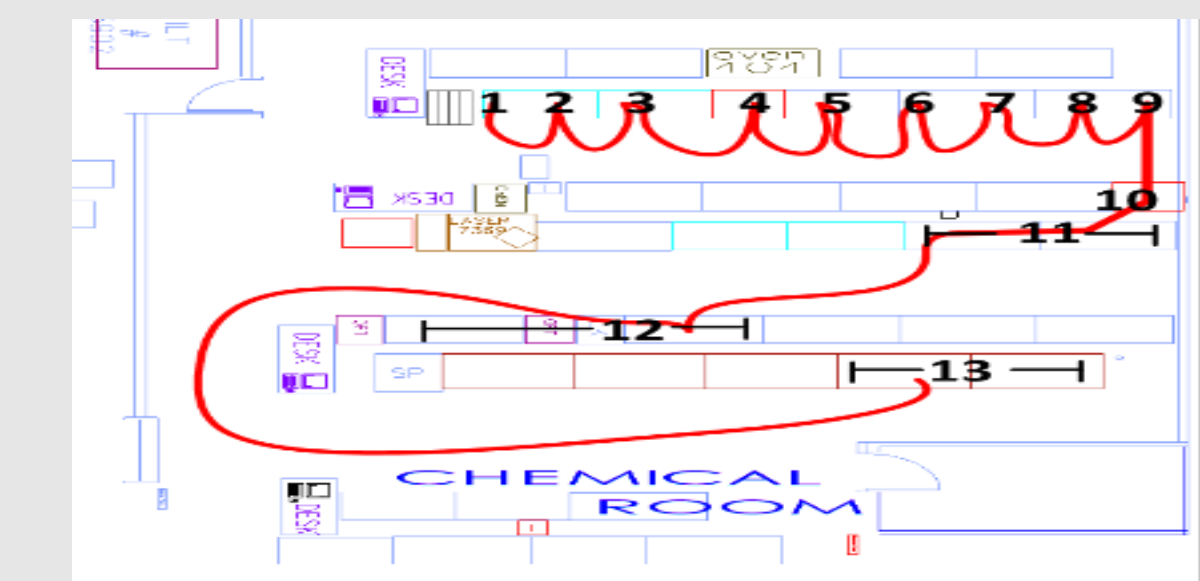


Figure 9: Enhanced Spaghetti Diagram for Model 4968

The creation of the Pull System in the manufacturing lines was part of the goal identified from the beginning of the project and at the analyze phase support our statement of creating a Pull Systema will help to provide solutions to our problem of improving the Fill Rate. The Kanban for the Pull System would be placed before the operation at "Install connector sleeve, labels, front seal" for the models 5038 and 4968. A Kanban will also be created for the Feeders to further improve the flow of the Models. After these Kanban's are implanted, the Lead Time will be shortened than the actuals time. The 5038 model had a Lead Time of 13.69 days and when implementing the Pull System, the Lead Time would be reduced to 3.07 days. With a difference of 10.62 days since only the times of the last four operations are counted and not the 17 that are in total. The 4968 model also had a Lead Time of 8.36 days and by implementing the Pull System the Lead Time would be reduced to 1.31 days with a difference of 7.05 days.

The Control phase is important to maintain the good results to avoid the reoccurrence of the same problems. After the implementation of the improvements, a meeting will be held to determine the people who will be in responsible of monitoring production with specific tasks. Table 1 will be printed and posted on the line's bulletin wall for proper illustration aid.

Table 1: Manufacturing Personal vs Tasks

Manufacturing Personal	Tasks
Coordinator or Supervisor	The Coordinator or Supervisor will be measuring the Lead Time of the lines to be able to observe the behavior in a matter of time for the units. This will help you see if there are continual improvement opportunities.
Coordinator or Supervisor	The Coordinator or Supervisor will be monitoring the number of units that are leave the line daily to have the knowledge and count of how many units are needed to comply with the Fill Rate.
Operators	Operators will be filling the Kanban's with units in WIP found in the Install Label operation. Operators will be carried away by cards designed to visually see how many units are needed in the Kanban.

CONCLUSIONS

The objectives set at the beginning of the project where met, decreasing the time of the operations for model 5038 and 4968 and complying with a weekly fill rate between 93% to 95% of the internal client. The main lesson learned related to this project was to develop as professionals and personal skills throughout improving on communication skill, presentation skill and direct contact with operators, planners, coordinators, supervisors, engineers, and managers.